Type 2 diabetes: prevention in people at high risk (standing committee update)

Consultation on draft guideline - Stakeholder comments table
24 May 2017 to 23 June 2017

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1.	Diabetes UK	Addendum & Short	General	General	Diabetes UK welcomes the opportunity to respond to this consultation. Over 5million people are at high risk of developing Type 2 diabetes. If we consider the total number of people at risk in the UK that figure soars to 11.9million people. [1] It is therefore imperative that alongside population level interventions those who are at increased risk are offered behaviour change interventions to support them in reducing their risk of developing Type 2 diabetes. Please see below our comments to the proposed recommendations amendments. We have also submitted comments on the key research recommendations in a separate document.	Thank you for your comment.
2.	Diabetes UK	Addendum & Short	General	General	We are surprised that NICE are only accepting comments on a small proportion of this guideline when the rest of the guideline is aligned to old evidence. We have significant comments on these sections that NICE are not accepting comments on based on more recent evidence. We would therefore welcome confirmation from NICE as to when the entire guideline will be considered for a complete update.	Thank you for your comment. The entire guideline was reviewed by NICE in August 2015 and this included consulting experts (including representatives from the original committee who developed the guideline), new evidence assessed and consideration of current practice. Based on these findings it was concluded that the guideline would be partially updated to incorporate new evidence on risk assessment and intensive lifestyle programmes. This guideline update addressed three specific interventions in individuals at

[1] Based on the latest 2014 dataset for the UK population (Office for National Statistics. Population Estimates for UK, England and Wales, Scotland and Northern Ireland - Mid-2014) and using the 10.7% found in the NCVIN analysis, Diabetes UK estimate that in the UK there are 5,978,535 people aged 16 and over with non-diabetic hyperglycaemia

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						high risk of developing type 2 diabetes, and it is therefore not possible to make changes to other sections of the guideline as part of this update. This guideline will be considered again for update in autumn 2017 and if new evidence or intelligence gathering from experts arises that would lead to a change to the current recommendations, then these other identified topics will be updated.
3.	Diabetes UK	Short	25 - 26	22 - 23	We support the revised recommendations regarding prescription of metformin in incidences where an intensive lifestyle-change programme has not worked or is not appropriate.	Thank you for your comment.
4.	Diabetes UK	Short	25 - 26	22 - 23	We would welcome clarity around the revised metformin BMI and the eligibility of ethnic minorities who will be at greater risk and potentially benefit from metformin at a BMI lower than 35.	Thank you for your comment. Findings from the clinical evidence are indicative of metformin being more effective for those with a BMI greater than 35 compared with those with a lower BMI. Metformin was also shown to be more cost effective in patients with a higher BMI. The clinical review of effectiveness also found differences between ethnicity subgroups however these were not clinically significant. The economic modelling also did subgroup analysis for outcomes which included ethnicity (white, black and minority ethnic groups). However, evidence of effectiveness of intensive lifestyle interventions and metformin

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						were not available for these population subgroups, and so these subgroups could not be considered separately in the economic model, and rigorous evidence on the progression to diabetes across ethnicities was not available. Therefore a recommendation for metformin was not made for specific ethnicities.
5.	Diabetes UK	Short	9 - 10	29 - 11	The only systematic, national intensive lifestyle-change programme available in England is the NHS DPP. Therefore it is vital that this update supports and aligns with this programme. It is our concern that by narrowing the criteria for the commissioning of, and subsequent referral to, an intensive lifestyle-change programme that the number of people being offered access to the NHS Diabetes Prevention Programme will be negatively affected. A recent subgroup analysis of the NHS DPP did find that targeting those with a higher HbA1c could be beneficial. However, this was significantly caveated with the recommendation for further research into the plausibility of delaying or avoiding a diagnosis of Type 2 once HbA1c has climbed as high. It is our concern that prioritising those with a higher HbA1c is not evidence based and may exclude those that may be most likely to benefit from the programme, as well as being a different range used by the NHS DPP.	Thank you for your comment. The prioritised high risk group (fasting plasma glucose of 6.5-6.9 mmol/l or HbA1c of 44-47 mmol/mol is based on the clinical review and cost effectiveness model which found that the interventions were most effective in this sub-group. The committee also noted that prioritising patients in whom treatment is the most cost-effective means that people with the highest capacity to gain will be targeted.

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6.	Diabetes UK	Short	9 - 10	29 - 11	The US showed that an HbA1c cut off of 5.7% was cost and clinically effective in identifying higher risk of Type 2 diabetes across a population.[2] However there is no absolute or proper threshold as to what constitutes risk for the lower bands of pre-diabetes. Where the division is put about the risk banding is dependent on what the cost envelope is and this was the reason that the range of 42-47mmol/mol (6.0%-6.4%) was used for 100,000 places on the NDPP. On this basis, we question the need to change the risk threshold from that used within the NDPP.	Thank you for your comment. The prioritised high risk group (fasting plasma glucose of 6.5-6.9 mmol/l or HbA1c of 44-47 mmol/mol is based on the clinical review and cost effectiveness model which found that the interventions were most effective in this sub-group.
7.	Diabetes UK	Short	9 - 10	29 - 11	The NHS DPP is a programme very much in its infancy with findings yet to be independently assessed and published. Due to this infancy, and being the first of its kind in the UK, there has been a degree of uncertainty from the outset about uptake and retention rates. As with any new programme there is also the potential for intended and unintended outcomes. For example, early data indicates that HbA1c rates may decline between an individual being referred to the programme and commencing it, meaning that those referred may not be going on to complete the programme as they think they are no longer at risk. This could suggest that the sheer act of referral may have an	Thank you for your comment. Your comment has been forwarded to NICE's Surveillance Team who will review any assessment reports on the effectiveness of the NHS DPP when the guideline is reviewed in autumn 2017.

