

Appendix B: Stakeholder consultation comments table

2018 surveillance of <u>CG189 Obesity</u>: identification, assessment and management (2014) and PH46 BMI: preventing ill health and premature death in black, Asian and other minority ethnic groups (2013)

Consultation dates: 19 March 2018 to 3 April 2018

CG189 Obesity: identification, assessment and management (2014)

1. Do you agree with the proposal for a partial update of this guideline?

Stakeholder	Overall response	Comments	NICE response
Association for the Study of Obesity	Yes	We agree with the proposed partial update and topics of focus	Thank you for your comment
		1.2.1 We agree that the instructions regarding measuring BMI to clinicians, especially GPs should be firmer, to facilitate the implementation of NICE quality standard QS127.	Thank you for your comments

We strongly support the suggestion for measuring BMI in order to identify overweight and obesity in black, Asian and other minority groups based on ethnicity-specific cut-offs.	
1.2.10 We support a more proactive approach to informing adults of their BMI and associated impact upon their future health in line with QS127.	Thank you for your comment
1.3.7, 1.3.10-1.3.12 We support the suggestion that these sections cross refer to the commissioning guidance relating to tier 3 services, to include a definition of tier 3 and 4 services.	Thank you for your comment
1.4.1, 1.4.2 and 1.4.5 We support the suggestion that these sections cross refer to NICE guideline PH53 for additional information on lifestyle interventions for adults.	Thank you for your comment
1.4.1, 1.4.2, 1.4.5, 1.4.12 and 1.4.13 We support the suggestion that these sections should cross refer to NICE guideline PH47 for additional information on lifestyle interventions for children.	Thank you for your comment
1.5.1 We support the suggestion that this section should cross refer to NICE guideline PH49 for adults and children	Thank you for your comment

		1.7.6 to 1.7.11 We support the suggestion that this section remains unchanged until longer term data are available. Data using VLCD and LEDs in different ethnic groups are also needed.	Thank you for your comment
British Dietetic Association - Obesity Group	Yes	A good case has been made for updating the proposed areas, and for not updating specific identified areas (please see section 3 below). We agree with cross-referencing to existing commissioning guidance specifically for tiers 3 and 4; it makes sense (and saves clinician time) to cross-reference and align guidance.	Thank you for your comment
British Obesity and Metabolic Surgery Society (BOMSS)	Yes	We agree with the partial update focusing on identification and classification of overweight and obesity, pharmacological interventions and physical activity.	Thank you for your comment
		1.2.1 We agree that instructions to clinicians, especially GPs, to measure BMI should be made much firmer, to facilitate the implementation of NICE quality standard QS127. In light of evidence that the adverse health conditions in black, Asian and other minority groups may not be identified, we agree that an update is needed that incorporates active case finding to detect overweight and obesity in these ethnic groups.	Thank you for your comments
		1.2.3 We suggest strengthened wording of waist circumference measurement from 'think about' to 'use'	Thank you for your comment. The collective new and previous surveillance evidence is consistent with NICE guideline CG189 in highlighting the value of waist circumference (WC) in addition to BMI. However, new evidence and expert feedback indicating the

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	superior discriminatory value of waist to height ratio (WHtR) as an alternative measure of adiposity has a potential impact on recommendations 1.2.2 and 1.2.3, to review the alternative measures, including WC and WHtR. The potential value of WHtR, as a proxy for central adipose tissue and a marker for early health risk, may also require exploration, although further studies may be needed to substantiate the evidence for this. The proposed review of the different measures of overweight and obesity will include consideration of the wording in recommendation 1.2.3.
1.7.6 to 1.7.11 We support the suggestion that this section remains unchanged at the moment as the vast majority of studies utilising VLED of LED show weight regain within 2-5 years. Thus, whilst the early data from the DiRECT study are encouraging we agree that longer term data (2 years +) with regard to weight loss and diabetes improvement/remission using ADA agree criteria are needed.	Thank you for your comments. The ongoing <u>DROPLET</u> trial and longer term results over 2 or more years from the <u>DiRECT</u> trial on very low energy diets (VLEDs) will be monitored for publication and potential impact on the guideline.
1.8.1 to 1.8.3 We strongly support the suggestion to review the evidence that liraglutide 3mg should be made available as a treatment option for adults for whom lifestyle and behavioural approaches have not been effective and for whom the potential benefits of treatment outweigh the risks.	
1.10.6 This section states that surgeons should submit data for a national clinical audit scheme. In England it is now	Thank you for your comment. The National Bariatric Surgery Registry is linked to in the footnote to recommendation 1.10.6 for national audit purposes.

		mandatory that all bariatric procedures are entered into the National Bariatric Surgery Registry (NBSR) http://nbsr1.e-dendrite.com We suggest that this section is altered so that it states the NBSR for operations undertaken in England.	
British Society of Gastroenterology Liver committee	Yes	No comment	Thank you
Diabetes UK		No comment for CG189	Thank you
National Obesity Forum		No comment for CG189	Thank you
NHS South Gloucestershire CCG	Yes	No comment	Thank you
Novo Nordisk Ltd	Yes	No comment	Thank you
Perspectum Diagnostics	Yes	1.2.1 - I agree with the expert feedback that instructions to clinicians, especially GP's, to measure BMI should be firmer. As well as having an impact on the implementation of NICE quality standard QS127 it also has an impact upon NICE quality standard QS152 (Statements 1 and 2 - People with non-alcoholic fatty liver disease are: 1) given advice on physical activity, diet and alcohol and 2) offered regular testing for advanced liver fibrosis.)	Thank you for your comments. NICE quality standard QS152 statements 1 and 2 focus on advice on physical activity, diet and alcohol, and testing for advanced liver fibrosis. Explicit instructions to measure BMI are not directly relevant to these statements and no impact is anticipated.

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Data that was collected on 1.6 million patients by the Royal College of GPs Research and Surveillance Centre found the following rates of BMI measurement:	
26.44% of patients had their BMI recorded in the past 12 months 58.45% of patients BMI had their recorded in the past 5 years	
(Williams <i>et al</i> (2017). Disease burden and costs from excess alcohol consumption, obesity, and viral hepatitis: forth report of the <i>Lancet</i> standing commission on Liver Disease in the UK.)	
These rates of measurement are very poor and improvement is urgently required. If patients are not having their BMI measured they will not be diagnosed and will therefore be unable to access the necessary support, guidance and treatment.	
1.2.10 – I agree that a proactive approach to informing people of their BMI should be pursued. I also agree that a mechanism for routine collection of BMI for all should be explored. If conversations between clinicians and patients about BMI are seen as routine it could help to reduce stigma and prevent people from feeling that they are being targeted. Non-alcohol related fatty liver disease (NAFLD) and Non-alcoholic Steatohepatitis (NASH) are potential long-term health problems that can develop in people who suffer from obesity.	Thank you for your comments. The wording of recommendation 1.2.10 covers provision of information on risk factors for developing long-term health problems. This includes non-alcohol related fatty liver disease and non-alcoholic steatohepatitis. NICE's guideline on Non-alcoholic fatty liver disease also cross refers to NICE guideline CG189 in relation to advising people with NAFLD about lifestyle modifications.

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		Obesity is the second most common indication for liver transplant in the UK (Williams et al (2017). Disease burden and costs from excess alcohol consumption, obesity, and viral hepatitis: forth report of the Lancet standing commission on Liver Disease in the UK.) However, in my experience there appears to be a considerable lack of public awareness regarding NAFLD/NASH. I am therefore keen to see NAFLD and NASH included in the information given to adults regarding the risk factors that are linked to obesity.	
		1.3.6 I believe that NAFLD/NASH should be added to the bullet point 'any comorbidities'. I appreciate that this list not meant to be exhaustive but given that 12% of the UK population could have NASH it is a significant issue that deserves to be given a higher priority if we are to stand any chance of tackling this issue. (Harrison et al. (2018). Prevalence and stratification of NAFLD/NASH in a UK and US cohort using non-invasive multiparametric MRI. EASL The International Liver Congress, Paris, 11-15 April 2018. Selected Poster tours)	Thank you for your comment. We did not find evidence in the surveillance review to justify adding NASH as an example comorbidity in the bullet points of 1.3.6, alongside the conditions with the highest disease burden (for example type 2 diabetes, hypertension, cardiovascular disease, osteoarthritis, dyslipidaemia and sleep apnoea).
Public Health England	Yes	 Identification and classification of overweight and obesity Recommendation. 1.2.1: Yes, agree this should be updated so that it does not rely on health professionals' individual judgement Yes, agree that instructions to clinicians, especially general practitioners (GPs), to measure body mass index (BMI) should be firmer, to facilitate the implementation of NICE quality standard QS127. Yes, the guidance should incorporate active case finding to detect obesity in black, Asian and other minority groups as adverse health conditions (increased risk for these groups at lower thresholds) 	Thank you for your comments. The partial update will consider new evidence and topic expert feedback relating to firmer instructions to clinicians, especially GPs, to measure BMI to facilitate the implementation of NICE quality standard QS127. It is proposed that NICE guideline CG189 cross refer to NICE's guideline on Behaviour change: individual approaches for further information on high intensity interventions, which includes appropriate training for health professionals. Topic expert feedback indicates that a more proactive approach to informing adults of their BMI is needed, indicating an implementation issue with recommendation 1.2.10, which advises that adults should be given information about their classification of

