NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Centre for Clinical Practice

and Centre for Public Health Excellence

Review consultation document

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

1 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 National Clinical Guideline Centre (formerly NCC Primary Care) and NICE's Centre for Public Health Excellence

This clinical and public health considerations have been presented separately within this review document.

2 Consideration of the evidence

2.1 Literature searches

Clinical

From initial intelligence gathering and a high-level randomised control trial (RCT) search, new evidence was identified that related to the following clinical areas covered within the guideline:

 Identification and classification of overweight and obese
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- Assessment
- Lifestyle interventions
- Pharmacology
- Surgery

(for Interventions to prevent obesity, please see sections under the Public heath review).

A sufficient number of studies were identified at this stage of the process to allow for an assessment for a proposed review decision and are summarised in table 1 below. All intervention studies that were related to children had a minimum of 6 month follow up, and intervention studies related to adults had a minimum of at least 12 months follow up.

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 require further focused literature searches.

The results of the high level RCT search are summarised in table 1 below. All references identified through the high-level RCT search, and initial intelligence gathering can be viewed in <u>Appendix 1</u>.

Table 1: Clinical evidence

Clinical area 1: Identification and classification of overweight and obese		
Clinical question	Summary of evidence	Relevance to guideline recommendations
What is the optimal way of identifying and classifying overweight and obesity?	Through the high level RCT search 6 studies relevant to the clinical question were identified and assessed using the abstract. The studies assessed various anthropometric measures, and no evidence was	No new evidence was identified that would change current guideline recommendations.
Relevant section of guideline Identification and classification of overweight	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 (1-6)	
and obese Recommendation 1.2.2	The Department of Health has recently asked NICE to assess BMI and waist circumference in adults in BME groups in the UK. This work is currently being undertaken by NICE's Centre for Public Health Excellence.	

Clinical area 2: Assessment		
Clinical question	Summary of evidence	Relevance to guideline recommendations
What are the common weight-related	Through the high level RCT search 33 studies relevant to the clinical question were identified and assessed using the abstract.	No new evidence was identified that would change
comorbidities and how do they impact on		current guideline recommendations, but
the health of the individual, both now	Overall obesity was associated with an increased risk of CVD (7-11) pregnancy/conception issues (12-16), cancer (17-23), depression (24;25),	rather confirms them.
and in the future?	diabetes (26;27), asthma (28), Barrett's oesophagus (29;30), decreased quality of life (31);(32), kidney disease (33), pancreatitis <i>(34)</i> , low back pain(35), periodontis	

Relevant section of guideline	(36), urinary incontinence (37).	
Assessment	No associations were found in studies considering obesity and CVD risk(38), (39),	
Recommendation	or obesity in childhood and asthma (40).	
1.2.3		

Clinical area 3: Lifestyle interventions		
Clinical question	Summary of evidence	Relevance to guideline recommendations
What organisational or professional	Through the high level RCT search 28 studies relevant to children, and 61 studies relevant to adults were identified and assessed using the abstract.	No new evidence was found that would change current
interventions are effective	Adults	guideline recommendations.
in improving	General lifestyle interventions were associated with moderate weight loss (41-49)	
the management of overweight/obesity in	Support from family, friends or the internet was not associated with increased weight loss (50;51)	
the clinical setting?	Hospital inpatient/outpatient intervention was successful at promoting weight loss (52)	
Relevant section of guideline	Behavioural interventions were found to be successful at promoting weight loss (53-62), whereas 4 studies found that the behavioural intervention examined failed	
Lifestyle interventions –	to show any additional benefit above usual care (63-66)	
General , behavioural, diet, and physical activity.	Cognitive based interventions were successful at promoting weight loss (49;67-70).	
	Motivational interviewing was a beneficial add on for treating obesity (71)	
Recommendation	Two systematic reviews of the evidence concluded that behavioural interventions	
1.2.4	are successful at inducing weight loss(61) and that group based behavioural interventions are superior to individual interventions (72)	
	Exercise alone was found to be inferior to diet alone at inducing weight loss(73), but exercise in combination with diet was found to be beneficial in 2 studies	

(74;75) and 1 systematic review (76)	
Diets were found to be beneficial for weight loss, and it appears that adherence to the diet is more important than the composition of the diet (73;76-98).	
Low carbohydrate diets were not superior to other diets in terms of weight loss, but may have improve cardiovascular risk factors and have additional benefits for people with insulin resistance (81;91-94).	
One study found that dietary interventions with one spouse had a beneficial effect on the other spouse (77)	
Very low Calorie Diets were unable to maintain weight loss over the longer term (99;100),	
Children	
Multi-component interventions were found to significantly reduce weight over the study period (101;102).	
Parent only interventions were found to provide similar weight loss results to parent and child interventions in four studies (103-106), and may therefore be more cost effective. 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(107).	
Slimfast (compared to conventional diet) improved short term weight loss in one study (108) but its continued use did not improve maintenance of lost weight.	
Exercise was found to be effective for reducing weight gain in one study (109) but removing financial barriers to exercise did not lead to weight loss in another study (110).	
Overall there is a large amount of new evidence, although none of it contradicts current guideline recommendations. Furthermore, the distinction between the various interventions is unclear, as the abstracts reviewed lacked a clear description of the components of the intervention(s) evaluated making summary of results difficult. Some of the general interventions describe a package of	

elements that may include any combination of behavioural, diet, or physical activity related interventions.	
Some studies relate to weight loss in obese patients and some to maintenance of weight loss.	
Some evidence may partially address research recommendation 1.	

