

**National Institute for Health and Clinical Excellence**

**Obesity Consultation Table: Clinical only**

**1st consultation**

**16 March – 11 May 2006**

<b>Organisation</b>	<b>Order No.</b>	<b>Document</b>	<b>Section</b>	<b>Page No.</b>	<b>Line No.</b>	<b>Comment</b>	<b>Response</b>
Abbott Laboratories Ltd	1	Full version	Drugs	General		"Pharmacotherapy for obesity is not licensed for use in patients of all ages. This should be brought to the attention of any prescriber who may be considering pharmacotherapy in this population. They should be advised to refer to the relevant Summary of Product Characteristics (SmPC) for further information"	We do recognise that these are drugs that are not licensed for use in children. However, this is not dissimilar to many other pharmacological options that are not licensed and that are prescribed to children with other conditions. We do, however, ensure that the caveats for this use are reflected in added detail in the recommendations, and that these are to be given only in exceptional circumstances, if severe life-threatening comorbidities are present, by multidisciplinary teams with experience of prescribing in this age group.
Abbott Laboratories Ltd	2	Full version	Ident	General		There is inconsistency in the BMI guidelines in relation to subgroups e.g. Asians and elderly), as they seem to differ between sections	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI

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							cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Abbott Laboratories Ltd	3	Full version	Misc	General		It may be helpful to further separate out guidance relating to the management of obesity in adults versus children	We considered this before consultation and the GDG's decision was to keep the current format.
Abbott Laboratories Ltd	4	Full version	Drugs	Appendix 17 Pg 2388 on-wards		As noted in the guideline, the statistical analysis presented in Appendix 17 has not been validated by a statistician. Given the implications of this data to affect the whole document, an opportunity should be provided to be consulted and comment on this section after the data has been reviewed by the statistician.	This section has now been validated by a consultant statistician, and revisions/modifications made where appropriate. Although a few minor changes have been made, these have not impacted on the recommendations.
Abbott Laboratories Ltd	7	Full version	Drugs	Page 43	5/6	<p>"Pharmacological treatment should usually only be recommended after dietary and exercise advice have been initiated..."</p> <p>Most patients will have already tried diet and exercise – suggest:</p> <p>"pharmacological treatment should be implemented for patients that have failed or reached a plateau on dietary</p>	We have revised the recommendations to reflect this and other stakeholder concerns.

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						and activity changes.”	
Abbott Laboratories Ltd	8	Full version	Drugs	Pg 43	8	Limitations in initiating different drug treatment should also include “potential impact on patient motivation”	Noted and revised.
Abbott Laboratories Ltd	9	Full version	CP	Pg 45	<u>Assessment</u> text box	– suggest 2 <sup>nd</sup> bullet should be inserted: “physical constraints e.g. inability to take adequate exercise”.	We have recommended in the detailed guidance that ability is considered.
Abbott Laboratories Ltd	10	Full version	CP	Pg 45	<u>Specialist management</u> text box	“Pharmacotherapy for obesity is not licensed for use in patients of all ages. This should be brought to the attention of any prescriber who may be considering pharmacotherapy in this population. They should be advised to refer to the relevant Summary of Product Characteristics (SmPC) for further information”	We have highlighted that this should only be undertaken in specialist settings (see recommendations for details).
Abbott Laboratories Ltd	11	Full version	CP	Pg 46	<u>Assessment</u> text box	“Presenting symptoms of obesity” – suggest “e.g. behavioural, social, genetic”	Noted, but we consider that healthcare professionals will use clinical judgement to assess as appropriate.
Abbott Laboratories Ltd	12	Full version	CP	Pg 46	<u>Assessment</u> text box	Suggest moving “eating behaviour” to bullet 2 (immediately after “presenting symptoms”) as it is a fundamental cause	The bullet points are not in order of importance.
Abbott Laboratories Ltd	13	Full version	CP	Pg 46	<u>Assessment</u> text box	Suggest moving “willingness and motivation to change” up to bullet 3 to emphasise that motivation levels should be managed appropriately throughout the assessment process.	The bullet points are not in order of importance, but throughout we stress the need to assess motivation.
Abbott Laboratories Ltd	14	Full version	CP	Pg 46	<u>Management</u> text box	“Suggest rewording “intensity of management will depend on level of risk...”	Noted, but we consider the wording to be appropriate.

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						To "intensity of management will depend on the extent of the obesity and the level of risk"	
Abbott Laboratories Ltd	25	Full version	Drugs	Page 107/108	1-8	"Pharmacotherapy for obesity is not licensed for use in patients of all ages. This should be brought to the attention of any prescriber who may be considering pharmacotherapy in this population. They should be advised to refer to the relevant Summary of Product Characteristics (SmPC) for further information"	We do recognise that these are drugs that are not licensed for use in children. However, this is not dissimilar to many other pharmacological options that are not licensed and that are prescribed to children with other conditions. We do, however, ensure that the caveats for this use are reflected in added detail in the recommendations, and that these are to be given only in exceptional circumstances, if severe life-threatening comorbidities are present, by multidisciplinary teams with experience of prescribing in this age group.
Abbott Laboratories Ltd	26	Full version	Lifestyle	Page 107	Point 17	This indicates a very low calorie diet (VLCD) is < 1000 kcals however the glossary of terms (page 16) indicates less than 800 kcals – consistency is required.	Noted, and recommendations and statements revised.
Abbott Laboratories Ltd	27	Full version	Drugs	pg 112	Point 5	This indicates that drug therapy should not be used as first- line therapy before surgery, and would be contradictory to standard practice. There is a wealth of data indicating that pre-operative weight loss can help minimise peri- or post-operative morbidity. Furthermore this contradicts the statement in the Full	We have recommended that all options (including drugs) should be tried before surgery, but in people with a BMI>50, the evidence for drugs is limited. Most drug trials excluded this group of people.

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						<p>guidance (pg 43, line 14-16), that “all non-surgical measures should be tried prior to surgery”</p> <p>-Please revise to include pharmacotherapy as a first-line option prior to surgery.</p>	
Abbott Laboratories Ltd	28	Full version	Lifestyle	Page 118	18 (iii)	Please also include “low calorie diet”	We are not sure exactly what this refers to.
Abbott Laboratories Ltd	29	Full version	Misc	pg 139	20	“Dietitian” should also be mentioned	Noted and revised as appropriate.
Abbott Laboratories Ltd	30			Pg 155	13	<p>The 52 week follow-up definition should allow some flexibility. This mainly relates to the '48-week" Wirth et al study (JAMA. 2001;286:1331-1339) and is considered to fulfill the regulatory requirements for 12 month study i.e. 1 year = 12 months = 12 x 4 weeks</p> <p>We would suggest that there should be a window of +/-4 weeks for this inclusion criterion. This may also apply to other similar length studies.</p>	We have reviewed the evidence using the criteria as agreed with the GDG.
Abbott Laboratories Ltd	31	Full version	Ident	Page 178	Table 5.2 3	Asian BMI missing from Table but presented in Section 1 (Full Version: pg 98-101) – please insert	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to

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							be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Abbott Laboratories Ltd	35	Full version	Drugs	Page 475	4	"Pharmacotherapy for obesity is not licensed for use in patients of all ages. This should be brought to the attention of any prescriber who may be considering pharmacotherapy in this population. They should be advised to refer to the relevant Summary of Product Characteristics (SmPC) for further information"	We do recognise that these are drugs that are not licensed for use in children. However, this is not dissimilar to many other pharmacological options that are not licensed and that are prescribed to children with other conditions. We do, however, ensure that the caveats for this use are reflected in added detail in the recommendations, and that these are to be given only in exceptional circumstances, if severe life-threatening comorbidities are present, by multidisciplinary teams with experience of prescribing in this age group.
Abbott Laboratories Ltd	36	Full version	Drugs	pg 475	4	There is no 5mg dose of sibutramine commercially available in the UK. Sibutramine is only available in 10mg and 15mg doses	This was reflected in evidence which was not from the UK.
Abbott Laboratories Ltd	37	Full version	Drugs	pg 475	4	Please change "Harms" to "adverse effects", as this better describes the outcomes detailed	We have chosen harms as a broader term that could be used across interventions.
Abbott	38	Full version	Drugs	pg 475	8	Add number of patients in each study	This has been included in the

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Laboratories Ltd							review.
Abbott Laboratories Ltd	39	Full version	Drugs	pg 476/7/8		Terminology for sibutramine as an "appetite suppressant" should be amended to "satiety enhancer" as described in the SmPC	Amended.
Abbott Laboratories Ltd	40	Full version	Ident	Page 477	14	The classification of obesity in children in the US (as per the American Heart Association) should be given as a reference, as "severe obesity" could imply BMIs higher than actually studied in the RCT.	'Severe obesity' has been removed to avoid being misleading.
Abbott Laboratories Ltd	41	Full version	Drugs	pg 477	22	Please note and incorporate another recently published RCT in adolescents treated for >6 months: <a href="#">Violante-Ortiz R, Del-Rio-Navarro BE, Lara-Esqueda A, Perez P, Fanghanel G, Madero A, Berber A.</a> Use of sibutramine in obese Hispanic adolescents. Adv Ther. 2005 Nov-Dec;22(6):642-9.	We have checked this study and it is not a RCT. As we already have RCTs in the review we do not feel it is necessary to downgrade the inclusion criteria.
Abbott Laboratories Ltd	42	Full version	Drugs	pg 478	5-13	There is no significant difference between these two groups at month 12. It should be noted that this is because "Placebo" subjects were able to switched to sibutramine in the open-label phase at 6-months to 12-months.	Revised.
Abbott Laboratories Ltd	43	Full version	Drugs	Page 478	20-21	The number of subjects requiring a dosage reduction should be qualified relative to the number of subjects per group.	We have added the initial number of participants for the sibutramine group.
Abbott Laboratories Ltd	44	Full version	Drugs	pg 616	6	Please also include a 12 month study by Wadden et al (2005). Wadden et al. (2005) Comparing lifestyle modification, with pharmacotherapy	Noted.