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may not currently be identified using opportunistic identification. Whilst the current NHS Health Check means that GP's actively prompt individuals between 40-74 years to undergo a full health check every five years (including BMI). The partial update should also consider more prompts to conduct anthropometric measurements to identify overweight and obesity as part of Make Every Contact Count. The partial update could consider any evidence to support regular screening at an earlier stage.	clinical obesity and the impact this has on risk factors for developing other long-term health problems. This will be passed to the NICE implementation team for consideration.
Identification and classification of overweight and obesity Recommendation 1.2.2 and 1.2.3: Our understanding is that the proposal is to consider the evidence as to whether waist to height ratio should be considered as an additional measure to BMI, as well as waist circumference.	Thank you for your comments and rationale for using waist to height ratio as an additional rather than replacement measure of adiposity. The rationale will be considered by the developers in the review of measures of overweight and obesity as part of the update.
Waist to height ratio should not replace BMI as the primary measure of adiposity but only be considered as an additional measure, despite new evidence and expert feedback on the use of waist to height ratio as a superior alternative measure of adiposity as against the use of BMI and waist circumference. This is because: BMI is an adequate proxy measure for monitoring the underlying increase in health risk due to excess weight at a population level and is well known and understood	

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 by the public. BMI calculation tools (e.g. NHS Choices BMI calculator) are readily available and easy to use Although BMI does have acknowledged drawbacks its use is widespread (worldwide) and there is a substantial amount of supporting literature which adds to the evidence base While waist to height ratio is a pragmatic tool. The evidence may be more limited than that identified in the preliminary review conducted and adopting different approaches at an individual versus population level will cause confusion in the already complex area of measuring weight status Waist to height ratio can also be more difficult to standardise than BMI Recommending the use of waist to height ratio would lead to inconsistency/confusion between measures for different ethnic groups (BMI and waist circumference still being proposed as obesity measures for black, Asian and other minority groups) Recommending the use of waist to height ratio would lead to inconsistency/confusion between measures for adults and for children From a population point of view, moving to waist to height ratio would mean a lack of published data with which to compare the resulting statistics, particularly around monitoring trends. 	
Identification and classification of overweight and obesity Comments relate to Section 1.2 Children As per the adults section (1.2.7), suggest inclusion of a table detailing the clinical BMI categories for children (based on UK90 BMI charts).	Thank you for your comments. Classification of overweight and obesity in children is covered by recommendations 1.2.12 and 1.2.13, which advises that BMI measurement in children and young people should be related to the UK 1990 BMI charts, including BMI z-scores or the Royal College of Paediatrics and Child Health UK-WHO growth charts to calculate BMI in children and young people. These include early years charts for 0-4 years and school age charts

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Suggest the inclusion of clinical reference for severe obesity 1.2.3 to support assessment/referral to tier 3/4 child weight management: The National Child Measurement Programme (NCMP) Local Authority Profile online data tool4 for child obesity for England was recently updated to include a new 'severe obesity' indicator, not reported on separately before. Severely obese children are at risk of developing a number of serious acute and chronic health problems. These children therefore pose a significant concern in terms of their health and wellbeing, and may require the provision of specialist tier 3 and 4 child weight management services. 1 Reilly JJ. Assessment of obesity in children and adolescents: synthesis of recent systematic reviews and clinical guidelines. J Hum Nutr Diet 2010;23:205-11. 2 http://adc.bmj.com/content/archdischild/100/7/631.full.pdf 3 https://www.cornwallhealthyweight.org.uk/OSCA_Guidelines.pdf 4 https://fingertips.phe.org.uk/profile/national-child-measurement-programme	for 2-18 years. The childhood and puberty close monitoring (CPCM) form may be used for longitudinal BMI monitoring in children over 4 years. The surveillance review did not identify evidence or intelligence to indicate that this advice should change. The new evidence submitted either precedes the surveillance search period or does not meet the surveillance study design eligibility criteria. However, the information highlighted by the consultee will be considered by the developer in the update process.
Generic principles of care: Recommendations in this section of the guideline p32 1.1.4 Coordinate the care of children and young people around their individual and family needs. Comply with the approaches outlined in the Department of Health's A call to action on obesity in England*.[2006, amended 2014]	Thank you for your comments. An amendment to recommendation 1.1.4 to cross refer to the cited national policy documents will be considered in the update process.

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The partial review should be updated to include more	
recent changes to policy including Public Health England's guides on weight management ¹ and the Childhood Obesity Plan ² .	
¹ Public Health England. Collection: Weight management: guidance for commissioners and providers. 2017 .Online. Available at: https://www.gov.uk/government/collections/weight-management-guidance-for-commissioners-and-providers	
^{2.} HM Government. Childhood Obesity a Plan for Action. (2016 (updated 2017)) Online. Available at: https://www.gov.uk/government/publications/childhood-obesity-a-plan-for-action	
Surveillance decision: The following editorial corrections are needed p49 'Topic expert feedback highlighted that NHS Choices is not considered to be an authoritative source. The reference to it in recommendation 1.4.8 and footnote 7 should be removed, and replaced with a reference and link to the Department of Health Eatwell guide.'	Thank you for your comments. NICE's position across all of its guidelines is not to cross refer to NHS Choices and instead to signpost to more direct sources where possible. The proposed cross reference to the Eatwell Guide will be amended to cite Public Health England as the source.
We do not agree with the statement that 'NHS Choices is not considered to be an authoritative source' or that it is removed as a reference, as Public Health England (PHE) work directly with NHS Digital (NHS Choices) providing scientific expertise to periodically review each webpage related to nutrition. This ensures information on NHS Choices is evidence based and aligns to government	

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guidance on healthy eating. However, we do agree that individuals should be signposted to the Eatwell Guide as the first point of call, in particular the booklet as this provides the most comprehensive information in addition to maintaining NHS choices – relevant link for the Eatwell Guide below: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/551502/Eatwell_Guide_booklet.pdf. In addition, Public Health England produced the Eatwell Guide (not the Department of Health) and we recommend that the text is updated to "Public Health England's Eatwell Guide" Editorial corrections: Lifestyle Interventions p95	
'Recommendations 1.4.1, 1.4.2 and 1.4.5 should cross refer to NICE guideline PH53 Weight management: lifestyle services for overweight or obese adults (May 2014) for additional information on lifestyle interventions for adults.' We recommend cross referencing to:	Thank you for your comments. An additional cross reference to the Public Health England guide will be considered in the update process.
PHE (2017) A guide to Delivering and Commissioning Tier 2 Adult Weight Management Services, London: PHE publications. Accessible at: https://www.gov.uk/government/uploads/system/uploads /attachment_data/file/623091/Tier2_adult_weight_manag ement_servicesguide.pdf	
This paper was developed in collaboration with and endorsed by: NICE, Local Government Association, Royal College of Physicians and Association of Directors of Public Health	

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Editorial corrections: Lifestyle Interventions p95 'Recommendations 1.4.1, 1.4.2, 1.4.5, 1.4.12 and 1.4.13 should cross refer to NICE guideline PH47 Weight management: lifestyle services for overweight or obese children and young people (October 2013) for additional information on lifestyle interventions for children.' We recommend cross referencing to: PHE (2017), A guide to commissioning and delivering tier 2 weight management services for children and their families, London: PHE publications. Accessible at: https://www.gov.uk/government/publications/child-weight-management-commission-and-provide-services This paper was developed in collaboration with and	Thank you for your comments. An additional cross reference to the Public Health England guide will be considered in the update process.
endorsed by: NICE, Royal College of Paediatrics and Child Health, Royal College of Physicians and Association of Directors of Public Health Editorial corrections: Lifestyle Interventions p95 – further recommendations We recommend cross referencing the following documents in this section: PHE (2017), Key Performance Indicators: Tier 2 Weight Management Services for Adults, London: PHE Publications, Accessible at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/656531/adult_weight_management_key_performance_indicators.pdf AND	Thank you for your comments. Additional cross references to the Public Health England documents will be considered in the update process.