[2] Zhuo X[1], Zhang P et.al (2012 Apr) Alternative HbA1c cut-offs to identify high-risk adults for diabetes prevention: a cost-effectiveness perspective. Am J Prev Med. 42(4):374-81. https://www.ncbi.nlm.nih.gov/pubmed/22424250

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					impact on behaviour change meaning that there is potential excess capacity in the programme.	
8.	Diabetes UK	Short	9 - 10	29 - 11	Furthermore, we are also concerned that the recommendation to change the divisions of risk is inconsistent with what is happening within the national NHS DPP programme and does not reflect what is happening on the ground. Whilst we accept that the higher the cut-off point the more effective the intervention may be, we urge NICE to seek the views of the teams on the ground and learnings from the programme to date before finalising this recommendation.	Thank you for your comment. Your comment has been forwarded to NICE's Surveillance Team who will review any assessment reports on the effectiveness of the NHS DPP when the guideline is reviewed in autumn 2017. We will also liaise with the NICE Implementation team so that information on current practice feeds into the review of the guideline
9.	Diabetes UK	Short	9 - 10	29 - 11	As outlined above the NHS DPP plugged a vacuum for many at risk individuals across England where they were eligible and in need of an intensive lifestyle-change programme but which simply did not exist in their area.[3] It is a significant risk that by prioritising those with the highest HbA1c that those who fall below will not be offered any support in reducing their risk of developing Type 2 diabetes, despite still falling into the eligible range according to the NHS DPP service specification.	Thank you for your comment. The committee noted that intensive lifestyle modifications were cost-effective across all high risk subgroups and that recommendation 1.5.4 in the current guideline be retained, supporting the recommendation to offer such programmes to all people at high risk If possible, all individuals meeting the high risk criteria should be offered an intensive lifestyle-change programme, as it is highly cost-effective for the entire group.

[3] NHS England (2016) NHS Diabetes Prevention Programme, Primary Care Toolkit to support local implementation of the NHSDPP. https://www.england.nhs.uk/wp-content/uploads/2016/07/dpp-pc-toolkit.pdf

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						The decision to prioritise lifestyle-change programmes for individuals FPG 6.5-6.9 or HbA1c 44-47 in cases where resources are limited was based on the findings of the economic model, which indicated that intervention in these individuals is more cost-effective than in individuals with lower FPG/HbA1c. This finding was primarily due to people with higher FPG/HbA1c being more likely to develop diabetes, meaning that intervention in this group prevents more cases of disease. In addition, a scenario analysis was carried out in which the effect of lifestyle intervention on reduction in HbA1c level was stratified by patients' baseline characteristics. Data from the US DPP indicated that people with a higher starting FPG achieve a larger reduction in HbA1c compared to individuals with a lower FPG, which, when applied to the economic model, further reinforced the cost-effectiveness of intervention in high FPG/HbA1c individuals.
10.	Diabetes UK	Short	9 - 10	29 - 11	The current language of the proposed amendment implies that from the outset of commissioning those with a higher HbA1c should be prioritised without noting that those with lower HbA1c are still eligible for referral to the NHS DPP. This could impact on the entire recruitment process from	Thank you for your comment. The committee noted that intensive lifestyle modifications were cost-effective across all high risk subgroups and that recommendation 1.5.4 in the current guideline be retained, supporting

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					the outset reducing the number of people at risk who are identified at a local area, also impacting on those who could benefit from a brief intervention.	the recommendation to offer such programmes to all people at high risk. If possible, all individuals meeting the high risk criteria should be offered an intensive lifestyle-change programme, as it is highly cost-effective for the entire group. The decision to prioritise lifestyle-change programmes for individuals FPG 6.5-6.9 or HbA1c 44-47 in cases where resources are limited was based on the findings of the economic model, which indicated that intervention in these individuals is more cost-effective than in individuals with lower FPG/HbA1c. This finding was primarily due to people with higher FPG/HbA1c being more likely to develop diabetes, meaning that intervention in this group prevents more cases of disease. In addition, a scenario analysis was carried out in which the effect of lifestyle intervention on reduction in HbA1c level was stratified by patients' baseline characteristics. Data from the US DPP indicated that people with a higher starting FPG achieve a larger reduction in HbA1c compared to individuals with a lower FPG, which, when applied to the economic model, further reinforced the cost-

