NICE National Institute for Health and Care Excellence

Appendix B: Stakeholder consultation comments table

2018 surveillance of PH38 Type 2 diabetes: prevention in people at high risk (2018)

Consultation dates: Wednesday 31 January to Tuesday 13 February 2018

Do you agree with the proposal to not to update the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
20one Clinic	No response provided	No comments provided	Thank you for your response.
Perspectum Diagnostics	No	Perspectum Diagnostics welcomes the opportunity to respond to this consultation. I noticed that in sections 1.1.8, 1.2.1 and 1.3.3 Non-alcohol related fatty liver disease (NAFLD) is not included in the list of conditions that put people at a higher risk of developing type 2 diabetes. I would like to highlight evidence that suggests that NAFLD is a risk factor for developing type 2 diabetes (1). I strongly believe that NAFLD should be added to the list of	Thank you for your comment. We will make an editorial amendment to footnote 1 of the recommendations (a list of conditions that can increase the risk of type 2 diabetes). This will note that NALD also increases risk of type 2 diabetes, with reference to Non-alcoholic fatty liver disease (NAFLD): assessment and management (NICE guideline NG49). On checking the references supplied, the report by Johnson et al. (2013) was published before the search dates for this surveillance review, and the abstract does not include any results from primary

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		conditions that increase the risk of developing type 2 diabetes. I am aware that this is already covered in NICE guidance on NAFLD (NG49, 1.2.12) which states that NAFLD is a risk factor for type 2 diabetes. However, in order to ensure that all NAFLD patients receive a type 2 diabetes risk assessment I feel that it would be prudent to include a specific reference to NAFLD within this guidance on diabetes. It is vital that all NAFLD patients are encouraged to have a risk assessment for diabetes because NAFLD patients with diabetes are more likely to progress to NASH, cirrhosis and death. (2) (1) Johnson AMF, Olefsky JMJM, Amar J, Chabo C, Waget A, Klopp P, et al. The origins and drivers of insulin resistance. Cell. 2013 Feb 14;152(4):673–84. pmid:2341521 (2) Younossi ZM, Koenig AB, Abdelatif D, Fazel Y, Henry L, Wymer M. Global epidemiology of nonalcoholic fatty liver disease-Meta-analytic assessment of prevalence, incidence, and outcomes. Hepatology. 2016 Jul;64(1):73–84. pmid:26707365	or secondary analysis of relevant data. Therefore it is not eligible for consideration in surveillance. The report by Younossi et al. (2016) addresses non-alcoholic fatty liver disease so is not directly relevant to surveillance of guidance on the prevention of type 2 diabetes. This study appears to have been considered during development of the guideline on non-alcoholic fatty liver disease. It is included as reference 229 of the full guideline. Therefore it is not eligible for consideration in surveillance of the guideline on diabetes prevention.
Obesity Group of the British Dietetic Association	Yes	We agree that based on current evidence the guidance should not be updated; the current guidance is in line with evidence which has been subsequently published. However we also agree that the proposed date for the next surveillance may need to be adjusted depending on evidence from studies which are currently underway. This	Thank you for your comment.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		flexibility is important in case the review date needs to be earlier than planned.	
South Sefton Clinical Commissioning Group	Yes	No comments provided	Thank you for your response.
Diabetes UK	Yes	We agree with the proposal not to update PH38 at this stage, however the evidence in relation to PH35 should be reviewed. PH35 has not been updated since 2012, in this time there have been key documents that would contribute to this guideline. The Scientific Advisory Committee on Nutrition report on carbohydrates and health (2015) and the evidence underlying the childhood obesity plan are examples. Additionally there is existing evidence relating to dietary patterns and specific foods in Type 2 diabetes prevention that should be considered- please see upcoming Diabetes UK nutritional guidelines.	Thank you for your comment. We have now summarised evidence identified on population and community-level interventions (relevant to NICE guideline PH35). The Scientific Advisory Committee on Nutrition (SACN) report on Carbohydrates and health (2015) recommended reductions in dietary intake of free sugars, particularly sugar sweetened beverages. In Type 2 diabetes prevention: population and community-level interventions (NICE guideline PH35), the section on achieving and maintaining a healthy weight notes: 'consume as little as possible of fried food; drinks and confectionery high in added sugars (such as cakes, pastries and sugar-sweetened drinks); and other food high in fat and sugar (such as some take-away and fast foods)'. This is broadly in line with SACN's findings, so an update is not considered to be necessary at this time. The guidelines on diabetes prevention cover adults only; however, NICE also has a guideline on obesity prevention (NICE guideline CG43) covering adults and children. In March 2017, surveillance of this guideline proposed to: 'Amalgamate update areas of obesity prevention (NICE guideline CG43) with partial update of weight management: lifestyle services for overweight or obese children and young people (NICE guideline PH47) to enable guideline development focusing on the 'promotion of health and wellbeing for children and young people.' This means

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

			an update covering this area as part of the diabetes prevention guideline is not necessary. In terms of the upcoming Diabetes UK nutritional guidelines, NICE's surveillance process does not use other organisations' guidelines as a source; however, we can look at the evidence that has informed those guidelines. We will check for publication of these guidelines and assess their impact on the NICE guidelines on preventing diabetes.
Merck Sharp & Dohme Limited	Yes	No comments provided	Thank you for your response.
Ascensia Diabetes Care UK Ltd	No	Professor Jack Winkler[1] recently spoke at a meeting of the All-Party Parliamentary Group for Diabetes (30.01.2018)[2] on the subject of the worsening diabetes situation, predicting that the implications surrounding the increasing diabetic population could trigger the financial collapse of the NHS if left unchecked. Currently, 8.5% (approx. 4 million) of the population of England has diabetes, this is predicted to rise to 9.5% (approx. 5 million) of the population according to Public Health England[3]. This would trigger a related rise in spending on diabetes by NHS	Thank you for your comments. The NHS Diabetes Prevention Programme is currently being rolled out, which indicates a high level of priority for diabetes prevention in the NHS in England. Of the references provided, references 1–4 provide useful background information, but do not provide new information to inform interventions to prevent type 2 diabetes. Therefore, they are not eligible for inclusion in this surveillance review. The accuracy of blood-glucose meters is an important issue; however, we have not identified any evidence that self-monitoring

