

Consultation on the draft report:

Lower carbohydrate diets for adults with type 2 diabetes

Comments Form

Organisation	X-PERT Health
Name of commentator and contact details	Dr Sean Wheatley X-PERT Health, Hebden Bridge

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General comments	Comments
	Please insert each new comment in a new row
Secretariat qualifications/experience	As members of the secretariat performed crucial parts of the data extraction and report preparation it would be beneficial to the reader to have an understanding of their profession and relevant qualifications
Carbohydrate intake	The report repeatedly refers to “achieved” carbohydrate intake, but this should be changed to “reported” carbohydrate intake to acknowledge limitations in measuring this
Unnecessarily limited in scope	<p>The decision to restrict the review to systematic reviews including meta-analyses of RCTs immediately made an important body of literature assessing lower carbohydrate diets in more ecologically valid settings unavailable for consideration. This literature could have helped to answer some of the questions that the identified systematic reviews were unable to, including around adherence and the impact of true low carbohydrate diets</p> <p>Future SACN reports should perhaps consider a consultation phase on the scoping of questions and the setting of inclusion/exclusion criteria to reduce issues of this nature, which are likely to be raised by a number of respondents during the consultation period</p>
Redundant data extraction	<p>The value of much the content extracted and summarised in paragraphs 5.28 to 5.33 and associated annexes is questionable, as the data inclusion was narrowed further (significantly) before the evidence was graded and considered. The reasons used to justify this would have been apparent before data extraction occurred, and the presentation of this information does not add any value</p> <p>Further, the information extracted from RCTs included in the identified reviews is never included in any meaningful analysis and is not considered in the grading of evidence – so the value of this exercise is unclear</p>
Failure to account for limitations	A number of important limitations were identified, but there does not appear to have been any attempt to consider them in the grading of evidence. Having extracted the information for all of the RCTs included in the meta-analyses it would have been possible to consider the studies which were less limited in relation to some of the key issues. For example, the review could have assessed the outcomes only in studies that had a reported carbohydrate intake in line with the definitions for low carbohydrate diets outlined in Table 5.1. Tables 6.2 and 6.3, and Figure 6.1, make it abundantly clear that the majority of the research does not validly compare diets based on carbohydrate intake (even ignoring the failure of many to be classified as low carbohydrate, there is an overlap in carbohydrate intake between the “lower” and “higher” groups in many); thus additional analyses of this nature would have been highly valuable

	<p>The number of limitations provides further support to calls to include non-RCT evidence in the review, as these were (somewhat ironically) omitted due to their perceived limitations</p>
No analyses favoured higher carbohydrate	<p>It is not acknowledged anywhere in the review that none of the analyses from the prioritised systematic reviews, which the grading of evidence was based solely on, favoured the higher carbohydrate group (i.e. ALL analyses either favoured lower carbohydrate diets or found no difference). This is very important, and suggests that lower carbohydrate diets are at least as effective as higher carbohydrate diets</p>
Classifications of “Inconsistent evidence” should include qualification	<p>For a number of outcomes the evidence is graded as inconsistent. Although this is true to an extent, in all analyses where this is the case the outcomes reported either favoured lower carbohydrate or found no difference between diets (i.e. no analyses favoured higher carbohydrate diets). “Inconsistent” incorrectly implies, or at the very least could easily be inferred to mean, that this inconsistency is across all possible outcomes. This is not true, and this should be reflected</p>
Absence of harm not fully acknowledged	<p>Lower carbohydrate diets are often criticised in relation to changes in lipoprotein markers, including total cholesterol (though the validity of using this as a marker of health in isolation is debatable) and LDL cholesterol (where there is again meaningful debate to be had around the relative importance of LDL-cholesterol compared to the number of LDL particles). Ignoring these nuances, in this review there were no differences between diets for these variables – suggesting this common criticism of lower carbohydrate diets is not supported by the evidence. The importance of this in the context of current beliefs should be acknowledged explicitly</p>
Failure to fully consider medication changes	<p>Despite highlighting its importance (see paragraph 6.77) we do not feel that this issue has been fully considered. Changes in the other outcomes are not considered in the context of medication changes (an omission that will affect consideration of changes in HbA1c in particular), 3 of the 4 prioritised SRs are not included in the consideration of medication changes despite reporting on them (the relevant findings are summarised in table A12.2 but not considered otherwise – findings are consistently in favour of lower carbohydrate diets), and the working group decline to provide a grading for this outcome due to the absence of a relevant meta-analysis despite the grading criteria set out in Table 5.3 allowing for evidence to be graded based on the findings of primary studies (a decision that is particularly questionable given the decision to grade the evidence for adverse events based on less, and less consistent, evidence).</p> <p>The findings across all reviews and RCTs are consistently in favour of lower carbohydrate diets, demonstrating that they regularly lead to a reduced requirement for anti-hyperglycaemic medications. A failure to consider this in the recommendations, which is what will occur if a grading is not provided for this outcome, will mean a key component of their possible benefits is not considered. As a result, their efficacy will be underestimated</p>