Clinical area 4:Pharmacology		
Clinical question	Summary of evidence	Relevance to guideline recommendations
What is the role of pharmacological interventions in the management of overweight/obesity in adults?	 Through the high level RCT search 7 studies relevant to children, and 30 studies relevant to adults were identified and assessed using the abstract. Orlistat (<i>Licensed and recommended in current guideline</i>), 3 studies found a beneficial effect in adults (111-113) 2 studies found a beneficial effect in children (114;115) 	No new evidence was identified that would change current guideline recommendations.
Relevant section of guideline Pharmacological interventions	 Metformin (<i>licensed no recommendations in current guideline</i>) 4 studies found a beneficial effect in children (116;117) (118;119) Phentermine/topirmate (<i>being considered for evaluation by Technology Appraisals programme. Phentermine is a US licensed appetite suppressant, topiramate is US and EU licensed anti-convulsant, with weight loss properties.</i>) One study found a beneficial effect in adults (120) 	
Recommendation 1.2.5	Lorcaserin hydrochloride (<i>being evaluated by Technology Appraisals programme</i>) one study found a beneficial effect in adults (121). Naltrexone/brupropion (<i>unlicensed</i>) 2 studies found a beneficial effect in adults (122) (123).	
	Taranabant (<i>Unlicensed</i>) 3 studies found a beneficial effect and one study found adverse effects in adults (124-126). Sibutramine (<i>License withdrawn, no longer recommended in the guideline</i>) 2	

studies found a beneficial effect (127;128). 3 studies found a beneficial effect in children (54;129;130) 2010). One study found no beneficial effect when combined with metformin in adults (128)	
Rimonabant (<i>License withdrawn</i>) 4 studies found a beneficial effect in adults (131-134) and one study found adverse effects in adults (135).	
One study found that orlistat, sibutamine and metformin were cost effective (136).	
The scope of the guidelines was to look at treating obesity in routine practice. Some of these drugs above will only be used in a small subgroup of patients / in specialist settings.	

Clinical area 5: Surgery		
Clinical question	Summary of evidence	Relevance to guideline recommendations
What is the role of surgical interventions in the management of severe obesity in adults?	Through the high level search 8 RCTs and 2 systematic reviews were identified. 2 studies (137;138) and 2 meta-analyses (139;140) found a beneficial effect of bariatric surgery on weight loss and mortality (via reduction of risk factors) in	No new evidence was found that would change current guideline recommendations.
Relevant section of guideline Surgery	adults, and 2 studies found a beneficial effect in children (141;142). No evidence was identified to indicate that the recommended cut offs for referral for bariatric surgery should be changed.	
Recommendation 1.2.6	Four studies found that bariatric surgery was cost effective, with two of the studies suggesting it is cost effective for all classes of obesity (143-146).	
	Some studies were identified that compared interventions prior to surgery to improve the outcome following surgery, and some studies were found comparing the effectiveness of different types of surgery. Both these issues were considered to be outside the scope of this guideline and so no further consideration was	

given to them.	
Some of these studies provide more (and higher quality) evidence to confirm effectiveness, which could make recommendations more robust.	
NCEPOD are producing a report on bariatric surgery which is due for publication at the end of 2012	

Public Health

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 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)

The results of these searches and feedback from the public health Guideline Development Group (see later section) have been assessed to inform the proposed review decision and are summarised in table 2 below. The study references are listed in Appendix 1.

Please note that the new pieces of public health guidance in development referred to in table 2 are listed towards the end of the document (see table 4), along with other related published NICE guidance.

Table 2: Public health evidence

Public Health area 1: Recommendations for the public			
Public health question	Summary of evidence	Relevance to guideline recommendations	
Achieving and maintaining a healthy weight Relevant section of guideline Recommendations for the public – everyone, including parents/ carers Recommendations 1.1.1.1 to 1.1.1.4 and 1.1.1.6	 Box 1 and Box 2 (recommendations 1.1.1.2 and 1.1.1.6 respectively) – some new evidence is likely to be available that could add nuance to this table of best practice (from evidence of determinants of obesity rather than evidence about interventions). The recommendations are supported by a systematic review of long-term lifestyle interventions to prevent weight gain and morbidity in adults (45). It may be possible to add additional advice about portion size and energy density, as well as more specific information on fat, sugar sweetened drinks and breakfast. More recent reviews have covered breakfast cereals (147) and sugar sweetened beverages (148). There does not appear to be new evidence available that would substantially change the wording on alcohol. Stakeholders have previously queried whether there is any more specific information size and over. However, no specific interventions have been identified as providing evidence for a specific time period. Stakeholders have previously queried the lack of information on sleep in children 	No new evidence was found that would change current guideline recommendations. However, there is new evidence that could provide nuance to some of the existing recommendations. It is uncertain whether this is significant enough to warrant an update at this time.	