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PHE (2017), Adult weight management services: collect and record data, London: PHE Publications, Accessible at: https://www.gov.uk/government/publications/adult-weight-management-services-collect-and-record-data

AND

PHE (2017), Child weight management services: collect and record data, London: PHE Publications, Accessible at: https://www.gov.uk/government/publications/child-weight-management-services-collect-and-record-data

AND

PHE (2018) Standard Evaluation Framework for Weight Management Interventions, London: PHE Publications, Accessible at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/685545/SEF_weight_management_interventions.pdf

AND

PHE (2017), Let's Talk About Weight: A step-by-step guide to brief interventions with adults for health and care professionals London: PHE Publications, Accessible at: <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/620405/weight_management_toolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolkitoolki

AND

PHE (2017) Let's Talk About Weight: A step-by-step guide to conversations about weight management with children and

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

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		families for health and care professionals London: PHE Publications, Accessible at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/649095/child_weight_management_lets_talk_about_weight.pdf	
		Research Recommendations The partial review should consider whether additional research recommendations is relation to follow up after Bariatric Surgery are required	Thank you for your comment. In the surveillance review, some new evidence was identified on follow up care after bariatric surgery, indicating that there is ongoing research activity in this area. It is not within the remit of the surveillance process to suggest the addition of new research recommendations.
Royal College of Paediatrics and Child Health	Yes	We are happy with the decision of this surveillance review proposal.	Thank you for your comment.
Royal Manchester Children's Hospital, Central Manchester University Foundation trust	Yes	No comment	Thank you.
Slimming World	Yes	No comment	Thank you.
Society for Endocrinology	Yes	1.8.1 to 1.8.3 We strongly support the suggestion that liraglutide 3mg should be made available as a treatment option for obesity in adults in addition to lifestyle and behavioural approaches. Clinical trial data show effectiveness in early-responders to liraglutide 3mg. Access to this medication would provide an effective option in the management of obese patients in Tier 3 settings where currently the only	Thank you for your comments. Liraglutide Thank you for your comments, which are consistent with the proposed update to the pharmacological interventions section.

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		alternative to failed lifestyle/behavioural interventions (with the exception of orlistat) is metabolic surgery. 1.2.1 We strongly agree that measurement of BMI by clinicians, especially in primary care, should be prioritised 1.2.3 Suggest using 'waist circumference' as standard practice rather than thinking about it 1.2.10 We strongly support the suggestion towards a more proactive approach towards discussing the diagnosis of obesity with patients and the associated complications 1.7.6 to 1.7.11 We support the suggestion that this section on VLED remains unchanged until long term data from trials such as DIRECT/DROPLET becomes available	Identification and classification The collective new and previous surveillance evidence is consistent with NICE guideline CG189 in highlighting the value of waist circumference (WC) in addition to BMI. However, new evidence and expert feedback indicating the superior discriminatory value of waist to height ratio (WHtR) as an alternative measure of adiposity has a potential impact on recommendations 1.2.2 and 1.2.3, to review the alternative measures, including WC and WHtR. The potential value of WHtR, as a proxy for central adipose tissue and a marker for early health risk, may also require exploration, although further studies may be needed to substantiate the evidence for this. The proposed review of the different measures of overweight and obesity will include consideration of the wording in recommendation 1.2.3.
The European Very Low Calorie Diet Industry Group	Yes	The European Very Low Calorie Diet (VLCD) Industry Group is the trade body for manufacturers and distributors of VLCD products set up to campaign for appropriate policy and legislation for slimming foods. Our members provide weight loss and weight management programmes designed for the overweight and obese based on both Very Low Calorie Diets (VLCDs) containing less than 800 kcals per day, Low Calorie Diets (LCDs) containing between 800 - 1200 kcals per day and individual meal replacements of 200+ kcal/serving. Both LCDs and VLCDs are formula food based diet programmes that are both calorie controlled and nutritionally complete providing 100% dietary reference	Thank you for your comments. The new and previous systematic review evidence supporting the use of low energy diets is consistent with recommendation 1.7.5 and the advice in recommendation 1.7.6 to consider low energy diets but to be aware of nutritional completeness. The new evidence suggesting that very low calorie diets are effective is limited by small sample sizes and short term follow up, and is unlikely to impact on recommendation 1.7.8, which advises VLEDs to be considered only as part of a multicomponent strategy for a maximum of 12 weeks. New evidence indicating non-inferiority of LELD diets compared to low energy carbohydrate diets may require further studies to substantiate the findings. The ongoing DROPLET trial on LELDs will be monitored for publication and potential impact on the guideline.

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values (DRV) of key vitamins and minerals, and other necessary nutrients in a defined number of portions. They are designed to replace more traditional, conventional food and meals in order to facilitate optimal weight loss. Usually in the form of shakes, soups, rehydrated meals, bars, mueslis, or desserts, they contain carefully formulated amounts of energy, protein, carbohydrate, fat, fibre and essential micro-nutrients.

The VLCD Industry Group agree with the partial update of this guidance. We are deeply concerned, however, by the decision not to update recommendations in section 1.7 despite the considerable amount of new evidence that has become available since the last update in 2014.

It is also important to note that NHS England has acknowledged the importance of total diet replacements (TDRs) as an option for addressing England's healthcare crisis with diabetes management.

The VLCD Industry Group believes that the review of the clinical evidence on the effectiveness, cost-effectiveness and safety of VLCDs conducted by NICE has been insufficient and has failed to take into account a number of relevant pieces of evidence. In particular, we believe that important studies published after 27 October 2017 should also be taken into account to ensure NICE guidelines are fully up to date and based on the latest available scientific evidence.

We believe it is important to draw NICE's attention to the evidence contained in the following papers:

The 12 month <u>DiRECT</u> trial results have published since the surveillance evidence review, but will be taken into account in the update process, along with any additional published economic analysis. The longer term 2 year results of the trial, in addition to the results from the DROPLET trial, may be necessary to establish whether there is a definite impact on the guideline recommendations.

The other cited study was included in the surveillance review but its findings may need to be substantiated by further studies with larger samples.

- Michael EJ Lean, et al. Primary care-led weight management for remission of type 2 diabetes (DiRECT): an open-label, cluster-randomised trial. www.thelancet.com Published online December 5, 2017 http://dx.doi.org/10.1016/S0140-6736(17)33102-1 We understand that a healthcare costs analysis of
- the DiRECT trial results will be published shortly.
- Purcell K, Sumithran P, Prendergast LA, Bouniu CJ, Delbridge E, Proietto J. The effect of rate of weight loss on long-term weight management: a randomised controlled trial. Lancet Diabetes Endocrinol. 2014 Dec;2(12):954-62.

The VLCD Industry Group is concerned by the decision not to update recommendations 1.7.5 and 1.7.6.

Recommendation 1.7.5 only recommends diets that have a 600kcal/day deficit. In light of the evidence, we believe that this recommendation should be updated to also include very low calorie diets (below 800 kcal) and low calorie diets (800 to 1200 kcal).

Furthermore recommendation 1.7.6 which refers to low calorie diets advises that these are less likely to be nutritionally complete. We would like to point out that low calorie diets are strictly regulated at both EU and national level, with legislation setting out strict compositional criteria ensuring that those diets are nutritionally complete (please see Regulation (EU) No 609/2013 of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control: Commission Directive 96/8/EC of 26 February 1996

Thank you for your comments.

In the evidence review for NICE guideline CG189, the guideline committee felt that there was little evidence of effectiveness of very low calorie diets (VLCDs) compared to LCDs (standard dietary advice) in the long-term, but they are relatively safe. The guideline committee noted that there was some evidence that VLCD worked in the short-term, but outcomes for weight loss at end of maintenance periods found no difference between VLCD and standard dietary advice. Evidence demonstrated that VLCDs achieve slightly greater weight loss over the short period of the intervention compared to LCDs; however this loss is not likely to be maintained. This was also supported by evidence to suggest a benefit in weight reduction at the start of a VLCD was not maintained over a long period of time.