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		England from £23.7bn in 2010/11 to £39.8bn[4] by 2035/36. Therefore, Ascensia believes that the current guidelines should be adjusted to take into account the current issues surrounding accuracy regulations, new technological innovations, and that more needs to be done to address the growing diabetic population in terms of prevention and education. In particular, for the people identified as pre-diabetic, it is crucial to have access to highly accurate measurement of blood glucose (with a presentation of blood glucose results in a simple and easy-to-review, personalised format) for the diabetes epidemic not to further worsen and increase the resulting financial implications for the NHS. [1]http://www.thesugarreductionsummit.co.uk/speaker/professor-jack-winkler/ [2] https://diabetesappg.wordpress.com/2018/01/17/next-meeting-next-steps-for-the-childhood-obesity-plan/ [3] https://www.gov.uk/government/publications/diabetes-prevalence-estimates-for-local-populations [4] Hex, N., et al., *Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs.* Diabetic	of blood glucose has a role of preventing diabetes. The issue of blood-glucose meter accuracy has been noted for consideration at the next surveillance of the guidelines on management of diabetes: • Type 1 diabetes in adults: diagnosis and management (NICE guideline NG17) • Type 2 diabetes in adults: management (NICE guideline NG28) • Diabetes (type 1 and type 2) in children and young people: diagnosis and management (NICE guideline NG18). References 5–10 do not provide any evidence to inform prevention of type 2 diabetes, so are not eligible for inclusion in this surveillance review. Reference 11 (Roberts et al. 2018) has been added to the summary of evidence. The findings of this study support the approach of the NHS Diabetes Prevention Programme, and current recommendations on lifestyle interventions and metformin use in the diabetes prevention guidance.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		Medicine, 2012. 29: p. 855-862 https://jdrf.org.uk/wp-content/uploads/2015/10/Hex-and-Bartlett.pdf [5] Ekhlaspour, L., et al., *Comparative Accuracy of 17 Point-of-Care Glucose Meters.* J Diabetes Sci Technol, 2017. 11(3): p. 558-566. [6] Diabetes Technology Society, Blood Glucose Monitor Surveillance Program: https://www.diabetestechnology.org/surveillance.shtml [7] Freckmann, G., et al., *Analytical Performance Requirements for Systems for Self-Monitoring of Blood Glucose with Focus on System Accuracy: Relevant Differences Among ISO 15197:20003, ISO 15197:2013, and Current FDA Recommendations.* J Diabetes Sci Technol, 2015. 9(4): p. 885-894. [8] McQueen, R.B., et al., Economic Value of Improved Accuracy for Self-Monitoring of Blood Glucose Devices for Type 1 Diabetes in Canada. [9] Gruman, J., et al., *From patient education to patient engagement: Implications for the field of patient education*. Patient Education and Counseling, 2010. 78(3): p. 350-356 [10] Matjaž Krošel, Lana Švegl, Luka Vidmar and Dejan Dinevski (2016). Empowering Diabetes Patient with Mobile Health Technologies, Mobile Health Technologies - Theories and Applications, Dr. Wilfred Bonney (Ed.), InTech, DOI: 10.5772/64620. Available from: https://www.intechopen.com/books/mobile-health-technologies-theories-and-applications/empowering-diabetes-patient-with-mobile-health-technologies	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		[11] Roberts, S., et al., *Economic evaluation of type 2 diabetes prevention programmes: Markov model of low- and high-intensity programmes and metformin in participants with different categories of intermediate hyperglycaemia*. BMC Medicine. 2018. 16:16	
X-PERT Health	No	Failure to fully appraise the evidence around, and consider an update to, these guidelines is not consistent with stated NHS and PHE priorities to focus on preventative health measures. The surveillance document states that PHE and NHS wish to postpone the update until after the 2020 appraisal of the NDPP: • This isn't a valid reason to wait, as there is evidence available now which may suggest a change in guidance is warranted • An appraisal of the NDPP would be unable to inform us whether or not an alternative approach is warranted, as even evidence of this programme being successful would not show whether an alternative approach could be more, or equally as, efficacious • If the appraisal of the NDPP shows limited success in any area and a review of the available evidence is not started until after this is demonstrated in 2020 there would be a prolonged wait for new reviews to be completed and guidelines to be developed. If this process is sooner any required amendments would be well informed sooner	Thank you for your comment. Previous surveillance of this guideline was conducted in 2015. Evidence published between 2010 and July 2014 was available for consideration in the 2015 surveillance review, therefore it was not re-assessed at this surveillance review. Guidelines are updated when new evidence indicates that a change to current recommendations may be necessary. The guideline on Type 2 diabetes: prevention in people at high risk (NICE guideline PH38) was subsequently updated in September 2017. Although outputs from the NHS Diabetes Prevention Programme were noted as potentially important drivers for future updates to the guidelines on diabetes prevention, we also noted that 'any other major developments in this area may result in the surveillance review being brought forward.' Thank-you for drawing our attention to the withdrawn Cochrane review. Unfortunately this was identified in our searches and our reference management software did not indicate the true status of this article. We will remove this study from the summary of evidence and investigate methods to avoid this happening in future. Our searches identified 5,255 references that were assessed for inclusion in this surveillance review. All references meeting our criteria were included.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		The only study referenced in the "Dietary Advice" section of the surveillance document is incorrect and inappropriately interpreted. The review is referenced as being published in 2016, but it is actually a 2007 review that was withdrawn in 2016 as it was considered out of date. At best this demonstrates a lack of care in this review. The summary states that the dietary advice given by the papers included in this Cochrane review were unknown, yet the findings are used as part of the evidence that the current guidelines do not require revisiting. If the authors are unaware of the content of a study it is inappropriate to use it as support. The section of the surveillance document regarding effectiveness of specific diets: • Is woefully inadequate as there is a large body of literature available evaluating a broad range of dietary approaches which include outcomes relevant to the at risk population these guidelines are intended for. Only four studies were included, so this is inadequate justification for maintaining existing guidelines • None of the included studies assess any form of carbohydrate restriction, but rather seem a cherry picked selection to try and support the existing guidelines • None of the conclusions in this summary show a superiority of a particular approach, thus the maintenance of guidelines recommending a single approach are not justified	In 2015, SACN published Carbohydrates and health, which recommended reductions in dietary intake of free sugars, particularly sugar sweetened beverages. However, the recommended level of carbohydrate consumption remained the same. Nevertheless, evidence on any dietary interventions in people with non-diabetic hyperglycaemia was considered in this surveillance review. The reports by Saslow et el. (2014), and the 12-month results Saslow et al. (2017) would not be eligible for consideration in this surveillance review because results for the group with non-diabetic hyperglycaemia are not reported as a distinct subgroup. The study by Maekawa et al. (2014) would not be eligible for consideration in surveillance because: • it appears to be an observational study with a sample size of 72 people and • observational studies were eligible for inclusion in this surveillance review if they had a sample size of 250 people or more. – this criterion was adopted from the 2017 update of the guideline, which set this limit for observational studies of lifestyle interventions. Stentz et al. (2016) was identified in our searches but was excluded because the follow-up period was only 6 months. The surveillance review included studies with at least 12 months follow-up. • This criterion was adopted from the 2017 update of the guideline, which set this limit for studies of lifestyle interventions and metformin.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		• Reference 92 provides evidence that MUFA can be beneficial yet guidelines continue to recommend restriction of fat with very limited qualification • Referring to certain approaches as "healthy diets" show an immediate bias towards these approaches, i.e. they demonstrate that the authors have pre-defined the diets in question as healthy • Reference 89 is meta-analysis of cohort studies that only included DASH and Mediterranean diets. If no other dietary approaches were included in studies or reviews included at this stage of evidence appraisal, the outcomes reached could never consider the addition of alternative dietary approaches to the existing guidelines The attention given to individual foodstuffs in the surveillance document, particularly relatively obscure ones, is completely disproportionate to the coverage given to broader dietary approaches and styles of eating. Type 2 diabetes is predominantly a dietary condition, so why was topic expert feedback not considered necessary for the dietary guidelines related to the prevention of it? In the impact statement of the surveillance document it says "Specific diets did not show effectiveness over other diets…". If this is the case, why do the guidelines only provide advice pertaining to a low-fat dietary approach? Statement 1.7.6 of the surveillance document (repeating a statement from NICE PH38) asserts that assessment of programmes should focus on consumption of fat, saturated fat and fibre. This method would not allow consideration of	Although we adopted some criteria from the 2017 update to aid in our selection of evidence, we did not require that studies needed to meet 9 of the 12 criteria for face-to-face lifestyle interventions. Surveillance is therefore able to identify evidence for new interventions that were not considered in the guideline. Hooper et al. (2015) is not eligible for consideration in this surveillance review because it focuses on cardiovascular outcomes. However, in checking the full text for outcomes relevant to diabetes prevention, one RCT dating from 2006 was identified. This study was published many years before the search dates for this surveillance so is not eligible for consideration at this time. Although in the UK, SACN has responsibility for providing guidance on nutrition, the USDA dietary guidelines have been checked for conflicts with current guidance. These guidelines may not set a specific upper limit on fats, but do recommend consumption of 'less than 10 percent of calories per day from saturated fats'. Overall, the advice aligns with recommendations in the guideline. The study by Forouhi et al. (2014) has been added to the summary of evidence from surveillance. However, the findings do not easily translate into pragmatic dietary advice at this time. The study by Alexander et al. (2016) does not include people with non-diabetic hyperglycaemia as a population, or prevention or reduction in incidence of type 2 diabetes as an outcome, therefore this study is not eligible for consideration in this surveillance review. No evidence was identified to fully address the research recommendation on different dietary regimens or in different subgroups. Should suitable new evidence arise, we will consider its impact on the guideline to decide whether an immediate update of