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						(sibutramine) (NEJM, 353 (20) pg 2111-2120).	
Abbott Laboratories Ltd	45	Full version	Drugs	pg 617	16	Please revise statement as the STORM study had sites in the UK	Revised.
Abbott Laboratories Ltd	46	Full version	Drugs	pg 620	15	States "no other outcomes were reported". In fact, a number of other outcomes were reported – Please correct	Noted and revised.
Abbott Laboratories Ltd	89	NICE version	Drugs	Pg 44	1.2.5	Please insert a description of the mechanism of action for sibutramine and orlistat	The GDG did not feel that it was necessary to include a description of the mechanism or action of these drugs.
Abbott Laboratories Ltd	90	NICE version	Deugs	Pg 45	1.2.5.7	Change: "see individual drug recs for details" to "see individual drug summary of product characteristics for details	Noted. But the GDG have made specific recommendations related to each drug, and we have also recommended that the summary of product characteristics for each drug be consulted.
Abbott Laboratories Ltd	91	NICE version	Drugs	Page 44/45	1.2.5.1–1.2.5.6	"Pharmacotherapy for obesity is not licensed for use in patients of all ages. This should be brought to the attention of any prescriber who may be considering pharmacotherapy in this population. They should be advised to refer to the relevant Summary of Product Characteristics (SmPC) for further information"	We do recognise that these are drugs that are not licensed for use in children. However, this is not dissimilar to many other pharmacological options that are not licensed and that are prescribed to children with other conditions. We do, however, ensure that the caveats for this use are reflected in added detail in the recommendations, and that these are to be given only in exceptional circumstances, if severe life-threatening comorbidities are present, by multidisciplinary teams with experience of prescribing in this



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							age group.
Abbott Laboratories Ltd	94	NICE version	Surgery	Pg 48	1.2.7.1	<p>Please insert the headline Incremental cost per QALY for the comparator intervention v.s. Gastric bypass; v.s. adjustable silicone gastric band; v.s. Vertical gastric banding treatment.</p> <p>or</p> <p>define the cost per QALY: stating the</p> <ul style="list-style-type: none"> <li>time-horizon (e.g. after 20-years of treatment)</li> <li>“Using a lifetime horizon would further increase the cost per QALY.”</li> <li>The patient population</li> </ul>	Noted. However, the technical team felt that, since the document from which the evidence was drawn was unwilling to compare interventions because of the significant uncertainty surrounding model parameters, the guideline developers should take the same approach.
Abbott Laboratories Ltd	95	NICE version Exec.summary	Surgery	Pg 48 Pg 43	1.2.7.1 14	It should be stated that all “appropriate non-surgical measures have been tried “ includes <u>pharmacological interventions</u> for clarity	All non-surgical measures include pharmacological options.
Abbott Laboratories Ltd	96	NICE version	Surgery	Pg 49	1.2.7.3	Please define “MDT”	Revised.
Association for Respiratory Technology & Physiology	1	NICE	Misc	general		Having scanned through the NICE version I note that there is no mention of obstructive sleep apnoea (OSA) and its treatments including nasal CPAP therapy. A lot of the poor quality of life in obesity is directly related to the dreadful hyper somnolence associated with OSA. There is excellent evidence to show the vast improvements in well-being	We appreciate the value of your comments, However it is not part of the remit to issue guidance on the management of obesity-related comorbidities. OSA is listed as one of the common comorbidities.

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						that can be used as a platform to initiate lifestyle changes. Whilst not all OSA is associated with obesity, many obese people have undetected and untreated OSA. This needs to be considered as a part of the patient pathway for those obese patients susceptible to OSA.	
Association for the Study of Obesity	9	NICE	Lifestyle	9	Line 7	Suggested change: ..decreased inactivity, improve the quality of the diet and make changes in eating behaviour in support of dietary goals.	We have revised this recommendation.
Association for the Study of Obesity	21	NICE	Assess	33	1.2	Given the frequency of overweight and obesity in the general population, patients need to be risk-assessed. Providing guidance on who is most at risk would aid management approaches.	The GDG considered that the care pathway and the recommendations regarding risk assessment in 1.1.2.10–12 address this question. It is important that recommendations in this area do not go beyond available evidence.
Association for the Study of Obesity	22	NICE	Assess	34	1.2.2.1	Why is routine measurement of weight and height not recommended in adults? Is this not required for monitoring and incentive purposes for prevention of further weight gain and encouraging weight loss? The sections on opportunistic identification/classification are confusing.	Population-based screening programmes for overweight or obesity are outside the remit of this guidance.  However, we do recommend that 'All adults should be encouraged to periodically check their weight, waist measurement, or a simple alternative, such as the "fit" of their clothes', as in PH recommendation 1.1.1.3. We have attempted to revise the text where possible.
Association for	23	NICE	Ident	35	1.2.2.4	Although there are centile charts for	There are lower-quality studies

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the Study of Obesity						waist circumference in children there is no definition for healthy/unhealthy.	that indeed propose cut-offs for waist circumference in children, but the GDG did not feel that in light of the evidence we could support the use of specific cut-offs for waist circumference.
Association for the Study of Obesity	24	NICE	Assess	35	1.2.2.6	Why is bioimpedance not recommended as a substitute for BMI?	There was no evidence that compared the use of bioimpedance to BMI, which is the question that was asked by the GDG.
Association for the Study of Obesity	25	NICE	Ident	35	1.2.2.7	There is no definition of childhood overweight/obesity based on BMI cutoffs. Neither are there any weight management targets given for children. This is especially important when advising non-paediatric professionals who may not be familiar in dealing with centile charts.	The GDG did not feel that, in light of the available evidence, we could confidently support one sole definition of childhood overweight/obesity.  The GDG recommended that 'Pragmatic indicators for action are the 91st and 98th centiles.'
Association for the Study of Obesity	26	NICE	Assess	36	1.2.2.9	Where is the evidence for different cut-offs for older people?	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights

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							the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Association for the Study of Obesity	27	NICE	Assess	36	1.2.2.10 and 1.2.3.1/2	The criteria for further investigation and assessment should be clearer. Although secondary obesity is uncommon there are well accepted clinical findings that would be suggestive of an underlying pathology such as poor linear growth and dysmorphism etc. As it stands the guidance given here is vague.	The GDG considered that the criteria for further investigation and assessment were sufficiently clear for a generalist audience.
Association for the Study of Obesity	28	NICE	Assess		1.2.3	Except for a brief mention, the identification and management of associated medical risks/comorbidities is not discussed.	We have recommended that associated risks and comorbidities be evaluated and investigated using clinical judgement. The management of comorbidities associated with overweight or obesity is outside the remit of this work.
Association for the Study of Obesity	29	NICE	Assess	38	1.2.3.2	What is meant by genetic tests? This is beyond routine laboratory investigations and would require tertiary referral	We have revised this recommendation to ensure that it is clear that genetic tests are examples of what can possibly be undertaken. Genetic tests include some that are routinely available, e.g. for Prader-Willi syndrome, as well as those that are specialist. Those with severe early onset obesity should be under specialist care, and most paediatricians are probably aware of the genetic tests available on the NHS and as

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							research tools.
Association for the Study of Obesity	30	NICE	Lifestyle	40	1.2.4.4	What does it mean by 'appropriate competencies'? This probably comes back to the training issue mentioned earlier.	<p>We have added an additional paragraph/section on training to both versions, based on information already included throughout the guidance</p> <p>The specifics of implementation – including local training needs and the skill mix required – are outside the remit of this work. The guidance allows local providers to interpret and implement the guidance as appropriate to their situation. However, a number of recommendations highlight the type of skills that should be acquired by staff, as appropriate.</p>
Association for the Study of Obesity	31	NICE	Lifestyle	41		<p>Behaviour interventions – the measures listed don't offer guidance to practitioners. Is there evidence to support the benefits of all of the measures listed?</p> <p>What are the cost benefits of such interventions, given its intensity of resources?</p>	<p>We have listed the behavioural techniques as evaluated in the trials reviewed. However, there is a lack of evidence on which technique is most effective.</p> <p>Health economics – please see the section on 'Health economics' in the full guideline for a discussion of this issue.</p>
Association for the Study of Obesity	32	NICE	Lifestyle	41	1.2.4.11	The target of 30 minutes per day activity is for good health. The CMO's report on physical activity suggested 45 minutes was more appropriate for weight loss.	Noted and revised.
Association for the Study of	33	NICE	Lifestyle	43	1.2.4.15 /16	Given its importance, the dietary guidance is inadequate. There is little	We have revised these recommendations following

