National Institute for Health and Care Excellence

Obesity (update)
Guideline Consultation Table
Consultation 11 July – 8 August 2014

Stakeholder	Order No	Document	Page No	Line No	Comments	Developer's Response
Alder Hey Children's NHS Foundation Trust	1	NICE	46	30	The MOCA study Kendall et al. does not appear to have been taken into account. It is an RCT of good quality. The pharmaceutical options for obesity management seem to be limited to orlistat when I think there is evidence for metformin use.	Thank you for your comment. Section 1.8 has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Alder Hey Children's NHS Foundation Trust	2	NICE	General	General	The document seems to be heavily weighted toward surgical management rather than medical when lifestyle measures fail.	Thank you for your comment. The current guideline update focused upon three areas of management for people who are overweight or obese, the use of very-low-calorie diets, bariatric surgery for people who are obese who have recent-onset type 2 diabetes and follow-up care following bariatric surgery. These areas were identified during scoping as areas in which there may be new evidence available to change existing recommendations. Recommendations on the use of lifestyle measures were not updated as part of the current guideline update, however recommendations from CG43 on the use of lifestyle measures have been retained within the guideline and can be found in section 1.4. Recommendations on the use of lifestyle weight management services can be found in NICE public health guidance 53 'Overweight and obese adults: lifestyle weight management services' and will complement section 1.4

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Arthritis Research UK	1		General		No comment	Thank you for your comment.
Association for Dance Movement Psychotherapy UK	1	Full	General	General	We are surprised to see that there is no mention in this guideline of the evidence surrounding the link between emotional eating and obesity, or treatments designed to address this. Please see, as an example of a research project that addresses this gap: Vaverniece, I., Majore-Dusele, I., Meekums, B. & Rasnacs, O. (2012). Dance movement therapy for obese women with emotional eating: a controlled pilot study. *The Arts in Psychotherapy,* 39: 126-133. doi:10.1016/j.aip.2012.02.004. This controlled study (pragmatic, with some features of randomisation) was included in a recent meta-analysis: Sabine Koch, Teresa Kunz, Sissy Lykou & Robyn Cruz (2014). Effects of Dance Movement Therapy and Dance on Health-Related Psychological Outcomes: A Meta-Analysis. *The Arts in Psychotherapy,* 41, pp. 46–64. The study has the following abstract (full paper available on request): *This study explored the effectiveness of dance movement therapy (DMT) in obese women with emotional eating who were trying to lose weight. 158 women were recruited from a commercial weight loss*	Thank you for your comment. It was outside the scope of CG43 and the current guideline update, both of which focus on the management of overweight and obesity, to consider a link between emotional eating and obesity or treatments designed to address this and we are therefore unable to make comment on these issues in more detail

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					programme: 92 with BMI ≥ 28 were identified as emotional eaters and divided into: an exercise control (n = 32) and non-exercisers (n = 60). The non-exercises were partially randomised to non exercise control (n = 30) and treatment group (n = 30). Using a pre- and post-intervention design, 24 of the DMT treatment group, 28 of the exercise control and 27 of the non-exercise control completed all measures on a battery of tests for psychological distress, body image distress, self-esteem and emotional eating. Findings were analysed for statistical significance. The DMT group showed statistically decreased psychological distress, decreased body image distress, and increased self-esteem compared to controls. Emotional eating reduced in DMT and exercise groups. The authors cautiously conclude that DMT could form part of a treatment for obese women whose presentation includes emotional eating. Further research is needed with larger, fully, and blindly randomised samples, a group exercise control, longitudinal follow-up, a depression measure, ITT, and cost analyses.	
Association for Respiratory Technology and	1	Full	General	General	There is little or no mention of obstructive sleep apnoea/hypopnoea syndrome which is commonly found with obesity. We think that mention of this condition is relevant to the majority of obese patients and needs better referral in the	Thank you for your comment. Sleep apnoea is mentioned in the guideline. Recommendation 29 recommends assessing other comorbidities such as sleep apnoea when discussing implications of a person's weight. Recommendation 78 recommends

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Physiology					document.	that physical comorbidities such as sleep apnoea are exceptions for the use of orlistat in children over 12 years. Our scope did not include a specific review question on these issues and we are therefore unable to make comment on this issue in more detail. We understand that NICE is due to develop a guideline specifically on sleep disorders in the future. Further information will become available on the NICE website (www.nice.org.uk) in due course
Association for Respiratory Technology and Physiology	2	Full	42	893	Mention need for diagnosing and treating obstructive sleep apnoea to counter the increased risk of driving accidents and to improve quality of life regarding daytime hypersomnolence.	Thank you for your comment. The evidence behind this 2006 recommendation was not reviewed as part of this update and as such we are not able to provide further information. Recommendation 29 recommends assessing other comorbidities such as sleep apnoea when discussing implications of a person's weight. Recommendation 78 recommends that physical comorbidities such as sleep apnoea are exceptions for the use of orlistat in children over 12 years.
Association for Respiratory Technology and Physiology	3	Full	37	792	There is a need for screening for OSA in surgery patients due to increased anaesthetic risk in the perioperative period.	Thank you for your comment. It was outside the remit of the guideline to provide recommendations on screening of patients being considered for surgery however, Section 5.12 provides recommendations on the use of bariatric surgery and recommendation 92 highlights that bariatric surgery is only a treatment option for people who are generally fit for anaesthesia and surgery.
Association for Respiratory	4	Full	General	General	There is no mention of sugar or fructose and aim of reducing this in obesity. The data in the studies within the document and many others show that	Thank you for your comments. The recommendations related to the use of very-low-calorie diets were informed by a protocol developed

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Technology and Physiology					calorie restriction per se does not work. All the studies reported here show regain of at least half the weight at the longest term follow-up. The only successful diets restrict fructose content, whether that be low carbohydrate or low fat. It is much more difficult to have low fat without the fructose as reduced fat products get dosed with fructose and /or artificial sweeteners (which turn to fructose in the blood) to give back the flavour which is removed when removing the fat. Fructose is a principal cause of obesity, metabolic disease and heart disease. It has increased massively in our diets over the last 30 + years and is the major cause of the global pandemic in obesity and diabetes, yet it is not mentioned in these guidelines. This needs re-dressing.	by the Guideline Development Group which consisted of a multidisciplinary group of professionals including dietitians and weight management physicians and endocrinologists. The protocol can be found on page 71 of the full guideline. They did not prioritise a review of evidence of restricted fructose (by low carbohydrate or low fat) for weight loss and as such we are unable to provide specific comment on the issues you address.
Association for the study of obesity	1	Full	General	General	This is a response on behalf of the Association for the Study of Obesity. The ASO is the UK's foremost organisation dedicated to the understanding and treatment of obesity. [redacted] ASO welcome the updated NICE Guidance (CG43) review on the clinical management of obesity. We welcome the focus on VLCD and surgical interventions, which are probably of most value to the obese adults BMI>35 kg/m2. We have commented specifically on the recommendations for clinical practice and for the need for additional research.	Thank you for your comment. We have responded to individual comments below.

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Association for the study of obesity	2	Full	43	45	The diet guidance section in places appears contradictory. Point 60 "do not use unduly restrictive and nutritionally unbalanced diets, because they are ineffective in the long term and can be harmful" may include VLCD and some LCD's. Fad diets may be a clearer term. Later points, 63-67 suggest the use of VLCD and other reduced calorie options in adults and caution these may be nutritionally incomplete Commercially prepared LCD's must comply to EU standards for nutritional completeness. Can the nutritional completeness statement be modified? "Homemade" LCD's are much more likely to be nutritionally incomplete. Many commercially available LCD's provide only just above the 800 kcal per day. So in many ways they are very similar to the VLCD's under discussion.	Thank you for your comment. We do not believe the recommendations are contradictory. Recommendation 60 refers to the long-term use as having the potential of being ineffective. Further clarification about the importance of the use nutritionally complete diets has been added to recommendation 66.
Association for the study of obesity	3	Full	44	65	Advice against the routine use of VLCD. This point discourages use though later on in point 66 the use is clarified. Remove point 65.	Thank you for your comment. The review of evidence has indicated a lack of effectiveness of VLCDs in maintaining weight loss. Therefore, the GDG wanted to emphasise that VLCDs were not routinely offered. However, the GDG were aware that there are also some specific circumstances when they may be of benefit and have specified examples of these in recommendation 66.
Association for the study of obesity	4	Full	44	67	Weight cycling: the point suggesting weight gain is likely and it does not reflect anyone's failure seems very likely to dissuade clinicians to invest in weight management treatment. It may imply that the intervention is being considered in	Thank you for your comments. The GDG, including patient members, discussed the available evidence and were consistent in their experience that people who have undertaken a very low calorie diet and subsequently regained weight did experience a

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					isolation rather than part of a structured programme. NICE guidelines have never advocated this "piece meal" approach.	sense of failure. Accordingly, the GDG felt that it was important to manage expectations and wished to highlight this within the Linking evidence to recommendations section of the full guideline. The GDG have amended the linking evidence to recommendation in section 6.2.13 for recommendation 66 to highlight their view that weight regain, whilst common with all weight loss strategies, may occur following a VLCD and must be managed appropriately. The recommendations on the use of VLCD are only part of this clinical guideline. Other recommendations within the guideline address the importance of other weight management strategies.
Association for the study of obesity	5	Full	45	1	How can the reader implement the suggestion that in overweight and obese children "total energy intake should be below their energy expenditure"? How can this be assessed? Why use the term sustainable, what duration does this apply to?	Thank you for your comment. Recommendation 62 was not updated as part of the current guideline update. Therefore, we have not been able to provide the further clarification you request in the recommendation
Association for the study of obesity	6	Full	49	109 to 111	The suggestion that recently diagnosed diabetics (10 years) ought to be assessed and offered bariatric surgery is a new one. Could the rationale be justified, especially as new research recommendations suggest insufficient monitoring data are available to determine long term effects? BMI 30-34.9 should not be accepted into clinical practice without good quality evidence on what the longer term benefits really are. We consider this may be premature.	Thank you for your comment. Please see the 'recommendations and link to evidence' section in 7.1.5 of the full guideline which explains the rationale behind each recommendation. The research recommendation is specifically related to long-term data on quality of life and potential complications which there was less data on. The GDG felt that, in light of the evidence showing that bariatric surgery consistently improved weight and diabetic outcomes compared to non-surgery in

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						people with recent onset T2D, it was appropriate to recommend assessment for bariatric surgery in these patients. The recommendations do not recommend that bariatric surgery should be offered routinely in patients with Type 2 diabetes and BMI 30-34.9, but only that these patients could be considered for assessment for bariatric surgery and only in certain circumstances (for example, people with other obesity related issues or where diabetes is not being sufficiently managed with alternative measures such as diet, exercise and pharmacological treatments as specified in section 7.1.5 of the full guideline). The wording of recommendation 110 is weaker ('consider') than for recommendation 109 ('offer') to reflect the evidence considered for these different groups (please see page 10 of the NICE guideline and section 3.5 of the full guideline). This is all highlighted in the 'recommendations and link to evidence' section (7.1.5 of the full guideline).
Association for the study of obesity	7	Full	50	34	The research recommendation regarding long term use of VLCD and weight maintenance is interesting. There is already at least two systematic reviews examining this issue (Tsai and Wadden and Johannson et al, 2013) which suggests at one year post VLCD weight loss does not differ from a LCD. A more useful research recommendation may be to examine the effect of 12 weeks VLCD plus multi-component support to a minimum of 1 year. This guideline has not included systematic reviews / meta analyses. Does the question refer to use of	Thank you for your comment. Areas for further research were identified by the GDG throughout development following the appraisal of the evidence. The GDG were then required by NICE to vote on their top 5 research recommendations to be highlighted in the guideline. The focus of this research recommendation was on patients with a BMI above 40kg/m2 as the GDG noted that there was limited information on this population despite VLCDs being increasingly used in this group.

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					VLCD beyond 12 weeks or follow-up over an extended period? Evidence on long term use to date only considers VLCD over the short term with little clarity as to whether or in what form the dietary advice and support post VLCD took.	Thank you for your suggested research recommendation proposal but these research recommendations must be based on the questions within this guideline, where there is limited information. VLCD with multi component support was not one of the prioritised review questions set by the GDG. This guideline had 5 review questions and all protocols specified RCTs or systematic reviews of RCTs would be included. However, systematic reviews were excluded if they did not meet the required methodology quality and then the RCTs were reviewed individually. We agree that this research needs to be long-term and have specified that there should be a minimum of 2 years follow up. Please see the full details of the research recommendations reported in Appendix L.
Association for the study of obesity	8	Full	52	11	Many studies include participants weight rather than BMI making it difficult to determine their effectiveness in those of BMI>35kg/m 2 or 40kg/m 2, as stated. Additional research may be justified with VLCD in those of high BMI.	Thank you for your comments. The GDG agree and believe that the research recommendations outlined in section 5.15 of the full guideline (see page 50, line 34) address the use of VLCDs in those with a high BMI.
Association for the study of obesity	9	Full	50	27	Can the definition of children in the context of surgery be made, and is there sufficient justification for surgery in this group given the research recommendation in this area? Some evidence for young adults concerning their	Thank you for your comment. The glossary defines children, for the purposes of this guideline, as those aged less than 18 years, though acknowledges that absolute cut-offs can vary between specialties. As per recommendation 103 and 104, surgery has

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					response to surgery is required.	only been recommended in very exceptional circumstances (if they have achieved or nearly achieved physiological maturity).
Association for the study of obesity	10	Full	50 to 51	34 and 1-3	The research recommendation to long term effects of LCD and VLCD weight cycling in those with BMI ≥40 following a VLCD could be expanded. Is there value in using a 3 month period of VLCD intermittently to maximise weight loss?	Thank you for your comments. The GDG believe this is covered by the current wording of the research recommendation.
Association for the study of obesity	11	Full	50	30	We agree that groups at high risk of obesity and co-morbidities such as those with chronic mental health conditions and intellectual disabilities remain in need of tailored approaches to weight management. Only preliminary evidence exists to date, further research is justified.	Thank you for your comment.
Association for the study of obesity	12	Full	General	General	Cost effectiveness of surgical interventions seems to include cost to deliver multidisciplinary care. Can this be clarified? Follow up costs, such as monitoring, assessment of micronutrient status and supplementation seem absent.	Thank you for your comment. The cost quoted in the guideline in the section 'unit costs' on page 115 was placed there for reference as to how much the surgery alone costs. However the GDG were aware that this figure only reflects a fraction of the overall cost of surgery and when making recommendations they mainly considered the conclusions from four economic evaluations presented in the 'published literature' section on pages 112-114. In these papers the full cost of bariatric surgery has been calculated and analysed incorporating follow-up costs and re-surgery costs.
Association for the study of obesity	13	Full	114	General	A rough estimate of cost for surgical intervention, were all those who NICE suggest should be in receipt of this treatment were given surgery could be £4billion. This may equate to 50% of the current total primary care spend on ALL drugs in	Thank you for your comment. The economic evidence presented in this guideline was to determine whether bariatric surgery is a cost-effective intervention for individuals with early on-set T2D.The GDG members were very aware of the

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					the UK!). This is based on the £2400 quote for surgery. Of course reoperation may be required, an additional cost. The estimate appears to include healthy professionals at grade 6 in the calculation. These seem high and appear to inflate the non-surgical option of care.	issues surrounding cost implication - these are issues that will need to be assessed by the NICE implementation and costing teams and as such have been passed to NICE for consideration. GDG considerations surrounding this issue have been added to the LETR section. The GDG noted that such high cost implications would only be realised if every candidate eligible for an assessment received an assessment and after an assessment all these candidates were referred for surgery. In reality a considerable number of individuals who are deemed eligible for an assessment will not be suitable for surgery and therefore be declined, on top of this some individuals choose not to have the surgery. This will significantly reduce the cost implication. The costs of the surgical and non-surgical options of care, which have been calculated by the four included economic evaluations, were deemed appropriate by the GDG and therefore we do not believe these overestimate the non-surgical option of care.
Association for the study of obesity	14	Full	119	Section including reference to tier 3 services	The GDG noted that for patients, the referral to a tier 3 service, including for consideration of bariatric surgery is Often seen as a failure for the individual. " Can it be clarified that the referral to tier three services is essential before patients Proceed to surgery.	Thank you for your comment. Recommendation 92 indicates that bariatric surgery is a treatment option if the person has been receiving intensive management in a tier 3 service. Further clarification has been provided by the inclusion of additional text in the Linking evidence to recommendations section that captures a GDG perspective that might guide healthcare professionals to tailor their approach for referral for assessment with the individual.
Association for the study	15	Full	50	Key Resea	The fact that three of the four research recommendations focus only on surgical	Thank you for your comment. The current guideline update focused on the use of very low calorie diets,

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of obesity				rch recommendations	approaches is a concern to ASO. However, the evidence concerning no comparator versus optimum medical treatment including VLCD or LCD or GLP-1 analogues is lacking and a question ought to focus on this. The use of low energy liquid diets as an alternative to surgery, following a defined approach appears to have been overlooked.	bariatric surgery for people with recent-onset type 2 diabetes and follow-up care after bariatric surgery. In line with the NICE Guideline manual, the guideline development group chose to prioritise five areas in which no evidence was identified on which to develop recommendations for further research. The research recommendations reflect the choices of the GDG which were informed by the evidence base considered. They did not prioritise further research into the use of VLCDs beyond the one recommendation about the long term effect of their use in people with BMI over 40kg/m2.
Association for the study of obesity	16	Full	50	Recommendations	There appears to be scant reference to the NCEpod report concerning after care in bariatric patients. http://www.ncepod.org.uk/2012bs.htm	Thank you for your comments. The NCEPOD report is one of the reasons why the review on follow-up care after bariatric surgery was prioritised in this guideline update. As a result, the recommendations in this guideline provide more detail subsequent to a formal evidence review than the recommendations from the NCEPOD report. The GDG did feel it was important to endorse the recommendations in this report for entering patients into the NBSR and this has now been added to the 'recommendations and link to evidence' section of the full guideline (8.2.3).
Association for the study of obesity	17	Full	50	Recommendations	We are aware that the 10 year relapse post-surgery is probably 40-50% since surgery cannot impact on genetics. It is proposed that any savings on diabetes drugs and clinics are probably made up on micronutrient monitoring and replacement and other types of follow-up needs - so the real world economics are less certain than modelling suggests. There is some available published data to suggest that most people with diabetes don't want bariatric surgery.	Thank you for your comments. We would note that in the Hoerger study bariatric surgery remained cost-effective after relapse rates doubled (annual probability of relapse modelled as 16.6%). It is also worth noting patient choice will not affect the cost-effectiveness of bariatric surgery. The GDG did not choose to make a research recommendation in the area you suggest although they have chosen to make a research recommendation on the long-term outcomes of bariatric surgery in people with type 2

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					These topics appear important research areas to consider	diabetes (see section 5.15)
British Heart Foundation	1	NICE	General	General	The British Heart Foundation (BHF) is the nation's leading heart charity. Our vision is of a world in which no one dies prematurely or suffers from cardiovascular disease. [redacted] The BHF therefore warmly welcomes the opportunity to respond to this guidance and feels that on the whole it is a helpful guidance document for clinicians. [redacted]	Thank you for your comment.
British Heart Foundation	2	NICE	General	General	The BHF would welcome more information about the recommended length of interventions or follow up periods offered as a rule. We would also like to know if this is monitored by a professional or is self-monitoring.	Thank you for your comment. The Linking evidence to recommendations section within the full guideline discusses the relevant follow up periods. The frequency within which patients are followed up within the first 2 years will be determined by the specialist bariatric service conducting the follow-up. With regards to annual monitoring, page 130 of the full guideline states that the subsequent annual monitoring should have no time limit. The GDG noted that follow up should be with specialist advice as a safety issue to ascertain nutritional status and therefore this does not suggest self-monitoring. The evidence behind the 2006 recommendations has not been reviewed as part of this update and we

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						are unable to provide further information behind the length of interventions recommended.
British Heart Foundation	3	NICE	4	80	The BHF welcomes the recommendation that the use of lower BMI thresholds for different ethnic groups. We believe this is vital to address differing risk thresholds for conditions, enabling effective prevention strategies.	Thank you for your comment.
British Heart Foundation	4				We welcome the wording change to include consideration of the impact of the wider environment on obesity. It is imperative to recognise that within the home, external 'environments' such as the internet and media can impact negatively on the consumption habits of children. Here, regulation is failing to protect children from advertisements for products that are high in saturated fat, salt or sugar (HFSS). The BHF is calling for tighter regulation online and a 9pm watershed ban for HFSS advertisements, a call which NICE endorse within PH25. This section could therefore be strengthened by a reiteration of this policy endorsement. We welcome NICE's acknowledgment that schools are a key enabling environment for healthy lifestyles. We would encourage NICE to strengthen this by expanding its definition of 'environments' to consider a whole life approach, for example by including workplaces, colleges, care homes, and early year settings.	Thank you for your comment. Recommendation 6 was not updated as part of the current guideline update. Therefore, we have been unable to amend the recommendation in line with your comment.

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British Heart Foundation	5	NICE	16	290	We agree with NICE's recommendation that it is vital that parents and carers take the 'main responsibility' for lifestyle changes in children under the age of 12. We also welcome the consideration of the age and maturity of the child. This section could be strengthened through considering any disabilities or medical conditions that children, young people or adults have and taking these into consideration when planning the techniques to intervene and the content of an intervention.	Thank you for your comment. However, this section has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
British Heart Foundation	6	NICE	20	378 to 390	To ensure successful assessment, clinicians must tailor their intervention approach to cater for different age groups, genders and ethnic groups.	Thank you for your comment. Recommendations 1.3.1 – 1.3.7 have not been updated as part of the current guideline update and have been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
British Heart Foundation	7	NICE	24	479	We agree that interventions should be multi-component and multi-disciplinary but the guidance is vague on what this will actually look like in practice. Similarly the guidance does not offer clarity on who would have the authority to determine which disciplines are needed within each team to deliver a successful intervention. This therefore makes it difficult for teams on the ground to ascertain whether they have the correct skills in place to deliver an intervention if they do not know what kind of service criteria they should be delivering.	Thank you for your comment. Section 1.4 has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
British Heart Foundation	8	NICE	29	588 to	We acknowledge that no change has been made to the physical activity recommendations. We	Thank you for your comment. As you correctly note, Section 1.6 has not been updated as part of the

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				633	welcome the attention to reducing sedentary behaviour alongside promoting physical activity.	current guideline update.
British Heart Foundation	9	NICE	33	673	The BHF strongly supports NICE's recommendation that a dietary approach alone is not enough and that it is only part of a multi-component intervention, of which we believe physical activity promotion should be a key component.	Thank you for your comment.
British Obesity and Metabolic Surgery Society	1	NICE	6	141	"It has been suggested that resolution of type 2 diabetes may be an additional …" we suggest is changed to 'Resolution of type 2 diabetes is an additional…"	Thank you for your comment however, we disagree and have retained the original text.
British Obesity and Metabolic Surgery Society	2	NICE	8 & 9	General	Patient Centred Care Access to care for patients with severe and complex obesity There should be equity of access to services and locally applied more restricted access is unethical if patients meet agreed national criteria.	The GDG were very aware of these issues and acknowledge your concerns - these are issues that will need to be assessed by the NICE implementation and costing teams and as such will be passed on to NICE for their consideration
British Obesity and Metabolic Surgery Society	3	NICE	31	653-654	BOMSS strongly endorses this recommendation	Thank you for your comment.
British Obesity and Metabolic Surgery Society	4	NICE	31	655 to 660	BOMSS strongly endorses this recommendation Surgery should be considered in this group as an alternative treatment strategy.	Thank you for your comment. Recommendations on the use of bariatric surgery as a treatment option for people who are overweight or obese can be found in Section 1.10 and 1.11.
British Obesity	5	NICE	31	661 to	BOMSS suggests inclusion of the following;	Thank you for your comment. Recommendation

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and Metabolic Surgery Society				669	Consider surgery as part of long term strategy in multi-component weight management strategies	1.7.9 which you refer to and which recommends what to consider before starting someone on a very-low-calorie diet should be viewed in light of recommendation 1.7.8 which only recommends VLCDs in very specific situations where people need to rapidly lose weight (such as in those requiring joint replacement surgery or seeking fertility services). The GDG have not considered the use of bariatric surgery in situations where people need to rapidly lose weight so it would be inappropriate to refer to bariatric surgery as part of this multi-component strategy.
British Obesity and Metabolic Surgery Society	6	NICE	37	777 to 778	BOMSS recognizes and strongly endorses removal of a specific time period to be spent in a Tier 3 medical weight management clinic, which is consistent with BOMSS Tier 3 commissioning guidance - BOMSS tier 3 commissioning guide 2014.	Thank you for your comment.
British Obesity and Metabolic Surgery Society	7	NICE	38	823-4	BOMSS recognizes and strongly endorses increased clarity regarding management of patients with a BMI of over 50. BOMSS opinion is that this could be made clearer still by stating that ".. referral for MDT assessment and consideration of bariatric surgery as the option of choice (instead of lifestyle interventions or drug treatment) for adults with a BMI of more than 50 kg/m2" and deleting "…when other interventions have not been effective." from the guidance. As currently drafted 823-4 introduces ambiguity as it implies that BMI >50 patients would not have direct access to surgery as first line treatment as they would have had to have tried other	Thank you for your comment. Recommendation 1.10.7 has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.

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					(ineffective) interventions first.	
British Obesity and Metabolic Surgery Society	8	NICE	42	891-3	BOMSS strongly endorses the offer recommendation for recent onset BMI 35+ type 2 diabetics.	Thank you for your comment.
British Obesity and Metabolic Surgery Society	9	NICE	42	894	BOMSS strongly endorses the consider recommendation for BMI 30-34.9 with recent onset type 2 diabetes. BOMSS opinion is that consider assessment should be strengthened to offer assessment for bariatric surgery for this group of patients.	Thank you for your comment. The GDG recognised the limited evidence available but felt that in some circumstances, this may be an appropriate treatment option and therefore chose to develop a recommendation using the most appropriate wording to reflect the strength of the evidence (please see page 10 of the NICE guideline and section 3.6 of the full guideline).
British Obesity and Metabolic Surgery Society	10	NICE	42	896	BOMSS strongly endorses the consider recommendation for a lower BMI threshold for people of Asian family origin with recent onset type 2 diabetes. BOMSS opinion is that consider assessment should be strengthened to offer assessment for bariatric surgery for this group of patients.	Thank you for your comment. The GDG recognised the limited evidence available but felt that in some circumstances, this may be an appropriate treatment option and therefore chose to develop a recommendation using the most appropriate wording to reflect the strength of the evidence.
British Obesity and Metabolic Surgery Society	11	NICE	42	900 to 910	Follow up care BOMSS strongly endorses the recommendation that patients are offered a follow up package for a minimum of 2 years within the specialist bariatric service.	Thank you for your comment.
British Obesity and Metabolic Surgery Society	12	NICE	43	911 to 915	BOMSS strongly endorses the shared care model of chronic disease management for patients who have had bariatric surgery. Responsibility of primary care for longer term follow up is welcomed by BOMSS, as is some	Thank you for your comment. As you have highlighted, the recommendation states that this annual monitoring should be part of a shared care model of chronic disease management. The GDG felt should be a collaboration between tier 3

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					clarity around the minimum standards that might be included within this. Follow up care should, however, only be offered within a service that is committed to, and has appropriate expertise in the management of this group of patients. BOMSS is concerned that the current level of knowledge and skill at a national level across primary care in the management of these patients is highly variable. A clear and comprehensive set of standards of care for follow up will allow for delivery of this care within a prescription of care, delivered by primary care, with a clear pathway back into specialist tier 3 or 4 care as required. Unless long-term follow up care is delivered within this environment, BOMSS is concerned that patient safety will potentially be compromised. e.g. unrecognised nutritional deficiency, pouch dilation after gastric band, undiagnosed internal hernia, significant weight regain and re-emergence of weight related co-morbidity. BOMSS suggests that unless appropriate shared care follow up services exist that, on grounds of patient safety, follow up should be within tier 3 services, upon discharge form tier 4 at 2 years. (BOMSS tier 3 commissioning guide 2014) BOMSS is also concerned that the cost assumptions for care upon discharge under-estimates the true cost (PbR tariff for single practitioner upper GI follow-up is more than double the estimate used in the analysis).	services, where available, and primary care. They felt the shared care protocol should obtain adequate information to ensure the appropriate follow-up is provided (see further response below) and when it is appropriate to refer back into the bariatric service. They felt the skills within a tier 3 service would be able to recognise the appropriate circumstances in which to referral people back into the bariatric service. The 'recommendations and link to evidence' section (8.2.3 of the full guideline) has been amended to be clearer about the shared care model for delivering annual monitoring. Furthermore, the GDG felt ideally that annual monitoring should contain a number of the same components that were recommended in recommendation 1.12.1, but they were conscious of the potential cost implications of lifetime monitoring and basing these recommendations on very little and very low quality evidence. Consequently, the GDG felt it was appropriate to make the resulting recommendation 1.12.2 as a minimum criterion related to safety and recommended nutritional monitoring and appropriate supplementation in order to prevent serious nutritional deficiencies. Regarding costs these are not calculated using the PbR tariff as this reflects the charge not the cost to the NHS. Staff costs are estimated using the PSSRU.

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British Obesity and Metabolic Surgery Society	13	NICE	43	911 to 915	Follow up care Within the shared model of chronic disease management patients who experience procedure failure, significant weight regain or significant re-emergence of weight related co-morbidity may occur. Management of these patients is often complex and they should be offered referral back into and reviewed by a surgical specialist MDT with the appropriate expertise(BOMSS tier 3 commissioning guide 2014).	Thank you for your comment. Our evidence review did not consider re-referral. The GDG would expect that the appropriate circumstances in which to refer patients back into the bariatric service would be included within the shared care protocol and that the skills within a tier 3 service would be able to recognise the appropriate circumstances in which to referral people back into the bariatric service.
British Psychological Society		Full	40 to 42	Additional recommendation to include psychological assessment and support in addition to general behavioural	Psychological Assessment and Support. Obesity is as much a psychological as a physical problem. Psychological issues can not only foreshadow the development of obesity, but they can also follow ongoing struggles to control weight. Because the psychological aspects of obesity are so important, psychological assessments and interventions should become an integral part of a multidisciplinary approach to treating obesity. 1) There are numerous psychological factors which may influence a person's ability to engage and succeed with weight management interventions. Obese individuals have typically made multiple attempts to lose weight, with little or no success. Their failed attempts result in	Thank you for your comments which we deal with in turn. 1) None of the recommendations in the section on behavioural interventions were updated as part of the current guideline update, as described in the section on guideline update on page 16 of the full guideline. We are unable therefore to make any amendments to these recommendations which includes recommendation 49 to which you refer. 2) The GDG acknowledges the issues you raise. The GDG recommendations on the use of VLCDs (recommendation 67) specifically require counselling and assessment for eating disorders or other psychopathologies in an attempt to identify those individuals who may be affected by mental health disorders. Recommendation 110 specifies psychological support tailored to the individual as part of bariatric surgery follow up care packages. A number of the original 2006 recommendations also

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				interve ntions.	discouragement, frustration, hopelessness, and learned helplessness about the prospect of losing weight in the future on their own. This impacts on their social and personal identity, such embedded psychological processes may hinder a individuals ability to accept, or engage with recommended interventions. UK Society views obesity very negatively and tends to believe that people who are obese are "weak-willed" and "unmotivated" (Carr, Friedman, 2005). Obese individuals are often aware of these negative views, and internalize them. They perceive interpersonal and work-related discrimination and stigma, often suffer from low self-esteem as a result, and feel uncomfortable with their bodies (i.e. body image dissatisfaction). These feelings may lead to strain on their intimate and romantic relationships (Wadden, Sarwer, Fabricatore Jones, Stack, &	identify the requirement for psychological assessment (29, 30, 31 100,101, 105). 3) The GDG acknowledges the issues you raise. An original 2006 recommendation (recommendation 31) identifies the requirement for psychological assessment in children to assess issues related to low self-esteem or bullying. The GDG note your comments regarding the role of CBT in supporting people who are obese to modify behaviours. Although not updated as part of this process, recommendations 49 and 50 identify strategies to be used in behavioural interventions for adults and children. Additional guidance in this area is provided in NICE public health guidance: Managing Overweight and Obesity among children and young people (PH47) and Overweight and obese adults: lifestyle weight management services (PH53).

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					Williams, 2007, See BPS Obesity Report, 2011). These individuals may not meet diagnostic criteria for mental health disorders, nevertheless they would benefit from psychological support to address these emotional difficulties (beyond that of basic behavioural interventions such as goal setting and problem solving page 42, lines 9-20).. 2) In addition, psychological issues may relate to a number of mental health characteristics. An increase in the prevalence of affective disorders with increasing body mass index (BMI) has been described in several studies (Hasler et al., 2004; Johnston et al., 2004; Tuthill et al., 2006). Hasler et al. (2004) found that psychiatric conditions were positively associated with being overweight and results were maintained after controlling for substance abuse, levels of physical activity, demographic variables and family history of weight problems. Similarly,	

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					Johnston et al. (2004) found that depression was more likely to occur in patients who were obese. A UK sample of patients attending specialist obesity centres reported 48% of patients had elevated scores for depression and 56% elevated scores for anxiety (Tuthill et al., 2006). These mental health aspects include: Depression, Anxiety, Mindless eating, Binge Eating Disorder; Night Eating Disorder; substance abuse, domestic/sexual abuse. Individuals who suffer from both obesity and common mental health disorders may also face particular risks to health and well-being, as it is likely that the conditions may perpetuate each other. (Markowitz, Friedman &, Arent, 2008; see Gatineau & Dent, 2011; BPS Obesity Report, 2011). Not all obese individuals will have mental health difficulties. Individuals with obesity should be screened for such mental health	

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					characteristics and if required referred on for psychological mental health assessment and support. The intervention may focus on primarily on the mental health issue and incorporate the psychological issues of obesity. 3) There are numerous psychological issues and difficulties that children may experience as a result of obesity; these may be similar for some to the mental health characteristics listed in point 2 above or to psychological issues listed in point 1 for adults. Children may require support to deal with issues around body image, self-esteem, self-worth, bullying; social identity, behavioural and sleep difficulties, relationship and communication issues. <u>Psychological Support/Intervention</u> *Behavioural and/or cognitive therapy* can be used as part of a program of lifestyle modification with diet and exercise for individuals who do not meet criteria for or do not want bariatric surgery. Traditional methods include classical and operant	

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					conditioning as therapy models (usually used in weekly sessions lasting 1-1.5 hours over a six-month period; Wing, 2002). Cognitive therapy and cognitive behavioural therapy (CBT) have become an important aspect of the treatment of obesity. Cognitions influence both feelings and behaviours, and they cannot be ignored when treating obesity. CBT is utilized in the treatment of obesity as a way to help individuals change their negative eating behaviours and incorporate healthy lifestyle changes. A comprehensive Cochrane review of psychological interventions for overweight or obesity concluded that behavioural and cognitive behavioural therapies make a significant difference to the success of weight management interventions, especially when combined with diet and physical activity. (Shaw, O'Rourke, Del Mar, & Kenardy, 2005) Family Therapy has been shown to be a useful intervention for childhood obesity. Specifically Standardised Obesity Family Therapy (SOFT). SOFT is based on systemic and solution-focused theories and has shown positive effects on the child with respect to degree of obesity, physical fitness, self-esteem, and family functioning in several studies. The distinguishing features of SOFT are the focus on family interactions as an important source for implementing and maintaining lifestyle changes, the multidisciplinary team approach, and a limited	

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					number of sessions (three to four per year. (See Nowicka, & Flodmark, 2010).	
British Psychological Society	1	Full	General	General	The Society welcomes this partial update of NICE clinical guidance 43, covering very low calorie diets, bariatric surgery in people with recent onset type 2 diabetes and follow-up care after bariatric surgery.	Thank you for your comment.
British Psychological Society	2	Full	General	General	We welcome the inclusion of psychologists as part of the MDT. However when referring to psychologists we request that you refer to the statutory title of **'Practitioner Psychologist(s)'** throughout, which is a HCPC registered title.	Thank you for your comment. We have amended the introductory text of page 120 of reflect your comment. Thank you for the references provided. However, they would not have been included in the reviews of evidence considered as part of this update (See Appendix C for more detail) although we would note that mention is made of the NCEPOD review in the chapter on follow-up.
British Psychological Society	3	Full	General	General	Then Society welcomes the inclusion of psychological support mentioned in sections of the guidance however we believe the distinction of what psychological assessment and support should consist of and who should conduct this should be made more explicit throughout the document. (See BPS obesity report, 2011).	Thank you for your comment. The GDG considered that the term psychological support is inclusive of wellbeing assessment and has been used to ensure consistency across recommendations. We did not include a specific review question about psychological assessment and support and are therefore unable to make comment on this issue in more detail. However, the Recommendations and link to evidence section in 8.2.3 have been amended to include 'wellbeing assessment, advice and support'.
British Psychological Society	4	Full	12	44 to 46	We recognise that this update relates directly to clinical management of obesity and that aspects	Thank you for your comment. All related NICE guidance, including the PH guidance to which you refer is outlined in the full guideline, section 2.3. In

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					of the public health recommendations have been removed and are the subject of a separate update by the Centre for Public Health Excellence. While we welcome specific public health guidance, since obesity is a complex topic across public health and clinical services, we would suggest that this guidance should explicitly cross-reference to NICE public health guidance that has substantial lifestyle behaviour change recommendations e.g. PH6, PH49, and PH38.	addition, the introductions to the full guideline and NICE guideline make specific mention of related NICE guidance. We believe this is sufficient cross-reference for the purposes of this guideline
British Psychological Society	5	Full	32	Flow diagram	Bariatric surgery in people with type 2 diabetes 'See recommendation 91'. This appears to be an error as recommendation 91 refers to Orlistat in children.	Thank you for your comment. The recommendation number has been corrected.
British Psychological Society	6	Full	38 to 39	Recommendation 29 & 30	We would recommend that there is clarification on the referral pathway and assessment inclusion for individuals who are obese BMI >30, with pre-diabetes and are therefore high-risk. We would suggest that these should be targeted for assessment and referred to weight management services.	Thank you for your comment. Recommendation 29 and 30 were not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.

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					(Pre-diabetes should be included as a referral criteria in line with those BMI>35 and hypertension. see PH38 to be consistent in message).	
British Psychological Society	7	Full	12	27	As the guidance is for both adults and children, and the treatment approaches are slightly different, it is recommended that this introductory paragraph should make a distinction between the treatment of adults and children. The Society recommends that a few lines be inserted on the specific treatment approaches that are recommended for children. Specifically, given that pharmacotherapy is considered only above a specific age and rarely used, and bariatric surgery is rarely considered for this client (children) group, this difference in treatment approaches should be highlighted. In this opening para insert the word 'adult' to differentiate from children's treatment, and then add some text specifically about children afterwards: "*Treatment options for **adult** obesity include non-surgical treatment and bariatric surgery. Non-surgical treatment usually takes a multicomponent approach, involving*	Thank you for your comment. As you highlight, the guideline focuses on the management of overweight and obesity in both adults and children. As identified in recommendation 104 of the full guideline, there are some situations in which surgery for obesity in young people may be considered. Therefore, we have amended the introductory paragraph on page 12 to acknowledge that 'Treatment options for obesity may include non-surgical treatment and bariatric surgery. Non-surgical treatment usually takes a multicomponent approach, involving dietary changes to reduce calorie in take, an increase in physical activity, behavioural modification, and where appropriate, psychological support or pharmacotherapy'. Further details on recommended treatment options for both adults and children can be found within the guideline's recommendations.

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					dietary changes to reduce calorie intake, an increase in physical activity, behavioural modification, ***psychological assessment and support*** *and rarely, pharmacotherapy." Treatment options for children….* The opening sentence of this para refers to adult treatment options and includes bariatric surgery. The para ends with 'rarely' (line 29) pharmacotherapy. Given that individuals will follow a pathway of care and be offered pharmacology prior to surgery (in line with recommendation 92- page 47 lines 11-12). We would suggest that this para is reworded, and the word rarely is removed prior to pharmacotherapy. (note: 392,000 prescriptions of Orlistat were issued in 2012, compared to around 8,000 bariatric surgery procedures performed between 2010- and of the 7,200 bariatric procedures in 2009/10 - 1,400 were for maintenance and not new cases (see Prescribing and Primary care Services, Health and Social Care Information Centre, 2013; National Confidential Enquiry into Patient Outcome and Death (2012). There is a lack of recognition of **psychological assessment and support** within this paragraph (behavioural modification should not be	

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					assumed to be the same), and we would welcome the inclusion of psychological intervention within this paragraph. **Please see comment on page 40-42 for evidence base.**	
British Psychological Society	8	Full	33	Flow diagram	'Discharged from bariatric services. 'It needs to be made clear that this is the service provider who completed the surgery and not a community 'bariatric/obesity' service. The last box on the flow diagram 'ensure people are offered annual monitoring' it is unclear who is responsible for completing this annual monitoring (bariatric service provider, community service, GP) and for how long does this annual monitoring continue. We would recommend that this is clarified.	Thank you for your comment. Further detail has been added to the linking evidence to recommendations section of chapter 7 to address the issues you raise. Recommendation 113 has been amended to reflect that annual monitoring should take place following discharge from bariatric services and the algorithm on page 34 has been amended to reflect this. Further detail on where this may be provided is available in the Linking evidence to recommendations section on page 129 the full guideline.
British Psychological Society	10	Full	38	12 to 15	Recommendation 27 *"Recognise that surprise, anger, denial or disbelief about their health situation may diminish people's ability or willingness to change. Stress that obesity is a clinical term with specific health implications, rather than a question of how people look; this may reduce any negative feelings."* The Society welcomes the recognition of the complex psychological reactions individuals may display as a result of being told they are obese.	Thank you for your comment. Recommendation 27 was not updated as part of the current guideline update. Therefore, we have not amended the recommendation in line with your comment.