	and adults. A review by Marshall et al (149) suggests that the relationship between sleep pattern and BMI is unclear in adults but clearer in children. There is growing evidence from observational studies but no interventions were identified. It may be possible to recommend adequate sleep / healthy sleep pattern, particularly in children, as a prevention measure. There is unlikely to be evidence available to be able to provide specific guidance on hours of sleep to prevent obesity.	
	It has been queried whether the guidance includes sufficient information on role modelling (peer, parents, carers) and parental perceptions on behaviours and body weight (for example, see review by Pocock et al (150).	
	Other issues to note:	
	Start active, stay active: a report on physical activity from the four home countries' Chief Medical Officers published July 2011 can be added as a technical amendment without the guideline being updated.	
	Box 1 and box 2 in recommendations 1.1.1.2 and 1.1.1.6 have been quoted and further edited in subsequent NICE guidance (eg PH35). This text could be edited for consistency even if the guideline is not updated (a technical amendment).	
	Reliable sources of information are flagged in appendix D (noted in 1.1.1.4) – this can be updated as a technical amendment without the guideline being updated.	
Relevant section of guideline	New evidence is available or forthcoming on the efficacy of commercial groups and meal replacements for adults (please see section 1.1.7 below).	New evidence is available, but commercial groups will be
Recommendations for the public – adults who wish to lose weight	However, this issue is likely to be covered by public health guidance in development (see table 4).	covered by public health guidance in development.
	Other issues to note:	

(see also Table 1 clinical recommendation 1.2.4, which specifically relate to interventions for people who are already obese)	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 1.1.1.5	The guideline does not explicitly state which popular diets or remedies do not work (this <i>may</i> be covered by public health guidance in development).	

Public Health 2: Recommendations for the NHS		
Public health question	Summary of evidence	Relevance to guideline recommendations
The role of the NHS	The ongoing structural changes to the NHS are important for this section; it may be more appropriate to direct some recommendations to local authorities in future.	It is probably not appropriate to make major changes to the
Relevant section of the guideline:) have already made some technical amendments to the wording of recommendations and it may be possible to include these in the guideline without	time, due to the continuing
Recommendations for managers and health professionals in primary	the need for an update.	changes to the NHS (response to the Public
care		Health White Paper consultation awaited and Health and Social Care bill
Recommendation:		2011 going through
1.1.2.1		Parliament).

Relevant section of the guideline: Recommendations for senior managers and budget holders; all health professionals; health professionals in primary care; health professionals in broader community settings.	 There may be some new evidence that would provide nuance to recommendations but would not change the spirit of recommendations. This section is supported by a range of subsequent public health guidance (particularly PH8, PH11, PH13, PH25 and PH35). Recommendation 1.1.2.3 that primary care settings "ensure systems in place" is covered by forthcoming guidance on <i>Obesity: working with local communities</i>. 1.1.2.3 and 1.1.2.5 will need updating when there is clarity about the structure of NHS / public health delivery. 	No new evidence was found that would change current guideline recommendations. However, there is new evidence that could provide nuance to the existing recommendations.
Recommendation: 1.1.2.2 to 1.1.2.16	Recommendations for health professionals working in community settings (1.1.1.12 to 1.1.2.16) covered by new guidance on prevention of type 2 diabetes (PH35) and forthcoming guidance on <i>Obesity: working with local communities</i> , as well as further guidance on <i>Type 2 diabetes: individual and group interventions for high risk adults</i> (see below).	
	There may be some new evidence in relation to parental involvement / family programmes of relevance to recommendation 1.1.2.16 but this may be covered by public health guidance in development.	
	There is some new evidence that would add nuance to recommendation 1.1.2.11 on interventions to support smoking cessation. The recommendation is not at odds with a 2009 Cochrane review, but the review also stresses the importance of tailored behavioural interventions, both in success in long term quitting success and long term effect on limiting weight gain (151).	

Relevant section of the guideline: Recommendations for health professionals working with children and family	New UK based evidence is available eg from MEND(152), WATCH IT (see below) and HENRY (see below). Also newer work on parenting styles (such as <u>http://www.noo.org.uk/uploads/doc/vid_4865_rudolf_TacklingObesity1_210</u> <u>110.pdf</u>) The DH framework for weight management providers and trainers was also published after the guideline was issued. These issues are likely to be covered by public health guidance in development (see table 4).	New evidence is available, but, for the most part, covered by public health guidance in development.
Recommendation: 1.1.2.17 to 1.1.2.18	Some concern has been raised about the wide age range for this recommendation – more recent evidence suggests that the effectiveness of interventions varies between primary and secondary school children	
Relevant section of the guideline: Recommendations for health professionals working with workplaces	No new evidence identified. Also addressed by recommendations in subsequent public health guidance (PH13 and PH22).	No new evidence was found that would change current guideline recommendations.
Recommendation: 1.1.2.19		

Public Health 3: Local authorities and partners in the community		
Clinical question	Summary of evidence	Relevance to guideline recommendations
The role of local	Updated by subsequent public health guidance (PH8, 25 and 35) and forthcoming	It is probably not appropriate

authorities and partners in the community Relevant section of the guideline: Recommendations for local authorities and partners in the community	guidance Obesity - working with local communities. Structural changes to the NHS and local authorities are fundamental to this section. It would be helpful to flag obesity as a priority for the new Health and Well-being Boards and their strategies, which will be replacing the local authority agreements and local strategic partnerships.	to make major changes to the layout of the guidance at this time, due to the continuing uncertainty about structural changes to the NHS and the public health role of local authorities
Recommendation: 1.1.3.1 to 1.1.3.9		