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						effectiveness of intervention in high FPG/HbA1c individuals.
11.	Diabetes UK	Short	9 - 10	29 - 11	There should still be consideration of all the individual risk factors of the person, assessing what factors are modifiable and what are not. For example a patient presenting with a higher HbA1c may have this score as a result of non-modifiable risk factors such as age, sex or ethnicity and therefore would not be a beneficial candidate for an intensive lifestyle-change programme in that the person presenting at high risk may have this risk as a result of non-modifiable risk factors. The text should be amended to reflect this.	Thank you for your comment. Subgroup analysis was conducted in the economic modelling to see if there were any differences. Outcomes for 24 subgroups were obtained. The Committee noted that there was no evidence to suggest there were defined populations of people in whom lifestyle interventions are not effective, and therefore agreed that it was appropriate this recommendation should cover the full population meeting the criteria in the stem of recommendation 1.5.4
12.	Diabetes UK	Short	General	General	We are aware that one aim of the update of PH38 is to review the cost effectiveness of digital intensive behaviour change programmes and we therefore note the lack of recommendation relating to digital behaviour change programmes in the guideline. We know that a huge amount of work is currently going into collating and reviewing the evidence base of digital interventions at NHS England with the aim of developing a digital NHS Diabetes Prevention Programme (NHS DPP). We therefore would welcome reassurance from NICE that they are linked in and discussing future recommendations on digital interventions with this team.	Thank you for your comment. The committee were unable to make a recommendation on digitally delivered lifestyle interventions due to a lack of high quality evidence. A research recommendation was made instead. Your comments have been forwarded to NICE's Implementation and Surveillance teams regarding the current review work on digital interventions and developing a digital NHS DPP so this feeds into the review of the guideline in autumn 2017.
13.	Janssen	Evidence review	General	General	Thank you for the opportunity for Janssen to participate in the consultation on this draft addendum to the update of	Thank you for your comment.

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					PH38. We have continued interest in diabetes management, however, on this occasion we have no comments.	
14.	Merck Serono Ltd	Short Version	25 26	Footnote & 22-27 1 - 24	Glucophage SR (Metformin MR) now has UK marketing authorisation for this indication please see the links below: http://www.mhra.gov.uk/public-assessment-reports/ http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1495172853852.pdf https://www.medicines.org.uk/emc/medicine/20952 Reduction in the risk or delay of the onset of type 2 diabetes mellitus in adult, overweight patients with IGT* and/or IFG*, and/or increased HbA1C who are: - at high risk for developing overt type 2 diabetes mellitus (see section 5.1) and - still progressing towards type 2 diabetes mellitus despite implementation of intensive lifestyle change for 3 to 6 months Treatment with Glucophage SR must be based on a risk score incorporating appropriate measures of glycaemic control and including evidence of high cardiovascular risk (see section 5.1). Lifestyle modifications should be continued when metformin is initiated, unless the patient is unable to do so because of medical reasons.	Thank you for your comment. The recommendation has now been updated so it no longer refers to standard-release metformin, and a footnote has been added to clarify this issue.
15.	Merck Sharp & Dohme Limited	Evidence review and Short	General	General	MSD welcome the 2017 addendum and the research recommendations on identifying and monitoring, lifestyle interventions and vulnerable groups.	Thank you for your comment.

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16.	Merck Sharp & Dohme Limited	Short	31 - 32	19 - 25, 1 - 5	We would encourage the research recommendations on lifestyle interventions to consider how these can be delivered and to consider the cost-effectiveness of the various ways of delivering these interventions, literature, face to face, electronics apps etc.	Thank you for your comment.
17.	Merck Sharp & Dohme Limited	Short	4 - 25	general	There are several positive recommendations for patients to engage and be advised on diet and exercise, and use technology such as pedometers. One clear gap that should be addressed is encouraging patients and health care professionals to consider using other technologies such as behaviour change apps as aids to behaviour change. For example the OURPATH application.	Thank you for your comment. However this relates to a section of the full guideline which was outside the scope for this update. Your comment however has been forwarded to NICE's Surveillance Team for consideration when the guideline is reviewed in autumn 2017.
18.	NHS England	Evidence review	General	General	It would be useful to also acknowledge that the NHS DPP interventions are being commissioned centrally by NHS England; the implication in the current draft is that the commissioning responsibility for intensive lifestyle-change programmes falls to locality-based commissioning (CCGs/local authorities/Health and Wellbeing Boards). I realise that this is a UK document, and that the NHS DPP is only being implemented in England, but this still constitutes around 85% of the UK.	Thank you for your comment. Information regarding the commissioning arrangements for the NHS DPP have been added to the evidence review (introduction and aims section of the economic model). .
19.	NHS England	Short	Section 1.8, page 14		Section 1.8: the evidence behind the statements around intervention characteristics have not been re-examined this time round, so correspond to the 2012 NICE recommendations. Does it need highlighting that this is why the NHS DPP Service Specification is not entirely aligned to the statements in this section, as they were based on a subsequent systematic review? I can understand though if you would prefer to leave this.	Thank you for your comment. Recommendation 1.8 on the content of intensive lifestyle-change programmes are outside the scope of this update. Further information has been added to the evidence review (introduction and aims section of the economic model) outlining that