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					However, we suggest that implying that their emotional reactions relate primarily to physical appearance is too simplistic. We would recommend this section is reworded to: *"Recognise that surprise, anger, denial or disbelief about their health situation may diminish people's ability or willingness to change. Stress that obesity is a clinical term with specific health implications,* ***and treatment approaches. Recognise that individuals may experience a range of psychological challenges related to accepting the label of obesity (this may relate to issues about appearance, identity, self-esteem, self-worth, stigma or a range of other emotional issues).****"*	
British Psychological Society	11	Full	38	8 10-11	Recommendation 30, we would recommend the following is added: 30. Consider referral to tier 3 services if: The underlying causes of being overweight or obese need to be assessed. The person has complex disease states and/or needs that cannot be managed adequately in tier 2 (for example, the additional support needs of people with learning disabilities, **or the individual has psychological needs – such as anxiety, depression, low self-esteem or other emotional difficulties**)	Thank you for your comment. Recommendation 30 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). The scenarios provided are examples of clinical scenarios where referral to tier 3 services may be considered and are not considered to be an exhaustive list of when individuals would be referred.

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British Psychological Society	12	Full	39	38	Recommendation 32, we would encourage the explicit reference to psychological needs within this recommendation. *"Have significant co-morbidities or complex needs (for example, learning disabilities, **psychological needs** or other additional support needs."*	Thank you for your comment. Recommendation 32 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). The scenarios provided are examples of clinical scenarios where referral to tier 3 services may be considered and are not considered to be an exhaustive list of when individuals would be referred.
British Psychological Society	13	Full	41	23 to 24	To be consistent with recommendation 27 we would recommend that emotional reactions are acknowledged within the consultations: "*Ensure there is adequate time in the consultation to provide information, answer questions, **and to offer support for any emotional reaction.**"* [2006, amended 2014]	Thank you for your comment. Recommendation 42 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details).
British Psychological Society	14	Full	44	33	Within recommendation 67: "Discuss the reintroduction of food with them." Implies that the individuals have had no food rather than <800kcal. This statement could be more specific: '*Discuss the **future increase in kcal consumption above 800kcal** with them'*	Thank you for your comment. The GDG wanted to highlight that the reintroduction of normal or solid food following a liquid diet and the transition to a normal diet and the encouragement of healthy eating patterns that should be discussed with the person. We have amended the recommendation and the evidence to recommendations section to provide further clarity.
British Psychological Society	15	Full	45	29	The Society suggests that when referring to "severe psychological comorbidities" as a possible indicator for pharmacological	Thank you for your comment. Recommendation 78 was not updated as part of the current guideline update and has been amended for clarity only (see

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					intervention in children, it should be stated that input from a practitioner psychologist/ psychiatrist should be sought. *"Co-morbidities (such as orthopaedic problems or sleep apnoea) or severe psychological co-morbidities* ***(with appropriate input from a practitioner psychologist / psychiatrist)*** *are present."*	Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
British Psychological Society	16	Full	45	36	We welcome the reference to the MDT; however the list provided recommends multiple intervention components and does not recommend specific MDT skills as required. We would recommend this section is amended to reflect the multiple intervention components recommended, followed by recommendations on specific staff groups that would contribute to a MDT Do not give orlistat to children for obesity unless **within** a multidisciplinary team, which would include the expertise of : • **Paediatrician** • **Practitioner Psychologist** • **Exercise Specialist** • **Dietician** **The assessment and interventions provided should include** • Drug monitoring	Thank you for your comment. Section 5.10 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.

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					• Psychological **assessment and** support • Behavioural interventions • Interventions to increase physical activity • Interventions to improve diet	
British Psychological Society	17	Full	47 to 48	General	We would recommend that the following is added into the referral criteria prior to bariatric surgery: **"Prior to referral to bariatric services, individuals should have received psychological assessment, advice and intervention support from a practitioner psychologist."** See BPS Obesity Report 2011 Where recommendations refer to 'psychological support before and after surgery' (page 48, line29) we would recommend that this is more specific to 'psychological **assessment, advice and intervention** before and after surgery'	Thank you for your comment. Recommendations 92 and 100 have not been updated as part of the current guideline update. Recommendation 92 has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have been unable to amend the recommendations in line with your comment.
British Psychological Society	18	Full	48	5	We welcome this auditing of outcomes, although would recommend that this includes psychological wellbeing as outcome measurement: "*Arrange prospective audit so that the outcomes and complications of different procedures, the impact on quality of life,* ***psychological wellbeing*** *and nutritional*	Thank you for your comment. Recommendation 96 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.

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					status, and the effect on comorbidities can be monitored in both the short and the long term."	
British Psychological Society	19	Full	50	9	While the Society recognises the limitations of guidance in considering coexisting conditions such as mental health problems, we would highlight that many overweight and obese individuals struggle with psychological and emotional difficulties (such as depression, anxiety, emotional issues, etc) (BPS Obesity Report, 2011). Research suggests that a high percentage of those involved in weight control programmes engage in binge eating (i.e. period when they experience lack of control over the high volumes of food consumed in a short period of time). Advice and referral of these individuals needs to address the psychological and emotional aspects of overeating as well as the practical and motivational. There is a complex interaction between psychological factors and obesity in relation to associations between the two and the relationship between psychological difficulties and outcome of weight management programmes. Therefore, we believe that it is important that psychological difficulties are assessed and managed appropriately at tier 2, and tier 3, and included within annual monitoring following discharge. We welcome the inclusion to the reference to	Thank you for your comment. The GDG acknowledge the psychological and emotional difficulties of individuals who are overweight or obese and highlighted psychological well-being as one of the important outcomes to consider in the effectiveness of a follow-up care package after bariatric surgery. The GDG considered that the term psychological support is inclusive of wellbeing assessment and has been used to ensure consistency across recommendations. However, the Recommendations and link to evidence section in 8.2.3 has been amended to include 'wellbeing assessment, advice and support'. The evidence review on follow-up care after bariatric surgery found very little evidence that was of adequate quality and was applicable to the UK context to base their recommendations on. As a result, the recommendations related to follow-up care were based on GDG consensus, informed by the experience of the clinical and patient members. While the GDG felt ideally that annual monitoring should contain a number of the same components that were recommended in recommendation 112, they were conscious of the potential cost implications of lifetime monitoring and basing these recommendations on very little and very low quality

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					psychological support but consider this vague, and would recommend this is amended: *"Psychological and wellbeing **assessment, advice and** support tailored to the individual."*	evidence. The GDG did feel it was appropriate to make the resulting recommendation 113 as a minimum recommendation related to safety and recommended nutritional monitoring and appropriate supplementation in order to prevent serious nutritional deficiencies. While the GDG did feel that annual monitoring should ideally contain psychological assessment and support, they did not feel the evidence was sufficient to recommend a potentially very costly intervention so have not changed the recommendation initially drafted in light of your comments.
British Psychological Society	20	Full	50 119	11 8.1	Recommendation 113. "After discharge from bariatric surgery service follow-up, ensure that all people are offered at least annual monitoring of nutritional status and appropriate supplementation according to need following bariatric surgery, as part of a shared care model of chronic disease management." The Society welcomes that people who receive bariatric surgery are offered follow-up monitoring. However, it is unclear from the guidance who is responsible for annual monitoring. We believe that it should clarify whether this is the bariatric service provider, a community obesity service or the patients GP. It is unclear how long annual monitoring should be carried out for (e.g. 2, 5, 10 years). Emotional struggles are common post-surgery,	Thank you for your comment. The recommendation states that this annual monitoring should be part of a shared care model of chronic disease management which the GDG felt should be a collaboration between tier 3 services, where available, and primary care. As a result, recommendation 113 has not been amended, but the 'recommendations and link to evidence' section (8.2.3 of the full guideline) has been amended to be clearer about this and the specific nature of shared care models and protocols in these circumstances. The 'Recommendations and link to evidence section' (section 8.2.3) on page 130 states that annual monitoring after discharge from a bariatric surgery service should have no time limit. The GDG acknowledge the psychological and emotional difficulties of individuals who are overweight or obese and highlighted psychological well-being as one of the important outcomes to

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					as bariatric surgery has significant psychic effects. Patients sometimes feel their weight loss is less than they anticipated and it takes longer. Frustration can lead to lack of motivation and difficulty adhering to the post-operative diet. Psychologists can assist these patients by utilising cognitive restructuring to help them rationally evaluate their progress, as well as behavioural activation to aid them in making healthy behaviour changes. Additionally, some patients who struggled with emotional eating before surgery may return to similar behaviours post-surgery, resulting in less than optimal weight loss. Psychologists can help these patients identify their triggers for emotional eating and encourage them to develop a coping repertoire that involves more constructive behaviours rather than eating. Another way patients may struggle emotionally post-surgery is by feeling uncomfortable with their "new look" and body image after losing a significant amount of weight. With rapid weight loss there often is sagging skin and many patients cannot afford cosmetic surgery to correct this. It is not uncommon for patients to discover body image dissatisfaction in a new way, which unfortunately may result in issues with their marriage and intimacy. Occasionally, female patients with histories of sexual abuse report some of their posttraumatic symptoms resurfacing, particularly if their weight had been a "protective barrier" for them for many years. These patients may require psychological assistance to work through their body image,	consider in the effectiveness of a follow-up care package after bariatric surgery. The evidence review on follow-up care after bariatric surgery found very little evidence that was of adequate quality and was applicable to the UK context to base their recommendations on. As a result, the recommendations related to follow-up care were based on GDG consensus, informed by the experience of the clinical and patient members. While the GDG felt ideally that annual monitoring should contain a number of the same components that were recommended in recommendation 112, they were conscious of the potential cost implications of lifetime monitoring and basing these recommendations on very little and very low quality evidence. The GDG did feel it was appropriate to make the resulting recommendation 113 as a minimum recommendation related to safety and recommended nutritional monitoring and appropriate supplementation in order to prevent serious nutritional deficiencies. While the GDG did feel that annual monitoring should ideally contain psychological assessment and support, they did not feel the evidence was sufficient to recommend a potentially very costly intervention so have not changed the recommendation in light of your comments.

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					emotional and/or relationship issues. Given the complex nature of long-term obesity, and the associated mental health and psychological difficulties clients develop we would recommend that annual monitoring should include an assessment of psychological health and wellbeing (see BPS Obesity report, 2011). If the annual monitoring uncovers a detrimental outcome (such as increased weight gain, psychological, activity or dietary needs, surgery revision or additional surgery) it needs to be clarified who is responsible for referring and providing this care and what care should this should be. We would recommend that psychological monitoring is included within this annual activity (see BPS Obesity report, 2011).	
British Psychological Society	21	Full	119	6	The guidelines state that the MDT should include 'psychologists'. As mentioned earlier it would be preferable to use the title statutory title regulated by the HCPC i.e. '**Practitioner Psychologist'** which should be used throughout when referring to psychologists. References: British Psychological Society (2011) Obesity in the UK: A psychological perspective – British Psychological Society publication http://www.bps.org.uk/sites/default/files/images/pat_rep95_obesity_web.pdf	Thank you for your comment. We have amended the introductory text on page 120 in line with your suggestion.

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					Carr D, Friedman MA (2005). Is obesity stigmatizing? Body weight, perceived discrimination, and psychological well-being in the United States. Journal of Health and Social Behaviour; 46(3):244-259. Gatineau M, Dent M. (2011) Obesity and Mental Health. Oxford: National Obesity Observatory. Hasler G, Pine DS, Gamma A, et al. (2004) The asso¬ciations between psychopathology and being overweight: A 20-year prospective study. Psy¬chological Medicine 34: 1047–1057. Johnston E, Johnson S, McLeod P and Johnston M (2004) The relation of body mass index to depressive symptoms. Canadian Journal of Public Health, 95: 179–183. Markowitz, S., Friedman MA., Arent, SM. (2008) Understanding the relation between obesity and depression: Causal mechanisms and implications for treatment. Clinical Psychology: Science and Practice 2008; 15(1): 1-20. National Confidential Enquiry into Patient Outcome and Death (2012). Too Lean a Service? A review of the care of patients who underwent bariatric surgery. London, www.ncepod.org.uk Nowicka, P., & Flodmark, C. E. (2010). Family therapy as a model for treating childhood obesity: Useful tools for clinicians. Clin Child Psychol	

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					Psychiatry, 16, 129. Prescribing and Primary Care Services, Health and Social Care Information Centre (2013). Prescriptions Dispensed in the Community: England 2002-12. www.hscic.gov.uk Tuthill A, Slawik H, O'Rahilly S and Finer N (2006) Psychiatric co-morbidities in patients attending specialist obesity services in the UK. QJM 99: 317–325. Shaw K, O'Rourke P, Del Mar C, Kenardy J. (2005) Psychological interventions for overweight or obesity. Cochrane Database of Systematic Reviews, 2. Wadden TA, Sarwer DB, Fabricatore AN, Jones L, Stack R, Williams NS (2007). Psychosocial and behavioral status of patients undergoing bariatric surgery: What to expect before and after surgery. The Medical Clinics of North America; 91:451-469. Wing RR. Behavioral weight control. In: Wadden TA, Stunkard AJ (2002). (Eds.) Handbook of obesity treatment. New York: Guilford Press.	
British Society of Gastroenterology	1	General	General	General	Obesity is one of the key challenges in our society. Without measures to tackle it now we will see huge rises in liver disease as well as a range of other major conditions. Without action this outcome would blight the lives of millions and come at a major financial cost. The BSG agree	Thank you for your comment. Any concerns regarding cost will be assessed by the NICE implementation team. GDG considerations surrounding this issue have been added to the LETR section. The GDG also noted that such high cost implications would only be realised if every

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					that action is needed now but also that these actions should be carefully targeted, evaluated and policies therefore monitored. We have some concerns about the cost of the recommendation that bariatric surgery be made more widely available as an intervention. We believe it is essential for an evaluation to run alongside all the major proposals outlined in the consultation, including the extension of bariatric surgery and its cost. Obesity is an important issue and as a society it is imperative that we find ways to tackle it. As a complex problem with a multitude of influences it is necessary to employ a range of tools to tackle the problem, and because of the complexity involved it's important that all interventions are carefully evaluated for patient outcomes and financial cost.	candidate eligible for an assessment received an assessment and after an assessment all these candidates were referred for surgery. In reality a considerable number of individuals who are deemed eligible for an assessment will not be suitable for surgery and therefore be declined, on top of this some individuals choose not to have the surgery. This will significantly reduce the cost implication. In relation to the request for an evaluation to run alongside the recommendations of bariatric surgery, the GDG have requested further research be conducted in the long-term effects of bariatric surgery on diabetes related complications and quality of life in those with type 2 diabetes compared with optimal medical treatment.
BSPGHAN	1	NICE	19	349	Why not include the child whose weight centile is > 2 centiles above the height centile and increasing through the centiles? Any child seen by a paediatrician should have height and weight plotted on centile charts routinely, but BMI charts are NOT routinely available	Thank you for your comment. Recommendations 1.2.12 – 1.2.14 have not been updated as part of the current guideline updated and have been amended for clarity only, therefore this scenario has not been included specifically. However, we agree that alternative growth charts are available and the footnote has been amended to cross refer to the RCPCH WHO-UK growth charts.
BSPGHAN	2	NICE	15	276	more guidance as to when obesity in children becomes a child protection/safeguarding issue	Thank you for your comment. Recommendation 1.1.5 of the NICE guideline (recommendation 5 of the full guideline) has not been updated as part of the current guideline update and has been amended

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						for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
BSPGHAN	3	NICE	22	432 to 445	not sure about phrases in the guidance suggesting an approach that is sensitive to when a family is ready to make changes deals with those who refuse to ever be ready for change.	Thank you for your comment. However, this recommendation has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
BSPGHAN	4	NICE	Children general	Children general	More about 'family' therapy rather than just focusing on the child	Thank you for your comment. Recommendations on general principles of care for children, including coordination of care for children and young people and creating a supportive environment, can be found in section 5.1.3 of the full guideline.
BSPGHAN	5	NICE	general	general	Adequate resources needed to tackle obesity. 'Sadly we have several weight management programs offered, but attendance &/or participation is poor.' 'Our paediatric dietetic dept is closed to obesity referrals, due to lack of funding, and poor outcomes' comments from paediatric dietitian in a major English teaching Centre	Thank you for your comment. NICE Implementation team will be providing resources to help with implementing the guideline's recommendations.
Cheshire West and Chester Council	1	Nice	22	440	I'd usually refer to specialist obesity services for assessment and bloods if significant childhood obesity (GP specialist in obesity)	Thank you for your comment. Recommendation 1.3.7 has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Cheshire West and	2	NICE	39	840	I always advise that plastic surgery is not routinely available on the NHS	Thank you for your comment. Recommendation 1.10.9 has not been updated as part of the current

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Chester Council					(GP specialist in obesity)	guideline. Therefore, we have not amended the recommendation in line with your comment.
Cheshire West and Chester Council	3	Nice	42	891	What is meant by recent onset type 2 diabetes, this is really important, is it 1 yr, 2 yrs 5 yrs? (GP specialist in obesity)	Thank you for your comment. The GDG considered that recent onset type 2 diabetes would include those people whose diagnosis has been made with a 10 year time frame. This is indicated in the footnote from recommendations in section 1.11 in the NICE version. Further discussion on the definition of 'recent onset type 2 diabetes can be found in the full guideline in section 7.1.5.
Cheshire West and Chester Council	4	NICE	General	General	there is a lack of guidance in here about tier 3 services in terms of bariatric pathways and preparation of patients which is a big commissioning issue. We have NHS England bariatric recommendation but the new NICE recommendation of bariatric surgery for BMI over 30 with new onset type 2 diabetes is in conflict with NHS England bariatric policy. Which do commissioners follow? (GP specialist in obesity)	Thank you for your comment. The GDG acknowledge the lack of clarity around the pathway for bariatric surgery and follow-up. Recommendations 1.11.1, 1.11.2, and 1.11.3 of the NICE guideline have now been amended to clarify that patients should also receive assessment within a tier 3 service. Once NICE has published the clinical guideline, health professionals and the organisations that employ them are expected to take it fully into account when deciding what treatments to offer people. We recognise that the NHS England commissioning policy published in 2013 already refers to the relevant NICE recommendations from CG43. We anticipate that, as with all iterations of NICE guidance, additional recommendations are incorporated into national policy documents in due course.
College of Occupational	1	Full	120	6 and	MDT for post bariatric surgery. There is evidence from the Aintree Specialist Weight Management	Thank you for your comment. The text on page 120 is intended as introductory text and is not intended

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Therapists				7	Service (Tier 4) that offers pre and post baratric surgery support, that occupational therapists as well as dietitians and physiotherapists are part of the MDT and would therefore wish to see them included in this list.	to provide an exhaustive list of the members of a multi-disciplinary team. We have amended the text to reflect this.
Counterweight Ltd			General	General	Counterweight Ltd welcome the updated NICE Guidance (CG43) on the clinical management of obesity. We welcome the focus on interventions for people with severe and complicated obesity but question the absence of the use of LCDs using nutritionally replete formula diets. There is robust data emerging to support the inclusion of this approach particularly in relation to the growing prevalence of severe and complicated obesity. Many of the statements around VCLDs would apply to LCDs and we have used the VLCD statements to make points about LCD (using nutritionally replete formula diets) use in weight management. We have commented specifically on the recommendations for clinical practice and the health economic aspect of the draft guidance. There would be value in making specific recommendations for the severe and complicated group in contrast to BMI>25kg/m2.	Thank you for your comment. The scope for this guideline focussed on the definition, safety and adherence issues of VLCDs including providing effective support. A review of the role of low calorie diets in the management of overweight and obesity was not prioritised. Reviews of the evidence have not been restricted by BMI but reflect the evidence considered in relation to BMI. The GDG have made a research recommendation on the long term effect of the use of VLCDs versus LCDs in people with a BMI of 40 or over as evidence was lacking in this group.
Counterweight Ltd	1	Full	16	20	We query the exclusion of nutritionally complete formula LCDs in this question [1,2,3,4]. We would also suggest systematic reviews inclusion[5,6].	Thank you for your comments. This guideline is an update of CG 43 which has been limited to the topics where new evidence may change recommendations. We have reviewed the evidence around the clinical and cost-effectiveness of very low calorie diets. However, LCDs were not prioritised for review in this update.

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						With regard to the references you provide: Reference 1: Reicke et al Osteoathritis and Cartilage (2010) 1-9. Incomplete citation. We presume this is referring to: Riecke B, Christensen R, Christensen P, Leeds A, Boesen M, Lohmander L, Astrup A & Bliddal H (2010) Comparing two low-energy diets for the treatment of knee osteoarthritis symptoms in obese patients: a pragmatic randomised clinical trial. Osteoarthritis and Cartilage, 18, 746-754. This paper has been included in the VLCD safety review but excluded elsewhere because the duration of the study was less than one year. Please refer to the excluded clinical studies table in Appendix J. Reference 2: Christensen et al Clinical Obesity (2011) 1, 31-40. Incomplete citation. We presume this is referring to: Christensen P, Bliddal H, Riecke B F et al. (2011) Comparison of a low-energy diet and a very low-energy diet in sedentary obese individuals: a pragmatic randomised controlled trial. Clinical Obesity 1: 31-40. doi: 10.111/j.1758-8111.2011.00006.x This paper has been excluded from the VLCD effectiveness (added to excluded clinical studies table, see Appendix J) and maintenance (see Appendix J) reviews because it is less than one year in duration. Reference 3: Christensen et al European Journal of Clinical Nutrition (2011) 1 – 6. Incomplete citation. We presume this is referring to:

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						to the excluded clinical studies table in Appendix J. Reference 6: Johansson et al Am J Clin Nutr. 2014 Jan;99 (1):14-23. Incomplete citation. We presume this is referring to: Johansson K, Neovius M & Hemmingsson E (2014) Effects of anti-obesity drugs, diet, and exercise on weight-loss maintenance after a very-low-calorie diet or low-calorie diet: a systematic review and meta-analysis of randomised controlled trials. Am J Clin Nutr, 99, 14-23. This systematic review was excluded from the maintenance review due to inadequate quality assessment / outcomes of interest are not included (added to excluded clinical studies table, see Appendix J).
Counterweight Ltd	2	Full	16	20	There is an opportunity to provide clarity around the differences between standard dietary approaches, LCD, LCD formula food and VCLD here. The complete exclusion of LCD formula preparations (nutritionally complete) may particularly cause confusion with readers.	Thank you for your comments. This guideline is an update of CG 43 which has been limited to the topics where new evidence may change recommendations. We have reviewed the evidence around the clinical and cost-effectiveness of very low calorie diets. However, LCDs were not prioritised for review in this update.
Counterweight Ltd	3	Full	21	12	Some key references have been omitted in the literature review [1,2,3,4,5,6++]	Thank you for your comment. With regard to the references you provide: Reference 1: Reicke et al Osteoathritis and Cartilage (2010) 1-9. Incomplete citation. We presume this is referring to: Riecke B, Christensen R, Christensen P, Leeds A, Boesen M, Lohmander L, Astrup A & Bliddal H (2010) Comparing two low-energy diets for the treatment of knee osteoarthritis symptoms in obese

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						patients: a pragmatic randomised clinical trial. Osteoarthritis and Cartilage, 18, 746-754. This paper has been included in the VLCD safety review but excluded elsewhere because the duration of the study was less than one year. Please refer to the excluded clinical studies table in Appendix J. Reference 2: Christensen et al Clinical Obesity (2011) 1, 31-40. Incomplete citation. We presume this is referring to: Christensen P, Bliddal H, Riecke B F et al. (2011) Comparison of a low-energy diet and a very low-energy diet in sedentary obese individuals: a pragmatic randomised controlled trial. Clinical Obesity 1: 31-40. doi: 10.111/j.1758-8111.2011.00006.x This paper has been excluded from the VLCD effectiveness (added to excluded clinical studies table, see Appendix J) and maintenance (see Appendix J) reviews because it is less than one year in duration. Reference 3: Christensen et al European Journal of Clinical Nutrition (2011) 1 – 6. Incomplete citation. We presume this is referring to: Christensen P, Bartels E M, Riecke B F et al. (2011) Improved nutritional status and bone health after diet-induced weight loss in sedentary osteoarthritis patients: a prospective cohort study. Eur T Cln Nutr 66(4): 504–509. This paper was not included because it is not a randomised controlled trial. Reference 4: Christensen et al Obesity (2013) 21(10):1982-1990.

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						meta-analysis of randomised controlled trials. Am J Clin Nutr, 99, 14-23. This systematic review was excluded from the maintenance review due to inadequate quality assessment / outcomes of interest are not included (added to excluded clinical studies table, see Appendix J).
Counterweight Ltd	4	Full	29	22 to 23	We would like greater acknowledgement on the practical and current cost implications around the recommendation for bariatric surgery which this section points to	Thank you for your comment. The economic evidence presented in this guideline was used to determine whether bariatric surgery is a cost-effective intervention for individuals with early onset T2D.The GDG members were very aware of the issues surrounding cost implication and these issues will be assessed by the NICE implementation and costing teams. Further GDG considerations surrounding this issue have been added to the LETR section.
Counterweight Ltd	5	Full	31	Algorithm	We query the reason for absence of nutritionally replete formula LCDs: clinical practice may consider LCDs and VCLDs as the same treatment (albeit incorrectly). We question the statement 'do not routinely use' as this is usually interpreted by clinicians as 'never use' and may lead to involvement of CCG Exclusion Committees to override for each patient which is impractical. There is good evidence to support the use of these approaches[1,2,3,4,5,6]. We would suggest there would be potential confusion around the term 'clinically assessed need to rapidly lose weight'. As per SIGN 2010[7] people with BMI>35kg/m^2 need to lose more weight than routinely achieved by lifestyle and there is robust evidence around the use of (nutritionally replete) formula LCDs/ VLCDs for this purpose.	Thank you for your comment. This guideline is an update of CG 43 which has been limited to the topics where new evidence may change recommendations. We have reviewed the evidence around the clinical and cost-effectiveness of very low calorie diets. However, LCDs were not prioritised for review in this update. The review of evidence has indicated a lack of effectiveness of VLCDs in maintaining weight loss. However, we have made a recommendation on the specific circumstances when they could be considered. The rationale for the GDG decisions in this area can be found in section 6.2.13. Recommendation 64, remains in this guidance supporting the use of low calorie diets and the

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					'Rapidly lose weight' needs to be defined.	specific detail related to the use. Further clarification has been added to section 6.2.13 to reflect the GDG interpretation of the circumstances when VLCDs may be used. With regard to the references you cite: Reference 1: Reicke et al Osteoathritis and Cartilage (2010) 1-9. Incomplete citation. We presume this is referring to: Riecke B, Christensen R, Christensen P, Leeds A, Boesen M, Lohmander L, Astrup A & Bliddal H (2010) Comparing two low-energy diets for the treatment of knee osteoarthritis symptoms in obese patients: a pragmatic randomised clinical trial. Osteoarthritis and Cartilage, 18, 746-754. This paper has been included in the VLCD safety review but excluded elsewhere because the duration of the study was less than one year. Please refer to the excluded clinical studies table in Appendix J. Reference 2: Christensen et al Clinical Obesity (2011) 1, 31-40. Incomplete citation. We presume this is referring to: Christensen P, Bliddal H, Riecke B F et al. (2011) Comparison of a low-energy diet and a very low-energy diet in sedentary obese individuals: a pragmatic randomised controlled trial. Clinical Obesity 1: 31-40. doi: 10.111/j.1758-8111.2011.00006.x This paper has been excluded from the VLCD effectiveness (added to excluded clinical studies table, see Appendix J) and maintenance (see Appendix J) reviews because it is

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Counterweight Ltd	6	Full	32	Algorithm	Not sure what the 'consider assessment' means? Seems vague. The recommendation around 'lower BMI' in the Asian population needs to define the specific readjustment of BMI categories. The specific Asians sub groups to which these should apply need defined as per lipid guidelines (throughout)	Thank you for your comment. It was outside the scope of the guideline update to define BMI categories for people of Asian family origin. Recommendations on assessing BMI and waist circumference thresholds in adults from black, Asian and other ethnic minority groups can be found in NICE Public health guidance 46 'Assessing body mass index and waist circumference thresholds for intervening to prevent ill health and premature death among adults from black, Asian and other ethnic minority groups in the UK'. The GDG have provided further detail in the linking evidence to recommendations section of chapter 7 (see section

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						7.1.5) regarding this issue.
Counterweight Ltd	7	Full	39	8	This seems to omit the updated NICE recommendation (in this guidance) around T2DM diagnosed within 10 years unless this means no need for referral to Tier 3 for T2DM being considered for surgery? Needs clarification.	Thank you for your comment. The recommendations in this guideline related to recent onset type 2 diabetes are specifically linked to the role of bariatric surgery. The GDG did not consider it necessary to specify particular referral to tier 3 services for those with type 2 diabetes as they consider the second bullet point in recommendation 30 would cover referral to tier 3 services for this group.
Counterweight Ltd	8	Full	41	10 & 11	For people with severe and complicated obesity: BMI>35kg/m^2 with associated co-morbidity or >40kg/m^2 this recommendation is wrong. Many clinical conditions require a greater level of weight loss in order to manage symptoms.[7] Evidence of greater weight loss maintenance with greater initial weight loss.[8]	Thank you for your comment. Recommendation 42 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details).
Counterweight Ltd	9	Full	42	20	Should now include rewards as per CALO-RE taxonomy of behaviour change.[9]	Thank you for your comment. Recommendation 42 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Counterweight Ltd	10	Full	43	45	"Do not use unduly restrictive and nutritionally unbalanced diets, because they are ineffective in the long term and can be harmful." This does not relate to nutritionally replete formula LCDs/ VCLDs as these have to adhere to EU legislation on nutritional content.[10] This message needs to be clear here.	Thank you for your comment. Recommendation 60 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Counterweight Ltd	11	Full	44	9	Need to state which group this approach would be appropriate for. Those requiring greater	Thank you for your comment. The evidence behind this 2006 recommendation was not reviewed as part

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					weight loss will need a more intensive approach than this.	of this update and as such we are not able to provide further information.
Counterweight Ltd	12	Full	44	14	This recognises the value of LCDs but completely omits the emerging importance of nutritionally replete formula LCDs which meet nutritional requirements EU regulations[10]. Needs reviewed.	Thank you for your comment. Recommendation 64 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Counterweight Ltd	13	Full	44	17 to 24	As before the statement on rapid weight loss is confusing and fails to note the importance of greater weight loss for those with a higher BMI	Thank you for your comment. We are uncertain as to the point of your comment and have interpreted it to mean that those with higher BMI's will require VLCDs. However, the GDG stand by the existing recommendation and rationale for their decision regardless of BMI as outlined in the LETR. The GDG recognise the limited evidence for greater BMIs but note the lack of efficacy demonstrated for VLCDs at lower BMIs. They have made a research recommendation to try and ascertain the long term effects on people with a BMI of 40kg/m2 to inform future recommendations for this group. The GDG discussed the concern when weight loss is 'too rapid' i.e., likely to result in excess loss of lean body mass & increase risk of gallstones. They noted that due to high variation in body weight it may be better to define this as % weight loss rather than kg weight loss. Recommendation 42 indicates a 0.5 – 1kg / week (i.e. 0.5- 1% for a 100kg person), but note that 1.5 kg would be considered acceptable for someone with a starting weight of 150kg. This may be more rapid in the first couple of weeks due to fluid loss. They did note that the maximum recommended without losing significant lean mass

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						is probably about 1.5% per week (remembering that the maximum weight loss / week required to not exceed this needs to be recalculated as weight is lost). Our review found that the most successful VLCD trials achieve a total weight loss of 8-12% over 12 weeks which is in keeping with a 1% per week loss.
Counterweight Ltd	14	Full	44	31	Studies mentioned earlier[1,2,3,4,5,6] would suggest the following statement to be inaccurate. "Tell them that this is not a long-term weight management strategy, and that regaining weight is likely and not because of their own or their clinician's failure ". Better wording would be that nutritionally replete LCDs (VLCDs) can form part of an effective approach to weight loss when used alongside a programme of behaviour change and structured support around weight loss and particularly around weight loss maintenance.	Thank you for your comments. This guideline is an update of CG43 which has been limited to the topics where new evidence may change recommendations. We have reviewed the evidence around the clinical and cost-effectiveness of very low calorie diets. However, LCDs were not prioritised for review in this update. The review of evidence has indicated a lack of effectiveness of VLCDs in maintaining weight loss. Therefore, the GDG wanted to ensure that VLCDs were not routinely offered. However, the GDG were aware that there are specific circumstances when they could be used and specified these in the recommendation 66. The GDG have also amended recommendation 66 to highlight their view that weight regain, whilst common with all weight loss strategies, may occur following a VLCD and must be managed appropriately. In regards to the references you cite: Reference 1: Reicke et al Osteoathritis and Cartilage (2010) 1-9. Incomplete citation. We presume this is referring to: Riecke B, Christensen R, Christensen P, Leeds A, Boesen M, Lohmander L, Astrup A & Bliddal H

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						weight-loss maintenance after a very-low-calorie diet or low-calorie diet: a systematic review and meta-analysis of randomised controlled trials. Am J Clin Nutr, 99, 14-23. This systematic review was excluded from the maintenance review due to inadequate quality assessment / outcomes of interest are not included (added to excluded clinical studies table, see Appendix J).
Counterweight Ltd	15	Full	47	11	There is a recommendation that bariatric surgery should be considered when "All appropriate non-surgical measures have been tried but the person has not achieved or maintained adequate, clinically beneficial weight loss". This highlights the importance of a more comprehensive review of evidence for VLCDs and nutritionally complete formula LCDs in this guideline update.	Thank you for your comment. Recommendation 92 has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not been able to amend the recommendation in line with your comment. .
Counterweight Ltd	16	Full	49	31 to 36	Have the costs of providing bariatric surgery for this population been considered and compared to the current level of investment in this intervention in England?	Thank you for your comment. The economic evidence presented in this guideline was used to determine whether bariatric surgery is a cost-effective intervention for individuals with early on-set T2D.The GDG members were very aware of the issues surrounding cost implication - these are issues that will be assessed by the NICE implementation and costing teams and this recommendation has already been selected for special consideration. Further GDG considerations surrounding this issue have been added to the LETR section.
Counterweight Ltd	17	Full	52	3	Why have nutritionally complete formula LCDs been omitted? Refs already provided [1,2,3,4,5,6].	Thank you for your comments. This guideline is an update of CG 43 which has been limited to the topics where new evidence may change recommendations. We have reviewed the evidence

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						around the clinical and cost-effectiveness of very low calorie diets. However, LCDs were not prioritised for review in this update. With regard to the references you cite: Reference 1: Reicke et al Osteoathritis and Cartilage (2010) 1-9. Incomplete citation. We presume this is referring to: Riecke B, Christensen R, Christensen P, Leeds A, Boesen M, Lohmander L, Astrup A & Bliddal H (2010) Comparing two low-energy diets for the treatment of knee osteoarthritis symptoms in obese patients: a pragmatic randomised clinical trial. Osteoarthritis and Cartilage, 18, 746-754. This paper has been included in the VLCD safety review but excluded elsewhere because the duration of the study was less than one year. Please refer to the excluded clinical studies table in Appendix J. Reference 2: Christensen et al Clinical Obesity (2011) 1, 31-40. Incomplete citation. We presume this is referring to: Christensen P, Bliddal H, Riecke B F et al. (2011) Comparison of a low-energy diet and a very low-energy diet in sedentary obese individuals: a pragmatic randomised controlled trial. Clinical Obesity 1: 31-40. doi: 10.111/j.1758-8111.2011.00006.x This paper has been excluded from the VLCD effectiveness (added to excluded clinical studies table, see Appendix J) and maintenance (see Appendix J) reviews because it is less than one year in duration.

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						Reference 3: Christensen et al European Journal of Clinical Nutrition (2011) 1 – 6. Incomplete citation. We presume this is referring to: Christensen P, Bartels E M, Riecke B F et al. (2011) Improved nutritional status and bone health after diet-induced weight loss in sedentary osteoarthritis patients: a prospective cohort study. Eur T Cln Nutr 66(4): 504–509. This paper was not included because it is not a randomised controlled trial. Reference 4: Christensen et al Obesity (2013) 21(10):1982-1990. Incomplete citation. We presume this is referring to: Christensen P, Frederiksen R, Bliddal H et al. (2013) Comparison of three weight maintenance programs on cardiovascular risk, bone and vitamins in sedentary older adults. Obesity (Silver Spring) 21(10):1982-90.(doi: 10.1002/oby.20413). This paper was excluded from the VLCD effectiveness review because the results are presented after the maintenance period only (added to excluded clinical studies table, see Appendix J). This paper was excluded from the VLCD maintenance review because the participants undertook a LCD before being randomised to a maintenance regime (please refer to the excluded clinical studies table in Appendix J). Reference5: Tsai and Wadden OBESITY Vol. 14 No. 8 (2006) 1283-1293. Incomplete citation. We presume this is referring to: Tsai A & Wadden T (2006) The Evolution of Very-Low-Calorie diets: an update and meta-analysis.

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						Obesity, 14, 8, 1283-1293. This systematic review was excluded from the VLCD effectiveness review due to inadequate quality assessment. Please refer to the excluded clinical studies table in Appendix J. Reference 6: Johansson et al Am J Clin Nutr. 2014 Jan;99 (1):14-23. Incomplete citation. We presume this is referring to: Johansson K, Neovius M & Hemmingsson E (2014) Effects of anti-obesity drugs, diet, and exercise on weight-loss maintenance after a very-low-calorie diet or low-calorie diet: a systematic review and meta-analysis of randomised controlled trials. Am J Clin Nutr, 99, 14-23. This systematic review was excluded from the maintenance review due to inadequate quality assessment / outcomes of interest are not included (added to excluded clinical studies table, see Appendix J).
Counterweight Ltd	18	Full	52	13	Not correct. Refs already provided [1,2,3,4,5,6]	Thank you for your comment. With regard to the references you cite: Reference 1: Reicke et al Osteoathritis and Cartilage (2010) 1-9. Incomplete citation. We presume this is referring to: Riecke B, Christensen R, Christensen P, Leeds A, Boesen M, Lohmander L, Astrup A & Bliddal H (2010) Comparing two low-energy diets for the treatment of knee osteoarthritis symptoms in obese patients: a pragmatic randomised clinical trial. Osteoarthritis and Cartilage, 18, 746-754. This paper has been included in the VLCD safety review but excluded elsewhere because the duration of the study was less than one year. Please refer to the excluded clinical studies table in Appendix J.

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						Reference 2: Christensen et al Clinical Obesity (2011) 1, 31-40. Incomplete citation. We presume this is referring to: Christensen P, Bliddal H, Riecke B F et al. (2011) Comparison of a low-energy diet and a very low-energy diet in sedentary obese individuals: a pragmatic randomised controlled trial. Clinical Obesity 1: 31-40. doi: 10.111/j.1758-8111.2011.00006.x This paper has been excluded from the VLCD effectiveness (added to excluded clinical studies table, see Appendix J) and maintenance (see Appendix J) reviews because it is less than one year in duration. Reference 3: Christensen et al European Journal of Clinical Nutrition (2011) 1 – 6. Incomplete citation. We presume this is referring to: Christensen P, Bartels E M, Riecke B F et al. (2011) Improved nutritional status and bone health after diet-induced weight loss in sedentary osteoarthritis patients: a prospective cohort study. Eur T Cln Nutr 66(4): 504–509. This paper was not included because it is not a randomised controlled trial. Reference 4: Christensen et al Obesity (2013) 21(10):1982-1990. Incomplete citation. We presume this is referring to: Christensen P, Frederiksen R, Bliddal H et al. (2013) Comparison of three weight maintenance programs on cardiovascular risk, bone and vitamins in sedentary older adults. Obesity (Silver Spring) 21(10):1982-90.(doi: 10.1002/oby.20413). This

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						paper was excluded from the VLCD effectiveness review because the results are presented after the maintenance period only (added to excluded clinical studies table, see Appendix J). This paper was excluded from the VLCD maintenance review because the participants undertook a LCD before being randomised to a maintenance regime (please refer to the excluded clinical studies table in Appendix J). Reference5: Tsai and Wadden OBESITY Vol. 14 No. 8 (2006) 1283-1293. Incomplete citation. We presume this is referring to: Tsai A & Wadden T (2006) The Evolution of Very-Low-Calorie diets: an update and meta-analysis. Obesity, 14, 8, 1283-1293. This systematic review was excluded from the VLCD effectiveness review due to inadequate quality assessment. Please refer to the excluded clinical studies table in Appendix J. Reference 6: Johansson et al Am J Clin Nutr. 2014 Jan;99 (1):14-23. Incomplete citation. We presume this is referring to: Johansson K, Neovius M & Hemmingsson E (2014) Effects of anti-obesity drugs, diet, and exercise on weight-loss maintenance after a very-low-calorie diet or low-calorie diet: a systematic review and meta-analysis of randomised controlled trials. Am J Clin Nutr, 99, 14-23. This systematic review was excluded from the maintenance review due to inadequate quality assessment / outcomes of interest are not included (added to excluded clinical studies table, see Appendix J).