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Obesity						evidence that a low fat diet itself would produce weight loss, and what is defined as 'low fat'? The use of VLCDs are proposed for use in the short term – how long is this?	discussion with the GDG and given more detail where possible.
Association for the Study of Obesity	34	NICE	Drugs	44	1.2.5.2–3	Orlistat and Sibutramine are not licensed for use in children in Europe. By recommending its use in children, it places paediatricians in an awkward position as it contravenes current guidance by NICE. If NICE are suggesting its use, previous guidance needs updating. This must also consider issues of responsibility especially in the event of serious adverse events Children with severe obesity need specialised support which might be reasonably restricted to secondary care. However Gps involvement is also critical for ongoing monitoring. For example if Sibutramine is prescribed regular blood pressure measurements need to be taken, which would not be feasible in the secondary care setting.	We do recognise that these are drugs that are not licensed for use in children. However this is not dissimilar to many other pharmacological options that are not licensed and that are prescribed to children with other conditions. We do however ensure that the caveats for this use are reflected in added detail in the recommendations, and that these are to be given only in exceptional circumstances if severe life-threatening comorbidities are present, by multidisciplinary teams with experience of prescribing in this age group.
Association for the Study of Obesity	35	NICE	Drugs	45	1.2.5.4	Diet is missed out in the list. Drugs are an adjunct to diet, not an alternative.	Noted and revised.
Association for the Study of Obesity	36	NICE	Drugs	46	1.2.5.9	What details should be listed in the proposed registry of unlicensed usage of drugs? How will this be 'policed'	We have given as much detail as possible as we feel appropriate in a clinical guideline in regard to the creation of a registry in the

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						Who will collect the data? Royal College? R&D? Any collection of data needs to be organised to prevent repetition of work and to ensure that appropriate use of the data is coordinated What support is in place for clinicians should an adverse event occur when an unlicensed drug is prescribed to a child?	research recommendations.
Association for the Study of Obesity	37	NICE	Drugs	47	1.2.5.10	Any individualised plan should also include individualised recommendations on diet and activity	This is implicit in the recommendation that this should only take place as part of an overall management plan.
Association for the Study of Obesity	38	NICE	Drugs	47	1.2.5.13	Which vitamin supplements and at what dose?	Recommendation has been revised.
Association for the Study of Obesity	39	NICE	Misc	47	1.2.6	In the changing NHS, the roles of secondary and specialist teams need to be clearly defined	We have used the Department of Health's document on specialised Services National definition set. For further details please refer to <a href="http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187&amp;chk=jAqaRv">http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187&amp;chk=jAqaRv</a>
Association for the Study of Obesity	40	NICE		48	1.2.7	The surgical section is vague and does not provide clear guidance for practitioners.  Surgery for children is not currently recommended by NICE – will this document override the existing NICE guidance on surgery?	We have revised this section in light of these and other comments.  These recommendations replace existing NICE guidance on bariatric surgery.

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						<p>The use of surgery in children needs more consideration and clarification (as per the guidance in North America).</p> <p>In both children and adults a risk-benefit analysis would be useful for each surgical procedure, as well as information about the potential weight loss and risks associated with each method.</p> <p>There is no mention of the use of surgery in the medical management or prevention of associated complications, where it may be of benefit.</p>	We have given guidance on when people should be referred for consideration of surgical intervention.
Association for the Study of Obesity	48		Lifestyle	42	20–21	Worthy but how exactly and what?	We have made some revisions in light of this comment and others.
Association for the Study of Obesity	49		Surgery	43	17-18	<p>This will be used to prevent patients getting surgery in our experience. Unless PCTs are forced to provide specialist services, they will say their lack of them means that patients can not have surgery. Specialist care may be focussed on likely need for surgery, but will not be able to be accessed by patients if the specialist care is part and parcel of funding is for surgery – a Catch 22. I think this could be resolved by replacing <b>has received</b> with <b>will receive</b>.</p>	Noted and revised.
Association for the Study of Obesity	50		Surgery	43	19	Self-evident. This begs the question not as to what makes you fit, but what makes you unfit. It also sits oddly with next statement about BMI >50 as	Noted. Have revised these recommendations in light of this and other comments.



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						these are most likely to present anaesthetic challenges.	
Association for the Study of Obesity	51		Assess	457	3	Genetic Tests. This must be spelt out – i.e. screening for genetic causes of obesity. The question is how and where? PWS is available through Regional Genetics, but screening for rare monogenic disorders is still a research procedure – in this country localised to Cambridge. I agree with the appropriateness of the advice, but NICE will then need to recommend establishment of such services.	We have revised this recommendation to ensure that it is clear that genetic tests are examples of what can possibly be undertaken. Genetic tests include some that are routinely available, e.g. for Prader-Willi syndrome, as well as those that are specialist. Those with severe early onset obesity should be under specialist care, and most paediatricians are probably aware of the genetic tests available on the NHS and as research tools. To recommend the establishment of such services is part of service delivery and is outside our remit.
Association for the Study of Obesity	55		Misc	99	Item 5	Such positive rejection of WHR sits oddly with results of Interheart which provides a high level of evidence for its value as regards IHD, and indeed shows marked superiority over W alone. We do not advocate either routine use of WHR on practical grounds, nor abandoning either W or BMI, but the rejection seems rather 'stark'.	Noted, but the Interheart study only related WHR to CV risk, and not overall risk.
Association for the Study of Obesity	56		Assess	100	Item 9	Where do these recommendations come from? I am opposed to age-related definitions of overweight (and there seems to be no definition of obese). By all means modify advice on action (it exists) in relation to	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered

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						overweight/obesity in the elderly but don't change definitions. The table on page 101 makes no differences in age for waist measurement – why not and how would the evidence behind this table for risk assessment be modified by a changed definition of overweight and obesity in the elderly? What happens at age 65 – does an overweight person become a normal healthy weight on their birthday?	that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Association for the Study of Obesity	57		Assess	103	Table	? missing text on investigations for adults.	We have given some examples of appropriate investigations for adults in 1.1.3.1. However, we cannot recommend on further specific details of the testing, as this is down to clinical judgement based on the patient (history, examination, results of other tests).
Association for the Study of Obesity	58		Misc	104	Item 3	This could apply to children also	Recommendations have been revised in light of the stakeholder comments.
Association for the Study of Obesity	59		Ident	105	Item 7	I think the guidelines should positively state that IBW or BMI 18.5 to 25, are not necessarily the optimal for obese patients. Thus it is unknown how much weight loss, or what 'target' weight is appropriate. This is needed to reinforce the advice on 'realistic targets' and prevent the continued discrimination by health professionals	We have added in detail to clarify.

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						setting unrealistic targets based on ideal body weights (e.g. in the setting of patients seeking joint replacement).	
Association for the Study of Obesity	60		Lifestyle	107	Item 16	Kcals as MJ or kJ. Should state what the targets for an ad lib low fat diet are (e.g. 20% of energy, no item >5% by energy fat, total 50-80 gm fat/day)	We have used Kcal throughout the guidance. The dietary recommendations have been revised in light of this and other comments.
Association for the Study of Obesity	61		Lifestyle	107	Item 18	Is a low fat diet 'unbalanced'? Aren't all lowered energy diets 'restrictive'. The word 'unduly' may be needed in front of these statements	Noted and revised.
Association for the Study of Obesity	62		Drugs	108	Item 4	We would like to see the statement on prescribing within the sPC enlarged to tackle the issue of how to deal with the statements that 'safety and efficacy have not been established beyond 1 (or 2) years'. This is true for nearly all drugs, but only in obesity is this statement then used to require cessation of medication at that time (with inevitable loss of efficacy. We think a statement that 'drugs should only be used beyond clinical trial evaluated safety and efficacy if clinical benefit outweighs any potential risk' should be made. Note that item 12 on next page, and item 17 on page 109 imply this but these two statements contradict each other.	We have recommended that prescribers should be aware of emerging evidence (especially on the long term effects of these treatments).
Association for the Study of Obesity	63		Surgery	110	Item 1	We agree with your comment about referral if surgery is being considered but note my comments [...] above.	Noted.
Association for	64		Assess	113	Item 8	See earlier comments on genetic	We have recommended that

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
the Study of Obesity						screening	certain tests can be performed as appropriate. However, we cannot recommend on further specific details of the testing, as this is down to clinical judgement based on the patient (history, examination, results of other tests); nor can we recommend the establishment of such services, as this is part of service delivery and is not part of our remit.
Association for the Study of Obesity	71		Ident	179	No. 4	See comments above re age-related definitions. This statement is acceptable – it states facts but does not redefine overweight	Thank you for your comment.
Association for the Study of Obesity	72		Ident	179	6 and 7	Should qualify this applies to Caucasians	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
Association for the Study of Obesity	73		Ident	179	8	Not sure it is less accurate but for sure it does not alter (much) with weight loss. See comments re Interheart above.	We have revised the evidence statement. The Interheart study only looked at risk of MI, and not at overall CVD risk. The evidence review does acknowledge, therefore, that different measures may reflect different risks.
Association for the Study of Obesity	74		Surgery	185		<p>Comments have been inserted here about the term 'excess body weight' that is used by bariatric surgeons. It is a term that snuck into the field and is widely used</p> <p><b>Excess weight</b> Difference between actual weight and normal weight (or ideal weight) before surgery</p> <p><b>Excess weight loss (EWL)</b> Is treated as a reference value to measure the success of treatment as a percentage (% EWL) in international literature <a href="http://www.surgery.ch/en/default.asp?ID=27545">http://www.surgery.ch/en/default.asp?ID=27545</a></p> <p>Thus the definition of EWL depends upon defining ideal body weight and this is undefined. Indeed the development of BMI was specifically in part to overcome the limitations of the concept of Ideal Body Weight (based as it was on the Metropolitan Life Tables). Only surgical series report results in terms of EWL, but they rarely give details as to how this</p>	Thank you for your comment. We accept the limitations of EWL, but this is most often reported in the surgical literature. However, we have added details of the change in BMI to the evidence statements (as were already in the evidence tables).