The adverse events section is highly biased and largely invalid	As per the specific comments we have laid out below (paragraphs 6.200 to 6.211), a number of statements in this section are not supported by the available evidence, utilise evidence in a non-systematic and non-transparent way, and include caveats regarding the long-term effects of lower carbohydrate diets that are equally true of other ways of eating but are seldom (if ever) used to qualify other diets. Further, the only study used to suggest a potentially greater rate of adverse events in lower carbohydrate diets (which is used to grade the evidence, despite the working group deciding not to grade evidence for medication changes where data from 6 shorter-term and 8 longer-term RCTs were available) is not a valid study in the context of considering the effects of lower carbohydrate diets (the lower carbohydrate diet was also a very low energy diet using protein shakes in the initial phases), and should be omitted from the review entirely
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Comments by paragraph	Comments
	Please insert each new comment in a new row
1.5	In the context of the current review, this should clarify that none of the studies included in the 2015 SACN report included individuals with Type 2 diabetes
2.9	The structure of the second sentence is somewhat difficult to follow
2.13	The second sentence requires qualification, i.e. the glucose requirement for these purposes is small and this glucose does not necessarily have to come from dietary carbohydrate
2.14	The first sentence should be more specific about how glucose is “under control” of insulin, there should be a comma after “insulin”, and it should be reflected that circulating insulin can increase <i>before</i> glucose is absorbed
2.17	Cut point for high GI classification should be provided, as it is for low GI
2.18	This paragraph conflates food quality and glycaemic index, but the two are not necessarily synonymous
3.5	This paragraph should reflect that the pattern of beta-cell insulin secretion is impaired (i.e. the first phase insulin response is reduced or lost) before the volume of insulin secretion is. Insulin levels are usually elevated in comparison to normoglycaemic individuals for multiple years before secretion begins to reduce

3.6	Refers to Type 1 diabetes, despite paragraph 3.4 stating that this would not be considered further in the report
3.7	Should reflect that Type 2 diabetes can also be classified based on the results of an OGTT, or on the basis an individual is prescribed anti-hyperglycaemic medications
3.13	<p>This paragraph would be better placed in the previous section (“Background on type 2 diabetes”) as it is not overtly included in existing NICE criteria for the management of Type 2 diabetes. It should perhaps also state that recent evidence has now made it clear that Type 2 diabetes need not be a progressive condition</p> <p>Evidence pertaining to the possibility of Type 2 diabetes remission following adoption of a very low carbohydrate diet should be included in this section. As it was deemed acceptable to include Sjostrom et al, 2014, an analysis of data from a prospective matched cohort study, there does not appear to be any justification for excluding non-RCT evidence of other forms; such as that provided by Athinarayanan et al, 2014* which provided good evidence that carbohydrate restriction can lead to remission of Type 2 diabetes</p> <p>*Athinarayanan SJ, Adams RN, Hallberg SJ, Mckenzie AL, Bhanpuri NH, Campbell WW, et al. Long-Term Effects of a Novel Continuous Remote Care Intervention Including Nutritional Ketosis for the Management of Type 2 Diabetes: A 2-year Non-randomized Clinical Trial. <i>Frontiers in Endocrinology</i>. 2018;10:348.</p>
3.16	<p>In the first sentence, “health dietary pattern” should be in quotation marks to avoid any suggestion that other ways of eating may not be healthy</p> <p>The second sentence implies the SACN 2015 report made recommendations for people with Type 2 diabetes, which is not the case</p> <p>The fourth sentence should reflect that the NICE NG28 recommendations regarding individualised advice specifically allude to carbohydrate intake, and that in the NICE response to comments during the 2019 consultancy on this guidance it was stated that “NICE guideline NG28 already advises individualising recommendations for carbohydrate intake, and meal patterns, which could include low carbohydrate and low calorie diets”* to make it clear that the promotion and support of LCDs for people with Type 2 diabetes is not precluded by existing guidance, an important point for providing context for the current review</p> <p>* https://www.nice.org.uk/guidance/ng28/evidence/appendix-b2-stakeholder-consultation-comments-table-ng28-pdf-6837997937</p>
3.20	Important, relevant statements from the ADA guidance are omitted, for example it is asserted that “Reducing overall carbohydrate intake for individuals with diabetes has demonstrated the most evidence for improving glycaemia and may be applied in a variety of eating patterns that meet individual needs and preferences”

