NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Centre for Clinical Practice

Centre for Public Health Excellence

Review of Clinical Guideline (CG43) – Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children

Background information

Guideline issue date: 2006

3 year review: 2009

6 year review: 2011

This is a joint clinical and public health guideline developed jointly by the National Clinical Guideline Centre (formerly NCC Primary Care) and NICE's Centre for Public Health Excellence.

Review recommendation

The guideline should be partially updated.

Factors influencing the decision

Literature search – Clinical

1. From initial intelligence gathering and a high-level randomised control trial (RCT) search clinical areas were identified to inform the development of clinical questions for focused searches. Through this stage of the process 99 studies were identified relevant to the guideline scope. The identified studies were related to the following clinical areas within the guideline:
    - Pharmacology (43 studies)
    - General lifestyle interventions (30 studies)

- Diet (12 studies)
- Exercise (6 studies)
- Surgery (4 studies)
- Alternative therapies (4 studies)

2. No additional clinical areas were identified from initial intelligence gathering, qualitative feedback from other NICE departments, feedback from the NICE implementation team and the views expressed by the clinical Guideline Development Group that required further focused literature searches.

3. Some new evidence was identified that was relevant to three of the research recommendations that were included in the original guideline:
    - What are the most effective interventions to prevent or manage obesity in children and adults in the UK?
    - How does the effectiveness of interventions to prevent or manage obesity vary by population group, setting and source of delivery?
    - What is the cost effectiveness of interventions to prevent or manage obesity in children and adults in the UK?

4. However, the new evidence identified is unlikely to fully address the questions posed in the research recommendations and more research is still needed.

5. In conclusion, no identified new evidence contradicts current guideline clinical recommendations. New evidence that is available could make recommendations more specific and directive but are unlikely to alter which interventions are recommended. This is particularly pertinent to treatment in the primary care setting, and the role of bariatric surgery.

6. Several ongoing clinical trials (publication dates unknown) were identified focusing on – Alternative therapies (5 studies), diet (12

studies), exercise (6 studies), general lifestyle interventions (27 studies) including the Trim Tots pre-school obesity prevention programme sponsored by the Institute of Child Health, lifestyle interventions during pregnancy (2 studies), pharmacology (42 studies), and surgery (4 trials) including Surgical Intervention for Morbidly Obese Adolescents from Gothenburg University.

Literature search – Public Health

7. The Centre for Public Health Excellence (CPHE) undertook a brief assessment of (1) key evidence known to the reviewers during the development of the original guideline and subsequently published and (2) evidence identified through quick, focused searches of particular aspects of the guideline where it was thought there may be new evidence. Focused searches primarily considered reviews and were undertaken on:
    - Recommendations to the public on strategies to maintain a healthy weight (in particular on portion size, energy density, sugar sweetened beverages, breakfast, sedentary behaviour and TV / screen viewing)
    - Awareness of obesity / obesity strategies
    - Workplace health – action by NHS, LA and large organisations
    - Information of relevance to recommendations on children at risk of obesity (i.e. recommendations 1.1.2.16 and 1.1.2.18)

8. The results of these searches and feedback from the public health Guideline Development Group were assessed to inform the proposed review decision.

9. No identified new evidence contradicts current public health recommendations in the guideline. Some new evidence is available that could add nuance to the existing recommendations, but this does not appear to change the direction or *substantially* change the spirit of the recommendations. For the most part, this evidence will be considered by public health guidance in development (on working with

local communities to address obesity and lifestyle weight management for overweight and obese adults and children). Where this isn't the case, it is considered that the new evidence is not significant enough to warrant an update at this time.

10. The guideline highlighted a range of areas where the evidence was uncertain, contradictory or absent. As far as we are aware there have not been any key papers which *substantially* change this position.

11. New evidence was identified that was relevant to research recommendations in the original guideline. However, the research recommendations are considered to still be of relevance. It is known that there are many ongoing trials and interventions that may report in the next few years that add nuance to the existing recommendations, particularly in the fields of community based prevention, the management of child obesity and commercial weight management.

Guideline Development Group and National Collaborating Centre perspective – Clinical

12. A questionnaire was distributed to GDG members and the National Collaborating Centre to consult them on the need for an update of the guideline. Three responses were received with respondents highlighting that since publication of the guideline more literature has become available on interventions for obesity. Also there was concern that obesity in children is currently poorly defined and that best practice guidelines would be useful for assessing childhood risk factors, but no new evidence is available that would alter recommendations in this area. The GDG members also suggested that the current scope of the current guideline could be expanded to include obesity associated with pregnancy, learning difficulties and mental illness. This would, however, encroach into the area of specialist management. This feedback contributed towards the development of the clinical questions for the focused searches.

13. Ongoing research was cited by GDG members including family-based behavioural treatment for childhood obesity, and also trials of bariatric surgical interventions.

14. One respondent commented that there is variation in current practice across the UK in relation to availability of bariatric surgery, with most PCTs now adopting much stricter criteria for surgery than recommended by NICE.

Programme Development Group perspective – Public Health

15. A questionnaire was distributed to the public health GDG members, several members of the clinical GDG who had been involved in aspects of the public health work and the Chair of NICE guidance under development on *Obesity working with local communities* (9 responses were received). A meeting was also held with the GDG Chair, several members of the GDG and the collaborating centre lead at the University of Teesside. It was considered that:
    - The uncertainty in the public health system with the *Health and Social Care Bill* means that this is not an ideal time to update the public health aspects of the guidance, though it is recognised that substantial changes to layout and wording of recommendations will be required once changes to the system have been finalised. Technical amendments should be made (for example, removing references to organisations which no longer exist), in line with changes already made to recommendations in the *NICE Pathways* on diet and activity (see http://pathways.nice.org.uk/).
    - Respondents recognised that no new evidence was available that contradicted any of the recommendations. Any new evidence would strengthen and add nuance to the existing recommendations. There is uncertainty whether there is sufficient new evidence to warrant a review to all or parts of the public health aspects of the guideline. It was considered important to update the guidance in relation to key

new reports or references to arms length bodies that no longer existed.

- New intervention evidence is clearly available on “lifestyle” management of obesity in non clinical settings for children and adults, particularly in relation to commercial weight management programmes. These areas are covered by public health guidance in development (see table 2). Respondents noted that the current guideline included insufficient information on the maintenance of weight following weight loss. They noted that while there are few formal trials addressing this issue, there is now more data available from trials extending beyond 1 year. Respondents agreed that the advice to aim for a “maximum weekly weight loss of 0.5-1kg’ was appropriate (as an average and realistic goal for most people). The Chair noted that he had been consulted by NICE in relation to correspondence from VLCD groups, by the ASA in a case on this matter and also in relation to references in the guideline to ‘clinical supervision’ and ‘on-going support’. It was agreed that any inconsistencies in the wording between the best practice list in recommendation 1.1.7.1 and the clinical recommendations in the guideline (and recommendation 1.2.4.33 in particular) could be considered in the new referral to CPHE on ‘Overweight and obese adults – lifestyle weight management’.
- Respondents noted that children under 2 years had been excluded from the scope of the current guideline. There was agreement that there is insufficient new intervention evidence to warrant including this group in any update to the guideline at this time. It was also noted that this age group is included in existing NICE public health guidance on maternal and child nutrition.
- Any new evidence relating to the recommendations for local authorities and their partners in the community has been more recently covered by public health guidance on the *Prevention of cardiovascular disease* and *Type 2 diabetes*; and there is public health guidance under development on *Walking and cycling,* and

Working with local communities. Any new evidence relating to early years settings has been covered by newer public health guidance on maternal and child nutrition (itself the subject of review in 2011). Pregnancy was excluded from this guideline but is partially covered by newer public health guidance on the *Prevention of obesity before, during and after pregnancy*.

- Respondents noted that the *National Child Measurement Programme* had been implemented since the publication of the guideline but it was unlikely that detailed, long term evaluation was yet available that would result in amended or new recommendations. New evidence is available that adds strength to the recommendation that school-based interventions were unlikely to result in harm – respondents were of the view that this might be an area where the current recommendation could be strengthened.
- Respondents noted that the public health aspects of the guideline had not been well implemented and that this was a cause for concern. However it was recognised that NICE was in the process of developing guidance on 'obesity – working with local communities'.

16. The majority of respondents felt that, while there was new evidence that could add nuance to the existing recommendations and may aid their implementation, the uncertainties surrounding changes to the NHS and public health system more widely meant that it may not be sensible to update the public health aspects of the guideline at this time.

Implementation and post publication feedback – Clinical and Public health

17. In total, 451 enquiries were received from post-publication feedback relating to both the clinical and public health aspects of the guideline. Most enquiries were routine. Key themes from the enquiries relating to the clinical aspects of the guideline were:

- Inconsistency in access to bariatric surgery as recommended within the guideline
- Lack of clarity in the wording of recommendations relating to very low calorie diets, and a change in legal status relating to the definition of very low calorie diets
- Some comments were received that the guidance focuses too much on physical activity and that it should have a greater emphasis on energy restricted diets for people who are *severely* obese. However the existing guideline is clearly sensitive to the needs of both severely obese people and people for whom weight maintenance or loss is problematic. The guideline notes that that the level of BMI and co-morbidities, along with personal preference and circumstance, need to be considered in treatment choice. The guideline includes a raft of specific recommendations for obese children and adults about energy reducing diets.

18. An analysis by the NICE implementation team indicated that pharmacological and surgical interventions have increased in line with recommendations in the NICE guidance.

19. This feedback contributed towards the development of the clinical questions for the focused searches.

Relationship to other NICE guidance

20. NICE guidance related to CG43 can be viewed in Appendix 1.

Summary of Stakeholder Feedback – clinical and public health

Review proposal put to consultees:
The guideline should not be updated at this time.
The guideline will be reviewed again according to current processes.

21. In total 41 stakeholders commented on the review proposal recommendation during the 2 week consultation period.

22. Eleven stakeholders agreed with the review proposal recommendation that this guideline should not be updated at this time, 24 stakeholders disagreed (see section 22 below), of which up to 6 were duplicate comments. In addition 6 stakeholders were ambivalent or replied to say that they had no comment.

23. Literature was submitted through stakeholder consultation relating to:
    - Pharmacological interventions (Liraglutide / receptor agonists)
    - Variation in provision of bariatric surgery
    - Childhood / early life obesity prevention
    - Treatment of childhood obesity (family therapy)
    - Referral to commercial weight loss programmes

    Many studies submitted would not have met the inclusion criteria used in the existing guideline.

24. During consultation, areas to consider for review in an update of the guideline were highlighted including:
    - Further guidance on obesity surgery procedure. However little high quality data are available that compare techniques, and there is an ongoing NCEPOD report into bariatric surgery that is not yet published and reviewing the guideline before this is available does not seem helpful
    - New pharmacological agents such as Seretonin / GLP receptor agonists (Exenitude, Liragatude, and lorcaserin). These agents are not in the original scope and are likely to be specialist treatments for obesity / diabetes
    - Classification for obesity / BMI cut-offs. However no new data are available that challenge current recommendations, which are echoed by a recent report from the Royal College of Paediatrics and Child Health.

- More precise recommendations on community based weight management programmes in children and adults would be welcomed. This area will be covered in new commissions for CPHE on 'Overweight and obese children – lifestyle weight management' and 'Overweight and obese adults – lifestyle weight management'.
- Variation in provision / access to surgery (with the guideline perceived as having less power compared to original technology appraisal). This is very much a local service provision / commissioning issue. Further work such as costing analysis could be undertaken by the NICE implementation team.
- Comments on how the guideline might be further developed or adapted following structural changes to the NHS. It was highlighted that changes to the NHS and increasing focus on the prevention, identification and management of obesity may have implications for the type of guidance that is needed and the training needs of staff.
- Updating some of the language used around obesity, healthy weight and weight gain, which has moved on since the guideline was published.
- Comments noting that some additional evidence was available for public health guidance portion size, energy density, sugar sweetened drinks and breakfast. It was noted that additional information may help support staff without detailed nutrition training. Additional evidence would add nuance to existing recommendations rather than change the direction of recommendations.

25. During consultation, additional areas to the scope to consider in an update of the guideline were highlighted including:
    - Recommendations for subgroups with obesity. This was outwith the scope of the existing guideline. However, for some subgroups, particularly the management of people with obesity and diabetes, this could be addressed in the obesity guideline if updated or alternatively in the diabetes guideline when it is reviewed.

- Children under 2 years of age. This was outside the scope of the existing guideline. The evidence considered for this review suggests that evidence of effectiveness for intervention in this group is currently lacking. Children under 2 are covered in existing NICE public health guidance on maternal and child nutrition.
- The clinical management of obesity during pregnancy. Pregnancy was excluded from the original scope. Subsequent public health guidance on 'Dietary interventions and physical activity interventions for weight management before, during and after pregnancy' excludes clinical management.

Anti-discrimination and equalities considerations

26. No evidence was identified to indicate that the guideline scope does not comply with anti-discrimination and equalities legislation. The original scope is not exclusive of any particular group and focuses on 'clinical management of morbid obesity'.

Conclusion

27. There are a number of uncertainties at the present time, relating to both the evidence base (there are a number of relevant ongoing primary studies and systematic reviews) and other relevant pieces of NICE guidance in development. In particular, there are two pieces of work being undertaken by the CPHE (see appendix 1) that will provide guidance on lifestyle weight management in overweight and obese adults and children, which should meet the concerns of a number of stakeholders who responded to consultation.

28. Some new evidence is available now that could add nuance to the existing recommendations, but this does not appear to change the direction or *substantially* change the spirit of the recommendations.

29. The ongoing structural changes to the NHS are important to many of the public health recommendations, since in future it may be more

appropriate for these to be aimed at local authorities. The *NICE Pathways* on diet and physical activity (see http://pathways.nice.org.uk/) have already made some technical amendments to the wording of recommendations and it may be possible to include these in the guideline. However it may not be appropriate to make major changes to the layout of the guidance at this time as there remains some uncertainty about structural changes to the NHS and the public health role of local authorities.

30. From the evidence and intelligence identified through the process, it suggests that some areas of the guideline may need updating (or extending), particularly in relation to:
    - Bariatric surgery, and choice of procedure
    - Treatment of obesity in the community
    - Recommendations for very low calorie diets
    - Specific guidance for certain patient subgroups such as pregnant women who are overweight or obese, children under two years, and people with comorbidities such as diabetes
    - Maintenance of weight loss.

Relationship to quality standards and core library of topics

31. Currently the draft core library suggests that quality standards for obesity may be commissioned from NICE, this might impact on the need for NICE guidance in particular areas of obesity care. The current library of topics that is under consideration includes titles of ‘obesity (adults)’ and ‘childhood obesity’.

32. The proposal to NICE’s Guidance Executive was to delay an update for two years, however Guidance Executive decided that the guideline should be partially updated at this time. .