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		whether other dietary components' inclusion or restriction was having a meaningful impact, an approach that is not logical when diabetes is a condition of carbohydrate metabolism. The dietary review for the surveillance document was of studies published between 1st July 2014 and 30th October 2017, whilst existing guidelines were based on a literature review carried out in September 2010. Thus, over 3 years' worth of research has potentially not been considered (it is unclear what evidence was considered in the 2015 evidence review). For example Saslow et al (Saslow LR, Kim S, Daubenmier JJ, Moskowitz JT, Phinney SD, Goldman V, et al. A Randomized Pilot Trial of a Moderate Carbohydrate Diet Compared to a Very Low Carbohydrate Diet in Overweight or Obese Individuals with Type 2 Diabetes Mellitus or Prediabetes. PLoS ONE. 2014;9(4):e91027) considered individuals with prediabetes as part of their study but has not been considered as it was published in this window not covered (Published April 9th 2014). The existing guidelines are based on research that is over seven years old, thus are overdue an update when the prevention of Type 2 diabetes is such an important issue on a population level. The existing guidelines are very limited in scope, particularly for the diet section which is only a single page long. Many healthcare professionals do not have any specific training in nutrition, and so more complete and flexible guidance would be of great benefit.	the guideline is necessary, or whether the reference should be included in the next scheduled surveillance review. We recognise that NICE has many guidelines that provide dietary advice. Differences between guidelines are frequently identified during surveillance, and if contradictory recommendations are identified we will address the issue. In terms of advice on healthy diets, we did not identify contradictory advice needing an update at this time. For specific dietary interventions, each guideline focuses on evidence relevant to its population. Carbohydrate measurement and control of intake is necessary in type 1 diabetes because of the need to accurately calculate the correct insulin dose. In type 2 diabetes, the person's residual insulin activity means that total carbohydrate control (as seen for type 1 diabetes) is not necessary. However, dietary advice about low-glycaemic index foods was made in the guideline on treating type 2 diabetes because high glycaemic index foods 'may cause hyperglycaemia in the presence of defective insulin secretory reserve.' For diabetes prevention, we identified no clear evidence that low carbohydrate diets prevent diabetes to a greater degree than reducing overall energy intake.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		There are a number of studies that provide evidence for the efficacy of different dietary approaches for the prevention of Type 2 diabetes, for example: • Saslow et al 2014 (Saslow LR, Kim S, Daubenmier JJ, Moskowitz JT, Phinney SD, Goldman V, et al. A Randomized Pilot Trial of a Moderate Carbohydrate Diet Compared to a Very Low Carbohydrate Diet in Overweight or Obese Individuals with Type 2 Diabetes Mellitus or Prediabetes. PLoS ONE. 2014;9(4):e91027.), which included individuals with prediabetes as well as with Type 2 diabetes, concluded "Our results suggest that a very low carbohydrate diet coupled with skills to promote behavior change may improve glycemic control in type 2 diabetes while allowing decreases in diabetes medications • Saslow et al 2017 (Saslow LR, Daubenmier JJ, Moskowitz JT, Kim S, Murphy EJ, Phinney SD, et al. Twelve-month outcomes of a randomized trial of a moderate-carbohydrate versus very low-carbohydrate diet in overweight adults with type 2 diabetes mellitus or prediabetes. Nutr Diabetes. 2017;7(12):304.), which included individuals with prediabetes as well as with Type 1 diabetes, concluded "In a 12-month trial, adults with elevated HbA1c and body weight assigned to a low-carb ketogenic diet had greater reductions in HbA1c, lost more weight, and reduced more medications than those instructed to follow a moderate-carb, calorie-restricted, low fat diet"	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		• Maekawa et al 2014 (Maekawa S, Kawahara T, Nomura R, Murase T, Ann Y, Oeholm M, et al. Retrospective study on the efficacy of a low-carbohydrate diet for impaired glucose tolerance. Diabetes, metabolic syndrome and obesity : targets and therapy. 2014;7:195-201.) concluded "The low carbohydrate diet is effective for normalizing blood glucose and preventing progression to type 2 diabetes in patients with IGT" – Stentz et al 2016 (Stentz FB, Brewer A, Wan J, Garber C, Daniels B, Sands C, et al. Remission of pre-diabetes to normal glucose tolerance in obese adults with high protein versus high carbohydrate diet: randomized control trial. BMJ Open Diabetes Research & Care. 2016;4(1):e000258.) concluded "This is the first dietary intervention feeding study, to the best of our knowledge, to report 100% remission of pre-diabetes with a HP diet and significant improvement in metabolic parameters and anti-inflammatory effects compared with a HC diet at 6 months." – There are also question marks of the validity of the current recommendation to reduce fat intake, including saturated fat guidelines: – Hooper et al 2015 (Hooper L, Martin N, Abdelhamid A, Davey Smith G. Reduction in saturated fat intake for cardiovascular disease. Cochrane Database Syst Rev. 2015;6:CD011737.). The current best evidence	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		regarding the impact of saturated fat on health comes from this Cochrane review which was updated in 2015. The review found no difference in mortality rates and no difference in rates of Type 2 diabetes between high and low saturated fat groups; and the difference in event rates was no longer present appropriate sensitivity analyses had been carried out (the 17% drop in cardiovascular events reported in the review's conclusion was reduced and was no longer significant when a sensitivity analysis was run whereby only studies that successfully reduced saturated fat content in the intervention group compared to the control group were included) – US dietary guidelines no longer recommend an upper limit for fat intake, reflecting the current research on the impact of dietary fat on weight management and health (Dietary Guidelines For Americans. 2015-2020. Eighth Edition. USDA) Existing guidelines said they would be reviewed after 3 years. It has already been 6 years, thus an update is long overdue; particularly in face of changing scientific and public opinion Future research recommendations of previous guidelines included: "How effective and cost effective are different types of dietary regime in reducing short- and long-term blood glucose levels and preventing or delaying type 2 diabetes? How does this vary for different subgroups, for example, African-Caribbean and black African and other	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		minority ethnic groups and for people of different ages, for example, aged 18–24, 25–39 and 75 and over?". This question has not been fully addressed. NICE guideline NG28, recommendation 1.3.6, states "Individualise recommendations for carbohydrate and alcohol intake, and meal patterns". Evidence suggests that this should be extended to other guidelines to promote freedom of choice. NICE guideline NG17 states that "Carbohydrate is the macronutrient that has the greatest impact on glycaemic control". It is illogical that this same assertion is not considered when setting guidance for individuals at increased risk of T2DM. The 2017 evidence reviews available online only included studies that included Metformin alongside the lifestyle interventions, and excluded studies which used interventions that didn't follow at least 9 of the existing criteria. This method precluded any evaluation of any interventions that are different to what is already being recommended, effectively closing the door on different approaches The 2015 recommendations from the dietary advice panel were that it would be helpful to align the carbohydrate guidance to the SACN report conclusions. The SACN report however did not included any studies using individuals with Type 2 diabetes and included very limited evidence in individuals with impaired glucose tolerance. Many of the studies actively excluded participants with these conditions. Thus the SACN report does not provide appropriate evidence to assess the prevention of Type 2	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		diabetes in many high risk individuals and so the basis of the existing guidelines is to an extent flawed. The 2015 evidence review, which also concluded no update was required to the dietary advice portion of the Type 2 diabetes prevention guidelines, only included 2 reviews in the dietary advice review section. One of these reviews was a meta-analysis of cohort studies and the other was a narrative review without systematic methods. Neither of these are appropriate forms of evidence, and any consideration of this review's outcomes in relation to whether there is grounds for updating the guidelines now is not valid. The demonization of all saturated fat is invalid as different chain lengths, and whether the chains have an odd or even number of carbons, are differentially associated with cardiovascular disease risk (e.g. Forouhi NG, Koulman A, Sharp SJ, Imamura F, Kröger J, Schulze MB, et al. Differences in the prospective association between individual plasma phospholipid saturated fatty acids and incident type 2 diabetes: the EPIC-InterAct case-cohort study. The Lancet Diabetes & Endocrinology. 2014;Oct;2(10):810-8. doi: 10.1016/S2213-8587(14)70146-9. Epub 2014 Aug 5.). The saturated fatty acids founds in dairy products have been associated with positive health outcomes (e.g. Alexander DD, Bylsma LC, Vargas AJ, Cohen SS, Doucette A, Mohamed M, et al. Dairy consumption and CVD: a systematic review and meta-analysis. Br J Nutr. 2016;115(4):737-50.), and as such the promotion of low-	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		fat milk and yoghurts is also not consistent with much of the currently available evidence.	
Public Health Collaboration	No	First, on page 2 in paragraph 3 of the surveillance review proposal document you state that "We found 132 relevant studies in a search for systematic reviews, randomised controlled trials, and observational studies published between 01 July 2014 and 30 October 2017." However, the previous update on guideline PH38 only included a literature review up to September 2010. We would like to know why the period between September 2010 and 01 July 2014 was not included in your literature search? Secondly, on page 36 of the surveillance review proposal document under the first subheading*"Dietary Advice"* of the 2018 surveillance summary a *"Chocrane review(88)"* is referenced to. It should be noted that this review has been withdrawn by Cochrane because *"The review is out of date and does not meet current Cochrane standards."* Nield L, Summerbell CD, Hooper L, Whittaker V, Moore HJ. Dietary advice for the prevention of type 2 diabetes mellitus in adults. Cochrane Database of Systematic Reviews 2016, Issue 1. Art. No.: CD005102. DOI: 10.1002/14651858.CD005102.pub3. http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005102.pub3/pdf This review has been superseded by *"Diet, physical activity or both for prevention or delay of type 2 diabetes mellitus and its associated complications in people at increased risk"*. Hemmingsen B, Gimenez-Perez G, Mauricio D, Roqué i Figuls M, Metzendorf M, Richter B. Diet, physical activity	Thank you for your comment. Please see the earlier response on the choice of search dates. Please see the earlier response on the withdrawn Cochrane review. The updated Cochrane review by Hemmingsen et al. (2017) has been added to the summary of evidence considered in this surveillance review. Please see the earlier response on the studies on low-carbohydrate diets (Saslow et el. 2014, Saslow et al. 2017, and Maekawa et al. 2014). As you noted, the meta-analyses by Meng et al. (2017) and Huntriss et al. (2017) assessed the effects of low carbohydrate diets in people with type 2 diabetes. Therefore, these studies are not eligible for consideration in this surveillance review. These studies have been noted for consideration in the next surveillance review of Type 2 diabetes in adults: management (NICE guideline NG28). The study by Dehghan et al. (2017) does not include people with non-diabetic hyperglycaemia as a population, or prevention or reduction in incidence of type 2 diabetes as an outcome, therefore this study is not eligible for consideration in this surveillance review.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		or both for prevention or delay of type 2 diabetes mellitus and its associated complications in people at increased risk of developing type 2 diabetes mellitus. Cochrane Database of Systematic Reviews 2017, Issue 12. Art. No.: CD003054. DOI: 10.1002/14651858.CD003054.pub4 http://www.cochrane.org/CD003054/ENDOC_diet-physical-activity-or-both-prevention-or-delay-type-2-diabetes-mellitus-and-its-associated Thirdly, under the next subheading *"Effectiveness of following specific diets"* we have noticed that there is no mention of studies involving low-carbohydrate diets. The reason for this might be because the literature search dates omit such peer reviewed published studies, which again we would like clarification on as to why these dates were set. Published on 9 April 2014 there was a 3 month randomised pilot trial comparing a moderate carbohydrate diet (MCCR) to a very low carbohydrate diet (LCK) in overweight or obese individuals with type 2 diabetes mellitus or prediabetes. This trial found that *"At 3 months, mean HbA1c level was unchanged from baseline in the MCCR diet group, while it decreased 0.6% in the LCK group; there was a significant between group difference in HbA1c change favoring the LCK group (−0.6%, 95% CI, −1.1% to −0.03%, p=0.04). Forty-four percent of the LCK group discontinued one or more diabetes medications, compared to 11% of the MCCR group (p=0.03); 31% discontinued sulfonylureas in the LCK group, compared to 5% in the MCCR group (p=0.05). The LCK group lost 5.5 kg vs. 2.6 kg lost in MCCR group (p=0.09). Our results suggest that a very low carbohydrate diet coupled with skills to promote behavior change may improve glycemic control in*	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		type 2 diabetes while allowing decreases in diabetes medications." Saslow LR, Kim S, Daubenmier JJ, Moskowitz JT, Phinney SD, Goldman V, et al. (2014) A Randomized Pilot Trial of a Moderate Carbohydrate Diet Compared to a Very Low Carbohydrate Diet in Overweight or Obese Individuals with Type 2 Diabetes Mellitus or Prediabetes. PLoS ONE 9(4): e91027. https://doi.org/10.1371/journal.pone.0091027 Published on 13 June 2014 there was a retrospective study which showed that *"the incidence of diabetes was significantly lower in the low-carbohydrate diet group than in the control group at 12 months".* It also found that *"The low-carbohydrate diet group showed a significant decrease in fasting plasma glucose, hemoglobin A1c, the homeostasis model of assessment of insulin resistance value, body weight and serum triglycerides at 12 months, while there was a significant increase of the serum high-density lipoprotein cholesterol level."* It concluded that *"The low-carbohydrate diet is effective for normalizing blood glucose and preventing progression to type 2 diabetes in patients with impaired glucose tolerance." Maekawa, S., Kawahara, T., Nomura, R., Murase, T., Ann, Y., Oeholm, M., & Harada, M. (2014). Retrospective study on the efficacy of a low-carbohydrate diet for impaired glucose tolerance. Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy, 7, 195–201. http://doi.org/10.2147/DMSO.S62681* Finally, on 21 December 2017 there was a follow up to the aforementioned randomised pilot trial comparing a moderate carbohydrate diet (MCCR) to a very low carbohydrate diet (LCK) in overweight or obese individuals	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		with type 2 diabetes mellitus or prediabetes. This trial found that *"At 12 months, participants in the LCK group reduced their HbA1c levels more than participants in MCCR group."* [Note that a figure has been removed from this comment by NICE because the copyright of this image lies with the journal Nutrition & Diabetes.] This trial also found that *"At 12 months, participants in the LCK group lost more weight and lowered their BMI more than participants in the MCCR group. On average, at 12 months participants in the LCK group lost 8.3% of body weight, whereas the MCCR group lost 3.8%."* The authors concluded that *"The results suggest that adults with prediabetes or noninsulin-dependent type 2 diabetes may be able to improve glycemic control with less medication by following an ad libitum very low-carbohydrate ketogenic diet compared to a moderate-carbohydrate, calorie-restricted low-fat diet." Saslow LR, Daubenmier JJ, Moskowitz JT, Kim S, Murphy EJ, Phinney SD, et al. (2017) Twelve-month outcomes of a randomized trial of a moderate-carbohydrate versus very low-carbohydrate diet in overweight adults with type 2 diabetes mellitus or prediabetes. Nutr Diabetes. 2017 Dec 21;7(12):304. doi: 10.1038/s41387-017-0006-9.https://doi.org/10.1038/s41387-017-0006-9* In regard to low-carbohydrate diets, it should also be noted that 2 meta-analyses were published in 2017 looking at randomised controlled trials comparing low-fat diets to low-carbohydrate diets with participants living with type 2 diabetes.	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		The first, published in July which falls into your literature search dates, found that the low-carbohydrate diet group had a significant decrease in HbA1c compared to the low-fat diet group. Alongside significantly decreased triglycerides and increased HDL cholesterol. The authors concluded that *"The results suggested a beneficial effect of LCD intervention on glucose control in patients with type 2 diabetes." Efficacy of low carbohydrate diet for type 2 diabetes mellitus management: A systematic review and meta-analysis of randomized controlled trials. Meng, Yan et al. Diabetes Research and Clinical Practice , Volume 131 , 124 – 131. http://dx.doi.org/10.1016/j.diabres.2017.07.006* The second meta-analysis was published in December, which falls out of your literature search dates, also showed statistical significance in favour of the low-carbohydrate diet for HbA1c, HDL cholesterol and triglycerides as well as systolic blood pressure. The authors concluded that *"reducing carbohydrate intake may promote favourable health outcomes in the management of type 2 diabetes"*. They also added that *"more research is needed to determine whether there is an optimal intake of dietary carbohydrate for patients with type 2 diabetes, and to challenge whether the UK national dietary reference value of 50% is appropriate for patients with type 2 diabetes."* Rosemary Huntriss, Malcolm Campbell, Carol Bedwell. (2017) The interpretation and effect of a low-carbohydrate diet in the management of type 2 diabetes: a systematic review and meta-analysis of randomised controlled trials. Eur J Clin Nutr. 2017 Dec 21. doi: 10.1038/s41430-017-0019-4. https://doi.org/10.1038/s41430-017-0019-4	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		Although these meta-analyses are in relation to individuals with established type 2 diabetes, it stands to reason that a diet that improves type 2 diabetes would also be one that would also prevent it in people at high risk. In Scotland, SIGN have recently updated their *"Management of diabetes"* guidelines. Specifically under guideline 3.7.1 they state that *"People with type 2 diabetes can be given dietary choices for achieving weight loss that may also improve glycaemic control. Options include simple caloric restriction, reducing fat intake, consumption of carbohydrates with low rather than high glycaemic index, and restricting the total amount of dietary carbohydrate (a minimum of 50 g per day appears safe for up to six months)."* We concur with SIGN that people with type 2 diabetes can be given dietary choices, which should include low-carbohydrate diets. We hope that NICE also take this under consideration. Finally, in regard to the recommendations to *"Increase their consumption of foods that are high in fibre, such as wholegrain bread and cereals, beans and lentils, vegetables and fruit."* and *"Choose foods that are lower in fat and saturated fat"* under guideline 1.14.3 we would like to draw your attention to the PURE study. *SIGN. (2017) Management of diabetes. A national clinical guideline.* *http://www.sign.ac.uk/assets/sign116.pdf* The PURE study followed 135,335 individuals in 18 countries and found that *"High carbohydrate intake was associated with higher risk of total mortality, whereas total fat and individual types of fat were related to lower total mortality. Total fat and types of fat were not associated with cardiovascular disease, myocardial infarction, or*	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		cardiovascular disease mortality, whereas saturated fat had an inverse association with stroke. Global dietary guidelines should be reconsidered in light of these findings." Associations of fats and carbohydrate intake with cardiovascular disease and mortality in 18 countries from five continents (PURE): a prospective cohort study. Dehghan, MahshidDiaz, R et al. The Lancet , Volume 390 , Issue 10107 , 2050 - 2062.https://doi.org/10.1016/S0140-6736(17)32252-3 With all of this evidence in mind, the Public Health Collaboration suggests that NICE should update this guideline as well as review the literature from the previous updates literature search dates (September 2010) to the present day.	
Johnson & Johnson Medical Ltd.	No	Johnson & Johnson Medical Ltd. welcome NICE's endorsement of bariatric surgery to treat type 2 diabetes as both clinically and cost effective on page 46 of the surveillance review proposal report. We also welcome NICE's impact statement that "evidence consistently shows that bariatric surgery may prevent diabetes". And, as NICE states at p46, recommendations endorsing the clinical and cost effectiveness of bariatric surgery to treat type 2 diabetes are indeed included in NICE Clinical Guideline 189 'Obesity: identification, assessment and management' at section 1.11. However, we wish to bring to NICE's attention that these recommendations are neither acknowledged nor accepted by payors, clinicians or the public within the mainstream treatment algorithm for type 2 diabetes in the UK. As a result, people with type 2 diabetes for whom bariatric surgery would be an	Thank you for your comment. The rationale for including recommendations on bariatric surgery only in the obesity guideline is because this intervention is indicated for the treatment of obesity, although it has beneficial effects on reducing the incidence of type 2 diabetes. It would not be indicated to prevent type 2 diabetes in people without obesity. In the guideline on diabetes prevention (NICE guideline PH38) recommendation 1.13.8 notes: 'If the weight management interventions in recommendations 1.13.1–1.13.7 have been unsuccessful, refer people to a specialist obesity management service (see NICE guidance on obesity).' We believe this is the most appropriate pathway for people with non-diabetic hyperglycaemia and obesity. Guidelines are updated if surveillance programme identifies evidence suggesting that recommendations need to change. We