	<p>(emphasis is ours) and “...from the current evidence, this eating pattern does not appear to increase overall cardiovascular risk...”, with the authors noting that this was the case even though most of the included trials did not restrict saturated fat. The inclusion of such statements is important to provide adequate context for the current review, as a non-specialist reader may not be aware of the increasing acceptance of such approaches internationally</p>
Table 3.1	<p>NICE are referred to as the “National Institute for Clinical Excellence”, this should read “National Institute for Health and Care Excellence”</p> <p>The value provided for NICE guidance on carbohydrate intake should include the caveat that individualised carbohydrate intake is recommended</p> <p>The information provided for SIGN and ADA guidance on carbohydrate intake should perhaps have accompanying statements, similar in nature to that provided for the DUK guidance</p> <p>The EASD guidance provided is inconsistent with the position in their 2018 joint position statement with the ADA*, which presumably supersedes the Mann et al, 2004, reference used here</p> <p>The footnote notation within the Diabetes Australia section appears to be incorrect</p> <p>* Davies MJ, D'Alessio DA, Fradkin J, et al. Management of Hyperglycemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care. 2018;41(12):2669-2701.</p>
4.3	<p>We disagree with the rationale for omitting blood pressure as a marker of interest. Blood pressure may be reduced through weight independent means, such as due to a reduced retention of sodium following a reduction in circulating insulin levels. Supporting this, there is evidence that low carbohydrate diets may be able to reduce blood pressure in a manner that is at least partly independent of weight reduction*</p> <p>* Unwin DJ, Tobin SD, Murray SW, Delon C, Brady AJ. Substantial and Sustained Improvements in Blood Pressure, Weight and Lipid Profiles from a Carbohydrate Restricted Diet: An Observational Study of Insulin Resistant Patients in Primary Care. International Journal of Environmental Research and Public Health. 2019;16(15):2680.</p>
4.9	<p>Question word choice of “around”, “at least” may be preferable</p>
4.10	<p>Although we acknowledge that evidence would likely be limited, some consideration of blood glucose beyond fasting levels would be of benefit; for example blood glucose variability or time in range. Even without the</p>