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						the NHS DPP has different lifestyle change intervention characteristics.
20.	NHS England	Short - glossary	34		Could the Glossary reference the terms "pre-diabetes" and "non-diabetic hyperglycaemia", as PH38 did?	Thank you for your comment. These terms are no longer in the updated guideline and have therefore been removed from the glossary.
21.	NHS England	Short	General	General	The recommendation to prioritise people with a fasting glucose 6.5-6.9 mmol/l or HbA1c of 44-47 mmol/mol is logical and very clearly justified in the larger document. I wonder however whether we could soften the recommendation a little – perhaps qualifying the statement a little to say "….if indeed NHS DPP capacity locally is limited and therefore requires further risk stratification to select participants". Or words to that effect.	Thank you for your comment. We have now amended recommendation 1.5.5 to make clear that these prioritisation criteria should only be applied if there are issues with capacity in the programme. If possible, all individuals meeting the criteria should be offered an intensive lifestyle-change intervention, as it is highly cost-effective for the entire group.
22.	NHS England	Short	General	General	It would be good to mention the NHS Diabetes Prevention Programme in the summary document – I note the NHS Health Check Programme is mentioned but the NHS DPP is not. It is mentioned in the main 500-page document, and indeed it is made clear in that document that considerations around the NHS DPP are driving this piece of work by NICE, but it does not appear in the summary document.	Thank you for your comment. This extra information has been added to the context section of the NICE guideline.
23.	Public Health England	Short	1,6	13	We welcome encouraging the use of this guidance alongside the NHS Health Check guidance. We also welcome highlighting the programme's fit with these recommendations.	Thank you for your comment.
24.	Public Health England	Short	9	29	The National Diabetes Prevention Programme is currently being rolled out and to change eligibility criteria would be counter-productive unless the programme is over-	Thank you for your comment. We have now amended recommendation 1.5.5 to make clear that these prioritisation criteria should only be

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					subscribed. It would be preferable to offer these thresholds for referral should prioritisation be necessary when demand exceeds supply.	applied if there are issues with capacity in the programme. If possible, all individuals meeting the criteria should be offered an intensive lifestyle-change intervention, as it is highly cost-effective for the entire group.
25.	Public Health England	Short	General	General	The update to the guidance does not provide a definition of the thresholds that should be used with each of the risk calculator tools to identify someone at high risk. This absence of information is confusing for commissioners and providers, and could lead to dramatic variation in practice. It would be helpful if NICE could provide general guidance on what threshold should be used for each of the risk calculators.	Thank you for your comment. Information on validated risk assessment tools have been added to the glossary (in the definition of level of risk) with a cross reference to the NHS Health Check best practice guidance.
26.	Royal College of Anaesthetists	Short	18	General	It is becoming increasingly acknowledged that surgery provides a 'teachable moment' for changing and improving lifestyle choices. Encouraging patients to promote smoking cessation, obesity reduction, healthier eating and exercise improves surgical outcome, as well as reducing the risk of Type 2 Diabetes Mellitus. These NICE guidelines can and should take advantage of the fact that patients with undiagnosed diabetes or at risk of diabetes often present for surgery, and can be identified in the pre-operative clinic. These patients then have an immediate and tangible reason for improving their lifestyle choices. Preoperative diagnosis of diabetes is especially important if, for example, implant surgery is being contemplated, as	Thank you for your comment. Preoperative diagnosis of diabetes and the opportunity to promote lifestyle change in patients having surgery are outside the scope of this update. Your comment has been passed to NICE's Surveillance team for consideration when the guideline is reviewed in autumn 2017.

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					an infective complication is a potential catastrophe for a diabetic patient. The Joint British Diabetes Societies guidelines on perioperative management of the surgical patient with diabetes, which is endorsed by the RCoA and the ASGBI (Association of Surgeons of Great Britain and Ireland), recognises the dangers of surgery in patients with poorly controlled Diabetes Mellitus and suggests that elective surgery should only be performed if the HBa1C is <8.5%/69mmol/mol. The same advice should be applied to all patients.	
27.	Royal College of Anaesthetists	Short	7	General	As an elevated preoperative blood sugar reading is a risk factor for a poor surgical outcome, we suggest that the referral letter for a surgical consultation includes whether a risk assessment for Type 2 Diabetes Mellitus has been performed within the past year and the result.	Thank you for your comment. Preoperative diagnosis of diabetes is outside the scope of this update. Your comment however has been forwarded to NICE's Surveillance Team for consideration when the guideline is reviewed in autumn 2017.
28.	Royal College of Anaesthetists	Short	7	General	Similarly, as elevated preoperative blood sugar level is a risk factor for a poor surgical outcome, we suggest that, if a risk assessment for Type 2 Diabetes Mellitus has not been performed in the past year, one should carried out prior to elective surgery.	Thank you for your comment. Preoperative diagnosis of diabetes is outside the scope of this update. Your comment however has been forwarded to NICE's Surveillance Team for consideration when the guideline is reviewed in autumn 2017.
29.	Royal College of Physicians	Short	General	General	The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with the Association of British Clinical Diabetologists and would like to make the following comments. Our experts believe that the suggested brief consultation (5-15 min) to discuss the risk and possible interventions to allow individuals to make an informed choice is unlikely to	Thank you for your comment. The time period for the brief consultation is suggested and was not determined by NICE. It reflects recognised