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		appropriate and cost effective treatment for their type 2 diabetes are being denied access to clinically and cost effective surgery. Its position only in NICE Obesity Guidelines and pathways, and not embedded within the NICE type 2 diabetes pathway may be further contributing to this. We therefore disagree with NICE's final conclusion not to include recommendations on bariatric surgery as a treatment for established type 2 diabetes specifically in this type 2 diabetes Public Health Guideline and request that NICE reconsiders this decision. Furthermore, recommendations on the impact of surgery in the prevention of type 2 diabetes are different to previous recommendations that focus on treating established type 2 diabetes, and should be explicitly called out. We raise this, particularly in light of NICE's new 'impact' report series and renewed focus on the impact its recommendations have on improving the diagnosis and treatment of patients.	may consider incomplete implementation of the guideline as evidence of a need to update, for example if current recommendations are unclear or difficult to interpret. This does not appear to be the cause of low uptake of the recommendations in this case. However, we have noted this issue with the implementation of NICE's recommendations on bariatric surgery.
South Asian Health Action Charity	Yes	Only if there are no perceived equality gaps.	Thank you for your comment. New evidence in this population was identified that supported these current recommendations and updating is not needed.
National Diabetes Prevention Programme team - Public Health	Yes	This is a useful summary of the latest evidence that relates to PH38, and the National Diabetes Prevention Programme (NDPP) agrees with the over-arching conclusion not to update the guideline at this time. However, the NDPP	Thank you for your comment. Thank-you for clarifying the misunderstanding about the National Diabetes Prevention Programme's views on the need to update the diabetes prevention guidelines.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