Public Health 4: Early years settings			
Public health question	Summary of evidence	Relevance to guideline recommendations	
The role of early years settings	New evidence likely to add nuance rather than change the spirit of recommendations. Systematic review by Hesketh and Campbell (2010) (153) supports the direction of recommendations. This area is also covered by	No new evidence was found that would change current guideline recommendations.	
Relevant section of the guideline:	subsequent public health guidance on maternal and child nutrition (PH11, reviewed in 2011).	There is new evidence that could provide nuance to the existing recommendations.	
Recommendations for directors of children's services;	There is probably now more information available on role modelling and parenting skills and styles (106;154).	Community based programmes for 2 to 5 year olds who are overweight or	
children and young	These issues are also covered by subsequently published UK based interventions	obese will be covered by	

people's strategic partnerships;	such as WATCH IT (155) and HENRY (156) of relevance. These may be picked up by public health guidance in development (see table 4).	public health guidance in development.
senior managers and staff in childcare and other early years settings; children's trusts, children's centres, Healthy Start and Sure Start teams; trainers working with childcare staff, including home-based childminders and nannies.	Other issues to note: Current guideline from age 2 onwards. Stakeholders have asked for guidance below 2 years of age but systematic review suggests the evidence limited. A recent review by Ciampa et al (157) concludes that "Limited evidence suggests that interventions may improve dietary intake and parental attitudes and knowledge about nutrition for children in this age group". This age group is also covered by existing public health guidance on maternal and child nutrition (PH11).	
Recommendation:		
1.1.4.1 to 1.1.4. 4		

Public Health 5: Schools		
Public health question	Summary of evidence	Relevance to guideline recommendations
The role of schools and those working with them	Brown and Summerbell published update to NICE review in 2009 (158). The conclusions are consistent with the recommendations, stating "The findings are inconsistent, but overall suggest that combined diet and physical activity school-	While there is likely to be more evidence on the
Relevant section of the guideline:	based interventions may help prevent children becoming overweight in the long term. Physical activity interventions, particularly in girls in primary schools, may help to prevent these children from becoming overweight in the short term "	effectiveness of school based interventions, this would add
Recommendations for directors of children's	The prevent these children from becoming overweight in the short term.	than change current guideline

services; senior managers and staff in schools; school governors; health professionals working in or with schools; children and young people's strategic partnerships; children's trusts.	There is some additional evidence on lack of harm. A systematic review by Carter and Bulik (2008) (159) concludes "The existing evidence does not support the view that childhood obesity prevention programs are associated with unintended psychological harm. However, because these variables have been so poorly assessed, conclusions about the possible iatrogenic effects of these programs are premature". Children's own views limited in the guideline – there is an EPPI centre systematic review of relevance (160), though probably adds nuance rather than changing the existing recommendations (see	recommendations. Public health guidance in development on lifestyle weight management of children who are overweight or obese may consider community based interventions that include a school based element.
Recommendation: 1.1.5.1 to 1.1.5.9	http://eppi.ioe.ac.uk/cms/LinkClick.aspx?fileticket=EKBQaBQeVgs%3D). The evidence base re vending machines and availability of drinking water in schools may still be weak.). The National Child Measurement Programme was launched after publication of the guideline and is therefore not currently mentioned.	

Public Health 6: Workplaces			
Public health question	Summary of evidence	Relevance to guideline recommendations	
The role of workplaces	Subsequent public health guidance of relevance (PH13, PH25).	No new evidence was found that would change current	
Relevant section of the	There may be some additional evidence that can add some nuance to existing recommendations but more recently published systematic reviews suggest that	However, there may be some	

guideline: Recommendations for senior managers; health and safety managers;	the recommendations still stand. For example, Archer et al (2011) (161) concluded that "The following six promising practices were identified: enhanced access to opportunities for physical activity combined with health education, exercise prescriptions alone, multicomponent educational practices, weight loss competitions and incentives, behavioral practices with incentives, and behavioral practices without incentives."	new evidence that could provide nuance to the existing recommendations.
occupational health staff; unions and staff representatives; employers' organisations and chambers of	There is also a review of workplace nutrition and physical activity interventions by Anderson et al (2009) (162).	
commerce; health professionals working with businesses.	Workplace weight loss programmes were excluded from the original guidance. Lifestyle weight management is covered by public health guidance in development (see table 4), but not specific to workplaces. A 2008 systematic review (163) concludes that "Worksite-based weight loss programs can result in	
Recommendations 1.1.6.1 to 1.1.6.5	modest short improvements in body weight; however, long-term data on health and economic outcomes are lacking."	
	Stakeholders have previously raised the issue of shift working (and see earlier comment re sleep), but there are few interventions studies that demonstrate effective diet or activity interventions (164).	