	ability to fully assess this the potential utility of such markers beyond single point measures should be acknowledged
4.11	<p>There does not appear to be any consideration of the possible effect of blood lipid lowering medications</p> <p>This should reflect that the pattern and/or type/size of lipoproteins may be important, beyond a simple consideration of amounts</p> <p>The third sentence adds no value, it is essentially a repeat of the preceding two sentences</p>
4.12	<p>It should be acknowledged here and/or in subsequent sections that the duration of fasting is a significant confounder when assessing changes in blood lipids</p> <p>The inclusion of total cholesterol in isolation can be challenged, as this is not a marker that would be used clinically due to the differential effects of different components of it</p>
4.13	<p>This section should be more specific regarding which symptoms were considered of interest</p> <p>We agree with the statement made in the second sentence, but this does not appear to have been fully considered subsequently (i.e. changes in health markers are considered independent of changes in medication, and the changes in medication are not considered fairly against the grading criteria set out in Table 5.3)</p>
5.1/5.2	Although the statement in paragraph 5.1 is not fundamentally incorrect we do not believe that this is sufficient justification for limiting the scope of the current review, in part because this limits the ability of the working group to assess any questions beyond those which are already subject to published systematic reviews with meta-analyses (which, for example, have not been able to assess evidence pertaining to Type 2 diabetes remission due to the relative novelty of the field). Paragraph 5.2 confirms that criteria are in place to include and validly assess evidence of other forms, which would have provided an opportunity to assess clinically relevant questions in more detail using evidence from routine practice and non-RCT evidence. Despite their limitations, which can be accounted for when appraising the evidence, alternative forms of evidence do have strengths in comparison to RCTs; such as being more ecologically valid
5.4 & 5.7	It is good practice when performing a systematic review to not place limits on the language of publication and to include grey literature. The resources available for the current review should have made it possible to follow such practices
5.9/5.10	As per our comments on paragraphs 5.1/5.2, we disagree with the decision to not include studies of this nature as they provide an important insight into the possible efficacy and effectiveness of low carbohydrate

	<p>dietary approaches. When considered alongside meta-analyses of RCTs they provide value and help to address some of the gaps and limitations with the body of research that was included in the current review. Again, the SACN evidence grading criteria allows for consideration of such research – thus the decision to exclude it can be questioned</p> <p>Future SACN reports should perhaps consider a consultation phase on the scoping of questions and the setting of inclusion/exclusion criteria to reduce issues of this nature, which are likely to be raised by a number of respondents during the consultation period</p>
5.24	<p>As the McArdle systematic review and Saslow et al, 2017 were identified before the end of the call for evidence the decision to omit them from the review appears to be unwarranted, and any consideration “post-consultation” raises some concerns as there will be no opportunity for stakeholders to provide feedback</p> <p>It should perhaps be acknowledged that although data from Tay et al, 2018 was included in the van Zuuren SR/MA the paper was not referenced in the main paper (it was only mentioned explicitly in the supplementary material), to avoid any confusion amongst individuals seeking to follow up on the evidence and references used within the SACN review</p>
5.32	<p>A large number of the publications (15 RCTs) referred to in paragraph 5.28 do not appear at all in Annex 6. It may be helpful to the reader to clarify what these other studies looked at, and/or to clarify the reason(s) for their omissions</p>
5.40	<p>The closed bracket is missing from the end of the first sentence</p>
6.2	<p>It is not a bad thing that Iqbal et al 2010 was omitted, as there were no statistically significant differences in macronutrient intake between the arms of the study at any time point (and the carbohydrate intake was actually slightly higher in the low carb group at multiple time points). This should perhaps be stated to make it clear that this will not prejudice the outcomes in any way</p>
6.4	<p>Based on this, which would have been apparent from the outset, it can be questioned why it was ever decided to permit the inclusion of this study? This essentially constitutes a change in review protocol</p>
6.6	<p>It should be acknowledged that all four prioritised systematic reviews considered medication changes, even if they were not stated as outcomes</p>
6.28	<p>Paragraph 6.2 states that there is only 1 RCT included in the initially identified reviews that was not included in the 4 prioritised reviews, but there were previously 48 studies listed and now there are only 32. The reasons for this should be clarified. Further, is there any value on focusing on these 32 RCTs instead of the 48 initially included? There does not appear to be any real justification for omitting the additional trials –</p>