England, Diabetes UK, and NHS England		recommends the following clarifications in the text of the consultation. Page 1/2. "Public Health England and NHS England noted that it would be prudent to postpone updating the guideline on population and community-level interventions (NICE guideline PH35) until evaluation data from the NHS Diabetes Prevention Programme is available (expected from 2020)." This comment was made by Public Health England (PHE) in relation to NICE PH38, not PH35. The Diabetes Prevention Programme (DPP) is a personalised lifestyle intervention delivered at scale to a targeted at risk group, and as such, it is directly relevant to PH38. PH35 however is concerned at population and community level interventions to address fiscal, social, and environmental outcomes facilitating lifestyle choices, but not in a personalised way. Therefore, the NDPP is unclear on the how evaluation data from the DPP could provide a rationale for deferring an update on population and community-level interventions. https://www.england.nhs.uk/diabetes/diabetes-prevention/ Page 48/49. "What are the demographic characteristics and rates of progression to type 2 diabetes among people with a high risk score but normal blood glucose levels (fasting plasma glucose of less than 5.5 mmol/l or HbA1c of less than 42 mmol/mol)? How does this compare with people who have both a high risk score and blood glucose levels that indicate impaired glucose regulation (fasting	We have amended the text, and have checked for evidence relating to population and community-level interventions. We have amended the text around the research recommendations in response to your comments. We also added your comments as topic expert feedback in the section on the use of technology, although the reference to the article by Murray et al. (2016) was not included because it is not directly applicable to the surveillance of the guidance on preventing type 2 diabetes. As noted in the summary of evidence, NICE has guidance on individual approaches to behaviour change (NICE PH49), which is being updated to consider the use of technology such as apps, text messaging and the internet to drive improvements in behaviours such as physical activity, diet and weight.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		plasma glucose 5.5–6.9 mmol/l or HbA1c 42–47 mmol/mol (6.0–6.4%)?" Contrary to the suggestion, the DPP will not inform this. This is because the DPP does not directly involve the risk assessment stage; risk assessment is undertaken prior to referral to the programme. The evaluation of the DPP will cover a range of issues including understanding change in outcomes associated with participation in the programme. Page 49. "What are the most effective and cost-effective methods of increasing uptake of type 2 diabetes risk assessments and monitoring among those at greatest risk?" This question suggests that the DPP will further inform this, but as noted above, the DPP does not directly involve the risk assessment stage. Page 52. "What is the effectiveness of providing digitally delivered intensive lifestyle-change programmes in preventing type 2 diabetes in adults at high risk of type 2 diabetes?" The NDPP recommends adding that the DPP will be contributing future evidence to this specific question; a pilot of 5,000 people is live, and will assess whether digital behaviour change interventions delivered at scale and under service conditions are associated with change in clinical outcomes associated with diabetes prevention. https://www.england.nhs.uk/diabetes/digital-innovations-to-support-diabetes-outcomes/nhs-diabetes-prevention-programme-digital-stream/ The NDPP advocates noting that digital interventions offer substantial potential for increasing the scalability of, access	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		to, and cost-effectiveness of lifestyle behaviour change advice. The NDPP acknowledge that the evidence base is not yet sufficiently robust to warrant inclusion in NICE guidance under current evidence standards. However, the NDPP recommends noting that leading academics working in this field (Murray et al, 2016, reference below) have highlighted the particular challenges with generating an evidence base to this level in this field As a result, the NDPP recommends NICE consider its approach to this specific evidence base with a view to an update on guidance in this area in the near future. Murray, E., et al. (2016). "Evaluating Digital Health Interventions: Key Questions and Approaches." Am J Prev Med 51(5): 843-851 https://www.ncbi.nlm.nih.gov/pubmed/27745684	
University of Nottingham	No	**Section 1.3 Risk assessment**: QDiabetes is widely used across the NHS and is integrated into the majority of NHS GP computer systems. In Nov 2017, an updated version of QDiabetes-2018 was published in the BMJ. http://www.bmj.com/content/359/bmj.j5019 . QDiabetes-2018 will be implemented into GP systems in 2018. QDiabetes-2018 includes additional risk factors all of which are known to increased risk of diabetes and which were selected, in part, because they had been highlighted in the 2017 update of PH38. The levels of increased risk of	Thank you for your comment. We have updated the evidence summary to correct the error in interpretation of the study by Hippisely-Cox. Recommendation 1.2.1 notes: Encourage the following to have a risk assessment: • all eligible adults aged 40 and above, except pregnant women • people aged 25–39 of South Asian, Chinese, African-Caribbean, black African and other high-risk black and minority ethnic groups, except pregnant women

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

diabetes associated with each risk factor is shown in the table below.

	Women increased risk %	Men increased risk %
atypical antipsychotics	74%	52%
statins	93%	79%
schizophrenia or bipolar affective disorder	30%	26%
learning disability	32%	26%
gestational diabetes	359%	n/a
polycystic ovary syndrome.	41%	n/a

All of these factors were highly statistically significant and the effect on diabetes risk for some patients will be dramatic (e.g. gestational diabetes where there was a 359% increased risk). **Using a risk calculator which DOES NOT include these risk factors will lead to substantial under-estimation in levels of risk to the extent where vulnerable groups of patients will not be identified by the Diabetes Prevention Program.**

- adults with conditions that increase the risk of type 2 diabetes*.

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

Additionally,

- the guideline Psychosis and schizophrenia in adults: prevention and management (NICE guideline CG178) recognises the added risk of type 2 diabetes and other metabolic problems, and cross-refers to the relevant NICE guidelines.
- the guideline Cardiovascular disease: risk assessment and reduction, including lipid modification (NICE guideline G181) appropriately cross-refers to the diabetes prevention guideline.

Therefore, populations at highest risk are already recognised across NICE's guidance in these areas.

Recommendations note that GPs and other primary healthcare professionals should use a validated computer-based risk-assessment tool. If a computer-based risk-assessment tool is not available, they should provide a validated self-assessment questionnaire, for example, the Diabetes Risk Score assessment tool. Other providers, such as pharmacists should offer a validated self-assessment tool, with the Diabetes UK tool cited as an example.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		Surely, given that these factors had already been highlighted by NICE very recently (and re-iterated in section 1.2.1, page 6 of the surveillance review proposal) and are now available in the most widely used diabetes risk calculator, section 1.3 of the PH38 guideline (pages 9 and 10) should be updated to reflect the evidence. Please note that the corresponding update to QRISK3 (which includes some of the same risk factors, such as serious mental illness and antipsychotics) has been welcomed by the NICE guideline group reviewing the updated to the lipid modification guideline CG181https://www.nice.org.uk/guidance/CG181/documents/surveillance-review-proposal **Page 12/13 consultation document**: We think the reviewers for PH38 may have misinterpreted the comment in the abstract of our BMJ paper which said "Additional external validation of models B and C in datasets with more completely collected data on blood glucose would be valuable before the models are used in clinical practice." This was referring model B and C which include glucose and HBA1C not model A which does not include HBA1C or FBS. In addition, please note that all three models (models A, B and C) have been validated on a large representative, independent sample of patients not used for the development of the score and that they showed improvement in performance over the current approach based solely on either HBA1C levels or FBS. Figure 2 of the QDiabetes-2018 paper in the BMJ paper (copied below) compares 4 strategies for identifying patients at high risk of developing diabetes. It shows that	With recommendations that are permissive of choice in risk assessment tools, and no clear indication of superiority of a particular tool, an update in this area is not necessary at this time.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		strategy 3 (based onQDiabetes-2018 model B) has the best sensitivity, identifying 67.3% of people who go on to get type 2 diabetes, compared with 63.8% using fasting glucose alone and 46.6% using HBA1C. Therefore, a strategy involving QDiabetes-2018 would identify a substantially higher proportion of patients who go onto get type 2 diabetes than 'risk identification (stage 2) and would therefore be more efficient and beneficial. Hence 1.4.1 and 1.4.2 on pages 13 and 14 should be updated so that it is based on the best available evidence. [Note that a figure has been removed from this comment by NICE because the copyright of this image lies with the BMJ.]	