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Counterweight Ltd	19	Full	52	16	We query the specific focus on the use of VLCDs "in people who are obese and have reached a plateau in weight loss". There is also a suggestion that individuals are managed by specialist services. There is a suggestion to assess whether the provision of VLCDs in general practice to individuals with co morbidity is of added benefit compared to the usual care provided at this level. The assumption that tier 3 services are or could offer interventions for the population in need.	Thank you for your comment. We have noted your concerns; however, we do not wish to change the text of the introduction. This guideline is an update of CG43. Please refer to recommendation 1.7.4.32, which notes the use of VLCDs in this population. The GDG believe that the appropriate delivery of VLCD within an NHS context is within tier 3 or specialist services.
Counterweight Ltd	20	Full	52	21	Incorrect as long term evidence already exists[4]. Again consider nutritionally replete formula LCDs	Thank you for your comments. . We have reviewed the evidence around the clinical and cost-effectiveness of very low calorie diets and specifically required a study duration of 1 year to assess long-term maintenance of weight loss. The evidence is discussed in section 6.2.13. We would note that the use of LCDs was not prioritised for review in this update. With regards to the reference you cite: Reference 4: Christensen et al Obesity (2013) 21(10):1982-1990. Incomplete citation. We presume this is referring to: Christensen P, Frederiksen R, Bliddal H et al. (2013) Comparison of three weight maintenance programs on cardiovascular risk, bone and vitamins in sedentary older adults. Obesity (Silver Spring) 21(10):1982-90.(doi: 10.1002/oby.20413). This paper was excluded from the VLCD effectiveness

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						review because the results are presented after the maintenance period only (added to excluded clinical studies table, see Appendix J). This paper was excluded from the VLCD maintenance review because the participants undertook a LCD before being randomised to a maintenance regime (please refer to the excluded clinical studies table in Appendix J).
Counterweight Ltd	21	Full	53	Table 7	The comparison group is inappropriate because: 1) An LCD using food is unlikely to be nutritionally adequate 2) A food based LCD therefore should not be used or advocated 3) The LCD involved in the studies would constitute much more than the recommended 500-800kcal daily deficit 4) This would explain the above- expected weight loss as compared to that observed in routine clinical care for 'standard approaches'.[11]	Thank you for your comments. The definition of LCDs has been amended to reflect the 2006 definition of 800 -1600 kcal/day. It is recognised that the definition is somewhat arbitrary. The energy deficit created by any 'fixed energy dietary recommendation' will also be dependent on the gender, weight, age and activity levels of the individual. However it is the view of the GDG that standard dietary advice is defined as 800-1600 kcal/day or 500/800 deficit diet. The methods used to assess literature in this review are according to the robust processes and standards set by NICE (for further information please refer to the methods section of this guideline and the NICE manual - http://www.nice.org.uk/article/PMG6/chapter/1%20Introduction).
Counterweight Ltd	22	Full	53	9	We disagree that "Standard dietary advice defined as: low-calorie (regular) diet (LCD) 800-1200 calories per day or 500/800 deficit diet" is standard dietary advice. It is in fact an LCD approach for all papers cited. Standard dietary	Thank you for your comments. The definition of LCDs has been amended to reflect the 2006 definition of 800 -1600 kcal/day. It is recognised that the definition is somewhat arbitrary. The energy deficit created by any 'fixed energy dietary

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					advice is generally 600kcal deficit but typically above 1300kcal. See point 21 above for severe and complicated group	recommendation' will also be dependent on the gender, weight, age and activity levels of the individual. However it is the view of the GDG that standard dietary advice is defined as 800-1600 kcal/day or 500/800 deficit diet. The methods used to assess literature in this review are according to the robust processes and standards set by NICE (for further information please refer to the methods section of this guideline and the NICE manual - http://www.nice.org.uk/article/PMG6/chapter/1%20Introduction).
Counterweight Ltd	23	Full	54	Table 8	All 'control groups' having LCDs and a number have very low mean start weight i.e. 92-93kg. Again not a severe and complicated group and data for this group of patients would be helpful.	Thank you for your comment. The GDG note the issue raised in your comment and acknowledge the lack of evidence in this area. They have made a research recommendation to determine the long term effects of the use of VLCDs in people with a BMI of greater than 40kg/m2 as evidence in this group was lacking. Please see section 5.15.
Counterweight Ltd	24	Full	59	Table 9	Outcomes for 'standard diet' far superior than observed in routine practice[11] due to use of restrictive LCDs (dietary) as opposed to routine 600-800kcal deficits. Outcomes observed in routine clinical practice should be considered and discussed. Comparator therefore inappropriate to test value of VLCDs. Studies cited are actually testing LCDs as opposed to routine care with the additional concern around nutritional inadequacy for the dietary LCDs	Thank you for your comments. The definition of LCDs has been amended to reflect the 2006 definition of 800 -1600 kcal/day. It is recognised that the definition is somewhat arbitrary. The energy deficit created by any 'fixed energy dietary recommendation' will also be dependent on the gender, weight, age and activity levels of the individual. However it is the view of the GDG that standard dietary advice is defined as 800-1600 kcal/day or 500/800 deficit diet. The methods used to assess literature in this review are according to the robust processes and standards set by NICE (for further information please refer to the methods

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						section of this guideline and the NICE manual - http://www.nice.org.uk/article/PMG6/chapter/1%20Introduction).
Counterweight Ltd	25	Full	63	12 to 13	We would question that the studies cited do not reflect this population particularly those with BMI>40kg/m^2. At mean baseline weight of 91 or 93kg two of the studies would have had to have mean height of <1.52m.	Thank you for your comment. The GDG note the issue raised in your comment and acknowledge the lack of evidence in this area. They have made a research recommendation to determine the long term effects of the use of VLCDs in people with a BMI of greater than 40kg/m2 as evidence in this group was lacking.
Counterweight Ltd	26	Full	63	17	There is a suggestion that individuals with a BMI over 40 kg/m2 and comorbidities "are likely to receive a different level of care (specialist input from a multi-disciplinary-team (MDT)) to ensure their comorbidities are properly monitored and controlled". Is there evidence suggesting we have this model of care on a national basis? In contrast to the statement about specialist teams, on page 120 it says Local tier 3 services still do not exist in the majority of areas. This highlights the level of gap in existing services to that being recommended in this guideline update.	Thank you for your comment. We note that the provision of tier 3 services is variable across the country. It is beyond the remit of this guideline to make comment on service provision. NICE recommendations are correctly aspirational and it is the GDG opinion that people with obesity who have additional comorbidities undertaking a VLCD should be offered additional support to monitor their conditions appropriately to ensure their safety. The costs presented represent the experience of the relevant specialist services who would be working with these individuals to support their use of a VLCD.
Counterweight Ltd	27	Full	66	8	As point 26.	Thank you for your comment. Please see response to point 26.
Counterweight Ltd	28	Full	70	10	The studies cited did **not** use standard dietary advice but LCD approaches (but with non-nutritionally replete formula)	Thank you for your comments. The definition of LCDs has been amended to reflect the 2006 definition of 800 -1600 kcal/day. It is recognised that the definition is somewhat arbitrary. The energy deficit created by any 'fixed energy dietary recommendation' will also be dependent on the

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						gender, weight, age and activity levels of the individual. However it is the view of the GDG that standard dietary advice is the equivalent of a diet defined as 800-1600 kcal/day or 500/800 deficit diet. This comparison allows the understanding of what added value VLCDs can bring to an individual in the NHS who will be trying an LCD first. The methods used to assess literature in this review are according to the robust processes and standards set by NICE (for further information please refer to the methods section of this guideline and the NICE manual - http://www.nice.org.uk/article/PMG6/chapter/1%20Introduction).
Counterweight Ltd	29	Full	70	25 to 41	Due to the relatively 'intense' 'standard care' which resulted in limited impact of VLCDs coupled with an overly intense monitoring programme for the VCLDs the economic case for formula diets has been severely compromised. If there was focus on nutritionally replete formula LCDs in this guidance then the costs for the intervention would be even less making a significantly better economic case.	Thank you for your comment. A variety of costs were considered for VLCDs in the sensitivity analysis and consideration was made to less intensive VLCD programmes for patients with no co-morbidities. However even when lower costs were used in the analysis the GDG did not consider VLCDs to be cost-effective as clinical evidence did not justify these costs. Our focus in the evidence review has been on the calorific content of VLCDs (under 800kcal per day) although the GDG note the importance also that these diets must be nutritionally complete and have added clarity to the relevant recommendation in this regard.
Counterweight Ltd	30	Full	71	Table 4	The group here acknowledge that the comparison is with LCD rather than standard care.	Thank you for your comment.
Counterweight	31	Full	71		There is a failure to recognise 'severe' events vs.	Thank you for your comment. At the start of the

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Ltd					manageable side effects when looking at this question. Severe event is medical problem/hospitalization. Side effects can be transient and less of a problem than being obese. Where is there evidence that disordered eating, depression and postural hypotension are the highest safety concerns?	guideline development process and with their clinical expertise, the GDG prioritised the outcomes which they considered to be most critical and important to decision making related to VLCDs. The GDG felt the potential adverse effects of VLCDs were important and felt it was essential to consider the evidence for these potential adverse effects, alongside the evidence on its clinical and cost effectiveness in considering whether to recommend the use of VLCDs.
Counterweight Ltd	32	Full	77	5	This is insufficient evidence to conclude this statement as only one very low quality study cited with n=45.	Thank you for your comment. The evidence statement referred to on binge eating (to which you refer) states that VLCDs 'may' result in more binge eating after 1 year compared with LCDs. Binge eating was found to be greater with VLCDs but the strength of the statement (with the use of the word 'may') reflects the relative uncertainty around this estimate. The evidence is interpreted according to the methods section in chapter 3, section 3.4.11 of the guideline.
Counterweight Ltd	33	Full	93	5	We disagree with the statement on refeeding as published studies are showing beneficial effects.[6,12]	Thank you for your comment. We deal with your references in turn Reference 6: Johansson et al Am J Clin Nutr. 2014 Jan;99 (1):14-23. This is an incomplete citation but we presume this is referring to: Johansson K, Neovius M & Hemmingsson E (2014) Effects of anti-obesity drugs, diet, and exercise on weight-loss maintenance after a very-low-calorie diet or low-calorie diet: a systematic review and meta-analysis

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						of randomised controlled trials. Am J Clin Nutr, 99, 14-23. This systematic review was excluded from the maintenance review due to inadequate quality assessment / outcomes of interest are not included (Please note that this has been added to added to excluded clinical studies table, see Appendix J). Reference 12: Gripeteg el al Br J Nutr. 2010 Jan; 103(1):141-8. Please note that this is an incomplete citation but we presume this is referring to: Gripeteg, L., Torgerson, J., Karlsson, J. & Lindroos, A.K. (2010). Prolonged re-feeding improves maintenance after weight loss with very-low-energy diets (VELDS). British Journal of Nutrition; 103, 1, 141-148. This paper was excluded from the VLCD review because it does not include the correct intervention (please refer to Appendix J – excluded clinical studies, maintenance review). As specified in the review protocol, study participants were required to take part in a lead in period of less than 800 calories.
Counterweight Ltd	34	Full	94	General	Consider adding to recommendations: 1. Nutritionally replete formula VLCDsand LCDs that are commercially prepared are a suitable intervention for weight loss and subsequent weight loss maintenance.[4,13] 2. Ongoing support, structure, catching weight regain early are all important strategies.[14] 3. Eating disorder assessments are flawed with problems, cannot make this a routine assessment in the absence of clinical psychology.	Thank you for your comments. Point 1). It is out of the scope of this GDG to comment on commercially prepared formulas. The focus of this review is the calorific content of VLCDs. Recommendation 66 (see full guideline) has been amended to note 'nutritionally complete' VLCDs. Point 2). It is the view of the GDG that this point is covered by recommendation 68 of the full guideline.

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					4. Discuss side effects and monitor to ensure only transient. Give information on how to manage these	Point 3). It is the view of the GDG that this point is covered by recommendation 67 of the full guideline which does not specify who should undertake the assessment but identifies the need to consider the potential for eating disorders before considering the appropriateness of such a diet. Additional information in this regard has been added to the LETR. We are also aware of existing NICE guidance (Core interventions in the treatment and management of anorexia nervosa, bulimia nervosa and related eating disorders) which has been scheduled into the NICE programme for update that may provide further guidance on this issue. We have therefore included the guidance into the section of related NICE guidance in the NICE version for consideration by stakeholders. Point 4). It is the view of the GDG that this point is covered by recommendation 67 of the full guideline. The LETR has been updated to reflect the importance of monitoring.
Counterweight Ltd	35	Full	95	general	There is a shift here from evidence to 'clinical experience' of the guideline group. While some populations e.g. those attending for bariatric surgery/ failed surgery may demonstrate these characteristics there is growing evidence around the effective use of nutritionally replete formula LCD/ VLCDs in achieving and maintaining long term lower weight of clinical benefit for those who need more than lifestyle intervention. There are some very strong statements which do not have evidence to back up such as may 'cause	Thank you for your comment. The section to which we believe you refer identifies a GDG discussion that the reflected the relative trade off between harms and benefits of the interventions considered (in this case VLCD). They are not statements of the evidence considered. The GDG selected the comparator for VLCDs as standard care to be LCD as they believed that, from the perspective of the provision of NHS services, this would be provided initially as a dietary weight

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					depression' 'this loss is not likely to be maintained'. It would not be normal NICE practice to give such weight to unreferenced, non-peer reviewed, opinion. Again the comparator has not reflected standard care so the value of formula diets is very much compromised. In terms of cost, again these have not been appropriately assessed. The statement that 'sufficient BMI changes to result in cost effectiveness being unlikely' is inaccurate as changes in this order are being observed in LCD/VCLD studies[1,2,3,4,5,6,15]	loss strategy and therefore it was appropriate to review evidence to identify the additional benefit of providing VLCD to these groups. We disagree with your assertion that the costs of providing these diets from the perspective of NHS services has not been properly assessed. The approaches used are clearly documented in section 6.2.2 Reference 1: Reicke et al Osteoathritis and Cartilage (2010) 1-9. Incomplete citation. We presume this is referring to: Riecke B, Christensen R, Christensen P, Leeds A, Boesen M, Lohmander L, Astrup A & Bliddal H (2010) Comparing two low-energy diets for the treatment of knee osteoarthritis symptoms in obese patients: a pragmatic randomised clinical trial. Osteoarthritis and Cartilage, 18, 746-754. This paper has been included in the VLCD safety review but excluded elsewhere because the duration of the study was less than one year. Please refer to the excluded clinical studies table in Appendix J. Reference 2: Christensen et al Clinical Obesity (2011) 1, 31-40. Incomplete citation. We presume this is referring to: Christensen P, Bliddal H, Riecke B F et al. (2011) Comparison of a low-energy diet and a very low-energy diet in sedentary obese individuals: a pragmatic randomised controlled trial. Clinical Obesity 1: 31-40. doi: 10.111/j.1758-8111.2011.00006.x This paper has been excluded from the VLCD effectiveness (added to excluded clinical studies table, see Appendix J) and maintenance (see Appendix J) reviews because it is

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						less than one year in duration. Reference 3: Christensen et al European Journal of Clinical Nutrition (2011) 1 – 6. Incomplete citation. We presume this is referring to: Christensen P, Bartels E M, Riecke B F et al. (2011) Improved nutritional status and bone health after diet-induced weight loss in sedentary osteoarthritis patients: a prospective cohort study. Eur T Cln Nutr 66(4): 504–509. This paper was not included because it is not a randomised controlled trial. Reference 4: Christensen et al Obesity (2013) 21(10):1982-1990. Incomplete citation. We presume this is referring to: Christensen P, Frederiksen R, Bliddal H et al. (2013) Comparison of three weight maintenance programs on cardiovascular risk, bone and vitamins in sedentary older adults. Obesity (Silver Spring) 21(10):1982-90.(doi: 10.1002/oby.20413). This paper was excluded from the VLCD effectiveness review because the results are presented after the maintenance period only (added to excluded clinical studies table, see Appendix J). This paper was excluded from the VLCD maintenance review because the participants undertook a LCD before being randomised to a maintenance regime (please refer to the excluded clinical studies table in Appendix J). Reference5: Tsai and Wadden OBESITY Vol. 14 No. 8 (2006) 1283-1293. Incomplete citation. We presume this is referring to:

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						Tsai A & Wadden T (2006) The Evolution of Very-Low-Calorie diets: an update and meta-analysis. Obesity, 14, 8, 1283-1293. This systematic review was excluded from the VLCD effectiveness review due to inadequate quality assessment. Please refer to the excluded clinical studies table in Appendix J. Reference 6: Johansson et al Am J Clin Nutr. 2014 Jan;99 (1):14-23. Incomplete citation. We presume this is referring to: Johansson K, Neovius M & Hemmingsson E (2014) Effects of anti-obesity drugs, diet, and exercise on weight-loss maintenance after a very-low-calorie diet or low-calorie diet: a systematic review and meta-analysis of randomised controlled trials. Am J Clin Nutr, 99, 14-23. This systematic review was excluded from the maintenance review due to inadequate quality assessment / outcomes of interest are not included (added to excluded clinical studies table, see Appendix J). Reference 15 has now been included as part of the discussion of the health economic evidence
Counterweight Ltd	36	Full	114	3	In terms of cost this would seem to reflect the cost of the procedure only and not fully include all prior and subsequent care needed. Some idea (as per the VCLD costs) of full costs would be helpful. This would also allow the resource need to be estimated should this guidance be implemented . The guidance is not clear on the continued need to go through 'tier 3' prior to surgery and what this would involve. e.g. an appropriate nutritionally replete formula LCD?	Thank you for your comment. The cost quoted in the unit cost section of the bariatric surgery review on page 115 was provided for reference as to how much the surgery alone costs. However the GDG were aware that this figure only reflects a fraction of the overall cost of surgery and when making recommendations they mainly considered the conclusions of four economic evaluations presented in the published literature section on pages 112-114, that used robust economic modelling to assess the

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						cost-effectiveness of bariatric surgery on early onset type-2 diabetics. In these papers, the full cost of bariatric surgery has been calculated and analysed together with the review of the procedure's effectiveness. As no economic evaluations were identified around VLCDs a different approach had to be taken to account for the economic implications and the detail of the approach taken is clearly captured in Chapter 6, section 6.2.2. Further clarification has now been provided in the recommendations about the role of tier 3 services within the context of referral for assessment for bariatric surgery in people with recent onset type 2 diabetes.
Counterweight Ltd	37	Full	114	8	While the effect of surgery is well established the comparison group for surgery is a relatively low level intervention compared with the strict LCD approach used as a comparator for VCLDs. This seems to favour the outcomes for surgery and of course would inflate the economic benefit.	Thank you for your comment. The GDG believe that they have selected the most appropriate comparators for both VLCDs and bariatric surgery, based on the alternative management individuals would receive.
Counterweight Ltd	38	Full	114	20 to 29	While the cost effectiveness data is noted to have potentially serious limitations further research would be warranted in the field of T2DM prior to these fairly significant recommendations being made in relation to surgery	Thank you for your comment. Although each economic review was noted as having 'potentially serious limitations' there was no study that suggested that bariatric surgery was not cost-effective. The ICERs produced from each study were also very low (<£5000 per QALY gained) which is far lower than NICE's recommended threshold of £20,000 per QALY gained. Given the overall quality of the evidence and when considering the relative strength of the recommendations made,

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						the GDG believes it is unlikely that any additional research will produce evidence which contradicts the current evidence base.
Counterweight Ltd	39	Full	115	General	Remission does not suggest 'cure' but a temporary reversal of the presence of symptoms/ disease. Appropriate to speak of T2DM remission. This may be quite prolonged but re-emergence of T2D is likely over years as residual beta-cell function deteriorates. One might liken the situation to that with gestational diabetes where many of these women develop T2D over subsequent years	Thank you for your comment. We have discussed the definition of 'remission' within the text of the full guideline (Section 7.1.2).
Counterweight Ltd	40	Full	124	Table 45	Only 2 of the 4 studies suggest clear benefit of surgery but no stats applied. A more critical review here may be appropriate. May indicate the need for clearer follow up packages of care. References 1. Reicke et al Osteoathritis and Cartilage (2010) 1-9 2. Christensen et al Clinical Obesity (2011) 1, 31-40 3. Christensen et al European Journal of Clinical Nutrition (2011) 1 - 6 4. Christensen et al Obesity (2013) 21(10):1982-1990 5. Tsai and Wadden OBESITY Vol. 14 No. 8 (2006) 1283-1293 6. Johansson et al Am J Clin Nutr. 2014 Jan;99 (1):14-23. 7. Management of obesity. SIGN guideline115. Edinburgh (2010)	Thank you for your comment. Please note that the relevant statistics are provided in the corresponding GRADE table in appendix N. Note that there are 2 studies but 4 outcomes reported by one study each.

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					8. Astrup and Rossner Obes Rev. 2000 May;1(1):17-9 9. Michie et al Psychol Health. 2011 Nov;26(11):1479-98 10. COMMISSION DIRECTIVE 96/8/EC of 26 February 1996 11. Logue et al. BMJ Open (2014) 4:e003747. 12. Gripeteg el al Br J Nutr. 2010 Jan;103(1):141-8 13. Wadden at al Obesity (2011) 19,(10):1987-1998 14. Rena Wing et al N Engl J Med (2006) 355;15: 1563-1571 15. Lean et al BJGP (2013) 115-124	
Department of Health	1	Full	36	Point 12	**Waist Circumference:** It is our understanding that waist circumference is a very useful measure of the spread of adiposity and clearly linked to increased risk of poor health, especially in south Asian communities. It would be helpful to clarify why the recommendation is 'only' to "think about using" rather than a stronger recommendation to increase the use of waist circumference measurement in assessing and monitoring patients.	Thank you for your comment. Recommendation 12 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Further recommendations on the use of waist circumference in this population can be found in NICE Public health guidance 46 'BMI and waist circumference - black, Asian and minority ethnic groups'.
Department of Health	2	Full	43	Point 52	**Physical Activity Goals:** It would be helpful to clarify what groups this recommendation is aimed at and how it relates to the existing CMO guidelines. Does the first part of the recommendation (45-60) relate to people who are a healthy weight (i.e. those who CMO recommends should exercise for 30 minutes, 5	Thank you for your comment. Recommendations 45 – 60 were not updated as part of the current guideline update. Therefore, we have not amended the recommendation in line with your comment.

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					times a week) or those who are overweight and don't want to become obese. If the latter, it is not clear how this relates to the second part of the recommendation, which suggests obese people who have lost weight may need to do 60-90mins per day to avoid putting on weight.	
Department of Health	3	Full	44	Point 67	**Weight regain after VLCD:** Do most patients put on weight after coming off VLCDs? I understand the use of VLCDs as a short-term dietary measure, but assume this would usually be followed up with a calorie controlled diet and other multi-component measures in most patients because VLCDs would be used for rapid weight loss – but you would want to see long term weight loss in patients?	Thank you for your comment. The evidence review conducted as part of this guideline clearly demonstrated that weight loss was not maintained following the initial dietary intervention. The GDG, including patient members, discussed the available evidence and were also consistent in their experience that people who have undertaken a very low calorie diet, regaining weight was common. Further detail is found in section 6.2.13. Recommendation 67 and 68 endorse the need for a dietary intervention of this type to be only considered as part of a multi-component weight strategy to maximise initial weight loss and avoid weight regain.
Department of Health	4	Full	46	Point 81	**Weight loss:** It would be helpful to clarify the difference between "maintaining weight loss" and "continue to lose weight". Is this statement trying to say that drugs may be used to keep patients at their level of weight loss, i.e. maintenance, rather than continuing to lose weight?	Thank you for your comment. Recommendation 81 was not updated as part of the current guideline update. Therefore, we have not been able to provide any further detail to the recommendation in line with your comment.
Dietitians in Obesity Management UK	1	Full	24	17	Should figure 3 in the text read figure 2?	Thank you for your comment. We agree and we have amended this.

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Dietitians in Obesity Management UK	2	Full	32	General	Recommendation 91 in the text relates to Orlistat use in children. It is not apparent how this relates to this flowchart. Is this an error?	Thank you for your comment. The recommendation number has been corrected.
Dietitians in Obesity Management UK	3	Full	32	General	'Consider assessing for bariatric surgery at a lower BMI'. How much lower? Additional clarity would be helpful.	Thank you for your comment. Recommendation 17 identifies that people of Asian family origin have comorbidity risk factors at lower BMIs and as such the GDG noted that assessment for surgery may be considered at lower BMIs accordingly. In the 'recommendations and link to evidence' section (7.1.5) under 'other considerations', the GDG noted that diabetes tends to occur at a lower BMI in these patients but they did not feel it was possible to specify an exact BMI threshold. However, they noted that the International Diabetes Federation recommends that for people of Asian origin, BMI thresholds for eligibility and prioritisation for bariatric surgery should be reduced by 2.5 BMI points.
Dietitians in Obesity Management UK	4	Full	33	General	Recommendation 110 in the text relates to offering bariatric surgery to those diagnosed with diabetes within the last 1o years with a BMI of 30-34.9kg/m^2. It is not apparent how this relates to this flowchart. Is this an error?	Thank you for your comment, this has been corrected.
Dietitians in Obesity Management UK	5	Full	33	General	The text within the final box appears to be incomplete: 'are offered appropriate dietary...'	Thank you for your comment, this has been amended.
Dietitians in	6	Full	34	Gener	Figure 6 shows the recommendations from 2006.	Thank you for your comment. As you correctly state,

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Obesity Management UK				al	We note that these include lifestyle interventions and are unclear why meal replacement approaches were not included in 2006 and therefore have been omitted from this update, although there is a wealth of research evidence attesting to their efficacy in a variety of settings including unsupported use in primary care. We would urge NICE to consider including meal replacement approaches within the updated guidance since they clearly fall within the remit of 'lifestyle interventions'.	meal replacement approaches were not included in the original 2006 guideline and were not identified as an area for an additional area for inclusion in the 2006 guideline during scoping. However, the guideline does provide recommendations on the provision of a very low calorie diet, as defined by calorific content rather than type of diet, which may include meal replacement approaches.
Dietitians in Obesity Management UK	7	Full	35	36 to 38	Although this recommendation relates to the original guidance of 2006, we would like to note that 'clinical judgement' assumes confidence, training and attainment of competencies by the practitioner that are not necessarily the case.	Thank you for your comment. Recommendation 33 was not updated as part of the current guideline update and therefore we are unable to comment further on the issue you raise
Dietitians in Obesity Management UK	8	Full	36	5 to 6	W would like 'think about using waist circumference in addition to BMI' to be restated in stronger terms. In reality waist circumference is infrequently measured, for a variety of reasons. However this is unlikely to improve in the absence of clear guidance from NICE. Given the strong evidence that distribution of body fat is a serious risk factor for co-morbidities, we would like the wording changed to 'Waist circumference in addition to BMI should be measured in those with a BMI < 35kg/m^2.	Thank you for your comment. Recommendation 12 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Dietitians in Obesity Management	9	Full	36	12 to 13	Although this recommendation relates to the original guidance of 2006, we would like to comment that there are no recommended cut off	Thank you for your comment. Recommendation 14 was not updated as part of the current guideline update and has been amended for clarity only (see

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UK					points for waist circumference in children so we are unclear how measuring it will give additional information on the risk of developing other long term health problems.	Appendix Q of the full guideline for details). Therefore, we are unable to make further comment on this issue
Dietitians in Obesity Management UK	10	Full	36	24	Although this recommendation relates to the original guidance of 2006 and as such is not open to comment, we observe that recommendation 35 in the new guidance does not appear to relate to classification.	Thank you for your comment. Section 5.4 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details).
Dietitians in Obesity Management UK	11	Full	37	6	Although this recommendation relates to the original guidance of 2006 and as such is not open to comment, we would like to observe that Level 1 of intervention should also include physical activity as this is relevant to everyone. Because physical activity is specified in Levels 2-4, it may seem that it is not relevant to Level 1.	Thank you for your comment. Recommendation 22 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Dietitians in Obesity Management UK	12	Full	37	11 to 13	We are unclear why the 2012 UK growth charts for 2-18 year olds are not recommended for use.	Thank you for your comment. The recommendations have now been amended and make reference to the RCPC WHO-UK growth charts as well as those charts for use in Childhood and Puberty close monitoring.
Dietitians in Obesity Management UK	13	Full	38	4 to 10	Although this recommendation relates to the original guidance of 2006 and as such is not open to comment, we would like to see 'raise the issue in a sensitive manner' inserted into the text.	Thank you for your comment. Recommendation 19 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Dietitians in Obesity Management	14	Full	38	9 to 10	Although this recommendation relates to the original guidance of 2006 and as such is not open to comment, we would like to see 'and	Thank you for your comment. Recommendation 26 was not updated as part of the current guideline update. Therefore, we have not amended the

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UK					reducing sedentary behaviours' added to the list of beneficial behaviours.	recommendation in line with your comment.
Dietitians in Obesity Management UK	15	Full	38	28	Although this recommendation relates to the original guidance of 2006 and as such is not open to comment, we would like to see a change from 'Assess' to 'Explore' readiness. This is in light of the importance of establishing a cooperative helping relationship, in which the individual is an active participant.	Thank you for your comment. Recommendation 27 was not updated as part of the current guideline update. Therefore, we have not amended the recommendation in line with your comment.
Dietitians in Obesity Management UK	16	Full	40	33 to 34	Clarification about what comprises relevant competencies and how those will be measured would be welcome.	Thank you for your comment. The evidence behind this 2006 recommendation was not reviewed as part of this update and as such we are not able to provide further information. Recommendation 14 in Overweight and obese adults: lifestyle weight management services (PH53) provides further guidance on training.
Dietitians in Obesity Management UK	17	Full	41	3 to 4	Although this recommendation relates to the original guidance of 2006 and as such is not open to comment, we would like to observe the importance of sincerity of all affirmations/praise in order to protect the helping relationship.	Thank you for your comment. Recommendation 33 was not updated as part of the current guideline update and therefore, this has not been amended in line with your comment.
Dietitians in Obesity Management UK	18	Full	41	31	Although this recommendation relates to the original guidance of 2006 and as such is not open to comment, we would observe that the person should be encouraged to *SEEK* support from partner or spouse.	Thank you for your comment. Recommendation 42 was not updated as part of the current guideline update. Therefore, we have not amended the recommendation in line with your comment.
Dietitians in Obesity Management	19	Full	42	6 to 7	Although this recommendation relates to the original guidance of 2006 and as such is not open to comment, it is not clear what is meant by	Thank you for your comment. Recommendation 48 was not updated as part of the current guideline update and therefore, we were unable to clarify what

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UK					'an appropriately trained professional' and we would welcome clarification of this.	was meant by 'trained' in any further detail. Therefore, we have not amended the recommendation in line with your comment.
Dietitians in Obesity Management UK	20	Full	42	9 to 20	Although this recommendation relates to the original guidance of 2006 and as such is not open to comment, we observe the importance of ensuring that all strategies are delivered in a patient centred way, using everyday language and avoiding the use of jargon. We would like this added to the text if possible.	Thank you for your comment. Recommendation 40 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Dietitians in Obesity Management UK	21	Full	42	29	As per point 15 above, we would like to emphasise the importance of sincerity and genuineness.	Thank you for your comment. Recommendation 40 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Dietitians in Obesity Management UK	22	Full	43	10	Although this recommendation relates to the original guidance of 2006 and as such is not open to comment, we observe that we are not aware of strong evidence supporting gardening as a weight management strategy although we recognise that all movement is important for health. In the specific context of weight management we do not think that gardening is a relevant example.	Thank you for your comment. Recommendation 53 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Dietitians in Obesity Management UK	23	Full	44	6 to 39	As per comment 6 above, we are unclear why meal replacement approaches have been excluded and feel that this update to the 2006 guidance is an ideal opportunity to include this important and efficacious approach to weight management.	Thank you for your comment. As you correctly state, meal replacement approaches were not included in the original 2006 guideline and were not identified as an area for inclusion in the 2006 guideline during scoping. However, the guideline does provide recommendations on the provision of a very low

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						calorie diet, as defined by calorific content rather than type of diet, which may include meal replacement approaches.
Dietitians in Obesity Management UK	24	Full	44	14	Although we agree with the principle that lower calorie intakes are less likely to be nutritionally complete, we do not agree that this is likely at an intake of 1600kcals/day.	Thank you for your comment. Recommendation 64 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Dietitians in Obesity Management UK	25	Full	44	17 to 18	Codex and SCOOP guidance identify very low calorie diets (VLCD) as those containing 450-800kcals/day. We would like this clarified: <800kcals/day does not necessarily include only VLCD but may also include diets supplying <450kcals/day which fall outside of this definition.	Thank you for your comments. The Codex and Scoop guidance informed the definition of VLCDs. This review was inclusive of all studies which have included VLCDs 800 kcal or less. Studies that included diets marginally less than 450 kcals were also included. The GDG considered it important to note that diets less than 800kcal, were carried out under clinical supervision and have amended their recommendation for the use of VLCDs in specific circumstances to make this clear (see recommendation 66 of the full guideline).
Dietitians in Obesity Management UK	26	Full	44	20 to 24	We would like to see the necessity for medical supervision throughout VLCD use added in here, and in addition we would like the importance of assessing suitability prior to starting VLCD in those with a clinically defined need for rapid weight loss.	Thank you for your comment. The recommendation highlights that VLCDs should be considered only with on-going clinical support, as part of a multicomponent weight management strategy (see recommendation 66). We believe the importance of considering suitability is covered by recommendation 67.
Dietitians in Obesity Management UK	27	Full	44 to 45	General	We would like to see the need for regular measurement of linear growth to be acknowledged in this section.	Thank you for your comment. This guideline is an update of CG 43. We have not reviewed the evidence behind the assessment and measurement of obesity as part of this update, and as such we are

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						not able to provide further information. Please refer to Managing Overweight and Obesity among children and young people (PH47) for further information.
Dietitians in Obesity Management UK	28	Full	45	1-2	We note that this recommendation is not in line with recommendation 46, which states that weight loss is not necessarily the goal of weight management programmes in children.	Thank you for your comment. Recommendation 72 was not updated as part of the current guideline update. Therefore, we have not amended the recommendation in line with your comment.
Dietitians in Obesity Management UK	29	Full	47	2 to 3	It is not immediately clear why a 6-12 month trial in children is recommended, given that in adults treatment should generally be discontinued after 3 months unless at least 5% weight loss has been achieved.	Thank you for your comment. Recommendation 91 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Dietitians in Obesity Management UK	30	Full	47	8 to 17	We note the resource implications of this recommendation, and the unlikelihood that the majority of patients now deemed eligible for bariatric surgery will ever receive this treatment, although we recognise that this is outside the scope of NICE.	Thank you for your comment the content of which is noted. The recommendation to which you refer (recommendation 92) was originally made in 2006 and has been advice to the NHS since that date.
Dietitians in Obesity Management UK	31	Full	47	8 to 17	We would like to see 'has been assessed as a suitable candidate for bariatric surgery and has committed to the need for lifelong changes to behaviour' added.	Thank you for your comment. Recommendation 92 has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not been able to amend the recommendation in line with your comment.
Dietitians in Obesity Management UK	32	Full	47	19 to 26	We would like to see 'need for life- long behaviour change' added.	Thank you for your comment. Recommendation 93 was not updated as part of the current guideline update. Therefore, we have not amended the recommendation in line with your comment.

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Dietitians in Obesity Management UK	33	Full	47	35 to 38	We agree with the need for regular specialist postoperative dietetic monitoring and are pleased to see this recognised. However we also stress the need for pre operative dietetic assessment, particularly given the importance of ascertaining whether patients recognise and are willing to make life long changes to eating behaviours, and also understanding their patterns of eating prior to surgery.	Thank you for your comment. Recommendation 92 has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not been able to amend the recommendation in line with your comment.
Dietitians in Obesity Management UK	34	Full	49	7 to 18	As per comment 30 above, we would also stress the importance of dietetic input prior to bariatric surgery in children. We also note that commitment to lifelong behaviour change will be required not just in children but also in their families.	Thank you for your comment. Recommendations 103 – 108 were not updated as part of the current guideline update. Therefore, we have not been able to amend the recommendation in line with your comment.
Dietitians in Obesity Management UK	35	Full	49	31 to 36	We note the high proportion of the population likely to be eligible for bariatric surgery as a result of these recommendations, and whilst we do not disagree with them, the resource implications for the NHS are considerable. We also feel it likely that many and perhaps most eligible patients will never receive bariatric surgery as a result of resource shortages.	Thank you for your comment. The GDG members were very aware of the issues surrounding cost implication - these are issues that will be assessed by the NICE implementation and costing teams and this recommendation has already been selected for special consideration. GDG considerations surrounding this issue have been added to the LETR section. The GDG noted that such high cost implications would only be realised if every candidate eligible for an assessment received an assessment and after an assessment all these candidates were referred for surgery. In reality a considerable number of individuals who are deemed eligible for an assessment will not be suitable for surgery and therefore be declined, on top of this some individuals choose not to have the surgery.

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						This will significantly reduce the cost implication.
Dietitians in Obesity Management UK	36	Full	49	31 to 16	Related to this, we stress that all interventions for weight management require life long changes to eating and activity behaviours which do not occur in a vacuum. The importance of an environment supportive of healthy weight management is crucial and we would like to see this acknowledged in this updated guidance, although we realise that it is also covered in other NICE guidance.	Thank you for your comment. Recommendations 109 and 110 have been amended to highlight that people with recent onset type 2 diabetes who have a BMI of 35 and over who are offered an expedited assessment for bariatric surgery, or those who have a BMI of 30 – 34.9 who are considered for an assessment for bariatric surgery should be receiving or receive assessment within a tier 3 service. To address the issue you raise regarding a supportive environment
Dietitians in Obesity Management UK	37	Full	50	11 to 14	We agree that at least annual review of nutritional status is needed after discharge from the bariatric service. We would like clarification about who should be carrying this out, and a recognition of the likely resource implications for primary care dietetic services.	Thank you. The recommendation states that this annual monitoring should be part of a shared care model of chronic disease management which the GDG felt should be a collaboration between tier 3 services, where available, and primary care. As a result, recommendation 113 has not been amended, but the 'recommendations and link to evidence' section (8.2.3 of the full guideline) has been amended to be clearer about this and the specific nature of shared care models and protocols in these circumstances.
Dietitians in Obesity Management UK	38	Full	51	15	We would like 'meal replacement options' changed to 'diet replacement options' to avoid confusion between VLCD and meal replacement approaches.	Thank you for your comment. 'Meal replacement options' have been amended to 'total diet replacement' (please refer to page 53 of the full guideline).
Dietitians in Obesity Management UK	39	Full	51	30	We welcome the change in definition of VLCE from the previous guidance. However we note that a definition of ≤800kcals/day is still not strictly in line with SCOOP and Codex definitions (450-800kcals/day). We would like this amended.	Thank you for your comments. Codex and Scoop guidance informed the definition of VLCDs. This review was inclusive of all studies which have included VLCDs 800 kcal or less. Studies that included diets marginally less than 450 kcals were

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						included. The GDG considered it important to note that diets less than 800kcal, were carried out under clinical supervision and have amended recommendation 66 to make this clear (see recommendation 66 of the full guideline).
Dietitians in Obesity Management UK	40	Full	52	34 to 36	We would like 'long-term' added to the review question and subquestions.	Thank you for your comment. We are unable to amend the clinical question as you suggest however we specifically required a study duration of 1 year to assess long-term maintenance of weight loss. The relevant evidence is discussed in section 6.2.13.
Dietitians in Obesity Management UK	41	Full	52	38	We would like the definition of 450-800kcals/day used.	Thank you for your comments. The Codex and Scoop guidance informed the definition of VLCDs. This review was inclusive of all studies which have included VLCDs 800 kcal or less. Studies that included diets marginally less than 450 kcals were included. The GDG did not wish to define a lower limit but considered it important to note that diets less than 800kcal, were carried out under clinical supervision and have amended a recommendation to make this clear (see recommendation 66 of the full guideline).
Dietitians in Obesity Management UK	42	Full	53	10	We note that a diet providing 400kcals/day is not strictly a VLCD, but an even more restrictive diet.	Thank you for your comments. The Codex and Scoop guidance informed the definition of VLCDs. This review was inclusive of all studies which have included VLCDs 800 kcal or less. Studies that included diets marginally less than 450 kcals were included. The GDG did not wish to define a lower limit for the evidence review but considered it important to note that diets less than 800kcal, were carried out under clinical supervision and have amended their recommendation to make this clear

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						(see recommendation 66 of the full guideline).
Dietitians in Obesity Management UK	43	Full	54 to 62		We note that many of the studies included used diets even more restrictive than VLCD, and which are not strictly speaking VLCD.	Thank you for your comments. The Codex and Scoop guidance informed the definition of VLCDs. This review was inclusive of all studies which have included VLCDs 800 kcal or less. Studies that included diets marginally less than 450 kcals were included. The GDG did not wish to define a lower limit. The GDG considered it important to note that diets less than 800kcal, were carried out under clinical supervision and have amended their recommendation to make this clear (see recommendation 66 of the full guideline).
Dietitians in Obesity Management UK	44	Full	65	7	We note the assumptions made about follow up visits to the dietitian, both in terms of numbers and length of appointments. We feel it is unlikely in most cases that this level of follow up will be available with existing resources.	Thank you for your comment. This costing exercise was undertaken with individuals who operate NHS run VLCD services and this level of care is currently being implemented in some services across the country. The GDG felt that from an NHS perspective, this level of follow-up is important to ensure re-introduction of food is done properly to ensure the safety and efficacy of the VLCD.
Dietitians in Obesity Management UK	45	Full	71	4	We note that a diet providing 400kcals/day is not strictly a VLCD, but an even more restrictive diet.	Thank you for your comments. Codex and Scoop guidance informed the definition of VLCDs. This review was inclusive of all studies which have included VLCDs 800 kcal or less. Studies that included diets marginally less than 450 kcals were included. The GDG considered it important to note that diets less than 600kcal, were carried out under clinical supervision and have amended a recommendation to make this clear (see recommendation 66 of the full guideline).