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p>was calculated. For an example:</p> <p><b><i>International Journal of Obesity</i></b>  <b>advance online publication</b>  <b>14 February 2006; doi:</b>  <b>10.1038/sj.ijo.0803247. Resting</b>  <b>energy expenditure and fuel</b>  <b>metabolism following laparoscopic</b>  <b>adjustable gastric banding in</b>  <b>severely obese women:</b>  <b>relationships with excess weight</b>  <b>lost. F Galtier<sup>1</sup>, A Farret<sup>1</sup>,</b>  <b>R Verdier<sup>3</sup>, E Barbotte<sup>3</sup>, D Nocca<sup>4</sup>,</b>  <b>J-M Fabre<sup>4</sup>, J Bringer<sup>2</sup> and</b>  <b>E Renard<sup>2</sup></b></p> <p>Subjects lost 22% of BW at 1 yr, and  32.5% of Excess weight</p> <p>Excess weight calculated from very  old Lorentz formula: e.g. patient 120  kg @ 175 cm  Lorentz IBW = 175 – 75- 12.5 = 62.5  <u>This corresponds to a BMI of 20.4</u></p> <p><b>Obesity Surgery, 8, 487-499.</b>  <b>Bariatric Analysis and Reporting</b>  <b>Outcome System (BAROS). Horatio</b>  <b>E. Oria, MD; Melodie K.</b>  <b>Moorehead, PhD2</b></p> <p>In this paper that developed concept  of EWL IBW comes out at a BMI of  22. Not defined how this was  determined but I suspect this</p>	

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p>corresponds to the midpoint of the medium frame Metropolitan Weight Tables.</p> <p>It is a very important issue as regards all of the surgical evidence – are you sure that you know how EWL was calculated? The ‘success’ will be biased as to whether the IBW is defined as 20.2, 22 or as is also often used I believe 25. Furthermore this makes results of surgery non-comparable with drugs or lifestyle.</p>	
Association for the Study of Obesity	75		Ident	208	Table	Rather confusing - are there are 3 columns for men or is it 2 and 2? Even so, why the groupings?	This table has been deleted.
Association for the Study of Obesity	77		Assess	436	21–24	<p>Is NICE speaking or existing guidelines of NHMRC here? Should not thyroid status be tested? Although a rare cause for obesity, it is relatively common and insidious and may not have ‘specific’ evidence of endocrine disease esp in children.</p>	<p>We have endorsed the National Health and Medical Research Council (NHMRC) proposals of tests that could be carried out, based on clinical judgement. The list is not intended to be comprehensive, but gives examples of some appropriate tests to consider.</p> <p>Regarding thyroid status in adults, it is important the guideline does not impede clinical judgement – a practitioner may choose to undertake thyroid status tests if the history/examination suggests this should be considered in the differential diagnosis.</p>
Association for	78			447	11-12	While high drop-out rates do make	We recognize the importance of

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
the Study of Obesity						interpretation more complex they are a fact of life and what really matters is how drop-outs are treated in the analysis and how this is translated ultimately into an NNT). This issue relates also to non-lifestyle interventions esp drugs. The biggest issue I think in many of these behaviour studies is their translatability. Many are carried out in highly selected small numbers of children, in 'intense' and 'intensive' academic units, using health professionals whose skills and experience is not generally available. In many of the studies only children with families willing to be included were considered eligible, i.e. selecting out the, I suspect, more common social setting where the family are relatively uninterested.	these comments. We decided to Include the listing of levels of drop-outs for the trials for Information purposes. In regard to the translatability of the trials, we did highlight the fact that because these studies were undertaken In such highly specialised centres that the validity and generalisability of the conclusions remains unclear.
Association for the Study of Obesity	79		Lifestyle	450	?	What is meant by 'large increments'? I realise not NICE speaking here or below.	As you note, this phrase is taken directly from the source document.
Association for the Study of Obesity	80		Lifestyle	450		Energy intake rather than calorie intake	This is taken from the source document, so has not been revised.
Association for the Study of Obesity	81		Surgery	479	Item 8	Excess weight loss – see earlier comments. These are particularly appropriate to adolescents where ideal body weight is even less well-defined than for adults	Thank you for your comment. We accept the limitations of EWL, but this is most often reported in the surgical literature. However, we have added details of the change in BMI to the evidence statements (as were already in the evidence tables).



Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
Association for the Study of Obesity	82		Surgery	486	2	<p>GI bypass in fact reduced food intake as its main method of maintaining weight loss Pilkington et al, Br Med J 1986. The issue of the effects of RNY,BPD,DS on food intake and appetite should be mentioned albeit that it is still a matter of active research. Sleeve gastrectomy, either as a first stage for super-obese, or increasingly as a definitive procedure should be considered – perhaps later in adult section.</p> <p>Sleeve gastrectomy and gastric banding: effects on plasma ghrelin levels. Langer FB, Reza Hoda MA, Bohdjalian A, Felberbauer FX, Zacherl J, Wenzl E, Schindler K, Luger A, Ludvik B, Prager G. Obes Surg. 2005 Aug;15(7):1024-9.</p> <p>Nguyen NT, Longoria M, Gelfand DV, Sabio A, Wilson SE. Staged laparoscopic Roux-en-Y: a novel two-stage bariatric operation as an alternative in the super-obese with massively enlarged liver.Obes Surg. 2005 Aug;15(7):1077-81.</p>	Noted and revised. Also staged surgery is reviewed.
Association for the Study of Obesity	83		Assess	512	Table item 1	Weight loss and weight loss maintenance (WLM). In terms of benefit the focus must be on WLM. Clearly WLM can only be achieved if WL is first achieved.	Noted, and the evidence statement has been revised as appropriate.
Association for the Study of Obesity	84		Assess	515	Table	Commented upon earlier but will re-iterate. Suggesting that RR for diabetes is >3 woefully	Noted.

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						underestimates the true RR even for those at BMI 35, let alone those higher. Such a table is unhelpful at defining the real risks of obesity, and some comment is needed	
Association for the Study of Obesity	85		Lifestyle	518	Table item 1	Again there appears to be no appreciation that the aim of obesity management is WLM. To say that WL requires an energy deficit (again – why the use of calorie which is an outdated measure of energy) but fail to mention that a permanently lowered EI or increased EE is needed to maintain weight loss betrays a misunderstanding of treatment goals. You must address the issue of WLM – if only to point out somewhere that all trials of >6m by definition include both WL and WLM. If you want to talk about WL don't restrict your search to 6m or longer studies.	We have added cross references to the 'Prevention' section as appropriate to address the issue of weight maintenance in adults.
Association for the Study of Obesity	86		Lifestyle	525	1	In section 1 you defined VLCD as <800 kcals. See earlier comments about LCLD. Have you referenced EU SCOOP report on VLCLDs?	We have clarified our recommendations on this, but have used definitions from the original health technology appraisal review.
Association for the Study of Obesity	87		Lifestyle	526	12	Are not the placebo arms of drug RCTs useful data to consider? I appreciate that these studies do not include a non-intervention arm, but they do provide corroborative data on what diet +/- behavioural intervention can achieve.	We consider that, as RCT evidence is available, lower levels of evidence (such as the placebo arms of drug trials) is not appropriate. Also, we would not be able to calculate the placebo drug effect, which may influence the results. Details of the placebo arms of the drug trials are,

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
							however, reported in the drug reviews.
Association for the Study of Obesity	88		Lifestyle	527	5	Abbreviations in table not defined – e.g. HOT, TAIM, HPT	Noted – these should refer to the narrative and evidence tables.
Association for the Study of Obesity	89		Drugs	595	Table 1, para 2	The word risk for HT and DM subjects is inappropriate – the outcome is what is wanted!	Noted and revised.
Association for the Study of Obesity	90		Drugs	597	Table 10,11,12,13,14	Lowering may be a better term than improving. Not all the subjects had 'abnormal' LDL-C levels so 'improving' implies and inappropriate clinical judgement	Noted and revised.
Association for the Study of Obesity	91		Drugs	599	19,20,21	As above for BP	Noted and revised as appropriate.
Association for the Study of Obesity	92		Drugs	601	25	The term 'statistically independent' should be used. These studies were not designed specifically to test true 'independence' and the findings are from post hoc statistical techniques that are, in my view, hypothesis generating and suggestive, but not proving. Only one study has specifically been designed to look at the issue of independent effects of orlistat – in relation to TGs and insulin resistance – <a href="#">Kelley DE, Kuller LH, McKolanis TM, Harper P, Mancino J, Kalhan S.</a> Effects of moderate weight loss and orlistat on insulin resistance, regional adiposity, and fatty acids in type 2 diabetes. Diabetes Care. 2004 Jan;27(1):33-40.	Noted and revised.