Public Health 7: Self help, commercial and community programmes		
Public health question	Summary of evidence	Relevance to guideline recommendations
The role of self help,	Significant new evidence has been published since the guideline was issued that	New evidence available but,

commercial and community programmes	could add nuance to the existing recommendations about what works best (165-168), for both "self help" and referral schemes.	for the most part, covered by public health guidance in
Relevant section of the guideline:	There are various papers related to the Counterweight programme (see <u>http://www.counterweight.org/Publications</u>). New evidence may also support the	development.
Recommendations for health agencies and local authorities; and health	development of more detailed guidance on commissioning weight management programmes. Further trial data is expected.	
professionals in primary and secondary care, and	This will be addressed by public health guidance in development (see table 4). Other issues to note:	
community settings	There are differences in the wording in the "best practice" list and the wording of clinical recommendations in relation to medical support (the best practice list states: "recommending and/or providing ongoing support", whereas	
Recommendations 1.1.7.1 to 1.1.7.4	recommendation 1.2.3.44 states: "under clinical supervision"). While these recommendations are aimed at different groups and have different purposes (recommendation 1.2.3.44 is concerned with very low calories diets, whereas the best practice list is aimed at a general population), it may be helpful to clarify this for practitioners and the public.	
	The House of Lords Science and Technology report on Behaviour change (2011) recommends that NICE should compile a list of approved weight management services that meet best practice guidance	

2.2 Summary of the evidence

Clinical

A large number of ongoing clinical trials (publication dates unknown) were identified which focus on:

- Pharmacology (43 studies)
- General lifestyle interventions (30 studies)
- Diet (12 studies)
- Exercise (6 studies)
- Surgery (4 studies)
- Alternative therapies (4 studies)

Some of these ongoing studies are in an UK adult population.

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?

However, the new evidence identified is unlikely to fully address the questions posed in the research recommendations and more research is still needed. In conclusion, no identified new evidence contradicts current guideline recommendations. New evidence could make recommendations more specific and directive but are unlikely to alter what interventions are recommended. This is particularly pertinent to treatment in the primary care setting, and the role of bariatric surgery.

Public health

It is known that there are many ongoing trials and interventions that may add nuance to the existing recommendations, particularly in the fields of community based prevention and management of child obesity and commercial weight management.

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. 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.

In conclusion, 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 (see table 4). Where this isn't the case, it is uncertain whether this new evidence is significant enough to warrant an update at this time.

3 Guideline Development Group and National Collaborating Centre perspective

Clinical

A questionnaire was distributed to the clinical 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:

 Obesity in children is currently poorly defined and best practice guidelines would be useful for assessing childhood risk factors. No new evidence was found relating to risk factors (in adults or children) that would alter recommendations in this area.

- 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.
- New published literature relating to interventions for obesity.

All three respondents felt that the guideline should be updated at this time. Any such update would be unlikely to alter substantial sections of the guideline in light of the new evidence available.

Issues relating to the guideline but not within the original scope of the guideline:

 The GDG clinical lead highlighted that screening was outwith the original remit of the guideline, however there has been some research (particularly in the US) and particularly in relation to children – this would relate to the public health aspect of the guidance.

Public health

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, the collaborating centre lead at the University of Teesside, and the Chair of NICE guidance under development on *Obesity working with local communities*. Nine responses were received with respondents highlighting:

- 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 this is sufficient new evidence to warrant a review to all or parts of the public health aspects of the guideline.

- 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 4). 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 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.
- 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*. 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.

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 healthy system more widely meant that it would not be sensible to update the public health aspects of the guideline at this time.

4 Implementation and post publication feedback

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.

Feedback from the implementation team revealed that pharmacological and surgical interventions have increased in line with recommendations in the NICE guidance.

The feedback document can be viewed in appendix 2.

In addition, NICE has received some criticism 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. NICE is of the view that the guideline is sensitive to the needs of severely obese people and that weight maintenance or loss is problematic for many people. The guideline states that the BMI and co-morbidities, along with personal preference and circumstance, need to be considered in treatment choice. Specific details on energy reducing diets are included in recommendations 1.2.4.26 to 1.2.4.37.

In summary, no new evidence was identified through post publication enquiries or implementation feedback that would indicate a need to update the guideline.

5 Relationship to other NICE guidance

The following NICE guidance is related to the clinical aspects of CG43:

Clinical Guidelines	Review date
CG9 Eating disorders: core	Jan 2014
interventions in the treatment and	
management of anorexia nervosa,	
bulimia nervosa and related eating	
disorders (2004).	
GC66 Type 2 diabetes: the	Review decision to update
management of type 2 diabetes	
(updated 2008)	
CG87 Type 2 Diabetes - newer	Review decision to update
agents (partial update of CG66)	
CG32 Nutrition support in adults:	Feb 2014
oral nutrition support, enteral tube	
feeding and parenteral nutrition	
(2006).	