The guideline committee did not consider overall that there were benefits to providing VLCDs to the majority of obese people who wish to lose weight and recommended that it should not be

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on foods intended for use in energy-restricted diets for weight routinely offered. However, the committee considered that there reduction; Commission Delegated Regulation (EU) 2017/1798 were likely to be some benefits to providing VLCDs to selected of 2 June 2017 supplementing Regulation (EU) No 609/2013 people who need to lose weight quickly for clinical reasons, for of the European Parliament and of the Council as regards the example, those people who are being considered for surgical specific compositional and information requirements for total procedures such as orthopaedic surgery or women who wish to diet replacement for weight control). conceive. The guideline committee defined 'rapid weight loss' appropriately as greater than that which can be achieved with Therefore, there is no reason or evidence for such a dietary and lifestyle changes. The guideline committee statement within the guidance, and we would be grateful if recommended the use of VLCDs in patients clinically assessed by NICE could reconsider and update this incorrect statement. the health care professional as likely to benefit from rapid weight As mentioned above, and in this context, we would also loss in these or analogous circumstances. wish to draw NICE's attention to the following study: Recommendations 1.7.5 and 1.7.6 are followed by advice in 1.7.8 that a very low calorie diets can be considered as part of a Michael EJ Lean, et al. Primary care-led weight management for remission of type 2 diabetes (DiRECT): an multicomponent strategy but for health professionals to ensure that: open-label, cluster-randomised trial, www.thelancet.com • the diet is nutritionally complete Published online December 5, 2017 http://dx.doi.org/10.1016/S0140-6736(17)33102-1 the diet is followed for a maximum of 12 weeks (continuously or intermittently) • the person following the diet is given ongoing clinical support. The collective advice in section 1.7 does allow for the use of very low calorie diets, as long as the diet is nutritionally complete. This would include compliance with the regulations referenced in the comments. The VLCD Industry Group is concerned by the calorie Thank you for your comment. We will pass this information over to thresholds outlined in recommendation 1.7.6 regarding low the developer and the definition of a low calorie diet will be calorie diet which are defined incorrectly as being within a reviewed in the guideline update process. range of 800 - 1600 kcal/day. Food legislation defines low calorie diets as being between 800 and 1200 kcal

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(Regulation (EU) No 609/2013 of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control; Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction; Commission Delegated Regulation (EU) 2017/1798 of 2 June 2017 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement for weight control).	
Recommendation 1.7.8 advises that very-low-calorie diets should be followed for a maximum of 12 weeks (continuously or intermittently). We would like to note that there is no scientific basis for the 12 weeks' limit and in fact, in many cases there is a requirement for further weight loss beyond this time and evidence for efficacy and safety for much longer periods than 12 weeks.	Thank you for your comment. The evidence review for NICE guideline CG189 found that the most successful VLCD trials achieve a total weight loss of 8-12% over 12 weeks. The period of 12 weeks was identified as being standard practice for the duration of a VLCD, following which all people who are being given a VLCD should be monitored and reviewed regularly and provided with support to help maintain weight loss. The duration of this support should be tailored to individual need as outlined in recommendation 1.4.4. No evidence was identified during the surveillance review to indicate the need to change this position and advice.
The VLCD Industry Group also believes that recommendation 1.7.9 should be updated as there is no evidence in favour of an approach in which clinicians are exhorted to point out to patients that "regaining weight is likely and not because of their own or their clinician's failure". A patient undertaking any method of weight loss will always regain weight unless he or she is able to limit	Thank you for your comment. In developing the guideline, the guideline committee noted that clinicians and people wishing to lose weight may find the benefit offered by immediate and rapid weight loss when adhering to a very-low-calorie diet attractive. The committee were very much aware that these diets are also available to individuals delivered by the commercial sector (at a cost to the individual). The guideline committee noted from their clinical

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food and drink consumption and is able to undertake the experience that weight regain following a VLCD was common, required amount of the right type of exercise. although weight regain may be slower with proper support in returning to a balanced diet and change in lifestyle. Weight regain in Therefore, we believe there is no reason for taking an people who have tried VLCDs may cause depression and perpetuate approach which highlights such a basic statement of fact a sense of failure in those people who are trying to manage weight. only within recommendations related to VLCDs and not If weight increases following a VLCD then this would also be with other weight loss methods, including diet and undesirable for the person. exercise, pharmacotherapy and surgery. The cited study was included in the evidence summary and was not We believe it is important to draw NICE's attention to the considered large enough in isolation to impact on the guideline. evidence contained in the following paper, which provides Further evidence in this area will be assessed at the next a long-term direct comparison between formula diets and surveillance review point. conventional food-based diets and shows similar outcomes in terms of weight regain. Purcell K, Sumithran P, Prendergast LA, Bouniu CJ, Delbridge E, Proietto J. The effect of rate of weight loss on long-term weight management: a randomised controlled trial. Lancet Diabetes Endocrinol. 2014 Dec:2(12):954-62. The VLCD Industry Group is also concerned by the Thank you for your comments. The commissioning guidance decision not to update 1.10 on surgical interventions. The referred to states that in the weight assessment and management review of the clinical evidence regarding the use of VLCDs clinic, encouragement should be provided for weight loss or in the immediate pre-operative phase of bariatric surgery maintenance, and structured eating plans, meal replacements and has failed to take into account a number of relevant pieces Very Low Energy Diets may be considered. VLCDs are mentioned as one of several alternative strategies that may be considered, but not of evidence. actively encouraged. It is also important to note that the NICE accredited The surveillance review did not identify any new evidence to change **BOMSS Commissioning Guidance and NHS England** this position. commissioning guidance both encourage the use of low and very low-calorie diets, as well as meal replacements.

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Similarly, the VLCD Industry Group believes that recommendation 1.12 on follow-up care after bariatric surgery should be reviewed to consider TDRs and meal replacements	Recommendation 1.12.1 advises dietary and nutritional assessment, advice and support, as part of a follow up care package for people who have had bariatric surgery. This will include consideration of appropriate diets, including VLCDs.
The VLCD Industry Group welcomes the decision to address the overlap between NICE guideline CG189 and NICE guideline PH53 Weight management: lifestyle services for overweight or obese adults. We believe however that a number of other inconsistencies have been missed, in particular inconsistencies between recommendations 1.7.7 and 1.7.8 of NICE guideline CG189 and recommendations 3 to 8 and 12 in PH53. Indeed, the recommendations set out in PH53 are supportive of the use of commercial weight management programmes in the framework of Tier 2 lifestyle interventions for the purpose of preventing and treating not only obesity but the condition's comorbidities – including Type 2 diabetes. It is also clear that recommendation 12 of PH53 implicitly supports the use of VLCDs in a Tier 2 setting by listing other commercial weight management providers whose programmes have been deemed as cost effective. This seems to contradict recommendations 1.7.7 and 1.7.8. We would therefore welcome a review of recommendations 1.7.7 and 1.7.8. The VLCD Industry Group also finds that the wording of recommendation 1.7.7 conflicts with the NHS England commissioning guidance. This guidance states that there	Thank you for your comments. NICE guideline PH53 does not explicitly recommend individual commercial weight management programmes but does state (recommendation 12) that providers of lifestyle weight management programmes (public, private or voluntary organisations) should demonstrate that their programmes are effective at 12 months or beyond. Although certain commercial programmes are stated as being deemed cost effective, the surveillance review did not identify sufficiently strong and conclusive evidence to indicate the need to explicitly recommend commercial weight loss programmes on a routine basis. Recommendation 1.7.1 advises tailoring dietary changes to food preferences and allowing for a flexible and individual approach to reducing calorie intake. These specific diets are encompassed within this broad recommendation. However, the consultee comments will be passed to the guideline developer, and a cross referral from NICE guideline CG189 to NICE guideline PH53 will be considered in the update process.

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		should be access to more intensive treatments such as low and very low calorie diets, pharmacological treatments, psychological support and specialist weight management programmes. This indicates that there is support for the routine consideration of VLCDs.	
Royal College of Physicians (RCP)	General	The RCP is grateful for the opportunity to respond to the above consultation. In doing so we would like to endorse the response submitted by the British Society of Gastroenterology (BSG). We have also liaised with our Advisory Group on Weight and Health and our Sport and Exercise Medicine Committee and would like to make the following comments.	Thank you for your comments.
	Yes	1.2.1 The suggestions in the surveillance review document that revision is needed in relation to recommendations for surveillance are timely and relevant as it would be helpful to provide stronger recommendations for clinicians to measure BMI and act on the findings.	Thank you for your comments.
		1.2.3 Likewise we would support the recommendation to state waist measurement should be measured rather than to consider its measurement in people with a BMI<35 in primary care.	
		1.2.3 It also seems sensible to review the evidence on using weight to height ratio as a measure of risk for adults	
		1.8.1 The surveillance review document suggests that revision is needed to the pharmacology section in particular in relation to liraglutide 3mg which is now licensed in the UK but has not been the subject of a NICE TA. This would be strongly supported by the RCP. Consideration should be given to its use in high risk patients with complex comorbidity attending tier 3 clinics – many of these patients are potentially eligible for bariatric surgery but this may not be an option for all of them (for multiple reasons including contraindications to surgery and patient choice).	Thank you for your comment. Consideration will be given to high risk patients with complex comorbidity in the update process.

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2. Do you agree with the proposal to withdraw recommendations 1.6.1-1.6.8 on physical activity and replace with recommendations in line with national advice from the Chief Medical Office (CMO) and related NICE public health guidance on physical activity?