Appendix 1

The following NICE guidance is related to CG43:

Table 1 Related Clinical Guidelines

Clinical Guidelines	Review date
CG9 Eating disorders: core interventions in the treatment and management of anorexia nervosa, bulimia nervosa and related eating disorders (2004).	Jan 2014
GC66 Type 2 diabetes: the management of type 2 diabetes (updated 2008)	Decision to update but as yet not scheduled
CG87 Type 2 Diabetes - newer agents (partial update of CG66)	Decision to update but as yet not scheduled
CG32 Nutrition support in adults: oral nutrition support, enteral tube feeding and parenteral nutrition (2006).	Feb 2014

Table 2 Related Public Health Guidance

Published public health guidance	Review date
PH2 Four commonly used methods to increase physical activity	Partial update due May 2013/ Next complete review due March 2013
PH6 Behaviour change	October 2011
PH7 School based interventions on alcohol	No plans to review
PH8 Physical activity and the environment	February 2014
PH9 Community engagement	June 2013
PH11 Maternal and child nutrition	July 2014
PH13 Promoting physical activity in the workplace	July 2014
PH17 Promoting physical activity in children	January 2012

and young people	
PH22 Promoting mental wellbeing at work	November 2012
PH24 Alcohol use disorders – preventing harmful drinking	June 2013
PH25 Prevention of cardiovascular disease	June 2013
PH35: Preventing type 2 diabetes – population and community interventions	May 2014
Related NICE guidance not included in CG43	
PH27: Weight management before, during and after pregnancy	July 2013
Related NICE guidance in progress	**Expected publication date:**
Prevention of type 2 diabetes – individual and group interventions for high risk adults	May 2012
Obesity: working with local communities	November 2012
Walking and cycling	October 2012
BMI and waist circumference – black and minority ethnic groups	TBC
Overweight and obese adults – lifestyle weight management	Autumn 2013 (scope Spring 2012)
Overweight and obese children – lifestyle weight management	Autumn 2013 (scope Spring 2012)

Appendix 2

Stakeholder consultation comments on review proposal (proposal was for 'no review)

Stakeholder	**Agree?**	**Comments** **Please insert each new comment in a new row.**	**Comments on areas excluded from original scope**	**Comments on equality issues**	**NICE comments**
RCP	Overall, disagree	The RCP is grateful for the opportunity to respond to this review request. Our experts have identified a number of points that may warrant looking again at the recommendation not to update CG43 at the present time. We have also liaised with the British Society of Gastroenterology. CG43 did not contain much discussion regarding the risks/benefits of the different procedures (eg duodenal switch, which seems to have a higher complication rate). Sleeve gastrectomy as a stand-alone procedure was not mentioned at all. Some guidance about which surgical procedures might be most suitable for which patients would be helpful, if a consensus could be reached.			Thank you for your comment. There did not appear to be sufficient evidence published at the time of this review to compare between different surgical procedures. Although this may change shortly. Any recommendations in this area are likely to be substantiated on GDG consensus rather than

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		An update should encompass pre- and post-surgical care in more detail. Our experts believe that there is a lot of new health economic data that could be considered, particularly in relation to surgery. In relation to the non-surgical options, the clinical value of low dose OTC orlistat should be considered There needs to be greater consideration of certain special groups, especially people with mental illness and pregnancy for example. CG43 makes no mention of the GI issues commonly seen in people with severe obesity and particularly in relation to bariatric surgery: iron and other micronutrient deficiencies, dumping syndrome, etc - conditions that are investigated and managed inconsistently, frequently at great expense, in non-specialist centres. The recent BSG guidelines on iron deficiency anaemia stated that 'Bariatric surgery can lead to iron deficiency, but iron supplementation is usually recommended after surgery to prevent the problem.' We believe			published evidence, until comparative trials are available. Four cost effectiveness studies were identified of which 2 suggested that surgery is cost effective in all classes of obesity. The original HTA Assessment of economics for surgery used in existing guideline also identified 4 studies. 5 studies on Orlistat were indentified it is not clear whether these were in OTC setting. The existing guideline considered HE evidence for optimal treatment length in the use of orlistat. The management of GI in severely obese patients was outside the scope of the existing guideline. However this might be considered in a review of with CG 43 or the diabetes guidelines The guideline aims to cover 80% of patients 80% of the time. The specialist management of deficiencies was not considered to be critical for the need to review

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		that any update of CG43 should go beyond this simple statement.			immediately.
Royal College of General Practioners	Agree	Agree that the guidelines does not need to be updated based on the evidence review			Thank you for your comment.
Novo Nordisk	Agree	Novo Nordisk agrees with the proposal not to update this guideline at the current time. We would however welcome the opportunity to be involved in future updates of this guideline. Liraglutide is currently in development for the management of obesity. The results of the phase II study have already been published (Astrup A *et al. Lancet* 2009; 374: 1606-1616 and Astrup A *et al. International Journal of Obesity* 2011; Aug 16. doi: 10.1038/ijo.2011.158. [Epub ahead of print]). The results from the first of three phase 3 studies conducted as part of the liraglutide development programme have been also reported (American Diabetes Association (ADA) 71st Scientific Sessions: Abstract 1859-P. Presented June 25, 2011) and two further phase 3a trials are ongoing. Further information on the development of liraglutide for the management of obesity will be communicated via the UK PharmaScan			Thank you for your comment. The guidance will be partially updated. Astrup A (2009) was identified in the scoping search for this review. Astrup (2011) was published after the review search date. Thank you for your comment. Liraglutide is currently licensed for diabetes, and not obesity per se. Other similar drugs were considered to be outwith the scope of the guideline

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		database in due course.			
Eli Lilly and Company Limited	Disagree with proposal not to update the guideline	The section on 'Pharmacological interventions' should include specific recommendations on the management of obese patients with co-morbidities like type 2 diabetes.			Thank you for your comment. Treatment of specific subgroups of patients with obesity is outside the scope of the guideline
Eli Lilly and Company Limited		The recommendations should take into consideration the role of GLP-1 receptor agonists like exenatide in the management of type 2 diabetes patients with obesity as recommended in NICE type 2 diabetes guideline (CG87). These treatments are licensed for the treatment of type 2 diabetes and have additional benefits in the form of weight loss.			Thank you for your comment. Like liraglutude this drug is a GLP-1 agonists to receptor which aims to increase insulin secretion Treatment of specific subgroups of patients with obesity is outside the scope of the guideline, and should be covered in Diabetes guideline. These are currently under consideration for review.
UK Faculty of Public Health	yes	I agree that this needs updating in the light of the NHS and PH reforms – it would be good to have a date or timescale on that, so that the new "owners" of H responsibilities have up to date guidance to work with.			Thank you for your comment. The guidance will be partially updated.
	no	The majority of issues mentioned in this section (planning, sports, etc) are unaffected by the PH reforms and therefore it is not inappropriate to make changes to this section	There is much activity at a national level regarding obesity – for example through the Responsibility		Thank you for your comments. Trans fats and advertising to children addressed by NICE public health guidance on prevention of CVD.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		at this time. This is a vital area in tackling obesity and the evidence is improving. This needs to be reflected.	Deal. The original guidance did not consider the evidence for national level interventions (eg bans on transfats, advertising to children). This is an important omission and needs to be considered by this review.		
Johnson & Johnson Medical Ltd	Johnson &Johnson Medical Ltd agree that a full review of CG43 is not required. However, there is merit for NICE to consider a partial update of the recommendations within CG43 to include	Overall, Johnson & Johnson Medical ltd (J&J) support the underlying principles of this report and agree that a full review of CG43 is not warranted. However, we would recommend a partial update which seeks to give further clarification of some sections in the guideline, as well as the additions of some sub-sections, as discussed in the points below. References to which we refer are detailed at the end of the document and placed here for convenience: 1. NICE Technology Appraisal (TA) 46: Obesity (morbid) - surgery: Guidance http://www.nice.org.uk/guidance/index.jsp?action=download&r=true&o=32419			Thank you for your comment. The guidance will be partially updated.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
	greater granularity around sub-groups and to explicitly reinstate the recommendations pertaining to Obesity Surgery which were originally made in TA46. Progress towards implementing the original Technology Appraisal has been exceptionally slow and arguably unsuccessful. It is our	2. Office for Health Economics (OHE). "Shedding the pounds: Obesity management, NICE guidance and bariatric surgery in England" (2010). http://www.rcseng.ac.uk/news/docs/BariatricReport.pdf 3. Gray, M, DaSilva. P(2010). NHS Atlas of Variation in Healthcare: Reducing unwarranted variation to increase value and improve quality. http://www.rightcare.nhs.uk/atlas/qipp_nhsAtlas-LOW_261110c.pdf) 4. Welbourn, R , Fiennes, A. Kinsman, R, Walton, P (2010). National Bariatric Surgery Registry. http://www.e-dendrite.com/publishing/reports/Gastrointestinal/79 5. NHS Choices website (Obesity Section): http://www.nhs.uk/Conditions/Obesity/Pages/Surgery.aspx			

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	understanding that subsuming TAs into guidelines is a practice which should take place when it can be demonstrated that the TA has been largely adopted. In this instance it is not the case and therefore the status of the TA should be re-activated.				
Johnson & Johnson Medical Ltd		J&J support the overarching principle of a holistic guideline covering Obesity but feel that unless the guideline makes explicit the recommendations pertaining to TA46: “Obesity		The current clinical guideline does not have	This guideline has superseded the TA46. This review suggests that the section on surgery remains relevant despite recent publications. It is

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		(morbid) - surgery: Guidance"[1] the signal for implementation to the NHS will be suboptimal. Indeed progress to implement the recommendations made by NICE have been very slow and research by the Office of Health Economics (OHE) [2] in 2010, estimated that there are significant numbers of patients in England who meet the criteria recommended by NICE and are willing to have surgery but currently remain untreated. Indeed they place the proportion of patients who are willing and eligible for surgery and actually receive the treatment at less than 1% of the total (0.33%). Hospital Episode Statistics (HES) data shows the actual number of surgical interventions for this population that took place in England in 2009-10 was 3,607. This highlights the severe lack of implementation which has blighted this condition and the provision of a clinically and cost effective treatment. Furthermore the NHS Atlas of variation in healthcare [3] (2010) highlights the 38-fold variation in Bariatric Surgery provision throughout the United Kingdom. The NHS choices website[5] also alludes to variation in criteria used per PCT for bariatric		mandatory implementati-on status, leading to inequitable decisions throughout different areas of England and Wales due to differing local decision-making processes and locally determined eligibility thresholds which differ from published NICE recommendations. We	unlikely that a review of guidance would improve implementation in this area. The issues that you raise will be forwarded to the NICE implementation team. The guideline development group were asked about variation in service provision as part of this review process and they did not highlight

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		surgery: *"There may be slightly different criteria at your local primary care trust (PCT) that could affect your access to surgery.* Returns from a questionnaire to PCTs, official statistics and modelling of predicted patient flows for the Office for Health Economic (OHE)'s report "Shedding the pounds: Obesity management, NICE guidance and bariatric surgery in England"(2010)[2] suggest that "adherence to the NICE guideline is inconsistent and sub-optimal" and indicated a "wide variation in practice". This is further demonstrated in that PCTs were invited to assess whether they follow NICE's guideline for Obesity. Nearly four in ten reported that their referral guidelines were in line with NICE in all respects. Nearly half responded by stating that elements of their guidelines matched CG43. One in ten PCTs responding to the questionnaire said that they do not follow the NICE guidelines at all. Furthermore, the OHE report[2] (referenced above) states that "results from the PCT		recommend NICE reinstate TA46[1] to aid in the equitable provision of clinically and cost effective interventions for these patients.	this as an area what would require revision of the guideline at this time

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		survey indicate that the current climate in the NHS will reduce the level of provision of service for obese patients". In order to aid the implementation of these important guidelines NICE should consider nesting the Technology Appraisal within the Clinical Guideline, an approach which we believe has been taken in the past when implementation has not been complete or uniform so the purpose of the TA has not been fully realised. Alternatively reinstating TA46 alongside this Clinical Guideline would achieve the same objective of ensuring that eligible patients can access these effective procedures in conjunction with the other therapies discussed in the guidelines.			
Johnson & Johnson Medical Ltd			J&J support the overarching principles stated regarding co-morbidities, but recommend the inclusion of a sub-section on Diabetes, as there is evidence which demonstrates that Bariatric surgery leads to diabetes		Treatment of specific subgroups of patients with obesity is outside the scope of the guideline, and might be covered in CG66 Diabetes guideline. These are currently under consideration for review.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
			resolution in the vast majority of patients, thereby reducing the associated complications and costs associated with managing this comorbidity. Detailed analysis of eligible sub-populations would be helpful when the NHS seeks to implement the guidance. The impact of bariatric surgery is shown definitively in the first publication of the National Bariatric surgery registry's (NBSR[4]) in 2010. The report confirms unequivocally the impact of bariatric surgery on diabetes. Data collected from 12,000 patients shows that, 2 years after bariatric surgery, "85.5% of patients with type 2 diabetes returned to a state		

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			of no indication of diabetes, meaning, in practice, that they were able to stop their diabetic medications." The data confirming the reduction in diabetes following surgery is drawn from the first published registry data from the United Kingdom on this subject[4]. This represents significant new evidence which confirms the validity of the recommendation and also demonstrates the importance of the NHS offering this intervention to eligible patients, particularly those with co morbidities such as diabetes. We note the current review consultation document does not explicitly detail this new evidence and therefore has not considered it. In		

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			addition we would question the rational for the consultation document listing studies comparing pre-and post-surgery outcomes as being out of scope. The longer term outcome and downstream impact of an intervention are of paramount importance. In the knowledge that the scope cannot be changed retrospectively, J&J therefore recommend the TA46: Obesity (morbid) – surgery[1] be reinstated and explicitly referred to within CG43 and a subsequent review of TA46 is considered by the Institute. Such review should fully examine the new evidence for the subgroup of patients who are morbidly obese and meet the eligibility		

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
			criteria for these procedures.		
Johnson & Johnson Medical Ltd			J&J support the current guideline on the care of this patient population and recognise the current lack of consensus in pre- and post- treatment protocols. In the Office for Health Economic (OHE)'s report "Shedding the pounds: Obesity management, NICE guidance and bariatric surgery in England" (2010)[2], PCTs reported that they did not routinely monitor post-operative care. J&J recommend further research in this category, including consultation with clinicians and experts to reach a consensus to enable the addition of sub-		Thank you for your comment. There does not seem to be any new published evidence since the guideline was published to help define treatment protocols surrounding surgery.

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			sections on pre- and post-surgical interventions (e.g. nutrition, patient monitoring, etc) that will aid recovery and weight loss to potentially improve patient outcome. This is currently listed as being excluded.		
Johnson & Johnson Medical Ltd		J&J support the importance of the patient and clinician working together to provide the most appropriate patient care and also recognise the importance of earlier intervention for qualifying morbidly obese patients. The NBSR (2010)[4] highlighted "the general trend is that as the BMI increases so does the ASA (The American Society of Anaesthesia) grade, very likely corresponding to the increase in obesity-related co-morbid disease that coincides with increasing BMI". Returns from a questionnaire to PCTs, official statistics and modelling of predicted patient flows for the Office for Health Economic (OHE)'s report "Shedding the pounds: Obesity management, NICE guidance and bariatric surgery in England" (2010)[2] further			Thank you for your comment. The review search identified 6 studies regarding classification of obesity and none found that body mass index was inferior to other methods of assessment for measuring adiposity change. It was concluded that the evidence base has not changed substantively since the guideline was published.

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		demonstrates this point; it indicated a wide variation in the BMI cut-offs specified in the responses to suitability for referral to surgery (i.e. from 35+ to 60+ were listed for surgical referral in the case of no co-morbidities, and 30+ to 50+ when co-morbidities were present. The only resolution to avoid unwarranted variation and inequitable access is definitive and mandatory national guidance from NICE in the form of an updated version of TA46[1], which J&J recommend the Institute consider.			This guideline has superseded the TA46. This review suggests that the section on surgery remains relevant despite recent publications. While implementation of technology appraisal is mandatory this is not the case with guidelines.
Johnson & Johnson Medical Ltd			J&J support the principles of the guidelines pertaining to surgical intervention and ensuring the appropriate evidence-based approach. We would, however, recommend adding a sub-		

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			section on the type of surgery. Although the review consultation document recognises these studies, it currently deems them out of scope. The original CG43 states (in section 1.2.6.6) that part of the decision-making criteria on the type of surgery will be based on the "best available evidence on effectiveness and long-term effects". As there is a wealth of new evidence on the newer types of procedures, not reviewing this could lead to patients not receiving the most effective care, based on the most current evidence. Additionally, the NBSR (2010)[4] states: "the NICE guidance is based on the		There did not appear to be sufficient evidence published at the time of this review to compare between different surgical procedures.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
			National Institutes of Health Guidelines from 1991, and, importantly, *these guidelines pre-dated both laparoscopic bariatric surgery and also adjustable gastric banding".* This report[4] also shows that patients having laparoscopic surgery have a reduced length of stay, resulting in cost savings. Reinstating TA46 would go some distance in addressing these concerns but in light of the wealth of new evidence on this subject, the ideal situation would be a review of TA46 to encompass the technological advances such as laparoscopic approach to surgery. An updated TA46 would		NICE guidance CG43 was based on an evidence base searched up to 2006. The review search considered to June 2011 and all new studies published in the interim were considered as part of the review recommendation

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			complement this guideline irrespective of whether this review under consideration is undertaken or not.		
RCPCH	Yes	Happy that a review is not required at the moment in light of no new evidence.			Thank you for your comment.
RCPCH	Yes	Public Health Advice for children/schools intervention awaited as suggested in review. Obesity in children should be addressed mainly in Community not General Paediatric Hospital clinics, but resources poor/DNAs common.			Thank you for these comments. Community based interventions will be covered in a new referral to CPHE on the lifestyle weight management of overweight and obese children.
RCPCH	Yes	Not enough or relevant new evidence to justify changes in the present guidance.	If possible, more clarity and more evidence on how obesity (or which level of obesity) in children is likely to cause “significant harm”. Presently, it is still extremely difficulty for Paediatricians to argue with Social Care for the need of protection for very obese children. If risks of obesity in children (medium and long		Thank you for your comment. Little new evidence regarding the issue you raise was available from the review search. One study found no link between obesity in childhood and asthma. And no evidence relating to levels of obesity were found.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
			term) could be clearly described, more help and support could be requested for these families.		
RCPCH	Yes/No	We basically agree that there is little in the way of new evidence that should substantially change the recommendations. However the guidelines fall down in the recommendations regarding the preschool years, particularly babyhood. The original review had a strong focus on the school years because, at the time, there was less awareness of the relationship of perinatal risk factors, infant growth and parenting to subsequent child obesity. While newer evidence may make only small changes in the nuance of existing recommendations, the lack of emphasis on the early years in the original document now needs to be addressed (see below). On page 15, it states that the 'issues of role modelling and parenting may be picked up by public health guidance in development in table 4'. However table 4 is disappointing as there	Importance of the perinatal period There is increasing evidence regarding perinatal risk factors and their association with the development of obesity later on in childhood. There are a number of systematic reviews and a systematic review of systematic reviews (Monasta et al)[1]. The DH has also commissioned three pieces of work in this area, two have been published on the National Obesity Observatory website[2,3] and the third (BERTIE) took place at RCPCH[4]. This all points to an importance of very early identification and intervention[5], which is not		Thank you for these comments. Since the publication of the guideline NICE has published public health guidance on weight management before, during and after pregnancy and on maternal and child nutrition. Both of these pieces of guidance pick up issues raised here. As part of the update review, we considered the evidence base for the prevention of obesity in very young children, even though this was outside the original scope and found that there remains a lack of evidence of effectiveness for intervention. Please note that a broad range of evidence is considered for the development of public health guidance (though the review of the guidance primarily considered evidence reviews). The new referral to CPHE on lifestyle weight management in overweight