	though the RCTs do not appear to have been used in any meaningful way in subsequent analyses, despite this data extraction having been undertaken
6.35 to 6.37	Why is there not a summary of outcomes for this section comparable to that in the preceding “Loss to follow up” section? The information presented in this section is largely redundant without a comparison between groups, considering differences at baseline as well as any differences in the change in medication use during the studies. This is a key outcome, thus the failure to appraise this evidence fully is a major omission
6.44 to 6.61	There is no consideration of diet quality. Although this may not have been possible in any meaningful way, this limitation should be acknowledged
6.46	If carbohydrate intake was not reported for 5 of the RCTs they should perhaps have been omitted
6.55 to 6.57 (and Table 6.2)	It would have been more informative to report the protein intake in absolute terms alongside the relative terms presented. The protein leverage hypothesis posits that individuals will continue to seek food until they have met their protein requirement (in absolute terms), and so differences in the relative proportion of protein in diets may help to explain any differences in total <i>ad libitum</i> energy consumption during a day (i.e. if the diet has a higher proportion of protein in it then the protein requirement for the day would be met earlier and with a lower total energy intake)
6.58 to 6.61 (and Table 6.2)	Consideration of energy intake should differentiate between where participants were provided with explicit targets and guidance compared to when they were instructed to consume food <i>ad libitum</i> . A number of studies provide specific targets to reduce energy intake to the higher carbohydrate arms whilst allowing the lower carbohydrate arms to consume food <i>ad libitum</i> . This, and possible differences in hunger between people on each diet, are important factors that have not been considered
Table 6.3	Regarding the ** footnote, it is unclear how this has been dealt with. As the lower range presented is 23 rather than 20 we assume the Wolever study has been omitted here, but as it was still included in the meta-analyses that have been considered in subsequent analyses there is no value to this. This possible limitation does not seem to have been acknowledged anywhere
6.66	Without evidencing this statement it is simply conjecture, and is inappropriate. In an analysis we have previously undertaken (limited to RCTs with greater than 50 participants and that lasted for at least 3 months – in line with previous NICE criteria for evidence inclusion - and where the low carb group were consuming less than 130g/day or 26% total energy from carbohydrate) there was little difference in adherence between groups; thus we do not feel this statement is supported by the available evidence
6.75	A large number of comparison groups provided guidance in line with current UK dietary guidance, thus it is questionable whether the last sentence of this paragraph is justified. Further, as data was extracted for all of

	the RCTs included in the SR/MAs why were further analyses not performed to assess this issue if it was deemed the SR/MAs themselves were not able to answer this question (which was the purpose of the review)
6.77	We fully agree with this paragraph, though do not believe that this is an issue that has been fairly and adequately considered subsequently
6.78	It is debatable whether the reasons for any improvements matters, the key point is the efficacy and effectiveness of the intervention – not the mechanisms. We therefore question the inclusion of this as an issue
6.79	The issues presented in this paragraph are also true for the higher carbohydrate arms of studies, but are presented as a limitation that favours the lower carbohydrate arms. This is unfair, and suggests a bias against low carbohydrate diets
6.81, 7.29 and 7.61	<p>In paragraph 6.29 it states that, in the 10 RCTs that reported ethnicity, the average number of white participants was 48.3% (range 14 to 75%). This is not consistent with the statement that the majority of participants were white</p> <p>That the majority of participants were overweight or obese is not a limitation in a review regarding the effects of an intervention for people with Type 2 diabetes, as this is a fair representation of the population of people with Type 2 diabetes</p>
6.85	The failure to consider within-group analyses can be questioned. The purpose of the review is not necessarily to demonstrate the superiority of one group over another. Where there are no differences between groups, the within group differences are important as they provide a picture of whether the intervention is likely to result in health improvements. The only criteria for recommending any intervention should be a) non-inferiority compared to current care guidelines, and b) evidence of likely benefit being greater than possible harm. Within-group analyses provide valuable information when considering these questions.
6.90	<p>The upper bound of the confidence intervals for the 3 months results should be “-0.23”, rather than a positive value</p> <p>The subgroup analyses from this SR are relevant, with a meaningful difference being observed between the low (<26% total energy) and high carbohydrate diets that has not been reported (WMD = -2.47kg, 95%CI - 3.33 to -1.60)</p>
6.109	We believe that the values for low compared to high carbohydrate diets should be reported as WMD -0.36%, 95%CI -0.62 to -0.09, $p = 0.008$, $I^2 = 0\%$, 5 RCTs (based on data presented in figure 1b)

