

Consultation on the draft report:

Lower carbohydrate diets for adults with type 2 diabetes

Comments Form

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General comments	Comments Please insert each new comment in a new row
	There are five fundamental flaws with this review and the process should be stopped until they have been addressed:
<p>P5 panel membership</p> <p>Clause 3.20</p> <p>Table 3.1</p> <p>Table 5.1</p> <p>Clause 5.42</p> <p>Clause 6.200</p> <p>Clause 6.203</p> <p>Clause 6.204</p> <p>Clause 6.206</p>	<p>Flaw 1 – Conflicts of interest.</p> <p>As is a feature of SACN committees, there are conflicts of interest among panel members (p5).¹</p> <p>a) Food and pharmaceutical organisations.</p> <p>One of the co-chairs and two other panel members have conflicts of interest with the International Life Sciences Institute (ILSI). Their members are a who's who of the fake food industry/manufacturers of processed carbohydrates including Coca-Cola, General Mills, Hershey, Kellogg's, PepsiCo, Red Bull and many more.²</p> <p>One of the co-chairs also has conflicts with the British Nutrition Foundation – another body representing the fake food industry/manufacturers of processed carbohydrates. British Nutrition Foundation members include British sugar, Coca-Cola, Cargill, General Mills, Kellogg, Mars, McDonalds, Nestle, Pepsi, Tate & Lyle sugar and many more.³</p> <p>Other panel conflicts include Unilever, Mars, American Association of Cereal Chemistry International, Nestle, World Sugar Research Organization (more carbohydrate conflicts) and Amgen, Bayer, and Lilly (pharmaceuticals to counter the effect of carbohydrates).</p> <p>b) The SACN carbohydrate review.</p> <p>One of the co-chairs and another panel member were on the SACN review "Carbohydrates and health" (2015).⁴ This concluded "<i>It is recommended that the dietary reference value for total carbohydrate should be maintained at an average population intake of approximately 50% of total dietary energy.</i>"</p> <p>An example of the bias that this leads to is captured in Clause 5.42 – just below Table 5.1 which defines low carbohydrate diets (see below). Clause 5.42 states "<i>According to the above categories of carbohydrate intake, government recommendations on carbohydrate intake for the general population (50% of TE) would be classified as high.</i>" Yes – that's the point. This is not the panel to overturn its own guidelines.</p> <p>c) Diabetes UK.</p> <p>Half the panel are employed by, research for, or have other conflicts with Diabetes UK. The official dietary advice from Diabetes UK is still low fat/high carbohydrate dominated. Diabetes UK published a position statement on low-carbohydrate diets in May 2017.⁵ Their position statement can be summarised as:</p>