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					work. Our experts believe that such short period of time in primary care is not enough to discuss this rather complex concept or risk of future diabetes and its health implications, give all the individualised information to help people make an informed choice. We suggest that this time period related to consultation be removed.	definitions for what might or is suggested to constitute 'brief advice'. Your comments have been forwarded to NICE's Surveillance team for consideration when they review the guideline in autumn 2017.
30.	Royal College of Physicians of Edinburgh	Evidence review	8		The aim of the update is to assess the clinical and cost effectiveness of lifestyle modification programmes, and also metformin use, in high risk populations, to enable commissioners to best target these interventions to those who will derive most benefit. Fifteen RCTs were included in the review, only three of which studied metformin use, but the modest recommended changes to the guideline (see below for more detail) have used a 'health economic decision model' and do not seem to have been directly derived from the scientific evidence presented in the trials included in the review, or elsewhere.	Thank you for your comment. The guideline committee discussed the evidence and agreed that the best way to address both the clinical and cost effectiveness of lifestyle modification programmes, and metformin use, in high risk populations was by a health economic model. Studies on intensive lifestyle interventions and the effectiveness of metformin were included in the NICE clinical effectiveness review which informed the economic model.
31.	Royal College of Physicians of Edinburgh	Short	25 – 26, 33	1.19.1	This section updates a section in the original guideline in relation to the possible use of metformin to prevent progression of high risk patients to the development of type 2 diabetes. The only alteration seems to be the addition of the phrase "if they have a BMI greater than 35". This section in the initial guideline attracted some adverse comment, as metformin was (and remains) unlicensed for	Thank you for your comment. Findings from the clinical evidence suggest that metformin was more effective for those with a BMI greater than 35 compared with those with a lower BMI. Metformin was also shown to be

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					use in the UK in such a population. In addition there is quite limited scientific evidence for its use in preventing the onset of type 2 diabetes. There is clearly a cost implication, albeit quite modest, in using metformin in this population, but the main barrier to its utilisation is the fact that it remains unlicensed in the UK for this indication. Doctors are generally reluctant to prescribe drugs outside their licensed indications, especially a drug like metformin, which can cause side-effects in a significant number of people. The fact that the manufacturers have not sought a licence for this indication, some 5 years after the NICE guideline was published, probably indicates that the pharmaceutical industry does not see use of the drug in this population as worthy of pursuing. The amendment to indicate that this treatment may be most appropriate in those with a BMI of greater than 35 again appears arbitrary and seems to have been suggested on grounds of economy rather than scientific evidence. It has been clearly shown that metformin is effective in treating type 2 diabetes whatever the BMI; Fellows have indicated that they are not aware of any evidence from the literature that it is more effective in reducing BG levels in a person with a BMI of, say, 39 than a person with a BMI of, say, 32. It is likely to be exactly the same in high risk individuals with pre-diabetes.	more cost effective in patients with a higher BMI and is licensed for use in these patients. Subgroup results in the economic modelling showed that metformin is expected to be especially cost effective in people with a high BMI. The committee agreed that this finding was consistent with the biological mode of action of metformin and is likely to accurately reflect clinical reality. They therefore decided that metformin should be prioritised for people with a high BMI in the recommendations.
32.	Royal College of	Short	9 - 10	1.5.4	This section deals with prioritising people who might be referred to intensive lifestyle-change programmes. The	Thank you for your comment. The decision to prioritise lifestyle-change programmes for

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	Physicians of Edinburgh				suggestion is that a subsection of the defined high risk group is prioritised, namely those with a FPG of 6.5-6.9 mmol/l or HbA1c of 44-47 mmol/mol. Clearly, offering intensive lifestyle-change programmes to a significant section of the population is a major challenge in terms of resources (personnel and finances) and such programmes are not currently widely available. The recommendation here than only a subsection of the high risk group is prioritised would potentially reduce the resources required. However, Fellows noted that there may not be adequate evidence from the scientific literature that sub-dividing the high risk group in such a way is clinically justified and commented that the cut-offs applied seem rather arbitrary and designed predominantly to save costs in terms of how many people will potentially be referred to these programmes. Fellows expressed concern that such a sub-division is flawed on clinical grounds; intuitively intervening when a person has, say, a FPG of 6.2 mmol/l may be more effective in preventing progression to type 2 diabetes than attempting intervention when a person has a FPG of 6.9 mmol, i.e. already on the cusp of type 2 diabetes and perhaps too far down the line to prevent progression.	individuals FPG 6.5-6.9 or HbA1c 44-47 in cases where resources are limited was based on the findings of the economic model, which indicated that intervention in these individuals is more cost-effective than in individuals with lower FPG/HbA1c. This finding was primarily due to people with higher FPG/HbA1c being more likely to develop diabetes, meaning that intervention in this group prevents more cases of disease. In addition, a scenario analysis was carried out in which the effect of lifestyle intervention on reduction in HbA1c level was stratified by patients' baseline characteristics. Data from the US DPP indicated that people with a higher starting FPG achieve a larger reduction in HbA1c compared to individuals with a lower FPG, which, when applied to the economic model, further reinforced the cost-effectiveness of intervention in high FPG/HbA1c individuals. We appreciate your point that intervention in an individual on the cusp of diabetes may be too late to prevent disease progression altogether. However, from an economic perspective, reducing weight and HbA1c levels and delaying the onset of diabetes (even if the individual does eventually develop

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						the disease) still results in a quality of life gain and a reduction in treatment costs. Regarding the arbitrary nature of the cut-off, the threshold of 6.5 for FPG and 44 for HbA1c was defined by the clinical evidence used to inform the economic evaluation. Therefore using another cut-off would not be backed by empirical evidence.
33.	South Sefton CCG	Short	26	3	We are aware that Metformin can be useful but locally we have advised that patients starting on metformin should be advised that once a year the metformin should be discontinued for six weeks and an HbA1c checked to ensure that they have not become diabetic and so are missing out on the relevant screening required for people with diabetes.	Thank you for your comment. Recommendation 1.19.6 of the original guideline states - Monitor the person's fasting plasma glucose or HbA1c levels at 3-month intervals and stop the drug if no effect is seen. This recommendation is outside the scope for this update.
34.	Tees, Esk and Wear Valleys NHS Foundation Trust	Short	9 - 10	26 - 11	Re 1.5.4: May not be appropriate to offer intensive life changing programmes for certain patients such as those with dementia because they may lack capacity to consent and/or they may not be able to undertake lifestyle change.	Thank you for your comment. The committee considered this issue and an additional recommendation has now been added. Recommendation 1.5.6 now states - ensure that intensive lifestyle-change programme are designed to help as many people as possible to access and take part in them (see sections 1.15 and 1.16 for recommendations on providing information and services, and supporting lifestyle change in people who may require particular support).