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Dietitians in Obesity Management UK	46	Full	71	14	We note that a diet providing 400kcals/day is not strictly a VLCD, but an even more restrictive diet.	Thank you for your comments. Codex and Scoop guidance informed the definition of VLCDs. This review was inclusive of all studies which have included VLCDs 800 kcal or less. Studies that included diets marginally less than 450 kcals were included. The GDG considered it important to note that diets less than 600kcal, were carried out under clinical supervision and have amended a recommendation to make this clear (see recommendation 66 of the full guideline).
Dietitians in Obesity Management UK	47	Full	73 to 76	General	We note that many of the studies included had dietary intakes that fell below 450kcals/day and therefore outside of the strict definition of VLCD.	Thank you for your comments. Codex and Scoop guidance informed the definition of VLCDs. This review was inclusive of all studies which have included VLCDs 800 kcal or less. Studies that included diets marginally less than 450 kcals were included. The GDG did not wish to define a lower limit for this review but considered it important to note that diets less than 600kcal, were carried out under clinical supervision and have amended their recommendation to make this clear (see recommendation 66 of the full guideline).
Dietitians in Obesity Management UK	48	Full	77	23	We would like the definition of 450-800kcals/day used.	Thank you for your comments. The Codex and Scoop guidance informed the definition of VLCDs. This review was inclusive of all studies which have included VLCDs 800 kcal or less. Studies that included diets marginally less than 450 kcals were included. The GDG did not wish to define a lower limit but considered it important to note that diets less than 800kcal, were carried out under clinical supervision and have amended a recommendation to make this clear (see recommendation 66 of the

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						full guideline).
Dietitians in Obesity Management UK	49	Full	80 to 89		We note that some of the studies included had dietary intakes that fell below 450kcals/day and therefore outside of the strict definition of VLCD.	Thank you for your comments. Codex and Scoop guidance informed the definition of VLCDs. This review was inclusive of all studies which have included VLCDs 800 kcal or less. Studies that included diets marginally less than 450 kcals were included. The GDG did not wish to define a lower limit for this review but considered it important to note that diets less than 600kcal, were carried out under clinical supervision and have amended their recommendation to make this clear (see recommendation 66 of the full guideline).
Dietitians in Obesity Management UK	50	Full	94	Point 66	We would like clarification of the evidence for limiting VLCD use to 12 weeks continuous or intermittent use.	Thank you for your comment. This guideline is an update of the systematic review conducted as part of CG 43, which noted the 12-week limit use of VLCDs, primarily out of safety concerns; and which considered both continuous or intermittent VLCD diets. The review for this update focused on a time frame outlined by CG43 but one which was also recognised in clinical practice and reflected what was used in the studies. It is the view of the GDG, based on clinical studies, that the greater the energy deficit and the longer the period of time, the greater the loss of lean body mass. The GDG note that there is concern that weight loss is not too rapid (i.e. likely to result in excess loss of lean body mass and increase risk of gallstones) and that it is important to manage safely.
Dietitians in Obesity	51	Full	94	Point 66	We would like clarification of what is meant by 'rapid weight loss' We also feel that more than	Thank you for your comments. The GDG define 'rapid weight loss' as greater than that which can be

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Management UK					two examples of such conditions such be given, including the potential need for rapid weight loss pre-bariatric surgery.	achieved with dietary and lifestyle changes. The GDG considered your comment but did not wish to make further additions of examples to the recommendation. They feel that they have noted examples were appropriate and sufficient to reflect the intention of the specific circumstances where VLCD use may be appropriate. For example, those with a specific weight loss target that must achieved before they can proceed with treatment (IVF, orthopaedic surgery, etc.). The list provided is suggestive and not exhaustive. The GDG noted that people are not required to lose weight rapidly prior to bariatric surgery; however they may need to follow a short term liver shrinking diet prior to surgery. The GDG note that there is concern that weight loss is not too rapid (i.e. likely to result in excess loss of lean body mass and increase risk of gallstones) and that it is important to manage safely. The usual recommendation is 0.5-1kg/week (i.e. 0.5-1% for a 100kg person). Weight loss may be more rapid in the first couple of weeks due to fluid loss. The GDG note that the maximum, safe, recommended without losing significant lean mass is approximately 1.5% per week, noting that the maximum weight loss per week required to not exceed this needs to be recalculated as weight is lost. The most successful VLCD trials achieve a total weight loss of 8-12% over 12 weeks which is in keeping with a 1% per week loss.
Faculty of Sport and Exercise Medicine	1	General	General	General	I have no specific comments (ie. none that could be backed up by quality published studies) to feedback to NICE	Thank you for your comment.

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Howard Foundation Research	1	Full	16	10	Although a clear framework was developed for the literature search process, the quality of the papers chosen from the vast medical and scientific literature available was biased by the requirement for placebo control double blinding which is not possible for VLCD.	Thank you for your comment. At the start of the guideline development process the GDG prioritised their clinical questions on VLCDs and developed specific protocols for the question and search strategy. The VLCDs were not compared to a placebo control but to LCDs or deficit diets. In the methodology chapter (Section 3.4) we explain in detail how each outcome may be downgraded dependant on risk of bias, inconsistency, imprecision or indirectness. Blinding is only one aspect of risk of bias and outcomes can be downgraded for other risk of biases including selection bias, incomplete outcome, outcome reporting and measurement bias.
Howard Foundation Research	2	Full	General	General	While the report refers to use of VLCD exclusively in the NHS, there is a strong implication that the negativity extends to the private sector which is unjustified. There is more than 30 years experience with documentation with UK VLCD services run by healthcare professionals providing evidence of safety, efficacy and medical benefit.	Thank you for your comment. It is the remit of NICE guidelines to provide recommendations on best practice within settings where NHS care is provided or commissioned. We have highlighted in the 'Linking evidence to recommendations section' of the full guideline (see page 99) that it is outside the remit of the guideline to consider issues related to use of VLCDs purchased by the individual. It is the role of NICE clinical guidelines to provide evidence based guidance for the NHS not the commercial sector.
Howard Foundation Research	3	Full	44	17	This is an excathedra proclamation that is totally without justification, even for the NHS and in the light of this statement being used out of context, the implication is very damaging to the current patients in pharmacy and private sector programmes..	Thank you for your comment. We disagree that this recommendation has been made without justification. Please refer to chapter 6 of the full guideline for further detail of the evidence considered to support this recommendation. The role of the NICE clinical guidelines programme is to

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						provide clear evidence based guidance for the NHS.
Howard Foundation Research	4	Full	44	20 to 24	This may be a consideration for the NHS, however, it should not be allowed to impact through misinterpretation, on the already successful GP and pharmacy programmes providing significant health and quality of life benefits to patients long term.	Thank you for your comment. This guideline focuses on NHS funded VLCDs as individuals still have the option to self- fund a VLCD if they so choose. The role of the NICE clinical guidelines programme is to provide clear evidence based guidance for the NHS only.
Howard Foundation Research	5	Full	44	31 to 33	A published meta-audit of weight maintenance after VLCD by Anderson (Ref) demonstrated that weight loss was considerably greater with VLCD than standard low calorie dieting and that after 5 years, the maintained weight losses of VLCD subjects was greater than the INITIAL weight loss by conventional dieting. We strongly agree that the re-introduction of food be discussed with the patients and indeed this is a required part of many commercial programmes which is why there is good maintenance data documented after VLCD and transfer to a normal healthy diet.	Thank you for your comments. You have provided an incomplete citation, however, we presume this is referring to: Anderson JW, Konz EC, Frederich RC, Wood CL. Long-term weight-loss maintenance: a meta-analysis of US studies. American Journal of Clinical Nutrition. 2001; 74(5):579-584. This systematic review was excluded from the VLCD effectiveness review due to inadequate quality assessment and inadequate/unclear methods. Please refer to the excluded clinical studies table in Appendix J. We are pleased to hear you agree with our recommendation related to re-introduction of food.
Howard Foundation Research	6	Full	49	31 to 34	The Journal report from JAMA Surgery 148 no 6,June 2013 found over 6 years post surgery that the financial justification for bariatric surgery is not valid. VLCD and bariatric surgery can produce comparable weight losses and impact on weight co-morbidities and the costs and risks of surgery far exceed that of VLCD treatment, however, either treatment is valid for type 2	Thank you for your comment. The journal report was not included as it did not meet our inclusion criteria (it was not a full economic evaluation and it was not on the correct population of interest to the review). The economic review undertaken for bariatric surgery in individuals with early-onset type-2 diabetes found four studies which all demonstrated that bariatric surgery for these individuals was cost-

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					diabetes.	effective with ICERs far below £20,000 per QALY. On the other hand, no economic studies were included which looked at the cost-effectiveness of VLCDs and a threshold analysis showed that a VLCD is unlikely to be cost-effective due to poor clinical outcomes as shown in the clinical review in chapter 6 of the guideline.
Howard Foundation Research	7	Full	52	15	Meal replacements are a separate category from total food replacements and are not VLCD	Thank you for your comment. 'Meal replacement options' has been amended to 'total diet replacement' (please refer to page 53 of the full guideline).
Howard Foundation Research	8	Full	52	21 to 23	Considerable data is available, but since it is impossible to conduct a placebo controlled double blind protocol, this data has been ignored. A good starting point should have been the published scientific report prepared on behalf of the European Scoop Report REPORTS ON TASKS FOR SCIENTIFIC COOPERATION (SCOOP) TASK 7.3 – COLLECTION OF DATA ON PRODUCTS INTENDED FOR USE IN VERY-LOW-CALORIE DIETS. REPORT SEPTEMBER 2002	Thank you for your comment. At the start of the guideline development process the GDG prioritised their questions on VLCD and developed specific protocols for the question and search strategy to answer their specific questions. We searched for studies comparing VLCDs to standard dietary advice which included LCDs or 500-800 deficit diets.
Howard Foundation Research	9	Full	53	17	In real life there is no end to maintenance period. There is, however considerable data from pharmacy based VLCD programmes where weight maintenance results are available for extended, but necessarily variable periods.	Thank you for your comment. The GDG recognise your statement and consider weight loss management as a life long journey.
Howard Foundation Research	10	Full	63	10	It may well incur some additional costs for VLCD in NHS treatment, however massive savings could be made by using healthcare professionals	Thank you for your comment. This guideline focuses on NHS funded VLCDs as the individual will still have the option to fund a VLCD if they so choose.

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					in pharmacy which are privately funded programmes. The pharmacist based VLCD programme only asks a diabetic patient's GP to authorise suspension of diabetic medication. The reason for this is that blood glucose will normalise within a very few days and continued medication can cause problems. If the patient succeeds in losing some weight, the diabetes will usually remain in remission, despite some weight regain if it occurs. The cost of a GP's agreement is small. All monitoring of the patient is done by the pharmacist. The savings on the medication costs more than compensates for any NHS involvement.	The GDG noted however that the NHS could incur a cost even for these types of VLCDs. If the individual is not already monitoring their blood glucose they may need to be provided with equipment and prescribed glucose testing strips. The individual may well phone their GP or practice nurse for advice. The impact on the GP practice is currenktly unknown. The GDG noted that concerning diabetics this is not a risk free undertaking and close medical supervision is essential for insulin-treated patients at least beyond that provided by a pharmacist.
Howard Foundation Research	11	Full	63	20	The pharmacist is a qualified healthcare professional and is competent to carry out an assessment of suitability of the patient for use of VLCD. The assistance of a GP is not required and therefore no cost to the NHS	Thank you for your comment. This guideline focuses on NHS funded VLCDs as the individual will still have the option to fund a VLCD if they so choose. The GDG noted however that the NHS could incur a cost even for these types of VLCDs. The impact on the GP practice is currently unknown however the GDG noted that many commercial providers require a GP assessment before providing the diet. This is further discussed in section on commercially run VLCDs on page 68 of the full guideline
Howard Foundation Research	12	Full	65	3	Follow up is provided by the pharmacy for extended periods at no cost to either the patient or the NHS.	Thank you for your comment. This guideline focuses on NHS funded VLCDs as any individual has the option to fund a VLCD if they so choose. The GDG noted however that the NHS could incur a cost even for these types of VLCDs. For example, in the case of people undertaking a VLCD with a complex condition such as diabetes. If the individual is not

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						already monitoring their blood glucose they may need to be provided with equipment and prescribed glucose testing strips. The individual may well phone their GP or practice nurse for advice. Therefore even non-NHS funded interventions may have an impact on the NHS costs.
Howard Foundation Research	13	Full	65	8	These costs may apply to the NHS, but there are private sector programmes with knowledgeable personnel as well as healthcare professionals in the pharmacy sector. These are long standing and well run programmes that do not incur these additional costs.	Thank you for your comment. This guideline mainly concerns itself with NHS run VLCD programmes. Some consideration was given to private sector schemes and although the NHS does not pay for them, the NHS would still incur some costs with regards to any adverse effects that arise from VLCDs as well as providing support for those with co-morbidities, such as T2D. For example, in the case of an individual undertaking a VLCD with a complex condition such as diabetes, If the individual is not already monitoring their blood glucose they may need to be provided with equipment and prescribed glucose testing strips. The individual may well also phone their GP or practice nurse for advice.
Howard Foundation Research	14	Full	66	8	A high percentage of patients being treated in pharmacy VLCD programmes are above BMI 40 at start. Tier 3 costs can be saved.	Thank you for your comment the contents of which have been noted. This guideline focuses on NHS funded VLCDs even though it is noted that individuals will still have the option to fund a VLCD if they so choose. The GDG noted however that the NHS could incur a cost even for provision of VLCDs in these circumstances. If the individual is not already monitoring their blood glucose they may need to be provided with equipment and prescribed glucose testing strips. The individual may well phone their GP or practice nurse for advice. Therefore even non-NHS funded

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						interventions may have an impact on the GP practice.
Howard Foundation Research	15	Full	68	16 to 21	Some commercially run VLCD programmes require medical assessments before and during the diet, however, pharmacy based VLCD services use healthcare professionals. The pharmacist is providing the complete service with only medical intervention for co-morbidities such as diabetes. In our 30 years experience with VLCD there have never been any adverse effects arising from undertaking a VLCD which required GP involvement. Minor discomforts are easily dealt with by the healthcare professionals in the pharmacy.	Thank you for your comment. This guideline focuses on NHS funded VLCDs as the individual will still have the option to fund a VLCD if they so choose. The GDG noted however that the NHS could incur a cost even for these type of VLCDs. For example, in the case of people undertaking a VLCD with a complex condition such as diabetes, if the individual is not already monitoring their blood glucose they may need to be provided with equipment and prescribed glucose testing strips. The individual may well phone their GP or practice nurse for advice. Therefore even non-NHS funded interventions may have an impact on the GP practice
Howard Foundation Research	16	Full	70	10	Due to the low quality of the evidence, this may have been indicated, however, in fact this is absolutely incorrect. The differences are well documented in the very extensive literature which was not considered by the GDG.	Thank you for your comment. At the start of the guideline development process and with their clinical expertise, the GDG prioritised the focus of the review question and the outcomes which they considered to be most critical and important to decision making related to VLCDs. Evidence statements were subsequently developed I line with the methods outlined in Chapter 3 of the full guideline.. The clinical evidence review, which identified all studies meeting the inclusion criteria set out in the review protocol, found that very low to low quality evidence suggested that there may be no clinical difference between VLCD and standard dietary advice in percentage ideal weight loss, withdrawals, weight in BMI change from start of study to end of weight maintenance period and weight change in kg from start of study to end of weight maintenance

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						period.
Howard Foundation Research	17	Full	72	4	It is well documented that the incidence of gallstones (usually high in obese people) is not overly present in UK or European VLCD experience (see research published for the EU SCOOP report) The excessive gallstone was an early American version of Optifast that was totally fat free. Once corrected, there has been no further problem. Constipation is generally not a problem with proper instruction for the patient.	Thank you for your comment. The GDG discussed what may be considered as adverse events and felt that the development of gallstones was an important adverse event to consider, from a patient perspective. However, we have amended the 'Recommendations and link to evidence section' of the full guideline (6.2.13) to reflect your comment.
Howard Foundation Research	18	Full	77	5-16	The 7 papers reviewed as declared were low to very low quality. All of the issues identified here can be answered by reference to better literature on the individual topics.	Thank you for your comment. The GDG prioritised an approach to examine RCT level evidence and as such have made recommendations on this gold standard level of evidence.
Howard Foundation Research	19	Full	94	65	This statement may be considered for NHS led programmes, however the data reviewed was very poor. This is absolutely not the case for privately run programmes and those in the pharmacy sector with healthcare professionals. Caution is needed about misleading representation to the public and General Practice limiting a valuable choice for patients.	Thank you for your comment. As highlighted in the scope of the guideline (see Appendix A), NICE guidelines provide recommendations only for use within NHS settings, or settings in which NHS care is commissioned. As such, it is outside the remit of the guideline to provide recommendations on the use of very-low-calorie diets purchased by the individual. This is highlighted in the 'Linking evidence to recommendations' section on page 100. It is the role of NICE clinical guidelines to provide evidence based guidance for the NHS not the commercial sector.
Howard Foundation	20	Full	94	67	See the report by Anderson – Meta-analysis of 27 papers showing that VLCD results in	Thank you for your comments

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Research					considerably more weight loss than standard diets and at 5 years the weight loss by VLCD is still greater than the INITIAL weight loss by traditional diets. Anderson et al. Am J Clin Nutr, 2001,74,579-584	Please note that this is an Incomplete citation however we presume this is referring to: Anderson JW, Konz EC, Frederich RC, Wood CL. Long-term weight-loss maintenance: a meta-analysis of US studies. American Journal of Clinical Nutrition. 2001; 74(5):579-584. This systematic review was excluded from the VLCD effectiveness review due to inadequate quality assessment and inadequate/unclear methods. Please refer to the excluded clinical studies table in Appendix J.
Howard Foundation Research	21	Full	General	General	The section from pages 94 to 101 on VLCD contains conclusions and opinions of the GDG based on very poor literature and are not supported by better evidence. A thorough scientific review on VLCD was published by the European SCOOP committee which clearly addresses all of these topics discussed within these pages and should not be ignored. The scientific report can be sent upon request.	Thank you for your comment. At the start of the guideline development process the GDG prioritised their questions on VLCD and developed specific protocols for the question and search strategy. We searched for RCTs or systematic reviews of RCTs for the 3 questions on VLCDs that were appropriate for the questions defined by the GDG. RCTs are considered the highest quality evidence for intervention reviews and the list of excluded studies with reasons for exclusion are listed in Appendix J. Thank you for highlighting the SCOOP report. Although, it is an interesting and thorough report it is a review of the literature rather than a systematic review of relevant RCTs and did not meet our inclusion criteria for these review questions protocols. Please see Appendix A for further information on the protocols.
Howard Foundation Research	22	Full	General	General	It was inappropriate to have released the draft report to the media for a number of important reasons. The stakeholders had not reached the	Thank you for your comment. We are uncertain of the process you define in your comment. As per the NICE Guidelines manual 2012 all draft NICE

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					end of the submission period, many of the recommendations were based upon extremely outdated conceptions, highly biased in favour of unsupported opinions and did not make it clear that the major contributions of the private sector were being ignored.	guidelines are available via the NICE website for the period of consultation and are available to stakeholders, the public and the media alike. The recommendations in the guideline have been developed by a multidisciplinary group of healthcare professionals and patient members who have been presented with best available evidence and have interpreted this evidence. Comments from registered stakeholder organisations only, which include those commercial and private organisations who are registered as stakeholders, are gathered during consultation on the guideline and all comments are considered equally by the Guideline Development Group prior to publication. We reject your assertion that our recommendations are unsupported by evidence. It is the role of NICE clinical guidelines to provide evidence based guidance for the NHS not the commercial sector.
Howard Foundation Research	23	Full	General	General	The section on bariatric surgery contains conclusions and opinions of the GDG based on very poor literature and are not supported by better evidence. It would be especially important for the GDG to consider the relevant paper "Impact of Bariatric Surgery on Health Care Costs of Obese Persons, Weiner et al, JAMA SURG/VOL 148 (NO 6) June 2013 pp555-562 including the invited critique at the end of the article. Also extremely critical for the GDG is to be aware of the paper Substance Use Following Bariatric	Thank you for your comments. This guideline is an update of CG 43 which will be limited to the topics where new evidence may change recommendations. We have reviewed the evidence around the clinical and cost-effectiveness of bariatric surgery for the management of recent onset type 2 diabetes in obese people. At the start of the guideline development process the GDG developed a specific protocol for this question and search strategy. We searched for RCTs or systematic reviews of RCTs for the question appropriate for the question defined by the GDG.

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					Weight Loss Surgery, Comason et al. JAMA SURG/VOL 148 (NO 2) Feb 2013 pp145-150	Thank you for bringing our attention to the references for the two papers mentioned. The Conason and the Weiner papers do not meet our inclusion criteria for this question. Neither study includes people with recent onset type 2 diabetes who are overweight or obese. Please see the protocol in Appendix A for further information.
HQT Diagnostics	1	Full	General	General	**Test and supplement Vitamin D to be above 100 nmol/L** There is evidence that this has 3 benefits for the severely obese: • Rebalances the appetite hormone Leptin • Makes exercise easier by improving muscle strength • Reduces bone pain & osteomalacia Source: Vitamin D Solution, by Michael Holick, P21-22 Source: www.vitamindwiki.com/Overview+Obesity+and+Vitamin+D	Thank you for your comment. It was outside the scope of the guideline update to consider vitamin D in the management of overweight and obesity. We are therefore unable to make comment on this issue.
HQT Diagnostics	2	Full	General	General	**Test and supplement Fatty Acids (Omega-3)** There is evidence that this: • Suppresses appetite • Improves circulation • Facilitates nutrient delivery to skeletal muscle • Changes gene expression to create leaner tissue • Enhances fat oxidation • Enhances energy expenditure • Reduces fat deposition	Thank you for your comment. It was outside the scope of the guideline update to consider omega-3s in the management of overweight and obesity. We are therefore unable to make comment on this issue.

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					Source: www.expertomega3.com/omega-3-study.asp?id=2#2.2.	
Johnson & Johnson Medical, Ltd	2	Full	39	15	We note the GDG's recommendation to consider referral to tier 3 services. Given the low and variable provision of tier 3 services within and across local health economies in England, we believe there to be a significant risk of exacerbating an already extant barrier to treatment for willing and eligible patients. Moreover, we would advocate for further research to be considered as to the clinical- and cost-effectiveness of delaying surgery for an additional two-years while patients are required to engage with tier 3 services. It is widely documented in the clinical and health economic literature that early intervention confers substantial benefits to patients, providers, payers, and society as a whole. This comes in the way of improved patient outcomes, as well as the prevention of downstream costs (here, we refer to two examples that appear within the Guideline: reductions in joint pain and urinary problems). We would also like to highlight the relevance of the GDG's recommendation to refer to tier 3 services from an equity perspective. In this regard, we note the Guideline's reference to the 2013 Royal College of Physician's report, *Action on Obesity*. It is our view that CG43 ought to be aligned with the RCP's findings, and as such, endeavour to ameliorate inequities in access to	Thank you for your comment. Recommendation 30 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment. We note your comments about the availability of services and the barriers imposed by lack of universal availability of tier 3 services in particular. However, NICE guideline recommendations are aspirational and can be considered as levers to influence change. We recognise the challenges in the provision of tier 3 services but are unable to comment further on this issue.

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					surgery. Given the present landscape and the challenges associated with tier 3 services, Johnson & Johnson wish to express significant concern as to the viability of the recommendations given the noted blockages in the patient pathway. For example, the RCP report features recent research by the Office of Health Economics (2010) which highlights a conservative estimate of 140,000 willing, eligible patients for bariatric surgery. An alternative estimate published in the NHS England Clinical Commissioning Policy on Complex and Specialised Obesity Surgery suggests a figure of 257,000 (based upon the NICE algorithm). However, HES data figures for both years indicate a total of 8,982 and < 9000 patients admitted for treatment, respectively. We commend the GDG for putting forth a guideline that begins to address this disparity by prioritising the unmet need of a subset of the T2D population, and hope that it will aid in catalysing a more coordinated metabolic strategy at the local and National levels. Such a paradigm shift is required if variations in provision are expected to be normalised at a meaningful scale, and if the Service is seen to be upholding the principles set out in the NHS Constitution.	
Johnson & Johnson Medical, Ltd	3	Full	41	24	We support the GDG's statement around ensuring adequate time for patient/Consultant interaction during a critical period in the patient pathway. We believe further clarification vis-à-vis	Thank you for your comment. Recommendation 45 has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for

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					'adequate' would be helpful from a systems/planning perspective. For example, would a double appointment offer the patient/Consultant a more appropriate opportunity to engage and ensure continuity with the next step in the pathway?	details). Therefore, we have been unable to amend the recommendation in line with your comment.
Johnson & Johnson Medical, Ltd	4	Full	47	17	We wish to reiterate our commentary from #2 above. Johnson & Johnson are concerned that the fragmented tier 3 landscape will hinder the successful provision of surgical intervention as recommended in Section 5.12. As put forward by the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), both National and local authorities need to consider the resources necessary to make provision for clinically- and cost-effective surgery. In the current context, this applies to tier 3 services, and, in our view, is the linchpin of ensuring a viable patient pathway**.** As stated above, we would advocate for further research in order to better understand the cost-effectiveness of the tier 3 services.	Thank you for your comment. It was outside the remit of the guideline to develop research recommendations on areas where we have not considered the evidence. Although we have conducted a review of the clinical and cost-effectiveness of the role of bariatric surgery for the management of recent onset type 2 diabetes, we have not updated the recommendation from 2006 to which you refer. It is beyond the remit of this update to consider the cost-effectiveness of the service model for obesity. We recognise the challenges in the provision of tier 3 services but are unable to comment further on this issue.
Johnson & Johnson Medical, Ltd	5	Full	115	109	We acknowledge the recommendations regarding *offering* and *considering* assessments, and also understand the rationale in differentiating the terminology based upon the available evidence base at the time of review. However, we would welcome further clarification from the GDG as to the ownership and accountability of carrying out the recommended assessments. It is the Johnson & Johnson view	Thank you. The evidence review conducted aimed to identify the clinical and cost-effectiveness of bariatric surgery as a management option for the treatment of type 2 diabetes in people who are also obese or overweight. We did not look at the components of the multidisciplinary team and are therefore unable to include any professional groups in the detail of our recommendations. The GDG discussion in this area suggests that such

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					that Clinical Guidelines are a critical component of informing evidence-based practice. In order to ensure the Guideline is translated into clinical practice, and indeed, the Service is ready and able to coalesce to realise the clinical and economic benefits of surgical intervention among the defined T2D population, we believe that further guidance is required as to the responsible individuals, groups, and organisations who are expected to deliver implementation of the Guideline. We would therefore call for a comprehensive strategy from NHS England aimed at not only supporting implementation of CG43, but also integration across tiers 1-4, and critically, providing clarity of pathway. The latter is borne out of a recognition that the dual pathway approach will require clinicians to have a clear understanding of the treatment 'algorithm' for patients in both cohorts. That is, those with diabetic endpoints (with BMI as a secondary indicator) *and* those with BMI endpoints *alone*. Such a clear strategy is necessary in order to ensure that neither pathway is compromised as a result of the other. Ultimately, this will act as a preventative measure to further inequity in access. Taking a longer term view, and prior to undertaking the next review of CG43, Johnson & Johnson would advocate for undertaking an impact assessment of the Guideline in order to understand the extent to which the recommendations have been adopted by the	assessments would be best delivered by a collaborative approach between tier 3 and tier 4 services. Once NICE has published clinical guidance, health professional and the organisations that employ them are expected to take it fully into account when deciding what treatments to give people.

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					named individuals, groups, and organisations. One such example would entail the use of HES data to understand the proportion of patients with a T2D diagnosis (with index following publication of CG43) subsequently receiving surgical intervention in accordance with CG43.	
Johnson & Johnson Medical, Ltd	6	Full	50	25	In the context of further research regarding long-term outcomes of bariatric surgery on individuals with T2D, Johnson & Johnson would like to highlight recent findings from the Swedish Obese Subjects (SOS) study, which demonstrates the positive impact of bariatric surgery on reductions in complications of microvascular and macrovascular diabetes at 18-year follow-up. While it is recommended that these findings be validated by undertaking RCTs, we would kindly refer the GDG to this seminal piece of research for a longitudinal view of the holistic value of surgical intervention.	Thank you for your comment. The GDG was aware of this observational study. This existing research and the need for RCTs in this area is highlighted in Appendix L which goes into more detail about the research recommendations.
Johnson & Johnson Medical, Ltd.	1	Full	36	6	We are encouraged by the GDG's recommendation to consider using supplemental measures to determine if a patient is overweight or obese. We agree that BMI is a crude measure when used in isolation, and as such, believe that it ought to be used together with additional, more robust clinical measures in order to assess adiposity in adults. Recent research from Busetto and colleagues (2014) further supports this stance, arguing that visceral fat accumulation and the presence of ectopic fat deposition in relevant organs are more accurate predictors of risk.	Thank you for your comment.

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Lifeblood: The Thrombosis Charity	1	Full	50	General	May we suggest that the increased risk of VTE in obesity, and especially post bariatric surgery, is mentioned in section 5.14 where monitoring is discussed?	Thank you for your comments. The GDG acknowledge the risk of VTE in surgery. However, it was felt that this was suitably covered by recommendation 100 which says that the surgery for obesity should be undertaken by a multidisciplinary team that can provide both preoperative assessment with risk-benefit analysis (including preventing complications), and regular postoperative assessment including surgical follow-up.
Luton & Dunstable Hospital (& Tower Hamlets weight Management Service)	1	Full	48	29	To state more clearly what is meant by 'psychological support' (particularly post operative issues can be complex and require specialist 'psychological intervention'.	Thank you for your comment. Recommendation 100 was not updated as part of the current guideline update. Therefore, we have not been able to amend the recommendation in line with your comment.
Luton & Dunstable Hospital (& Tower Hamlets weight Management Service	2	Full	48	39	To clarify, what constitutes 'failure of the original operation'. Is this mechanical/medical problem that then requires revisional surgery. Or does failure mean less weight loss than 50%excess body weight? In which case should we not ask why? Or is failure that requires a further bariatric surgery due to lack of implementation of lifestyle behaviour change. Really important issue that requires clarity.	Thank you for your comment. Recommendation 102 was not updated as part of the current guideline update. Therefore, we are not able to comment further on this issue.
NHS Barking & Dagenham CCG	1	NICE	36	750 to 757	This statement is taken directly from the licence and is far too simple if left unqualified a number of people will be treated unnecessarily. NICE should also comment on treatment of people who are muscular and are not necessarily fat and	Thank you for your comment. Recommendation 1.9.11 has not been updated as part of the current guideline update and have been amended for clarity only (see Appendix Q of the full guideline for details) and to reflect changes in the marketing authorisation

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					patients who have a high BMI and low waist circumference as in section 1.2.9 (or even refer to it) because these patients are not high risk compared to patients who have a high BMI and are fat.	for orlistat. Recommendation 1.2.9 has not been updated as part of the current guideline update and it was outside the scope of the original guideline and the current update to consider people who have a high BMI who are considered muscular, as well as those who have a high BMI and a low waist circumference.
NHS Barking & Dagenham CCG	2	NICE	36	761	Since Sibutramine has been suspended, there are no other drugs so perhaps this statement is obsolete if there are no new weight loss drugs anticipated in the near future. Or add in brackets or footnote wording to the effect that at the time of publication there were no other drugs on the market but is a relevant statement should any new drugs arise.	Thank you for your comment. Recommendation 1.8.1 has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
NHS England	1	Full	38	40	Liver disease must be mentioned as a specific comorbidity to be assessed – as over 30% of obese patients will have fatty liver disease and some may have more progressive liver disease	Thank you for your comment. Recommendation 23 was not updated as part of the current guideline update. Therefore, we have not amended the recommendation in line with your comment. However, recommendations on the assessment of non-alcoholic fatty liver disease will be included in the NICE clinical guideline 'Liver disease (non-alcoholic fatty)', due for publication in July 2016.
NHS England	1	NICE	42	894 to 898	In the full draft version, the evidence behind these bullet points is as follows: "There was only 1 study with a mean BMI of 30-35 kg/m2 and the GDG felt that this was not sufficient to support the routine use of bariatric surgery in this population. The GDG felt that bariatric surgery in this group should only be	Thank you for your comment. The GDG recognised the limited evidence available but felt that in some circumstances, this may be an appropriate treatment option and therefore chose to develop a recommendation using the most appropriate available wording for the evidence available (see page 117 for the 'recommendations and link to

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					considered in exceptional circumstances (for example, people with other obesity related issues or where diabetes is not being sufficiently managed with alternative measures such as diet, exercise and pharmacological treatments). Because, bariatric surgery may be of some benefit to some individuals, the GDG considered that it was important that healthcare professionals at least considered offering an assessment for individual patients with BMI less than 35 kg/m2 on a case-by-case basis and made a weaker recommendation in this regard reflecting the evidence considered." The concern here is that extending the possible BMI threshold down to 30 will increase the numbers with type 2 diabetes who could be potentially considered for bariatric surgery by around 900,000. In the main document, the evidence base for this is acknowledged to be poor, but the recommendations are likely to be taken quite literally, and there is a sense that once something is approved by NICE, it can be viewed as an entitlement. Of course at this point, there is not the capacity within the NHS to absorb the additional numbers or indeed the commissioning resources to create such capacity. Nor are there any clear indicators as to which individuals with recent onset type 2 diabetes with a BMI of 30–34.9 could gain benefit or how they may be selected. Is the word "consider" too strong, given the paucity of the evidence base currently? Do NICE have a word	evidence' section in 7.1.5 of the full guideline and page 10 of the NICE guideline which explains about the wording of recommendations). The GDG also noted that such high cost implications would only be realised if every candidate eligible for an assessment received an assessment and after an assessment all these candidates were referred for surgery. In reality, a considerable number of individuals who are deemed eligible for an assessment will not be suitable for surgery and therefore be declined, on top of this some individuals choose not to have the surgery. This will significantly reduce the cost implication.

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					to reflect a weaker category of evidence?	
NHS England	2	Full	39	22	Liver disease must be mentioned as a specific comorbidity to be assessed – as a significant proportion of obese patients will have fatty liver disease and some may have more progressive liver disease – this applies to children as well as adaults	Thank you for your comment. Recommendation 23 was not updated as part of the current guideline update. Therefore, we have not amended the recommendation in line with your comment. However, recommendations on the assessment of non-alcoholic fatty liver disease will be included in the NICE clinical guideline 'Liver disease (non-alcoholic fatty)', due for publication in July 2016.
NHS England	2	NICE	38	821 to 824	I foresee the potential for controversy here: do those with BMI more than 50 need to spend time in tier 3 services, a very clear requirement of the service specification produced by the NHS England specialised commissioning CRG, or does the on-going inclusion of this 2006 recommendation imply that individuals should be able to bypass tier 3 so that bariatric surgery can be first-line treatment? It would be useful if the lines of the CRG service specification could be backed up by the NICE guidelines so that tier 3 remains a requirement for all. This was one of the exemptions that we have discussed previously at the CRG, but it was felt by the CRG that tier 3 should still be a requirement for those with BMI more than 50.	Thank you for your comment. The recommendation to which you refer was made in 2006 and extant before the drafting of the commissioning CRG specification and as this has not been part of this update we are unable to comment or amend further. The GDG have provided further clarity in chapter 7 regarding the link between tiered services for those people with type 2 diabetes and the role of expediting bariatric surgery in this group.
Novo Nordisk	1	NICE	5	128	Duplication of word 'guideline'	Thank you for your comment, we have amended this line.
Novo Nordisk	2	NICE	42	889	We welcome the inclusion of the section on 'Bariatric Surgery for people with recent onset type 2 diabetes' as acknowledgement of the important implications of obesity in people with type 2 diabetes. And the associated benefits of	Thank you for your comment.

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					weight loss in this group of people.	
Obesity Action Campaign	1	NICE	42	894 to 898	Given that the current population prevalence of obesity in adults in the UK is at 30% and projected by the Government Foresight report to reach 50% by 2050, although it is accepted that this level will be reached much before then, the sheer cost to the NHS of "considering and offering Bariatric surgery to people (adults) with recent onset diabetes and with BMI over 30 and at lower BMI if of Asian origin" (line 894-898) will be prohibitive. Is this cost to be met centrally or to be met by the CCG's. If to be met by the CCG's the impact on other services will in all likelihood be negative. Even if met centrally, the impact on the overall NHS budget will be negative and will impact on other services.	Thank you for your comment. The economic evidence presented in this guideline was to determine whether bariatric surgery is a cost-effective intervention for individuals with early on-set T2D.The GDG members were very aware of the issues surrounding cost implication - these are issues that will be assessed by the NICE implementation and costing teams and this recommendation has already been selected for special consideration. It is worth noting that there will be considerable future cost savings in other areas such as the reduced need for diabetic medication and the avoided costs associated with diabetes and obesity related complications. These recommendations ensure that, when appropriate, bariatric surgery is conducted timely to ensure the maximum benefit is realised as the longer an individual has T2D the worse their outcomes after bariatric surgery. The GDG noted that such high cost implications would only be realised if every candidate eligible for an assessment received an assessment and after an assessment all these candidates were referred for surgery. In reality a considerable number of individuals who are deemed eligible for an assessment will not be suitable for surgery and therefore be declined, on top of this some individuals choose not to have the surgery. This will significantly reduce the cost implication.
Obesity Action Campaign	2	General	General	General	Irrespective of whether centrally funded or locally funded by CCG's this sends out the wrong public health message – basically it says "Don't worry	Thank you for your comment. The recommendations regarding bariatric surgery are part of a number of recommendations in this best practice advice on the

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					the State will pay for you to have surgery, you do not have to take any responsibility for your health, maintain your unhealthy ways". There should be a more aggressive public health approach to obesity and not this capitulating approach. The impact of this on children will also be negative. This capitulating approach was not the approach that was adopted neither with smoking nor with HIV. We should not adopt this approach now.	care of adults and children who are obese or overweight. The spectrum of recommendations relate to lifestyle interventions, measurement and assessment as well as surgery. Further NICE Public Health guidance makes recommendations around preventative strategies to minimise obesity. The evidence reviews conducted and recommendations made as part of this update have aimed to minimise adverse health consequences for people who are currently obese or overweight. We do not believe this is capitulation.
Obesity Action Campaign	3	Full	49	31 to 32	The BMI at which bariatric surgery should be offered should remain at 35 with co-morbidities.	Thank you for your comment. The guideline reviewed only the evidence relating to the effectiveness of bariatric surgery in people who have recent onset type 2 diabetes. The GDG chose to recommend that, given the benefits associated with weight loss and 'remission' of diabetes in this population, these individuals should be offered an expedited assessment for bariatric surgery at 35 or over. The GDG also felt that an assessment for bariatric surgery should be considered for those people with a BMI of 30 – 34.9 who have recent onset type 2 diabetes. Further details on how the GDG came to this decision can be found in the section 'Linking evidence to recommendations' on page 115. Recommendation 92 outlines criteria for people with obesity and other significant disease and this recommendation has not been updated as part of the current guideline update.
Public Health England	1	Full	36	15	Can a recommendation be given for whether body volume index (BVI) should or should not be	Thank you for your comment. Section 5.3 was not updated as part of the current guideline update and

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					used for adults and children?	has been amended for clarity only (see Appendix Q of the full guideline for details) and therefore did not consider the use of body volume index for measuring obesity. We are therefore unable to make further comment on this issue
Public Health England	2	Full	38	12 to 14	This statement is under the adults section, but also applied to children / child obesity. We suggest it is also included on page 39 around line 21 or 28 regarding willingness to change.	Thank you for your comment. Recommendation 28 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Public Health England	3	Full	39	37	Says "Consider referral to an appropriate specialist for children who are overweight or obese", but overweight and obese have not been defined (since only BMI centile thresholds for referral are now given in section 5.4.2)	Thank you for your comment. Recommendation 32 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Public Health England	4	Full	43	26	It would be helpful to quantify the amount of daily physical activity that children who are already overweight should be doing.	Thank you for your comment. Recommendation 55 was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Public Health England	5	Full	47	8	Adult BMI thresholds are used here, but this section also applies to children, so should appropriate child BMI centile thresholds be included?	Thank you for your comment. However, recommendations 84 – 90 apply to adults only.
Public Health England	6	Full	49	20-22	The "national core standards as defined in 'A Call to Action on Obesity in England'" are referred to a number of times in this document, but it is not clear from looking at the Call to Action what these standards are, as there is no reference to	Thank you for your comment. To avoid confusion, we have amended the relevant recommendations. Recommendation 5 now reads: Coordinate the care of children and young people

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					core standards in the Call to action itself. It would be helpful to refer to a specific section for easy access to the standards and to avoid confusion.	around their individual and family needs. Comply with the approaches outlined in A Call to Action on Obesity in England. Recommendation 106 now reads: Coordinate surgical care and follow up around the child or young person and their family's needs. Comply with the approaches outlined in A Call to Action on Obesity in England.
Public Health England	7	NICE	4	88	Fatty liver disease is reference on line 948 as a co-morbidity and we suggest it is additionally included here.	Thank you for your comment, this has been amended.
Public Health England	8	NICE	5	101	The National Obesity Observatory is now part of Public Health England, so please refer to 'the former National Obesity Observatory, now Public Health England's obesity knowledge and intelligence team'.	Thank you for your comment, this has been amended.
Public Health England	9	NICE	5	122 to 125	The wording of this section could be mis-interpreted. We suggest changing it to 'NHS England and Public Health England published a working group report on Joined up clinical pathways for obesity in March 2014. Comments from national and local stakeholder organisations were invited, principally concerning implementation at a local level and implications for delivery.' At this stage we are developing approaches to considering local implementation. We suggest deleting line 124/125.	Thank you for your comment. We have amended this section in line with your suggestion.
Public Health	10	NICE	5	130	National Obesity Observatory – comments as for	Thank you for your comment, this has been

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England					line 101	amended.
Public Health England	11	NICE	8	203 to 241	Does text need to be included around exploring patients 'readiness to change'?	Thank you. This section you have commented on is from a short version guideline which is based upon a standard NICE template / text. We note your comments related to 'readiness to change'. The full guidance provides detail behind the evidence considered in this update. We are unable to comment in more detail on the recommendations and their referral to 'readiness to change' in earlier versions of the guidance but we would note that the last bullet of recommendation 1.10.1 does state that in order to be considered for bariatric surgery, a person commits to the need for long-term follow-up which can be considered a component of needing to be ready to change.
Public Health England	12	NICE	42	899	It would be useful to clarify the difference between 'follow up care' and' line 920 'post-operative care'.	Thank you for your comment. We agree and we have amended the research recommendation to use consistent terminology.
Royal College of General Practitioners	1	Full	31	General	Patients sometimes attend very keen to try VLCD having tried other ways of losing weight unsuccessfully. Should doctors refuse to sanction them in these circumstances? Commercial meal replacements are also popular and useful for some patients; could these aspects be covered?	Thank you for your comment. The GDG were aware of the interest in the use of VLCDs and the frequent requests made to General Practitioners to support this method of losing weight. The GDG considered it important therefore to assess the added benefit of the use of VLCDs over and above usual care (other diets). The recommendations made indicate the circumstances in which VLCDs may be recommended. The GDG were keen to point out that in the comparisons reviewed, weight loss in people using a VLCD was not likely to be maintained. The use of commercial meal replacements were eligible for inclusion in the

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						review providing their calorific content was less than or equal to 800 kcal a day.
Royal College of General Practitioners	2	Full	36	5	Waist measurement is recognised as a useful tool in patients with a BMI under 35. Some clinicians may be uncertain about how to obtain an accurate waist measurement – is it worth clarifying here?	Thank you for your comment. Recommendation 12 clarifies that healthcare professionals may wish to consider the use of waist circumference in people with a BMI of less than 35 however, this recommendation was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we are unable to make further comment on this issue. Recommendations on the use of waist circumference in people from black, Asian and other minority ethnic groups can be found in NICE Public health guidance 46 'Assessing body mass index and waist circumference thresholds for intervening to prevent ill health and premature death among adults from black, Asian and other minority ethnic groups in the UK.'
Royal College of General Practitioners	3	Full	35	15	Bio impedance is sometimes used by personal trainers and gym instructors and patients can relate to it; could it not be considered as a useful motivational tool for tracking body composition in certain patients in the clinical setting?	Thank you for your comment. Recommendation 15 has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details).
Royal College of General Practitioners	4	Full	38	25	Weight loss is a way of managing co-morbidities and many patients opt to try a lifestyle change initially before resorting to medication or other treatments.	Thank you for your comment. Recommendation 25 was not updated as part of the current guideline update. Therefore, we have not amended the recommendation in line with your comment.
Royal College of General	5	Full	38	42	Good to clarify that lipids are ideally measured when fasting as sometimes there are conflicting	Thank you for your comment.