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		is nothing proposed that relates to pre-school children and babies, or indeed parenting in these years. There is a section on the 'role of early years settings'. However this section completely omits the main setting for babies and young children, namely the family home and parents. Page 21, it states that there is no new evidence relating to risk factors in adults or children that would alter recommendations. However there *is* new evidence relating to risk factors perinatally as indicated above. (page 1-literature searches) we are puzzled by the focus on randomised controlled trials alone in the search for new evidence. For neither 'identification and classification of overweight and obese' and 'assessment' are randomised controlled trials the optimal research design to seek. We hope that other important new evidence has not been missed as a result.	adequately reflected in the guideline. Interventions in the Pre-School Years There are a number of randomised controlled trials underway internationally with promising results emerging pointing to the benefits and components of interventions in the preschool years -e.g. the EMPOWER project which was developed under the auspices of RCPCH[6]; and Healthy Beginnings and NOURISH, both publishing results from Australia. At a public health level a national evaluation of HENRY[7,8] is indicating promising changes in lifestyle. We believe this merits separate consideration of		and obese children will cover children from 2 years of age and may consider role modelling and parenting within the context of lifestyle weight management programmes for overweight and obese children. Children under 2 are included in existing NICE public health guidance on maternal and child nutrition.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
			interventions in the first 2 years of life, rather than clumping babies into sections that address lifestyle change and weight management in school age children. Parenting Although parenting is mentioned in the guidelines it does not get enough prominence. RCTs have been cited but there is not enough consideration of other high quality evidence such as good cohort studies showing the association of authoritative parenting with healthy weight in childhood[2]. This has clear implications for highlighting the importance of parenting skills alongside diet and physical activity as component of weight management and		

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			obesity prevention programmes. REFERENCES 1. Monasta, L., et al., *Early-life determinants of overweight and obesity: a review of systematic reviews.* Obesity Reviews, 2010. 11(10): p. 695-708. 2. Rudolf MCJ. Tackling obesity through the Healthy Child Programme. Recommendations and their evidence base. Department of Health 2009. Published on www.noo.org.uk/Mary_Rudolf 3. Dahly, D and Rudolf, MCJ		

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
			Identifying obesity risk in the early years, Department of Health, 2010 Published on the National Obesity Observatory Website www.noo.org.uk. 4. The BERTIE project - Babies and Early years Risk: Trying to Implement the Evidence. A collation of the evidence and consensus process held at RCPCH in July 2011. 5. Rudolf, MCJ, Predicting Babies Risk of Obesity, Archives Disease in Childhood, Online First published August		

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			2011 6. Barlow J, Whitlock S, Hanson S, Davis H, Hunt C, Kirkpatrck S, Rudolf M. Preventing Obesity: Parental views about the EMPOWER programme. Child: Care, Health & Development.2010 . 7. Rudolf MCJ, Hunt C, George J, Hajibagheri K, Blair M. HENRY: Development, Pilot and Long Term Evaluation of a Programme to Help Practitioners Work More Effectively with Parents of Babies and Preschool		

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
			Children to Prevent Childhood Obesity" Child: Care, Health & Development 2010. 36(6):850-857 8. Willis TA, Hunt C, Potrata B, Rudolf MCJ. Training community practitioners to work more effectively with parents to prevent childhood obesity: the impact of HENRY upon Children's Centres and their staff (in prep)		
RCPCH	Yes	We have already had opportunity to comment on the public health part of the review and most of the comments have been addressed or will be picked up in the Public Health guidance in preparation.	We have already expressed the desire to include children under 2, but the evidence base is very limited. Interventions will come into public health	Adequately addressed. Ethnic variations are addressed in adult sections	Thank you for these comments. The current guidance already mentions these issues. However, NICE did identify these issues as areas where – while there may not be more evidence available – greater

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		For example, we would like to see more information about TV viewing, sleep recommendations, availability of drinking water in schools, vending machines etc. Also interventions to support parents such as HENRY programme. These could all come within public health guidance. Re Clinical area 1, the classification of overweight and obesity: Reference could be made to the position statement drawn up by a SACN / RCPCH group chaired by Alan Jackson in 2010 “Use of BMI thresholds for defining underweight, overweight and obesity in children aged 4-18 years in England”.	guidance.	and there is limited evidence for children.	prominence could be considered if the guidance was updated. The HENRY programme will be considered as part of the new referral to CPHE on the lifestyle weight management of overweight and obese children. Thank you for your comment. The review search did not identify sufficient evidence to warrant a review of the assessment section of the guideline. This is in line with the The SACN/RCPCH Expert Group that concluded that ‘BMI centile thresholds would be based ideally on scientific evidence of a link between specific BMI centile values in children and short- and long-term health risks, but there are currently no data available to demonstrate such a link with a specific BMI value.’
RCPCH	Yes	Despite all the new evidence, this topic has really not moved on in 6 years. Obese children are easily identified with co-morbidities by			Thank you for your comment.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		screening, but paediatricians are relatively powerless to achieve significant weight loss in these patients due to a lack of motivation from children and parents alike to stick to calorie restricted diets, exercise programmes and other lifestyle interventions. Anecdotal evidence suggests that most of the children seen by paediatricians have already been through a MEND programme or two, and have received community-based interventions. Drugs are not the answer. Bariatric surgery may be the only solution for the older children. Obesity requires a social not a medical solution.			
RCPCH	Yes	While we agree there are strong arguments for not updating the guideline at this time, we would like some assurance that the "current processes" referred to in Section 8 will ensure that the guideline is updated in the not too distant future when: a) The organisational changes resulting from the Health and Social Care Bill become clear. b) The work-in-progress public health guidance referred to in many sections	It would be excellent to include children under two years of age in the updated guideline if there is sufficient evidence to make this feasible.	See above: children under two years old are currently being treated unequally, which is of relevance given that eating habits established below two are	Thank you for these comments. Children under 2 years of age were excluded from the original scope. Systematic reviews that we have considered suggest that there remains a lack of evidence of effectiveness for intervention in this age group. Please note that children under 2 are covered by existing NICE public health guidance on maternal and child nutrition

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		is published. c) At least *some* of the salient research studies currently in progress are completed and published.		almost certainly related to subsequent BMI.	
Weight Concern		General comment: We are concerned about the level of evidence used throughout this review, specifically, the use of abstracts, rather than full publications in the evaluation process. We feel this is completely inadequate to gain a full understanding of the evidence cited. Additionally, in the summary of clinical evidence (2.2) you refer to a number of on-going clinical trials, with unknown publication dates, some of which are in UK adult populations. This conveys a sense that the quality and relevance of the evidence in relation to the UK population is quite unclear. We also feel that there is a strong need to make recommendations in obesity management more specific and directive for different populations, therefore, the conclusion that there is new evidence in this area, but that it will not be included in the new guidance, seems unjustified.			Thank you for your comment. The review process only assesses abstracts without conducting a full systematic review. The process and methods of guidelines review are being evaluated and will be out for public consultation as part of the Guideline Manual Update in January 2012. We would welcome any comments on these methods during the consultation. Only limited evidence is available on efficacy of interventions for specific subgroups. The scope of the guideline includes 'clinical management of morbid obesity' and the guidance is aimed to cover the majority of obese patients but not the specialist management of particular subgroups.
Weight		Recommendation 1.2.3: This point appears			Thank you for your comment.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
Concern		very misleading. Numerous studies have shown that obese children have an elevated risk of having CVD risk factors. I am not familiar with reference 38, but reference 39 relates to the risk of adult CVD risk from being obese in childhood. This review shows that tracking of risk factors from childhood obesity appears to be reliant on weight tracking. The recommendation as it stands suggests that there are no associations in childhood rather than, more accurately, associations between child obesity and adult CVD risk is unclear. Additionally re this recommendation, there are studies showing associations between child obesity and asthma- were these considered and deemed to be outweighed by the evidence from reference 40?			The current recommendations for children state 'After measurements have been taken and the issue of weight raised with the child and family, an assessment should be done, covering: • comorbidities (such as hypertension, hyperinsulinaemia, dyslipidaemia, type 2 diabetes, psychosocial dysfunction and exacerbation of conditions such as asthma) and risk factors' The study from Peters et al (2011) (reference 40) was the only one relating to Asthma and childhood obesity that was indentified during the period of the updated search. The conclusions did not appear to contradict the recommendation in section 1.2.3 of the guideline.
Weight Concern		Recommendation 1.2.4 (children): Were cost-effectiveness analyses carried out? And if not, why not, since this appears to key? There appear to be several omissions in the evidence cited for this review. Were the			Cost effectiveness models are not re-run as part of the guideline review process. However any relevant published cost effectiveness papers were selected.

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		following considered? Coppins et al, 11; Ford et al, 10; Margery et al, 11; Okely et al, 10; Reinehr et al, 10; Sacher et al, 10; Taveras et al, 11; Tsiros et al, 08; Wafa et al, 11; West et al, 10. Why were only the abstracts reviewed- it appears quite obvious that these would contain limited detail re the intervention content?			The references provided are not in their full form and so it is difficult to identify the exact studies. However, based on the name and date, it appears that all the studies listed were identified in the review process and were included, or were excluded because they were not Randomised Controlled Trials (for intervention studies), because they had a follow up period of less than 6 months for children, or because they had a follow up period of less than 12 months for adults. The review process only assesses abstracts without conducting a full systematic review. The process and methods of guidelines review are being evaluated and will be out for public consultation as part of the Guideline Manual Update in January 2012. We would welcome any comments on these methods during the consultation. Coppins (2011) was not identified in

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					review searches. Only RCT data was considered for obesity interventions. Ford (2010) was identified in searches and is relevant to behavioural interventions in children. Margery (2011) was not identified in review searches – cannot identify study from consultee comment Okely (2010) was identified in searches but not clear from abstract whether the follow up was 6 months or more, this was an exclusion criteria from the existing guideline Reinehr (2010) was identified in searches and is relevant to diet interventions in children it was considered as part of the review process but was not specifically highlighted in the consultation document. Sacher (2010) was identified in the review searches and was included in the review of recent evidence in the consultation document (reference 152) Taveras (2011) was identified in review searches. Only RCT data was

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					considered for obesity interventions Tsiros (2008) was identified in searches the follow up was < 6 months, this was an exclusion criteria from the existing guideline. Wafa (2011) was indexed after review searches were performed. West (2010) was identified in review searches the follow up was < 6 months, this was an exclusion criteria from the existing guideline.
National Obesity Observatory	Disagree	We feel it is important to provide an update on new evidence around lifestyle interventions – particularly with regards to very low calorie diets and behaviour change – with appropriate cross-references to NICE guidance.			Thank you for these comments. These issues will be covered by the new referral to CPHE on lifestyle weight management for overweight and obese adults
		Whilst we are aware NICE are undertaking a review of obesity measurement in BME groups – it is important the guidelines are updated by this.			Thank you for these comments. This issue is covered by a new referral to CPHE on BMI cut offs in BME groups.
		We feel the current guidance needs updating to reflect the risks of maternal obesity with appropriate cross-referencing to other NICE documents.			Thank you for these comments. Since the publication of this guidance, NICE has published public health guidance on the prevention of obesity before, during and after

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					pregnancy. The management of obesity was not covered within the scope of this guidance.
		We feel that it would be beneficial to strengthen the current guidance in light of the new evidence supporting the detrimental impact of sedentary behaviour – with cross reference to the new PA guidelines.			Thank you for these comments. Please note that these issues have also been addressed in more recent NICE public health guidance, for example, on physical activity and the build environment and physical activity in children and young people. The CPHE at NICE is also currently developing guidance on walking and cycling.
		We feel it would be beneficial if the revised guidance could draw attention to the literature supporting the increased risks of overweight in shift workers,			Thank you for these comments. Our consideration on the evidence of this area suggested that the evidence base was still equivocal on this issue and there is a lack of evidence for the effectiveness of particular interventions.
		We feel it is important to the guidance to be revised to reflect the new changes in NHS and LA structures and responsibilities.			Thank you for these comments. Our view is that the roles, responsibilities and structures of the NHS and LA remain unclear and that the guidance cannot be updated until there is greater clarity.
		The guidance is also quite different from other			Thank you for your comment. NICE

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		more recent NICE guidance – not doubt reflecting NICE's more refined review and guidance development methodologies. Revised guidance would benefit from NICE's improved systems and approaches and would be likely to be more focused and impactful.			guideline production methodology has indeed progressed since the existing guideline was produced. However, the decision to update a guideline is based on a change in the evidence base or clinical practice, not on the age of the guideline or on the original methods used.
		Generally we feel that it would be beneficial to have an updated evidence base given the rapid growth in this area and constant need for update to date evidence.			Thank you for your comment. The guidance will be partially updated.
Allergan	Disagree with proposal to not update			Post Code Lottery: According to the Shedding the Pounds Report (2010) it is now well established that a postcode lottery exist in UK obesity surgery	Thank you for your comment. It is unlikely that an update of the guideline would improve implementation in this area. The issues that you raise will be forwarded to the NICE implementation team.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
				provision. This report shows huge variations in the numbers of procedures carried out per year between Trusts, ranging from just a single procedure in one Trust to 192 in another Trust. The development and consistent implementation of bariatric surgery commissioning indicators in-line with NICE CG 43 Bariatric	

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				Surgery Eligibility criteria could help to address this inequality of access to bariatric surgery across England and Wales.	
Allergan	Disagree with proposal to not update	Lower Provision of Bariatric Surgery: There remains a gap between policy implementation at a local nd . level. According Shedding the Pounds Report (2010) around on million people in England meet NICE criteria approximately a quarter of those motivate receive surgery - yet only 4,300 weight operations were carried out in 2009. This is f complicated by Commissioners inappro modification of NICE Bariatric Surgery Elig criteria at a local level. According to the She			Thank you for your comment. It is unlikely that an update of guideline would improve implementation in this area. The issues that you raise will be forwarded to the NICE implementation team.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		the Pounds report data demonstrates that Trus either ignoring professional guidelines and rati care for all but most severely ill patients, or of no provision at all. The raising of surgery barr that only the most seriously ill patients – those v BMI of 50 to 60 qualify for surgery is not in line clinical evidence. These severely obese patients are more likely to suffer post ope complications. Intervening earlier in the disease progressi particular in obese type 2 diabetics would result in imp patient outcomes (Dixon, et al 2005). The effective and consistent implementation of CG 43 Bariatric Surgery Eligibility criteria would expected to result in both improved patient outc and healthcare systems benefit. The Office of Health Economics (2010) analysis shows: If just five per cent of NICE-eligible patients to receive bariatric surgery, the total net gain to the eco			

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		within three years would be £382m. If 25 per cent of NICE-eligible patients we receive bariatric surgery, the total net gain t economy within three years would be £1.3bn. The UK government could also expect savir benefit payments in the region of £35m-£150m. Direct healthcare cost savings of around £55 annum to the NHS in reduced prescriptions and GP visi NICE guidance was followed. We recommend that NICE develop commissi indicators for bariatric surgery in line with the NICE CG order to drive the adoption of this cost effective techn from both a healthcare and societal perspective.			
Allergan	Disagree with proposal to not	Long-term follow-up of all patients who undergo bariatric procedures is necessary to ensure efficacy and patient well being. Current commissioning pathways provide variable			Thank you for your comment. No evidence was found from the review search relating to follow up after bariatric surgery that would suggest

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	update	access to long-term follow-up. ASMBS guidance recommends all centres providing bariatric surgery are required to provide life-long follow-up for all patients with an audit standard of 75% patient follow-up. Consistent commissioning of services across the UK is necessary to protect patients and ensure safety and efficacy for all bariatric procedures.			the existing recommendations are no longer appropriate. Currently the guidance recommends in section 1.2.6.4' Regular, specialist postoperative dietetic monitoring should be provided,
Allergan	Disagree with proposal to not update	The European, Australian & American regulatory agencies have reviewed and evaluated both published and data on-file with the manufacturer resulting in the LAP-BAND AP adjustable gastric band system securing widened indications in specific areas. We recommend that these additional indications be reflected in the updated CG-43 guidance to assist commissioners and General Practice with decision making in relation to bariatric surgery. Indications specific to the LAP-BAND AP system include: Weight-loss associated with the LAP-BAND			There did not appear to be sufficient evidence published at the time of this review to compare between different surgical procedures.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		system has been shown to improve or lead to the remission of type 2 diabetes in patients with BMI greater than or equal to 35; European regulatory agency- LNE/G-MED (Laboritoire national de metrologie ed d'essais), Australian regulatory agency - TGA (Therapeutic Goods Administration) and American regulatory agency – FDA (Food and Drugs Administration). LAP-BAND AP system is indicated for use in severely obese patients 14 years and older who have failed more conservative weight-reduction alternatives such as supervised diet, exercise and behavioral modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives; European regulatory agency- LNE/G-MED (Laboritoire national de metrologie ed d'essais), Australian regulatory agency - TGA (Therapeutic Goods Administration) LAP-BAND AP system is indicated for use in weight reduction for severely obese patients with a BMI of at least 35 or a BMI of at least			