	<p>begrudgingly supporting low-carbohydrate diets in the short term only; issuing cautions about safety; and thinking that lowering blood glucose is an issue rather than a highly desirable outcome.</p> <p>Clause 3.20 and Table 3.1 sets out the Diabetes UK position. Table 3.1 summarises the current position among the peers of Diabetes UK and thus sets as a foundation the belief that carbohydrates should be 45-60% of intake, fat should be less than 35% and protein should be no more than 20%. With half the panel conflicted with Diabetes UK, this, again, is not the panel to overturn its own guidelines.</p> <p>The draft SACN report is dated January 2020 and so Clause 3.20 should have captured the US consensus report published in May 2019.⁶ This report examined low-carbohydrate diets (26-45% of total calories) as well as very low-carbohydrate diets (20-50g of carbohydrate a day). Both diets were reported to reduce HbA1c, deliver weight loss, lower blood pressure, and improve the lipid profile. The US consensus report did <i>not</i> caution that (very) low-carbohydrate diets were only safe and effective in the short term. The US consensus report did <i>not</i> use isolated papers to issue unnecessary safety concerns. The US consensus report contained 345 references. It went as far as to advise eating <i>non-starchy</i> vegetables.</p> <p>Further example of bias was shown in the reporting of adverse events. Two of the SRs/MAs did not report on adverse events. One reported that the most serious adverse event was in the higher carbohydrate diet (clause 6.200). None of the 13 primary RCTs, included in the SRs with MAs, which reported on adverse events reported any serious adverse events related to the diet (clause 6.204). This did not stop the draft report noting “<i>All 4 SRs with MAs observed the potential of carbohydrate-restricted diets to detrimentally impact CVD risk markers.</i>” (Clause 6.203). Furthermore, despite the 4 chosen studies and 13 primary RCTs providing no evidence of harm, the SACN panel added their own comments in a section called “<i>Potential long-term concerns.</i>” The first comment in this section (clause 6.206) stated “<i>The implications of long-term restriction of carbohydrates in adults with T2D are currently unknown since there is a lack of data from longer-term studies.</i>” (See Flaw 5).</p> <p>The review started off with confirmation bias and thus we can have no expectation of a genuinely independent outcome.</p>
<p>Clause 1.1</p> <p>Table 5.1</p> <p>Clause 5.9</p> <p>Clause 5.10</p>	<p>Flaw 2 – Not addressing what the review set out to address.</p> <p>The opening clause, Clause 1.1, stated: “<i>The purpose of this report is to review the evidence on lower carbohydrate diets compared to current UK government advice for adults with type 2 diabetes (T2D). It was initiated in 2017, in response to a request from Public Health England (PHE), in recognition that such diets are gaining attention and increasingly being promoted.</i>”</p> <p>I am not aware of anyone promoting lower carbohydrate diets for T2D. I am aware of a number of academic and medical doctors, in the UK and US especially, researching, publishing academic papers about, and promoting very low carbohydrate diets (and low carbohydrate diets as an upper, not lower, limit) – definitions in Table 5.1 below.</p>

	<p>Clauses 5.9 and 5.10 are remarkable.</p> <p>- Clause 5.9 opens with: “A number of clinical studies (including Saslow et al (2017); Bhanpuri et al (2018), Hallberg et al (2018), Athinarayanan et al (2019)) and case reviews (Unwin & Tobin, 2015) have assessed the effectiveness of lower carbohydrate diets on glycaemic control and other markers in adults with T2D.”⁷</p> <p>- Clause 5.10 then states: “These studies were not considered in this report because of the number of limitations associated with this study type. They also did not meet the inclusion criteria for study selection.”</p> <p>These clauses effectively state, “we’ll set the inclusion criteria and then we’ll dismiss – in two paragraphs – all evidence from the genuinely low-carbohydrate doctors and academics.” There were more publications not even cited and dismissed. These are in my EndNotes, just as examples.⁸ There will be many more still if the panel were minded to look for them.</p> <p>Facing a crisis of the scale that Type 2 diabetes presents, you would think that any and all evidence would be welcomed with open arms. It would seem not.</p>																	
Clause 3.13 Table 5.1 Table 6.1 Clause 6.2 clause 6.62 Clause 6.130 Clause 6.140 Clause 6.163	<p>Flaw 3 – The decision to <i>not</i> study low carbohydrate diets.</p> <p>a) The SACN draft report shows that it knows what low and very low carbohydrate diets are...</p> <p>Table 5.1: Categories of dietary carbohydrate intakes*</p> <table><tr><th rowspan="2">Description</th><th colspan="2">Amount of carbohydrate</th></tr><tr><th>g/day</th><th>% TE (based on 2000 kcal/day)</th></tr><tr><td>Very low carbohydrate[∞]</td><td>20 to 50</td><td>≤10</td></tr><tr><td>Low carbohydrate</td><td>>50 to <130</td><td>>10 to <26</td></tr><tr><td>Moderate carbohydrate</td><td>130 to 230</td><td>26 to 45</td></tr><tr><td>High carbohydrate</td><td>>230</td><td>>45</td></tr></table> <p>*Based on Feinman et al (2015) and Accurso et al (2008) [∞]Also referred to as ketogenic diets.</p>	Description	Amount of carbohydrate		g/day	% TE (based on 2000 kcal/day)	Very low carbohydrate [∞]	20 to 50	≤10	Low carbohydrate	>50 to <130	>10 to <26	Moderate carbohydrate	130 to 230	26 to 45	High carbohydrate	>230	>45
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... and yet it has then chosen to ignore them.