Stakeholder	Overall response	Comments	NICE response
Association for the Study of Obesity	Yes	No comment	Thank you.
British Dietetic Association - Obesity Group	Yes	In our view it makes sense to align national guidance	Thank you for your comment.
British Obesity and Metabolic Surgery Society (BOMSS)	Yes	No comment	Thank you.
British Society of Gastroenterology Liver committee	Yes	No comment	Thank you.
Diabetes UK		No comment for CG189	Thank you.
National Obesity Forum		No comment for CG189	Thank you.

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NHS South Gloucestershire CCG	Yes	No comment	Thank you.
Novo Nordisk Ltd	Yes	No comment	Thank you.
Perspectum Diagnostics	Yes	No comment	Thank you.
Public Health England	Yes	PHE has no objection to the plan to revise the guideline content on physical activity but we would not support removal of the physical activity component without replacement.	Thank you for your comment. The proposal is to replace the physical activity component of the guideline and to develop new recommendations for adults and children in line with national advice from the Chief Medical Office (CMO) and related NICE public health guidance on physical activity: • PH44 physical activity: brief advice for adults in primary care (May 2013) • PH41 physical activity: walking and cycling (November 2012) • PH17 physical activity for children and young people (January 2009) • PH8 physical activity and the environment (January 2008)
Royal College of Paediatrics and Child Health	Yes	No comment	Thank you.
Royal Manchester Children's Hospital, Central Manchester	Yes	However the CMO recommendations need to be condensed down. The recommendation 1.6.4 in the current documents however should stay as it is important that	Thank you for your comment, which is largely consistent with the surveillance review proposals. The CMO recommendations provide for engaging children in physical activity even if they don't lose

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University Foundation trust		children continue to engage in physical activity even if they don't lose weight.	weight, and therefore recommendation 1.6.4 is also proposed for replacement.
Slimming World	Yes	This seems a logical decision and we agree it is helpful if national guidance is consistent.	Thank you for your comment.
Society for Endocrinology	Yes	No comment	Thank you.
The European Very Low Calorie Diet Industry Group	Not answered	The VLCD Industry Group agrees with the need to address any overlap between recommendations, and therefore supports the withdrawal of recommendations 1.6.1 – 1.6.8.	Thank you for your comment.
Royal College of Physicians (RCP)	Yes	Yes, this should help reduce the risk of conflicting messages being provided to people seeking advice and guidance (both professionals and the general public).	Thank you for your comment.

3. Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
Association for the Study of Obesity	No	No comment	Thank you.
British Dietetic Association - Obesity Group	Yes	We note that no update is recommended for the section on Assessment for children. Point 1.3.8 specifies that assessment of co-morbidity should be considered for children with BMI at or above the 98 th centile (i.e. obese). We are concerned that if assessment for co-morbidity is not considered at BMI at or above the 91 st centile (i.e. overweight), then children with additional health needs	Thank you for your comments.

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may not be identified. In fact points 1.3.10 and 1.3.11 specify children who are 'overweight or obese'. In our view point 1.3.8 needs to be updated to include the overweight category.

We note that no update is recommended for the section on Behavioural Interventions. We note that point 1.5.1 suggests that any behavioural intervention for children and adults is delivered by an 'appropriately trained professional', however there is no clarity about what that actually means in practice. It would be helpful to clarify this.

We feel that the dietary and behavioural intervention sections need to be updated and included within the scope. to take into account updates in research since 2006. With regard to the surveillance summary for 2018 on diet types, we are concerned that only low energy liquid diets have been specified since low energy diets are available in many additional different formats (e.g. bars porridges). We are unclear whether evidence on all types of formula total diet replacements has been included or if it has been restricted unnecessarily to only those in liquid state. Instead of the term 'low energy liquid diets; this section should be named 'formula total diet replacements' and evidence on all formats included. This may affect the recommendations for this section. New evidence on the use of these diets is also likely to be published in 2018; we appreciate that this may fall outside the time deadline for this update but it may affect the recommendations made. In addition the recent DiRECT trial which demonstrated remission of type 2 diabetes within primary care in almost half of patients (n=149) using total diet replacements which provided 825-853kcals/day for 3-5 months does not appear to have been included (Lean et al (2018) Primary care-led weight management for remission of type 2 diabetes (DiRECT): an

Assessment

An amendment to the wording of recommendation 1.3.8 will be considered as part of the update, to ensure consistency with the wording of recommendations 1.3.10 and 1.3.11.

Behavioural interventions

Recommendation 1.5.1 used broad terminology for an appropriately trained health professional to allow for the range of health professionals involved in multidisciplinary care and the varying training requirements required of them.

Dietary interventions

The surveillance review considered all diet types, including sections on dietary interventions where evidence was identified. These included low energy liquid diets, low carbohydrate and low fat diets, high and low protein diets, vegetarian diets, commercial and Mediterranean diets.

New evidence indicating non-inferiority of LELD diets compared to low energy carbohydrate diets may require further studies to substantiate the findings. The ongoing <u>DROPLET</u> trial on LELDs will be monitored for publication and potential impact on the guideline.

The 12 month <u>Direct</u> trial results have published since the surveillance evidence review, but will be taken into account in the update process, along with any additional published economic analysis. The longer term 2 year results of the trial, in addition to the results from the DROPLET trial, may be necessary to establish

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		open-label, cluster-randomised trial. Lancet 391: 541-5. Available from: http://www.thelancet.com/pdfs/journals/lancet/PIISO140-6736(17)33102-1.pdf). A recent update on behavioural and dietetic management of obesity is adults may provide additional useful information (BDA Obesity Specialist Group (23018) Dietetic Obesity Management Interventions in Adults: Evidence Review & Clinical Application. Available from: https://www.bda.uk.com/regionsgroups/groups/obesity/dietetic obesity management interventions 2018). In addition the term 'energy' rather than 'calorie' should be used throughout, since a calorie is a unit of energy (e.g. 'low energy diet' in place of 'low calorie diet'. We would also like to see weight loss maintenance included within the scope as there is a growing evidence base on the importance of and factors involved in maintaining a lower body weight after weight loss. Larger weight loss will be required to achieve sustained improvements in co-morbidities in those with BMI>35kg/m² as outlined in the SIGN obesity guidance (SIGN (2010) Management of obesity. A national clinical guideline. Guideline 115. Available from: http://www.sign.ac.uk/assets/sign115.pdf); we would like this included and evidence on interventions which achieve greater weight loss in this group included in the scope.	whether there is a definite impact on the guideline recommendations. The following cited document did not report search sources or inclusion and exclusion criteria for studies. It therefore did not meet the systematic review study design eligibility criteria for inclusion in the surveillance review: BDA Obesity Specialist Group (23018) Dietetic Obesity Management Interventions in Adults: Evidence Review & Clinical Application Weight loss Maintenance The surveillance review did not identify sufficiently strong evidence in the area of weight loss maintenance to justify the inclusion of new recommendations in this area.
British Obesity and Metabolic Surgery Society (BOMSS)	No	No comment	Thank you.

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British Society of Gastroenterology Liver committee	1.3.6 1.10.17	Liver disease should be added to the list of co-morbidities NASH+fibrosis of the liver should be an indication for bariatric surgery	Thank you for your comments. The wording of recommendation 1.3.6 covers investigation of all comorbidities, including liver disease. We did not find strong evidence in the surveillance review to justify adding liver disease as an example comorbidity in the bullet points of 1.3.6, alongside the conditions with the highest disease burden (for example type 2 diabetes, hypertension, cardiovascular disease, osteoarthritis, dyslipidaemia and sleep apnoea). We did not find strong evidence in the surveillance review to justify explicitly stating NASH + fibrosis of the liver as indications for bariatric surgery.
Diabetes UK		No comment for CG189	Thank you.
National Obesity Forum		No comment for CG189	Thank you.
NHS South Gloucestershire CCG	Yes	The advice on a low fat diet is outdated. A low carbohydrate diet is more likely to produced satiety and weight loss	Thank you for your comment. The surveillance evidence review did not identify evidence to indicate any impact on the advice relating to low fat diets.
Novo Nordisk Ltd	Yes	In 2018 surveillance summary for liraglutide, 1) Please specify dose of liraglutide. i.e. liraglutide 3.0 mg 2) The NICE report states:	 Thank you for your comments. The dose of lirglutide will be stated in the evidence summary as reported in the abstract of each study. The attrition and potential consequential bias of all included trials will be taken into consideration in the update process.

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a. "There were high drop-out rates in both the liraglutide and placebo groups in all of the studies so continuation with treatment may be a problem in practice."

This is a general problem in obesity research and liraglutide should not be penalised exclusively for this. Also, the SCALE RCTs did not factor in stopping rules in the study designs, so non-responders were continued within the full length of the trial and this may have be a cause for the drop-out rates. So if stopping rule is adhered to in practice, drop-out rates may be different vs SCALE trials. The STRIVE study will potentially provide clarity on this.