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		30 with one or more severe comorbid conditions; European regulatory agency- LNE/G-MED (Laboritoire national de metrologie ed d'essais), Australian regulatory agency - TGA (Therapeutic Goods Administration) and American regulatory agency – FDA (Food and Drugs Administration).			
British Liver Trust	Disagree Clinical area 2: Assessment What are the common weight-related comorbiditie s and how do they impact on the health of the individual, both now and in the	This aspect of the guidance should recognise the issue of Non-Alcoholic Fatty Liver Disease (NAFLD).	NAFLD is a condition/disease that is consistent with the increasing rates of obesity and is closely related to metabolic disorders. Until recently fatty liver was considered rare and relatively harmless, however liver specialists are warning that Non-alcoholic fatty liver disease (NAFLD) and Non alcoholic steatohepatitis (NASH) are set to overtake alcohol as the leading cause of liver disease.		Thank you for your comment. This is outwith the scope of the guideline. The scope of the guideline includes 'clinical management of morbid obesity' and the guidance is aimed to cover the majority of obese patients but not the specialist management of particular subgroups.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
	future?		NAFLD is actually a term for a wide range of conditions characterised by the build-up of fat in the liver cells of people who do not drink alcohol excessively. Ninety per cent of morbidly obese individuals have fatty livers, and most liver experts now believe that obesity plays a key role in the development of liver disease[i]. In fact, some hepatologists believe that up to 35% of the population might be affected by NAFLD or NASH[iii]. The British Medical Journal (BMJ) published two papers in March this year that proved that there is a link between alcohol and obesity as contributory factors to liver diseass.This		

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			data provides us with compelling evidence to support what we (hepatologists and patient groups) have known for a long time – that there is double whammy effect when two causes of liver disease both impact on a person's liver collectively, and that impact is greater than the sum of the two parts.		
	AGREE: Recommendation 1.1.1.5	Stakeholders have previously queried the statement re losing no more than 0.5-1kg week; the public health GDG noted that this is considered best practice for lifestyle weight management in non-clinical settings. Issue re „very low calorie diets‟ (VLCD) or surgery where initial losses much higher addressed in other parts of the guideline.	It is important that people who have obesity-related liver disease do not lose weight rapidly as this can exacerbate the damage to their liver.		Thank you for these comments. The scope of the guideline includes 'clinical management of morbid obesity' and the guidance is aimed to cover the majority of obese patients but not the specialist management of particular subgroups.
Royal College of Nursing	Agree	6: Workplace The elements are there in the guidance already to address and manage weight in the workplace. However a recent audit of implementation of NICE workplace guidance			Thank you for these comments.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		indicated this is very poorly implemented in the NHS and staff are not adequately supported. Focus on support to implement current guidance would be helpful. http://www.nice.org.uk/newsroom/news/nhsauditofworkplaceguidance.jsp			
Notts HC	Agree	Would be helpful to review when more data available – particularly in relation to weight loss medication			Thank you for your comment.
Notts HC	Disagree	Page 10 - portion size is an issue for our service users so would be useful to have information included on this. Page 13 - ….we have found that ongoing support/education for family/carers is often vital in the success of our service users in weight reduction. P22(first statement)…If our service users do use generic services it would be useful to have a statement about 'reasonable adjustments' and what would be expected to ensure support for our service users (i.e. appropriate documentation, more time to establish lifestyle changes, longer appointments in appropriate venues)			Thank you for these comments. Our brief review of evidence available since publication of the guideline does flag portion size as an issue where it may be possible to give more specific guidance.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
Royal College of Psychiatrists		I am looking at it from the perspective of people with learning disabilities. Overall the review assessment does not consider that the current guidance needs to be review at this time because no new evidence has been presented. The guidance states that it wishes to avoid special interest groups specifically mention of people with learning difficulties. The guidance should correct this term since it confuses disability with difficulty. The preferred terminology in the UK is learning disability. Yet, there is guidance under construction on the measuring of BMI and waist circumference in BME groups. I believe the guidance should make specific reference to people with learning disabilities since the evidence demonstrates the prevalence of obesity in this population. The aetiology of obesity in people with learning disabilities is not related to specific factors such as the use of anti-psychotic or anticonvulsant medication but to lifestyle factors for example, mobility, sedentary living. The health outcomes for people with learning disabilities are poorer than for the general population and many of			Thank you for your comment. We are able to correct items of factual accuracy in the online versions, without conducting an update. However, the guideline development group specifically chose the wording in this instance. In any case, this does not impact on our decision whether or not to update the guideline.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		the outcomes are related to or strongly associated with obesity. The rates of diabetes mellitus, cardiovascular disease, gastrointestinal diseases are higher in people with learning disabilities. The relevant evidence on prevalence of obesity in people with learning disabilities is listed below. You might consider this as part of your response to NICE from RCPsych.			
NHS Central Lancashire	Disagree	Concerns about the discrepancies between the recommendations for bariatric surgery and increased criteria for access in a number of areas.			Thank you for your comment. It is unlikely that an update of the guideline would improve implementation in this area. The issues that you raise will be forwarded to the NICE implementation team.
NHS Central Lancashire	Disagree	Further Information on definitions and efficacy of low calorie and very low calorie diets is required.			Thank you for your comment. We identified 2 studies on very low calorie diets for clinical management of obesity which concluded that they were unable to maintain weight loss over the longer term. It was considered that this was insufficient evidence to warrant an update of this section of the guideline. However,

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					very low calorie diets may be considered as part of the new referrals to CPHE on lifestyle weight management for overweight and obese adults.
NHS Central Lancashire	Disagree	Not enough information currently about mental health impacts and psychological support required.			Thank you for your comment. Only 2 new studies were identified form the review search that explored the association between obesity and depression (references 24 and 25)
NHS Central Lancashire	Disagree	Whilst the guidance considers specialist treatment in relation to bariatric surgery and pharmacotherapy. The lifestyle interventions are not differentiated between community level i.e. tier 2 and specialist level i.e. tier 3. The recommendations do not therefore currently reflect a comprehensive care pathway approach to weight management treatment.			Thank you for your comment. This process to consider reviewing the existing guideline does not relate to current service provision. Evidence available will have come from a range of settings making it difficult to be prescriptive.
PHNN	Disagree		The current guidance does not mention the range of providers, such as Health Trainers, community workers, etc.		Thank you for these comments. The list of providers is not intended to be exhaustive. We agree that the range of providers will need to be re-considered once there is clarity in the public health responsibilities of the NHS and LAs.
PHNN	Disagree		The current guidance does not identify what		Thank you for these comments. This issue may be covered in the new

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
			competencies people providing weight management interventions should meet. It states that staff may be able to give advice with specific training, but it is not clear what this training should entail, or the evidence base for this.		referral to CPHE on lifestyle weight management for overweight and obese adults.
PHNN	Disagree	The decision not to review the guidance is based on there being no new high level evidence that would substantially change the recommendations in most areas. However, much of the evidence emerging in this field is lower level evidence, rather than RCTs and systematic reviews. This biases the guideline towards pharmaceutical and surgical interventions, where an RCT study design is easier to implement, and where funding is more readily available. This has a significant impact on commissioning and therefore resource allocation for weight management interventions. Obesity prevention and treatment is an emerging evidence base, and it is important that practice based evidence is captured and contributes to guidance.		The hierarchy of evidence considered in this review biases against less 'technological' interventions which are less likely to attract research funding.	Thank you for these comments. The review of the public health aspects tended to focus on reviews but also included primary studies other than RCTs, given that the development of public health guidance at NICE considers a broad range of evidence, as appropriate. The review of new clinical evidence used the same inclusion and exclusion criteria that were employed in the development of the existing guideline in order to provide a like with like comparison of the evidence base.

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PHNN	Disagree	The additional information on portion sizes, energy, fat, sugar, sweetened drinks and breakfast cereals referenced in the review document would be a welcome addition to the guidance. The current guidance is not specific enough in terms of dietary recommendations to support staff without detailed nutrition training to give evidence based advice to service users.			Thank you for your comment. We agree that some additional evidence is available, but this will add nuance to existing recommendations rather than change the direction of recommendations. It was considered that the new evidence available was insufficient to warrant an update of this section of the guideline at the present time.
The VLCD Industry Group	Review recommendation Disagree	The VLCD Industry Group is the trade body for manufacturers and distributors of VLCD products which provide weight loss programmes designed for the very overweight and obese. We take a great interest in the *NICE guidance CG43, Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children* and strongly disagree with NICE's provisional decision not to update this guideline at this time. Since 2006 when the original guideline was issued, a considerable amount of research has been published studying obesity, its causes and what can be done to tackle it. We			Thank you for these comments. Thank you for your comment. Only 2 new studies were identified from the review search that explored the association between obesity and depression (references 24 and 25)

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		are consequently highly concerned that this guideline on an ever more pressing public health problem is not being updated to reflect this new evidence.			
		Consistency of guidance and the importance of CG43. A further general point is to highlight the importance of CG43, a guidance that influences a number of other documents throughout the UK. CG43 is not only the basis for other pieces of NICE guidance relating to obesity and weight loss, but it is also the basis for other documents produced by organisations in other parts of the UK e.g. the Scottish Intercollegiate Guidance Network. In addition to that, CG43 is the basis for rules on various matters established by other institutions. For example, the Advertising Standards Authority has a ban on advertising that recommends losing more than a certain amount of weight due to a recommendation in CG43. This shows the importance of CG43 in many different areas of obesity policy and treatment			Thank you for these comments. We do not agree that the guideline contained inaccuracies at the time of publication. The development of new public health guidance on lifestyle weight management for overweight and obese adults will follow rigorous, standard methodology and any recommendations will be developed based on the best evidence available. There will be an opportunity for stakeholders to comment on the scope for this work in Spring 2012.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		throughout the UK. The VLCD Industry Group are therefore concerned that NICE is not taking this opportunity to correct inaccuracies contained within CG43 (please see our comments below for further information on this). Furthermore, we are also worried that future public health guidance may propagate these mistakes by referring to CG43. This may indeed have important consequences on the ability of weight loss and weight management providers to treat the increasing prevalence of obesity in the UK.			
	Recommendation 1.1.7.1 to 1.1.7.4 Disagree	Commercial weight loss programmes. We are concerned by the fact that NICE decided not to update CG43, while at the same time recognising that there is “significant new evidence” that “could add nuance to existing recommendations about what works best”. We understand that this new evidence will be covered by public health guidance “in development”. However, we are worried by the fact that this public health guidance which will cover much of this new evidence, “overweight and obese adults – lifestyle weight management”, has only just begun the earliest			Thank you for these comments. The review search identified a number of new studies relating to diet. However it was felt the that direction of conclusions were largely in line with the existing guidance, and that nothing has been published that substantively contradicts these recommendations to an extent that a review would be warranted at this time. CPHE received the referral for this

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		stages of development. There is currently no date for when stakeholders will even be able to contribute to a consultation on this guidance, let alone when it will be published. This can lead to further delays in drawing up guidance for medical professionals throughout England to use when recommending weight loss and weight management services to overweight and obese individuals. Considering the scale of the obesity problem in the UK, this is highly problematic.			new piece of work in July 2011. Initial work has begun to draw up a timeline and undertake scoping searches. The NICE website will be updated as soon as the timeline is agreed. It is likely that stakeholders will have an opportunity to comment on the scope for this work in Spring 2012 and the final guidance will be published in Autumn 2013.
	Recommendation 1.1.7.1 to 1.1.7.4 Disagree	Medical support/clinical supervision. NICE acknowledge that it "may be useful" to clarify the differences in the wording in relation to medical support. The VLCD Industry strongly agree with this and can only regret that NICE have not taken the opportunity to do this in a review of the CG43. We are concerned that such clarification, which will be useful for weight management providers, medical professionals and patients, will await public health guidance to be published at some point in the future.			Thank you for these comments. This issue will be considered as part of the new referral. However, as stated in the review consultation: "Stakeholders have previously queried the statement re losing no more than 0.5-1kg week; the public health GDG noted that this is considered best practice for lifestyle weight management in non-clinical settings. Issue re „very low calorie diets‟ (VLCD) or surgery where initial losses much higher addressed in

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					other parts of the guideline. “
	Recommendation 1.1.7.1 to 1.1.7.4 Disagree	List of approved weight management services. NICE also refer to the recommendation by the House of Lords Science and Technology Committee’s sub-committee on Behaviour Change that they should compile a list of approved weight management services that meet best practice guidelines. This list would usefully highlight the services, such as the ones offered by the members of the VLCD Industry Group - based on solid peer reviewed evidence. Once again, we regret that NICE have not even expressed a view on whether they will compile this list, even at some point in the future.			Thank you for this comment. The new referral to CPHE will consider best practice. This does not impact on the decision as to whether to update the CG43 guideline at this time.
	Recommendation 1.1.1.5 Disagree	Rate and amount of weight loss. The most important, specific inaccuracy in this guidance is the recommendation that people should not lose more than 0.5-1kg (1-2lb) in weight per week. In some circumstances it may be recommended or more appropriate that people lose more weight than this. Indeed, publicly available research demonstrates that weight			Thank you for these comments. However, we disagree with this view. As stated in the consultation document: “Stakeholders have previously queried the statement re losing no more than 0.5-1kg week; the public health GDG noted that this is considered best practice for lifestyle weight management in non-clinical settings. Issue re „very low

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		loss of greater than 1kg a week is safe and effective when an individual is participating in a controlled LCD/VLCD weight-loss programme. It is particularly important to note that current evidence from the Diogenes trial in which an 800kcal/d LCD was used for the initial weight reduction (Larsen 2010) shows clearly that greater rates of weight loss are associated with better results at six months. In previous correspondence with the VLCD Industry Group dating back to November 2007 and repeated in October 2009, NICE has indicated that, with appropriate supervision, it may be acceptable for people to lose greater amounts of weight than that specified in CG43. Yet as noted above, such is the importance of CG43 that the figures in this guidance are used by a number of organisations, including those within the NHS, as a standard for "responsible" weight loss, significantly disadvantaging VLCDs.			calorie diets‟ (VLCD) or surgery where initial losses much higher addressed in other parts of the guideline. " Larsen (2010) was identified in the review search but the follow up was < 6 months, this was an exclusion criteria from the existing guideline Please note that NICE has only received the referral from DH to develop guidance on lifestyle weight management for overweight and obese adults in July 2011; the scope for this work has not yet been considered in detail and stakeholders will get in opportunity to comment in Spring 2012.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		The VLCD Industry Group is consequently surprised that NICE is not reviewing this recommendation, despite previously acknowledging that it is inaccurate in some circumstances. The VLCD Industry Group also fears that, without a review now and specifically of CG43, this mistaken recommendation will be repeated in future public health guidance, to the detriment of medical professionals and patients.			
	1.2.4.32	VLCDs should be used for only 3 months (12 weeks) maximum. In addition, CG43 states that VLCDs should be used for only 3 months maximum. In many cases there is a requirement for further weight loss beyond this time and recent evidence provides safety data for up to one year (J. Diabetes 2009). The National Obesity Forum have also stated this in a recent evidence-based statement (National Obesity Forum (2010): Position Statement on Very Low Energy Diets for the weight loss phase of obesity management) and support the use of VLCD treatment over a time-base commensurate with the amount of			Thank you for your comment. This consultation relates to the need for a review of the guideline and is not a consultation of the content of the existing guideline.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		weight loss required for maximum health benefit. Indeed, patients who complete extended use of VLCD management have an average weight loss of 31kg which is comparable to the best bariatric surgery outcomes (J. Diabetes 2009).			
Cambridge Weight Plan (Cambridge)	Review recommendation Disagree	Cambridge strongly disagree with NICE's provisional decision not to review this Clinical Guidance 43 (CG43). For ease of reference we will make our individual points in boxes below. On a general point, the original guidance was published in 2006 and was the culmination of work over several years. Since then a considerable amount of research has been published studying obesity, its causes and what can be done to tackle it. That guidance published five years ago, on an ever more pressing public health problem, is not being updated to reflect this new evidence is concerning.	None	None	Thank you for your comment. The review of evidence published since the guideline was written identified a large number of studies for the clinical management and prevention of obesity. However the studies further support the existing recommendations rather than challenge them.
		Consistency of guidance and the importance of CG43. A further general point is to highlight the importance of CG43.	None	None	Thank you for these comments. We do not agree that the guideline contained inaccuracies at the time of