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
Association for the Study of Obesity	93		Drugs		End	<p>There are no considerations of recent papers on orlistat and NASH, PCOS <a href="#">Zelber-Sagi S, Kessler A, Brazowsky E, Webb M, Lurie Y, Santo M, Leshno M, Blendis L, Halpern Z, Oren R.</a>A Double-Blind Randomized Placebo-Controlled Trial of Orlistat for the Treatment of Nonalcoholic Fatty Liver Disease. Clin Gastroenterol Hepatol. 2006 Apr 17</p> <p><a href="#">Jayagopal V, Kilpatrick ES, Holding S, Jennings PE, Atkin SL.</a>Orlistat is as beneficial as metformin in the treatment of polycystic ovarian syndrome.J Clin Endocrinol Metab. 2005 Feb;90(2):729-33. Epub 2004 Nov 9.</p>	<p>Zelber 2006 is outside our searches cut-off date (Dec 2005).</p> <p>Jayagopal 2005 – the aim of this trial was to evaluate and compare the effect of treatment with orlistat vs. metformin on the hormonal and biochemical features of patients with polycystic ovarian syndrome, not primarily to reduce weight. The treatment of PCOS was outside our scope.</p>
Association for the Study of Obesity	94		Drugs	603	31	Or vice versa since those attending hospital/specialist clinics, or participating in trials may be more resistant than patients seen in primary care.	Noted and revised.
Association for the Study of Obesity	95		Drugs	610	1	An important methodological issue is that most/all of these trials included a 4 week active dietary run-in. Weight loss during this period is excluded from the outcome analysis. Also the true baseline for biochemical parameters in my view is from start of study, not randomisation. It clearly is neither possible nor appropriate to re-analyse data but a statement that	Thank you for this comment – the point is acknowledged.

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						such study design may underestimate the benefits of the 'total' intervention would be worthwhile. Thus if BP falls by 3-4 mm during the 4-week run-in, it is in effect 'lost' from the randomised part of the trial even though in real world clinical practice one would consider the benefits (or otherwise) of the whole intervention – run-in + active therapy. This holds true for sibutramine trials too. The only parameter where this effect works in an opposite direction is in relation to HDL-C levels which might be expected to fall during the 4 week run-in, thus 'artificially' lowering the apparent 'baseline' level.	
Association for the Study of Obesity	96		Drugs	613	6	This is an odd conclusion. How can you overestimate a success rate in WLM in subjects who have not lost weight? The trial outcomes describe accurately the clinical scenario. Disagree that it could overestimate the results.	Evidence statement has been revised.
Association for the Study of Obesity	97		Drugs	613	8	Elevating this conclusion to an evidence-based statement seems odd. Why negative findings in this category? Thus, for example, you do not have a similar statement re HDL-C for orlistat. Not aware of any claim that sibutramine does alter total Cholesterol levels.	Noted and revised.
Association for the Study of Obesity	98		Drugs	617	16	Exclusively in the UK. Other studies were conducted, in part in the UK	This has been revised.

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
Association for the Study of Obesity	99		Surgery	621/2	Table 2	See earlier comments on EWL. It would be helpful to have actual weight loss figures as well as the spurious EWL figures	Noted and added to evidence statements where possible.
Association for the Study of Obesity	100		Misc	655	6	Is some statement about the failure of SHAs and PCTs to implement NICE Guidance 46 is warranted here, using Dr Foster report as evidence? While this has a 'political' tint to it, it is a clear demonstration of the reluctance of Health Care Purchasers/providers to implement NICE guidance although on can only surmise why	Noted, and there is additional work on the implementation to be published to support this guidance.
Association of British Clinical Diabetologists	7		Lifestyle	42	20-21	Worthy but how exactly and what?	We have made some revisions in light of this comment and others.
Association of British Clinical Diabetologists	8		Surgery	43	17-18	This will be used to prevent patients getting surgery in my experience. Unless PCTs are forced to provide specialist services, they will say their lack means that patients can not have surgery (current situation in Norfolk, Suffolk and Cambridgeshire). Specialist care may be focussed on likely need for surgery, but will not be able to be accessed by patients if the specialist care is part and parcel of funding is for surgery – a Catch 22. I think this could be resolved by replacing <b>has received</b> with <b>will receive</b> .	Noted and revised.
Association of British Clinical Diabetologists	9		Misc	43	19	Self-evident. This begs the question not as to what makes you fit, but what makes you unfit. It also sits oddly with next statement about BMI >50 as	Noted.

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						these are most likely to present anaesthetic challenges.	
Association of British Clinical Diabetologists	10		Assess	457	3	Genetic Tests. This must be spelt out – i.e. screening for genetic causes of obesity. The question is how and where? PWS is available through Regional Genetics, but screening for rare monogenic disorders is still a research procedure – in this country localised to Cambridge. I agree with the appropriateness of the advice, but NICE will then need to recommend establishment of such services.	We have revised this recommendation to ensure that it is clear that genetic tests are examples of what can possibly be undertaken. Genetic tests include some that are routinely available, e.g. for Prader-Willi syndrome, as well as those that are specialist. Those with severe early onset obesity should be under specialist care, and most paediatricians are probably aware of the genetic tests available on the NHS and as research tools. We cannot recommend the establishment of such services as this is part of service delivery and is not part of our remit.
Association of British Clinical Diabetologists	14		Ident	99	Item 5	Such positive rejection of WHR sits oddly with results of Interheart which provides a high level of evidence for its value as regards IHD, and indeed shows marked superiority over W alone. I do not advocate either routine use of WHR on practical grounds, nor abandoning either W or BMI, but the rejection seems rather 'stark'.	We discussed this issue with the GDG and have decided to omit this recommendation.
Association of British Clinical Diabetologists	15		Assess	100	Item 9	Where do these recommendations come from? I am opposed to age-related definitions of overweight (and there seems to be no definition of obese). By all means modify advice	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						on action (it is exists) in relation to overweight/obesity in the elderly but don't change definitions. The table on page 101 makes no differences in age for waist measurement – why not and how would the evidence behind this table for risk assessment be modified by a changed definition of overweight and obesity in the elderly? What happens at age 65 – does an overweight person become a normal healthy weight on their birthday?	BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Association of British Clinical Diabetologists	16		Assess	103	Table	? missing text on investigations for adults.	We have given some examples of appropriate investigations for adults in 1.1.3.1. However, we cannot recommend on further specific details of the testing, as this is down to clinical judgement based on the patient (history, examination, results of other tests).
Association of British Clinical Diabetologists	17		Misc	104	Item 3	This could apply to children also	Recommendations have been revised in light of the stakeholder comments.
Association of British Clinical Diabetologists	18		Ident	105	Item 7	I think the guidelines should positively state that IBW or BMI 18.5 to 25, are not necessarily the optimal for obese patients. Thus it is unknown how much weight loss, or what 'target' weight is appropriate. This is needed to reinforce the advice on 'realistic targets' and prevent the continued	We have added in detail to clarify.



Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						discrimination by health professionals setting unrealistic targets based on ideal body weights (e.g. in the setting of patients seeking joint replacement).	
Association of British Clinical Diabetologists	19		Lifestyle	107	Item 16	Kcals as MJ or kJ. Should state what the targets for an ad lib low fat diet are (e.g. 20% of energy, no item >5% by energy fat, total 50-80 gm fat/day	We have used Kcal throughout the guidance. The dietary recommendations have been revised in light of this and other comments.
Association of British Clinical Diabetologists	20		Lifestyle	107	Item 18	Is a low fat diet 'unbalanced'? Aren't all lowered energy diets 'restrictive'. I think you may need 'unduly' in front of these statements	Noted and revised.
Association of British Clinical Diabetologists	21		Drugs	108	Item 4	I would like to see the statement on prescribing within the sPC enlarged to tackle the issue of how to deal with the statements that 'safety and efficacy have not been established beyond 1 (or 2) years'. This is true for nearly all drugs, but only in obesity is this statement then used to require cessation of medication at that time (with inevitable loss of efficacy. I think a statement that 'drugs should only be used beyond clinical trial evaluated safety and efficacy if clinical benefit outweighs any potential risk' should be made. Note that item 12 on next page, and item 17 on page 109 imply this but these two statements contradict each other.	Noted and clarified.
Association of British Clinical Diabetologists	22		Misc	110	Item 1	I agree with your comment about referral if surgery is being considered but note my comments on page 43 above.	Noted.

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
Association of British Clinical Diabetologists	23		Assess	113	Item 8	See earlier comments on genetic screening	We have revised this recommendation to ensure that it is clear that genetic tests are examples of what can possibly be undertaken. Genetic tests include some that are routinely available, e.g. for Prader-Willi syndrome, as well as those that are specialist. Those with severe early onset obesity should be under specialist care, and most paediatricians are probably aware of the genetic tests available on the NHS and as research tools. We cannot recommend the establishment of such services as this is part of service delivery and is not part of our remit.
Association of British Clinical Diabetologists	30		Ident	179	No 4	See comments above re age-related definitions. This statement is acceptable – it states facts but does not redefine overweight	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
							different risks at the same BMI, but allows for the exercise of clinical judgement.
Association of British Clinical Diabetologists	31		Ident	179	6 and 7	Should qualify this applies to Caucasians	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Association of British Clinical Diabetologists	32		Ident	179	8	Not sure it is less accurate but for sure it does not alter (much) with weight loss. See comments re Interheart above.	We have revised the evidence statement.
Association of British Clinical Diabetologists	33		Surgery	185		I have inserted comments here about the term 'excess body weight' that is used by bariatric surgeons. It is a term that snuck into the field and is widely used  <b>Excess weight</b> Difference between actual weight and	Thank you for your comment. We accept the limitations of EWL, but this is most often reported in the surgical literature. However, we have added details of the change in BMI to the evidence statements (as were already in the evidence tables).