- 3) Second review paper (ref 331) refers to exenatide which is not licensed for weight management. Also the liraglutide data included in this analysis was 1.2mg/ day liraglutide. So it may be inappropriate to refer to this review paper in this section.
- 4) Ref 334, 335 and 336 all reference liraglutide at doses up to 1.2 mg or 1.8 mg in a patient population that may not have obesity. These doses are not the licensed dose for weight management. Need to either be more transparent on the doses of liraglutide and patient population reported in these papers or not refer to these RCTs where liraglutide (up to 1.8 mg) is the active agent.

- The review paper in question included studies on liraglutide monotherapy, as well as studies covering exenetide, and is therefore eligible for inclusion in the surveillance evidence summary.
- 4) The licensed starting dose for liraglutide (Saxenda[®]), also stated in the summary of product characteristics, is 0.6 mg daily and the maintenance dose is 3.0 mg daily. The dose should be increased to 3.0 mg daily in increments of 0.6 mg with at least 1 week intervals to improve gastrointestinal tolerability. If escalation to the next dose step is not tolerated for 2 consecutive weeks, discontinuation of treatment should be considered. Daily doses higher than 3.0 mg are not recommended. It is therefore possible for people to receive doses lower than 3.0 mg as part of weight management, including 1.2 mg and 1.8 mg.
- 5) The licensed dose is stated where appropriate.
- 6) The surveillance review did not identify evidence to indicate how long liraglutide 3.0 mg should be continued for, but any new data in this area will be considered in the update process.
- 7) All evidence, including the SCALE trials, will be considered collectively in the update process.
- 8) The collective new evidence, expert feedback and updated NICE-accredited BOMSS Commissioning Guidance and NHS England commissioning guidance indicate that there is a need for recommendations 1.3.7, 1.3.10-1.3.12 to cross refer to the commissioning guidance relating to tier 3 services, to include a definition of tier 3 and 4 services. The

Impact statement

- 5) Specify dose of Saxenda® (liraglutide 3.0 mg) when possible.
- 6) Although the SmPC does not mention how long liraglutide 3.0 mg should be used for, Novo Nordisk recommends the section mentions that data exists for liraglutide 3.0 mg use for up to 160 weeks reported in the SmPC.
- 7) Again, the high drop-out rate in RCT may be different to clinical practice where stopping rule will be implemented. Patients in SCALE trials were followed until EOT irrespective of whether they were responders vs non-responders.

Editorial and factual corrections identified during surveillance

- " Assessment "
- 8) Novo Nordisk would like to request that the definition of Tier2/Tier 3 settings also include leads by other specialists including, but not limited to

- definition will align with the related commissioning guidance, which included input from appropriate specialists.
- 9) As part of the update to the pharmacological interventions section of the guideline, guidance around the use of pharmacotherapy as an option in Tier 3 weight management services will be considered.
- 10) The evidence reviews for the NICE guideline CG189 and the original guideline CG43 found that the evidence on the effectiveness of pharmacological interventions for people with a BMI of 50 kg/m2 or more is extremely limited. This led to the recommendation for referral to specialist Tier 3 services for this group of people.

		endocrinologists or GPs with specialist interest as outlined in the NICE accredited BOMSS Commissioning Guidance.	
		9) Further guidance around the use of pharmacotherapy as an option in Tier 3 weight management services should be considered as well as those who are not considering bariatric surgery.	
		10) Can reviewers provide more rationale/ reasoning as to why a referral criteria to tier 3 service is:	
Perspectum Diagnostics	No	No comment	Thank you.
Public Health England	Yes	We understand that the evidence base to support specific NICE guidance on tier 3 Multi-Disciplinary Team (MDT) services is still under development and that there is research ¹ underway that NICE and PHE and other organisations need to be aware of and be prepared to factor into guidance.	Thank you for your comment. The ongoing research highlighted will be noted for consideration in the update process.
		¹ Specifically PROSPERO 2016 CRD42016040190 http://www.crd.york.ac.uk/PROSPERO/display_record.php ?ID=CRD42016040190	

Royal College of Paediatrics and Child Health	No	No comment	Thank you.
Royal Manchester Children's Hospital, Central Manchester University Foundation trust	Yes	An update on VLCDs is required as there is more data on this in the recent 12-18 months.	Thank you for your comment. The new and previous systematic review evidence supporting the use of low energy diets is consistent with recommendation 1.7.5 and the advice in recommendation 1.7.6 to consider low energy diets but to be aware of nutritional completeness. The new evidence suggesting that very low energy diets are effective is limited by small sample sizes and risk of bias among included studies, and is unlikely to impact on recommendation 1.7.8, which advises VLEDs to be considered only as part of a multicomponent strategy for a maximum of 12 weeks. New evidence indicating non-inferiority of LELD diets compared to low energy carbohydrate diets may require further studies to substantiate the findings. The ongoing DROPLET trial on LELDs will be monitored for publication and potential impact on the guideline. The 12 month DiRECT trial results have published since the surveillance evidence review, but will be taken into account in the update process, along with any additional published economic analysis. The longer term 2 year results of the trial, in addition to the results from the DROPLET trial, may be necessary to establish whether there is a definite impact on the guideline recommendations.
Slimming World	Yes	In section 1.4.8 the guidance refers to providing relevant information on 'realistic targets for weight loss' and cross refers to NICE guideline PH53. We'd suggest that this recommendation (within this guidance, as well as guideline	Thank you for your comment. Neither the current surveillance review of NICE guideline CG189 nor the 2017 surveillance review of NICE guideline PH53 identified any eligible evidence on realistic targets to indicate an impact on recommendation 1.4.8. The cited

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		PH53) is reviewed in terms of the evidence for the rationale for setting 'realistic goals'. Within this evidence review, the following paper, which demonstrates that setting ambitious goals can be helpful, may be of interest: Avery A., Langley-Evans S.C., Harrington M., Swift J.A. (2016) Setting targets leads to greater long-term weight losses and 'unrealistic' targets increase the effect in a large community-based commercial weight management group. <i>J Hum Nutr Diet</i> . 29, 687–696 doi: 10.1111/jhn.12390	reference did not meet the eligibility criteria for this section of the guideline. The data set was incomplete, with 12-month weight being not recorded for a significant number of people in the original sample.
Society for Endocrinology	No	No comment	Thank you.
The European Very Low Calorie Diet Industry Group	No	No comment	Thank you.
Royal College of Physicians (RCP)	No	No comment	Thank you.

4. Do you have any comments on equalities issues?

Stakeholder	Overall response	Comments	NICE response
Association for the Study of Obesity	Yes	Excess weight and obesity are increasingly common in people with learning difficulties and/or mental health problems. The management of obesity in these patients is challenging due to the complex behavioural challenges and	Thank you for your comment. The potential equality issue relating to people with learning difficulties or mental health problems will be noted for consideration in the update. No evidence was identified in this area in the surveillance review.

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		the complex pharmacotherapy that usually worsen the excess weight. Despite these challenges, access to and provision of weight management services to these two groups is poor. Did the team examine the evidence regarding this and whether measuring BMI and referral to specialist weight management services in these groups impacts upon health outcomes?	
British Dietetic Association - Obesity Group	Yes	We are pleased and agree with the proposal that instructions to clinicians particularly GPs to measure BMI should be firmer; in practice BMI is often not measured and/or recorded. We do not think that additional payment (e.g. through QOF) should be required in order to facilitate this; regular measurement and recoding of BMI is good clinical practice in our view. However measuring BMI is only part of it and this should be linked to the need for action in those with raised BMI. If those with raised BMI are not identified and/or action is not taken in those with raised BMI, there is potential for health inequalities to worsen, since overweight and obesity are disproportionately clustered in low income groups. Although it is currently recommended that measurement of WC is considered for those with BMI of less than 35kg/m², it is currently not measured routinely in practice (perhaps because BMI itself is often unmeasured and/or unrecorded). We are interested in the possible superiority of waist to height ratio. However the advantage in practice of WC is that it requires only a single measurement, and this may impact on the clinical usefulness of waist to height ratio. Both potentially impact on inequalities since they describe increased risk associated with overweight and	1.2.3.

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		obesity, which are disproportionately clustered in low income groups. We also agree that review is needed relating to the ability of healthcare professionals to use clinical judgements accurately in deciding when to measure height and weight. This is particularly pertinent to children and young people, whose height as well as weight is changing. If risks are not identified in this group, they will not be signposted to appropriate weight management services. This is a concern both in the short and long term due to tracking of excess weight from childhood into adolescence and adulthood. This will potentially result in inequalities in children and young people, and in particular the high risk subgroups within those age categories.	
British Obesity and Metabolic Surgery Society (BOMSS)	Yes	There is an increased prevalence of overweight and obesity in people with learning difficulties and people with mental health problems. However, access to and provision of weight management services to these two groups is poor. Did the team review any studies regarding this and whether measuring BMI in these groups together with referring for weight management impacts upon their health	Thank you for your comments. The potential equality issue relating to people with learning difficulties or mental health problems will be noted for consideration in the update.
British Society of Gastroenterology Liver committee	No	outcomes? No comment	Thank you.