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		Not only is CG43 the basis for other pieces of NICE guidance relating to obesity and weight loss, but it is also the basis for other documents produced by organisations in other parts of the UK e.g. the Scottish Intercollegiate Guidance Network. Further to that, CG43 is the basis for rules on various matters established by other institutions. For example, the Advertising Standards Authority has a ban on advertising that recommends losing more than a certain amount of weight due to a recommendation in CG43. This underlines the importance of CG43 in many different areas of obesity policy and treatment throughout the UK. Cambridge are therefore worried that NICE is not taking the opportunity presented by this review to correct inaccuracies contained within CG43, of which more below. Furthermore, future public health guidance may propagate these mistakes by referring to CG43. Though easily corrected, these flaws within			publication. The development of public health guidance on lifestyle weight management for overweight and obese adults will follow rigorous, standard methodology and any recommendations will be developed based on the best evidence available. There will be an opportunity for stakeholders to comment on the scope for this work in early 2012.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		CG43 threaten to have a serious impact on the ability of weight loss and weight management providers to treat the growing number of obese people around the UK.			
	Recommendation 1.1.7.1 to 1.1.7.4 Disagree	Commercial weight loss programmes. In its "Review Consultation Document", NICE acknowledge that there is "significant new evidence" that "could add nuance to existing recommendations about what works best". NICE also refer to new evidence emerging from the Counterweight programme in Scotland, with which Cambridge have had some involvement. In light of this acknowledgement that this is significant new evidence, Cambridge find it confusing that NICE are not to update CG43. We note that NICE have said that this new evidence will be covered by public health guidance "in development". However, the public health guidance which will cover much of this new evidence, "overweight and obese adults – lifestyle weight management", has only just begun the earliest stages of development.	None	None	CPHE received the referral for this new piece of work in the Summer. Initial work has begun to draw up a timeline and undertake scoping searches. The NICE website will be updated as soon as the timeline is agreed. It is likely that stakeholders will have an opportunity to comment on the scope for this work Spring 2012, the draft guidance will be out for consultation in Spring 2013 and that the final guidance will be published in 2013.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		There is currently no date for when stakeholders will even be able to contribute to a consultation on this guidance, let alone when it will be published. Cambridge is concerned that this will mean further delays in drawing up guidance for medical professionals throughout England to use when recommending weight loss and weight management services to overweight and obese individuals. Considering the scale of the obesity problem facing this country, this could be problematic.			
	Recommendation 1.1.7.1 to 1.1.7.4 Disagree	Medical support/clinical supervision. NICE acknowledge that it “may be useful” to clarify the differences in the wording in relation to medical support. Cambridge strongly agree with this and can only regret that NICE have not taken the opportunity to do this in a review of the CG43. Once again, Cambridge are concerned that such clarification, which will be useful for weight management providers, medical professionals and patients, will await public health guidance to be published at some point	None	None	Thank you for these comments. This issue will be considered as part of the new referral. However, as stated in the review consultation: “Stakeholders have previously queried the statement re losing no more than 0.5-1kg week; the public health GDG noted that this is considered best practice for lifestyle weight management in non-clinical settings. Issue re „very low calorie diets‟ (VLCD) or surgery where initial losses much higher addressed in other parts of the guideline. “

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		in the future.			
	Recommendation 1.1.7.1 to 1.1.7.4 Disagree	List of approved weight management services. NICE also refer to the recommendation by the House of Lords Science and Technology Committee's sub-committee on Behaviour Change that they should compile a list of approved weight management services that meet best practice guidelines. This list would usefully highlight the services, such as Cambridge, that put considerable effort into supporting their programmes with a solid evidence base of peer-reviewed research. Once again, we regret that NICE have not even expressed a view on whether they will compile this list, even at some point in the future.	None	None	Thank you for this comment. The new referral to CPHE will consider best practice. This does not impact on the decision as to whether to update the guideline at this time.
	Recommendation 1.1.1.5 Disagree	Rate and amount of weight loss. The most important, specific inaccuracy in this guidance is the recommendation that people should not lose more than 0.5-1kg (1-2lb) in weight per week. In some circumstances it may be recommended or more appropriate that people lose more weight than this. Indeed, publicly available research demonstrates that weight	None	None	Thank you for these comments. However, we disagree with this view. As stated in the consultation document: "Stakeholders have previously queried the statement re losing no more than 0.5-1kg week; the public health GDG noted that this is considered best practice for lifestyle weight management in non-clinical settings. Issue re „very low

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		loss of greater than 1kg a week is safe and effective when an individual is participating in a controlled LCD/VLCD weight-loss programme. It is particularly important to note that current evidence from the Diogenes trial in which an 800kcal/d LCD was used for the initial weight reduction (Larsen 2010) shows clearly that greater rates of weight loss are associated with better results at six months. In previous correspondence with the VLCD Industry Group, to which Cambridge belongs, dating back to November 2007 and repeated in October 2009, NICE has indicated that, with appropriate supervision, it may be acceptable for people to lose greater amounts of weight than that specified in CG43. Yet as noted above, such is the importance of CG43 that the figures in this guidance are used by a number of organisations, including those within the NHS, as a standard for "responsible" weight loss, significantly disadvantaging VLCDs.			calorie diets‟ (VLCD) or surgery where initial losses much higher addressed in other parts of the guideline. " Larsen (2010) was identified in the review search but the follow up was < 6 months, this was an exclusion criteria from the existing guideline Please note that NICE has only just received the referral from DH to develop guidance lifestyle weight management for overweight and obese adults; the scope for this work has not yet been considered in detail and stakeholders will get in opportunity to comment in Spring 2012.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		Cambridge is surprised that NICE is not reviewing this recommendation, despite previously acknowledging that it is inaccurate in some circumstances. Cambridge also fears that, without a review now and specifically of CG43, this mistaken recommendation will be repeated in future public health guidance, to the detriment of medical professionals and patients.			
	1.2.4.32	VLCDs should be used for only 3 months (12 weeks) maximum. In addition, CG43 states that VLCDs should be used for only 3 months maximum. In many cases there is a requirement for further weight loss beyond this time and recent evidence provides safety data for up to one year (J. Diabetes 2009). The National Obesity Forum have also stated this in a recent evidence-based statement (National Obesity Forum (2010): Position Statement on Very Low Energy Diets for the weight loss phase of obesity management) and support the use of VLCD treatment over a time-base commensurate with the amount of weight loss required for maximum health	None	None	Thank you for your comment. This current consultation relates to the need for an update of the guideline, and is not a consultation of the content of the existing guideline.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		benefit. Indeed, patients who complete extended use of VLCD management have an average weight loss of 31kg which is comparable to the best bariatric surgery outcomes (J. Diabetes 2009).			
LighterLife	Review recommendation Disagree	LighterLife is a UK company offering weight loss and weight-management programmes for people who are clinically obese or overweight. LighterLife links research, knowledge, skill and experience to structure a unique programme designed to help the obese. We offer a very low calorie diet (VLCD) programme primarily for individuals who are obese, as well as LighterLife Lite, a low calorie diet (LCD) for those who are overweight but not obese. LighterLife strongly disagree with the decision not to update the Clinical Guidance 43 (CG43). Since the original guidance was issued in 2006, a considerable amount of research studying obesity, its causes and ways to tackle it has been published. Furthermore, obesity rates continue to rise in the UK. 2007's Foresight report predicts that,	None	None	Thank you for your comments. The review of evidence published since the guideline was written identified a large number of studies for the clinical management and prevention of obesity. However the studies further support the existing recommendations rather than challenge them.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		by 2050, obesity will affect 60 per cent of men, 50 per cent of women and 25 per cent of children. As a consequence, we are highly concerned that this guidance, published five years ago, is not being updated to reflect the new evidence.			
		Importance of CG43 and consistency of guidance: We would like to stress the importance of CC43, a guidance that influences a number of other documents throughout the UK. It serves as the basis for other NICE guidance documents relating to obesity and weight loss. In addition, it is also the basis for documents produced by organisations in other parts of the UK e.g. the Scottish Intercollegiate Guidance Network. CG43 is also used by other institutions to establish rules on various matters. For example, the Advertising Standards Authority (ASA) prohibits any advertising that recommends losing more than a certain amount of weight due to a recommendation in	None	None	Thank you for these comments. We do not agree that the guideline contained inaccuracies at the time of publication. The development of public health guidance on lifestyle weight management for overweight and obese adults will follow rigorous, standard methodology and any recommendations will be developed based on the best evidence available. There will be an opportunity for stakeholders to comment on the scope for this work in Spring 2012.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		CG43. Given the importance of CG43 in these many different areas of obesity policy and treatment throughout the UK, LighterLife is highly concerned that NICE is not taking the opportunity to correct inaccuracies contained within CG43 (please see our comments below for further information on this). We are also concerned that future public health guidance may further propagate these mistakes by simply referring to CG43. This may indeed have important consequences on the ability of weight loss and weight management providers to treat the increasing prevalence of obesity in the UK.			
	Recommendation 1.1.7.1 to 1.1.7.4 Disagree	Commercial weight loss and weight management programmes. LighterLife finds it highly confusing that NICE is not intending to update CG43, despite acknowledging that there is significant new evidence.	None	None	Thank you for these comments. The review search identified a number of new studies relating to diet. However it was felt the that direction of conclusions were largely in line with the existing guidance, and that nothing has been published that

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		Indeed, the Review Consultation Document states that "*significant new evidence has been published since the guideline was issued that could add nuance to existing recommendations about what works best*". NICE also refers to new evidence emerging from the Counterweight programme in Scotland, with which LighterLife have had some involvement. While we understand that this new evidence will be covered by public health guidance *in development*, we would like to stress that this guidance has only just begun the earliest stages of development. In addition, there is currently no date for when stakeholders will even be able to contribute to a consultation on this guidance, not to mention when it will be published. LighterLife is worried that this will mean further delays in drawing up guidance for medical professionals throughout England to use when recommending weight loss and weight management services to overweight and obese individuals. This is especially concerning given the scale of obesity problem			substantively contradicts these recommendations to an extent that a review would be warranted at this time. CPHE received the referral for this new piece of work in the Summer. Initial work has begun to draw up a timeline and undertake scoping searches. The NICE website will be updated as soon as the timeline is agreed. It is likely that stakeholders will have an opportunity to comment on the scope for this work in Spring 2012, the draft guidance will be out for consultation in Spring 2013 and that the final guidance will be published in 2013.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		in the Uk.			
	Recommendation 1.1.7.1 to 1.1.7.4 Disagree	Medical support/clinical supervision. The Review Consultation Document acknowledges that it “may be useful” to clarify the differences in the wording in relation to medical support. While LighterLife strongly agrees with this, we can only regret that such clarification, which will be useful for weight management providers, medical professionals and patients, will have to await public health guidance to be published at some point in the future.	None	None	Thank you for these comments. This issue will be considered as part of the new referral. However, as stated in the review consultation: “Stakeholders have previously queried the statement re losing no more than 0.5-1kg week; the public health GDG noted that this is considered best practice for lifestyle weight management in non-clinical settings. Issue re „very low calorie diets‟ (VLCD) or surgery where initial losses much higher addressed in other parts of the guideline. “
	Recommendation 1.1.7.1 to 1.1.7.4 Disagree	List of approved weight management services. While NICE refers to the recommendation by the House of Lords Science and Technology Committee’s sub-committee on Behaviour Change that they should compile a list of approved weight management services that meet best practice guidelines, it is regrettable that they have not even expressed a view on whether they will compile this list, even at some point in the future.	None	None	Thank you for this comment. The new referral to CPHE will consider best practice. This does not impact on the decision as to whether to update the guideline at this time.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		Such a list would usefully highlight the service providers, such as LighterLife, that put considerable effort into supporting their programmes with a solid evidence base of peer-reviewed research.			
	Recommendation 1.1.1.5 Disagree	Rate and amount of weight loss. One of the most important inaccuracies in the CG43 guidance is the recommendation that people should not lose more than 0.5-1kg (1-2lb) in weight per week. In some circumstances it may be recommended or more appropriate that people lose more weight than this. Indeed, publicly available research demonstrates that weight loss of greater than 1kg a week is safe and effective when an individual is participating in a controlled LCD/VLCD weight-loss programme. It is particularly important to note that current evidence from the Diogenes trial in which an 800kcal/d LCD was used for the initial weight reduction (Larsen 2010) shows clearly that greater rates of weight loss are associated	None	None	Thank you for these comments. However, we disagree with this view. As stated in the consultation document: “Stakeholders have previously queried the statement re losing no more than 0.5-1kg week; the public health GDG noted that this is considered best practice for lifestyle weight management in non-clinical settings. Issue re „very low calorie diets‟ (VLCD) or surgery where initial losses much higher addressed in other parts of the guideline. “ Larsen (2010) was identified in the review search but the follow up was < 6 months, this was an exclusion criteria from the existing guideline

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		with better results at six months. In previous correspondence with the VLCD Industry Group, of which LighterLife is a member, dating back to November 2007 and repeated in October 2009, NICE has indicated that, with appropriate supervision, it may be acceptable for people to lose greater amounts of weight than that specified in CG43. Given that the figures in this guidance are used by a number of organisations, including those within the NHS, as a standard for "responsible" weight loss, this is highly problematic as it significantly disadvantages VLCDs. Lighter life is not only surprised that NICE is not reviewing this recommendation, despite previously acknowledging that it is inaccurate in some circumstances, but is also worried that without a review of CG43, this mistaken recommendation will be repeated in future public health guidance, to the detriment of medical professionals and patients.			Please note that NICE has only just received the referral from DH to develop guidance lifestyle weight management for overweight and obese adults; the scope for this work has not yet been considered in detail and stakeholders will get in opportunity to comment in Spring 2012.
	1.2.4.32	VLCDs should be used for only 12 weeks maximum. CG43 states that VLCDs should be	None	None	Thank you for your comment. This consultation relates to the need for

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		used for a maximum of only 12 weeks. In many cases there is a requirement for further weight loss beyond this time and recent evidence provides safety data for up to one year (J. Diabetes 2009). The National Obesity Forum have also stated this in a recent evidence-based statement (National Obesity Forum (2010) - Position Statement on Very Low Energy Diets for the weight loss phase of obesity management) and supports the use of VLCD treatment over a time-base commensurate with the amount of weight loss required for maximum health benefit. Indeed, patients who complete extended use of VLCD management have an average weight loss of 31kg which is comparable to the best bariatric surgery outcomes (J. Diabetes 2009).			an update of the guideline and is not a consultation of the content of the existing guideline.
MHRA		Through the process, no additional areas were identified which were not covered in the original guideline scope or would indicate a significant change in clinical practice. There are no factors described above which would invalidate or change the direction of current guideline recommendations. The guideline			Thank you for your comment.

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		should not be updated at this time.			
Association for the Study of Obesity	Disagree	The ASO strongly believes the 2006 obesity guidance should be reviewed and updated. More recent NICE guidance has frequently touched upon obesity and it is likely that this will continue to be the case in the future, making it important that the guidance is as up to date as possible.	Whist new research has generally not contradicted the existing guidance, the evidence has strengthened in many areas, allowing more precise recommendations, and in some situations new interventions have become available, for example OTC Orlistat (Alli). This is particularly true with regard to treatment interventions for weight loss, including, but not limited to evidence related to surgical procedures. For example 1. There was not really much discussion in the existing guidance about the risks / benefits of different procedures (eg duodenal switch, which seems to	There needs to be greater consideration of certain special groups, for example especially people with mental illness and during pregnancy	Thank you for your comment. The assessment of evidence from the review search identified 3 studies found a beneficial effect of Orlistat in adults, and 2 studies in children. However none of these were specifically in the community setting. There did not appear to be sufficient evidence published at the time of this review to compare between different

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			have a higher complication rate) and sleeve gastrectomy as a stand-alone procedure is not mentioned at all. 2. Some guidance about which surgical procedures might be most suitable for which patients might be helpful if a consensus could be reached. 3. The guidance should encompass pre- and post-surgical care and support in more detail. 4. There is also a lot of new health economic data that could be considered, particularly in relation to surgery		surgical procedures. Although new evidence is emerging. A review of the recommendations in this area is only likely to be based on consensus of clinical opinion rather than high quality evidence, and as such this would not represent a priority for review. There does not seem to be significant new published evidence since the guideline was published to help define treatment protocols surrounding surgery. Four studies were identified in the review search identifying that bariatric surgery was cost effective, with two of the studies suggesting it is cost effective for all classes of obesity. These studies seem to concur with the health economic

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					modelling conducted as part of the development of the existing guideline
		There is also real opportunity to do some more detailed modelling on cost-effectiveness			Thank you for your comment. No formal re-assessment of economic models is undertaken as part of the normal guideline review process, however if a review were considered clinically relevant then new modelling would be undertaken as part of the update.
		As part of the review ASO strongly urges that consideration be given to separating the prevention and treatment issues more clearly - as they will frequently apply to different audiences, and this will help bring greater clarity to the guidance. The division between public health and clinical guidance should also be reviewed since many community-based lifestyle interventions bridge these two areas.			Thank you for your comment. The Guideline was initially scoped to cover prevention, identification and treatment aspects in a single guideline, in order to provide a cohesive piece of guidance for a range of healthcare professionals. The importance of ensuring integrated, consistent guidance was a key aspect of the work of the guideline development groups who worked on this guideline. This review considered both aspects, however the relevance of maintaining a single piece of guidance, or not, was not

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					identified by either the original public health or clinical guideline development groups.
		Finally, an updated review would be timely given the forthcoming shift of responsibilities for many aspects of obesity prevention and treatment to local authorities. It would provide an opportunity to reinforce the importance of obesity interventions to reduce the burden of ill health, provide an authoritative synthesis of the evidence and clear guidelines for implementation.			Thank you for your comment.
Department of Health		I wish to confirm that the Department of Health has no substantive comments to make regarding this consultation.			Noted, thank you.
Liverpool Primary Care Trust	Agree		When this is updated consideration should be given to 'raising the issue'. All professionals seem to have difficulties in opening a dialogue.		Thank you for your comment. The guidance does include a section on 'Person-centred care: principles for health professionals' however no specific recommendations are made regarding approaches to opening a dialogue. We will forward these comments to the implementation team at NICE.
			Planners should be included in the guidance –		Thank you. Recommendations are directed to planners in the guideline.