6.130 and 7.32	Based on the analysis in its current form, we disagree (to an extent) with the classification for the evidence for studies between 12 and 24 months. Although the evidence is inconsistent all analyses either favoured lower carbohydrate or found no difference. "Inconsistent" incorrectly implies, or at the very least could easily be inferred to mean, that this inconsistency is across all possible outcomes. This is not true, and this should be reflected
6.131, 6.152 and 6.177	The results from the van Zuuren MAs should be included for completeness, in a similar manner to how the weight loss results of less than 12 months were (though it is unclear why the discussion of this MA is in a separate paragraph for the triglyceride and HDL cholesterol sections but not the fasting plasma glucose section?)
6.163 and 7.39	Based on the analysis in its current form, we disagree (to an extent) with the classification for the evidence for studies of longer than 12 months in duration. Although the evidence is inconsistent all analyses either favoured lower carbohydrate or found no difference. "Inconsistent" incorrectly implies, or at the very least could easily be inferred to mean, that this inconsistency is across all possible outcomes. This is not true, and this should be reflected
6.188, 7.41 and 7.42	Based on the analysis in its current form, we disagree (to an extent) with the classification for the evidence. Although the evidence is inconsistent all analyses either favoured lower carbohydrate or found no difference. "Inconsistent" incorrectly implies, or at the very least could easily be inferred to mean, that this inconsistency is across all possible outcomes. This is not true, and this should be reflected
6.193/6.194	These sections should acknowledge that all of the non-significant findings still showed greater reductions in favour of lower carbohydrate diets, thus ALL studies with relevant data favoured the lower carbohydrate arm.
6.198 and 7.44	<p>We strongly disagree with the decision to not grade the evidence for medication changes. The justification provided is the absence of a meta-analysis, but the grading criteria set out in Table 5.3 explicitly allows for a gradation without a requirement for one. Evidence can be graded as "adequate" if "... there is convincing evidence of a consistent significant effect/association in the primary studies considered." This is clearly the case with this outcome, as even within the single review included for this outcome ALL of the RCTs found results that favoured lower carbohydrate diets (differences that were statistically significant in 5/6 short-term studies and 4/8 longer-term studies). All other priority reviews, and a number of other systematic reviews that were not included as priority reviews, considered medication changes too - and universally concluded that reductions were greater with lower carbohydrate diets.</p> <p>This is a highly important issue as the decision to grade this evidence defines whether or not it is included when making the final recommendations, and the absence of this evidence prejudices low carbohydrate diets and will result in their possible benefits being underestimated (particularly as the other outcomes have not</p>

	been considered in the context of medication changes, an omission that will have significant implications for HbA1c changes in particular)
Table 6.4	As per previous comments, the “inconsistent” findings should be qualified (“Inconsistent” incorrectly implies, or at the very least could easily be inferred to mean, that this inconsistency is across all possible outcomes – whereas all outcomes favoured lower carbohydrate diets or found no difference) and we strongly disagree with the decision to not grade the evidence for medication changes
6.201	It is not fair to include this statement when the authors have stated that they did not systematically assess the matter. Without assessing the primary research fully there is no way to know how the rates of adverse events compared between groups, and without a full assessment this information is invalid and potentially biased
6.203	This statement is completely unjustified and invalid, it is purely based on conjecture which was not borne out in the outcomes (including those reported in the current review, where NONE of the included analyses demonstrated an increased in any risk factors compared to the higher carbohydrate group). This statement again implies a bias against lower carbohydrate diets and it should be removed.
6.204	This paragraph should clarify whether there was any difference in the reported rates of these minor adverse events between diets
6.205	The study cited here (which is not actually included in the reference list, but was easily identifiable) should not be included in the review. The lower carbohydrate diet in this study was in fact a very low energy diet (which you have stated in paragraph 5.44 should not be confused with a lower carbohydrate diet) using protein shakes for the first two phases, and as such is not a fair representation of a lower carbohydrate diet and none of the reported adverse events can be causally linked to carbohydrate restriction. This paragraph should be deleted, and its use in this manner is concerning – particularly in the light of the fact it is the only occasion in this review where a single study is used to justify a point, and is used for the only graded evidence statement in the review which is negative for lower carbohydrate diets
6.206 and 6.211	This statement should acknowledge that this is true for all dietary approaches, as there is an absence of high quality, long-term studies of any way of eating. It is unfair to expect lower carbohydrate diets to clear a higher barrier than other diets can, or to include caveats when discussing lower carbohydrate diets which are rarely, if ever, used for other diets
6.208 and 7.49	<p>The reference used in paragraph 6.208 is inappropriate, as this review found no cases of nutrition deficiencies and didn't even look at fibre</p> <p>The overall statement in both 6.208 and 7.49 is purely conjectural, and without adequate evidence being presented it should not be included. If fibre intake was deemed to be an issues of concern, why was this data</p>