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Diabetes UK		No comment for CG189	Thank you.
National Obesity Forum		No comment for CG189	Thank you.
NHS South Gloucestershire CCG	No	No comment	Thank you.
Novo Nordisk Ltd	No	No comment	Thank you.
Perspectum Diagnostics	No	No comment	Thank you.
Public Health England	No	No comment	Thank you.
Royal College of Paediatrics and Child Health	No	No comment	Thank you.
Royal Manchester Children's Hospital, Central Manchester University Foundation trust	No	No comment	Thank you.
Slimming World	No	No comment	Thank you.

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Society for Endocrinology	Yes	Access to obesity services in patients with mental health is poor, measuring BMI in this group of people and referral to weight management services may improve health outcomes in this group	Thank you for your comments. The potential equality issue relating to people with learning difficulties or mental health problems will be noted for consideration in the update.
The European Very Low Calorie Diet Industry Group	No	No comment	Thank you.
Royal College of Physicians (RCP)	Yes	It is important to consider evidence in relation to assessment and treatment of obesity in people with learning difficulties and mental health problems, as it is difficult for these groups to access weight management services.	Thank you for your comments. The potential equality issue relating to people with learning difficulties or mental health problems will be noted for consideration in the update.

PH46 BMI: preventing ill health and premature death in black, Asian and other minority ethnic groups (2013)

1. Do you agree with the proposal to withdraw the NICE guideline on BMI: preventing ill health and premature death in black, Asian and other minority ethnic groups and incorporate the recommendations into NICE guideline CG189 Obesity: identification, assessment and management?

Stakeholder	Overall response	Comments	NICE response
Association for the Study of Obesity	Yes	No comment	Thank you.
British Dietetic Association - Obesity Group	Yes	Aligning guidance is pragmatic and practical and will save practitioner time.	Thank you for your comments.
British Obesity and Metabolic Surgery Society (BOMSS)	Yes	No comment	Thank you.
British Society of Gastroenterology Liver committee	Yes	No comment	Thank you.
Diabetes UK	Yes	Diabetes UK agrees with the proposal to incorporate the NICE guideline on BMI: preventing ill health and premature death in black, Asian and other minority ethnic groups into CG189 Obesity: identification, assessment and	Thank you for your comments.

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management. We agree with this proposal because we think these recommendations could have more impact and widespread awareness if they are located alongside the mainstream obesity guidance. We recognise that the lower BMI thresholds of BAME groups which put them at an increased risk and higher risk of developing type 2 diabetes respectively needs to be highlighted.	
Section 1.2 Identification and classification of overweight and obesity. Diabetes UK recommends the lower BMI and waist circumference thresholds for the South Asian population should be stated clearly and included in the beginning of this section, as this population has a higher risk of developing Type 2 diabetes and cardiovascular diseases. Including this here will help to increase awareness. We also suggest including Box 1: International guidance on BMI/waist circumference thresholds on page 13/14 of the PH46 guideline in this section.	Thank you for your comments. The surveillance proposal is to incorporate all the recommendations from NICE guideline PH46 including Box 1: International guidance on BMI/waist circumference. We are proposing that no information is lost when the guidelines merge.
Section 1.3 Assessment We recommend that the assessment consultation is used to increase awareness and communicate the lower BMI and	Thank you for your comments. The surveillance proposal is to update the section on assessment and this will include providing information to people from black, Asian and other minority ethnic groups. This update will also consider wording of recommendations for referrals to tier 3 services.
waist circumference thresholds and associated health risks to persons from a South Asian background.	TOT TOTALINGS TO THE O'SELVICES.

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Due to the increased risk of Type 2 diabetes and cardiovascular disease for people from South Asian backgrounds. We recommend that wording in this section reflects the lower BMI and waist circumference thresholds for people from South Asian backgrounds when considering referrals to tier 3 weight management services.	
Section 1.4 – 1.7 Interventions When choosing treatments, healthcare professionals should take into account lower BMI and waist thresholds for people from a South Asian background. This should be discussed and relayed to individuals from South Asian groups when being treated.	Thank you for your comments. The surveillance proposal is to update the sections of NICE guideline CG189 on assessment and interventions which will consider the evidence for providing information and training for healthcare professionals. The update to the interventions section will include a review of the evidence for behavioural, physical activity, dietary and surgical interventions. Evidence specific to BAME populations will be considered in these areas.
Ensure healthcare professionals are trained and competent in delivering interventions specifically to people from BAME communities.	
Behavioural, physical activity and dietary interventions need to be tailored to cultural backgrounds. Part of this means exploring the social and family network and how this could hinder or support intervention and that support measures should be put in place depending on this.	

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Section 1.9 Surgical interventions	Thank you for your comments.
Bariatric surgery should be considered for people from a South Asian background at a lower BMI threshold,	NICE guideline CG189 provides relevant recommendations relating to people of an Asian family origin:
especially due to their higher risk of developing Type 2 diabetes and CVD.	Recommendation 1.11.3 of NICE guideline CG189 advises consideration of an assessment for bariatric surgery for people of Asian family origin who have recent-onset type 2 diabetes at a
Support for people undergoing bariatric surgery should be culturally tailored.	lower BMI than other populations (see recommendation 1.2.8) as long as they are also receiving or will receive assessment in a tier 3 service (or equivalent).
	Recommendation 1.2.8 advises using clinical judgment in considering risk factors in subgroups, including people of Asian family origin, using the classification table in recommendation 1.2.7.
We recommend that the guideline stresses the importance of commissioning a range of weight management services locally in order for the individuals who are identified can be appropriately assessed, referred and treated.	Thank you for your comments. The update to NICE guideline CG189 will consider evidence for weight management services and make recommendations for assessment, referral and treatment.
Diabetes UK agrees that there should be active case finding of people who are at risk due to their BMI (including at a lower threshold for people from BAME groups). Once identified, these should also be assessed for eligibility for the NHS DPP and actively referred if appropriate.	Thank you for your comments. The surveillance proposal is to include active case finding in the update to NICE guideline CG189 and may consider recommendations for referrals to available services.

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		Currently this guideline does not make any referral to the programme.	
		Diabetes UK proposes that in the CG189 guideline, the recommendations for generic principles of care in children and adults should take into account cultural needs and sensitivities, gender, ethnicity, social and economic circumstances when tailoring the components of weight management programmes.	Thank you for your comments. The update to NICE guideline CG189 will take into account the specific needs of individuals who access weight management programmes. An additional cross-reference to NICE guideline PH53 on weight management will also be made.
		Diabetes UK recognises that there is a huge need for health promotion materials that communicate specifically that people from BAME communities have an increased risk of developing type 2 diabetes at a lower BMI threshold. We recommend that commissioners and providers of local weight management services actively communicate this.	Thank you for your comments. Although the surveillance review did not find evidence specific to health promotion materials, NICE guideline PH46 does include recommendations which advise practitioners to follow recommendations on awareness raising as set out in NICE guideline PH42 Obesity: working with local communities.
National Obesity Forum	Yes	As it currently stands, anyone accessing CG189 will find no emphasis on minority ethnic groups, which must be corrected. They may not automatically turn their attention to PH46, as the title doesn't imply a relationship to obesity per se. Because of its opening statement, PH46 may instead, without specific scrutiny, imply any cause of premature death in these groups, such as hypertension and stroke in lean individuals of African descent, sickle cell, HIV, cerebral malaria or even urban gun crime.	Thank you for your comments. The proposed merge of the guidelines will incorporate recommendations specific to BAME populations within a major obesity guideline. This will raise awareness of recommendations specific to BAME populations.

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		These groups are therefore subject to possible disadvantage and health inequality.	
NHS South Gloucestershire CCG	No	No comment	Thank you.
Novo Nordisk Ltd	Yes	No comment	Thank you.
Perspectum Diagnostics	Yes	No comment	Thank you.
Public Health England	Yes	Yes, incorporating the recommendations of PH46 into CG189 means they will be an integral part of the main guideline thus giving them more weight and highlighting their importance. We are supportive of this decision as long as no content is lost in this process	Thank you for your comments. The proposed merge of the guidelines will not result in the loss of any unique information contained within NICE guideline PH46.
Royal College of Paediatrics and Child Health	Not answered		
Royal Manchester Children's Hospital, Central Manchester University Foundation trust	Yes	Although the intent to identify this higher at risk group for obesity related comorbidities, this can be encompassed within the current guideline	Thank you for your comments.
Slimming World	Yes	We feel it will be useful for this guideline to be incorporated into CG189.	Thank you for your comments.