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			to improve local environments to discourage sedentary behaviour and to encourage activity – for example in many buildings stairs are invisible.		You may also wish to refer to NICE public health guidance on physical activity and the built environment and to the prevention of CVD.
			Consideration should be given to including a municipal approach to tacking obesity.		As above.
	1.1.2.9	Cross reference with NICE guidance for physical exercise and healthy eating in pregnancy.			Thank you for this comment. Other relevant NICE guidance and recommendations are cross-referenced in NICE Pathways http://pathways.nice.org.uk/
	1.1.41		Government should provide National guidance for nutritional requirements of pre school children		Thank you for your comment, however this is not an issue for NICE.
	1.2.2. agree	BMI although not an ideal measurement is the least intrusive and agree with the evidence.	1.2.3 Primary Care should have access to specialist equipment when providing general care for people who are severely obese.		Thank you for this comment. No new evidence regarding assessment was identified that contradicts existing recommendations. Provision of specialist equipment for treating obese patients is outwith the

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					scope of this guideline.
	1.2.1.4	Add eating behaviour to this list			Thank you for this comment. This consultation focuses on the need to update the guideline, and not on specific recommendations within the existing guideline.
	1.2.1.6	Supportive environments should help children and parents motivation to change lifestyle and behaviours.			Thank you for this comment. This consultation focuses on the need to update the guideline, and not on specific recommendations within the existing guideline.
	1.2.1.8	General comment that we should use the term unhealthy weight rather than obesity, the term obese is seen as derogatory and should be used sparingly. Our experience seems to suggest that unless a child or adult is very obese they do not see the term as having anything to do with them.			Thank you for this comment. Discussions about language have moved on since the publication of the guidance. For example, DH now tends to focus on increasing the prevalence of healthy weight and preventing excess weight gain, rather than obesity.
	1.2.2.12	Should consideration be given to children with below the 91st Centile who are in the health system for other conditions and children who are to be placed on psychotropic medication.			Thank you for this comment. This consultation focuses on the need to update the guideline, and not on specific recommendations within the existing guideline.
			Cross reference CMO report which for the last two years has focussed on		Thank you for your comment. If the guideline was to be reviewed relevant reports would be cross

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			physical activity		referenced. More recent reports will have been added to relevant NICE pathways. .
			Consider physical activity advice for babies and infants.		Thank you for your comment. The scope of the guideline limits to children aged 2 years or older. There is likely to be considerably less evidence for this patient population.
				Consider language – people of Asian origin rather than Asians	Thank you for this comment. The wording was chosen from the original wording in the evidence. Please note that this issue can be covered in the recent referral to CPHE to develop guidance on BMI cut offs for BME groups.
NHS SW London - Kingston	Clinical area 1 or 2 (disagree)	Please consider including additional guidance on the clinical use of BMI centile definitions for severe, very severe and extreme obesity in children and young people, as per the UK90 child BMI Management charts. The charts feature both +3.5 SDS and +4 SDS. This guidance would provide a basis to aid monitoring for extremely obese children and provide a guideline for physicians on when pharmacological and/or surgical treatment should be considered for young people.			Thank you for your comment. No new evidence was identified that related to methods of assessment / classification using specific BMI centiles.

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		Refer to SIGN 115: Management of obesity. P.9 quick reference guide, Feb 2010			
NHS SW London - Kingston	Clinical area 3 (disagree)	Although the new evidence doesn't change the existing recommendations, is it at all possible to provide an indication/guide for both adult and child obesity lifestyle interventions on the optimal frequency and intensity of delivery and clinical contact hours required to achieve a clinically significant change in weight and/or BMI? Advising offer 'regular contact/long-term follow-up' is vague. Is there an optimal number of weeks or contact time shown in the studies to help provide better/consistent models of care. The American Academy of Pediatrics Expert Committee Recommendations for the treatment of child obesity, 2007 suggest there is consistent evidence to advise a minimum of 8-12 weekly visits to help maintain new behaviour changes.			Thank you for your comment. No data are available from the review search to more specifically define the optimum follow up schedule at this time.
NHS SW London - Kingston	Public health area 1	Additional information on portions sizes, energy density and sugar-sweetened beverages would be very welcome. The more specific guidance can be on target behaviours to tackle, which can have a direct impact on weight and BMI changes the better. The more exact information is the easier it is to			Thank you for your comment. We agree that some additional evidence is available, but this will add nuance to existing recommendations rather than change the direction of recommendations. It was considered that the new evidence available was

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		disseminate a consistent public health message. Vague messages are difficult for individuals to adopt to bring about changes in weight.			insufficient to warrant an update of this section of the guideline.
DOM UK	Disagree		We feel that there is additional evidence to consider, and the scope of the guidance should be increased. For example, the guidance contains no information on meal replacements, and the definition of VLEDs (very low energy diets) is not correct.		Thank you for your comment. Meal replacements were not considered during this review of guidance, it has not been highlighted widely by other stakeholders / consultees. Factual inaccuracies can be corrected in the existing guidance.
DOM UK	Disagree	The SIGN (Scottish Intercollegiate Guidelines Network) are easy to use and broader. They use a wider range of evidence, (not just RCTs and systematic reviews), and clearly indicate the level of evidence recommendations are based on, and the grade of the recommendation made	Limiting the evidence review to RCTs and systematic reviews means that much good evidence is not used.		Thank you for your comment. The original guidance was based on evidence using a range of study designs. It is only the review search for clinical aspects of the guideline that was limited to RCTs and systematic reviews. In the event of none of these study designs being found, the methodology for reviews does allow for focused searching of specific clinical questions without filters for study methodology.

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					However in this instance it was not necessary owing the weight of evidence identified by top level searches.
DOM UK	Disagree		Limiting the evidence review to RCTs and systematic reviews mean that much evidence is ignored. This can lead to an over-reliance on surgical and pharmaceutical interventions, because these interventions are more likely to attract research funding, and are easier to study using an RCT design. Ignoring other study designs is a particular issue in a field such as obesity where practice is developing, and with it, the evidence base.		Thank you for your comment. The original guidance was based on evidence using a range of study designs. It is only the review search that was limited to RCTs and systematic reviews.
DOM UK	Disagree	Given the growing emphasis on the crucial role of the environment, a clearer focus on the role of governments, local authorities and the food industry on this would be helpful			Thank you for these comments. You may wish to refer to NICE public health guidance on the prevention of CVD.

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		particularly relating to evidence on financial incentives and disincentives such as taxation			
INS	Agree	Intragastric stimulation technology (IGS) is still in clinical research but may be an effective, low morbidity option bridging between behavioural, pharmacological and surgical interventions. It deserves inclusion if only to suggest an area worthy of further research			Thank you for your comment. The role of NICE guidelines is to consider which effective interventions are to be recommended. Surgical interventions that are not yet in widespread use, and whose efficacy and safety are still in question are first assessed by the NICE interventional procedures programme before becoming treatment options to be included in a guideline.
ESCO	Disagree, we would propose that the review is significantly updated	We would like to see reproduction (male and female) included in the guidelines; fertility (and not just infertility) should be considered a co-morbidity, given the obstetric complications associated with obesity. This should also include a review of post surgery supplements e.g. to routinely include folic acid for all women of childbearing age (dose?) Traditionally, women are advised to avoid vitamin A supplements in pregnancy due to possible teratogenic effects of vit A overload. The safety of routine vit A use			Thank you for your comment. Treatment of specific subgroups of patients with obesity is outside the scope of the guideline

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		should be reviewed			
		Further discussion is required about the risks / benefits of the different procedures e.g. duodenal switch.	Sleeve gastrectomy as a stand-alone procedure is not mentioned		There did not appear to be sufficient evidence published at the time of this review to compare between different surgical procedures. Although more evidence is emerging.
		Some guidance about which procedures might be most suitable for which patients			There did not appear to be sufficient evidence published at the time of this review to compare between different surgical procedures. Although more evidence is emerging.
		The review should encompass pre- and post-surgical care in more detail.			Thank you for your comment. There does not seem to be any new published evidence since the guideline was published to help define treatment protocols surrounding surgery.
		Additional new health economic data should be considered			Cost effectiveness models are not re-run as part of the guideline review process. However any relevant published cost effectiveness papers were selected. Four studies found that bariatric surgery was cost effective, with two of the studies suggesting it is cost effective for all classes of obesity however it was not

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					felt that these contradicted the recommendations in the existing guideline. Rather, they support them.
		In relation to the non-surgical options low dose OTC orlistat should be considered			The assessment of evidence from the review search identified 3 studies found a beneficial effect of Orlistat in adults, and 2 studies in children. However none of these were specifically in the community setting.
		There needs to be greater consideration of certain special groups, especially people with mental illness and pregnancy for example.			Thank you for these comments. The scope of the guideline includes 'clinical management of morbid obesity' and the guidance is aimed to cover the majority of obese patients but not the specialist management of particular subgroups.
		There needs to be a review of surgery with respect to Diabetes Mellitus - and whether the criteria of 35 with co morbidities is still appropriate.	Lack of recommendations around nutrition and bariatric surgery		Thank you for your comment. No evidence was identified to indicate that the recommended cut offs for referral for bariatric surgery should be changed. And no new studies that identify age criteria or comorbidities were found. This is an area that is likely to remain a matter of consensus.

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		The current guidance does not have sufficient strength to support HCPs and their decision making. We therefore would strongly recommend that the original HTA for obesity management is updated and imposed. This would make decision making for HCPs significantly easier, evidence and cost based			This guideline has superseded the TA46. This review suggests that the section on surgery remains relevant despite recent publications. While implementation of technology appraisal is mandatory this is not the case with guidelines.
Leeds Teaching Hopsitals		Re: Childhood obesity I basically agree that there is little in the way of new evidence that should substantially change the recommendations. However the guidelines fall down in the recommendations regarding the preschool years, particularly babyhood. The original review had a strong focus on the school years because, at the time, there was less awareness of the relationship of perinatal risk factors, infant growth and parenting to subsequent child obesity. While newer evidence may make only small changes in the nuance of existing recommendations, the lack of emphasis on the early years in the original document now needs to be addressed (see below).			Thank you for these comments. Since the publication of the guideline NICE has published public health guidance on weight management before, during and after pregnancy and on maternal and child nutrition. Both of these pieces of guidance pick up issues raised here. As part of the update review, we considered the evidence base for the prevention of obesity in very young children, even though this was outside the original scope and found that there remains a lack of evidence of effectiveness for intervention. Please note that a broad range of evidence is considered for the development of public health guidance (though the review of the guidance primarily

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					considered evidence reviews).
			1. Importance of the perinatal period There is increasing evidence regarding perinatal risk factors and their association with the development of obesity later on in childhood. There are a number of systematic reviews and a systematic review of systematic reviews (Monasta et al)[1]. The DH has also commissioned three pieces of work in this area, two have been published on the National Obesity Observatory website[2,3] and the third (BERTIE) took place at RCPCH[4]. This all points to an importance of very early identification and intervention[5], which is not adequately reflected in the Guideline.	4. On page 15, it states that the 'issues of role modelling and parenting may be picked up by public health guidance in development in table 4'. However table 4 is disappointing as there is nothing proposed that relates to pre-school children and babies, or indeed parenting in these years.	The new referral to CPHE on lifestyle weight management in overweight and obese children will cover children from 2 years of age and may consider role modelling and parenting within the context of lifestyle weight management programmes for overweight and obese children. Children under 2 are included in existing NICE public health guidance on maternal and child nutrition.

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				5. There is a section on the 'role of early years settings'. However this section completely omits the main setting for babies and young children, namely the family home and parents! 6. Page 21, it states that there is no new evidence relating to risk factors in adults or children that would alter	

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				recommendations. However there *is* new evidence relating to risk factors perinatally as indicated above. 7. Lastly, (page 1- literature searches) I am puzzled by the focus on randomised controlled trials alone in the search for new evidence. For neither 'identification and classification of overweight and obese'	

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				and 'assessment' are randomised controlled trials the optimal research design to seek. I hope that other important new evidence has not been missed as a result	
			2. Interventions in the Pre-School Years There are a number of randomised controlled trials underway internationally with promising results emerging pointing to the benefits and components of interventions in the		The new referral to CPHE on lifestyle weight management in overweight and obese children will cover children from 2 years of age and may consider role modelling and parenting within the context of lifestyle weight management programmes for overweight and obese children. Children under 2 are included in existing NICE public

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			preschool years -e.g the EMPOWER project which was developed under the auspices of RCPCH[6]; and Healthy Beginnings and NOURISH, both publishing results from Australia. At a public health level a national evaluation of HENRY[7,8] is indicating promising changes in lifestyle. I believe this merits separate consideration of interventions in the first 2 years of life, rather than clumping babies into sections that address lifestyle change and weight management in school age children		health guidance on maternal and child nutrition.
			3. Parenting Although parenting is mentioned in the guidelines it does not get enough prominence. RCT's have		

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			been cited but there is not enough consideration of other high quality evidence such as good cohort studies showing the association of authoritative parenting with healthy weight in childhood[2]. This has clear implications for highlighting the importance of parenting skills alongside diet and physical activity as component of weight management and obesity prevention programmes		
		Adults			
		We appreciate that there is little new evidence which would result in significant changes to the recommendations. There are some areas that we feel would benefit from additional input.	Some of the surgical procedures such as the sleeve gastrectomy as a stand alone procedure and the duodenal switch were relatively new at the time of the last guidance. These need to be evaluated especially with regard to	It can be difficult to make decisions about treatment options for people with learning	There did not appear to be sufficient evidence published at the time of this review to compare between different surgical procedures. Although this may change shortly.

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			risks and benefits.	disabilities, especially if surgery is being recommended	
			Additional information on the appropriateness of some procedures for certain patients. For instance the gastric bypass would be favoured for high BMIs with diabetes - however the patient's preference may be for a gastric band.		There did not appear to be sufficient evidence published at the time of this review to compare between different surgical procedures. Although this may change shortly.
			The impact of surgery on nutrition and the nutritional monitoring afterwards. There is no UK consensus about nutritional supplements after surgery and level of monitoring. Protein malnutrition may result from poor dietary compliance. We now know that patients who have a gastric bypass are at risk of		There does not seem to be significant new published evidence since the guideline was published to help define treatment protocols surrounding surgery.