	<p>not extracted from the primary RCTs included in the identified SR/MAs for analysis? Further, it is unclear why it is deemed acceptable to introduce sources of evidence outside of those identified through the stated search and inclusion criteria for this purpose when other evidence sources that may favour lower carbohydrate diets have not been permitted. The decision made here again appear to be biased against lower carbohydrate diets</p>
6.210	<p>This statement appears to be based on a single study. Beyond the fact the study used (Goday et al, 2016) should not have been included in the review anyway (see comment pertaining to paragraph 6.205), the criteria for grading evidence set out in Table 5.3 does not allow for a gradation above “Insufficient” when there are “<3-4 eligible randomise control trials”</p> <p>Further, the decision to award this statement a grade when changes in medication were not graded (despite data being available from 6 shorter-term and 8 longer-term RCTs) appears inconsistent, and bias against lower carbohydrate diets (i.e. RCTs have been used to grade inconsistent evidence which is negative for lower carbohydrate diets but have not been used despite more, and more consistent, evidence when it favoured lower carbohydrate diets)</p>
7.53	<p>This statement is mainly true based on the decision to restrict the analyses primarily to the 4 prioritised SR/MAs. By using the identified RCTs it would have been possible to perform additional analyses, even if they were limited in scope and numbers, to address the initially posed questions more specifically</p> <p>This statement does not full acknowledge that, when reported carbohydrate intake was considered, none of the 4 prioritised SR/MAs considered low carbohydrate diets (the mean intake in the SR/MA with the lowest reported intake was 31%) and that all 4 of them had an overlap in the reported carbohydrate intake between the lower and higher carbohydrate groups when the ranges reported were considered</p>
7.55	<p>The longer-term outcomes for HbA1c should be summarised more specifically, to acknowledge that a number of analyses favoured lower carbohydrate diets and thus they may be superior (and, again, that no analyses favoured higher carbohydrate diets)</p> <p>Again, the use of the term “inconsistent” should be qualified to reflect that this was between favouring lower carbohydrate diets and there being no difference. Without this qualification it is implied there was inconsistency across all outcomes, but no analyses favoured higher carbohydrate diets</p> <p>Disagree with wording around medication use, the available evidence (whether you limit this to the single systematic review that included it as a stated outcome, include all 4 prioritised systematic reviews, or include all identified systematic reviews and consider the RCTs independently) is clear and consistent in favour of lower carbohydrate diets</p>

7.56	<p>This paragraph should state clearly that none of the findings favoured higher carbohydrate diets</p> <p>This paragraph should state that the evidence demonstrates that lower carbohydrate diets appear to be at least as effective as higher carbohydrate diets, if not more so, for the management of Type 2 diabetes; and that there was no evidence of harm (either in terms of an increased risk of adverse events or due to an increase in cardiovascular disease risk factors)</p> <p>The statement that the long-term effects are unclear should be qualified, as per our comment on paragraph 7.55 and on earlier sections.</p> <p>We disagree with the conclusion that there was no difference for HDL cholesterol, as all findings either favoured lower carbohydrate diets or showed no difference.</p>
7.57	<p>This statement is irrelevant and should be removed. The reason for any improvement is not important in the context of whether a lower carbohydrate diet can be a suitable option for people with Type 2 diabetes</p>
7.58	<p>This issue is not considered within the review, so it is unusual that it appears here. Unless there is any evidence that use, or change in use, of these medications is different between diets then this point is not really relevant</p>
7.60 and 7.63	<p>The statements made in paragraph 7.60 and the last sentence of 7.63 are equally true of all diets, in any meaningful way. It is not appropriate to highlight this for low carbohydrate diets as if it is an issue that is specific to them, particularly when such qualifiers are seldom applied to other ways of eating</p>