Table 3 Related Clinical Guidelines

The following NICE guidance is related to the public health aspects of CG43:

Published public health guidance	Review date
PH2 Four commonly used methods to	Partial update due May 2013/
increase physical activity	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

Table 4 Related Public Health Guidance

PH9 Community engagement	June 2013
PH11 Maternal and child nutrition	July 2014
PH13 Promoting physical activity in the	July 2014
workplace	
PH17 Promoting physical activity in children	January 2012
and young people	
PH22 Promoting mental wellbeing at work	November 2012
PH24 Alcohol use disorders – preventing	June 2013
harmful drinking	
PH25 Prevention of cardiovascular disease	June 2013
PH35: Preventing type 2 diabetes –	May 2014
population and community interventions	
Related NICE guidance not included in CG	43
PH27: Weight management before, during	July 2013
and after pregnancy	
Related NICE guidance in progress	· · · · · · · · · · · · · · · · · · ·
	Expected publication date:
Prevention of type 2 diabetes – individual	May 2012
and group interventions for high risk adults	
Obesity: working with local communities	November 2012
Walking and cycling	October 2012
BMI and waist circumference – black and	TBC
minority ethnic groups	
Overweight and obese adults – lifestyle	ТВС
weight management	
Overweight and obese children – lifestyle	TBC
weight management	

6 Anti-discrimination and equalities considerations

No evidence was identified to indicate that the guideline scope does not comply with anti-discrimination and equalities legislation. The original scope is inclusive of the cclinical management of overweight and obesity in adults and children aged 2 years or older.

7 Conclusion

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 should not be updated at this time.

8 Review recommendation

The guideline should not be updated at this time.

The guideline will be reviewed again according to current processes.

Centre for Clinical Practice and Centre for Public Health Excellence

12 September 2011

Appendix 2 – References

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Appendix 2 – NICE Implementation team feedback

1. Routine healthcare activity data

NICE implementation uptake reports provide information on national trends and activity associated with recommendations in NICE guidance.

<u>NICE</u> implementation uptake report: **Surgical and pharmacological interventions for obesity** (available from: http://www.nice.org.uk/media/899/9C/UptakeReportObesityFinal.pdf)

Summary

There was a rapid uptake of orlistat and sibutramine following publication of the NICE technology appraisals in March 2001 and October 2001 respectively. Following publication of the NICE clinical guideline on obesity in December 2006, uptake increased over the first six months of 2007, followed by a decrease. This pattern was repeated for the subsequent 2 years. Analysis of prescribing in relation to specific age groups shows very low levels of prescribing in the under 18 age groups. This appears to be in line with NICE guidance. A high proportion of patients (92.62%) who received orlistat in 2009 had a BMI over 30 which is in line with NICE recommendations. The rate of bariatric surgery procedures carried out in NHS Hospitals in England is increasing. In 2008/2009, 3,686 Finished Consultant Episodes for bariatric surgery were performed compared to 566 in 2005/06.

2. Implementation studies from published literature

Information is taken from the **ERNIE** website

- 2.1 NHS Information Centre for Health and Social Care (2009) <u>Use of NICE appraised</u> medicines in the NHS in England-Experimental Statistics
- Estimated numbers of eligible patients were derived from NICE costing templates. Data for orlistat and sibutramine was obtained from: Prescription Cost Analysis database (PCA), Prescription and Cost system (ePACT), Hospital Pharmacy Audit Index. The NICE costing template expected an annual number of 311.3 thousand patients. The observed use in 2008 was 40,676.9 thousand defined daily doses, a ratio of 0.5 to 1.
- **2.2** Office of Health Economics (2010) <u>Shedding the pounds: obesity management, NICE</u> guidance and bariatric surgery in England

Questionnaires were sent to all 152 PCT's. Of these 93 returns were received by August 3rd 2010. PCT's were invited to assess whether they follow the NICE guidelines for obesity. Nearly 4 in 10 reported that their referral guidelines were in line with NICE in all

respects. Nearly half responded by stating that elements of their local guidelines matched NICE. One in ten PCT's responded that they do not follow the NICE guideline at all.

• **2.3** Burns E et al (2010) Introduction of laparoscopic bariatric surgery in England: observational population cohort study *British Medical Journal* 341:c4296

The authors conducted an observational population cohort study. 6953 primary bariatric procedures were carried out during the study period. A marked increase occured in the numbers of bariatric procedures done, from 238 in 2000 to 2543 in 2007, with an increase in the percentage of laparoscopic procedures over the study period (285 (66/238) in 2000 compared with 74.5% (1894/2543) in 2007.

• **2.4** Haboubi NY et al (2010) Effectiveness of multi-disciplinary weight management clinics *Obesity reviews* 11 (Suppl. 1) 1-472

A retrospective case controlled study was carried out on 114 randomly selected patients who have attended a clinic for at least 12 months. 91.2% of the study population lost on average 14.8kg relating to 6.9% of their initial body weight. 87.7% of those achieved the guidelines maintained there weight loss up to 12 months as compared to 70.8% of those who exceeded the NICE guidelines.

 2.5 O'Callaghan M et al (2010) <u>Management of obesity in medical clinics within Children's</u> <u>Community Health Service in relation to recently published NICE guidance</u> *Journal of Clinical Audits* Vol 2(2); p11-22

Identification of overweight and obese children under the direct care of Children's Community Health Service (CCHS) by Single Point Access referrals and Patient Audit Tracking forms. The ultimate cohort was 25 cases. Results found that recorded family history was not taken in 20 cases, case histories of recorded psychosocial distress was not taken in 19 cases. Height and weight were recorded in all cases but was rarely converted and plotted to give BMI.

• **2.6** Royal College of Physicians (2011) <u>Implementing NICE public health guidance for the</u> workplace: a national organisational audit of NHS trusts in England

282 trusts in England participated in the audit. This comprised 91% of ambulance trusts,
73% of acute trusts, 67% of mental health trusts and 52% of primary care
trusts.Participating trusts employ nearly 900,000 NHS staff. Results found 32% of trusts
had a policy to encourage and support employees to be more physically active. Only 15%

of trusts had a plan or policy to help reduce obesity amongst their staff. 73% of trusts had a plan or policy to encourage and support employees to stop smoking.