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			vitamin D deficiency. Patients with a duodenal switch are at higher risk from protein malnutrition and fat soluble vitamins deficiency.		
			Management of pregnancy after bariatric surgery and the nutritional supplementations. For instance, although vitamin A is usually contra-indicated patients who have a duodenal switch may need to continue on vitamin A supplements.		There does not seem to be significant new published evidence since the guideline was published to help define treatment protocols surrounding surgery.
			New surgical techniques are being developed. Do these need to be reviewed?		There did not appear to be sufficient evidence published at the time of this review to compare between different surgical procedures. Although this may change shortly.
Royal Pharmaceutical society	(see comments)	The Royal Pharmaceutical Society is concerned that changes in the pharmacological management of obesity involving pharmacists that have occurred since the previous guidance, have not been			Thank you for your comment. Four cost effectiveness studies were identified of which 2 suggested that surgery is cost effective in all classes of obesity. These were not

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		highlighted. The provision of orlistat to eligible adult patients together with the necessary advice and monitoring has been undertaken by community pharmacist since its licensing as a pharmacy medicine in 2007; a scenario that is not reflected in the current guideline. Community pharmacies with their informal settings, longer opening hours, often central location and easy access continue to offer a viable and convenient option for those patients who may benefit from pharmacological treatment and we feel this information should be included in the pharmacological management section.			considered to contradict the existing guideline. The HTA Assessment of economics for surgery used in existing guideline also identified 4 studies. 5 studies on Orlistat were indentified it is not clear whether these were in OTC setting.
	(see comments)	Currently weight management programmes are being undertaken in community pharmacies in a number of PCT's e.g. Eastern and Coastal Kent PCT, Walsall PCT. The recent introduction of Healthy Living Pharmacies aims to increase the role of community pharmacies within their community through the provision and promotion of high quality health services including weight management, and will be another step towards promoting healthy living locally. We feel this key development should be included in the health professionals operating in			Thank you for your comment. This issue may be covered by public health guidance NICE is currently developing on "obesity – working with local communities" and "overweight and obese adults – lifestyle weight management"

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		broader community settings sections.			
	(see comments)	Community pharmacists in various PCT's including Hull PCT, Lewisham PCT, Richmond and Twickenham PCT, South Tyneside PCT are also currently involved in the provision of targeted NHS health checks which include BMI calculation, following the introduction of these checks in 2009, and we feel that the availability of these checks outside GP surgeries should be highlighted in the identification and classification of overweight and obese patients section.			Thank you for your comment. This process to consider reviewing the existing guideline is not influenced by variation in current service provision.
HENRY	Disagree	The current guidance begins only at the age of 2 years. The need for intervention in babyhood is suggested by research showing that heavier babies are at increased risk of later obesity. Baird J, Fisher D, Lucas P, Kleijnen J, Roberts H, Law C. Being big or growing fast: systematic review of size and growth in infancy and later obesity. *BMJ*. Oct 22 2005; 331 (7522):929). Whitaker RC, Wright JA, Pepe MS, Seidel KD, Dietz WH. Predicting obesity in young adulthood from childhood and parental obesity. *N Engl J Med*. Sep 25 1997; 337 (13): 869-873BMJ. Whitaker RC. Predicting pre-schooler obesity			Thank you for these comments. Children under 2 years of age were excluded from the original scope. Systematic reviews that we have considered suggest that there remains a lack of evidence of effectiveness for intervention in this age group. Please note that children under 2 are covered by existing NICE public health guidance on maternal and child nutrition

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		at birth: the role of maternal obesity in early pregnancy. *Paediatrics.* 2004 114(1): p. e29-36			
		We think that the role of parenting styles and skills (and these skills in childcare settings) needs to be highlighted more vigorously than it is in the current guidance. Gerards SM, Sleddens EF, Dagnelie PC, de Vries NK, Kremers SP. Interventions addressing general parenting to prevent or treat childhood obesity. *Int J Pediatr Obes*. 2011 Jun;6(2-2):e28-45. Epub 2011 Jun 10; Sleddens EF, Gerards SM, Thijs C, de Vries NK, Kremers *SP.* General parenting, childhood overweight and obesity-inducing behaviors: a review. *Int J Pediatr Obes.* 2011 Jun 9; Epub 2011 Jun 9. Available at http://www.ncbi.nlm.nih.gov/pubmed/21657834; Barlow J,Whitlock S, Hanson S, Davis H, Hunt C,Kirkpatrick S, Rudolf M. Preventing obesity at weaning: parental views about the EMPOWER programme. *Child: care, health and development*, April 2010 Golan M, Weizman A, Apter A, Fainaru M. Parents as the Exclusive Agents of Change in the Treatment of Childhood Obesity. *American*			Thank you for your comment. Gerards (2011) was not identified as part of the review searches, as only RCTs were considered for interventions to treat obesity. Sleddens (2011) was not identified as part of the review searches it is likely that it was not indexed at the time of the search – June 2011. Barlow (201) was not identified as part of the review searches, as only RCTs were considered for interventions to treat obesity.

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		J Clinical Nutrition 67(6):1130-1135. June 98 Rudolf M. *Tackling Obesity through the Healthy Child Programme: A Framework for Action*, noo.org.uk Also, national evaluation of Let's Get Healthy with HENRY course for parents, Dr T. Willis, University of Leeds, in preparation.			Golan (1998) was part of the evidence base upon which the existing guideline is based. Rudolf (In preparation) was not identified as part of the review searches it is likely that it was not indexed at the time of the search – June 2011
		The value of and need for training for professionals to build their knowledge, skills and confidence to tackle the question of overweight with parents of babies and young children needs to be given greater emphasis. Edmunds L. Parents' perceptions of health professionals' responses when seeking help for their overweight children. *Family Practice* 2005, 22:287-292 HENRY paper cited in consultation document. HENRY e-survey, Rebecca Brown, University of Leeds, in preparation. Other research cited in Rudolf, M. as above.			Thank you for your comment. No evidence was identified regarding communications between healthcare professionals and parents. Edmunds (2005) was not identified as part of the review searches, as only RCTs were considered for interventions to treat obesity.
		It would be helpful if the guidelines			Thank you for your comment. Four

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		emphasised the links between parental obesity and child obesity, to encourage a holistic approach to any interventions to prevent or intervene with child obesity. (See, e.g. Rudolf M, cited above.) We appreciate the need to provide separate guideline information for adults and for children, but as far as children are concerned a healthy lifestyle is a family affair.			studies were identified in the review search that concluded that parent only interventions provide similar weight loss results to parent and child interventions (References 103-106). In addition one study found that the active parental involvement in the weight loss intervention did not significantly improve weight loss in comparison to a child only intervention (Refernce 107).
NOO	Disagree	I'm a bit confused - your response says that NOO agrees that the guidance should NOT be updated - but I think it should most definitely be updated - ok the key outcomes will probably not change massively - but there is certainly advances in terms of longer term interventions, wider environmental interventions and links with morbidity and mortality - particularly for children and ethnic minority groups that certainly needs mentioning. I think this has to be in by tomorrow - have you sent this yet - if not could we change our tact??			Thank you for your comment. However, we are not clear what longer term interventions are being referred to here. The review search identified 6 studies regarding classification of obesity and none found that body mass index was inferior to other methods of assessment for measuring adiposity change. It was concluded that the evidence base has not changed substantively since the guideline was published.

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					Treatment of specific subgroups of patients with obesity is outside the scope of the guideline
NOO	agree	The only argument not considered by NICE is the extent to which an update would help to focus more publicity on action on obesity. But it is likely the forthcoming obesity with local communities guidance will help in this respect.			Thank you for your comment. Stakeholder agrees with review consultation
Weight Watchers UK	Disagree	Weight Watchers would challenge NICE's conclusion not to update its Guideline of Obesity (CG43) for a number of reasons:			Thank you for your comment.
		1. Specifically there is new evidence relevant to the effectiveness of commercial programmes for NHS patients. Specifically a recently published randomised controlled trial indicated that weight loss outcomes at one year were significantly greater in overweight and obese patients referred to Weight Watchers compared to those who received standard care which GPs were able to provide within the time constraints of primary care (*Jebb et al 2011,Primary care referral to a commercial provider for weight loss treatment versus*		Currently there are massive inequalities in patient access to weight management services across England. For example, for many, referral to Weight Watchers through GP	Thank you for these comments. The effectiveness of commercial weight management programmes will be considered by the new referral to CPHE on lifestyle weight management in overweight and obese adults. A number of studies were identified

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		standard care: a randomised controlled trial, Lancet, S0140-6736(11)61344-5). This study is corroborated by an additional trial (The Lighten Up Trial) conducted by Paul Aveyard's team from the University of Birmingham, which has been accepted for publication in the British Medical Journal. These 2 studies suggest that time intensive 'lifestyle change' weight management interventions in primary care might better be delivered by organisations like Weight Watchers whilst the skills of GPs might be more cost effectively harnessed to motivate the huge tranche of pre-contemplative overweight and obese patients so they are 'ready to change'. Contrary to NICE's conclusion, this new evidence is likely to alter which interventions are recommended in primary care.		practices is only available to the 'select few' even though there is now clear evidence of effectiveness.	relating to commercial weight loss interventions. However it was not felt that there was sufficient new data at this time to warrant an immediate update of guidance. Ahern (2011) was identified in the consultation document (reference168)
		2. The Health and Social Care Bill will change, redesign and reconfigure publically funded weight management services. Commissioners of such services will have varying levels of			Thank you for these comments. We are of the view that the guidance should not be updated until there is more clarity on the structures and roles of the NHS and LAs.

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		expertise and knowledge of the weight management literature. For these reasons it is vital that NICE provides clear 'black and white' guidance for commissioners on: - defining effectiveness of weight management interventions for adults and specifically what outcomes to expect over a specified time frame; frequency of 5% and 10% weight loss (intention to treat level) - which interventions are effective for NHS patients - which interventions are most cost effective - what level of evidence should commissioners look for when evaluating whether an intervention is effective or not. In other words, what level of evidence constitutes effectiveness within an NHS setting?			
AFT	Disagree	Recommendations for systemic family therapy will mean that many issues for those who have obesity, particularly for children, can be addressed, and this needs to occur at Tier 3			Thank you for your comment. Four studies were identified in the review search that concluded that parent only interventions provide similar

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		as well as in public health. Family therapy is not addressed in the CG43 or in the review, although the value of involving families is increasingly recognised. Whilst there is current research on systemic family therapy for obesity in progress, and some services offering family therapy in the UK are being developed, there is evidence from Sweden and USA: Norwicka, P., Flodmark, C-E. (2010): Family therapy as a model for treating childhood obesity: Useful tools for clinicians. Clin.Child Psychol. Psychiatry. 16. 129-146. Epstein, L.H. et al (1995): Effects of decreasing sedentary behaviour and increasing activity on weight change in obese children. Health Psychol. 14. 109-15. Epstein, Valoski, Wing and McCurley (1994): Ten-year outcomes of behavioral family-based treatment for childhood obesity. Health psychology. 13. 373-183			weight loss results to parent and child interventions (References 103-106), In addition one study found that the active parental involvement in the weight loss intervention did not significantly improve weight loss in comparison to a child only intervention (Refernce 107). Norwicka (2010) was not identified as part of the review searches, as only RCTs were considered for interventions to treat obesity. Epstein (1995) was part of the evidence base upon which the existing guideline is based. Epstein (1994) was part of the evidence base upon which the existing guideline is based.
		A UK research project based on the Healthy Eating Lifestyle Programme in the community is in progress, and the pilot project is soon to			Thank you for alerting us to this evidence; however the study has not yet been published.

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		be published: Bryant M, Farrin A, Christie D, Jebb S, Cooper A, Rudolf M Results of a randomised controlled feasibility trial for obese children and adolescents Clinical Trials (in press). It uses systemic techniques with families with a child with obesity.			
		The major related CG is for Eating Disorders, which has considerable evidence on the effectiveness of systemic family therapy, and there is more evidence in the recent review. So it would be helpful for there to be stronger recommendations for involving families, and access to family therapy because of the ways that families need to be involved and how difficult some families find to make changes.			Thank you for your comment. No studies were indentified relating to family therapies that would suggest that the recommendations within the existing guideline are inappropriate.
Slimming World	Disagree	Public Health area 7: Self help, Commercial and Community groups. We note new evidence on commercial groups has been referred to within this section, however a significant piece of evidence appears to have been missed (Stubbs et al, 2011) which demonstrates results from real-life experience of what has been happening with referral schemes in a large number of PCTs across the country over the past 6 years. In light of this alongside other new research and the fact that commercial partners have now become			Thank you for flagging this evidence. This issue will be addressed in the new referral to CPHE on lifestyle weight management in overweight and obese adults. Stubbs (2011) was not identified in the clinical review update search as only RCT and systematic review evidence for lifestyle interventions was considered for assessment of

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		an integral part of many weight management care pathways we would suggest the guidance should reflect this and make stronger recommendations about these services. The guidance should clearly recommend: - Commercial partners should be included in care pathways - Identifying opportunities for commissioning a referral partnership - The need for health professionals to find out about their local services (which meet best practice) to enable them to recommend to their patients. Reference Stubbs, J. Pallister, C. Whybrow, S. Avery, A. Lavin, J. Weight outcomes audit for 34,271 adults referred to a primary care/commercial weight management partnership scheme. Obes facts. 2011; 4(2):113-20.			the need to review the existing guideline.
		While it is noted that recommendation of/referral to commercial weight management organisations may be addressed in new public health guidance under development we strongly feel that this also needs to be clearly addressed in this guidance due to its use by			Thank you for this comment. The new guidance will complement the existing recommendations in CG43 and links between recommendations will be made in NICE pathways.

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		the NHS and NHS commissioners.			
		We agree with the recommendation from the House of Lords Science and Technology report on behaviour change which states that NICE should compile a list of approved weight management services which meet best practice.			Thank you for your comment. This recommendation does not impact on the decision to update the existing guidance, but may be considered as part of the new referral to the PH programme.
		Public Health area 1: Recommendations for the public – adults who wish to lose weight. As previously raised, we question the evidence base behind the 0.5-1kg/week recommendation and propose that this be altered to say 'averaging 0.5-1kg/week over time' to take account of likely higher weight losses in the first few weeks of embarking on a weight loss journey (especially in those people with a high starting BMI). Many people access Slimming Worlds service with start BMI's in the region of what would be recommended for pharmacotherapy or even surgery, in fact recent research has shown over 25% have a BMI greater than 40kg/$m^{2.}$ People with large amounts of weight to lose are likely to lose more than 0.5-1kg per week to begin with when making changes to their diet and activity levels. This should be acknowledged.			Thank you for these comments. This consultation relates to the need for an update of the guideline and is not a consultation of the content of the existing guideline. However, the public health guideline group briefly considered the wording of the "best practice" list in the guideline. They concluded that the recommendation to lose no more than 0.5-1kg per week was appropriate as this is an average and suggesting greater weight losses is unhelpful and unrealistic for most people.

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		Reference Stubbs, J. Pallister, C. Whybrow, S. Avery, A. Lavin, J. Weight outcomes audit for 34,271 adults referred to a primary care/commercial weight management partnership scheme. Obes facts. 2011; 4(2):113-20.			
		Public Health area 1: Recommendations for the public. Achieving and maintaining a healthy weight. We note the mention of energy density and agree that more could be said in the dietary recommendations about this area. We would recommend that advice around energy density and satiety is integrated in the guidance i.e. advising that management of hunger is addressed in dietary programmes via macronutrient content and energy density. This would reflect the research in this area (see references below). Reference could also be given to a new patient tool, the BNF leaflet on energy density and weight loss (available at www.nutrition.org.uk) References Ello-Martin J A et al. (2007) Dietary energy density in the treatment of obesity: a year long			Thank you for your comment. We agree that some additional evidence is available, but this will add nuance to existing recommendations rather than change the direction of recommendations. It was considered that the new evidence available was insufficient to warrant an update of this section of the guideline.

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		trial comparing 2 weight loss diets. Amer J Clin Nutr. 85 (6): 1465-1477 Stubbs J et al (2000). Energy density of foods: Effects on energy intake. Critical reviews in food science and nutrition 40 (6): 481-515 Stubbs et al (2010). Dietary amnd lifestyle measures to enhance satiety and weight control. Nutrition Bulletin 35: 113-125			
RCOG	Agree				Thank you for your comment
Salford Royal Hospital		Just noticed a typo on the last line – reads the instead of they			Noted, thank you.
Child Growth Foundation		The Foundation will not be part of the consultation.			Noted.
Association for Respiratory Technology & Physiology	Need to update	In regards to the section on sleep (15.2) we are unaware of any data detailing how much (or little) sleep is needed to avoid obesity certainly not simply in hours. The answer probably is as much as an individual needs to not be so sleepy that their physical activity is limited in the daytime			Thank you for your comment.
Association for Respiratory	Need to update	Clearly sleep quality is essential to activity and motivation and to suggest that patients complaining of excessive			Thank you for your comment. We considered that any evidence available was insufficient to warrant

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Technology & Physiology		sleepiness/tiredness, to a degree which limits their physical activity should be advised on Sleep Hygiene may be a valid proposal			an update of this section of the guideline at this time.
Association for Respiratory Technology & Physiology	Need to update	We are unaware of any data which shows advice on sleep hygiene to be effective or that shows screening for sleep disordered breathing to be economic solely from an obesity point of view. (Certainly a disappointing number of suddenly non-sleepy CPAP patients go on to increase weight, generally using the increased number of hours of wakefulness to eat more rather than exercise more)			Thank you for your comment. We agree that some additional evidence is available, but this will add nuance to existing recommendations rather than change the direction of recommendations. It was considered that the new evidence available was insufficient to warrant an update of this section of the guideline.
Association for Respiratory Technology & Physiology	Need to update	We are slightly surprised to see such emphasis on high carbohydrate diets rather than high protein diets, which can be effective (e.g. The Atkins diet.)			Thank you for your comment. There was no restriction in the types of diet when the review search was undertaken for assessment of clinical interventions to treat obesity. A number of studies were identified regarding diet, but there was insufficient evidence to warrant a review at this time
Association for Respiratory Technology & Physiology	Need to update	We feel there is insufficient emphasis on the role that using CPAP in obese patients with sleep apnoea gain significant benefit to be motivated to change lifestyle and to consider weight loss or even surgery when the cannot			Thank you for your comment. Only limited evidence is available on efficacy of interventions for specific subgroups. The scope of the guideline includes 'clinical

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		tolerate CPAP.			management of morbid obesity' and the guidance is aimed to cover the majority of obese patients but not the specialist management of particular subgroups.
NOF	Disagree	NICE needs to establish and/or give advice on whether the focus of CG43 in the future will be prevention or management. The Foresight report (2007) suggested that management is more cost-effective, and that there remains a significant lack of evidence for preventative measures that have been shown to have any effect (EPODE has been shown to have an effect on a population level, but there is very little evidence that the prohibitably expensive Change4Life programme, the social marketing arm of the Department of Health's white paper Healthy weight, healthy lives, has made a difference. If the revised CG43 is to encourage prevention, then a comprehensive evidence review to help indicate which interventions are effective needs to be undertaken. If it is management-focused, examples of best practice at each tier of intervention, preferably after a suitable evidence review should be given.			Thank you for your comment. The existing guidance addresses prevention, identification and management. The decision not to review the current guidance will not preclude additional / related pieces of guidance being produced. CPHE at NICE have recently started working on three new referrals from the Department of Health on lifestyle weight management in overweight and obese children and adults, and BMI cut offs for BME groups.