It is worth noting that the very low-calorie DiRECT diet was a low-carbohydrate diet. It provided 825-853 kcal/day, of which 59% was carbohydrate, thus providing 122-126g of carbohydrate a day.⁹ That's low carbohydrate in Table 5.1 above. DiRECT was thus low carbohydrate *and* very low calorie and yet no concerns about its safety were issued in the draft report.

b) Clause 6.2 informs us that just four systematic reviews with meta-analysis were used to provide the entire evidence in the SACN draft report. Normally SRs with MAs would provide the best evidence available, but the goal of this review was ostensibly to review the growing interest in (very) low carbohydrate diets, and this evidence is gathering at the current time – to ignore all of this is to render the draft review pointless.

c) Earlier evidence was also ignored in the draft report (2008). Clause 3.13 states “*Currently, there is no cure for T2D but data from dietary weight management programmes and bariatric surgery confirm that weight loss can result in remission (Diabetes UK, 2018b).*”

In 2008, Dr Eric Westman *et al* published “*The effect of a low-carbohydrate, ketogenic diet versus a low-glycemic index diet on glycemic control in type 2 diabetes.*”¹⁰ The latter was a randomised controlled trial which randomised people to either a ketogenic diet (<20g carbohydrate daily) or a reduced calorie diet (500 cal deficit). The ketogenic diet achieved significantly better results for HbA1c, body weight, and reduction/elimination in diabetes medications. This provided evidence, back as far as 2008, that a genuinely low carbohydrate diet can put T2D into remission – the authors used the phrase “reversing”, rather than remission, in the abstract.

The Feinman *et al* paper¹¹ should have been used in the draft report for all of its evidence – not merely for the definitions of low carbohydrate diets. As the abstract summarises: “*Here we present 12 points of evidence supporting the use of low-carbohydrate diets as the first approach to treating type 2 diabetes and as the most effective adjunct to pharmacology in type 1. They represent the best-documented, least controversial results. The insistence on long-term random-controlled trials as the only kind of data that will be accepted is without precedent in science. **The seriousness of diabetes requires that we evaluate all of the evidence that is available. The 12 points are sufficiently compelling that we feel that the burden of proof rests with those who are opposed.***” (My emphasis).

d) Table 6.1 summarised the “carbohydrate intake comparisons” in the four studies forming the entire basis for the SACN draft report. In what follows, TE is total energy:

Huntriss *et al* (2018) – “*low carb diet must have achieved lower carbohydrate intake than the control group.*” (That was it – just lower – no amount specified).

Korsmo-Haugen *et al* (2018) – “*Diet <40% TE versus diet >40% TE from carbohydrates.*”

Sainsbury *et al* (2018) – “*Diet ≤45% TE versus diet >45% TE from carbohydrates.*”

Van Zuuren *et al* (2018) – “*Diet ≤40% TE from carbohydrates versus low fat diet (≤30% TE).*”