Do you have any comments on areas excluded from the scope of the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
20one Clinic	Yes	Do you think there is any role in freestyle libre continuous interstitial glucose monitoring patches, for those that can afford?	Thank you for your comment. We did not identify any evidence to suggest a role for continuous glucose monitoring in people with non-diabetic hyperglycaemia.
Perspectum Diagnostics	No	No comments provided	Thank you for your response.
Obesity Group of the British Dietetic Association	No	No comments provided	Thank you for your response.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

South Sefton Clinical Commissioning Group	No	No comments provided	Thank you for your response.
Diabetes UK	No	No comments provided	Thank you for your response.
Merck Sharp & Dohme Limited	No	No comments provided	Thank you for your response.
Ascensia Diabetes Care UK Ltd	Yes	Ascensia believes that although current guidelines are encouraging and proactive, there are certain key areas missing from their scope: NICE Guidelines need to empower healthcare professionals and carers to move beyond patient education and towards patient engagement, as well as ensuring that accurate and appropriate blood testing is provided for patients. Testing for type 2 diabetes currently requires blood glucose testing. However, although current guidelines (1.4.2) require blood glucose tests to conform to national quality guidelines, namely EN ISO 15197:2015 Accuracy Standards, there is clear evidence that there are several devices currently in use in the UK that do not conform to these standards[5],[6],[7]. This lack of accuracy is directly	As noted in the earlier response, we did not identify any evidence to suggest a role for self-monitoring of blood glucose in people with non-diabetic hyperglycaemia. Recommendation 1.8.5 of the guideline clearly refers to self-monitoring in relation to lifestyle changes, and does not mention blood-glucose monitoring.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		impacting economic outcomes for the NHS through the long-term negative effects on patient outcomes demonstrated in a Canadian study on type 1 diabetes[8]. Current guidelines do not recognise that patients ought to be educated on the meaning of test results and their implications. There is an essential link missing between physical activity (see recommendations 1.12 Providing tailored advice on physical activity), weight management (see recommendations 1.13 Weight management advice), dietary advice (see recommendations 1.14 Dietary advice) and blood glucose testing in patient education. The provision of integrated care packages, such as that offered by Ascensia Diabetes Care through their combination of blood glucose monitoring devices and diabetes self-management support app, can help individuals understand and act to improve their own health outcomes without increasing pressure on healthcare professionals. Structured education, informing people at risk of type 2 diabetes of the direct links between causative factors (weight, physical activity and diet) and blood glucose levels in a demonstrable way can effect meaningful lifestyle change and improve health outcomes[9].	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		While the recommendations for interventions and lifestyle-change programmes are proactive, there is currently a gap between guideline 1.8.5 and guideline 1.9.2. 1.8.5 describes self-monitoring by patients, which Ascensia supports as a means of empowering individuals to manage their own behavioural and lifestyle changes. While 1.9.2 describes information provision, goal setting and action planning in terms of lifestyle changes. However, patients are unlikely to see a healthcare professional again for another 12 months (see 1.6.5). Therefore, Ascensia recommends the provision of a trial period with an easy-to-use blood glucose monitoring kit and lifestyle-related health support application[10] to high-risk individuals as identified by healthcare professionals. This is designed to both aid understanding and visualisation of the direct effects of dietary and activity programmes on blood glucose at a personal level. This suggestion relies on the principle that individuals who are empowered to test themselves and see direct results more often than a yearly check-in with their GP or HCP are more likely to effect meaningful and positive lifestyle changes. This in turn would reduce numbers of individuals	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		developing type 2 diabetes and reduce long-term costs to the NHS as demonstrated by Roberts, et al[11].	
X-PERT Health	Yes	Prediabetes and diagnosed Type 2 diabetes are both conditions of impaired glucose tolerance, and are essentially the same condition separated by an arbitrarily defined cut point. The underlying pathophysiology is the same, and individuals can be anywhere along the spectrum of this condition. Therefore the guidelines, and consideration of evidence to inform them, does not need to be considered completely independently; particularly where there is an absence of evidence considering prevention compared to what is available in relation to management and possible reversal. Only including studies that "reported progression to type 2 diabetes as an outcome" is unnecessary and limits the pool of available evidence. There are a number of other outcomes which could produce valid evidence, for example change in HbA1c could be reported giving meaningful information without the paper explicitly reporting progression to T2DM. Changes in anthropometric measures and/or cardiovascular disease risk markers also provide important indicators of changing health status,	Unfortunately, it was not possible to identify what aspect of the consultation document suggested that we only included studies that reported progression to type 2 diabetes as an outcome. In the summary of evidence we included outcomes such as reductions in blood glucose and increased weight loss; however, the population was restricted to people with non-diabetic hyperglycaemia. The guideline focused on progression to type 2 diabetes, which is the most appropriate outcome for this guideline. NICE has several guidelines covering obesity and weight management, cardiovascular disease, and diabetes. These conditions are complex and have substantial overlap, but we cannot assume that: • interventions in one population are suitable for another population (for example, more extreme dietary intervention may be acceptable in people with diabetes than in people with non-diabetic hyperglycaemia) • results in one population are generalisable to other populations, or • changes in one particular outcome such as bodyweight would definitively affect the incidence of diabetes.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		particularly where there is a lack of evidence that fits the current, narrow criteria. As the underlying pathophysiology of prediabetes is the same as that causing Type 2 diabetes, the available evidence for managing diagnosed Type 2 diabetes should be considered to guide the prevention guidelines. There are at least 8 RCTs demonstrating that low carbohydrate diets can be as effective, or more so, for managing Type 2 diabetes. In many cases the outcomes are comparable or superior whilst also reducing medication requirements. Thus it is overly restrictive to only include a single dietary approach in guidelines related to this: 1. Stern et al 2004 (Stern L, Iqbal N, Seshadri P, Chicano KL, Daily DA, McGrory J, et al. The effects of low-carbohydrate versus conventional weight loss diets in severely obese adults: one-year follow-up of a randomized trial. Ann Intern Med. 2004;140(10):778- 85.): Conclusion "Participants on a low-carbohydrate diet had more favourable outcomes overall at 1 year than did those on a conventional diet. Weight loss was similar between groups, but effects on atherogenic dyslipidaemia and glycaemic control were still more favourable with a low-carbohydrate diet after adjustment for differences in weight loss" 2. Daly et al 2005 (Daly ME, Paisey R, Paisey R, Millward BA, Eccles C, Williams K, et al. Short-term effects of severe dietary carbohydrate-restriction advice in Type 2 diabetes-a randomized controlled trial. Diabet Med. 2005;23(1):15-20.): Conclusion "Carbohydrate restriction was an effective method of achieving short-term weight loss compared with standard advice, but this was at the expense of an increase	The studies by Stern et al. (2004), Daly et al. (2006), Westman et al. (2008), Davis et al. (2009), Guldbrand et al. (2012), Jonasson et al. (2014), Sato et al. (2017), Tay et al. (2017), Tay et al. (2014), Tay et al. (2015), Hallberg et al. (2018), Unwin et al. (2014) include a population with type 2 diabetes so are not eligible for inclusion in this surveillance review. However, some of these studies may be relevant to Type 2 diabetes in adults: management (NICE guideline NG28) and we have noted these studies for consideration at the next surveillance of this guideline. Studies that address weight loss, but include populations other than people with non-diabetic hyperglycaemia are not eligible for consideration in surveillance of guidance on diabetes prevention (population and community level interventions, NICE PH35, or prevention in people at high risk, NICE PH38). However, these studies will be considered for inclusion in surveillance of the guideline on identification, assessment and management of obesity (CG189). This includes Naude et al. (2014), Bueno et al. (2013), Nordmann et al. (2006), Hashimoto et el. (2016), Hu et al. (2012), Tobias et al. (2015), Estruch et al. (2016), Mancini et al. (2016), Hession et al. (2009), Santos et al. (2012), Sackner-Bernstein et al. (2015), Mansoor et al. (2016). The Diabetes UK Position statement: Low-carb diets for people with diabetes (2017) provides advice for people with diabetes, not for people with non-diabetic hyperglycaemia, so is not directly relevant to diabetes prevention.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		in relative saturated fat intake" (N.B. An increase in relative saturated fat intake in the absence of any detrimental effect on health should not be treated as a negative outcome) 3. Westman et al 2008 (Westman EC, Yancy WS, Jr., Mavropoulos JC, Marquart M, McDuffie JR. The effect of a low-carbohydrate, ketogenic diet versus a low-glycemic index diet on glycemic control in type 2 diabetes mellitus. Nutr Metab (Lond). 2008;5:36.): Conclusion "Dietary modification led to improvements in glycemic control and medication reduction/elimination in motivated volunteers with type 2 diabetes. The diet lower in carbohydrate led to greater improvements in glycemic control, and more frequent medication reduction/elimination than the low glycemic index diet. Lifestyle modification using low carbohydrate interventions is effective for improving and reversing type 2 diabetes." 4. Davis et al 2009 (Davis NJ, Tomuta N, Schechter C, Isasi CR, Segal-Isaacson CJ, Stein D, et al. Comparative study of the effects of a 1-year dietary intervention of a low-carbohydrate diet versus a low-fat diet on weight and glycemic control in type 2 diabetes. Diabetes Care. 2009;32(7):1147-52.): Conclusion "Among patients with type 2 diabetes, after 1 year a low-carbohydrate diet had effects on weight and A1C similar to those seen with a low-fat diet. There was no significant effect on blood pressure, but the low-carbohydrate diet produced a greater increase in HDL cholesterol." 5. Guldbrand et al 2012 (Guldbrand H, Dizdar B, Bunjaku B, Lindström T, Bachrach-Lindström M, Fredrikson M, et al.	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		In type 2 diabetes, randomisation to advice to follow a low-carbohydrate diet transiently improves glycaemic control compared with advice to follow a low-fat diet producing a similar weight loss. Diabetologia. 2012;55(8):2118-27.): Conclusion “Weight changes did not differ between the diet groups, while insulin doses were reduced significantly more with the LCD at 6 months, when compliance was good. Thus, aiming for 20% of energy intake from carbohydrates is safe with respect to cardiovascular risk compared with the traditional LFD and this approach could constitute a treatment alternative.” 6. Jonasson et al 2014 (Jonasson L, Guldbrand H, Lundberg AK, Nystrom FH. Advice to follow a low-carbohydrate diet has a favourable impact on low-grade inflammation in type 2 diabetes compared with advice to follow a low-fat diet. Annals of medicine. 2014;46(3):182-7.): Conclusion “To conclude, advice to follow LCD or LFD had similar effects on weight reduction while effects on inflammation differed. Only LCD was found significantly to improve the subclinical inflammatory state in type 2 diabetes.” 7. Sato et al 2017 (Sato J, Kanazawa A, Makita S, Hatae C, Komiya K, Shimizu T, et al. A randomized controlled trial of 130 g/day low-carbohydrate diet in type 2 diabetes with poor glycemic control. Clin Nutr. 2017;36(4):992-1000.): Conclusion “Our study demonstrated that 6-month 130 g/day LCD reduced HbA1c and BMI in poorly controlled Japanese patients with T2DM. LCD is a potentially useful nutrition therapy for Japanese patients who cannot adhere to CRD.”	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		8. Tay et al 2017 (Tay J, Thompson CH, Luscombe-Marsh ND, Wycherley TP, Noakes M, Buckley JD, et al. Effects of an energy-restricted low-carbohydrate, high unsaturated fat/low saturated fat diet versus a high carbohydrate, low fat diet in type 2 diabetes: a 2 year randomized clinical trial. Diabetes, obesity & metabolism. 2017.): Conclusion "Both diets achieved comparable weight loss and HbA1c reductions. The LC sustained greater reductions in diabetes medication requirements, and improvements in diurnal blood glucose stability and blood lipid profile, with no adverse renal effects, suggesting greater T2D management optimisation." Previous publications from the same trial were published in: • 2014 (Tay J, Natalie D L-M, Thompson CH, Noakes M, Buckley JD, Wittert GA, et al. A Very Low Carbohydrate, Low Saturated Fat Diet for Type 2 Diabetes Management: A Randomized Trial. Diabetes Care. 2014;37:2909–18.) Conclusion "Both diets achieved substantial improvements for several clinical glycemic control and CVD risk markers. These improvements and reductions in GV and antiglycemic medication requirements were greatest with the LC compared with HC. This suggests an LC diet with low saturated fat may be an effective dietary approach for T2DM management if effects are sustained beyond 24 weeks." • 2015 (Tay J, Luscombe-Marsh ND, Thompson CH, Noakes M, Buckley JD, Wittert GA, et al. Comparison of low- and high-carbohydrate diets for type 2 diabetes management: a randomized trial. The American journal of clinical nutrition. 