• **2.7** Puttha R et al (2010) Management of childhood obesity and overweight in a paediatric out-patient setting *Archives of Disease in Childhood* 95 Suppl 1

Clinical notes and letters of patients attending paediatric out-patients over a selected time period were reviewed. Of the 105 children audited in a district general hospital (DGH) 21% were obese and 10% overweight. At the children's hospital (CH) 24% were obese and 5% overweight, out of 42 children. No overweight children (both hospitals) were identified as overweight and did not have tailored intervention or assessment. 47% and 62% of DGH and CH obese patients respectively had an assessment.

3. Qualitative input from the field team

The implementation field team have recorded the following feedback in relation to this guidance:

Subject	Notes
Topic selection	Could we also look at Rimonobant for obesity?
	The obesity guideline was taken to the scrutiny
	committee who couldn't use it (did not know
	where to start) then it was taken to LSP but they
	had a similar experience. Could not find a home
Clinical guidelines	for obesity guideline.
	The size of the guidance is a barrier – obesity
	was hundreds of pages long. If the guidance is
	nuge it makes it more difficult to implement
	especially across different settings.
	critical of the perverse incentive offered by the
	cuideline that recommends surgery for those with
	a BMI of $50\pm$ suggesting that some people may
	be encouraged to put on weight in order to
Clinical guidelines	qualify for surgery.
	Not much new evidence on obesity and the focus
	tends to be on the surgical end, but they are
	trying to do the right thing in primary care and
Clinical guidelines	about to commission Weight Watchers services.
	DPH are disappointed by the Obesity clinical
	guideline. Apparently it contained nothing new
	and should have concentrated on a programme
Clinical guidelines	rather than an intervention approach.
	Currently writing a local guideline on obesity in
Tania a da stian	pregnancy - finding little or conflicting evidence -
I opic selection	Would welcome a full NICE review.
	The Director of Commissioning feit that the
	scope of the obesity guidance during go lar
	people becoming overweight e.g. fitness
Clinical quidelines	campaigns, and attaining the criteria for bariatric
Cinnical guidennes	campaigns, and attaining the chiena for ballatile

	surgery. Generally, clinical guidelines are good but the scope doesn't cover the earlier parts of the pathway, which is prevention.
Legacy feedback - unspecified	Hope that the new obesity guidance covers new ground. It would help to have the evidence base for schemes nationally and their targets e.g. Sport England, increase physical activity by 1%.
	Felt disappointed in the first two PH guidance - felt that they did not add any new evidence based practice to the existing HDA and other guidelines. Already had very good smoking cessation services. Hope that the pext tranch of
Legacy feedback - unspecified	PH guidance will be more cutting edge with greater evidence based activities, particularly in the area of obesity management as this is a high priority for the health community.
Clinical guidelines	Obesity - they have altered the threshold for bariatric surgery to a BMI >50 in order to make this affordable.
Pathways	She was keen that the pathways should incorporate prevention where appropriate (diabetes was given as an example of something that could have a huge negative impact on a child's education due to illness and hospital attendance and so was seen very much as a LA issue as much as a health issue. Recommendations re: obesity, physical activity etc should fit within the diabetes pathway).
	Health Impact Assessment is going to be central to the new public health function within local authorities - so has NICE engaged with: 1) Marmott - "our authority uses Marmott as the bible" 2) Local Government Improvement and Development (LGID). This LA has true integrated commissioning. DPH has moved all the obesity monies in to public health and commissioned a complete pathway of care. People can self refer to the "lose weight, feel great" pathway where they will be offered support. Have used social marketing to engage hard to reach through community engagement (sport and leisure). Bariatric surgery commissioned from Aintree but this entire programme has actually decreased the need for surgery by 73% and improved outcomes. Independent evaluation currently being written up (hope to secure this example for shared learning and QIPP databases) "To engage local authorities, NICE needs to focus more on places as well as population" and needs to support health impact assessment as this will become key for authorities and their new public
Public health guidance	health role.
Legacy feedback -	guidance, but had not associated the guidance with NICE. Upon looking quickly at it he said 'it's what we do all the time and sometimes hear it as just carry on. So it needs to include a minimum standard or some guantification, or some ideas
unspecified	we hadn't thought of before'.