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35.	Tees, Esk and Wear Valleys NHS Foundation Trust	Short	General	General	It is recognised that individuals with mental illnesses often have poorer physical health and there will be a number of those who would benefit from testing and intervention to prevent progression of diabetic disease. We use the Lester tool for people experiencing psychosis and schizophrenia. The guidance refers to people with physical health problems and learning disabilities but not those with mental health issues including dementia. Given the increasing prevalence of both diabetes and dementia, there will be an increasing number of individuals with both conditions who should be recognised in this guidance.	Thank you for your comment. The committee considered this issue and an additional recommendation has now been drafted. Recommendation 1.5.6 now states - ensure that intensive lifestyle-change programme are designed to help as many people as possible to access and take part in them (see sections 1.15 and 1.16 for recommendations on providing information and services, and supporting lifestyle change in people who may require particular support).
36.	The Dirac Foundation	Evidence review	General	General	As a recent Caribbean epidemiologist, and public health field researcher/statistician (e.g. for the Cayman Heart Fund) seeking to resolve some relevant preliminary observations * I am concerned that the NICE draft report seems to lack of consideration of recent publications that could impact any final recommendations. While the draft report has 89 end references of largely bibliographic nature, the data primarily used in systematic review and discussion are 15 sources (representing just 13 independent research groups), 9 dated 2001-2006, 4 dated 2012-2013. The remaining two others are dated 2016 but primarily addressing benefits of weight loss and exercise. The primary key source as prior study is Knowler et al. in 2002 [Knowler WC, Barrett-Connor E, Fowler SE, et al. .; Diabetes Prevention Program Research Group . Reduction in the incidence of type 2	Thank you for your comment and for suggesting these publications. Unfortunately your comments concern matters which are outside the scope for this update. This update was commissioned to address three specific interventions in individuals at high risk of developing type 2 diabetes, intensive face to face lifestyle-change programs, digitally delivered lifestyle-change programmes or metformin. We are therefore unable to make changes to other sections of the guideline as part of this update. Of your suggested papers, we did not include Bannister et al. (2014) and Costanzo et al. (2015) as these investigated patients with type

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					diabetes with lifestyle intervention or metformin. N Engl J Med 2002; 346:393–403]. Nonetheless, while any notion that "exercise is good" always appears uncontroversial, there are well known counterintuitive data that impact the above, modifying the picture in terms of patient benefit and national cost that do not appear to have been adequately addressed. Notably there is the study of the significant collateral benefits of metformin that would also have overall cost impact [A. Bannister et al. (2014), "Can people with type 2 diabetes live longer than those without? A comparison of mortality in people initiated with metformin or sulphonylurea monotherapy and matched, non-diabetic controls", *Diabetes, obesity and Metabolism*, 16(11), 1165-1173] and the issue of the "obesity" paradox that obese patients may live longer than non-obese patients [https://en.wikipedia.org/wiki/ Obesity_paradox]. While this long-standing issue has been in the balance, it is at least recently indicated that here is an "overweight paradox". P. Costanzo et al. (2015) "The Obesity Paradox in Type 2 Diabetes Mellitus: Relationship of Body Mass Index to Prognosis: A Cohort Study" *Ann Intern Med.*; 162(9), 610-618, Being overweight was associated with a lower mortality risk (although being obese was not) https://en.wikipedia.org/wiki/Obesity_paradox. In addition, better attention should be really given to aetiology and the nature of conditional probabilities in reporting and recommending. Generally speaking,	2 diabetes whereas this update is on prevention of type 2 diabetes in people at high risk.

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					authorities emphasize that P (obesity if type 2 diabetes) = P (obesity | type 2 diabetes) = 0.9 (90%, and approx.) Yet consider https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/338934/Adult_obesity_and_type_2_diabetes_.pdf, "In England, 12.4% of people aged 18 years and over with obesity have diagnosed diabetes, five times that of people with a healthy weight". Disturbing, but we can deduce from that (and other studies) that P (obesity if type 2 diabetes) = P (obesity | type 2 diabetes) = circa 0.1 to 0.2 (20%) or at most roughly 30% in other study), which raises issues as to what most often causes what (these issues are of course well known to researchers, but really promoted). Especially considering the relatively very cheap cost of metformin, the above aspects should surely be discussed. * FYI. The sample had a strong tendency to obesity while currently available life expectancy tables suggest significant longevity compared with the US. The study is using standard (a) and new (b) methods as follows (attached with form submission). (a) B. Robson (2017) "Preliminary Analysis of a Clinical Data Collection in the Cayman Islands" (report to the Cayman Heart Fund) (b) Robson, B. and Boray, S. (2015). "Implementation of a web based universal exchange and inference	