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p>normal weight (or ideal weight) before surgery</p> <p><b>Excess weight loss (EWL)</b> Is treated as a reference value to measure the success of treatment as a percentage (% EWL) in international literature</p> <p><a href="http://www.surgery.ch/en/default.asp?ID=27545">http://www.surgery.ch/en/default.asp?ID=27545</a></p> <p>Thus the definition of EWL depends upon defining ideal body weight and this is undefined. Indeed the development of BMI was specifically in part to overcome the limitations of the concept of Ideal Body Weight (based as it was on the Metropolitan Life Tables). Only surgical series report results in terms of EWL, but they rarely give details as to how this was calculated. For an example:</p> <p><i>International Journal of Obesity</i> advance online publication 14 February 2006; doi: 10.1038/sj.ijo.0803247. Resting energy expenditure and fuel metabolism following laparoscopic adjustable gastric banding in severely obese women: relationships with excess weight lost. F Galtier<sup>1</sup>, A Farret<sup>1</sup>, R Verdier<sup>3</sup>, E Barbotte<sup>3</sup>, D Nocca<sup>4</sup>, J-M Fabre<sup>4</sup>, J Bringer<sup>2</sup> and E Renard<sup>2</sup></p>	

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p>Subjects lost 22% of BW at 1 yr, and 32.5% of Excess weight</p> <p>Excess weight calculated from very old Lorentz formula: e.g. patient 120 kg @ 175 cm  Lorentz IBW = <math>175 - 75 - 12.5 = 62.5</math>  <u>This corresponds to a BMI of 20.4</u></p> <p><b>Obesity Surgery, 8, 487-499. Bariatric Analysis and Reporting Outcome System (BAROS). Horatio E. Oria, MD; Melodie K. Moorehead, PhD2</b></p> <p>In this paper that developed concept of EWL IBW comes out at a BMI of 22. Not defined how this was determined but I suspect this corresponds to the midpoint of the medium frame Metropolitan Weight Tables.</p> <p>I think this is a very important issue as regards all of the surgical evidence – are you sure that you know how EWL was calculated? The ‘success’ will be biased as to whether the IBW is defined as 20.2, 22 or as is also often used I believe 25. Furthermore this makes results of surgery non-comparable with drugs or lifestyle.</p>	
Association of	34		Ident	208	Table	Rather confusing – I am not sure I	This table has been deleted.

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British Clinical Diabetologists						understand - are there are 3 columns for men or is it 2 and 2? Even so, why the groupings?	
Association of British Clinical Diabetologists	36		Assess	436	21-24	I am unclear whether this section is NICE speaking or existing guidelines of NHMRC. Should not thyroid status be tested? Although a rare cause for obesity, it is relatively common and insidious and may not have 'specific' evidence of endocrine disease esp in children.	<p>We have endorsed the NHMRC proposals of tests that could be carried out, based on clinical judgement. The list is not intended to be comprehensive, but gives examples of some appropriate tests to consider.</p> <p>Regarding thyroid status in adults, it is important the guideline does not impede clinical judgement – a practitioner may choose to undertake thyroid status tests if the history/examination suggest this should be considered in the differential diagnosis.</p>
Association of British Clinical Diabetologists	37		Misc	447	11-12	While high drop-out rates do make interpretation more complex they are a fact of life and what really matters is how drop-outs are treated in the analysis and how this is translated ultimately into an NNT in my view). This issue relates also to non-lifestyle interventions esp drugs. The biggest issue I think in many of these behaviour studies is their translatability. Many are carried out in highly selected small numbers of children, in 'intense' and 'intensive' academic units, using health professionals whose skills and experience is not generally available.	We recognize the importance of these comments. We decided to Include the listing of levels of drop-outs for the trials for Information purposes. In regard to the translatability of the trials, we did highlight the fact that because these studies were undertaken In such highly specialised centres that the validity and generalisability of the conclusions remains unclear.

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						In many of the studies only children with families willing to be included were considered eligible, i.e. selecting out the, I suspect, more common social setting where the family are relatively uninterested.	
Association of British Clinical Diabetologists	38		Lifestyle	450	?	What is meant by 'large increments'? I realise not NICE speaking here or below.	As you note, this phrase is taken directly from the source document.
Association of British Clinical Diabetologists	39		Lifestyle	450		Energy intake rather than calorie intake	This is taken from the source document, so has not been revised.
Association of British Clinical Diabetologists	40		Surgery	479	Item 8	Excess weight loss – see earlier comments. These are particularly appropriate to adolescents where ideal body weight is even less well-defined than for adults	Thank you for your comment. We accept the limitations of EWL, but this is most often reported in the surgical literature. However, we have added details of the change in BMI to the evidence statements (as were already in the evidence tables).
Association of British Clinical Diabetologists	41		Surgery	486	2	GI bypass in fact reduced food intake as its main method of maintaining weight loss Pilkington et al, Br Med J 1986. I think that somewhere the issue of the effects of RNY,BPD,DS on food intake and appetite should be mentioned albeit that it is still a matter of active research. Sleeve gastrectomy, either as a first stage for super-obese, or increasingly as a definitive procedure should be considered – perhaps later in adult section. Sleeve gastrectomy and gastric banding: effects on plasma ghrelin	Noted and revised. Also staged surgery is reviewed.

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						<p>levels. Langer FB, Reza Hoda MA, Bohdjalian A, Felberbauer FX, Zacherl J, Wenzl E, Schindler K, Luger A, Ludvik B, Prager G. Obes Surg. 2005 Aug;15(7):1024-9.</p> <p>Nguyen NT, Longoria M, Gelfand DV, Sabio A, Wilson SE. Staged laparoscopic Roux-en-Y: a novel two-stage bariatric operation as an alternative in the super-obese with massively enlarged liver. Obes Surg. 2005 Aug;15(7):1077-81.</p>	
Association of British Clinical Diabetologists	42		Assess	512	Table item 1	Weight loss and weight loss maintenance (WLM). I have only just realised at this point that weight loss is a used term. IN terms of benefit the focus must be on WLM. Clearly WLM can only be achieved if WL is first achieved.	Noted, and the evidence statement has been revised as appropriate.
Association of British Clinical Diabetologists	43		Assess	515	Table	Commented upon earlier but will re-iterate. Suggesting that RR for diabetes is >3 woefully underestimates the true RR even for those at BMI 35, let alone those higher. I think such a table is unhelpful at defining the real risks of obesity, and some comment is needed	Noted.
Association of British Clinical Diabetologists	44		Assess	518	Table item 1	Again there appears to be no appreciation that the aim of obesity management is WLM. To say that WL requires an energy deficit (again – why the use of calorie which is an outdated measure of energy) but fail	We have used calorie units as most people will be familiar with kCal, despite kJ being the preferred SI unit of measurement. We accept the importance of weigh maintenance and have



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						to mention that a permanently lowered EI or increased EE is needed to maintain weight loss betrays a misunderstanding of treatment goals. You must address the issue of WLM – if only to point out somewhere that all trails of >6m by definition include both WL and WLM. If you want to talk about WL don't restrict your search to 6m or longer studies.	aimed to stress that the goals agreed should be tailored to the individual – so may be weight loss (WL) or weight loss maintenance (WLM), as appropriate.
Association of British Clinical Diabetologists	45		Lifestyle	525	1	I think that in section 1 you defined VLCD as <800 kcals. See my earlier comments about LCLD. Have you referenced EU SCOOP report on VLCLDs?	We have clarified our recommendations on this, but have used definitions from the original health technology appraisal review.
Association of British Clinical Diabetologists	46		Lifestyle	526	12	Are not the placebo arms of drug RCTs useful data to consider? I appreciate that these studies do not include a non-intervention arm, but they do provide corroborative data on what diet +/- behavioural intervention can achieve.	We consider that, as RCT evidence is available, lower levels of evidence (such as the placebo arms of drug trials) is not appropriate. Also, we would not be able to calculate the placebo drug effect, which may influence the results. Details of the placebo arms of the drug trials are, however, reported in the drug reviews.
Association of British Clinical Diabetologists	47		Lifestyle	527	5	Abbreviations in table not defined – e.g. HOT, TAIM, HPT	Noted – these should refer to the narrative and evidence tables.
Association of British Clinical Diabetologists	48		Drugs	595	Table 1, para 2	The word risk for HT and DM subjects is inappropriate – the outcome is what is wanted!	Noted and revised.
Association of British Clinical Diabetologists	49		Drugs	597	Table 10,11,12,13,14	Lowering may be a better term than improving. Not all the subjects had 'abnormal' LDL-C levels so	Noted and revised.

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						'improving' implies and inappropriate clinical judgement	
Association of British Clinical Diabetologists	50		Drugs	599	19,20,21	As above for BP	Noted and revised as appropriate.
Association of British Clinical Diabetologists	51		Drugs	601	25	I think the term 'statistically independent' should be used. These studies were not designed specifically to test true 'independence' and the findings are from post hoc statistical techniques that are, in my view, hypothesis generating and suggestive, but not proving. Only one study has specifically been designed to look at the issue of independent effects of orlistat – in relation to TGs and insulin resistance – <a href="#">Kelley DE, Kuller LH, McKolanis TM, Harper P, Mancino J, Kalhan S.</a> Effects of moderate weight loss and orlistat on insulin resistance, regional adiposity, and fatty acids in type 2 diabetes. Diabetes Care. 2004 Jan;27(1):33-40.	Noted and revised.
Association of British Clinical Diabetologists	52		Drugs		End	There are no considerations of recent papers on orlistat and NASH, PCOS <a href="#">Zelber-Sagi S, Kessler A, Brazowsky E, Webb M, Lurie Y, Santo M, Leshno M, Blendis L, Halpern Z, Oren R.</a> A Double-Blind Randomized Placebo-Controlled Trial of Orlistat for the Treatment of Nonalcoholic Fatty Liver Disease. Clin Gastroenterol Hepatol. 2006 Apr 17  <a href="#">Jayagopal V, Kilpatrick ES, Holding S,</a>	Zelber 2006 is outside our searches cut-off date (Dec 2005).  Jayagopal 2005 – the aim of this

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<a href="#">Jennings PE, Atkin SL</a> . Orlistat is as beneficial as metformin in the treatment of polycystic ovarian syndrome. J Clin Endocrinol Metab. 2005 Feb;90(2):729-33. Epub 2004 Nov 9.	trial was to evaluate and compare the effect of treatment with orlistat vs. metformin on the hormonal and biochemical features of patients with polycystic ovarian syndrome, not primarily to reduce weight. The treatment of PCOS was outside our scope.
Association of British Clinical Diabetologists	53		Drugs	603	31	Or vice versa since those attending hospital/specialist clinics, or participating in trials may be more resistant than patients seen in primary care.	Noted and revised.
Association of British Clinical Diabetologists	54			610	1	An important methodological issue is that most/all of these trials included a 4 week active dietary run-in. Weight loss during this period is excluded from the outcome analysis. Also the true baseline for biochemical parameters in my view is from start of study, not randomisation. It clearly is neither possible nor appropriate to re-analyse data but a statement that such study design may underestimate the benefits of the 'total' intervention would be worthwhile. Thus if BP falls by 3-4 mm during the 4-week run-in, it is in effect 'lost' from the randomised part of the trial even though in real world clinical practice one would consider the benefits (or otherwise) of the whole intervention – run-in + active therapy. This holds true for sibutramine trials too. The only parameter where this effect works in	Thank you for this comment – the point is acknowledged.