Legacy - Field Visit	The default position towards guidance is "comply or explain" - sometimes they do explain and agree not to implement parts of the guidance e.g. with respect to maternity guidance and obesity they adopt an upper figure of 35 rather than
Overview	NICE'S 30 BMI.
	Morbid obesity surgery - felt that a major issue was omission of prevalence data in the health economic modelling. This has been brought up with NICE previously and they were informed that the unpublished assumption was that the prevalence pool would be offset by 30 years. This omission has necessitated a local approach to development of access criteria. They would like more detailed feedback on why prevalence
Technology appraisals	was omitted from the analysis.
Public health guidance	Director of HR raised the issue that NICE guidance does not take account of size and complexity of the organisations when making recommendations. For example, obesity guidance – to have healthy food in all canteens. The Trust has over 120 sites and not all have food provision services or ability to control what is offered.
	New DPH felt that smoking and physical activity
	guidance were useful and were being
Legacy feedback - unspecified	implemented locally. However, disappointed in the obesity guidance feeling that it did not go far enough.
Topic selection	New topic suggestion - obesity in pregnancy. Although aware that this will present some major implementation challenges.
Clinical guidelines	Obesity recommendations were "too vague" to be turned into a useful action plan.
Clinical guidelines	Obesity - useful piece of guidance but preferred the Foresight Report (www.foresight.gov.uk) which was more accessible and more focussed on practical aspects of implementation.
Clinical guidelines	Obesity guidance was very much appreciated and led to the redesign of the Trust's approach to tackling the issue within the workplace. However there is a suspicion that many trusts will have developed similar approaches and plans and it would be very helpful if NICE could take the guidance a step further and produce what are in effect a range of end-user (i.e. member of staff) tools - perhaps in the form of DVDs or dedicated web pages.
guidennoo	Obesity in pregnancy: "an increasing problem".
Topic selection	Prevention and management of pressure damage in pregnancy (linked to obesity).
	The DPH had used the costing tool for the obesity guideline, but the HRG bandings were apparently incorrect (gastric banding was off tariff). The DPH said that she had reported this to
Costing tools	NICE.

	The group agreed to use the guidance in two ways, firstly for ideas for improving existing
	services and secondly for benchmarking current
	services/processes. The group said they were
	particularly struggling with 'obesity models' (i.e.
	ways to reduce staff obesity) and hoped that
	some of the NICE guidance might be able to help
	provide practical models. It's finding practical
Public health guidance	models that people seem to be struggling with.
	This Council director felt that NICE should take
	the beyond the NHS' partners more into account
	when preparing guidance, and that if this was
	seen to happen, then more local authorities
	would recognise the importance of the guidance
	and example of recognising the need to
Clinical quidelines	address a wider audience
	Tonic – CEMACH is currently doing an audit on
	obesity in pregnancy. They have very high c-
	section rates foetal monitoring issues general
Topic selection	care arrangements. etc.
	Topics: pregnancy and obesity. NSF says all
	obese women should have preconception
	advice. There is guidance in the Trust on advice,
	handling, risk issues. They have a new obesity
	service and this meeting has highlighted the
	need to make the links with maternity services.
	For other topics look at NPSA data, e.g. iron
	infusions is risky for anacaphalis, but evidence is
Topic selection	sparse.

Information is taken from the field team CRM database.

4. Implementation issues from tool development

Implementation issues raised at the time of guidance publication

The key areas of resource impact identified were:

Training and development

Training in referral to non-pharmacological interventions, knowledge of healthy nutrition and how to overcome barriers to behaviour change is required. This could have a significant resource impact.

Weight management clinics

The establishment of weight management clinics will have an impact on resources. Initial research has found that not all PCTs have set these up.

Pharmacological and surgical interventions in children

If physical or severe comorbidities are present, the guidance recommends treatment of Orlistat or Sibutamine in children aged 12 and older. It should be started in a specialist paediatric setting by multidisciplinary teams with expertise in prescribing to this age group. This will incur cost for additional prescribing and the specialist input.

Savings and benefits

There are clear benefits to reducing the number of obese people in the population, and the report will highlight these. However, the data on which to make assumptions regarding long-term improvement and quantify impact on costs to treat obesity is limited.

Other implementation issues:

A number of complex communication needs were identified such as the need to tailor advice for patients, how to enable patients to make informed decisions about their care, how to address language and other barriers and the need for written evidence-based information.

Obesity is an area where a wide range of initiatives and actions were taking place, so we took the opportunity of using the publication of the guidance to signpost to relevant resources and try and pull these together. Sources of external support identified were;

Healthy Start, Healthy Schools Programme and Investors in People that support implementation in schools, workplaces and other settings. Specific sources of external support for implementation included:

- Lightening the Load: Tackling Overweight and Obesity. A toolkit for developing local strategies to tackle overweight and obesity in children and adults tackling overweight and obesity lightening the load: Produced by the National Heart Forum in association with the Faculty of Public Health (2006). We worked jointly with the NHF to update the toolkit and endorse it.
- 2005 Directory of Obesity Training Courses for Primary Care. Produced for the Department of Health by representatives from: Dieticians in Obesity Management DOM UK, National Obesity Forum (NOF) and The Association for the Study of Obesity (ASO)
- Quality and Outcomes Framework
- Central Office of Information for the Department of Health (2006). Obesity Care Pathway and Your Weight, Your Health.
- Obesity social marketing campaign Autumn 2006 onwards

The action we took to support the guideline was five implementation tools at the point of launch:

- a slide set to support awareness raising activities, outlining key messages for local discussion
- a guide to resources to signpost users to resources and national initiatives that support this locally
- audit criteria to assist organisations in reviewing and monitoring practice against NICE guidance
- costing tools to assess cost impact and potential savings.

The CQC added compliance with the obesity guideline to their list of indicators which form part of the annual health check in 07/08. The following website provides documents for the annual health check for all years.

http://www.cqc.org.uk/guidanceforprofessionals/nhstrusts/annualassessments/annualhealthch eck2005/06-2008/09.cfm