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		NICE should consider reviewing their 3 tier model of obesity, to be in line with the 4 tier model that has been adopted by many areas (eg Rotherham) and many organisations (eg NOF). This has tier 1 as primary activity (encouraging HCPs, leisure services, pharmacists, schools etc to weigh & measure, highlight those overweight and obese and refer accordingly), tier 2 as community weight management programmes (mainly time-limited education based programmes and encouraging self-help programmes), tier 3 which are specialist MDT approaches (eg Rotherham Institute of			Thank you for your comment. NICE considers that the existing guideline does address the 4 tiers outlined in the Rotherham model, with tiers one and two being primarily addressed in the public health / prevention and clinical identification parts of the guideline and tiers 3 and 4 being covered in the clinical parts of the guideline.

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		Obesity), which are responsible for the appropriate triage and management of all patients being considered for bariatric surgery based on BMI, and tier 4 which is specialist secondary care intervention (mainly bariatric surgery, but will include specialist endocrinology and genetics etc). Below these 4 tiers of intervention is the population based public health measures.			
		The MDT assessment for bariatric surgery should be done primarily in primary care pre- and post- op, and only the actual surgery should be done in tertiary centres (freeing up more time for the surgeons to actually operate, and more access for patients in the primary care setting). Training should be made available at every level for health care professionals to provide the right level of advice and expertise.Specific mention should be made for the role of talking therapies (CBT, NLP, EFT, hypnotherapy, life-coaching etc) as a key way to identify whether patients are appropriate for and will do well at surgery. Where possible, an evidence review should be done to evaluate the effectiveness of these methods compared with other more traditional			Thank you for your comment. This process to consider reviewing the existing guideline is not influenced by changes to local service provision.

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		interventions, both for weight loss per se, but also in identifying those patients with eating disorders, and habit/comfort/emotional eating issues that without treatment will otherwise still be present after surgery and ultimately hinder its success. it is vital to try to identify those patients who are not suitable for surgery; those with an identifiable eating disorder, or those for whom the change in lifestyle required post surgery is not achievable or sustainable.			
		Where possible, evidence should be gathered and advice given regarding the likelihood of excess skin with (any) rapid weight loss (eg VLCDs, bariatric surgery), and advice on who should receive apronectomies and/or cosmetic procedures as part of the overall bariatric surgery input (and when this should be received). This evidence should be linked to the training given to health care professionals advising patients as to their options surrounding weight loss. Patients may decide not to undertake bariatric surgery if they are unable to have body contouring surgery as an adjunct, and this needs to be made clear at the initial assessment.			Thank you for your comment. Excess skin would be an important outcome in the assessment of the evidence, but does not impact on the guideline review process. The existing guideline suggests 'Advice, treatment and care should take into account people's needs and preferences. People should have the opportunity to make informed decisions about their care and treatment, in partnership with their health professionals.

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					Good communication between health professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient's needs.' No amendment appears necessary at this time
		More realistic weight loss targets should be set: Aiming for 10% weight loss is well evidenced as being beneficial (Jung 1997), but there needs to be clarification that 5% at 6m can still convey considerable health benefits, and may be considerably more achievable for patients, and HCPs in weight loss clinics. Furthermore, in the obese/morbidly obese who have had increasing weight over many years, weight stabilisation and constancy, in the absence of actual weight loss, may still be beneficial and considered a success (re Obesity Consensus guidelines 2009).			Thank you for your comment. The existing guidance suggests 'helping people assess their weight and decide on a realistic healthy target weight (people should usually aim to lose 5–10% of their original weight)' No amendment appears necessary at this time.
		Successful obesity management must encompass a whole range of parameters, including lipid levels, liver function tests, glucose and Hba1c levels, blood pressure and fitness levels. Patients need to be encouraged			Thank you for your comment. The review search identified 6 studies (references 1 to 6) that evaluated assessment of obesity. The studies assessed various anthropometric

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		in their weight loss journey- success may be considered as a measure of reduction in waist circumference (and/or improvements in bio-impedence) in the absence of weight loss per se. Furthermore, NICE should clarify the importance of measuring waist circumference (in addition to, not instead of BMI) in patients with a BMI less than 35, and/or body composition measurements, especially in athletic individuals. Fitness levels or even hours of exercise per week should be included in the inital and subsequent assessments. Initial assessment should also include a review of all patients' risk factors and appropriate bloods accordingly (eg include lipid profile).			measures, and no evidence was found to indicate that waist circumference or bioelectrical impedance was superior to body mass index for measuring adiposity change, and no evidence was found that body mass index was inferior to other methods of assessment for measuring adiposity change. On basis no review of the existing guideline appears necessary. In addition, CPHE at NICE are currently working on a new piece of guidance considering BMI cut offs for BME groups. This new piece of work will complement CG43.
		NICE should seek to give more specific advice on issues that should be included in an initial OSN assessment, such as understanding calories, hypocaloric diet, effect of a night off the diet, hidden calories in sugary drinks and alcohol, hazards of high calorie low-fat foods etc. NICE should also clarify (based on evidence review) the fact that studies over the last 10 years reinforce the hypothesis that for			Thank you for your comment. There was no restriction in the types of diet when the review search was undertaken for assessment of clinical interventions to treat obesity. A number of studies were identified regarding diet (including two on VLCD – references 99 and 100), but there was insufficient evidence to

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		weight and important co morbidities such as diabetes/CVD the most important thing is overall calorie intake in the overweight/obese patient rather than what is eaten (eg, macronutrient composition), and that weight loss in these individuals convey more health benefits that simply improving nutritional balance whilst remaining overweight/obese. There should be clear guidelines for health care professionals to follow when advising about low carbohydrate/low fat or VLCD diets, so that patients may have truly informed choice about how to address their risk factors.			warrant a review at this time
		Clarification should be made on the latest beliefs in relation to the genetic factors conveyed by the numerous genes associated with weight and fat distribution, with robust evidence provided on the effect of supplements such as chromium, lecithin and the like. Advice should be given on medications that (directly or indirectly) contribute to weight gain, such as some atypical antipsychotic medications including quetapine. Adive should also be given about medications that are not licensed for weight loss, that are considered			Thank you for your comment. Assessment of the genetic factors relating to obesity was without the scope of the guideline which focuses on prevention and treatment. Evaluation of supplements as an intervention to treat obesity was not included in the scope of the existing guideline. The existing guideline includes a recommendation on assessing 'medical problems and medication' in

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		weight-friendly and/or induce weight gain eg diabetic medications such as sulphonylurea (induces weight gain), or GLP-1 (which induces weight loss).			section 1.2.3.7. No new evidence was identified that would suggest that this is no longer appropriate. .
		NICE should clarify that treating childhood obesity should be considered as preventing adult obesity, and part of the same integrated treatment pathway. Families should be treated together, using evidenced based, culturally sensitive programmes such as MEND. With specific reference to children, an explanation and clarification of BMI centiles and growth charts is required, including definition of overweight/obesity. eg, RCPaeds, RCGP, RCP etc use BMI centiles of above 91st for overweight, and above 98th for obese (based on good evidence, and reinforced by SIGN). However, DH insist on using 85th for overweight and 95th for obese in the NCMP leading to confusion and misunderstanding for patients and even clinicians. Above all, advice should be clear, robust and evidenced based. NICE should consider adopting the SIGN-style of including advice that is based on the current best practice of experts and peers, even in the			Thank you for your comment. The Existing guideline was scoped to include guidance on both children and adults in one document. No new evidence was identified from the review search that related to methods of assessment / classification using specific BMI centiles.

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		absence of published evidence and RCTs etc. Training for health care professionals must be readily accessible to all, especially in Primary care. It must be acknowledged that obesity management is a complex disease area and as such deserves extra training in order to be carried out with sensitivity and expertise by multi-disciplinary teams.			The NICE guideline methodology does allow for consensus of expert opinion to be used as a source of evidence to support recommendations Provision and organisation of training is outwith the scope of this guideline
		Collaboration with commercial slimming groups and exercise programmes must be considered and given a higher priority, in order to improve the health of local communities. Collaborative working arrangements must also extend to schools, work places as well as local authority in order to continue to empower patients who are already obese, and also those who are overweight and at risk, to start to lead healthier lives by reducing their risk of co-morbidites.			Thank you for your comment. NICE's Centre for Public Health Excellence received a referral for a new piece of work on lifestyle modification to prevent obesity in the Summer. Initial work has begun to draw up a timeline and undertake scoping searches. The NICE website will be updated as soon as the timeline is agreed. It is likely that stakeholders will have an opportunity to comment on the scope for this work in Spring 2012
KasTech Ltd	Disagree	1.2.4 – Effective Lifestyle Interventions 1.1.2.1 and 1.1.2.2 to 1.12.16- Recommentations for the NHS	12 week pilot RCT in UK primary care demonstrates that a comprehensive,		Thank you for your comment.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		1.1.7.1 tp 1.1.7.4 – Self help, commercial and community programmes, Public Health 12 week pilot RCT in UK primary care using ProHealth*Clinical* software and its' Structured Lifestyle Protocol intervention demonstrated an increased weight loss (4.0kg) for patients receiving the computer tools and guidance compared to control patients (1.2kg) Ref: Br J Gen Pract 2009; 59:349-355. Weight-management interventions in primary care: a pilot randomised controlled trial. www.kastech.co.uk (news14/09/2009: A RCT shows ProHealth*Clinical* improves Practice Nurse led weight loss outcomes	multi-component lifestyle computer programme, ProHealth*Clinical* and Practice Nurse training can increase patient weight loss by over three times the amount in the control patients.		Nanchahal (2009) was indentified in the review update searches the follow up was < 6 months, this was an exclusion criteria from the existing guideline. Nanchahal (2011) is cited in the review consultation in the section on the role of self help, commercial and community programmes (reference 166). However it was concluded that this would be covered by the public health guidance work currently in development.
KasTech Ltd	Disagree	1.2.4 – Effective Lifestyle Interventions 1.1.2.1 and 1.1.2.2 to 1.12.16-	Structured lifestyle interventions using		Thank you for your comment,

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		Recommentations for the NHS 1.1.7.1 tp 1.1.7.4 – Self help, commercial and community programmes, Public Health 12 week pilot RCT in UK primary care using ProHealth*Clinical* software and its' Structured Lifestyle Protocol resulted in 34% of patients in the lifestyle treatment group achieving a 5% or more weight loss. Ref: Br J Gen Pract 2009; 59:349-355. Weight-management interventions in primary care: a pilot randomised controlled trial.	evidence-based ProHealth*Clinical* tools produce significant weight loss in primary care.		Nanchahal (2009) was indentified in the review update searches the follow up was < 6 months, this was an exclusion criteria from the existing guideline. Nanchahal (2011) is cited in the review consultation in the section on the role of self help, commercial and community programmes (reference 166). However it was concluded that this would be covered by the public health guidance in development.
KasTech Ltd	Disagree	1.2.4 – Effective Lifestyle Interventions 1.1.2.1 and 1.1.2.2 to 1.12.16- Recommentations for the NHS 1.1.7.1 tp 1.1.7.4 – Self help, commercial and community programmes, Public Health ProHealth*Clinical* patients were more than twice as likely to: i) be satisfied with their weight loss ii) feel they met their expectations and	Patients receiving comprehensive evidence-based ProHealth*Clinical* computer lifestyle tools in primary care identify key areas of satisfaction.		Thank you for your comment, Nanchahal (2009) was indentified in the review update searches the follow up was < 6 months, this was an exclusion criteria from the existing guideline.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	NICE comments
		iii) report they found the programme helpful in achieving their goals (Table 4) Ref: Br J Gen Pract 2009; 59:349-355. Weight-management interventions in primary care: a pilot randomised controlled trial.			Nanchahal (2011) is cited in the review consultation in the section on the role of self help, commercial and community programmes (reference 166). However it was concluded that this would be covered by the public health guidance work currently in development.
KasTech Ltd	Disagree	1.2.4 – Effective Lifestyle Interventions 1.1.2.1 and 1.1.2.2 to 1.12.16- Recommentations for the NHS 1.1.7.1 tp 1.1.7.4 – Self help, commercial and community programmes, Public Health ProHealth*Clinical* patients described computer tools as “very to extremely helpful” 91% agreeing lifestyle changes 82% discussing weight goal 80% tracking lifestyle changes 75% receiving computer feedback and personalised printouts 62% receiving meal suggestions and 62% receiving physical activity guidance (Table 3) Ref: Br J Gen Pract 2009; 59:349-355. Weight-management interventions in primary	Patients receiving comprehensive evidence-based ProHealth*Clinical* computer lifestyle tools in primary care identify key areas they found helpful.		Thank you for your comment, Nanchahal (2009) was indentified in the review update searches the follow up was < 6 months, this was an exclusion criteria from the existing guideline. Nanchahal (2011) is cited in the review consultation in the section on the role of self help, commercial and community programmes (reference 166). However it was concluded that this would be covered by the public health guidance currently in

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		care: a pilot randomised controlled trial.			development.
KasTech Ltd	Disagree	1.2.4 – Effective Lifestyle Interventions 1.1.2.1 and 1.1.2.2 to 1.12.16-Recommentations for the NHS 1.1.7.1 tp 1.1.7.4 – Self help, commercial and community programmes, Public Health ProHealth*Clinical* lifestyle interventions in both individual primary care and community-based group programmes are listed in The House of Lords Science and Technology report on Behaviour Change (2011) (BC 69) Sandy Evans, ProHealth*Clinical* www.publications.parliament.uk/pa/ld201012/ldselect/ldsctech/179/17913.htm	Eight pages of ProHealth*Clinical* tools, interventions, outcomes and examples are included in the 2011 Science and Technology Committee Behaviour Change Written Evidence from D-G. (BC 69) Sandy Evans, ProHealth*Clinical*		Thank you for your comment, The House of Lords Science and Technology report on Behaviour change (2011) was highlighted in the review consultation document. This area will be covered in a new piece of work on lifestyle modification to prevent obesity to be developed by NICE's Centre for Public Health Excellence. Initial work has begun to draw up a timeline and undertake scoping searches. The NICE website will be updated as soon as the timeline is agreed .
KasTech Ltd	Disagree	1.2.4 – Effective Lifestyle Interventions 1.1.2.1 and 1.1.2.2 to 1.12.16-Recommentations for the NHS	An interactive, practical skills-based approach to primary care adult groups		Thank you for your comment

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		1.1.7.1 tp 1.1.7.4 – Self help, commercial and community programmes, Public Health Primary Care group-based ProHealth*Clinical* Lifestyle Improvement Programme at The Spinney Surgery, Cambridgeshire recognised in the 2005 nhs*alliance* Commissioning Obesity Services PCTs as an example of best practice in primary care. Chapter 4 and won ASO, NOF and RCGP best practice awards. www.kastech.co.uk (news 27/04/2008: ProHealth*CHIP* presented at the 2008 Annual UK Public Health Conference	provides a cost-effective way to initiate lifestyle changes.		
KasTech Ltd		We have also just finished a joint report with Hertfordshire PCT, Tom May using ProHealth*Clinical* in 24 GP Practices and the key 12 week outcomes include: • 37.6% of people achieved a body weight loss of 5 per cent or more • 4.2% of people achieved weight loss of 10% or more • 27.1% of people dropped to a lower BMI category • The serviced proved to be particularly good at attracting men (26.7%) • The average cost of each client supported was approximately £64			Thank you for your comment. This study was not published at the time of the development of the review consultation document. It could be considered at part of the forthcoming NICE guidance on lifestyle modification to prevent obesity

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		• Benchmarking shows this service is cost-effective compared to other evaluated weight management services The Hertfordshire outcomes above have just been published in their Hertfordshire PCT Weight Management Pilot Evaluation Report, September 2011.			
BOMSS		I think there is considerable new published literature especially looking at efficacy and cost effectiveness of surgery. Then there is the use of weight loss surgery in Type II diabetes when it may be that operating on folk between a BMI of 30 and 35 is justified. Then there are the changes in emphasis when it comes to what operation should be done. I think BPD is less prevalent, but gastric sleeve is more popular. Finally there are a wide range of newer minimal acess procedures from gastric pacemakers to the endosleeve procedure.			Thank you for your comment. Four studies were identified in the review search identifying that bariatric surgery was cost effective, with two of the studies suggesting it is cost effective for all classes of obesity. These studies seem to concur with the health economic modelling conducted as part of the development of the existing guideline. There did not appear to be sufficient evidence published at the time of this review to compare between different surgical procedures, or to usefully inform cost effectiveness modelling.

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		It is an area of considerable endeavour in the surgical community and one with rapid change and development (and obviously the volume of peer reviewed literature published every year reflects this).			