Scientific Advisory Committee on Nutrition

Consultation on the SACN draft report Saturated Fats and Health Report

Comments Form

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Closing date: 5pm 3 July 2018

General comments	Comments Please insert each new comment in a new row
Example: References	*Example: Please check that referencing is consistent across all the chapters.*
Methods (section 2)	Given the lack of effectiveness of low fat dietary advice based largely on PCSs and limited RCT evidence, over the last 30 years, it is most surprising to see such an archaic methodological approach based on the SACN Framework for the Evaluation of Evidence still being used.
As above	The associations noted were assumed to be causal of changes in saturated fatty acid intake or their MUFA, PUFA, carbohydrate or protein substitutions, when in fact the changes could have readily been associated with changes in dietary (food group) composition.
Recommendations	It would be disingenuous to make Recommendations (as is currently the case in draft Section 16.6) to the public without simultaneously indicating what benefits are likely to be achieved through restricting saturated fats and substituting with PUFAs or MUFAs. For example, in communicating recommendations, it should be made clear that no benefit was found in the data reviewed for reduced CVD mortality or cancer. Any benefit for reduced CHD events should be explained by the expected reduction in defined CHD events over a lifetime or within an age range. It should also be made clear that these recommendations do not apply to people with pre-existing disease, including obesity and type 2 diabetes.
As above	The 46 RCTs and PCSs that met inclusion criteria included healthy subjects at baseline with ethnicities, socio-economic status and level of physical activity among many factors that were not generally considered in the synthesis. The conclusions drawn cannot necessarily be applied to the current population on which the majority of adults are obese, where 80% of current 10 to 14-year-olds are likely to become obese adults (Agha & Agha. Int J Surg Oncol (N Y). 2017 Aug; 2(7): e17).
As above	For the reasons indicated in our comments on the scientific methodologies (see Comments by paragraph) on which the studies selected by SACN have been based, providing an inflexible maximum for saturated fat intake (10 or 11% of total energy) does not mean that all or even most healthy people (regardless of the fatty acid profile, ethnicity, socio-economic status, age group, gender and physical activity level) who maintain this intake or less of saturated fat consumption will benefit more than if they exceeded it. There is inadequate effort made to communicate what kinds of benefits in terms of say increased life expectancy might be conferred based on modelling studies. Gary Taubes made this point as early as 2001 and explained that longevity gains are indeed very modest at most; referring to Browner's work published in JAMA in 1991, Taubes commented as follows: "a woman who might otherwise die at 65 could

	expect to live two extra weeks after a lifetime of avoiding saturated fat. If she lived to be 90, she could expect 10 additional weeks." (Taubes G. Science 2001; 291 (5513): 2538).
As above	The overall methodology used, namely the qualitative analysis of a very methodologically diverse range of RCTs and PCSs to then establish a direction of association or effect, and subsequently to provide recommendations based on often very small, sometimes null, effects, needs to be tested. Clinical trials designed to 'break' the 'lower saturated fat/improved outcomes' hypothesis should be conducted (see below) prior to the recommendations being issued which are intended to be relevant population-wide.
Research recommendations	Clinical trials with specific fatty acid profiles should be conducted to ensure that the presently weak 'lower saturated fat/improved outcomes' hypothesis is not able to be disregarded simply because lower saturated fat diets with substitutions as studied in the reviewed RCTs and PCSs are generally healthier diets (e.g. increased polyphenols, fewer heat damaged/contaminated foods (e.g. PAHs, HAs), fewer advanced glycation end (AGE) products, increased polyphenols, etc). Such trials should be developed using the expert base on healthier FA profiles, e.g. reduced palmitic acid, increased palmitoleic acid, etc.
As above	It would also be of great value to examine clinical data from clinician/researchers such as Drs David Unwin and Trudi Deakin in the UK, and Dr Sarah Hallberg in the USA. It seems likely that the positive results derived from using higher fat diets in these cases may be linked to careful selection of fatty acid profiles as well as carefully considered carbohydrate reduction. These clinical data represent real-world data and while they cannot be relied upon in isolation, they are of immense importance for validation and hypothesis testing.