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Practitioners					opinions about this.	
Royal College of General Practitioners	6	Full	44	10	Low calorie and low fat diets are mentioned but there is no reference to reducing calories obtained from sugar. Given the large amounts of sugar consumed by many people and recent extensive media coverage perhaps it would it be useful to mention this?	Thank you for your comment. The evidence behind this 2006 recommendation was not reviewed as part of this update and as such we are not able to provide further information.
Royal College of General Practitioners	7	Full	45	17	Would it be helpful here to discuss specific medications - not just orlistat but also medications that are licensed in the US but not in the UK such as phentermine-ER topiramate and lorcaserin. Some private slimming companies issue these medications and patients sometimes request them; clinicians working in the UK need guidance on these issues.	Thank you for your comment. Recommendation 101 was not updated as part of the current guideline update and therefore we are unable to comment further on the use if the drugs you refer to. NICE do not usually consider drugs without UK marketing authorisation. For further information, please refer to the NICE Guidelines manual 2012.
Royal College of Nursing	1	General	General	General	We recommend the use of an online pathway to make it easier to negotiate the guideline; currently, recommendations seem to be lost in the document. Without the flow chart recommendations could be challenging for clinicians to follow especially if they are under time pressures.	Thank you for your comment. NICE Pathways (http://pathways.nice.org.uk/) will be developed to provide an online pathway for the recommendations from this guideline.
Royal College of Nursing	2	General	General	General	There is a significant increase in the number of individuals who should be considered for Bariatric surgery. Under the current funding situation, it could be a challenge to identify available resources to meet the needs of the service. It is important that there are structures in place to enable decision making and equality of opportunity.	Thank you for your comment. The GDG members were very aware of the issues surrounding cost implication - these are issues that will be assessed by the NICE implementation and costing teams and this recommendation has already been selected for special consideration. GDG discussion surrounding this issue has been added to the LETR section.

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Royal College of Paediatrics and Child Health	1	NICE	44	2.4 (Research recommendations – learning disability	It's encouraging to see that learning disability is acknowledged as a risk factor for obesity and so it is appropriate to recommend research into how to help those with a learning disability and obesity (and how to prevent obesity in this group). However, it is disappointing that specific reference is not made in this section (or elsewhere in the guidance), to those with a physical disability limiting mobility, because this is also a risk factor for obesity. Research into how to prevent obesity in those with a physical disability, and how to manage obesity in such people, would be useful.	Thank you for your comment. we recognise the issues you raise and the GDG have chosen to amend the research recommendation in this area to reflect the needs of those with a physical disability that limits movement.
Royal College of Pathologists	1	NICE	31 to 33	653 to 672	Agree with the recommendations and their wording regarding the use of very-low calorie diets that indeed should not be used to manage obesity in the long term	Thank you for your comment.
Royal College of Pathologists	2	NICE	42 to 43	889 to 915	Agree with the addition of the guidance regarding consideration of patients with type 2 diabetes mellitus for <10 years and a BMI 30.0-34.9 for bariatric surgery. This is a large group of patients had limited treatment options in the past and now they stand to benefit from surgery. The recommendation for a 2 year follow-up care package of patients in the bariatric service is a very important one. I suggest that the committee consider specifying the maximum intervals of follow-up appointment and also who should deliver this type of follow-up, i.e. a physician,	Thank you for your comments. The evidence review for follow up care looked at the clinical and cost effectiveness of components of a follow up care package. We did not review the evidence surrounding the structure or provision of follow up care though the GDG indicated that the 2-year follow up should be within the bariatric service for 2 years and after, at least annually within a shared care model of chronic disease management. The GDG felt this shared care model would usually be in collaboration between tier 3 and primary care (the 'recommendations and link to evidence' section

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					surgeon, specialist nurse, dietician, psychologist/psychiatrist, exercise/sports medicine specialist and physiotherapist, all of which should have training and experience in bariatric care. There is very little benefit in patients being assessed by healthcare professionals who are either not interested in the field or have negative bias/views of the obese. The later problem is still widespread. I also suggest that patients should be monitored for surgical and medical complications and this should be made clear in the guidance. If these develop, patients should be managed locally if there is enough expertise or referred to a tertiary centre that has it. I suggest that following discharge from the bariatric service, patients are monitored not only for nutritional status, but also for all the other parameters mentioned on lines 903-910 of the draft guidance. In addition, there should be clear instructions to primary care as to when to refer patients back to the bariatric service.	[8.2.3 of the full guideline] has been amended to be clearer about this and the specific nature of shared care models and protocols in these circumstances). The 'Recommendations and link to evidence section' (section 8.2.3) on page 130 states that annual monitoring after discharge from a bariatric surgery service should have no time limit. Furthermore, the evidence review on follow-up care after bariatric surgery found very little evidence that was of adequate quality and was applicable to the UK context to base their recommendations on. As a result, the recommendations related to follow-up care were based on GDG consensus, informed by the experience of the clinical and patient members. While the GDG felt ideally that annual monitoring should contain a number of the same components that were recommended in recommendation 112, they were conscious of the potential cost implications of lifetime monitoring and basing these recommendations on very little and very low quality evidence. The GDG did feel it was appropriate to make the resulting recommendation 113 as a minimum recommendation related to safety and recommended nutritional monitoring and appropriate supplementation in order to prevent serious nutritional deficiencies. This recommendation remains unchanged. Our evidence review did not consider re-referral. The GDG would expect that the appropriate

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						circumstances in which to refer patients back into the bariatric service would be included within the shared care protocol and that the skills within a tier 3 service would be able to recognise the appropriate circumstances in which to referral people back into the bariatric service.
Royal College of Physicians (RCP)	1	Full/ NICE	General	general	The RCP is grateful for the opportunity to comment on the draft guideline and welcomes the inclusion of references to some of the treatment challenges highlighted in the Royal College of Physicians' 2013 report Action on Obesity.	Thank you for your comment.
Royal College of Physicians (RCP)	2	Full/ NICE	General	General	We believe that the guideline would benefit from heavy signposting between the different pieces of related guidance. For instance, we recognise that public health guidance is not included in this guideline and that NICE's Centre for Public Health Excellence is currently updating its guideline on the 'public health' aspects of obesity. However, we strongly advocate heavy signposting between the two pieces of guidance.	Thank you for your comment. Related NICE guidelines, including clinical guideline and public health guidance, are outlined in the full guideline and NICE guideline in Section 3.2. A NICE Pathway will soon be available which will incorporate recommendations from this clinical guideline, as well as those from related public health guidance. For further details, please see the NICE website at www.nice.org.uk.
Royal College of Physicians (RCP)	3	Full/ NICE	General	general	We believe that public health considerations should be incorporated into clinical practice and that clinicians should be supported in doing this	Thank you for your comment. NICE are to develop a NICE Pathway which will incorporate recommendations from this clinical guideline, as well as those from related public health guidance, which will help healthcare professionals to incorporate both into their clinical practice. The NICE implementation team will also be developing implementation tools to help support the

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						implementation of this guideline, as well as related public health guidance. For further details, please see the NICE website at www.nice.org.uk.
Royal College of Physicians (RCP)	4	Full/ NICE	General	General	We believe that there should be prioritisation of preventative intervention and that clinicians should be supported to do this.	Thank you for your comment. We agree, however the guideline is focused on the management of overweight and obesity in children, young people and adults. Recommendations on the prevention of overweight and obesity can be found in NICE Public health guidance 'Maintaining a healthy weight and preventing excess weight gain amongst children and adults', which is due for publication in February 2015.
Royal College of Physicians (RCP)	5	Full/ NICE	General	general	The different tiers of obesity management need to be clearly set out. The guidance does not appear to use tiers 1-4 to differentiate between different stages of obesity prevention and management. These labels may be helpful signposts for clinicians (and indeed commissioners) and we would strongly advocate their inclusion.	Thank you for your comment. Where possible, we have amended the recommendations from the 2006 guideline to indicate the appropriate tiered service (for example, recommendation 1.3.7, 1.3.10 and 1.10.1). However, not all recommendations from 2006 indicated appropriate service settings and therefore this has not been possible to apply consistently throughout the recommendations. We have provided information within the glossary around tiered services and where relevant, referred to it in the Linking evidence to recommendations section of the full guideline for each recommendation.
Royal College of Physicians (RCP)	6	Full/ NICE	General	General	The emotional and psychosocial causes and effects of obesity need to be taken into account within the guidance.	Thank you for your comments. The GDG acknowledge the psychological and emotional difficulties of individuals who are overweight or obese. The introduction section of the full guideline notes that psychological and psychiatric morbidities are linked to obesity (page 12). Furthermore, the GDG looked for evidence of psychological effects of VLCDs (specifically for

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						depression) and bariatric surgery follow-up care in the reviews completed as part of this update (see review protocols in appendix C). The importance of considering psychological factors is set out in recommendations 29, 78, 79, 100, 101, 105. 107, and 112 and the importance of psychological assessments and support is also highlighted within the 'recommendations and link to evidence' sections of the guidance (6.2.13 and 8.2.3).
Royal College of Physicians of Edinburgh	1	Full	42	30 to 36	The College emphasises the role of local authorities in providing facilities for physical activity, particularly for those with physical and learning disabilities and hopes this will be included in public health guidelines if excluded here.	Thank you for your comment. Recommendations on the provision of facilities to promote physical activity can be found in the suite of NICE public health guidance. Further information can be found in section 2.3 'Related NICE Public health guidance'.
Royal College of Physicians of Edinburgh	2	Full	50	30 to 33	The College particularly welcomes the inclusion within the research recommendations of obesity management for people with learning disabilities. http://www.ncbi.nlm.nih.gov/pubmed/23711556 http://www.medscape.com/viewarticle/751659_3	Thank you for your comment.
Royal College of Physicians of Edinburgh	3	Full	110 to 113	General	The College wishes to record concern about the financial implications of a significant extension to bariatric surgery given the limitations on the research evidence cited. The College also wishes to raise concern at the absence of any reference within the guidelines to endoscopic techniques (ref http://www.ncbi.nlm.nih.gov/pubmed/23711556 http://www.medscape.com/viewarticle/751659_3.	Thank you for your comment. The economic evidence presented in this guideline was to determine whether bariatric surgery is a cost-effective intervention for individuals with early on-set T2D. The GDG prioritised the surgical interventions of choice and these are detailed within the relevant protocol in Appendix C. The GDG were very aware of the issues surrounding cost implication - these are issues that will need to be assessed by the

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					Although the role of endoscopically placed prostheses is not yet clearly established, these have been used to good effect in several reported trials (Gersin et al 2010, Schouten et al 2010) and may well provide a safer and less expensive alternative to surgery in the next 3-5 years, once the ABCD study reports (http://www.diabetologists-abcd.org.uk/research/endobarrier_study.htm).	NICE implementation and costing teams and as such have been passed to NICE for consideration. GDG considerations surrounding this issue have been added to the LETR section. The GDG noted that such high cost implications would only be realised if every candidate eligible for an assessment received an assessment and after an assessment all these candidates were referred for surgery. In reality a considerable number of individuals who are deemed eligible for an assessment will not be suitable for surgery and therefore be declined, on top of this some individuals choose not to have the surgery. This will significantly reduce the cost implication. It was outside the scope of the guideline to consider the effectiveness of endoscopic techniques.
Royal College of Surgeons of Edinburgh	1	Full	General	General	The Royal College of Surgeons of Edinburgh welcomes this document as an attempt to provide clarity to the medical profession in treating obesity.	Thank you for your comment.
Slimming World	1	NICE	16	297	'Clinical judgement' assumes a certain level of training, confidence and competencies which are not adequately recognised. The issue of weight needs to be raised sensitively and health care professionals need to be supported in being able to do this confidently and effectively. Understanding the overweight patient is key and to acknowledge how they might be feeling about their weight given the different barriers people face.	Thank you for your comment the content of which is noted.
Slimming	2	NICE	16	301	Reference to 'making every contact count' would	Thank you for your comment. However,

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World					be appropriate and the effective brief intervention.	recommendation 1.1.7 has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Slimming World	3	NICE	19	349	Could the relevant updated guidelines be referred to in the text rather than as a foot-note.	Thank you for your comment. NICE recommendations define the action required. It would be inappropriate to add the full detail of the footnote in the body of the recommendation. Please note that the footnotes have been amended following consultation.
Slimming World	4	NICE	20	372	Socioeconomic status and mental health are two examples which can affect a person's ability and willingness to change and need to be sensitively addressed.	Thank you for your comment. However, this recommendation has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Slimming World	5	NICE	20	374	So perhaps health care practitioners should not use the term obesity with patients?	Thank you for your comment. It was outside the remit of the guideline to consider communication of diagnosis. Recommendations on communication with patients can be found in NICE clinical guideline 138 'Patient experience in adult NHS services'.
Slimming World	6	NICE	20	383	As above, whilst these groups are at greater risk, there are also more barriers which can make weight loss more difficult to achieve.	Thank you for your comment. Recommendations 1.3.1 – 1.3.7 have not been updated as part of the current guideline update and have been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Slimming World	7	NICE	26	521	Over what time frames should these %weight losses be achievable? ? 5% over a 3 month period and 10% over a 6 month period. Of course those people with high starting BMIs will need to	Thank you for your comment. We have amended recommendation 1.4.8 to cross refer to NICE Public health guidance 53. It was outside the scope of the guideline update to provide recommendations on

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					lose a greater % and maintain this loss.	the time frames over which realistic weight loss could be achieved.
Slimming World	8	NICE	26	522 to 525	Again those people with higher starting BMIs may need to readjust their lifestyle modifications after 6 months to keep their weight loss journey continuing over a longer time period in order for them to achieve a healthier weight.	Thank you for your comment. Recommendations 1.4.8 and 1.4.9 have not been updated as part of the current guideline update and have been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Slimming World	9	NICE	27	550	Could this statement (1.4.12) be updated in order to provide greater clarity?	Thank you for your comment. Recommendation 1.4.12 was not updated as part of the current guideline update and therefore, this has not been amended in line with your comment.
Slimming World	10	NICE	31	648	Diets lower in energy density and higher in satiety value are appropriate to reduce the feeling of hunger.	Thank you for your comment. It is outside the scope of the guideline to consider diets lower in energy density and higher in satiety value and as such we have been unable to make comment on this issue.
Slimming World	11	NICE	31	649	Could greater clarity be given to 'intensive follow up'?	Thank you for your comment. The evidence behind this 2006 recommendation was not reviewed as part of this update and as such we are not able to provide further information. Recommendation 68 provides further guidance on follow-up following a VLCD.
Slimming World	12	NICE	33	670	It is recommended that research is undertaken to consider whether there would be benefits of providing the follow up care in groups rather than individually.	Thank you for your comment. We did not consider the clinical or cost effectiveness of combination therapies versus individual therapies for obesity and therefore, we did not choose to develop a research recommendation in this area. In line with the NICE Guideline manual, the guideline development group chose to prioritise five

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						areas in which no evidence was identified on which to develop recommendations for further research.
Slimming World	13	NICE	33	681	How much below? Given this recommendation it is important that linear growth is monitored regularly – for example every 3 months.	Thank you for your comment. Recommendation 1.7.14 was not updated as part of the current guideline update and therefore, this has not been amended in line with your comment.
Slimming World	14	NICE	36	General	Do we know if bariatric surgery is equally available to all ethnic and socioeconomic groups?	Thank you. While one of the aims of NICE guidelines is to ensure equal access across all protected characteristics, it is beyond the remit of this guideline to make comment about the equality of service provision. Recommendation 1.11.3, for example, has specifically reflected evidence that suggests that people an Asian family origin present with comorbidity risk factors that are of concern at a lower BMI and that therefore assessment for consideration for surgery may be of benefit at a lower BMI
Slimming World	15	NICE	38	811	Outcomes for bariatric surgery are traditionally expressed as % excess weight loss. In order to standardise outcome measures across all weight management interventions could % weight loss be used?	Thank you for your comment. Recommendation 1.10.5 has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
Slimming World	16	NICE	42	900	It is recommended that research is undertaken to consider whether there would be benefits of providing the follow up care in groups rather than individually.	Thank you for your comment. The GDG developed and prioritised a number of research recommendations based on the reviews of evidence in this guideline - please see section 5.15 of the full guideline.
Slimming World	17	NICE	43	921	Agree – this is an area where further research is required. Anecdotally post-bariatric surgery patients do access commercial slimming organisations for additional support.	Thank you for your comment.

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The Chartered Society of Physiotherapy	1	Full	General	General	The Chartered Society of Physiotherapy welcomes this guidance. We recognise that this is part of an important suite of publications on obesity.	Thank you for your comment.
The Chartered Society of Physiotherapy	2	Full	General	General	The ISCP and the CSP believes that the Guidelines should highlight the management of barriers (as stated in its document e.g. pain, breathing difficulties, ORCLLS, confidence/past experience of exercise - pacing, physical activity guidance/practice). The ISCP suggests one small addition to the recommendation list. The Guidelines suggest when buying new weighing scales that this accommodates the highest weight of patients; this should also state '*and is accessible for people using wheelchairs'*. The specialised clinics use a flat platform to meet this need.	Thank you for your comment. It was outside the scope of the current guideline update to update the recommendations on the provision of equipment. We are therefore unable to make comment on this issue or on this issue of the management of barriers.
The Chartered Society of Physiotherapy	3	Full	General	General	The ability to appropriately manage patients in a holistic and professional manner is vital to best outcome and the patient care experience. Established professional bodies such as the Chartered Society of Physiotherapy and the Irish Society of Chartered Physiotherapists ensure high quality professional standards are met. Chartered physiotherapists are among the most established group of allied health care professionals within the multidisciplinary team, as such they help to set standards of patient care and to ensure issues such as audit, research and continued professional development are adhered	Thank you for your comment.

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					to in order to ensure high standards in the delivery of care. Some additional benefits of having physiotherapists as part of the multidisciplinary team are summarised below: <u>Pain Management and Biomechanical Analysis</u> It is well established that weight management patients have a much higher rate of pain compared to a healthy weight population[(1)]. A recent audit of 147 adult patients who attended the weight management clinic at St. Columcille's Hospital found that 73% of patients reported significant levels of pain often in multiple locations. The most common source of pain is low back pain (52%), followed by knee pain (43%) and least frequent but still increased at other locations (29%). Similarly, in paediatrics, up to 72% of children who are obese report pain and up to 40% have sustained fractures [(2-4)]. Physiotherapy plays a strong and unique role here as experts in pain assessment and triage, diagnosis, biomechanical analysis, treatment and appropriate onward referral where necessary. As front line professionals, physiotherapists are undoubtedly providing the most cost effective means to manage obesity related pain issues. Without early point of contact to a physiotherapist physical function will not be optimised which dramatically influences exercise capacity, weight and overall health outcome. <u>Respiratory Disease</u>	

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					Approximately 10% of patients in obesity class III have a clinical diagnosis of type 2 respiratory failure (Audit data n=257), which is a serious respiratory disease characterised by a chronic decrease in blood oxygen levels and an increase in retained carbon dioxide levels. Type 2 respiratory failure is caused by inadequate pulmonary ventilation and is associated with chronic functional deficits and increased mortality. Additionally, asthma and obstructive sleep apnoea are highly prevalent with weight management patients. These respiratory diseases must be managed professionally with graded therapeutic exercises and specific breathing exercises to maximise participation and functional improvement. Physiotherapists are experts in respiratory disease and are well placed to manage these associated chronic respiratory diseases with respect to prescribed appropriate exercise in a weight management setting. <u>Type 2 Diabetes</u> Another disease associated with obesity is Type 2 diabetes. The prevalence of the disease is rising dramatically. Some common problems facing this cohort of patients that require physiotherapy input are lifestyle and exercise counselling, peripheral neuropathy and pain, and increased musculoskeletal pain. Physiotherapy treatment of youth who are obese has been shown to be effective in reversing insulin	

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					resistance and pre-diabetes[5]. Obesity Related Chronic Lymphoedema Like Skin Changes (ORCLLS)" This is also a significant barrier to physical activity engagement and physiotherapists'	
The Chartered Society of Physiotherapy	4	Full	44	26 to 37	Recommendations 67-69. Although physiotherapy is mentioned as part of the MDT in the assessment of costings, we would recommend more specific mention in the recommendations themselves, as this has more visibility to clinicians and decision makers. Specialist bariatric physiotherapy is an emerging area of practice. Increasing levels of physical activity can be particularly challenging in obese individuals, who often experience a wide range of limitations including shortness of breath, musculoskeletal disorders, muscle weakness, joint pain, skin breakdown, urinary stress incontinence, difficulty with basic mobility including changing position, walking, climbing stairs, using transportation, managing personal hygiene[6] and psychological distress related to exercising in public[7-11]. Physiotherapists recognise the physical stresses associated with obese bodies and how a patient's particular body shape will impact on their neuromusculoskeletal and cardiorespiratory systems, movement, function and exercise-related risks. They also have the communication	Thank you for your comment. The introduction to the chapter on follow up care packages mentions physiotherapists as an important member of the multidisciplinary team involved in the follow up management of people following bariatric surgery. The evidence review conducted aimed to identify which components of a follow-up care package were clinically and cost effective compared to usual care. We did not look at the components of the multidisciplinary team and are therefore unable to include any professional groups in the detail of our recommendations.

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					skills to build up the trusting relationship required to fully elicit any psychological and emotional barriers to taking up physical activity and accessing appropriate services. The physiotherapy assessment of individuals attending for weight management is intended to evaluate global fitness in order to identify the existence of structural impairments which may limit time spent in the activity required for weight management. The aims of physical testing are to: assess symptoms, exercise tolerance and the cardiorespiratory response to exercise intensity* in a controlled setting. Furthermore testing is used as an outcome measure to assess the effectiveness of the weight management programme in improving the fitness profile of patients referred. Structural impairments such as reduced muscle strength, muscle inflexibility, reduced range of movement and impaired balance are reported in this population and each of these factors can contribute to reduced function and an increased risk of falls and injury[2,3]. Physiotherapy assessment and management of these concerns are vital in order to treat primary complaints, prevent secondary injury and promote optimal function. For patients who are obese and have co-morbidities, we would advocate physiotherapists as being the most ideally placed clinicians to input on increasing levels of physical activity	

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The Chartered Society of Physiotherapy	5	Full	50	1 to 14	Although physiotherapy is mentioned as part of the MDT in the post bariatric surgery follow up care package, we would recommend more specific mention in the recommendations themselves, as this has more visibility to clinicians and decision makers. Physiotherapists are ideally placed to offer physical activity advice and support, providing education and counselling related to the risks associated with obesity, either in isolation or as adjuncts to the management of associated or precipitating symptoms. These may include osteoarthritis in weight bearing joints, musculoskeletal injuries or disorders and chronic medical conditions including diabetes and heart disease. Adult education to facilitate lifestyle change requires specialised education and a high level of experience of patient contact and counselling. Physiotherapists are well versed in this area as it forms a routine part of almost every patient contact in routine care. Without such patient contact experience education and empowerment regarding sustained lifestyle change will not be optimal. The area of weight management has inherent hazards with regard patient communication. It has been shown that if communication is not managed in a professional and empathetic manner with careful attention to language and	Thank you for your comment. The introduction to the chapter on follow up care packages mentions physiotherapists as an important member of the multidisciplinary team involved in the follow up management of people following bariatric surgery. The evidence review conducted aimed to identify which components of a follow-up care package were clinically and cost effective compared to usual care. We did not look at the components of the multidisciplinary team and are therefore unable to include any professional groups in the detail of our recommendations

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					realistic goal setting there can be undesirable consequences to lifestyle changes[12] which underlines to necessity for the delivery by qualified professional healthcare workers. Patients who attend for weight management present with a broad spectrum of barriers and specific problems. Physiotherapist with a broad education and wide range of clinical experience are well placed to deal with the majority of patient specific problems in a timely and efficient manner. Results to date are promising whereby physiotherapy-led weight management has been effective in reducing body mass index[13].	
The Chartered Society of Physiotherapy	6	Full	63	25	We welcome the inclusion of a physiotherapist as part of the MDT initial assessment costings for VLCD with an exercise component.	Thank you for your comment.
The Chartered Society of Physiotherapy	7	Full	120	7	We welcome the inclusion of a physiotherapist as part of the MDT in post bariatric surgery follow up care package. References 1. Stone AA, Broderick JE. Obesity and Pain Are Associated in the United States. Obesity, (19 January 2012) | doi:10.1038/oby.2011.397 2. O'Malley G, Hussey J, Roche E. A Pilot Study to Profile the Lower Limb Musculoskeletal Health in Children with Obesity. Pediatric Physical Therapy 2012; 00:1–7 3. Bell LM, Curran JA, Byrne S, et al. High incidence of obesity comorbidities in young children: a cross-sectional study. J Paediatric	Thank you for your comment.

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					Child Health. 2011; 47(12):911-917. 4. Krul M, van der Wouden JC, Schellevis FG, van Suijlekom-Smit LW, Koes BW. Musculoskeletal problems in overweight and obese children. Ann Fam Med. 2009;7(4):352-356. 5. Savoye M, Nowicka P, Shaw M, Yu S, Dziura J, Chavent G, O'Malley G, Serrecchia JB, Tamborlane WV, Caprio S. Long-term results of an obesity program in an ethnically diverse pediatric population. Pediatrics. 2011 Mar;127(3):402-10 6. Association CP. Physiotherapists and the management of obesity Ontario, Canada; 2007. 7. Barofsky I, Fontaine KR, LJ C. Pain in the obese: impact on health-related quality-of-life. Ann Behav Med. 1997;19(4):408-10. 8. W. D. Stigma of obesity – consequences of naïve assumptions concerning the causes of physical deviance. . Journal of Health and Social Behaviour 1980;21(1):75-87. 9. Lean ME. Pathophysiology of Obesity. Proceedings of the Nutrition Society. 2000;59(3):331-6. 10. Hakala K, Mustajoki P, Aittomaki J, et al. Improved gas exchange during exercise after weight loss in morbid obesity. Clinical Physiology. 1996;16(3):229-38. 11. Peltonen M, Lindroos AK, Torgerson JS. Musculoskeletal pain in the obese: a comparison with a general population and long-term changes after conventional and surgical obesity treatment. Pain Clinic. 2003;104(3):549-57.	

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					12. Puhl RM, Heuer A. The Stigma of Obesity: A Review and Update. Obesity (2009) 17, 941–964. doi:10.1038/oby.2008.636 13. O'Malley G; Brinkley A; Moroney K; McInerney M; Butler J and Murphy N. Is the Temple Street W82GO Healthy Lifestyles Programme effective in reducing BMI SDS? Obesity Facts 2012;5(S1):10	
The Royal College of Surgeons of Edinburgh	2	Full	32	Figure 4	It is important that the role of bariatric surgery has been fully acknowledged, with detailed recommendations about which patients should be eligible. The recommendations regarding surgery for patients with type-2 diabetes is particularly welcome.	Thank you for your comment.
The Royal College of Surgeons of Edinburgh	3	Full	36	5	As BMI does not distinguish between body fat and lean body mass, and can be inaccurate in the elderly, children and body builders, this document needs to include guidance for signposting to alternative measurement strategies. The Royal College of Surgeons of Edinburgh recommend the use of the hip to waist ratio alongside BMI, as well as an increased use of Air-Displacement Plethysmography.	Thank you for your comment. Recommendation 11 and 12 recommend the use of BMI as a practical measure of adiposity in adults. Section 5.4 has not been updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we are unable to make further comment on this issue
The Royal College of Surgeons of Edinburgh	4	Full	14	37	Specific guidance should be given for pregnant women.	Thank you for your comment. The scope of the guideline excludes the management of overweight and obesity in pregnant women and we are therefore unable to make comment on this issue in more detail . Recommendations on weight management before, during and after pregnancy can be found in NICE Public health guidance 27

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						'Weight management before, during and after pregnancy.' (2010).
UK Health Forum	1	Full	General	General	The review is comprehensive and we only have minor comments for consideration.	Thank you for your comment.
UK Health Forum	2	Full	19		Line 14 should say equal to or over?	Thank you for your comment. We agree and we have amended this.
UK Health Forum	3	Full	38 to 39	35 to 35	Consider signposting to appropriate, validated tools in which to measure e.g. eating behaviours, lifestyle, psychosocial distress, motivation to change etc.	Thank you for your comment. Recommendation 27 was not updated as part of the current guideline update. Therefore, we have not amended the recommendation in line with your comment.
UK Health Forum	4	Full	39	18 to 35	Clarify whether, for adolescents, it is recommended that parents are present or not for assessment. Consider recommending that parents are weighed and measured as part of the consultation/family-based therapy (or in section 5.63)	Thank you for your comment. Section 5.5.3 has not been was not updated as part of the current guideline update and has been amended for clarity only (see Appendix Q of the full guideline for details). Therefore, we have not amended the recommendation in line with your comment.
UK Health Forum	5	Full	40	22	At what point (age of child) is the parent's preference taken into account over the child's if these differ? That is, are adolescents to be given more choice over treatment preference relative to younger children?	Thank you for your comment. Evidence in this area was not reviewed as part of this update process and therefore the GDG are unable to comment. However, recommendation 9 addresses issues related to lifestyle choices of the child and advises that the age and maturity of the child should be taken into account when considering treatment options. Further information on this area can be found on page 8 of the NICE version of the guideline, entitled 'Patient-centred care'.
UK Health Forum	6	Full	45	5	Is there evidence of combination therapies being effective – should this be a research recommendation if not?	Thank you for your comment. We did not consider the clinical or cost effectiveness of combination therapies in the management of overweight or obesity in children, young people or adults and therefore, we are unable to develop a research

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						recommendation in this area.
Weight Watchers	1	NICE version* (*i.e. with appropriate text shaded in grey and marked with year)	31	656	For clarity, it might be useful to define either here, or at an earlier stage, what is meant by a multicomponent weight management strategy.	Thank you for your comment. The components of a multicomponent weight strategy are defined in recommendation 1.4.1.
Weight Watchers	2	NICE version*	31	663	Weight Watchers would suggest that the first bullet point on the list provided is that before considering on a VLCD all other behavioural avenues have been fully explored, perhaps by inserting as the first bullet point: "Before considering a VLCD, ensure the person has explored all other avenues to make lifestyle changes using an evidence-based behaviour change interventions, as outlined in NICE Public Health Guidance 53: *Managing overweight and obesity in adults – lifestyle weight management services*."	Thank you for your comment. As emphasised in recommendation 1.7.8, the use of VLCDs should only be considered as part of a multicomponent weight management strategy, which should include all other behavioural interventions. The Linking evidence to recommendation table in the full guideline includes the importance of ensuring that VLCDs are only used within this situation. The NICE guideline has a section on related NICE guidance and the PH guideline is included here for cross reference.
Weight Watchers	3	NICE versi	31	658	There seems to be a word missing here – presumably an 'and'?	Thank you for your comment. We have amended recommendation 1.7.8 as per your suggestion.

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		on*				
Weight Watchers	4	NICE version*	31	669	The final recommendation "Discuss the reintroduction of food" could perhaps be expanded upon to read: "Discuss the reintroduction of food and set behavioural goals on how to achieve this in a controlled and safe manner."	Thank you for your comment. We have amended this recommendation to focus on the reintroduction of a normal diet. Further detail has also been added to the linking evidence to recommendations section for this recommendation (see 6.2.13 of the full guideline).
Weight Watchers	5	NICE version*	31	669	It would be constructive to make an additional recommendation here on *how* to offer ongoing support to people who have completed a VLCD, for example: "On completion of a VLCD, refer to local lifestyle weight management services that are able to provide ongoing, behavioural weight management support, as detailed in NICE Public Health Guidance 53: Managing overweight and obesity in adults – lifestyle weight management services."	Thank you for your comment. We believe that this is covered by 1.7.8, which highlights that VLCDs should only be used as part of a multicomponent weight management strategy. The NICE guideline has a section on related NICE guidance and the PH guideline is included here for cross reference.
Weight Watchers	6	NICE	37	777	Weight Watchers welcomes that pre-bariatric assessment and preparation has been clearly defined as needing to happen in tier 3. Perhaps the link to the NHS England report on *Joined up clinical pathways for obesity* (previously given on page 22) could be usefully offered again at this point.	Thank you for your comment. This report does appear to be referenced at this point in a footnote.
Weight Watchers	7	NICE	42	889	The section 'Bariatric surgery for people with recent onset type 2 diabetes' and does not align	Thank you for your comment. Recommendations 1.11.1, 1.11.2, 1.11.3 have been amended to clarify

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					with recently updated NICE Guidance 87 on *The management of type 2 diabetes*, recommends a stepped care approach but does not include surgery. Weight Watchers would suggest that it is made clear that all lifestyle and pharmacologic interventions are fully explored before this step is taken.	that assessment for bariatric surgery should be made 'as long as they are also receiving or will receive assessment in a tier 3 service (or equivalent)'. The GDG did not necessarily feel that all lifestyle and pharmacologic interventions be fully explored before people are offered bariatric surgery. They did feel that, based on the evidence they considered, for those with a BMI of 35 or more and type 2 diabetes, that at an assessment for bariatric surgery as a treatment option be under taken more quickly than otherwise. Those with BMI 30 to 34.9 with special circumstances or those of an Asian family origin should also be considered for assessment for bariatric surgery alongside other treatment options. These assessments would usually be undertaken in tier 3 services where other options are also considered. Recommendation 1.10.1 refers now to the new 2014 recommendations on consideration for assessment for surgery for those with T2D and obesity. The recommendations in this guideline should be considered alongside the recommendations for behavioural and lifestyle interventions considered within the public health guidance and also within the NICE guideline on type 2 diabetes (CG87 and CG66). The recommendations within the current guideline add an additional component to the stepped approach provided within the public health guidance.
Weight Watchers	8	NICE	42	891	Weight Watchers is concerned that the BMI cut offs for offering bariatric assessment for people with type 2 diabetes is unrealistically low, particularly considering the level of bariatric	Thank you for your comment. The GDG have not recommended bariatric surgery to patients with type 2 diabetes and a BMI of 35 or greater. They have, however, recommended that these patients be

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					services that are currently available and the radical implications of surgery for the patient. A challenge faced by many people with type 2 diabetes is the often poor/patchy provision of evidence based lifestyle support available. Recommending bariatric options at such low cut offs will do little to influence the development of better support services for people with type 2 diabetes. Weight Watchers would suggest that the Update offers clears guidance on the need for provision of local evidence based behavioural approaches for the management of type 2 diabetes, in addition to surgical options, and that the BMI cut offs are raised. In addition this section is not consistent with the stepped care approach of lifestyle and then pharmacological interventions advised in NICE Guidance PH38 *Preventing type 2 diabetes: risk identification and interventions for individuals at high risk*.	offered an assessment for surgery. This assessment will normally occur within the tier 3 service, which would take into consideration patient preferences and other issues related to the suitability of patients for surgery and alongside other possible treatment. Recommendation 1.10.1 refers now to the new 2014 recommendations on consideration for assessment for surgery for those with T2D and obesity. Recommendations 1.11.1, 1.11.2, 1.11.3 has now been amended to clarify that assessment for bariatric surgery should be made 'as long as they are also receiving or will receive assessment in a tier 3 service (or equivalent)'.The recommendations in this guideline should be considered alongside the recommendations for behavioural and lifestyle interventions considered within the public health guidance and also within the NICE guideline on type 2 diabetes (CG87 and CG66). The recommendations within the current guideline add an additional component to the stepped approach provided within the public health guidance.
Weight Watchers	9	NICE	General	General	It would be useful if the Update specifically identified that people who are obese and who have been diagnosed with pre-diabetes are at particularly high risk, both of diabetes and a range of other co-morbidities, and therefore should be a specific target for lifestyle weight management services. This would be would be consistent with NICE Guidance PH38 *Preventing type 2 diabetes: risk identification and interventions for individuals at high risk*.	Thank you for your comment. It was outside the scope of the update of this guideline to consider lifestyle weight management services and who is appropriate for these services. We agree that further detail can be found in PH38 which provides some guidance on lifestyle interventions.

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Whitehouse Consultancy (Cambridge Weight Plan)	1	General	General	General	Cambridge Weight Plan (Cambridge) would like to thank NICE for the opportunity to comment on the partial update of Clinical Guidance (CG) 43 on Obesity. Whilst Cambridge welcomes NICE's effort to partially update CG43, we believe that the review process has suffered from a number of serious shortcomings, which if not appropriately addressed , risk compromising the quality and consistency of the final guidance. We hope that the points made below will be fully taken into account before a final version is presented.	Thank you for your comment. CG43 has been updated in line with the processes outlined in the NICE Guidelines manual 2012. We have responded to individual comments separately
Whitehouse Consultancy (Cambridge Weight Plan)	2	Full	44	14 to 18	Cambridge welcomes the clarity which the draft guidelines bring with regards to outlining the correct calorie thresholds and ranges for very low calorie diets (VLCDs). At the same time, we fear that the thresholds associated with low calorie diets (LCDs) might cause confusion as they refer to a range of 800-1600 kcal/day, as opposed to the more widely accepted range of 800-1200 kcal/day. This issue is compounded by the fact that there are references to the 800-1200 kcal/day range for LCDs in other sections of the draft guidance, such as on page 53 (Table 7) and on page 71 (Table 27). We hope that NICE will address this issue by providing more clarity on the correct calorie thresholds and ranges for LCDs in the	Thank you for your comments. The definition of LCDs has been amended to reflect the 2006 definition of 800 -1600 kcal/day. Please refer to tables 7 and 27 of the guideline (PICO tables) and the review protocols in Appendix C. The review has included all relevant studies for kcal diets in this range and remains unchanged. It is recognised that the definition is somewhat arbitrary. The energy deficit created by any 'fixed energy dietary recommendation' will also be dependent on the gender, weight, age and activity levels of the individual.