2015;102:780–90.) Conclusion "Both	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		diets achieved substantial weight loss and reduced HbA1c and fasting glucose. The LC diet, which was high in unsaturated fat and low in saturated fat, achieved greater improvements in the lipid profile, blood glucose stability, and reductions in diabetes medication requirements, suggesting an effective strategy for the optimization of T2D management." Existing guidelines (NICE PH38) say "A diet that helps people who are overweight or obese to lose weight and sustain the weight loss will help them to reduce their risk of diabetes (Paulweber et al. 2010)", thus evidence related to weight loss should be admissible as evidence of other dietary approaches being beneficial for reducing risk of Type 2 diabetes. Weight loss advice in the UK (NICE CG189) states that "Diets that have a 600 kcal/day deficit (that is, they contain 600 kcal less than the person needs to stay the same weight) or that reduce calories by lowering the fat content (low-fat diets), in combination with expert support and intensive follow-up, are recommended for sustainable weight loss." There is an abundance of evidence demonstrating that alternative dietary approaches can be as effective as, or more effective than, low fat diets for weight management. The list below includes a number of meta-analyses that reached conclusions supporting this assertion (N.B. The quality of each of these reviews is not considered here, but nevertheless the abundance of evidence implying that alternative dietary approaches can be superior or comparable to a low fat dietary approach supports the assertion that alternatives should be	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		considered for inclusion in the guidelines. The reported conclusions only are reported for simplicity): 1. Naude et al 2014 (Naude CE, Schoonees A, Senekal M, Young T, Garner P, Volmink J. Low carbohydrate versus isoenergetic balanced diets for reducing weight and cardiovascular risk: a systematic review and meta-analysis. PLoS One. 2014;9(7):e100652.) "Trials show weight loss in the short-term irrespective of whether the diet is low CHO or balanced. There is probably little or no difference in weight loss and changes in cardiovascular risk factors up to two years of follow-up when overweight and obese adults, with or without type 2 diabetes, are randomised to low CHO diets and isoenergetic balanced weight loss diets." 2. Bueno et al 2013 (Bueno NB, de Melo IS, de Oliveira SL, da Rocha Ataide T. Very-low-carbohydrate ketogenic diet v. low-fat diet for long-term weight loss: a meta-analysis of randomised controlled trials. Br J Nutr. 2013;110(7):1178-87.) "Individuals assigned to a VLCKD achieve a greater weight loss than those assigned to a LFD in the long term; hence, a VLCKD may be an alternative tool against obesity." 3. Nordmann et al 2006 (Nordmann A, Nordmann A, Briel M, Keller U, Yancy W, Brehm B, et al. Effects of low-carbohydrate vs low-fat diets on weight loss and cardiovascular risk factors: a meta-analysis of randomized controlled trials. Archives of internal medicine. 2006;166:285 - 93.) "Low-carbohydrate, non–energy-restricted diets appear to be at least as effective as low-fat, energy-restricted diets in inducing weight loss for up to 1 year."	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		4. Hashimoto et al 2016 (Hashimoto Y, Fukuda T, Oyabu C, Tanaka M, Asano M, Yamazaki M, et al. Impact of low-carbohydrate diet on body composition: meta-analysis of randomized controlled studies. Obesity Reviews. 2016:n/a-n/a.) “LCD, especially very LCD, might be effective for decrease in fat mass in obese individuals.” 5. Hu et al 2012 (Hu T, Mills KT, Yao L, Demanelis K, Eloustaz M, Yancy WS, Jr., et al. Effects of low-carbohydrate diets versus low-fat diets on metabolic risk factors: a meta-analysis of randomized controlled clinical trials. American journal of epidemiology. 2012;176 Suppl 7:S44-54.) “These findings suggest that low-carbohydrate diets are at least as effective as low-fat diets at reducing weight and improving metabolic risk factors. Low-carbohydrate diets could be recommended to obese persons with abnormal metabolic risk factors for the purpose of weight loss.” 6. Tobias et al 2015 (Tobias DK, Chen M, Manson JE, Ludwig DS, Willett W, Hu FB. Effect of low-fat diet interventions versus other diet interventions on long-term weight change in adults: a systematic review and meta-analysis. The lancet Diabetes & endocrinology. 2015;3(12):968-79.) “When compared with dietary interventions of similar intensity, evidence from randomised controlled trials does not support low-fat diets over other dietary interventions for long-term weight loss.” and also found that "In weight loss trials, higher-fat weight loss interventions led to significantly greater weight loss than low-fat interventions".	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		7. Estruch et al 2016 (Estruch R, Martínez-González MA, Corella D, Salas-Salvadó J, Fitó M, Chiva-Blanch G, et al. Effect of a high-fat Mediterranean diet on bodyweight and waist circumference: a prespecified secondary outcomes analysis of the PREDIMED randomised controlled trial. The Lancet Diabetes & Endocrinology. 2016.) "A long-term intervention with an unrestricted-calorie, high-vegetable-fat Mediterranean diet was associated with decreases in bodyweight and less gain in central adiposity compared with a control diet. These results lend support to advice not restricting intake of healthy fats for bodyweight maintenance." 8. Mancini et al 2016 (Mancini JG, Filion KB, Atallah R, Eisenberg MJ. Systematic Review of the Mediterranean Diet for Long-Term Weight Loss. Am J Med. 2016;129(4):407-15 e4.) "Our findings suggest that the Mediterranean diet results in similar weight loss and cardiovascular risk factor level reduction as comparator diets in overweight or obese individuals trying to lose weight." 9. Hession et al 2009. (Hession M, Rolland C, Kulkarni U, Wise A, Broom J. Systematic review of randomized controlled trials of low-carbohydrate vs. low-fat/low-calorie diets in the management of obesity and its comorbidities. Obesity Reviews. 2009;10(1):36-50.) "Evidence from this systematic review demonstrates that low-carbohydrate/high-protein diets are more effective at 6 months and are as effective, if not more, as low-fat diets in reducing weight and cardiovascular disease risk up to 1 year. More evidence and longer-term studies are needed to	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		assess the long-term cardiovascular benefits from the weight loss achieved using these diets." In this review energy consumption on the low carb diet was ad libitum, whereas for the low fat diet it was calorie controlled. This is important in relation to how effective the approach is likely to be in free living individuals. 10. Santos et al 2012. (Santos FL, Esteves SS, da Costa Pereira A, Yancy Jr WS, Nunes JPL. Systematic review and meta-analysis of clinical trials of the effects of low carbohydrate diets on cardiovascular risk factors. Obesity Reviews. 2012;13(11):1048-66.) "The low-carbohydrate diet was shown to have favourable effects on body weight and major cardiovascular risk factors; however the effects on long-term health are unknown." In this review energy consumption on the low carb diet was ad libitum, whereas for the low fat diet it was calorie controlled. This is important in relation to how effective the approach is likely to be in free living individuals. 11. Bueno et al 2013. (Bueno NB, de Melo IS, de Oliveira SL, da Rocha Ataide T. Very-low-carbohydrate ketogenic diet v. low-fat diet for long-term weight loss: a meta-analysis of randomised controlled trials. Br J Nutr. 2013;110(7):1178-87.) "the present meta-analysis demonstrates that individuals assigned to a very-low-carbohydrate ketogenic diet achieve significantly greater long-term reductions in body weight, diastolic blood pressure and triglycerides, as well as greater LDL and HDL increases when compared with individuals assigned to a low-fat diet; hence, the very-low-carbohydrate ketogenic diet may be an alternative tool against obesity.	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		Investigations beyond that of blood cardiovascular risk factors merit further study." In this review energy consumption on the low carb diet was ad libitum, whereas for the low fat diet it was calorie controlled. This is important in relation to how effective the approach is likely to be in free living individuals. 12. Sackner-Bernstein et al. 2015 (Sackner-Bernstein J, Kanter D, Kaul S. Dietary Intervention for Overweight and Obese Adults: Comparison of Low-Carbohydrate and Low-Fat Diets. A Meta-Analysis. PLoS ONE. 2015;10(10):e0139817.) Low-carbohydrate diets appear to achieve greater weight loss and reduction in predicted risk of atherosclerotic cardiovascular disease risk events compared with low-fat diets." In this review energy consumption on the low carb diet was ad libitum, whereas for the low fat diet it was calorie controlled. This is important in relation to how effective the approach is likely to be in free living individuals. 13. Mansoor et al. 2016 (Mansoor N, Vinknes KJ, Veierød MB, Retterstøl K. Effects of low-carbohydrate diets v. low-fat diets on body weight and cardiovascular risk factors: a meta-analysis of randomised controlled trials. Br J Nutr. 2016;115(03):466-79.) Compared with subjects on low-fat diets, subjects on low-carbohydrate diets experienced significantly greater weight loss, greater triglycerides reduction and greater increase in HDL-cholesterol after 6 months to 2 years of intervention. In this review energy consumption on the low carb diet was ad libitum, whereas for the low fat diet it was calorie controlled. This is	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		important in relation to how effective the approach is likely to be in free living individuals. Diabetes UK's position statement regarding low carb diets, issued in May 2017, is reflective of changing attitudes towards carbohydrate restriction for the management of Type 2 diabetes. As stated previously it is prudent to consider evidence and practice related to the management of Type 2 diabetes in the context of attempts to improve Type 2 diabetes prevention. The growing popularity and evidence of success of diabetes.co.uk's online programme provides further evidence of a change in opinion and culture related to the use of carbohydrate restriction for the management of Type 2 diabetes. The success demonstrated by Virta Health's 12 month outcomes (Hallberg SJ, McKenzie AL, Williams PT, Bhanpuri NH, Peters AL, Campbell WW, et al. Effectiveness and Safety of a Novel Care Model for the Management of Type 2 Diabetes at 1 Year: An Open-Label, Non-Randomized, Controlled Study. Diabetes Therapy. 2018) further supports the efficacy of a low carbohydrate approach for the management and possible reversal of Type 2 diabetes. These outcomes also demonstrate that motivated individuals are able to adhere to this approach, and there was also no evidence that this approach was unsafe in any way. Evidence of low carbohydrate approaches for the management of Type 2 diabetes can also be seen in real word scenarios, for example in David Unwin's GP practice (e.g. Unwin D, Unwin J. Low carbohydrate diet to achieve	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		weight loss and improve HbA1c in type 2 diabetes and pre-diabetes: experience from one general practice. Practical Diabetes. 2014;31(2):76-9.). This again is supportive of a growing acceptance and awareness of the potential benefits of alternative approaches.	
Public Health Collaboration	No	No comments provided	Thank you for your response
Johnson & Johnson Medical Ltd.	Yes	Johnson & Johnson Medical Ltd. welcome NICE's endorsement of bariatric surgery to treat type 2 diabetes as both clinically and cost effective on page 46 of the surveillance review proposal report. We also welcome NICE's impact statement that "evidence consistently shows that bariatric surgery may prevent diabetes". And, as NICE states at p46, recommendations endorsing the clinical and cost effectiveness of bariatric surgery to treat type 2 diabetes are indeed included in NICE Clinical Guideline 189 'Obesity: identification, assessment and management' at section 1.11. However, we wish to bring to NICE's attention that these recommendations are neither acknowledged nor accepted by payors, clinicians or the public within the mainstream treatment algorithm for type 2 diabetes in the UK. As a result, people with type 2 diabetes for whom bariatric surgery would be an appropriate and cost effective treatment for their type 2 diabetes are being denied access to clinically and cost effective surgery. Its position only in NICE Obesity Guidelines and pathways, and not embedded within the	Please see the earlier response on bariatric surgery.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		NICE type 2 diabetes pathway may be further contributing to this. We therefore disagree with NICE's final conclusion not to include recommendations on bariatric surgery as a treatment for established type 2 diabetes specifically in this type 2 diabetes Public Health Guideline and request that NICE reconsiders this decision. Furthermore, recommendations on the impact of surgery in the prevention of type 2 diabetes are different to previous recommendations that focus on treating established type 2 diabetes, and should be explicitly called out. We raise this, particularly in light of NICE's new 'impact' report series and renewed focus on the impact its recommendations have on improving the diagnosis and treatment of patients.	
South Asian Health Action Charity	Yes	Would like to ask how High Risk South Asian Patients have been engaged with the surveillance reviews and any patients working groups.	Thank you for your response. This surveillance review did not seek views from specific patients' groups. Any groups registered as stakeholders were invited to participate in the consultation. We conducted a broad search that identified new evidence relevant to this population which supported current recommendations, and updating is not needed.
National Diabetes Prevention Programme team - Public Health England, Diabetes UK, and NHS England	Yes	The NDPP recommends that NICE to review the scope for the surveillance review for PH35. The NDPP maintains that research gaps identified in PH35 are not fully addressed by the current scope. This is based on the position set out	Thank you for your response. We have now checked for evidence related to population and community-level interventions for preventing diabetes (NICE PH35).