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					language for medicine. Sparse data, probabilities and inference in data mining of clinical data repositories", Computers in Biology and Medicine, 66, 82-102 (using the Cayman island data)	
37.	The Dirac Foundation	Short	General	General	As above, to the extent that the "deformalized" recommendations of the short draft are affected by the above.	Thank you for your comment.
38.	University of Nottingham	Short	27	20	The link to 'tools and resources' appears not to work so stakeholders cannot see what is being proposed or whether this has changed. Please confirm whether there are any changes to this and if so when stakeholders will be able to review and comment	Thank you for your comment. Information on validated risk assessment tools have been added to the glossary (in the definition of level of risk) with a cross reference to the NHS Health Check best practice guidance.
39.	University of Nottingham	Short	35	24 - 25	Previously on page 43 and 49 of the current NICE guidance (PH38), the QDiabetes risk assessment tool was included alongside the Leicester and Cambridge scores but QDiabetes is not mentioned now in the update document. QDiabetes is the only risk assessment tool which is embedded in the majority of GP computer systems and is in regular use. QDiabetes is recommended in the NHS Health Checks Best Practice Guidance (2017) and has been independently and externally validated and has improved performance compared with either the Leicester or Cambridge scores. It also takes account of the effect of deprivation and how diabetes risk varies by age, sex, deprivation and ethnicity so is likely to be fairer in terms of the equity impact assessment.	Thank you for your comment. Information on validated risk assessment tools have been added to the glossary (in the definition of level of risk) with a cross reference to the NHS Health Check best practice guidance.

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40.	University of Nottingham	Short	7	5	The link to computer-based risk assessment appears not to work so stakeholders cannot see what is being proposed or whether this has changed. Please confirm whether there are any changes to this and if so when stakeholders will be able to review and comment	Thank you for your comment. Information on validated risk assessment tools have been added to the glossary (in the definition of level of risk with a cross reference to the NHS Health Check best practice guidance.
41.	University of Nottingham	Short	9	26	"For people confirmed as being at high risk (a high risk score and fasting glucose of 5.5-6.9)". There is no definition of 'high risk' score that we can find in the update document. Please consider using the definition of 'high risk' from the NHS Health Checks Best Practice Guidance 2017 http://www.healthcheck.nhs.uk/document.php?o=1308 for consistency. The following definition for high risk can be found on page 23 • QDiabetes score is greater than 5.6 • Cambridge diabetes risk score is greater than 0.2 • Leicester practice risk score is greater than 4.8 • Leicester risk assessment score is greater than or equal to 16 The evidence for the definition of high risk for the QDiabetes score in the NHS Health checks Best Practice Guide is based on an analysis of thresholds published here[1] and here http://www.qdiabetes.org/QDiabetes-2015-risk-thresholds.pdf Previously on page 43 and 49 of the current NICE guidance (PH38), the QDiabetes risk assessment tool	Thank you for your comment. Definition of high risk is outside the scope of this update. Your comment however has been forwarded to NICE's Surveillance Team for consideration when the guideline is reviewed in autumn 2017. Information on validated risk assessment tools have been added to the glossary (in the definition of level of risk with a cross reference to the NHS Health Check best practice guidance.

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					was included alongside the Leicester and Cambridge scores but QDiabetes is not mentioned now in the update document which, we understand, is a subset of the original document. However, since there is nothing in the update document to suggest that pages 43 and 49 will be changed, we presume that the original recommendations regarding the inclusion of QDiabetes as one of the examples of risk scores will still apply and QDiabetes will be continue to be mentioned in the forthcoming update. It is particularly important that QDiabetes continues to be mentioned since is the only risk assessment tool which is embedded in the majority of GP computer systems and is in regular use. QDiabetes is recommended in the NHS Health Checks Best Practice Guidance (2017) and has been independently and externally validated[2-5] and has improved performance compared with either the Leicester or Cambridge scores. QDiabetes also takes account of the effect of deprivation and how diabetes risk varies by age, sex, deprivation and ethnicity so is likely to be fairer in terms of the equity impact assessment[1]. 1. Hippisley-Cox J, Coupland C, Robson J, et al. Predicting risk of type 2 diabetes in England and Wales: prospective derivation and validation of QDScore. *BMJ* 2009;338:b880-. doi: 10.1136/bmj.b880 2. Collins GS, Altman DG. External validation of the QDScore for predicting the 10-year risk of developing Type 2 diabetes. *Diabetic Medicine*	

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					2011;28:599-607. doi: 10.1111/j.1464-5491.2011.03237.x 3. Mathur R, Noble D, Smith D, et al. Quantifying the risk of type 2 diabetes in East London using the QDScore: a cross-sectional analysis. *The British Journal of General Practice* 2012;62(603):e663. 4. Collins G, Mallett S, Omar O, et al. Developing risk prediction models for type 2 diabetes: a systematic review of methodology and reporting. *BMC Med* 2011;9(1):103. 5. Kengne AP, Beulens JWJ, Peelen LM, et al. Non-invasive risk scores for prediction of type 2 diabetes (EPIC-InterAct): a validation of existing models. *The Lancet Diabetes & Endocrinology* 2013(0) doi: http://dx.doi.org/10.1016/S2213-8587(13)70103-7	
42.	Very Low Calorie Diet (VLCD) Industry Group	Evidence review	39	15 - 17	The VLCD Industry Group also notes that many people at high risk of getting Type 2 Diabetes are overweight or obese. However, we also refer back to the comments it submitted to the consultation on the partial update of Clinical Guidance 43 on Obesity and wish to state that these recommendations failed to acknowledge the effectiveness of VLCDs and LCDs in tackling obesity in a safe, fast and effective way.	Thank you for your comment. Very Low Calorie Diets and Low Calorie Diets were outside the scope for this update. We are unable to comment on the conclusions from the CG43 obesity prevention clinical guideline. Your comments have been forwarded to NICE's Surveillance team for consideration when they review the CG43 obesity prevention guideline.
43.	Very Low Calorie Diet (VLCD)	Evidence review	General	General	The VLCD Industry Group welcomes the opportunity to comment on the guidance on Type 2 diabetes: prevention in people at high risk. We hope that NICE will be able to	Thank you for your comment. Very Low Calorie Diets and Low Calorie Diets were outside the scope for this update. Your