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					final version of the guidance.	
Whitehouse Consultancy (Cambridge Weight Plan)	3	Full	44	17- to 24	Recommendation 65: Do not routinely use very-low- calorie diets (800 kcal/day or less) to manage obesity (defined as BMI over 30) Recommendation 66: Only consider very-low-calorie diets, with ongoing support, as part of a multicomponent weight management (See recommendation 35) strategy for a maximum of 12 weeks (continuously or intermittently) in people who are obese who have a clinically-assessed need to rapidly lose weight (for example, people who require joint replacement surgery or who are seeking fertility services). Cambridge would like to note its strong disappointment with the wording of dietary recommendations 65 and 66, which we believe are not grounded in clinical evidence, as illustrated by the comments made above. Cambridge also considers that Recommendations 65 and 66 are inconsistent with NICE's own guidance and other relevant guidance published by NHS bodies, such as the NHS Commissioning Board. In particular, we would like to draw attention to the apparent contradiction between the assessment recommendation that referral to Tier 3 services should be considered if "specialist intervention (such as very low-calorie diet) may	Thank you for your comment. We do not believe the recommendations are contradictory. Recommendation 66 refers to the long-term use as having the potential of being ineffective. We note your comment on the NHS commissioning board policy for complex and severe obesity, however, our review of evidence has indicated a lack of effectiveness of VLCDs in maintaining weight loss and this evidence may be used to support future iterations of this policy. In the interim, recommendations remain in this guidance supporting the use of low calorie diets and the specific detail related to the use, where appropriate, of VLCDs. We note your reference to PH 53. This guidance does note that lifestyle weight management services may include commercial weight management programmes in tier 2 services. We further note that this guideline recommends those services which are effective at 12 months or beyond. This guidance further notes the following programmes currently available in the UK to have been shown to be effective at 12 to 18 months: [in alphabetical order] Rosemary Conley, Slimming World and Weight Watchers.). The purpose of the review into the use of very-low-calorie diets has been to determine their clinical and cost effectiveness for use in the NHS which is the remit for the NICE clinical guidelines programme which commissioned this guideline update.

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					be needed" (Page 39, line 14), and the subsequent recommendations 65 and 66. The recommendation that VLCDs should only be used "in people who are obese who have a clinically-assessed need to rapidly lose weight", suggests that VLCDs should be considered solely to help individuals who are already obese and in need of undergoing treatment for other conditions that may be exacerbated by their weight, such as knee operations or fertility treatment. Cambridge also believes that recommendations 65 and 66 are inconsistent with existing NICE public health guidance on 'Managing overweight and obesity in adults – lifestyle weight management services' (PH53), published in May 2014. We note that the recommendations set out in PH53 - particularly recommendations 3 to 8, and 12 - clearly support the use of commercial weight management programmes in Tier 2 community-based lifestyle and behaviour interventions for the purpose of preventing and treating not only obesity but the condition's comorbidities – including type-2 diabetes. In particular, we would wish to highlight the fact that recommendation 12 of PH53 implicitly supports the use of VLCDs in a tier 2 setting, as it lists commercial weight management providers	

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					like Weight Watchers, whose programmes have been deemed as cost effective. Cambridge wishes to further highlight that the wording of recommendation 66 proposing a restriction on the use of VLCDs to "obese [individuals] who have a clinically-assessed need to rapidly lose weight" may conflict with the clinical guidance issued by the NHS Commissioning board policy for complex and severe obesity. Cambridge notes that the NHS Commissioning Board's "Clinical Commissioning Policy: Complex and Specialised Obesity Surgery" (2013) suggests patients should be managed in a non-surgical, medical Tier 3 setting for 12-24 months, during which all other interventions, including VLCDs, should be considered. This indicates that the NHS Commissioning board supports the routine consideration of VLCDs for patients with a BMI of 35+ and co-morbidities, with a BMI of 40+, or with BMI 30+ and suffering from diabetes, that have tried all other interventions. These comments also apply to the following pages / lines: page 31, line 2 (algorithm); page 94 (recommendations).	
Whitehouse Consultancy (Cambridge Weight Plan)	4	Full	52	38	<u>Intermittent use of VLCDs</u> Cambridge would like to question the rationale behind the inclusion of intermittent diets within the same intervention group as VLCDs, in	Thank you for your comment. This guideline is an update of the CG 43 evidence review in this area. This review considered both continuous and intermittent VLCD diets. As part of this evidence review, three papers on the use of intermittent

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					particular as there is currently insufficient evidence to draw conclusions on their effectiveness. Cambridge believes that such intermittent use of VLCDs should not be mentioned within this guidance, in the absence of adequate evidence. We believe that NICE should have acknowledged the lack of evidence, instead of suggesting their ineffectiveness. These comments also apply to the following pages / lines: page 44 line 21, page 53 line 11, page 94 paragraph 66, as well as page 95 and 97.	VLCDs were identified. However, our review prioritised calorific content rather than mode of delivery Therefore, providing calorific content was less than or equal to 800 calories per day, the relevant data has been included in the review. The GDG noted that some patients find intermittent diets easier to follow and comply with. The GDG did not feel that there was an appropriate body of evidence to recommend against the use of intermittent VLCDs or make specific recommendations around the mode of delivery (intermittent or continuous).
Whitehouse Consultancy (Cambridge Weight Plan)	5	Full	53	1	<u>Effectiveness of very low calorie diets (VLCDs) in reducing weight – clinical evidence</u> Cambridge would like to note that the assessment and the conclusions made on the clinical effectiveness of VLCDs did not consider important pieces of research that have been published on this subject. Only three papers have been considered in addition to those included in the previous review, and all of them were published before the year 2000. Cambridge therefore requests that the following papers are reviewed as part of the evidence base for this guidance:	Thank you for your comments. We will deal with the references you provide in turn: Reference – Moreno 2014: This paper has been excluded from the VLCD review because it does not include the correct intervention - as specified in the review protocol, participants did not receive a low calorie deficit or deficit diet. Reference – Christensen 2011A: This paper has been excluded from the VLCD effectiveness (Please note that this has now been added to excluded clinical studies table, see Appendix J) and maintenance (see Appendix J) reviews because it is less than one year in duration. Reference – Christensen 2011B: This paper was not

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					- Moreno B1, Bellido D, Sajoux I, Goday A, Saavedra D, Crujeiras AB, Casanueva FF. Comparison of a very low-calorie-ketogenic diet with a standard low-calorie diet in the treatment of obesity. Endocrine. 2014 Mar 4. [Epub ahead of print] The randomised controlled trial reported in this paper compares a very low calorie ketogenic diet intervention versus a standard low calorie diet and reports on reductions of weight after a 12 months period. - Christensen P, Bliddal H, Riecke B F et al. (2011A) Comparison of a low-energy diet and a very low-energy diet in sedentary obese individuals: a pragmatic randomised controlled trial. Clinical Obesity doi: 10.111/j.1758-8111.2011.00006.x - Christensen P, Bartels E M, Riecke B F et al. (2011B) Improved nutritional status and bone health after diet-induced weight loss in sedentary osteoarthritis patients: a prospective cohort study. Eur j Clin Nutr 60 doi:10.1038/ejcn.2011.201 - Christensen P, Frederiksen R, Bliddal H, Riecke BF, Bartels EM, Henriksen M, Juul-S Rensen T, Gudbergsen H, Winther K, Astrup A, Christensen R.Obesity (Silver Spring). 2013 Oct;21(10):1982-90.	included because it is not a randomised controlled trial. Reference - Christensen 2013: This paper was excluded from the VLCD effectiveness review because the results are presented after the maintenance period only (Please note that this has now been added to excluded clinical studies table, see Appendix J). This paper was excluded from the VLCD maintenance review because the participants undertook a LCD before being randomised to a maintenance regime (please refer to the excluded clinical studies table in Appendix J). Reference – Johansson 2009: This paper has been excluded from the VLCD review because it does not include the correct intervention (please refer to Appendix J – excluded clinical studies). As specified in the review protocol, participants in the control group did not receive a low calorie deficit or deficit diet. Reference – Johansson 2011: This paper has been excluded from the VLCD review because it is not a randomised controlled trial. Reference – Johansson 2013A: Presume this is referring to: Johansson K, Neovius M & Hemmingsson E (2014) Effects of anti-obesity drugs, diet, and exercise on weight-loss maintenance after a very-low-calorie diet or low-calorie diet: a systematic review and meta-analysis of randomised controlled trials. Am J Clin Nutr, 99,

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					doi: 10.1002/oby.20413Comparison of three weight maintenance programs on cardiovascular risk, bone and vitamins in sedentary older adults. Epub 2013 Apr 13. These three papers all report different aspects of a study on elderly obese individuals with knee osteoarthritis. Christensen P et al (2011A) describes the weight changes in the first 16 weeks. Christensen P et al (2013) describes results at 68 weeks (16 + 52), and Christensen P etal (2011B) described body composition changes, bone mineral and bone density at 16 weeks - Johansson K, Neovius M, Lagerros YT et al. (2009) Effect of a very low energy diet on moderate and severe obstructive sleep apnoea in obese men: a randomised controlled trial. BMJ 2009; doi: 10.1136/bmj.b4609 - Johansson K, Hemmingsson E, Harlid R, et al. (2011) Longer term effects of very low energy diet on obstructive sleep apnoea in cohort derived from randomised controlled trial: prospective observational follow-up study. BMJ 2011;342:d3017 doi:10.1136/bmj.d3017 The latter paper reports a randomised controlled trial on the effect of weight loss with VLCD compared to conventional care in obese men	14-23. This systematic review was excluded from the maintenance review due to inadequate quality assessment / outcomes of interest are not included (added to excluded clinical studies table, see Appendix J). It was the focus of this review to assess the effectiveness, safety and maintenance of VLCDs. The role of VLCDs in the pre-operative phase was not prioritised as part of the scope for this update. All evidence that met the strict criteria for the included reviews as set in the protocols was robustly assessed according to NICE methods.

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					with severe and moderate obstructive sleep apnoea. The VLCD was used for 7 weeks followed by 2 weeks of 1200kcal/d food re-introduction diet. After the randomised controlled trial, the control subjects followed the active intervention and all were then offered weight maintenance with partial use of formula diet up to week 52. - Johansson K, Hemmingsson E, Neovius M (2013A) Effects of anti-obesity drugs, diet, and exercise on weight-loss maintenance after a very-low-calorie diet or low-calorie diet: a systematic review and meta-analysis of randomized controlled trials. Am J Clin Nutr doi: 10.3945/ajcn.113.070052. This paper analyses and reports on randomised controlled trials of weight maintenance interventions after weight loss with VLCDs or LCDs, showing that three interventions (high protein diets, drugs, part use of formula diets) result in significantly greater amounts of weight loss maintained. In addition to the evidence outlined above, Cambridge would also like to ask why all the research on the use of VLCDs in the immediate pre-operative phase for bariatric surgery was excluded from consideration when preparing this draft guidance. We believe that that the evidence available in this area is of great relevance to this	

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					guidance.	
Whitehouse Consultancy (Cambridge Weight Plan)	6	Full	63	25	Cost effectiveness of VLCDs Cambridge would like to note that the economic analysis (pages 63 to 70) of the costs borne by the NHS for providing VLCDs is based purely on assumptions and not on actual practice. In particular, we would like to note that the analysis contains a number of speculations in respect of the time that a bariatric multi-disciplinary team would need to commit. However, there are no documentary literature sources to support such assumptions. In particular, Cambridge would like to object to the following statement on page 65, line 9 and 10: "During the time the VLCD is being undertaken there are additional pressures placed on the service to accommodate people undertaking a VLCD". We would like to note that there is no literature reference supporting this statement. Similarly, no evidence supports the following statement on page 65, line 11 to 13: "Individuals on a VLCD will be seen more and therefore more time will be spent by an administrator making appointments, entering additional information into a database and sending more letters to the individual's GP".	Thank you for your comment. The economic review found no evidence regarding the cost-effectiveness of VLCDs. As economic considerations need to be made with every recommendation a costing exercise was undertaken in collaboration with GDG members with experience and expertise in running VLCDs to determine how much they cost to the NHS. The costing exercise reported is therefore built on actual practice that is seen in NHS run VLCDs. Further clarification on this approach has been made in the final guideline in the VLCD unit cost section on page 64. Any assumptions where it was recognised that there could be variation in NHS practice, mainly concerning blood tests and MDT time, were varied in the sensitivity analysis. GDG members who have experience of running VLCDs noted the extra amount of time spent providing care for individuals on a VLCD, especially those with T2D and hypertension who need blood glucose and blood pressure monitoring. A study by Lean et al ,although excluded from the clinical review, has now been discussed in the economic evidence. It recognises the additional GP time needed to conduct a VLCD which supports the reporting of increased administration time.
Whitehouse Consultancy	7	Full	70	25	Cost effectiveness of VLCDs Cambridge notes with concern that NICE was	Thank you for your comment. The Lean study was excluded from the economic evidence as it only

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(Cambridge Weight Plan)					unable to identify any relevant economic evaluations upon which to base its assessment of the cost effectiveness of VLCDs. To address this, Cambridge would like to put forward the following paper for consideration by NICE: - Lean M, Brosnahan N, McLoone P, McCombie L, Higgs AB, Ross H, Mackenzie M, Grieve E, Finer N, Reckless J, Haslam D, Sloan B, Morrison D. British Journal of General Practice Feb;63(607):e115-24. doi: 10.3399/bjgp13X663073. Feasibility and indicative results from a 12-month low-energy liquid diet treatment and maintenance programme for severe obesity (2013)	derives the costs of a low energy liquid diet with no comparison to what the cost might be for another intervention. It is worth noting that the nurses and dietitians used in the Lean study were familiar with the counterweight programme and so the training and minutes of nurse time are likely to be an underestimate of the cost of providing the programme. The GDG noted that VLCDs are fairly unfamiliar to most nurses and GPs and there are significant training issues such as dealing with monitoring blood glucose levels. Finally the exclusion criteria for the participants in the study were fairly wide and this would therefore exclude a large number of individuals that would be seen in a tier 3 service. Although this study was excluded as it is not a full economic evaluation, costs from Lean et al have now been quoted in the final version of the guideline in the VLCD 'economic considerations' section on pages 70-71 and they fall within the costs quoted in the consultation version of the guideline. The clinical review for VLCDs found no evidence that weight loss, relative to standard dietary advice, was sufficiently sustained for VLCDs to be cost-effective at a £20,000 per QALY threshold.
Whitehouse Consultancy (Cambridge Weight Plan)	8	Full	71	1	<u>Safety of VLCDs</u> Cambridge would like to note that the assessment of safety of VLCDs has not been comprehensive. We would request that the following papers are also reviewed as part of the evidence base for this guidance:	Thank you for your comments. As per Appendix G (clinical evidence tables), Christensen et al. (2011) has been included in the same evidence table as Riecke et al. (2010) since it is a report from the same study. However, the safety data was extracted from Riecke et al. (2010) rather than Christensen et al. (2011) since the former is reported to be at 16 weeks while the later was reported to be at 8 weeks.

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					- Comparison of three weight maintenance programs on cardiovascular risk, bone and vitamins in sedentary older adults. Christensen P, Frederiksen R, Bliddal H, Riecke BF, Bartels EM, Henriksen M, Juul-S Rensen T, Gudbergsen H, Winther K, Astrup A, Christensen R.Obesity (Silver Spring). 2013 Oct;21(10):1982-90. doi: 10.1002/oby.20413 Epub 2013 Apr 13. This randomised controlled trial meets the inclusion criteria for study design, reports adverse events according to Good Clinical Practice, and reports on short-term safety data. - Improved nutritional status and bone health after diet-induced weight loss in sedentary osteoarthritis patients: a prospective cohort study. Christensen P, Bartels EM, Riecke BF, Bliddal H, Leeds AR, Astrup A, Winther K, Christensen R. Eur J Clin Nutr. 2012 Apr;66(4):504-9. doi: 10.1038/ejcn.2011.201. Epub 2011 Dec 21 and - Comparison of a low-energy diet and a very low-energy diet in sedentary obese individuals: a pragmatic randomized controlled trial P. Christensen, H. Bliddal, B. F. Riecke, A. R. Leeds, A. Astrup, and R. Christensen. Clinical Obesity (2011) 1(1): pp31-40	We could not find any data on bone density in Christensen et al. (2011). This Christensen et al. (2011) reference has now been added to the Riecke et al. (2010) reference in the summary table in the main guideline. The review protocol (found in appendix C) specifies that we were interested in VLCD compared to LCD. However, Christensen et al. (2013) compares safety after different maintenance regimens, not of VLCD to LCD. all patients randomised to the maintenance regimens had either VLCD or LCD. Christensen et al. (2012) was not included as it is not an RCT. As the consultee states, both papers by Jensen et al. are about safety after a low calorie diet, not a very low-calorie diet. As a result, they do not fit the requirements of the review protocol (found in appendix C).

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					The above two manuscripts also provide safety data with regards to bone density. - Effect of weight loss on the severity of psoriasis: a randomized clinical study.Jensen P, Zachariae C, Christensen R, Geiker NR, Schaadt BK, Stender S, Hansen PR, Astrup A, Skov L. JAMA Dermatol. 2013 Jul;149(7):795-801. doi: 10.1001/jamadermatol.2013.722. Erratum in: JAMA Dermatol. 2013 Aug;149(8):997. - Effect of Weight Loss on the Cardiovascular Risk Profile of Obese Patients with Psoriasis. Jensen P, Zachariae C, Christensen R, Geiker NR, Schaadt BK, Stender S, Astrup A, Hansen PR, Skov L. Derm Venereol. 2014 Feb 20. doi: 10.2340/00015555-1824. [Epub ahead of print] The two documents mentioned above report on an intervention using a low energy diet. They report on the cardiovascular risk profile in patients as well as other adverse events including constipation, diarrhoea, gallstones and nausea These comments also apply to the recommendations made by the GDG on page 94.	
Whitehouse	9	Full	77	10	Safety of VLCDs: constipation	Thank you for your comment. The GDG discussed

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Consultancy (Cambridge Weight Plan)					Cambridge notes that the evidence statement includes a reference to a potential higher frequency of constipation after VLCDs. This statement is extracted from the study by Riecke et al., which was considered by the GDG. The results of this study have been clearly misinterpreted, as the paper concluded that there was no greater likelihood of diarrhoea and constipation after VLCDs than after LCDs. Cambridge would also like to note that the composition of formula-based VLCDs is such that the daily intake of fibre - when following a VLCD - often exceeds the average consumed by the general population. This mitigates the low fibre consumption which may cause constipation. These comments also apply to the recommendations made by the GDG on pages 94 and 95.	what may be considered as adverse events and felt that constipation was an important adverse event to consider, from a patient perspective. The GDG discussed your comment and noted that the Riecke et al study you refer to did report a higher rate of constipation in those who had VLCDs compared with those who had LCDs. They also noted that there was some uncertainty around this result. However, they felt that the statement which stated that constipation 'may' be higher with VLCDs was an appropriate reflection of the evidence. As a result, the evidence statement has not been amended. The GDG noted your comment regarding the make-up of formula based VLCDs but did not wish to add further detail to the guideline in this regard as the evidence review was linked to all diets of 800kcal or less regardless of formulation.
Whitehouse Consultancy (Cambridge Weight Plan)	10	Full	77	17	<u>Safety of VLCDs: bone density</u> Cambridge would like to note that there is good evidence showing there is not an exacerbated reduction in bone density as a result of VLCD use. Some additional evidence has been provided, and is outlined once again below, for your convenience: - Improved nutritional status and bone health after diet-induced weight loss in	Thank you for your comment. We could not find any data on bone density in Christensen et al. (2011). Christensen et al. (2012) was not included as it is not an RCT.

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					sedentary osteoarthritis patients: a prospective cohort study. Christensen P, Bartels EM, Riecke BF, Bliddal H, Leeds AR, Astrup A, Winther K, Christensen R. Eur J Clin Nutr. 2012 Apr;66(4):504-9. doi: 10.1038/ejcn.2011.201. Epub 2011 Dec 21 and - Comparison of a low-energy diet and a very low-energy diet in sedentary obese individuals: a pragmatic randomized controlled trial P. Christensen, H. Bliddal, B. F. Riecke, A. R. Leeds, A. Astrup, and R. Christensen. Clinical Obesity (2011) 1(1): pp31-40 These comments also apply to the recommendations made by the GDG on page 94.	
Whitehouse Consultancy (Cambridge Weight Plan)	11	Full	77	14	<u>Safety of VLCDs: serum uric acid</u> With regards to the use of raised serum uric acid levels as a surrogate outcome of gout, Cambridge would like to highlight the following systematic review which shows that whilst changes in hepatic and renal outcomes were variable, generally there was either no change or improvements in either of these: - The effect of very low-calorie diets on renal and hepatic outcomes: a systematic review Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy 2013:6	Thank you for your comment. The GDG discussed and prioritised what may be considered the most important adverse events in relation to VLCDs. While gallstones were one of the prioritised outcomes, general and hepatic and renal measurements (which were reported in this systematic review) were not prioritised as outcomes to present to the GDG and, as a result, the paper by Rolland et al. (2013) was not included in guideline.

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					393–40 (Rolland et al) Cambridge asks that due account is taken of this research.	
Whitehouse Consultancy (Cambridge Weight Plan)	12	Full	94		<u>Safety of VLCDs: disorder eating, depression and postural hypertension.</u> Cambridge would like to note that a number of conclusions reached by the GDG are not grounded on appropriate scientific evidence. In particular, it is stated that "dramatic calorie reduction in diet with VLCDs, even though for a short period, may create or worsen pre-existing unhealthy eating patterns, or disordered eating, such as binge eating, bulimia nervosa, or night eating syndrome". It is also added that there are particular concerns with "the development of or worsening of depression in people who initially lose weight but then later gain it back". In relation to these statements, the document makes specific reference to the GDG's members "clinical experience", an expression which is not based on evidence and seems inappropriate. It is concerning that such references are used in place of the normally high evidence standards used by NICE. We hope that NICE will be able to withdraw such	Thank you for your comments. The section you refer to in the 'Recommendations and link to evidence' section (6.2.13) explains the rationale behind the choice of outcomes that the GDG, including patient members, chose to examine in the literature. Based on their expertise, they identified the adverse events that they considered important to consider, from a patient perspective. These are not statements about the evidence. The evidence is discussed in the subsequent sections of section 6.2.13. The wording in this section has been amended to clarify this.

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					statements unless they can demonstrate they are backed by solid scientific evidence.	
Whitehouse Consultancy (Cambridge Weight Plan)	13	Full	78	38	<u>Effective management strategies for maintaining weight loss after very low calorie diets – Clinical evidence</u> Cambridge considers that relevant evidence regarding the assessment of effective management strategies for maintaining weight loss after VLCDs in people who are overweight or obese has been overlooked, and would like to put forward the following papers for consideration by NICE: - Comparison of a low-energy diet and a very low-energy diet in sedentary obese individuals: a pragmatic randomized controlled trial P. Christensen, H. Bliddal, B. F. Riecke, A. R. Leeds, A. Astrup, and R. Christensen. Clinical Obesity (2011) 1(1): pp31-40 - Comparison of a very low-calorie-ketogenic diet with a standard low-calorie diet in the treatment of obesity. Endocrine. 2014 Mar 4. [Epub ahead of print] Moreno B1, Bellido D, Sajoux I, Goday A, Saavedra D, Crujeiras AB, Casanueva FF. - Effects of anti-obesity drugs, diet, and exercise on weight-loss maintenance after	Thank you for your comments. We address your submitted papers in turn Reference - Christensen 2011: This paper has been excluded from the VLCD effectiveness (Please note that this has been added to excluded clinical studies table, see Appendix J) and maintenance (see Appendix J) reviews because it is less than one year in duration. Reference – Moreno 2014: This paper has been excluded from the VLCD review because it does not include the correct intervention - as specified in the review protocol, participants did not receive a low calorie deficit or deficit diet. Reference - Johansson 2014: This systematic review was excluded from the maintenance review due to inadequate quality assessment / outcomes of interest are not included (Please note that this has been added to added to excluded clinical studies table, see Appendix J).

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					a very-low-calorie diet or low-calorie diet: a systematic review and meta-analysis of randomized controlled trials.Johansson K, Neovius M, Hemmingsson E.Am J Clin Nutr. 2014 Jan;99(1):14-23. doi: 10.3945/ajcn.113.070052. Epub 2013 Oct 30. Review.	
Whitehouse Consultancy (Cambridge Weight Plan)	14	Full	95		<u>VLCD maintenance – weight regain</u> Cambridge wishes to highlight that NICE's conclusion that "weight regain following a VLCD was common" does not have any evidential basis and is based solely on the "clinical experience" of the GDG. Given the low standard of evidence used to support such a statement, we hope that NICE will clarify whether it has now started forming recommendations based on the opinions of clinicians. As mentioned above, to Cambridge's knowledge, NICE has a stated practice of drafting guidance that has been informed by published evidence, not based on established best practice or clinical experience. In this respect, it is worth noting that existing evidence does not indicate that the proportion of potential weight regain after following a VLCD is any higher or more likely with a VLCD than with any other intervention, as implied by NICE's	Thank you for your comments. We have reviewed the evidence around the clinical and cost-effectiveness of very low calorie diets. The GDG, including patient members, discussed the available evidence and were consistent in their experience that people who have undertaken a very low calorie diet, regaining weight was common. We reject your assertion that the GDG have made their recommendations solely based on their clinical experience. The GDG have reviewed the evidence presented and made recommendations based on that evidence. The GDG believe that recommendations for the application of the evidence for NHS services for people who are overweight or obese has been appropriately supplemented by their clinical expertise and experience in line with NICE processes. How that has been applied is clearly documented in all the relevant evidence discussion sections in the guideline. With regards to the reference you provide - Haitman 1999: this paper has been excluded from the VLCD review because it is not a randomised controlled trial.

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					statement. The evidence available in this area is considerable, but we would like to highlight, in particular, the following paper: - Haitman BL and Garby L (1999 – Int J Obes Relat Metab Disord) which shows that a certain degree of weight regain can occur with every weight loss intervention including pharmacotherapy or bariatric surgery. Cambridge suggests that consideration should be given to scientific evidence before any firm recommendation is made on weight regain following a VLCD. These comments also apply to the recommendations made by the GDG on page 99.	
Whitehouse Consultancy (Cambridge Weight Plan)	15	Full	95		<u>VLCD maintenance – depression</u> Once again, Cambridge would like to challenge the GDG's conclusions – based on its "clinical experience" – that the potential weight regain following a VLCD "may cause depression and perpetuate a sense of failure in people trying to manage their weight". As noted, scientific evidence does not suggest that weight regain after VLCD is distinctly higher or more probable than with any other method of	Thank you for your comment. The GDG, including patient members, discussed the available evidence and were consistent in their experience that people who have undertaken a very low calorie diet and subsequently regained weight did experience a sense of failure and wished to highlight this within the Linking evidence to recommendations section of the full guideline.

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					weight loss. Cambridge would like to stress that any emotional side effects that accompany weight regain are not unique to VLCDs.	
Whitehouse Consultancy (Cambridge Weight Plan)	16	Full	96		Cambridge would like to point the GDG towards a number of recent studies which contradict their statement that "the evidence on adverse events was weak and that there could be other adverse events which would increase costs and reduce quality of life, making VLCDs even less likely to be cost-effective." In particular, we hope that NICE will be able to fully take into account the following evidence and consider it ahead of producing the final version of the guidance: • Johansson K, Neovius M, Lagerros YT et al. (2009) Effect of a very low energy diet on moderate and severe obstructive sleep apnoea in obese men: a randomised controlled trial. BMJ 2009; doi: 10.1136/bmj.b4609 • Johansson K, Hemmingsson E, Harlid R, et al. (2011) Longer term effects of very low energy diet on obstructive sleep apnoea in cohort derived from randomised controlled trial: prospective observational follow-up study. BMJ 2011;342:d3017	Thank your comments. Johansson et al (2009) was excluded as the control group was not a low calorie diet or deficit diet as specified in the review protocol (see Appendix C). Johansson et al. (2011), Johansson et al. (2013) and Christensen et al. (2012) (referred to as Christensen 2011B) are not included as they are not RCTs. The review protocol specifies that we were interested in VLCD compared to LCD. However, Christensen et al. (2013) compares safety after different maintenance regimens, not of VLCD to LCD. Furthermore, all patients randomised to the maintenance regimens had either VLCD or LCD.

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					doi:10.1136/bmj.d3017 These studies reported the rate for gout. • Johansson K, Sundström, Marcus C et al. (2013) Risk of symptomatic gallstones and cholecystectomy after a very-low-calorie diet or low-calorie diet in a commercial weight loss programme: 1-year matched cohort study. International Journal of Obesity doi:10.1038/ijo.2013.83 This paper gave the rate for hospitalisations for gallstone treatment after VLCD and after conventional 1200kcal/d diets. - Christensen P, Bartels E M, Riecke B F et al. (2011B) Improved nutritional status and bone health after diet-induced weight loss in sedentary osteoarthritis patients: a prospective cohort study. Eur T Cln Nutr 60 doi:10.1038/ejcn.2011.201 The Danish knee osteo-arthritis study (CAROT-LIGHT) was designed to include bone density and bone mineral values as secondary variables. This paper gave the bone mineral and bone density values at 16 weeks after an 8 week VLCD compared to an 810kcal/d LCD followed in both cases by an 8 week 1200kcal/d mixed	

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					formula and conventional food diet. - Christensen P, Frederiksen R, Bliddal H, Riecke BF, Bartels EM, Henriksen M, Juul-S Rensen T, Gudbergsen H, Winther K, Astrup A, Christensen R.Obesity (Silver Spring). 2013 Oct;21(10):1982-90. doi: 10.1002/oby.2013 Comparison of three weight maintenance programs on cardiovascular risk, bone and vitamins in sedentary older adults. Epub 2013 Apr 13 This paper gave figures for bone mineral and bone density – changes at 68 weeks were less than expected based on fat mass loss in the formula diet maintenance group probably because of the maintenance of improved vitamin D status.	
Whitehouse Consultancy (Cambridge Weight Plan)	17	Full	99	34	<u>Recommendations and link to evidence: Other considerations – commercial programmes</u> The draft guidance notes that "*It is outside the remit of this guideline to consider issues related to the use of VLCDs purchased by the individual*". As briefly mentioned above, this statement is inconsistent with other considerations within this draft guidance, as well as NICE public health guidance PH53 'Managing overweight and obesity in adults – lifestyle weight management services', which included consideration of	Thank you for your comment. As highlighted in the scope of the guideline (see Appendix A), NICE guidelines provide recommendations only for use within NHS settings, or settings in which NHS care is commissioned. As such, it is outside the remit of the guideline to provide recommendations on the use of very-low-calorie diets purchased by the individual. This is highlighted in the 'Linking evidence to recommendations' section on page 100. It is the role of NICE clinical guidelines to provide evidence based guidance for the NHS not the commercial sector.

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					commercial providers that might be contracted by commissioners. Reference and acknowledgement of commercial programmes is made on page 52, line 5 and line 15 of this draft guidance, as well as in the cost effectiveness analysis on page 63, line 10, and on page 68, line 14. It is therefore unclear why commercial programmes have been excluded on page 99. We believe that, rather than taking an approach which does not include consideration of commercial providers, NICE could have chosen to consult these providers about their risk management processes. The experience of commercial providers in applying risk management processes is being used by healthcare professionals worldwide, and could represent a useful support for healthcare providers in the public sector wanting to minimise risks of adverse outcomes related to the use of VLCDs purchased by individuals. Finally, it must be noted that groups as diverse as general practitioners or the Advertising Standards Authority use NICE CG43 as a basis for their work, and NICE should recognise this instead of excluding commercial programmes from the scope of this guidance.	
Whitehouse Consultancy	18	Full	114	1 to	Cambridge would like to note its strong disappointment with the little consideration that	Thank you for your comment. The cost quoted in unit cost section of the bariatric surgery review on

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(Cambridge Weight Plan)				5	has been given to the overall cost of bariatric surgery compared to VLCDs. Whilst for VLCDs a comprehensive – albeit inaccurate – overview of all the costs has been given, for bariatric surgery the draft guidance only includes references to the costs of stomach bypass procedures and restrictive stomach procedure. This approach does not take into account the full costs related to bariatric surgery, which are considerable. Cambridge would therefore like to ask for clarifications as to why different approaches have been taken when evaluating the costs for these interventions.	page 115 was provided for reference as to how much the surgery alone costs. However the GDG were aware that this figure only reflects a fraction of the overall cost of surgery and when making recommendations they mainly considered the conclusions of four economic evaluations presented in the published literature section on pages 112-114, that used robust economic modelling to assess the cost-effectiveness of bariatric surgery on early on-set type-2 diabetics. In these papers, the full cost of bariatric surgery has been calculated and analysed together with the review of the procedure's effectiveness. As no economic evaluations were identified around VLCDs a different approach had to be taken to account for the economic implications and the detail of the approach taken is clearly captured in Chapter 6, section 6.2.2.
Whitehouse Consultancy (LighterLife)	1	Full	General	General	LighterLife welcomes the opportunity to respond to this draft guidance. However we believe that the development process for this partial update has been unsatisfactory and risks compromising its final outcome. As such, we have provided several specific comments throughout our response, which serve to highlight a number of issues that adversely affect the overall quality and consistency of the draft guidance. We hope that NICE will be able to fully take these points into account before drafting the final version of this guidance.	Thank you for your comment. CG43 has been updated in line with the processes outlined in the NICE Guidelines manual 2012. We have responded to individual comments below.

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Whitehouse Consultancy (LighterLife)	2	Full	101	Paragraph 3	LighterLife wishes to enquire why no peer-reviewed, published papers reporting on clinically relevant outcomes after following a VLCD during the immediate pre-operative phase in advance of bariatric surgery have been included for consideration when preparing this draft guidance. We believe that the available evidence in this area would have been highly relevant to the development process of the draft guidance.	Thank you for your comment. It was outside the scope of this guideline update to consider pre-operative assessment. The review on bariatric surgery conducted as part of this update focussed on the clinical and cost effectiveness of surgery as a treatment of recent-onset type 2 diabetes only. Furthermore, the GDG were interested in assessing the use of VLCDs as a long-term maintenance strategy so, at the start of the guideline development period they specified in the review protocol (see Appendix C) that they were only interested in studies at least of one year. They felt that the use of VLCDs as a pre-surgical treatment was a separate issue. However, as the GDG noted an initial weight loss in the studies (though, which was not maintained), they felt it appropriate to recommend that the use of VLCDs for shorter term weight loss may be appropriate in specific circumstances (see recommendation 66).They further recommended that VLCDs should only be used as part of a multi-component weight management strategy.
Whitehouse Consultancy (LighterLife)	3	Full	44 to 52	14 to 18	LighterLife welcomes the new clarity with regards to the correct calorie thresholds and ranges for VLCDs on page 44. However, we would like to highlight that the draft guidance is inconsistent as it contains references to LCDs as being 800-1200 kcal/day (Table 7, page 53; and Table 27, page 71) whereas they are described as being 800-1600kcal/day on p44. We hope that NICE will be able to amend the final version of this guidance in line with currently accepted practice whilst taking into consideration current definitions based on	Thank you for your comments. The definition of LCDs has been corrected to reflect the 2006 definition of 800 -1600 kcal/day. Please refer to tables 7 and 27 of the guideline (PICO tables) and the review protocols in Appendix C. The review has included all relevant studies for kcal diets in this range and remains unchanged. It is recognised that the definition is somewhat arbitrary. The energy deficit created by any 'fixed energy dietary recommendation' will also be dependent on the gender, weight, age and activity levels of the

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					relevant pieces of legislation. This would be to avoid confusion and ensure that the thresholds and ranges are consistent throughout the document.	individual.
Whitehouse Consultancy (LighterLife)	4	Full	44	14	LighterLife notes the recommendation around LCDs but would suggest to the Guideline Development Group (GDG) that further evidence on the use of individual meal replacement products (MRPs) in the management of overweight and obesity is considered and additionally suggested as an area of further research.	Thank you for your comment. It was outside the scope of the guideline to consider the effectiveness of individual meal replacement products in the management of overweight and obesity. Additionally, in line with the NICE Guidelines manual, research recommendations are prioritised by the GDG in areas where limited evidence was identified during a review of the available evidence. As such, the GDG did not develop a recommendation for further research in this area.
Whitehouse Consultancy (LighterLife)	5	Full	44	14 to 17	LighterLife believes that the recommendation with regards to the restricted use of VLCDs is inconsistent with NICE's own guidance and other relevant guidance published by NHS bodies such as the NHS Commissioning Board. LighterLife wishes to draw attention to the apparent contradiction between the recommendations regarding the section on assessment (page 39, line 14) and the subsequent recommendation made on page 44, line 17, on limiting the use of VLCDs. We observe that on line 14 in the 'assessment' section, NICE states that referral to tier 3 services should be considered if "specialist intervention such as VLCD may be needed,"	Thank you for your comment. We do not believe the recommendations are contradictory. We note your comment on the NHS commissioning board policy for complex and severe obesity, however, our review of evidence has indicated a lack of effectiveness of VLCDs in maintaining weight loss and this evidence may be used to support future iterations of this policy. In the interim, recommendations remain in this guidance supporting the use of low calorie diets and the specific detail related to the use, where appropriate, of VLCDs that may be pursuant to the bullet point you identify from recommendation 30.

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					indicating that consideration of VLCDs sits within the treatment pathway for obesity. However, the recommendation on page 44 which states that VLCDs should only be used "in people who are obese who have a clinically-assessed need to rapidly lose weight" suggests that VLCDs should be considered solely to help individuals who are already obese and in need of undergoing treatment for other conditions that may be exacerbated by their weight, such as knee operations or fertility treatment.	
Whitehouse Consultancy (LighterLife)	6	Full	44	17 to 24	LighterLife also believes that the recommendations on the limited use of VLCDs is inconsistent with existing NICE public guidance PH53 'Managing overweight and obesity in adults – lifestyle weight management services', published in May this year. We note that both the tone and recommendations set out in PH53 - particularly recommendations 3 to 8, and 12 - clearly support the use of commercial weight management programmes in tier 2 community-based lifestyle and behaviour interventions for the purpose of preventing and treating not only obesity but the condition's comorbidities – including type-2 diabetes. The argument made in this draft that VLCDs should not "routinely" be considered for use outside of the limited tier 3 setting is therefore inconsistent. In particular, we would wish to highlight the fact that recommendation 12 of	We do not believe the recommendations are contradictory. Recommendation 66 refers to the long-term use of VLCDs as having the potential of being ineffective. We note your comment on the NHS commissioning board policy for complex and severe obesity, however, our review of evidence has indicated a lack of effectiveness of VLCDs in maintaining weight loss and this evidence may be used to support future iterations of this policy. In the interim, recommendations remain in this guidance regarding the use of low calorie diets and the specific detail related to the use, where appropriate, of VLCDs. We note your reference to PH 53. This guidance does note that lifestyle weight management services may include commercial weight management programmes in tier 2 services. We further note that this guideline recommends those services which are effective at 12 months or beyond. This guidance further notes the following programmes currently available in the UK to have been shown to be effective at 12 to 18 months: [in

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					PH53 implicitly supports the use of VLCDs in a tier 2 setting, as it lists commercial weight management providers like Weight Watchers, whose programmes have been deemed as cost effective. LighterLife contends that the use of VLCDs is more effective and cost-effective than other commercial weight management providers, as shown by the pieces of evidence to which we refer in our comments below. Consequently, we believe it is unsustainable for NICE to recommend restricting the use of VLCDs on the basis that they are not cost effective, when evidence exists to show that they are more cost effective than other commercial weight management programmes endorsed by NICE. LighterLife wishes to further highlight that the wording of this recommendation proposing a restriction on the use of VLCDs to "obese [individuals] who have a clinically-assessed need to rapidly lose weight" may conflict with the clinical guidance issued by the NHS Commissioning board policy for complex and severe obesity. LighterLife notes that the NHS Commissioning Board's "Clinical Commissioning Policy: Complex and Specialised Obesity Surgery" (2013) suggests patients should be managed in a non-surgical, medical tier 3 setting for 12-24 months, during which all other interventions, including VLCDs, should be considered. This indicates that the NHS Commissioning board supports the routine consideration of VLCDs for patients with a BMI of	alphabetical order] Rosemary Conley, Slimming World and Weight Watchers.). The purpose of the review into the use of very-low-calorie diets has been to determine their clinical and cost effectiveness for use in the NHS which is the remit for the NICE clinical guidelines programme which commissioned this guideline update.