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

		above that evaluation of the DPP would not be relevant to PH35 guidance. PHE advocates that NICE review these gaps and the scope of the surveillance review, in order to ensure that the decision to not update the guidance is based on the most up to date evidence base.	
University of Nottingham	No	No comments provided	Thank you for your response

Do you have any comments on equalities issues?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
20one Clinic	No response provided	No comments provided	Thank you for your response
Perspectum Diagnostics	No	No comments provided	Thank you for your response
Obesity Group of the British Dietetic Association	No	No comments provided	Thank you for your response
South Sefton Clinical Commissioning Group	No	No comments provided	Thank you for your response
Diabetes UK	No	No comments provided	Thank you for your response

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Merck Sharp & Dohme Limited	No	No comments provided	Thank you for your response
Ascensia Diabetes Care UK Ltd	No	No comments provided	Thank you for your response
X-PERT Health (Registered by Dr Trudi Deakin)	No	No comments provided	Thank you for your response
Public Health Collaboration	No	No comments provided	Thank you for your response
Johnson & Johnson Medical Ltd.	No response provided	No comments provided	Thank you for your response
South Asian Health Action Charity	Yes	Yes I would like to ask if any equality impact assessments have been done and if so would like to see a copy. If not will there be any done?	Thank you for your comment. No equality impact assessment was conducted as part of the surveillance review, which is the standard process for surveillance reviews. The equalities impact assessment conducted during development of the guideline update in 2017 recognised a potential equality issue in timely access to intensive lifestyle modification programmes. However it concluded that: 'research in this area is at an early stage and the committee agreed that it was not appropriate to make a different recommendation for this group based on current evidence.' New evidence in this population was identified in surveillance which supported the current recommendations, and updating is not needed.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

National Diabetes Prevention Programme team - Public Health England, Diabetes UK, and NHS England	Yes	As noted above, digital approaches may offer the scope to increase access to particular demographic groups (including but not limited to: those in rural communities, those of working age, and those whose first language is not English). By limiting the evidence review, and therefore the development of guidelines around these approaches, there is a risk that opportunities to address these inequalities may not be realised.	Thank you for your comment. As noted above, and in the summary of evidence, NICE has guidance on individual approaches to behaviour change (NICE PH49), which is being updated to consider the use of technology such as apps, text messaging and the internet to drive improvements in behaviours such as physical activity, diet and weight. Therefore, the guideline on diabetes prevention should not be updated to cover technology-based interventions at this time.
University of Nottingham	Yes	By not updating the guideline to allow use of Qdiabetes-2018, then people with severe mental illness and those on atypical antipsychotics will have their risk underestimated and this will lead to fewer people with these conditions being offered interventions **which will make inequalities for this vulnerable group of patients worse**. Similarly, not including gestational diabetes and polycystic ovarian syndrome will adversely affect women with these conditions, leading to **gender inequalities.**	Thank you for your comment. Please see the earlier response on QDiabetes-2018.

Additional Comments

1 The Royal College of Nursing have no comments to submit on the PH38 consultation at this time.

© NICE 2018. All rights reserved. Subject to Notice of rights.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.