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	Industry Group				fully take the points presented in this submission into account before drafting the final version of this guidance.	comments have been forwarded to NICE's Surveillance team for consideration when they review the guideline in autumn 2017.
44.	Very Low Calorie Diet (VLCD) Industry Group	Evidence review	General	General	The VLCD Industry Group welcomes the evidence presented in the draft addendum, though recommends NICE also take into account the following study: • *Christensen, P., Fogelholm, M., Westerterp-Plantenga, M., Macdonald, I., Martinez, A., Handjiev, S., . . . Raben, A. (2016). Metabolic outcomes after an 8 weeks low-calorie-diet in overweight, pre-diabetic individuals: the role of gender in the PREVIEW study. In Obesity Facts Vol. 9 (pp. 48)* This study showed that Low Calorie Diet (LCD) interventions resulted in weight loss and a decrease in blood pressure, HbA1c and fasting serum insulin (FSI) among pre-diabetic subjects. It also indicated that larger decreases were found in men than in women. The VLCD Industry Group also recommends NICE take into account the results of the following two studies, once published: • *The DIRECT (DIabetes REmission Clinical Trial) study: Remission of Type 2 diabetes using non-surgical weight management with low energy*	Thank you for your comment. Very Low Calorie Diets and Low Calorie Diets were outside the scope for this update. The references you have provided have been forwarded to NICE's Surveillance team for consideration when they review the guideline in autumn 2017.

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					liquid diet and long-term maintenance within routine NHS care This research study, funded by Diabetes UK, is currently investigating whether intensive programmes for weight loss and weight loss maintenance would be beneficial for people with Type 2 diabetes and will run until October 2018. The study builds on a research trial conducted by Newcastle University, which tested LCDs in 11 people with Type 2 diabetes. After 8 weeks, these people were found to have reduced amounts of fat in their liver and pancreas, which improved insulin production and put their Type 2 diabetes into remission. After 3 months, most participants had maintained normal blood glucose control, showing the effectiveness of LCDs in reversing Type 2 Diabetes and controlling glucose levels on a long-term. • *PREVIEW: PREVention of diabetes through lifestyle Intervention and population studies in Europe and around the World*. This project, funded by the European Commission, aims to identify the most effective lifestyle interventions for preventing Type 2 Diabetes in obese or overweight pre-diabetic people.	

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					Preliminary findings of this project showed that Total Diet Replacements (TDRs) resulted in weight loss of around 10kg in eight weeks and reduced levels of blood pressure and cholesterol. This in turn resulted in a decrease in insulin resistance, thereby reversing the development of Type 2 Diabetes. Since it is known that weight reduction is the most important component of any diabetes prevention programme and since the amount of weight lost and maintained has a direct effect on the reduction of diabetes development in a group with pre-diabetes, it follows that a method that can deliver a 10% weight loss and maintenance with a high degree of compliance and a low adverse event rate should be considered as an option in diabetes prevention programmes. The PREVIEW study demonstrates the effectiveness of TDRs in delivering the needed amount of weight loss in the diabetes prevention context, and taken with the existing published evidence for weight maintenance following weight loss with TDR ought to be considered during this consultation on prevention of Type 2 Diabetes in people at high risk. The full report on the first phase of the PREVIEW study is complete and ready for submission for publication – the authors may be prepared to provide a copy on a confidential basis.	

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45.	Very Low Calorie Diet (VLCD) Industry Group	Evidence review	General	General	The VLCD Industry Group would like to highlight the effectiveness of TDRs, including VLCDs, in tackling obesity and preventing and/or reversing diabetes in people at high risk. We wish to draw NICE's attention to the fact that TDRs are strictly regulated and carefully designed to take into account scientific research, which ensures they consist of compositionally sound food products that provide 100% of the recommended dietary allowances, including good quality protein and essential fats. Bearing in mind the role of magnesium deficiency in driving insulin resistance and the relatively low intakes of magnesium in UK diets, achieving weight loss with a magnesium replete TDR formulation may prove to be an effective intervention. This gives TDRs an advantage over 'conventional foods' for those wishing to lose weight: it is almost impossible to maintain nutritional requirements through the consumption of 'conventional foods' alone once daily consumption falls below 1000 kcal. For this reason, the VLCD Industry Group recommends NICE examine in more detail the evidence concerning TDRs and their effect in being able to deliver the initial weight loss of 10%, or approximately 10kg, in people at high risk of developing Type 2 Diabetes.	Thank you for your comment. Very Low Calorie Diets, Low Calorie Diets and Total Diet Replacements were outside the scope for this update. Your comment has been forwarded to NICE's Surveillance team for consideration when they review the guideline in autumn 2017.