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					35+ and co-morbidities, with a BMI of 40+, or with BMI 30+ and suffering from diabetes, that have tried all other interventions.	
Whitehouse Consultancy (LighterLife)	7	Full	50	16	LighterLife wishes to highlight that NICE's conclusion that "weight regain following a VLCD was common", whereby the direct implication is that the issue of regain is solely a problem for those who have followed a VLCD rather than any other method, does not have any evidential basis. Rather, this appears to be based solely on the "clinical experience" of the GDG. We would like to draw attention to the evidence set out in a paper by *Wadden TA, Phelan S. Behavioral assessment of the obese patient. In: Wadden TA, Stunkard AJ, eds. Handbook of obesity treatment. New York: Guilford Press, 2002:186-226* which is just one of many papers on the subject and which shows that a certain degree of weight regain occurs with *every* weight loss intervention including pharmacotherapy and bariatric surgery. Moreover, this evidence does not indicate that the proportion of potential weight regain after following a VLCD is any greater or more prevalent when compared with potential regain after any other intervention – including diet and exercise, pharmacotherapy and surgery. LighterLife suggests further research is undertaken and that consideration should be	Thank you for your comments. The evidence review conducted as part of this guideline clearly demonstrated that weight loss was not maintained following the initial dietary intervention. The GDG, including patient members, discussed the available evidence and were consistent in their experience that people who have undertaken a very low calorie diet, regaining weight was common. They did not wish to amend the recommendation in this area but further clarification has been added to section 6.2.13 to indicate that weight re-gain is common to other weight loss interventions also. The reference you provide (Wadden 2002) does not meet the criteria set out in the review protocol (please see appendix C). In response to your points about the use of the GDG clinical experience to inform recommendations we would respond that the GDG have used their clinical and personal expertise and experience to appropriately interpret the clinical evidence presented. The evidence presented and the GDG interpretation of that evidence is discussed in section 6.2.13. Further we would respond that the proposed constitution of the GDG was consulted upon as part of the scope consultation and we would contest that it is not representative of clinical expertise of relevance to the NHS use of such diets.

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					given to the above paper as well as other articles regarding *all* of the aforementioned weight loss methods so that an appropriate comparison can be made and certainly before any firm recommendations are made on weight regain following a VLCD. In addition, LighterLife would like to query why NICE considers "clinical experience" to be a sufficient evidence base for its recommendations in this instance. Whilst valuable to clinicians, this is arguably the lowest category of evidence available and is an inappropriate one on which to base recommendations in this draft guidance. Furthermore and to our knowledge, NICE has a stated practice of drafting guidance that has been informed by published evidence and not based on established best practice. Therefore, we request that NICE clarifies whether it has now started forming recommendations based on the opinions of clinicians. If this is the case, LighterLife asks that NICE provides justification for relying on the opinion of the GDG which we note is not made up of a body of individuals who are representative of the broader range of other medical weight management professionals Finally, we contend that the opinion of the GDG is that of a select group of clinicians and as such, NICE should refrain from relying on their opinion	

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					and should instead ensure that guidelines are always based on evidence.	
Whitehouse Consultancy (LighterLife)	8	Full	52	38	LighterLife would like to seek clarification on the rationale behind the inclusion in this draft guidance of intermittent VLCD use (such as the 5:2 diet), as being one and the same as VLCD use by way of total dietary replacement and for a much longer period of time, as is the generally accepted definition of a VLCD. We contend that it is not at all rational to include the use of VLCD products, consumed as part of a 5:2 diet within these guidelines. Furthermore, we would like to stress that there is no one widely accepted definition of intermittent fasting and that in addition, there is insufficient evidence to draw any conclusions with regards to the effectiveness of intermittent VLCD use. At the very least, NICE should have stated that that there is insufficient evidence to give guidance on the intermittent use of VLCDs, rather than categorically suggesting that the intermittent use of VLCDs is not effective. We contend that in the absence of adequate evidence establishing the effectiveness of intermittent VLCD use, no mention should be made of intermittent VLCD use in this draft guidance and we request removal of this.	Thank you for your comment. This guideline is an update of the CG 43 evidence review in this area. This review considered both continuous and intermittent VLCD diets. As part of this evidence review, three papers on the use of intermittent VLCDs were identified. However, our review prioritised calorific content rather than mode of delivery. Therefore, providing calorific content was less than or equal to 800 calories per day, the relevant data has been included in the review. The GDG noted that some patients find intermittent diets easier to follow and comply with. The GDG did not feel that there was an appropriate body of evidence to recommend against the use of intermittent VLCDs or make specific recommendations around the mode of delivery (intermittent or continuous).

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Whitehouse Consultancy (LighterLife)	9	Full	53	2	LighterLife suggests that the assessment and conclusions made on the clinical effectiveness of VLCDs with regards to weight loss and maintenance by the GDG, and contrary to that acknowledged by NICE, did not in fact consider key pieces of available research that have been published on this subject and which are widely available. LighterLife therefore requests that the following articles are reviewed as part of the evidence base for this guidance: - Moreno B1, Bellido D, Sajoux I, Goday A, Saavedra D, Crujeiras AB, Casanueva FF. *"Comparison of a very low-calorie-ketogenic diet with a standard low-calorie diet in the treatment of obesity."* Endocrine. 2014 Mar 4. [Epub ahead of print] - Christensen P, Frederiksen R, Bliddal H, Riecke BF, Bartels EM, Henriksen M, Juul-S Rensen T, Gudbergsen H, Winther K, Astrup A, Christensen R.Obesity (Silver Spring). 2013 Oct; 21(10):1982-90. doi: 10.1002/oby.20413: *"Comparison of three weight maintenance programs on cardiovascular risk, bone and vitamins in sedentary older adults"* Epub 2013 Apr 13. - Johansson K, Neovius M, Lagerros YT et	Thank you for your comments. We will deal with the reference s you provide in turn: Reference – Moreno 2014: This paper has been excluded from the VLCD review because it does not include the correct intervention - as specified in the review protocol, participants did not receive a low calorie deficit or deficit diet. Reference - Christensen 2013: This paper was excluded from the VLCD effectiveness review because the results are presented after the maintenance period only (Please note that this has now been added to excluded clinical studies table, see Appendix J). This paper was excluded from the VLCD maintenance review because the participants undertook a LCD before being randomised to a maintenance regime (please refer to the excluded clinical studies table in Appendix J). Reference – Johansson 2009: This paper has been excluded from the VLCD review because it does not include the correct intervention (please refer to Appendix J – excluded clinical studies). As specified in the review protocol, participants in the control group did not receive a low calorie deficit or deficit diet. Reference – Johansson 2011: This paper has been excluded from the VLCD review because it is not a randomised controlled trial. Reference - Johansson 2013A: This systematic

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					al. (2009) *Effect of a very low energy diet on moderate and severe obstructive sleep apnoea in obese men: a randomised controlled trial.* BMJ 2009; doi: 10.1136/bmj.b4609 - Johansson K, Hemmingsson E, Harlid R, et al. (2011) *Longer term effects of very low energy diet on obstructive sleep apnoea in cohort derived from randomised controlled trial: prospective observational follow-up study*. BMJ 2011;342:d3017 doi:10.1136/bmj.d3017 - Johansson K, Hemmingsson E, Neovius M (2013A) *Effects of anti-obesity drugs, diet, and exercise on weight-loss maintenance after a very-low-calorie diet or low-calorie diet: a systematic review and meta-analysis of randomized controlled trials.* Am J Clin Nutr doi: 10.3945/ajcn.113.070052.	review was excluded from the maintenance review due to inadequate quality assessment / outcomes of interest are not included (added to excluded clinical studies table, see Appendix J).
Whitehouse Consultancy (LighterLife)	10	Full	63	25	LighterLife believes that the calculations of the costs borne by the NHS for providing a VLCD are not based on actual practice. The figures provided in the draft guidance appear to be based on assumptions and speculation with respect to the time that a bariatric multi-disciplinary team would need to commit. In addition, there is no documented literature source, peer-reviewed or otherwise, to support these assumptions.	Thank you for your comment. The economic review found no evidence regarding the cost-effectiveness of VLCDs. As economic considerations need to be made with every recommendation a costing exercise was undertaken with individuals with experience and expertise in running VLCDs to determine how much they cost to the NHS. The costing exercise is therefore built on actual practice that is seen in NHS run VLCDs. This has been made clearer in the final guideline in the VLCD unit

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					We would also like to point out that tier 3 services are commissioned for a set fee and Key Performance Indicators are based mainly on throughput and success outcomes, unlike in secondary care settings where the cost of service is determined by the tariff price per consultation, and the number of consultations. Therefore, we believe that the estimates of the GDG regarding the amount of time and cost apportioned to the interventions are unrealistic and disproportionate and should be removed from the 'evidence-base' used to draft this partial update These comments also apply to the following pages / lines: page 64, line 10; page 64, line 11; page 64, line 19; page 65, line 2; page 65, line 7; page 65, line 21; page 66, line 1; page 66, line 20; page 67, line 11; page 67, line 14; page 68, line 8; page 68, line 12; page 69, line 13; and page 69, line 19.	cost section on page 64. Any assumptions where it was recognised that there may be variation in NHS practice, mainly concerning blood tests and MDT time, were varied in the sensitivity analysis. It is worth noting this exercise calculates the cost to the NHS by calculating the amount of resources used to carry out a VLCD. The fee that is reimbursed to the service does not reflect the actual cost to the NHS which could be higher or lower.
Whitehouse Consultancy (LighterLife)	11	Full	65	9 to 10	LighterLife objects to the statement "During the time the VLCD is being undertaken there are additional pressures placed on the service to accommodate people undertaking a VLCD." We are unable to find any evidence in support of this statement and hope that NICE will be able to either present the evidence supporting this statement or consider removing it from the final version of the guidance.	Thank you for your comment. After careful consideration the GDG decided not to change the statement. The VLCD costs were based on actual VLCD programmes run by several NHS services across the UK. The GDG felt that extra time should be spent on patients undertaking a VLCD to ensure the safety and efficacy of the diet. This requires much more intensive monitoring especially if the individual has co-morbidities that need considering alongside their use of a VLCD.

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Whitehouse Consultancy (LighterLife)	12	Full	65	11 to 12	LighterLife also objects to the statement "Individuals on a VLCD will be seen more and therefore more time will be spent by an administrator making appointments, entering additional information into a database and sending more letters to the individual's GP." Again and as argued above, we believe NICE should withdraw such a statement unless they can present supporting evidence based on literature. If indeed this statement is based on clinical experience, then we refer to earlier comments made within this document and with regards to the both the quality of this category of evidence as well as the make-up of the GDG.	Thank you for your comment. After careful consideration the GDG decided not to change the statement. The VLCD costs were based on experience from operating actual VLCD programmes run by several NHS services across the UK informed by key members of the guideline development group. We believe the group is reflective of services across England and appropriate to inform decision making in this area. This has now been made clearer in the final guideline in the VLCD unit cost section on page 64. A study by Lean et al, although excluded from the clinical review has now been discussed in the economic evidence. It recognises the additional GP time needed to conduct a VLCD which supports the notion of increased administration time.
Whitehouse Consultancy (LighterLife)	13	Full	70	25	LighterLife notes that NICE was not able to identify any relevant economic evaluations upon which to base its assessment of the cost effectiveness of VLCDs. To address this, LighterLife would like to put forward the following papers for consideration by NICE as they provide relevant economic evidence on the cost effectiveness of VLCDs. A short summary of the relevance of each paper is also included below. - *The cost-effectiveness of LighterLife as an intervention for obesity in the England* (2014) Lily Lewis, Matthew Taylor, Iain Broom, Kelly Johnston**.** Clinical Obesity	Thank you for your comment. The Lewis et al paper was not picked up in our searches due to its recent publication. Our search cut-off date was 06/02/2014. This paper has now been assessed. Using NICE methods, as found in the guideline manual (http://www.nice.org.uk/article/PMG6B/chapter/Appendix-G-Methodology-checklist-economic-evaluations), it would be excluded as it is partially applicable with very serious limitations. Regarding the study's applicability, the paper does not analyse the cost of VLCDs to the NHS, rather it reports the cost to Lighterlife. Standard dietary advice/low calorie diet is also not considered as a comparator. Methodologically, the study only uses a ten year

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					4(3): 180-88 This highly relevant paper, which provides important and comprehensive data that was collected in a period exceeding 1 year and was published in the journal *Clinical Obesity*, is unlikely to have been identified in the searches conducted in MEDLINE, Embase, The Cochrane Library or PsycINFO. - *Feasibility and indicative results from a 12-month low-energy liquid diet treatment and maintenance Programme for severe obesity* (2013) Lean M, Brosnahan N, McLoone P, McCombie L, Higgs AB, Ross H, Mackenzie M, Grieve E, Finer N, Reckless J, Haslam D, Sloan B, Morrison D. British Journal of General Practice Feb;63(607):e115-24. doi: 10.3399/bjgp13X663073. This paper, whilst investigating the feasibility of Low Calorie Diets (800kcal and above) provides the costs per patient for the delivery of a formula-based weight loss programme within routine primary NHS care, the costs of which are consistent with that for VLCDs and which are highly relevant to this review.	time horizon rather than the lifetime time-horizon NICE recommends. If a lifetime horizon was used then it is unlikely VLCDs would remain cost-effective as the study demonstrates that eventually individuals put on more weight using a VLCD as opposed to using a Weightwatchers diet. The benefits of a VLCD are therefore only accumulated in the short term. The short ten year time horizon biases the results in favour of VLCDs. The GDG noted that the paper also attaches a very high quality of life benefit to four years of rapid weight loss and weight regain. The GDG further noted that this is unhelpful in the management of obesity as they are aware of the well-documented literature on the dangers of weight cycling. The clinical evidence used to inform the paper is considered to be weak: the clinical data for the effectiveness of VLCD is based on observational data which is highly subject to bias. For these reasons, the paper by Lewis et al is excluded from the evidence review conducted for the guideline. The Lean study was excluded from the economic evidence as it only derives the costs of a low energy liquid diet with no comparison to what the cost might be for another intervention. It is worth noting that the nurses and dietitians used in the Lean study were familiar with the counterweight programme and so the training and minutes of nurse time are likely to be an underestimate of the cost of providing the programme. The GDG noted that VLCDs are fairly unfamiliar to most nurses and GPs and there are significant training issues such as dealing with

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						monitoring blood glucose levels. Finally the exclusion criteria for the participants in the study were fairly wide and this would therefore exclude a large number of individuals that would be seen in a tier 3 service. Although this study was excluded as it is not a full economic evaluation, costs from Lean et al have now been quoted in the final version of the guideline in the VLCD 'economic considerations' section on pages 70-71 and they fall within the costs quoted in the consultation version of the guideline. The clinical review for VLCDs found no evidence that weight loss, relative to standard dietary advice, was sufficiently sustained for VLCDs to be cost-effective at a £20,000 per QALY threshold.
Whitehouse Consultancy (LighterLife)	14	Full	71	6	LighterLife believes that relevant evidence regarding the assessment of the safety and adverse effects of VLCDs when used to reduce and maintain weight loss in overweight and obese individuals has been overlooked, and would request NICE to consider the following articles as part of the evidence base for this draft guidance. A brief summary outlining the relevance of each paper is also included below. - *Comparison of three weight maintenance programs on cardiovascular risk, bone and vitamins in sedentary older adults.* Christensen P, Frederiksen R, Bliddal H, Riecke BF, Bartels EM, Henriksen M, Juul-S Rensen T, Gudbergsen H, Winther K, Astrup A, Christensen R.Obesity (Silver Spring). 2013 Oct;21(10):1982-90.	Thank you for your comments. As per Appendix G (clinical evidence tables), Christensen et al. (2011) has been included in the same evidence table as Riecke et al. (2010) since it is a report from the same study. However, the safety data was extracted from Riecke et al. (2010) rather than Christensen et al. (2011) since the former is reported to be at 16 weeks while the later was reported to be at 8 weeks. We could not find any data on bone density in Christensen et al. (2011). This Christensen et al. (2011) reference has now been added to the Riecke et al. (2010) reference in the summary table in the main guideline. The review protocol (found in Appendix C) specifies that we were interested in VLCD compared to LCD. However, Christensen et al. (2013) compares safety

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					doi: 10.1002/oby.20413 Epub 2013 Apr 13. This randomised controlled trial meet the inclusion criteria for study design and reports adverse events according to Good Clinical Practice as well as reporting on short-term safety data. - *Improved nutritional status and bone health after diet-induced weight loss in sedentary osteoarthritis patients: a prospective cohort study.* Christensen P, Bartels EM, Riecke BF, Bliddal H, Leeds AR, Astrup A, Winther K, Christensen R. Eur J Clin Nutr. 2012 Apr;66(4):504-9. doi: 10.1038/ejcn.2011.201. Epub 2011 Dec 21 and - *Comparison of a low-energy diet and a very low-energy diet in sedentary obese individuals: a pragmatic randomized controlled trial* P. Christensen, H. Bliddal, B. F. Riecke, A. R. Leeds, A. Astrup, and R. Christensen. Clinical Obesity (2011) 1(1): pp31-40 These papers report on various aspects of a study which investigated VLCD use in elderly obese participants with knee osteoarthritis. In summary, Christensen P et al. (2012) describes the weight changes in the first 16 weeks, and	after different maintenance regimens, not of VLCD to LCD. Furthermore, all patients randomised to the maintenance regimens had either VLCD or LCD. Christensen et al. (2012) was not included as it is not an RCT.

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					Christensen P et al (2013) describes results at 68 weeks (16 + 52). Finally, Christensen P et al (2011) described body composition changes, bone mineral and bone density at 16 weeks This randomised controlled trial compared a VLCD intervention versus a standard formula low calorie diet and reports on changes in bone minerals and bone density, which we should highlight were less than expected and likely to be due to improved nutritional status as a result of following a VLCD.	
Whitehouse Consultancy (LighterLife)	15	Full	77	10-11	We note that the evidence statements within this draft guidance include a reference to a potentially higher frequency of constipation after VLCDs. This statement is extracted from the study by Riecke et al. which was considered by the GDG. However, it is apparent that the results of the study have been misinterpreted by GDG members, as the paper concluded that there was no significantly greater effect of VLCDs compared with LCDs on diarrhoea and constipation. We also wish to highlight that the compositional make-up of formula-based VLCDs is such that the daily intake of fibre when following a VLCD often exceeds the average consumed by the general population (https://www.gov.uk/government/statistics/national-diet-and-nutrition-survey-results-from-years-1-to-4-combined-of-the-rolling-programme-for-2008-and-2009-to-2011-and-2012) which helps	Thank you for your comment. The GDG discussed what may be considered as adverse events and felt that constipation was an important adverse event to consider, from a patient perspective. The GDG discussed your comment and noted that the Riecke et al study you refer to did report a higher rate of constipation in those who had VLCDs compared with those who had LCDs. They also noted that there was some uncertainty around this result. However, they felt that the statement which stated that constipation 'may' be higher with VLCDs was an appropriate reflection of the evidence. As a result, the evidence statement has not been amended. The GDG noted your comment regarding the make-up of formula based VLCDs but did not wish to add further detail to the guideline in this regard as the evidence review was linked to all diets of 800kcal or less regardless of formulation.

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					mitigates low fibre consumption which may lead to constipation.	
Whitehouse Consultancy (LighterLife)	16	Full	77	14	LighterLife wishes to refer the GDG to the following systematic review which references a large selection of papers examining, amongst other things, increased serum uric acid levels after VLCD usage: - *The effect of very low-calorie diets on renal and hepatic outcomes: a systematic review Diabetes, Metabolic Syndrome and Obesity:* Targets and Therapy 2013:6 393–40 (Rolland et al) We would like to highlight that the paper in itself shows that whilst changes in hepatic and renal outcomes were variable, generally there was either no change or improvements in either of these. LighterLife suggests that the GDG take into account of this research as part of their evidence review.	Thank you for your comment. The GDG discussed and prioritised what may be considered the most important adverse events in relation to VLCDs. While gallstones were one of the prioritised outcomes, general and hepatic and renal measurements (which were reported in this systematic review) were not prioritised as outcomes to present to the GDG and, as a result, the paper by Rolland et al. (2013) was not included in guideline.
Whitehouse Consultancy (LighterLife)	17	Full	94	General	LighterLife asserts that the GDG's conclusion that dramatic calorie reduction in VLCDs - even though for a short period - may create or exacerbate existing eating disorders should be grounded in evidence and not based on the GDG's "clinical experience." This is not a sufficient basis for drawing up important recommendations. We hope that NICE will be able to withdraw this	Thank you for your comments. The section you refer to the in the 'Recommendations and link to evidence' section (6.2.13) explains the rationale behind the choice of outcomes that the GDG, including patient members, chose to examine in the literature. Based on their expertise, they identified the adverse events that they considered important to consider, from a patient perspective. These are not statements about the evidence. The evidence is discussed in the subsequent sections of section

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					conclusion unless it is backed by solid scientific evidence which we would welcome reference to.	6.2.13. The wording in this section has been amended to clarify this.
Whitehouse Consultancy (LighterLife)	18	Full	95	General	LighterLife challenges the GDG's report, based on its "clinical experience" that the potential weight regain following a VLCD "may cause depression and perpetuate a sense of failure in people trying to manage their weight." As noted above, the evidence we have highlighted does not suggest that weight regain after VLCD is distinctly higher or more probable than with any other method of weight loss. LighterLife wishes to emphasise accordingly that any emotional side effects that accompany weight regain are not unique to any such regain following a VLCD. LighterLife would like to seek an explanation as to why, nevertheless, the GDG has reserved this view for VLCDs, rather than acknowledging this to be a blanket issue with any method of weight loss. LighterLife would also like NICE to clarify the evidential basis for this view as set out by the GDG In addition, LighterLife hopes that the GDG will consider the additional evidence referenced above in order to assess if the benefit of rapid weight loss, offset against safety and maintenance of weight loss, may result in any further changes to these recommendations.	Thank you for your comment. The GDG, including patient members, discussed the available evidence and were consistent in their experience that people who have undertaken a very low calorie diet and subsequently regained weight did experience a sense of failure and wished to highlight this within the Linking evidence to recommendations section of the full guideline.

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Whitehouse Consultancy (LighterLife)	19	Full	96		The GDG explain that "the evidence on adverse events was weak and that there could be other adverse events which would increase costs and reduce quality of life, making VLCDs even less likely to be cost-effective." LighterLife strongly disagree with this based on a number of pieces of well-designed clinical studies that appear not to have been considered. In addition to the Christensen papers cited above, this includes: • Johansson K, Sundström, Marcus C et al. (2013) Risk of symptomatic gallstones and cholecystectomy after a very-low-calorie diet or low-calorie diet in a commercial weight loss programme: 1-year matched cohort study. International Journal of Obesity doi:10.1038/ijo.2013.83 This paper gave the rate for hospitalisations for gallstone treatment after VLCD and after conventional 1200kcal/d diets.	Thank your comments. In line with the study design outlined in the protocol, Johansson et al. (2013) has not been included in the review as it is not an RCT.
Whitehouse Consultancy (LighterLife)	20	Full	99		Lighterlife notes that the GDG states it is "outside the remit of this guideline to consider issues related to the use of VLCDs purchased by the individual." We consider this statement to be disingenuous, given that GDG members will surely be aware of the impact that NICE guidelines have on other relevant stakeholders	Thank you for your comment. As highlighted in the scope of the guideline (see Appendix A), NICE guidelines provide recommendations only for use within NHS settings, or settings in which NHS care is commissioned. As such, it is outside the remit of the guideline to provide recommendations on the use of very-low-calorie diets purchased by the

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					such as, for example, clinicians or the Advertising Standards Authority. It is clear that these guidelines will have a considerable effect on the use of commercially available VLCDs, and we believe this should have been explicitly recognised by the GDG. In addition, there would have been some obvious benefit in consulting commercial providers with regards to a number clinically relevant areas including their risk management procedures, how protocols which minimise the risks of adverse outcomes related to the use of VLCDs, are developed and written to name but a few. Certainly there is a growing body of knowledge that could be used to help inform the use of VLCDs in a healthcare setting.	individual. This is highlighted in the 'Linking evidence to recommendations' section on page 100. It is the role of NICE clinical guidelines to provide evidence based guidance for the NHS not the commercial sector.
Whitehouse Consultancy (LighterLife)	21	Full	114	1 to 5	LighterLife would like to highlight how little consideration has been given in the draft guidelines to the overall costs of bariatric surgery compared to VLCDs. While in the case of VLCDs NICE has set out a comprehensive overview of the all the costs related to VLCDs, in the case of bariatric surgery the draft guidelines only include references to the cost of stomach bypass procedure and restrictive stomach procedure. This approach does not take into account the costs related to bariatric surgery, which are considerable and which have been taken into account in the case of VLCDs.	Thank you for your comment. The cost quoted in the unit cost section of the bariatric surgery review on page 115 was provided for reference as to how much the surgery alone costs. However the GDG were aware that this figure only reflects a fraction of the overall cost of surgery and when making recommendations they mainly considered the conclusions of four economic evaluations presented in the published literature section on pages 112-114, that used robust economic modelling to assess the cost-effectiveness of bariatric surgery on early onset type-2 diabetics. In these papers, the full cost of bariatric surgery has been calculated and analysed together with the review of the procedure's

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					We would like to obtain clarifications from NICE as to why different approaches have been taken when evaluating costs for these interventions.	effectiveness. As no economic evaluations were identified around VLCDs a different approach had to be taken to account for the economic implications and the detail of the approach taken is clearly captured in Chapter 6, section 6.2.2
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	1	Full	General	General	The Very Low Calorie (VLCD) Industry Group welcomes the opportunity to comment on the partial update of Clinical Guidance 43 on Obesity. We believe that the development process for this partial update has suffered from a number of significant shortcomings, which risk compromising its final outcome. We have set out in our comments below a number of issues which seriously affect the overall quality and consistency of the draft guidance, and we hope that NICE will be able to fully take these points into account before drafting the final version of this guidance.	Thank you for your comment. CG43 has been updated in line with the processes outlined in the NICE Guidelines manual 2012. We have responded to individual comments below.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	2	Full	General	General	We would like to ask NICE why relevant research regarding the use of VLCDs in the immediate pre-operative phase for bariatric surgery was excluded from consideration when preparing this draft guidance. We believe that the available evidence in this area would have been highly relevant to the development process of the draft guidance.	Thank you for your comment. Thank you for your comment. It was outside the scope of this guideline update to consider pre-operative assessment. The review on bariatric surgery conducted as part of this update focussed on the clinical and cost effectiveness of surgery as a treatment of recent-onset type 2 diabetes only. Furthermore, the GDG were interested in assessing the use of VLCDs as a long-term maintenance strategy so, at the start of the guideline development period they specified in the review protocol (see

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						Appendix C) that they were only interested in studies at least of one year. They felt that the use of VLCDs as a pre-surgical treatment was a separate issue. However, as the GDG noted an initial weight loss in the studies (though, which was not maintained), they felt it appropriate to recommend that the use of VLCDs for shorter term weight loss may be appropriate in specific circumstances (see recommendation 66).They further recommended that VLCDs should only be used as part of a multi-component weight management strategy.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	3	Full	44	14	The VLCD Industry Group notes the recommendation around low calorie diets (LCDs) and would suggest to the Guideline Development Group (GDG) that further research on the use of not just LCDs but also meal replacement products (MRPs) is undertaken.	Thank you for your comment. It was outside the scope of the guideline to consider the effectiveness of individual meal replacement products in the management of overweight and obesity. Additionally, in line with the NICE Guidelines manual, research recommendations are prioritised by the GDG in areas where limited evidence was identified during a review of the available evidence. As such, the GDG did not develop a recommendation for further research in this area.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	4	Full	44	14 to 18	The VLCD Industry Group welcomes the new clarity with regards to the correct calorie thresholds and ranges for VLCDs (800 kcal/day or less) compared to the previous guidance. However, we would like to highlight that the draft guidance is inconsistent with regards to the thresholds and ranges for LCDs. While on page 44 the draft guidance makes reference to LCDs	Thank you for your comments. The definition of LCDs has been corrected to reflect the 2006 definition of 800 -1600 kcal/day. Please refer to tables 7 and 27 of the guideline (PICO tables) and the review protocols in Appendix C. The review has included all relevant studies for kcal diets in this range and remains unchanged. It is recognised that the definition is somewhat arbitrary. The energy deficit created by any 'fixed energy dietary

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					as being within a range of 800-1600 kcal/day, they are defined elsewhere as being between 800-1200 kcal/day (Table 7, page 53; and Table 27, page 71). We believe that the definition of LCDs in the draft guidance should be aligned to the latter range (800-1200 kcal/day), and we hope that NICE will be able to amend the final version of this guidance to avoid confusion.	recommendation' will also be dependent on the gender, weight, age and activity levels of the individual.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	5	Full	44	17 to 24	The VLCD Industry Group would like to state its strong disappointment with the wording of dietary recommendations 65 and 66, which we believe are not grounded in clinical evidence. We also believe that these recommendations are inconsistent with NICE Public Health guidance on *Managing overweight and obesity in adults – lifestyle weight management services* (PH53), which was published in May 2014. The recommendations set out in PH53, and particularly recommendations 3 to 8, and 12, are supportive of the use of commercial weight management programmes in the framework of Tier 2 community-based lifestyle and behaviour interventions, for the purpose of preventing and treating not only obesity but the condition's comorbidities – including type-2 diabetes. In addition, it is clear that recommendation 12 of PH53 implicitly supports the use of VLCDs in a Tier 2 setting by listing commercial weight management providers such as Weight Watchers, whose programmes have been deemed as cost effective.	Thank you for your comment. We do not believe the recommendations are contradictory. Recommendations 65 and 66 refer to the long-term use as having the potential of being ineffective. We note your comment on the NHS England commissioning board policy for complex and severe obesity, however, this guidance supersedes this policy and our review of evidence has indicated a lack of effectiveness of VLCDs in maintaining weight loss and this evidence may be used to support future iterations of this policy. In the interim, recommendations remain in this guidance supporting the use of low calorie diets and the specific detail related to the use, where appropriate, of VLCDs. We note your reference to PH 53. This guidance does note that lifestyle weight management services may include commercial weight management programmes in tier 2 services. We further note that this guideline recommends those services which are effective at 12 months or beyond. This guidance further notes the following programmes currently available in the UK to have been shown to be effective at 12 to 18 months: [in alphabetical order] Rosemary Conley, Slimming

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					The VLCD Industry Group also finds that the wording of recommendation 65 may conflict with the clinical commissioning policy regarding severe and complex obesity issued by the NHS Commissioning board in 2013. This guidance states that patients should be managed in a non-surgical (Tier 3) setting for 12-24 months, during which all alternative interventions, including VLCDs, should be considered. This indicates that the NHS Commissioning Board supports the routine consideration of VLCDs for patients with a BMI of 35+ and co-morbidities, with a BMI of 40+, or with BMI 30+ and suffering from diabetes. We would welcome a review of recommendations 65 and 66 in light of recent evidence provided in our comments, below, supporting the effective, safe use of VLCDs for weight loss and weight management.	World and Weight Watchers.). The purpose of the review into the use of very-low-calorie diets has been to determine their clinical and cost effectiveness for use in the NHS which is the remit for the NICE clinical guidelines programme which commissioned this guideline update.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group- VLCD)	6	Full	44	31 to 32	The VLCD Industry Group believes 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." As highlighted in our comments below, a patient undertaking any method of weight loss will always regain weight unless he or she is able to limit food and drink consumption and is able to undertake the required amount of the right type of exercise.	Thank you for your comment. The GDG, including patient members, discussed the available evidence and were consistent in their experience that people who have undertaken a very low calorie diet and subsequently regained weight did experience a sense of failure. Accordingly, the GDG felt that it was important to manage expectations and wished to highlight this within the Linking evidence to recommendations section of the full guideline. The inclusion of the text in the Linking evidence to recommendations section captures a GDG perspective that might guide healthcare

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					Therefore, we believe there is no reason for taking an approach which highlights such a basic statement of fact only within recommendations related to VLCDs and not with other weight loss methods.	professionals to tailor their discussions with the individual. We are aware that other diets and weight loss methods may have a similar profile to that outlined in this guidance for VLCDs. However, we have not reviewed the evidence in relation to these weight loss methods and can only comment on these issues in relation to the review conducted on the effectiveness of VLCDs.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	7	Full	50	16	We have noted in our comment number 16, below, the GDG's conclusion that "weight regain following a VLCD was common." We believe that such a statement lacks any scientific basis and we would have expected the GDG to recommend further research in this area, given the concerns based on their "clinical experience." A patient undertaking any method of weight loss will always regain weight unless he or she is able to limit food and drink consumption and is able to undertake the required amount of the right type of exercise. The VLCD Industry Group strongly questions why this basic statement of fact is included only within recommendations related to VLCDs and not with other weight loss methods, including diet and exercise, pharmacotherapy and surgery. We believe it is important to draw NICE's attention to the evidence contained in the following paper, which shows that a certain degree of weight regain can occur with *every*	Thank you for your comment. The clinical review found RCT evidence for VLCDs that showed weight regain was fairly common and significant for individuals undertaking a VLCD. Evidence of weight regain was not found for other interventions assessed in this guideline and although it may occur it is far less common. This statement reflects not only clinical experience but is backed up by evidence presented in the guideline. The reference cited (Wadden 2002) does not meet the criteria set out in the review protocol. Specifically, it was not the interest of this review to compare weight regain across various weight loss interventions.

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					weight loss intervention including pharmacotherapy or bariatric surgery: Wadden TA, Phelan S. *Behavioral assessment of the obese patient.* In: Wadden TA, Stunkard AJ, eds. Handbook of obesity treatment. New York: Guilford Press, 2002:186-226. We believe that consideration should be given to the above paper and to the other papers referenced in the VLCD Industry Group response to this consultation before making any recommendations regarding weight regain following a VLCD. The VLCD Industry Group finds it particularly striking that NICE considers "clinical experience" to be a sufficient evidence base for its recommendations, and that it does not believe further research should have been conducted before deciding whether to support or reject such a statement.	
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	8	Full	53	2	The VLCD Industry group believes that the review of the clinical evidence on the effectiveness of VLCDs conducted by NICE has been clearly insufficient and has failed to take into account a number of relevant pieces of evidence. Only three papers have been considered in addition to those included in the previous review, and all of them were published before the year 2000.	Thank you for your comments. We will deal with the references you provide in turn: Reference – Moreno 2014: This paper has been excluded from the VLCD review because it does not include the correct intervention - as specified in the review protocol, participants did not receive a low calorie deficit or deficit diet. Reference - Christensen 2013: This paper was

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					We consider this to be a very notable shortcoming and we would like to highlight five pieces of evidence on the clinical effectiveness of very low calorie diets in reducing weight, which the Industry Group believes should have been included in the review, as listed below: • Moreno B, Bellido D, Sajoux I, Goday A, Saavedra D, Crujeiras AB, Casanueva FF. *Comparison of a very low-calorie-ketogenic diet with a standard low-calorie diet in the treatment of obesity*. Endocrine. 2014 Mar 4. The randomised controlled trial reported in this paper compares a VLCD ketogenic intervention against a standard low calorie diet (LCD) and reports on reductions of weight after a 12 months period. • Christensen P, Frederiksen R, Bliddal H, Riecke BF, Bartels EM, Henriksen M, Juul-S Rensen T, Gudbergsen H, Winther K, Astrup A, Christensen R.Obesity (Silver Spring). 2013 Oct;21(10):1982-90. doi: 10.1002/oby.2013 *Comparison of three weight maintenance programs on cardiovascular risk, bone and vitamins in sedentary older adults.* Epub 2013 Apr 13 This paper reports on mean changes in weight and anthropometry as the result of an RCT which compared a very low calorie diet intervention versus a standard low calorie diet	excluded from the VLCD effectiveness review because the results are presented after the maintenance period only (Please note that this has now been added to excluded clinical studies table, see Appendix J). This paper was excluded from the VLCD maintenance review because the participants undertook a LCD before being randomised to a maintenance regime (please refer to the excluded clinical studies table in Appendix J). Reference – Johansson 2009: This paper has been excluded from the VLCD review because it does not include the correct intervention (please refer to Appendix J – excluded clinical studies). As specified in the review protocol, participants in the control group did not receive a low calorie deficit or deficit diet. Reference – Johansson 2011: This paper has been excluded from the VLCD review because it is not a randomised controlled trial. Reference - Johansson 2013A: This systematic review was excluded from the maintenance review due to inadequate quality assessment / outcomes of interest are not included (added to excluded clinical studies table, see Appendix J).