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Society for Endocrinology	Yes	No comment	Thank you.
The European Very Low Calorie Diet Industry Group	Yes	The VLCD Industry group supports this proposal.	Thank you for your comment.
Royal College of Physicians (RCP)	Yes	No comment	Thank you.

2. Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
Association for the Study of Obesity	No	No comment	Thank you.
British Dietetic Association - Obesity Group	No	No comment	Thank you.
British Obesity and Metabolic Surgery Society (BOMSS)	No	No comment	Thank you.
British Society of Gastroenterology Liver committee	No	No comment	Thank you.

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Diabetes UK	No	This is already covered in the comments given in question 1	Thank you for your comments.
National Obesity Forum	No	No comment	Thank you.
NHS South Gloucestershire CCG	No	No comment	Thank you.
Novo Nordisk Ltd	No	No comment	Thank you.
Perspectum Diagnostics	No	No comment	Thank you.
Public Health England	No	No comment	Thank you.
Royal College of Paediatrics and Child Health	Not answered		
Royal Manchester Children's Hospital, Central Manchester University Foundation trust	No	No comment	Thank you.
Slimming World	No	No comment	Thank you.
Society for Endocrinology	No	No comment	Thank you.

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The European Very Low Calorie Diet Industry Group	No	No comment	Thank you.
Royal College of Physicians (RCP)	No	No comment	Thank you.

3. Do you have any comments on equalities issues?

Stakeholder	Overall response	Comments	NICE response
Association for the Study of Obesity	Not answered	Excess weight and obesity are increasingly common in people with learning difficulties and/or mental health problems. The management of obesity in these patients is challenging due to the complex behavioural challenges and the complex pharmacotherapy that usually worsen the excess weight. Despite these challenges, access to and provision of weight management services to these two groups is poor. Did the team examine the evidence regarding this and whether measuring BMI and referral to specialist weight management services in these groups impacts upon health outcomes?	Thank you for your comment. The potential equality issue relating to people with learning difficulties or mental health problems will be noted for consideration in the update of NICE guideline CG189. No evidence was identified in this area in the surveillance review.
British Dietetic Association - Obesity Group	Yes	We acknowledge the difficulty of identifying specific cut- off points for different ethnic groups which themselves are heterogeneous and whose own subgroups may have differential health risks. Nonetheless if the elevated risk of	Thank you for your comments. The proposed merge of the guidelines will incorporate recommendations specific to BAME populations within a major obesity guideline. This will raise awareness of recommendations specific to BAME populations.

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		ill-health faced by ethnic subgroups as a whole is not recognised and acted upon in clinical practice, then this will potentially lead to or exacerbate health inequalities. We would like to see more firm guidance to primary and public healthcare practitioners to instigate action at lower cut-off points in these groups. We agree that opportunistic identification may not be sufficient to identify adverse health conditions in Asian, black and other minority ethnic groups. However we do not think this only relates to these groups; opportunistic identification is likely to miss adverse health risks in other groups especially those who do not use healthcare systems or use them less (e.g. men). We agree with the research recommendations made. However in addition to RR-08 (p25), we think that identifying the extent of referral to and uptake of lifestyle interventions in people from black, Asian and other minority ethnic groups compared to the general population is important from a health inequalities perspective.	The proposed update will include a review of evidence for opportunistic identification across all populations and this will encompass demographic categories. The proposal is to also include active case finding specific to BAME populations. The proposal is to maintain the research recommendations for future evidence to be considered. The surveillance review did not find any evidence related to the uptake of interventions, however, this was beyond the scope of the guideline.
British Obesity and Metabolic Surgery Society (BOMSS)	Not answered	There is an increased prevalence of overweight and obesity in people with learning difficulties and people with mental health problems. However, access to and provision of weight management services to these two groups is poor. Did the team review any studies regarding this and whether measuring BMI in these groups together with	Thank you for your comment. The potential equality issue relating to people with learning difficulties or mental health problems will be noted for consideration in the update of NICE guideline CG189. No evidence was identified in this area in the surveillance review.

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		referring for weight management impacts upon health outcomes?	
British Society of Gastroenterology Liver committee	No	No comment	Thank you.
Diabetes UK	Yes	Diabetes UK recognises that the South Asian community includes a variety of subgroups and that the use of waist circumference thresholds should not be generalised, we ask that the guideline should highlight this.	Thank you for your comments. The surveillance review of NICE guideline PH46 did find evidence for different thresholds in subgroups within BAME populations. However, the evidence was considered insufficient in volume and the results insufficiently conclusive for inclusion in the guideline.
		We would like to emphasise that health care professionals to be more knowledgeable and understanding in the wider population of BAMES.	Thank you for your comments. The proposal to incorporate NICE guideline PH46 into a major obesity guideline will increase the awareness of recommendations specific to a BAME population.
		We recognise that there is a need for further research into the effectiveness of weight management interventions for particular BAMES communities.	Thank you for your comments.
National Obesity Forum	No	No comment	Thank you.
NHS South Gloucestershire CCG	No	No comment	Thank you.
Novo Nordisk Ltd	No	No comment	Thank you.

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Perspectum Diagnostics	No	No comment	Thank you.
Public Health England	Yes	There is no mention of developing guidelines for tackling increased health risk due to obesity/weight status in children and young people from black and minority ethnic (BME) groups. This group has been left out and a review of the evidence is needed. It is acknowledged that there is increased health risk for adults from black, Asian and other minority groups at lower BMI than the white population, and this is likely also to be the case for children and young people from those groups (possibly not manifesting as health conditions until adulthood). This is particularly likely to be the case for South Asian children (see below) and NICE guidance for public health action to reduce health risk is needed. The evidence is mostly about diabetes (which in itself a risk factor for cardiovascular disease and many other conditions/complications in adult life). Relevant studies may include: Whincup PH, Nightingale CM, Owen CG, Rudnicka AR, Gibb I, McKay CM, et al. Early emergence of ethnic differences in type 2 diabetes precursors in the UK: The Child Heart and Health Study in England (CHASE Study). PLoS Med 2010; 7(4):e1000263. Ehtisham S. Ethnic differences in insulin resistance and body composition in United Kingdom Adolescents. Journal	Thank you for your comments. The surveillance review of NICE guideline PH46 did not search for evidence related to children and young people as this age group was out of scope. The proposed update to CG189 will consider evidence for children and young people and this includes those from BAME populations. Thank you for providing references to studies related to health risks in children from BAME populations. These studies are out of the scope for NICE guideline PH46 however will be considered during the update to NICE guideline CG189.

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		of Clinical Endocrinology & Metabolism 2005; 90(7):3963-69.	
		Candler TP et al. Continuing rise of Type 2 diabetes incidence in children and young people in the UK. Diabetic Medicine: A journal of the Diabetic Association 2018; doi: 10.1111/dme.13609 Link: https://www.ncbi.nlm.nih.gov/pubmed/29460341	
		We also recommend that a research recommendation is made for further research examining body composition, weight status and co-morbidity risk in children from BME groups.	
Royal College of Paediatrics and Child Health	Not answered		
Royal Manchester Children's Hospital, Central Manchester University Foundation trust	No	No comment	Thank you.
Slimming World	No	No comment	Thank you.

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Society for Endocrinology	Yes	Access to obesity services in patients with mental health is poor, measuring BMI in this group of people and referral to weight management services may improve health outcomes	Thank you for your comments. The surveillance review did not find any evidence for people with learning difficulties and/or mental health problems. The update to the sections on assessment and interventions will consider any new evidence in these populations when drafting recommendations.
The European Very Low Calorie Diet Industry Group	No	No comment	Thank you.
Royal College of Physicians (RCP)	Yes	1.) Consider evidence in relation to assessment and treatment of obesity in people with learning difficulties and mental health problems, as it is difficult for these groups to access weight management services. 2.) Understand that those in ethnic groups may have more difficulty with access to facilities enabling physical activity such as gyms	Thank you for your comment. The potential equality issue relating to people with learning difficulties or mental health problems will be noted for consideration in the update of NICE guideline CG189. No evidence was identified in this area in the surveillance review. The surveillance review of NICE guideline PH46 did not find evidence related to access to services, cultural attitudes to exercise, and inactivity related diseases. The proposed update will include a review of relevant evidence in these areas and recommendations will cross-refer to other NICE guidelines where this information already exists.
		3.) Understand cultural attitudes to activity/exercise within these groups and any group based activities with level 3 professionals would need to consider this.	
		4.) To reiterate and emphasise that many ethnic minorities have greater morbidity/mortality from inactivity	

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	related disease inc obesity, CVD, Diabetes. Therefore recommendations may need to increase levels of activity above those of the CMO for national guidelines.	
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