	<p>LowER carbohydrate really does simply mean just lowER in carbohydrate than the other diet. Below 45% vs above 45% of carbohydrate intake. That's all it needs to mean. The entire review is nonsensical. This was reported as a limitation of the SACN review (clause 6.62). It should have been reported as a fatal flaw.</p> <p>e) Notwithstanding that low carbohydrate diets were not studied, lowER carbohydrate diets performed better in the significant findings:</p> <p><u>HbA1C</u>. At 3 and 6 months, there were significantly greater reductions in HbA1c in the lower compared to the higher carbohydrate group. The evidence was graded as adequate. (Clause 6.130)</p> <p><u>Fasting plasma glucose</u>. In shorter-term studies (3-12 months), there was a greater reduction in fasting plasma glucose in the lower carbohydrate group. The evidence was graded as moderate. (Clause 6.140)</p> <p><u>Triacylglycerol</u>. Greater reduction in triglycerides in the lower carbohydrate diet in shorter-term studies (3-12 months). The evidence was graded as adequate. (Clause 6.163)</p> <p>Imagine what results could have been achieved with a proper review of very low carbohydrate diets (low carbohydrate as an upper limit)?</p>
<p>Section 2.2</p> <p>Cause 3.1</p> <p>Clause 3.7</p> <p>Clause 3.8</p>	<p>Flaw 4 – The absence of common sense.</p> <p>The clauses “classification of carbohydrates” (section 2.2) inform us that:</p> <ul style="list-style-type: none"> i) glucose is one of the three main monosaccharides; ii) glucose is present in fruit and milk (glucose is present in all three disaccharides); iii) starch is “a polysaccharide of glucose monomers.” <p>This section confirms that every food that contains carbohydrate contains glucose.</p> <p>Clause 3.1 states “<i>Diabetes is a condition in which the body does not produce sufficient insulin to regulate blood glucose levels and the insulin produced does not work effectively. This leads to elevated blood glucose concentrations which causes damage to blood vessels and nerves.</i>”</p> <p>Clause 3.7 states “<i>Diagnosis of T2D is on the basis of elevated blood glucose concentrations...</i>”</p> <p>Clause 3.8 states “<i>Elevated blood glucose concentrations over time can have serious long-term consequences such as heart attacks, strokes, kidney diseases, blindness, lower-limb amputations and premature death.</i>”</p> <p>If diabetes is a condition in which the body cannot regulate blood glucose levels and raised blood glucose levels are catastrophic, why would diabetics be advised to consume the majority of their diet in the form of carbohydrate – the only macronutrient to provide glucose?</p>

<p>Clause 5.1</p> <p>Clause 5.2</p> <p>Clause 6.206</p>	<p>Flaw 5 – if only the same bar had been set for the introduction of low fat high carbohydrate guidelines.</p> <p>Clause 5.1 informed us that only “evidence provided by systematic reviews (SRs) with meta-analyses (MAs)” will be considered and only from RCTs (clause 5.2).</p> <p>Clause 6.206 stated “<i>The implications of long-term restriction of carbohydrates in adults with T2D are currently unknown since there is a lack of data from longer-term studies.</i>”</p> <p>The implications of long-term restriction of fat (and concomitant increase in carbohydrates) in all adults was unknown at the time of the introduction of precisely these dietary guidelines (1977 US/1983-84 UK).</p> <p>My PhD was an examination of the evidence base (using only systematic review and meta-analysis) for the introduction of the low-fat (high-carbohydrate) guidelines. There was <i>no</i> evidence at the time these guidelines were introduced from SR and MA of RCTs.¹² (There was no evidence from cohort studies either.¹³) There has been no more evidence from SR and MA of RCTs since.¹⁴ We had no idea of the implications of long-term restriction of fat (and concomitant abundance of carbohydrate) and yet we introduced these dietary guidelines anyway.</p> <p>It would appear that the bar to change the guidelines (back to where they were) is substantially higher than the zero-bar applied to their introduction.</p>
	<p>In summary, there are five fundamental flaws with this review and this review should be stopped until they have been addressed. Otherwise this draft report risks becoming the official position on T2D and low carbohydrate diets (the semantics of lowER will soon be lost) and that would be a travesty. The review requires:</p> <ol style="list-style-type: none"> 1) An independent panel with no conflicts of interest. 2) Examination of the actual diets gaining attention, as the review claimed it set out to address. 3) Genuine study of very low carbohydrate diets (low carbohydrate diets as an upper limit). 4) Some common sense. 5) Some humility and acknowledgement of how low the bar was set to get us into a public health crisis of obesity and type 2 diabetes and how high the bar has been set to get us out of this. And then an acceptance of the Feinman <i>et al</i> position: <i>The seriousness of diabetes requires that we evaluate all of the evidence that is available. The 12 points are sufficiently compelling that we feel that the burden of proof rests with those who are opposed.</i>