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						an opposite direction is in relation to HDL-C levels which might be expected to fall during the 4 week run-in, thus 'artificially' lowering the apparent 'baseline' level.	
Association of British Clinical Diabetologists	55		Drugs	613	6	This is an odd conclusion. How can you overestimate a success rate in WLM in subjects who have not lost weight? The trial outcomes describe accurately the clinical scenario. I disagree that it could overestimate the results.	Evidence statement has been revised.
Association of British Clinical Diabetologists	56		Drugs	613	8	Elevating this conclusion to an evidence-based statement seems odd. I am not sure why negative findings are in this category. Thus, for example, you do not have a similar statement re HDL-C for orlistat. I am not aware of any claim that sibutramine does alter total Cholesterol levels.	Noted and revised.
Association of British Clinical Diabetologists	57		Drugs	617	16	Exclusively in the UK. Other studies were conducted, in part in the UK	This has been revised.
Association of British Clinical Diabetologists	58		Surgery	621/2	Table 2	See earlier comments on EWL. It would be helpful to have actual weight loss figures as well as the spurious EWL figures	Noted and added to evidence statements where possible.
Association of British Clinical Diabetologists	59		Misc	655	6	I wonder if some statement about the failure of SHAs and PCTs to implement NICE Guidance 46 is warranted here, using Dr Foster report as evidence. While this has a 'political' tint to it, it is a clear demonstration of the reluctance of	Noted, and there is additional work on the implementation to be published to support this guidance.

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						Health Care Purchasers/providers to implement NICE guidance although on can only surmise why	
Barnsley PCT	3		Drugs	9	Adults	Is there going to be detailed advice on how long an individual is expected to control excess weight before drug interventions are recommended? If so, there should be some comment on this page and where it can be found in the document.	The GDG did not consider that it was appropriate to establish a limit.
Barnsley PCT	4		Drugs	9		Drugs should only be used with lifestyle approaches in place – important point	We have taken care to ensure that this is reflected in the recommendations.
Barnsley PCT	5		Ident	9		Please clarify whether the 1995 charts should be used.	We recommend using the 1990 BMI charts as these apply to the UK.
Barnsley PCT	17		Ident	34	1.2.2.1	Does this mean that routine measurement is not recommended in a clinical setting? – needs more explanation.	Population-based screening programmes for overweight or obesity are outside the remit of this guidance. We have deleted original recommendation 1.1.2.1.  However, we do recommend that 'All adults should be encouraged to periodically check their weight, waist measurement, or a simple alternative, such as the "fit" of their clothes', as in PH recommendation 1.1.1.3.
Barnsley PCT	18		Ident	34	1.2.2.1	Routine Ht/Wt is NOT recommended – needs to be clearer.	The recommendation has been revised.
Barnsley PCT	19		Ident	34	Point 1.2.2.1 & 1.2.2.2	Public perceptions have changed as to what is 'normal weight' and 'overweight and obese' due to the number of overweight and obese	This document is intended to guide healthcare professionals, and cannot replace individual experience and expertise.

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						people in the population. I am not sure that 'health practitioners can use their clinical judgement' – they need to use guidance as not be swayed by personal beliefs	We have, however, revised these recommendations in order to be as clear as possible.
Barnsley PCT	20		Ident	34	1.2.2.2	What does 'Use clinical judgement re: weighing' mean? This needs clarification	We have revised this recommendation to be as clear as possible.
Barnsley PCT	21		Ident		1.2.2.2	Needs more explanation.	We have revised this recommendation to be as clear as possible.
Barnsley PCT	22		Ident	36	Table 1.2.2.10	I do not understand the dots in this table.	The dots mean not applicable.
Barnsley PCT	23		Ident	Pages 36 & 37	Table 1.2.2.11	I do not understand this table.	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Barnsley PCT	24		Ident	Pages 36 & 37		Waist Charts are NOT very clear – need to be set out more clearly	Noted, and we have asked for editorial input.

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Barnsley PCT	25		Assess	38	Point 1.2.3.2	The cost of implementing this? Would funding be provided? What are the guidelines for UK NHS follow up of failed bariatric surgery undertaken overseas?	National and local funding issues are outside the remit of NICE. However, audit and implementation tools are currently being developed to aid the implementation of the guidance (see section 3 of the NICE version).  We have made a recommendation on revisional surgery.
Barnsley PCT	26		Lifestyle	39	Note 10	Where are the recommendations on behavioural interventions?	These are in recommendations 1.2.4.8 and 1.2.4.9.
Barnsley PCT	27		Lifestyle	40	1.2.4.4	Are the relevant competencies and training identified anywhere in the document?	We do recommend that any healthcare professional involved in the delivery of interventions for weight management must have the relevant competencies. However, to issue guidance on the specific set of competencies is outside our remit. We have added an additional paragraph/section on training, based on information already included throughout the guidance. The specifics of implementation – including local training needs and the skill mix required – are outside the remit of this work. The guidance allows local providers to interpret and implement the guidance as appropriate to their situation. However, a number of recommendations highlight the

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							type of skills that should be acquired by staff, as appropriate.
Barnsley PCT	28			41	1.2.4.8	Include 'goal setting' for adults	Added.
Barnsley PCT	29		Lifestyle	42	1.2.4.11	These are the recommendations for general population adults, the guidelines for obese adults are much greater than this. 45-60 minutes to prevent transition from being overweight to obese. 60-90 minutes per day to prevent weight re-gain	Noted and revised – thank you.
Barnsley PCT	30		Lifestyle	Page 43	1.2.4.15	The recommendation that weight management in children should aim to bring about a reduction in total energy intake is inaccurately worded and I do not believe this is intended. My understanding has always been that children should 'grow into their weight' and calorie restriction could be harmful. It is not clear if this recommendation refers to overweight or obese children.	This has been clarified.
Barnsley PCT	31		Lifestyle	Page 43	1.2.4.15	Strict calorie restrictions are inappropriate in children and the aim of treatment is to maintain weight as height increases. Therefore have concern about statement regarding reduction in total energy intake in children.	This has been clarified.
Barnsley PCT	32		Lifestyle	Page 43	1.2.4.16	Is 1000 calories not too low? Should this not be 1200 – 1600Kcals (sustainable & more likely to cover nutritional requirements). Also should be clear that this would not be appropriate for individuals with higher BMI's.	The GDG considered that, based on evidence reviewed, and because of range, that 1000kcal is considered acceptable. It was also noted that the degree of overweight should be considered.



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Barnsley PCT	33		Lifestyle	Page 43	1.2.4.17	<p>This is the most disappointing section – very little detail or clarification on other dietary options.</p> <p>Meal replacements are not mentioned – I think that they should be as a suitable alternative (NB with support). They have been shown to be AS effective as low calorie diets (Heymsfield 2003 – wonder why this meta analysis was not included in evidence?).</p> <p>VLCDs only under medical &amp; dietetic supervision for those needing urgent weight loss.</p> <p>Difference between Meal Replacements (1200 – 1600 kcals) and Very Low Calorie Diets (less than 800 kcals) is not clarified. There is a clear difference, both practically and in relation to the evidence.</p>	We have considered the issue of meal replacements at length. We consider that the use of meal replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.
Barnsley PCT	34		Lifestyle	Page 44	1.2.4.18	<p>Long term weight maintenance and the need for support needs to be included here.</p>	We have a recommendation on the need for long-term support, and have added in more detail on the difference between weight loss and weight maintenance. We have also added in more linkage between the prevention and treatment recommendations.
Barnsley PCT	35		Drugs	P 44	1.2.5	<p>Should there be reference to previous NICE documents on drugs for the treatment of obesity?</p>	We have asked the editors to make clear that these recommendations replace previous guidance.
Barnsley PCT	36		Drugs	P 44	1.2.5.2	<p>Needs more detail and to specify the time and effort that goes into diet and exercise changes.</p>	We have revised this recommendation in light of this and other stakeholder comments.