Comments by paragraph	Comments Please insert each new comment in a new row
2.2	There has been no attempt to justify or explain the limitations of the SACN Framework for the Evaluation of Evidence, claimed as being the “expected and required standard for assessing evidence.” The use of RCTs and PCSs in nutrition is well-recognised as having such serious limitations as to make them meaningless as a means of guiding dietary choices by individuals, each with unique disease risk profiles as well as unique epigenetic, physiological, environmental, social, socio-economic, ethnic and cultural backgrounds. Limitations applying to both RCTs and PCSs include: lack of adequate characterisation of the “normal” and “healthy” population from which subjects for longitudinal studies have been selected (Manrai et al. JAMA. 2018; 319(19):1981-1982), inadequate consideration of how changes to the food matrix (because of nutrient substitution) alter the biological effect of different saturated FAs when diets of higher or lower saturated (or total) fat content are compared (Magni et al. Adv Nutr. 2017; 8(4): 532–545), lack of sufficient stratification to determine relative impacts of ‘higher saturated fat + lower refined carbohydrate’ intake compared with ‘lower saturated fat + higher refined carbohydrate’ consumption among overweight or obese subjects (Hu. Am J Clin Nutr. 2010 Jun; 91(6): 1541–1542), and – not least – multiple issues relating to bias, confounding and scientific distortion (Brown AW. Adv Nutr. 2014; 5(5): 563-5). Maki et al detail a range of methodological limitations for PCSs that have not been adequately considered by SACN, including measurement error, collinearity, displacement/substitution effects, healthy or unhealthy consumer bias, confounding and effect modification, and a high risk of false positives owing to weak diet-disease effects (Maki et al. Adv Nutr. 2014; 5(1): 7–15). RCTs also have numerous limitations that include the limited ability to control for multiple exposures, incomplete adherence to treatment or control arms, the inability to blind complex, behavioural exposures, limited generalisability for the specific exposure and study sample, and possibly most importantly, questions over the applicability of findings to real-world situations (Treweek S, Zwarenstein M. Trials 2009;10:37; Attanasio OP. Scand J Public Health 2014; 42(13 Suppl)28–40; Hébert et al. Adv Nutr. 2016; 7(3): 423–432). Given these limitations, it is now extraordinary and scientifically reprehensible that the SACN has limited itself to such narrow inclusion criteria and the top three study types of the evidence-based hierarchy, namely meta-analyses/systematic reviews, RCTs and PCSs. This means that the SACN has directly avoided using a totality of evidence approach which is increasingly seen as essential in the field of nutrition given the well-recognised limitations of RCTs and PCSs. Other data that should have been considered as a means of ensuring totality of evidence for the SACN review include: 1) results from case control studies, 2) results from cases/medical records, and 3) views from relevant experts who have clinical experience of working with individuals consuming diets containing different qualities and amounts of fat.
8.47	In Chowdhury et al (2014), a significant increase in CHD was noted when the highest tertile SFA groups was compared with the lowest. But this significance cannot be assumed to be caused by the saturated fat intake – it was more likely the result of a substitution effect such as higher carbohydrate intake in the highest SFA intake tertile.

16.6	There is inadequate scientific basis to make the Recommendations given in this Section to all children over 5 and all adults given that it remains unclear how much the generally modest effects or associations are linked to changes in the food matrix, particularly where substitutions have occurred. New trends such as changes in quality of foods and oils, cooking methods, reliance on increasing amounts of processed foods and very great differences in biological responses between people of different ethnicities, ages, socio-economic status and physical activity, need to be considered. The Recommendations, currently based on methodologically weak, association analysis, which fails to consider the likely benefit to members of the public who follow the Recommendations, are a defective public health policy instrument.