References

- ¹ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/841591/SACN_Register_of_Interests_v21.pdf
- ² <https://ilsina.org/about-us/membership/>
- ³ <https://www.nutrition.org.uk/aboutbnf/corporate/memberorganisations.html>
- ⁴ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/445503/SACN_Carbohydrates_and_Health.pdf
- ⁵ <https://www.diabetes.org.uk/resources-s3/2017-09/low-carb-diets-position-statement-May-2017.pdf>
- ⁶ Evert AB *et al.* Nutrition Therapy for Adults With Diabetes or Prediabetes: A Consensus Report. *Diabetes Care* 2019. <https://care.diabetesjournals.org/content/diacare/42/5/731.full.pdf>
- ⁷ Saslow LR *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.
- Bhanpuri NH *et al.* Cardiovascular disease risk factor responses to a type 2 diabetes care model including nutritional ketosis induced by sustained carbohydrate restriction at 1 year: an open label, non-randomized, controlled study. *Cardiovasc Diabetol* 2018.
- Hallberg SJ *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 Ther* 2018.
- Athinarayanan SJ *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. *Front Endocrinol (Lausanne)* 2019.
- Unwin D and Tobin S. A patient request for some "deprescribing". *Bmj* 2015.
- ⁸ Unwin D, Unwin J. Low carbohydrate diet to achieve weight loss and improve HbA1c in type 2 diabetes and pre-diabetes: experience from one general practice. *Practical Diabetes* 2014.
- Unwin DJ *et al.* A pilot study to explore the role of a low-carbohydrate intervention to improve GGT levels and HbA1c. *Diabetes in Practice* 2015.
- Saslow RL *et al.* Outcomes of a Digitally Delivered Low-Carbohydrate Type 2 Diabetes Self-Management Program: 1-Year Results of a Single-Arm Longitudinal Study. *JMIR Diabetes*. 2018.
- Unwin DJ *et al.* 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.

Saslow LR *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.

Evert AB *et al.* Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report. Diabetes Care. 2019.

McKenzie LA *et al.* A Novel Intervention Including Individualized Nutritional Recommendations Reduces Hemoglobin A1c Level, Medication Use, and Weight in Type 2 Diabetes. JMIR Diabetes. 2017.

⁹ Lean MEJ, Leslie WS, Barnes AC, *et al.* Primary care-led weight management for remission of type 2 diabetes (DiRECT): an open-label, cluster-randomised trial. The Lancet 2017.

¹⁰ Westman EC *et al.* The effect of a low-carbohydrate, ketogenic diet versus a low-glycemic index diet on glycemic control in type 2 diabetes mellitus. Nutrition & metabolism 2008.

¹¹ Feinman RD, Pogozelski WK, Astrup A, *et al.* Dietary Carbohydrate restriction as the first approach in diabetes management. Critical review and evidence base. *Nutrition (Burbank, Los Angeles County, Calif)* 2014.

¹² Harcombe Z *et al.* Evidence from randomised controlled trials did not support the introduction of dietary fat guidelines in 1977 and 1983: a systematic review and meta-analysis. Open Heart 2015.

¹³ Harcombe Z *et al.* Evidence from prospective cohort studies did not support the introduction of dietary fat guidelines in 1977 and 1983: a systematic review. Br J Sports Med 2016.

¹⁴ Harcombe Z, Baker JS, DiNicolantonio JJ, *et al.* Evidence from randomised controlled trials does not support current dietary fat guidelines: a systematic review and meta-analysis. Open Heart 2016.

Harcombe Z. Dietary fat guidelines have no evidence base: where next for public health nutritional advice? Br J Sports Med 2016.