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					and which reports changes in weight over a 68-week period. • Johansson K, Neovius M, Lagerros YT et al. (2009) *Effect of a very low energy diet on moderate and severe obstructive sleep apnoea in obese men: a randomised controlled trial.* BMJ 2009; doi: 10.1136/bmj.b4609 • Johansson K, Hemmingsson E, Harlid R, et al. (2011) *Longer term effects of very low energy diet on obstructive sleep apnoea in cohort derived from randomised controlled trial: prospective observational follow-up study*. BMJ 2011;342:d3017 doi:10.1136/bmj.d3017 These papers report a randomised controlled trial on the effect of weight loss with VLCD compared to conventional care in obese men with severe and moderate obstructive sleep apnoea. The VLCD was used for 7 weeks followed by 2 weeks of 1200kcal/d food re-introduction diet. After the randomised controlled trial the control subjects followed the active intervention and all were than offered weight maintenance with partial use of formula diet up to week 52. • Johansson K, Hemmingsson E, Neovius M (2013A) *Effects of anti-obesity drugs, diet, and exercise on weight-loss maintenance*	

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					after a very-low-calorie diet or low-calorie diet: a systematic review and meta-analysis of randomized controlled trials. Am J Clin Nutr doi: 10.3945/ajcn.113.070052. This paper analysed and reported on randomised controlled trials of weight maintenance interventions after weight loss with VLCDs or LCDs, showing that three interventions (high protein diets, drugs, part use of formula diets) resulted in significantly greater amounts of weight loss maintained.	
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	9	Full	53	11	We note the inclusion among the clinical evidence considered of three papers on the intermittent use of VLCDs (such as the 5:2 diet, for example). We believe that there is not yet enough scientific evidence available to draw conclusions on the effectiveness of this type of interventions, and therefore we argue that no references to them should have been included in the draft guidelines. We believe that, in the absence of adequate evidence, the draft guidelines should not have suggested the intermittent use of VLCD is not effective.	Thank you for your comment. This guideline is an update of the CG 43 evidence review in this area. This review considered both continuous and intermittent VLCD diets. As part of this evidence review, three papers on the use of intermittent VLCDs were identified. However, our review prioritised calorific content rather than mode of delivery. Therefore, providing calorific content was less than or equal to 800 calories per day, the relevant data has been included in the review. The GDG noted that some patients find intermittent diets easier to follow and comply with. The GDG did not feel that there was an appropriate body of evidence to recommend against the use of intermittent VLCDs or make specific recommendations around the mode of delivery (intermittent or continuous).
Whitehouse Consultancy (the Very Low	10	Full	63	25	The VLCD Industry Group believes that the calculations of the costs borne by the NHS for providing a VLCD diet are not based on actual	Thank you for your comment. The economic review found no evidence regarding the cost-effectiveness of VLCDs. As economic considerations need to be

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Calorie Diet Industry Group-VLCD)					practice. The analysis outlined in the draft guidance seems to contain a number of assumptions and speculations in respect of the time that a bariatric multi-disciplinary team would need to commit, and there is no documentary literature source to support these assumptions. We would also like to point out that Tier 3 services are commissioned for a set fee and Key Performance Indicators are based mainly on throughput and success outcomes, unlike in secondary care settings where the cost of service is determined by the tariff price per consultation, and the number of consultations. Therefore, we believe that the estimates of the Guidance Development Group (GDG) regarding the amounts of time and cost apportioned to the interventions are unrealistic and disproportionate. These comments also apply to the following pages / lines: page 64, line 10; page 64, line 11; page 64, line 19; page 65, line 2; page 65, line 7; page 65, line 21; page 66, line 1; page 66, line 20; page 67, line 11; page 67, line 14; page 68, line 8; page 68, line 12; page 69, line 13; and page 69, line 19.	made with every recommendation a costing exercise was undertaken with individuals with experience and expertise in running VLCDs in the NHS to determine how much they cost. The costing exercise is therefore built on actual practice that is seen in NHS run VLCDs. This has been made clearer in the final guideline in the VLCD unit cost section on page 64. Any assumptions where it was recognised that there may be variation in NHS practice, mainly concerning blood tests and MDT time, were varied in the sensitivity analysis.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-	11	Full	65	9 to 10	We object strongly to the statement "During the time the VLCD is being undertaken there are additional pressures placed on the service to accommodate people undertaking a VLCD," as there is no literature reference supporting it.	Thank you for your comment. After careful consideration the GDG decided not to change the statement. The VLCD costs were based on actual VLCD programmes run by several NHS services across the UK. The GDG felt that extra time should be spent on patients undertaking a VLCD to ensure

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VLCD)					We hope NICE will be able to present evidence supporting this statement or consider dropping it from the final version of the guidance.	the safety and efficacy of the diet. This requires much more intensive monitoring especially if the individual has co-morbidities that need considering alongside their use of a VLCD.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	12	Full	65	11 to 12	We also strongly object to the statement "Individuals on a VLCD will be seen more and therefore more time will be spent by an administrator making appointments, entering additional information into a database and sending more letters to the individual's GP." As argued above, we believe NICE should withdraw such a statement unless they can present supporting evidence based on literature.	Thank you for your comment. The VLCD costs were based on experience from operating actual VLCD programmes run by several services across the UK. This has been made clearer in the final guideline in the VLCD unit cost section on page 64. A study by Lean et al, although excluded from the clinical review has now been discussed in the economic evidence. It recognises the additional GP time needed to conduct a VLCD which supports the notion of increased administration time.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	13	Full	70	25	We note with concern that NICE was unable to identify any relevant economic evaluations upon which to base its assessment of the cost effectiveness of VLCDs. We would like to highlight the following papers which we believe are of relevance with regards to the assessment of cost effectiveness of VLCDs: Lily Lewis, Matthew Taylor, Iain Broom, Kelly Johnston. Clinical Obesity 4(3): 180-88. *The cost-effectiveness of LighterLife as an intervention for obesity in the England* (2014). Lean M, Brosnahan N, McLoone P, McCombie L, Higgs AB, Ross H, Mackenzie M, Grieve E, Finer N, Reckless J, Haslam D, Sloan B, Morrison D. British Journal of General Practice Feb;63(607):e115-24. doi: 10.3399/bjgp13X663073. *Feasibility and*	Thank you for your comment. The Lewis et al paper was not picked up in our searches due to its recent publication. The cut-off date for our searches was 06/02/2014. This paper has now been assessed using NICE methods, as found in the guideline manual (http://www.nice.org.uk/article/PMG6B/chapter/Appendix-G-Methodology-checklist-economic-evaluations). The study has been excluded as it is partially applicable with very serious limitations. Regarding the study's applicability, the paper does not analyse the cost of VLCDs to the NHS, rather it uses the cost to Lighterlife. Standard dietary advice/low calorie diet is also not considered as a comparator. Methodologically the study only uses a ten year time horizon rather than the lifetime time-horizon NICE recommends. If a lifetime horizon was used then it is unlikely VLCDs would remain cost-

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					indicative results from a 12-month low-energy liquid diet treatment and maintenance programme for severe obesity (2013)	effective as the study shows eventually individuals put on more weight using a VLCD as opposed to going on a Weightwatchers diet. The benefits of a VLCD are therefore only accumulated in the short run making a short ten year time horizon highly bias the results in favour of VLCDs. The paper also attaches a very high quality of life benefit to four years of rapid weight loss. The GDG further noted that weight re-gain is unhelpful in the management of obesity as they are aware of a well-documented literature on the dangers of weight cycling. Amongst other issues, the clinical evidence used to inform the paper is very weak; the clinical data for the effectiveness of VLCD is based on observational data which is highly subject to bias. For these reasons, the paper by Lewis et al is excluded from the evidence review conducted for the guideline. The Lean study was excluded from the economic evidence as it only derives the costs of a low energy liquid diet with no comparison to what the cost might be for another intervention. It is worth noting that the nurses and dietitians used in the Lean study were familiar with the counterweight programme and so the training and minutes of nurse time are likely to be an underestimate of the cost of providing the programme. The GDG noted that VLCDs are fairly unfamiliar to most nurses and GPs and there are significant training issues. Finally, the exclusion criteria for the participants in the study were wide and this would therefore exclude a large number of individuals that would be seen in a tier 3 service. Although this study was excluded as it is not a full

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						economic evaluation, costs from Lean et al have now been quoted in the final version of the guideline in the VLCD 'economic considerations' section on pages 70-71 and it is noted that they fall within the costs quoted in the consultation version of the guideline. The clinical review for VLCDs found no evidence that weight loss, relative to standard dietary advice, was sufficiently sustained for VLCDs to be cost-effective at a £20,000 per QALY threshold.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	14	Full	71	6	We also note that relevant evidence concerning the safety of VLCDs when used to reduce weight and maintain weight loss have been overlooked, and we would therefore ask NICE to take into account the following papers as part of the evidence base for this draft guidance: • Christensen P, Frederiksen R, Bliddal H, Riecke BF, Bartels EM, Henriksen M, Juul-S Rensen T, Gudbergsen H, Winther K, Astrup A, Christensen R. Obesity (Silver Spring). Oct;21(10):1982-90. doi: 10.1002/oby.2013 Epub (2013).*Comparison of three weight maintenance programs on cardiovascular risk, bone and vitamins in sedentary older adults*. • Christensen P, Bartels EM, Riecke BF, Bliddal H, Leeds AR, Astrup A, Winther K, Christensen R. Eur J Clin Nutr. 2012 Apr;66(4):504-9. doi: 10.1038/ejcn.2011.201. Epub (2011A). *Improved nutritional status and bone health after diet-induced weight*	Thank you for your comments. As per Appendix G (clinical evidence tables), Christensen et al. (2011) (referred to as 2011B) has been included in the same evidence table as Riecke et al. (2010) since it is a report from the same study. However, the safety data was extracted from Riecke et al. (2010) rather than Christensen et al. (2011) since the former is reported to be at 16 weeks while the later was reported to be at 8 weeks. We could not find any data on bone density in Christensen et al. (2011) (referred to as 2011B) and this paper has not been included in the effectiveness review as the study duration is less than 1 year. This Christensen et al. (2011) reference has now been added to the Riecke et al. (2010) reference in the summary table in the main guideline. The review protocols for both the safety and effectiveness reviews (see appendix C) specifies that we were interested in VLCD compared to LCD. However, Christensen et al. (2013) compares both safety and effectiveness after different maintenance

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					loss in sedentary osteoarthritis patients: a prospective cohort study. • P. Christensen, H. Bliddal, B. F. Riecke, A. R. Leeds, A. Astrup, and R. Christensen. Clinical Obesity (2011B) 1(1): pp31-40. *Comparison of a low-energy diet and a very low-energy diet in sedentary obese individuals: a pragmatic randomized controlled trial.* These papers all report different aspects of a study on elderly obese individuals with knee osteoarthritis. The paper by Riecke has already been identified as reference by the GDG in the reference list (on page 136, line 36) but Christensen P et al. (2011A) describes the weight changes in the first 16 weeks, and Christensen P et al (2013) describes results at 68 weeks (16 + 52). The randomised controlled trial compared a VLCD intervention versus a standard formula low calorie diet. Christensen P et al (2011B) described body composition changes, bone mineral and bone density at 16 weeks.	regimens, not of VLCD to LCD. Furthermore, all patients randomised to these regimens had either VLCD or LCD. Christensen et al. (2012) (referred to as 2011A) was not included as it is not an RCT.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	15	Full	77	10-11	We note that the evidence statements include a reference to a potential higher frequency of constipation after VLCDs. This statement is extracted from the study by Riecke et al., which was considered by the GDG. We believe that the results of the study have been misinterpreted by GDG members, as the paper concluded that there was no greater effect of VLCDs on	Thank you for your comment. The GDG discussed what may be considered as adverse events and felt that constipation was an important adverse event to consider, from a patient perspective. The GDG discussed your comment and noted that the Riecke et al study you refer to did report a higher rate of constipation in those who had VLCDs

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					diarrhoea and constipation than after LCDs. The VLCD Industry Group would like to highlight that the compositional make-up of formula-based VLCDs is such that the daily intake of fibre when following a VLCD often exceeds the average consumed by the general population (for further information on this please see the latest National Diet and Nutrition Survey https://www.gov.uk/government/statistics/national-diet-and-nutrition-survey-results-from-years-1-to-4-combined-of-the-rolling-programme-for-2008-and-2009-to-2011-and-2012). This mitigates the low fibre consumption which may cause constipation.	compared with those who had LCDs. They also noted that there was some uncertainty around this result. However, they felt that the statement which stated that constipation 'may' be higher with VLCDs was an appropriate reflection of the evidence. As a result, the evidence statement has not been amended. The GDG noted your comment regarding the make-up of formula based VLCDs but did not wish to add further detail to the guideline in this regard as the evidence review was linked to all diets of 800kcal or less regardless of formulation.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	16	Full	77	14-16	We also note the evidence statement regarding increased levels of serum uric acid for participants of VLCDs, and we would like to highlight the following evidence paper which shows that whilst changes in hepatic and renal outcomes were variable during VLCDs, generally there was either no change or improvements in either of these: Rolland et al. The *effect of very low-calorie diets on renal and hepatic outcomes: a systematic review Diabetes, Metabolic Syndrome and Obesity:* Targets and Therapy 2013:6 393–40	Thank you for your comment. The GDG discussed and prioritised what may be considered the most important adverse events in relation to VLCDs. While gallstones were one of the prioritised outcomes, general and hepatic and renal measurements (which were reported in this systematic review) were not prioritised as outcomes to present to the GDG and, as a result, the paper by Rolland et al. (2013) was not included in the guideline.
Whitehouse Consultancy (the Very Low	17	Full	94		**VLCD safety** The VLCD Industry Group notes that the GDG's conclusion that "dramatic calorie reduction in diet	Thank you for your comments. The section you refer to the in the 'Recommendations and link to evidence' section (6.2.13) explains the rationale

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Calorie Diet Industry Group-VLCD)					with VLCD, even though for a short period, may create or worsen pre-existing unhealthy eating patterns, or disordered eating" is not grounded in scientific evidence. The document makes specific reference to the GDG members' "clinical experience," something that we find very concerning in consideration of the normally high evidence standards used by NICE. We hope that NICE will be able to withdraw this statement unless they can demonstrate it is backed by solid scientific evidence.	behind the choice of outcomes that the GDG, including patient members, chose to examine in the literature. Based on their expertise, they identified the adverse events that they considered important to consider, from a patient perspective. These are not statements about the evidence. The evidence is discussed in the subsequent sections of section 6.2.13. The wording in this section has been amended to clarify this.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	18	Full	95		**VLCD maintenance** The VLCD Industry Group would like to highlight once again the highly unusual approach taken by the GDG in taking into account the view that "initial weight loss in people using VLCDs was not sustained." This view seems to be based on the clinical experience of GDG members which, as mentioned above, is highly unusual.	Thank you for your comments. We have reviewed the evidence around the clinical and cost-effectiveness of very low calorie diets. The GDG, including patient members, discussed the available evidence and were consistent in their experience that people who have undertaken a very low calorie diet, regaining weight was common. We reject your assertion that the GDG have made their recommendations solely based on their clinical experience. The GDG have reviewed the evidence presented and made recommendations based on that evidence. The GDG believe that recommendations for the application of the evidence for NHS services for people who are overweight or obese has been appropriately supplemented by their clinical expertise and experience in line with NICE processes. How that has been applied is clearly documented in all the relevant evidence

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						discussion sections in the guideline.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	19	Full	95		**Trade-off between clinical benefits and harms** The GDG's conclusion that "weight regain following a VLCD was common" does not have any evidence basis and, once again, seems to be solely based on the "clinical experience" of GDG members. Given the low standards of evidence used to support such a statement, we hope that NICE will clarify whether it has now started forming recommendations based on the opinions of clinicians. We would like to point out that the opinion of the GDG is that of a selected group of clinicians who are not representative of the broader medical weight management professionals. As such, we believe NICE should avoid basing their guidelines on the opinions of a few individuals and should instead ensure that guidelines are always based on solid evidence. Indeed, scientific evidence available does not support the opinion of the GDG, showing that the likeliness of weight regain following a VLCD is not higher than following any other intervention. The evidence available in this sense is considerable, but we would like to highlight in particular the following paper: Haitman BL & Garby L (1999). *Patterns of long term weight changes in overweight developing Danish men and women aged between 30 and*	Thank you for your comments. We have reviewed the evidence around the clinical and cost-effectiveness of very low calorie diets. The GDG, including patient members, discussed the available evidence and were consistent in their experience that people who have undertaken a very low calorie diet, regaining weight was common. We reject your assertion that the GDG have made their recommendations solely based on their clinical experience. The GDG have reviewed the evidence presented and made recommendations based on that evidence. The GDG believe that recommendations for the application of the evidence for NHS services for people who are overweight or obese has been appropriately supplemented by their clinical expertise and experience in line with NICE processes. How that has been applied is clearly documented in all the relevant evidence discussion sections in the guideline. With regards to the reference you provide - Haitman 1999: this paper has been excluded from the VLCD review because it is not a randomised controlled trial.

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					60 years. Int J Obes Relat Metab Disord.; 23: 1074-78	
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	20	Full	95		Once again, we must challenge the GDG's conclusions, based on its "clinical experience," that the potential weight regain following a VLCD "may cause depression and perpetuate a sense of failure in people trying to manage their weight." As noted above, the evidence we have highlighted does not suggest that weight regain after VLCD is distinctly higher or more probable than with any other method of weight loss. The VLCD Industry Group would like to stress that any emotional side effects that accompany weight regain are not unique to weight regain following a VLCD.	Thank you for your comment. The GDG, including patient members, discussed the available evidence and were consistent in their experience that people who have undertaken a very low calorie diet and subsequently regained weight did experience a sense of failure and wished to highlight this within the Linking evidence to recommendations section of the full guideline.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	21	Full	96		The VLCD Industry Group noted the GDG's statement that "the evidence on adverse events was weak and that there could be other adverse events which would increase costs and reduce quality of life, making VLCDs even less likely to be cost-effective." Recently designed and executed studies have collected data on adverse events. We believe the GDG did not consider the following evidence: • Johansson K, Neovius M, Lagerros YT et al. (2009) Effect of a very low energy diet on moderate and severe obstructive sleep	Thank your comments. Johansson et al (2009) was excluded as the control group was not a low calorie diet or deficit diet as specified in the review protocol (see appendix C). Johansson et al. (2011), Johansson et al. (2013) and Christensen et al. (2012) (referred to as Christensen 2011B) are not included as they are not RCTs. The protocol specifies that we were interested in VLCD compared to LCD. However, Christensen et al. (2013) compares safety after different maintenance regimens, not of VLCD to LCD. Furthermore, all patients randomised to the

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					apnoea in obese men: a randomised controlled trial. BMJ 2009; doi: 10.1136/bmj.b4609 • Johansson K, Hemmingsson E, Harlid R, et al. (2011) Longer term effects of very low energy diet on obstructive sleep apnoea in cohort derived from randomised controlled trial: prospective observational follow-up study. BMJ 2011;342:d3017 doi:10.1136/bmj.d3017 These studies reported the rate for gout. • Johansson K, Sundström, Marcus C et al. (2013) Risk of symptomatic gallstones and cholecystectomy after a very-low-calorie diet or low-calorie diet in a commercial weight loss programme: 1-year matched cohort study. International Journal of Obesity doi:10.1038/ijo.2013.83 This paper gave the rate for hospitalisations for gallstone treatment after VLCD and after conventional 1200kcal/d diets. - Christensen P, Bartels E M, Riecke B F et al. (2011B) Improved nutritional status and bone health after diet-induced weight loss in sedentary osteoarthritis patients: a	maintenance regimens had either VLCD or LCD.

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					prospective cohort study. Eur T Cln Nutr 60 doi:10.1038/ejcn.2011.201 The Danish knee osteo-arthritis study (CAROT-LIGHT) was designed to include bone density and bone mineral values as secondary variables. This paper gave the bone mineral and bone density values at 16 weeks after an 8 week VLCD compared to an 810kcal/d LCD followed in both cases by an 8 week 1200kcal/d mixed formula and conventional food diet. - Christensen P, Frederiksen R, Bliddal H, Riecke BF, Bartels EM, Henriksen M, Juul-S Rensen T, Gudbergsen H, Winther K, Astrup A, Christensen R.Obesity (Silver Spring). 2013 Oct;21(10):1982-90. doi: 10.1002/oby.2013 Comparison of three weight maintenance programs on cardiovascular risk, bone and vitamins in sedentary older adults. Epub 2013 Apr 13 This paper gave figures for bone mineral and bone density – changes at 68 weeks were less than expected based on fat mass loss in the formula diet maintenance group probably because of the maintenance of improved	

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					vitamin D status.	
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	22	Full	99		We note that GDG members argued that "many patients regain the weight lost during the initial VLCD period and often end up gaining weight." As highlighted above, basing such considerations solely on the members' experience is highly unusual and not in line with NICE's high standards regarding clinical evidence. We are extremely disappointed by the singling out of VLCDs, given that weight regain is inevitable after weight loss achieved with any other methods, unless people change their behaviours.	Thank you for your comments. This guideline is an update of CG 43 which will be limited to the topics where new evidence may change recommendations. We have reviewed the evidence around the clinical and cost-effectiveness of very low calorie diets. The GDG, including patient members, discussed the available evidence and were consistent in their experience that people who have undertaken a very low calorie diet, regaining weight was common. We do not accept your assertion that the GDG have made their recommendations solely based on their clinical experience. The GDG have reviewed the evidence presented and made recommendations based on that evidence. The GDG believe that recommendations for the application of the evidence for NHS services for people who are overweight or obese has been appropriately supplemented by their clinical expertise and experience in line with NICE processes. How that has been applied is clearly documented in all the relevant evidence discussion sections in the guideline.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	23	Full	99		We also note that the GDG states it is "outside the remit of this guideline to consider issues related to the use of VLCDs purchased by the individual." We consider this statement to be highly disingenuous, given that GDG members will surely be aware of the impact that NICE guidelines have on other relevant stakeholders such as, for example, clinicians or the Advertising	Thank you for your comment. As highlighted in the scope of the guideline (see Appendix A), NICE guidelines provide recommendations only for use within NHS settings, or settings in which NHS care is commissioned. As such, it is outside the remit of the guideline to provide recommendations on the use of very-low-calorie diets purchased by the individual. This is highlighted in the 'Linking

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					Standards Authority. It is clear that these guidelines will have a considerable effect on the use of commercially available VLCDs, and we believe this should have been explicitly recognised by the GDG. In addition, despite the above statement we believe there could have been merit in consulting commercial providers about their risk management processes. How commercial providers develop and write their protocols, and minimise risks of adverse outcomes related to the use of VLCDs purchased by individuals is a body of knowledge that could inform the use of VLCDs in a healthcare (NHS) context. Indeed, health care professionals in many countries around the world are already applying the risk management processes developed in the commercial environment.	evidence to recommendations' section on page 100. It is the role of NICE clinical guidelines to provide evidence based guidance for the NHS not the commercial sector.
Whitehouse Consultancy (the Very Low Calorie Diet Industry Group-VLCD)	24	Full	114	1 to 5	The VLCD Industry Group would like to highlight that it is absolutely remarkable to observe how little consideration has been given in the draft guidelines to the overall costs of bariatric surgery compared to VLCDs. While in the case of VLCDs NICE has set out a comprehensive – albeit inaccurate, as pointed out above – overview of the all the costs related to VLCDs, in the case of bariatric surgery the draft guidelines only include references to the cost of stomach bypass procedure and restrictive stomach procedure.	Thank you for your comment. The cost quoted in the unit cost section of the bariatric surgery review on page 115 was provided for reference as to how much the surgery alone costs. However the GDG were aware that this figure only reflects a fraction of the overall cost of surgery and when making recommendations they mainly considered the conclusions of four economic evaluations presented in the published literature section on pages 112-114, that used robust economic modelling to assess the cost-effectiveness of bariatric surgery on early onset

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					This approach does not take into account the costs related to bariatric surgery, which are considerable and which have been taken into account in the case of VLCDs. In particular, we note that NICE has not taken into account significant costs of bariatric interventions, such as pre- and post-operative screening and routine follow-ups for a number of years, for example. Such costs include pre-operative workup borne within pre-operative preparation (these are not necessarily included in the quoted cost of the bariatric surgical procedure): sleep study; upper gut endoscopy; echocardiography; pre-op dietary intervention to achieve liver shrinkage. Post-op costs can include: annual review by the GP (after discharge from the surgical unit), including annual blood tests and bone density scans; nutritional supplements (such as vitamin B12 injections, oral vitamin and mineral supplements) taken indefinitely; drugs to treat bone-thinning; cost of revision surgery in failed cases; cost of body contouring (plastic surgery). We would like to obtain clarifications from NICE as to why different approaches have been taken when evaluating costs for these interventions.	type-2 diabetics. In these papers, the full cost of bariatric surgery has been calculated and analysed together with the review of the procedure's effectiveness. As no economic evaluations were identified around VLCDs a different approach had to be taken to account for the economic implications and the detail of the approach taken is clearly captured in Chapter 6, section 6.2.2.
WLSInfo	1	Full	52	General	WLSinfo supports the use of VLCD's in people who need to lose weight in preparation for specific operations such as joint replacements. We support the NICE recommendations regarding VLCD's.	Thank you for your comment.
WLSInfo	1	Full	52	Gener	WLSinfo supports the use of VLCD's in people	Thank you for your comment.

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				al	who need to lose weight in preparation for specific operations such as joint replacements. We support the NICE recommendations regarding VLCD's.	
WLSInfo	2	Full	115	General	WLSinfo welcomes the recommendations outlined in points 107 and 108. We fully support assessments for bariatric surgery in people who have recent - onset Type 2 diabetes and who have a lower BMI than those who would have previously been considered for surgery. Anecdotally, WLSinfo have seen many cases where diabetes has gone into remission within a couple of weeks of bariatric surgery.	Thank you for your comment.
WLSInfo	2	Full	115	General	WLSinfo welcomes the recommendations outlined in points 107 and 108. We fully support assessments for bariatric surgery in people who have recent - onset Type 2 diabetes and who have a lower BMI than those who would have previously been considered for surgery. Anecdotally, WLSinfo have seen many cases where diabetes has gone into remission within a couple of weeks of bariatric surgery. We would be interested to see whether the potential surgery performed at the lower BMI's would be different to that currently performed and be tailored to those with less weight to lose to avoid potential issues with too much weight loss as has occasionally been encountered by our members. We feel this could become more of an issue in the future.	Thank you for your comment. It is beyond the remit of the guideline to comment on the specifics of how bariatric surgery is performed in practice.
WLSInfo	3	Full	128		We welcome the minimum of two years aftercare	Thank you for your comments. It is the intention of

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					and are particularly encouraged to see the importance of support groups being recognised. It is important to note that WLSinfo is one of the main support organisations for both physical and online support and we are a charitable organisation that relies on donations to continue to offer that support. WLSinfo suggests that it is important GP's understand their responsibilities to their bariatric patients after the two year clinical aftercare comes to an end. This is especially important with regards to the monitoring of deficiencies through blood work. Our members report difficulties with getting help from their GP regarding deficiencies and other health issues relating to their bariatric surgery. This is especially important for hernias and similar that can turn life threatening. We also feel it important that patients get copies of all correspondence relating to their surgery and aftercare including results of investigations and blood work results.	recommendation 113 that patients are followed up appropriately annually after discharge from a bariatric service. The recommendation states that this annual monitoring should be part of a shared care model of chronic disease management which the GDG felt should be a collaboration between tier 3 services, where available, and primary care. As a result, recommendation 113 has not been amended, but the 'recommendations and link to evidence' section (8.2.3 of the full guideline) has been amended to provide further clarification about this. The GDG also acknowledge the importance of communicating effectively with patients. However, the NICE patient experience guideline (CG138) already recommends important aspects of communication, including the provision of both oral and written communication so this has not been added to this guidance.
WLSInfo	3	Full	128		We welcome the minimum of two years aftercare and are particularly encouraged to see the importance of support groups being recognised. It is important to note that WLSinfo is one of the main support organisations for both physical and online support and we are a charitable organisation that relies on donations to continue to offer that support.	Thank you for your comments. It is the intention of recommendation 113 that patients are followed up appropriately annually after discharge from a bariatric service. The recommendation states that this annual monitoring should be part of a shared care model of chronic disease management which the GDG felt should be a collaboration between tier 3 services, where available, and primary care. As a result, recommendation 113 has not been amended,

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					WLSinfo suggests that it is important GP's understand their responsibilities to their bariatric patients after the two year clinical aftercare comes to an end. This is especially important with regards to the monitoring of deficiencies through blood work. Our members report difficulties with getting help from their GP regarding deficiencies and other health issues relating to their bariatric surgery. We also feel it important that patients get copies of all correspondence relating to their surgery and aftercare including results of investigations and blood work results.	but the 'recommendations and link to evidence' section (8.2.3 of the full guideline) has been amended to provide further clarification about this. The GDG also acknowledge the importance of communicating effectively with patients. However, the NICE patient experience guideline (CG138) already recommends important aspects of communication, including the provision of both oral and written communication so this has not been added to this guidance.
WLSInfo	4	Full	64	3	We welcome the inclusion of the 12 week diet programme and we would like to see more psychological monitoring of patients both before and after surgery.	Thank you for your comment about the inclusion of the 12 week diet programme. In relation to your second point, the GDG acknowledge the psychological and emotional difficulties of individuals who are overweight or obese and highlighted psychological well-being as one of the important outcomes to consider in the effectiveness of a follow-up care package after bariatric surgery. As per recommendation 112, the GDG have recommended that psychological support be included as part of the initial 2 year follow-up within a bariatric service. However, the evidence review on follow-up care after bariatric surgery found very little evidence that was of adequate quality and was applicable to the UK context to base their recommendations on. As a result, the recommendations related to follow-up care were based on GDG consensus, informed by the experience of the clinical and patient members.

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						While the GDG felt ideally that annual monitoring should contain a number of the same components that were recommended in recommendation 112, they were conscious of the potential cost implications of lifetime monitoring and basing these recommendations on very little and very low quality evidence. The GDG did feel it was appropriate to make the resulting recommendation 113 as a minimum recommendation related to safety and recommended nutritional monitoring and appropriate supplementation in order to prevent serious nutritional deficiencies. While the GDG did feel that annual monitoring should ideally contain psychological assessment and support, they did not feel the evidence was sufficient to recommend a potentially very costly intervention so did not change the recommendation in light of your comments. It was outside the scope of the guideline to consider pre-operative assessment.

These organisations were approached but did not respond:

4Children
5 Borough Partnership NHS Foundation Trust
AbbVie
Academy of Medical Royal Colleges
Action for Sick Children
Action on Pre Eclampsia
Advertising Association
Aintree University Hospital NHS Foundation Trust
All Wales Dietetic Advisory Committee

All Wales Senior Nurses Advisory Group
Allergan Ltd UK
Allocate Software PLC
Amgen UK
AMORE health Ltd
AMORE Studies Group
Anglian Community Enterprise
Apetito Ltd
Arthritis and Musculoskeletal Alliance
Arthritis Care

Assocation of NHS Occupational Physicians
Association for Continence Advice
Association for Family Therapy and Systemic Practice in the UK
Association for the advancement of meridian energy techniques
Association of Anaesthetists of Great Britain and Ireland
Association of Breastfeeding Mothers
Association of British Clinical Diabetologists
Association of British Healthcare Industries
Association of British Insurers
Association of Children's Diabetes Clinicians
Association of Clinical Pathologists
Association of Directors of Adult Social Services
Association of Directors of Children's Services
Association of Occupational Health Nurse Practitioners
Association of Surgeons of Great Britain and Ireland
Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland
Astrazeneca UK Ltd
Atkins Nutritional Inc
Audit Commission
B. Braun Medical Ltd
Barnsley Hospital NHS Foundation Trust
Basildon and Thurrock University Hospitals NHS Foundation Trust
Bath Spa University
Belfast Health and Social Care Trust

Big Lottery Fund
Birmingham City Council
Black and Ethnic Minority Diabetes Association
Black Country Cancer and Cardiac Network
Blackpool Council
blackpool teaching hospitals nhs trust
Blood Pressure UK
Boehringer Ingelheim
Bolton Council
Boots
Bradford District Care Trust
Bristol University
Bristol Myers Squibb Pharmaceuticals Ltd
British Acupuncture Council
British Association for Counselling and Psychotherapy
British Association for Nursing in Cardiovascular Care
British Association for Parenteral & Enteral Nutrition
British Association of Behavioural and Cognitive Psychotherapies
British Association of Dramatherapists
British Association of Plastic Reconstructive and Aesthetic Surgeons
British Association of Psychodrama and Sociodrama
British Association of Sport and Exercise Medicine
British Cardiovascular Society
British Dental Trade Association
British Dietetic Association
British Geriatrics Society Gastro enterology and Nutrition Special Interest Group
British Geriatrics Society
British Healthcare Trades Association
British Heart Foundation National Centre for Physical Activity & Health
British Hypertension Society
British Liver Trust
British Lymphology Society
British Medical Association
British Medical Journal
British National Formulary

British Nuclear Cardiology Society
British Nutrition Foundation
British Obesity Surgery Patients Association
British Obesity Surgery Society
British Orthopaedic Association Patient Liaison group
British Pharmacological Society
British Red Cross
British Society for Paediatric Endocrinology and Diabetes
British Society of Paediatric Gastroenterology Hepatology and Nutrition
British Specialist Nutrition Association
British Thoracic Society
Calderstones Partnerships NHS Foundation Trust
Cambian Willows
Cambridge Manufacturing Co Ltd
Cambridge Neurotechnology
Cambridge University Hospitals NHS Foundation Trust
Camden Link
Cancer Research UK
Capsulation PPS
Capsulation PPS
Cardiff and Vale NHS Trust
Care Quality Commission
Cegedimrx
Central & North West London NHS Foundation Trust
Central London Community Health Care NHS Trust
Central London Community Health Care NHS Trust
Centre for Health Services Studies
Centrepoint
Chartered Physiotherapists in Mental Health
Chartered Physiotherapists Promoting Continence
Child Growth Foundation
Children, Young People and Families NHS Network
Christian Medical Fellowship
Church Grange Surgery
CIS' ters

City Hospitals Sunderland NHS Foundation Trust
Clarity Informatics Ltd
Cochrane Developmental, Psychosocial and Learning Problems
Colchester Hospital University NHS Foundation Trust
Community Practitioners' & Health Visitors Association
Complementary and Natural Healthcare Council
Co operative Pharmacy Association
Counselling and Psychotherapy Trust
Countess of Chester Hospital NHS Foundation Trust
Covidien Ltd.

Croydon Clinical Commissioning Group
Croydon Health Services NHS Trust
Croydon University Hospital
Cumbria Partnership NHS Foundation Trust
Cumbria Partnership NHS Trust
CWHHE Collaborative CCGs
Cwm Taf Health Board
Cyberonics
David Lewis Centre, The
Deltex Medical
Department of Academic Psychiatry Guy's
Department of Health, Social Services and Public Safety Northern Ireland
Derbyshire County Council
Device Access UK Ltd
Devon Partnership NHS Trust
Diabetes & Wellbeing Ltd
Diabetes Management and Education Group
Diabetes UK
Diennet Ltd
Diet Plate Ltd, The
Doncaster Council
Ealing Hospital NHS Trust
Ealing Public Health
East and North Hertfordshire NHS Trust

East Kent Hospitals University NHS Foundation Trust
East Riding of Yorkshire Council
Eastbourne District General Hospital
Eating Disorder Association (NI)
Economic and Social Research Council
Education for Health
Eisai Ltd
Eli Lilly and Company
Equalities National Council
Ethical Medicines Industry Group
European Atherosclerosis Society
Expert Patients Programme CIC
Experts in Severe and Complex Obesity
Faculty of Dental Surgery
Faculty of Public Health
Fair Play for Children
Fatherhood Institute
Federation of Bakers
Fibroid Network Charity
Fitness Industry Association
Five Boroughs Partnership NHS Trust
Food Advertising Unit
Food Standards Agency
Foundation for Liver Research
Foundation Trust Network
Gelita UK Limited
General Hypnotherapy Register
GeneWatch UK
George Eliot Hospital NHS Trust
GlaxoSmithKline
Gloucestershire County Council
Gloucestershire LINk
GP update / Red Whale
Gravitas
Great Western Hospitals NHS Foundation Trust

Greater Manchester West Mental Health NHS Foundation Trust
Green Machine, The
Guy's and St Thomas' NHS Foundation Trust
H & R Healthcare Limited
Hampshire Partnership NHS Trust
Havencare
Hayward Medical Communications
Health & Social Care Information Centre
Health and Care Professions Council
Healthcare Improvement Scotland

Healthcare Infection Society
Healthcare Quality Improvement Partnership
Healthier Weight Centre, The
Healthwatch Cumbria
Healthwatch East Sussex
Heart of Mersey
HEART UK
Hertfordshire Partnership NHS Trust
Hertfordshire Partnership University NHS Foundation Trust
Herts Valleys Clinical Commissioning Group
Hindu Council UK
Hockley Medical Practice
Homerton Hospital NHS Foundation Trust
Humber NHS Foundation Trust
IGD
Independent Healthcare Advisory Services
Independent Pharmacy Federation
Infant and Toddler Forum
Institute of Sport and Recreation Management
Integrity Care Services Ltd.
International Centre for Lifecourse Studies, Public Health and Epidemiology Department, University College London
International Neuromodulation Society
International Size Acceptance Association
Intuitive Surgical

iQudos
Janssen
JKP Analysts, LLC
Johnson & Johnson
Joint Royal Colleges Ambulance Liaison Committee
KasTech Ltd
KCI Medical Ltd
Ki Performance
Kidney Cancer Support Network
King's College Hospital NHS Foundation Trust

Kingston University and St Georges, University of London
Lactation Consultants of Great Britain
Lancashire Care NHS Foundation Trust
Lanes Health
Laurence Moon Bardet Biedl Society
Leeds Community Healthcare NHS Trust
Leeds Metropolitan University
Leeds North Clinical Commisioning Group
Leeds Teaching Hospitals NHS Trust
Leg Ulcer Forum
Leicestershire county council
Leicestershire Partnership NHS Trust
Lilly UK
Limbless Association
Lincolnshire County Council
Liverpool John Moores University
Liverpool Women's NHS Foundation Trust
Living Streets
Local Government Association
Local Government Information Unit
Maidstone Hospital
Maquet UK Ltd
McNeil Nutritionals Ltd
Meat & Livestock Commission

Medical Support Systems Limited
Medicines and Healthcare products Regulatory Agency
Mencap
MEND
Mental Health Group British Dietetic Association
Mid Staffordshire NHS Foundation Trust
Mid Yorkshire Hospitals NHS Trust
Midwives Information and Resource Service
Mind Wise New Vision
Mindfulness Centre of Excellence

Ministry of Defence (MOD)
Morecambe Bay Public Health Development
MRC Centre of Epidemiology for Child Health
MRC Human Nutrition Research
Msb consultancy
National Association of British and Irish Millers
National Association of Primary Care
National Centre for Eating Disorders
National Children's Bureau
National Clinical Guideline Centre
National Collaborating Centre for Cancer
National Collaborating Centre for Mental Health
National Collaborating Centre for Women's and Children's Health
National Deaf Children's Society
National Institute for Health Research Health Technology Assessment Programme
National Institute for Health Research
National Institute for Mental Health in England
National Nurse Consultants in CAMHS forum
National Obesity Forum
National Patient Safety Agency
National Public Health Service for Wales
National Youth Advocacy Service
Natural England
NDR UK

Neonatal & Paediatric Pharmacists Group
Nestle UK Ltd
Newcastle University
Newcastle upon Tyne Hospitals NHS Foundation Trust
NHS Barnsley Clinical Commissioning Group
NHS Camden
NHS Choices
NHS Confederation
NHS Connecting for Health
NHS Cornwall and Isles Of Scilly
NHS County Durham and Darlington
NHS Derbyshire county
NHS England Greater Manchester
NHS Greater Manchester Commissioning Support Unit
NHS Halton CCG
NHS Hampshire
NHS Hardwick CCG
NHS Health at Work
NHS Improvement
NHS Milton Keynes
NHS Newcastle
NHS North Somerset CCG
NHS North West
NHS Plus
NHS Sheffield CCG
NHS South Cheshire CCG
NHS Southern Derbyshire CCG
NHS Sussex
NHS Sutton and Merton
NHS Wakefield CCG
NHS Wandsworth
NHS Warwickshire North CCG
Nightingale Care Beds Ltd
NLSSM The School of Sports Massage
Nordic Surgical Ltd.

Norgine Limited
North and East London Commissioning Support Unit
NORTH EAST LONDON FOUNDATION TRUST
North of England Commissioning Support
North Tees and Hartlepool NHS Foundation Trust
North West London Hospitals NHS Trust
North West London Perinatal Network
Northamptonshire county council
Northern Health and Social Care Trust
Northern Region Endoscopy Group

Northumberland, Tyne & Wear NHS Trust
Nottingham City Council
Nottingham City Hospital
Nottingham Healthcare NHS Trust
Nottingham University Hospitals NHS Trust
Nottinghamshire County Council
Nottinghamshire Healthcare NHS Trust
Nuffield Council on Bioethics
Nursing and Midwifery Council
Nutmeg UK Ltd
Nutricia Advanced Medical Nutrition
Nutrition Society
Obesity Management Association
Obstetric Anaesthetists' Association
Optical Confederation, The
Overeaters Anonymous
Oxford Health NHS Foundation Trust
Oxfordshire Clinical Commissioning Group
Oxfordshire County Council
Pancreatic Cancer Action
Parenteral and Enteral Nutrition Group
Pathfinders Specialist and Complex Care
Patient Assembly
Perfect Portion Control Ltd

PERIGON Healthcare Ltd
Perspectum Diagnostics Ltd
Peterborough City Hospital
Pfizer
Pharmacosmos
Pharmametrics GmbH
PharmaPlus Ltd
PHE Alcohol and Drugs, Health & Wellbeing Directorate
Play England
Plymouth Community Healthcare CIC

Plymouth Hospitals NHS Trust
Powys Local Health Board
PrescQIPP NHS Programme
Primary Care Cardiovascular Society
Primary Care Dermatology Society
Primary Care Diabetes Society
Primary Care Partnerships
Primary Care Pharmacists Association
Primary Care Rheumatology Society
Primrose Bank Medical Centre
PROMIS Recovery Centre
Proprietary Association of Great Britain
Psychologists in Obesity Network
Public Health Agency for Northern Ireland
Public Health Wales NHS Trust
Quality Institute for Self Management Education and Training
Queen Elizabeth Hospital King's Lynn NHS Trust
Queen's University Belfast
Randox Laboratories Limited
Rarer Cancers Foundation
Renal Nutrition Group, British Dietetic Association
Residential Community Care Services
RioMed Ltd.
Robert Jones & Agnes Hunt Orthopaedic & District Hospital NHS Trust

Roche Products
Rosemary Conely Food and Fitness
Rotherham Metropolitan Borough Council
Royal Berkshire NHS Foundation Trust
Royal Brompton Hospital & Harefield NHS Trust
Royal College of Anaesthetists
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists

Royal College of Paediatrics and Child Health , Gastroenetrology, Hepatology and Nutrition
Royal College of Psychiatrists
Royal College of Psychiatrists in Wales
Royal College of Radiologists
Royal College of Surgeons of England
Royal Cornwall Hospital NHS Trust
Royal Cornwall Hospitals NHS Trust
Royal Free Hospital NHS Foundation Trust
Royal Manchester Children's Hospital
Royal National Institute of Blind People
Royal Pharmaceutical Society
Royal Society of Medicine
Royal United Hospital Bath NHS Trust
Sands, the stillbirth and neonatal death charity
Sanofi
School Food Trust
Scottish Intercollegiate Guidelines Network
Sheffield Children's Hospital
Sheffield Hallam University
Sheffield Health and Social Care NHS Foundation Trust
Sheffield Teaching Hospitals NHS Foundation Trust
Sin and Slim Diet, The
Slender Thoughts
Slim Fast Foods Limited

SNDRi
Social Care Institute for Excellence
Social Interface
Society for Academic Primary Care
Society for Endocrinology
Society for Obesity and Bariatric Anaesthesia
Society for Research in Rehabilitation
South Asian Health Foundation
South Belfast Partnership Board
South Eastern Health and Social Care Trust
South Gloucestershire Council
South London & Maudsley NHS Trust
South London Cardiac and Stroke Network
South Warwickshire NHS Foundation Trust
South West Yorkshire Partnership NHS Foundation Trust
Southern Health & Social Care Trust
Southern Health Foundation Trust
Southport and Ormskirk Hospital NHS Trust
Sport England
St Andrews Healthcare
St Andrew's Hospital
St Georges Healthcare NHS Trust
St Mary's Hospital
Staffordshire and Stoke on Trent Partnership NHS Trust
STEM4
Stockport Clinical Commissioning Group
Sure Start Ashfield
Sure Start Tamworth
Surrey and Borders Partnership NHS Foundation Trust
Sussex Partnership NHS Foundation Trust
Sustrans
Tanita UK Ltd
Tavistock Centre for Couple Relationships
Tees, Esk and Wear Valleys NHS Trust
Telemedcare Ltd

Teva UK
The Association for Clinical Biochemistry & Laboratory Medicine
The Association of the British Pharmaceutical Industry
The British Homeopathic Association & Faculty of Homeopathy 131134
The Chartered Institute of Environmental Health
The Fostering Foundation
The Hospital Group
The National LGB&T Partnership
The Natural Ketosis Company
The Patients Association
The Princess Alexandra Hospital NHS Trust
The Rotherham NHS Foundation Trust
The Stroke Association
The Work Foundation
Tissue Viability Society
Tommy's The Baby Charity
UK National Screening Committee
UK Specialised Services Public Health Network
Unite the Union
United Kingdom Council for Psychotherapy
United Lincolnshire Hospitals NHS
University College London
University College London Hospital NHS Foundation Trust
University Hospital Aintree
University Hospital Birmingham NHS Foundation Trust
University Hospitals Birmingham
University of Bath, The
University of Leeds
University of Salford
University of Wales, Newport
Vifor Pharma UK Ltd
W.L. Gore & Associates
Walsall Local Involvement Network
Weight Concern
Weight Management Centre

Welsh Ambulance Services NHS Trust
Welsh Endocrine and Diabetes Society
Welsh Government
Welsh Scientific Advisory Committee
West Hertfordshire Hospital Trust
West London Mental Health NHS Trust
West Middlesex Hospital
West Middlesex University Hospital NHS Trust
West Sussex Public Health
Western Health and Social Care Trust
Western Sussex Hospitals NHS Trust
WHSSC
Wigan Leisure and Culture Trust
Wirral University Teaching Hospital NHS Foundation Trust
Worcestershire Acute Hospitals Trust
World Cancer Research Fund
World Obesity Federation
Wound Care Alliance UK
Wye Valley NHS Trust
York Hospitals NHS Foundation Trust
Young Diabetlolgists Forum