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Barnsley PCT	37		Drugs			More detail is required regarding extent of dietary and exercise advice and behaviour modification required before pharmacological treatment is started.	We have revised the wording to clarify this point.
Barnsley PCT	38		Drugs	Page 44	1.2.5.3	Do 'looked after children' need to be treated differently? Should there be a lead health advisor for adult and children when a variety of advice is being given so that the advisor can help individuals bring this all together? Especially if the advice is coming from different levels such as primary & secondary care?	Noted. This is a suggested service delivery recommendation and as such is outside the scope of the guidance.
Barnsley PCT	39		Drugs	P 46		Need to clarify what the associated risk factors are. Also need to specify if this is an update on Orlistat & Sibutramine guidance and if it supersedes earlier NICE documents of these products.	Risk factors are included in the recommendation: type 2 diabetes or dyslipidaemia.  Clarification on the status of previous NICE guidance has been added.
Barnsley PCT	40		Drugs	P 47	1.2.6	How does secondary and specialist care differ? Is specialist care tertiary care?	We have used the definition of specialised/specialist services as outlined by the DH in 2002 National Definition Set 35.
Barnsley PCT	41		Misc		1.2.6.1	Referral to <u>specialist</u> care needs defining. What sort of care? Specialist obesity dietician? Physician?	Have not been prescriptive to allow for different skill mix – see Implementation section.
Barnsley PCT	42		Misc	P 47	1.2.6. 1	Needs to link with point above (1.2.4.17) re VLCDs, making it clear that under specialist supervision only, whereas, MR can be safely used in community settings, with proper support.	These recommendations have been revised in light of this and other comments.

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						<p>We need to be able to offer alternatives that work, to those who struggle with conventional low calorie diets</p> <p>NB: No emphasis is placed on the importance of nutritionally adequate diets especially with vulnerable groups &amp; those with special dietary needs.</p>	
Barnsley PCT	43		Surgery	P 48	Surgical Interventions	<p>The table needs to be more prescriptive about what needs to be done prior to surgery being considered. 6 months of attempted weight loss is a very short time before surgery is considered. Moreover, need to define what failure to achieve/maintain weight loss is. Also need to define what the non-surgical interventions should be. This should include exercise, diet, psychological support as well as drug therapy. All these should be tried not just one. Furthermore, when considering surgery as an option the level of BMI i.e. above 40 or above 50 needs to be considered.</p>	<p>We have recommended that <u>all</u> appropriate non-surgical options have been tried, and also that anyone with severe obesity (see Identification section) may benefit from surgery. Also recommended that the degree of obesity be taken into account when discussing options.</p>
Barnsley PCT	44		Assess			<p>There is no reference to which comorbidities should be seen as priority for undergoing surgery as in NICE 2002 guidance. Does such a priority still exist?</p>	<p>Although examples were given, the NICE 2002 guidance did not specify those comorbidities which should be given priority. The recommendations on surgery should allow for people who would benefit from surgery getting access to the appropriate care.</p>
Barnsley PCT	45		Surgery		1.2.7.1	What is the evidence base for 6	We have noted that this is a

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						months failure? Seems too short a time. The specialist obesity services referred to do not exist in most areas. No BMI limit specified in this section.	pragmatic cut-off considered as appropriate by the GDG. We have used the term 'severe' to describe the degree of obesity limit for this section.
Barnsley PCT	46		Ident	Pages 48 & 49		What is a severely obese person? Is this obese level III?	A severely obese person is considered to have obesity level III or BMI above 40kg/m <sup>2</sup> .
Barnsley PCT	47		Surgery	P 49	1.2.7.4	Why should bariatric surgery be considered as first line treatment for people with BMI > 50? This has the potential to dissuade overweight and obese people from losing weight and encourage them to think of surgery as a magic bullet.	Most drug trials did not include people with BMI>50, therefore the GDG considered that based on the evidence, surgery should be considered as a first line option.  In addition, this group will probably have comorbidities (possibly severe and multiple), and weight loss using lifestyle changes and drugs are very unlikely to achieve a clinically significant benefit.
Barnsley PCT	48		Surgery			BMI 750kg/M? This threshold is consistent with the current interpretation of guidance in the NORCOM area. It seems a pragmatic threshold, however there is probably limited evidence for this and need to do RCT of medical vs surgical intervention for patients with BMI's in vicinity of 45 – 55.	Noted.
Barnsley PCT	49		Surgery		1.2.7.5	Need to clarify why drug therapy is not the first line option for people who are suitable for surgery. Surely drug intervention should be tried before surgery unless there is a likelihood of	Most drug trials did not include people with BMI>50, therefore the GDG considered that based on the evidence, surgery should be considered as a first line option.

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						imminent death?	In addition, this group will probably have comorbidities (possibly severe and multiple), and weight loss using lifestyle changes and drugs are very unlikely to achieve a clinically significant benefit.
Barnsley PCT	50		Surgery	P 50	1.2.7.9	Should the choice of surgical intervention also reflect the past eating habits of the patient e.g. nibbler or volume eater?	Noted, but this is not evidence based. We have however recommended that a comprehensive assessment (including commitment to changes) be made.
Barnsley PCT	57		CP	P 73		Re Pathway for children. Will funding be provided for referrals to the paediatrician? If so, will there be allocated funding for associated tests and services such as Dietetics?	National and local funding issues are outside the remit of NICE. However, audit and costing tools are currently being developed to aid the implementation of the guidance (see section 3 of the NICE version).
Barnsley PCT	58		CP	P 74	Clinical Pathway for Adults	This pathway needs to be clearer and more prescriptive about what happens at specific levels of overweight and obesity. Could also suggest where these interventions take place e.g. primary, secondary or tertiary levels. Moreover, if the guideline does not want to be too prescriptive about where the interventions will take place etc., NICE guidance should indicate that local guidance will need to be developed and indicate where this local guidance will be needed.	The specifics of implementation are outside the remit of this work. However, we consider that the pathway shows the options (in brief) for adults. The guidance allows professionals/clinicians to exercise their own clinical judgement as appropriate, and for local providers to interpret and implement the guidance as appropriate to their situation.

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Barnsley PCT	59		Surgery			The assessment implies a multidisciplinary team is needed. Guidance on this is needed, especially on the importance of these issues in relation to each other. Where is the multidisciplinary team based? Is this primary or secondary care? There is a danger that obese people will be referred to a surgeon without going through a multidisciplinary assessment. What profession is going to lead the assessment?	We have specified the skill-mix needed in the team, and the process by which people should be referred and assessed. However, detailed service delivery is outside our remit.
Barnsley PCT	60		CP	P 74		Consider moving 'willingness and motivation to change' to be the first bullet point (if the patient is not ready or willing to change then the rest of the assessment may be futile)	The bullet points are not in order of importance, but throughout we have stressed the importance of willingness and ability to change.
Barnsley PCT	62	<b>General Comments:</b>	Misc			In Barnsley we have recently developed an Obesity Referral Guidance that includes:  <ol style="list-style-type: none"> <li>1. An initial risk assessment by a primary care professional which categorises people by BMI and disease risk (as measured by waist circumference).</li> <li>2. Next, based on the risk assessment some patients will be referred to the Dietetics department and assessed by a dietician. They will arrive at the Dietetics Dept. with the primary care professional having completed a referral form that</li> </ol>	Thank you for your comments and information. We are not able to comment specifically on your guidance, but we would expect that local pathways will be developed in response to local need, using the NICE guidance.

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						<p>specifies what interventions have been tried to date.</p> <p>3. The dietician can refer patients to weight wise Barnsley if BMI is 30 – 30.9, where they take part in a 3 month weight loss programme and 9 month follow-up.</p> <p>4. With BMI 40 – 40.9, patients will attend special exercise sessions. BMI 50+, patients will attend a specialist obesity clinic.</p> <p>5. If the interventions in (4) above are not successful, then drug intervention is considered.</p> <p>6. If (5) above is unsuccessful, patients are referred to a psychologist.</p> <p>7. If (6) above is unsuccessful, then surgery is considered.</p> <p>We don't think that the drug therapy should be initiated until the patient has seen a dietician.</p> <p>We are reviewing this pathway at the moment and your comments would be appreciated.</p>	
Barnsley PCT	63	NICE	CP			The DOH obesity care pathway is very useful – is this to be incorporated into the NICE guidance?	The DOH care pathway was interim guidance to be replaced by the NICE obesity guidance.
Barnsley PCT	64		Misc			Guidance doesn't appear to state what it is superseding e.g. NICE Obesity Surgery 2002; Drug Interventions	The guidance will be superseding the previous technology appraisals on both pharmacological treatments and for surgery.

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Barnsley PCT	65		Misc			Guidance does not appear to state how it dovetails with other guidance e.g. NICE exercise 2006; anything on breastfeeding	While it is recognised that this is an important area, the guidance covers children aged 2 onwards (see scope). Pregnancy / breastfeeding/weaning/under 2's are outside the remit of this work. However, NICE is currently developing <i>Guidance for midwives, health visitors, pharmacists and other primary care services to improve the nutrition of pregnant and breastfeeding mothers and children in low income households</i> , due to be published May 2007. For further information see <a href="http://www.nice.org.uk/page.aspx?o=MaternalandChildNutritionMain">www.nice.org.uk/page.aspx?o=MaternalandChildNutritionMain</a>
Barnsley PCT	66		Surgery			Guidance (small document) needs to state more prescriptively what should happen as part of the multidisciplinary team.	We have specified the skill-mix needed in the team, and the process by which people should be referred and assessed. Each assessment should be tailored to the needs of the individual, so prescriptive guidance is not appropriate.
Barnsley PCT	73		Lifestyle			Are special exercise classes for very obese people recommended i.e. where obese people can exercise privately?	The clinical recommendations are limited to the clinical setting. However, we have drafted the recommendations to allow for different activity strategies to be used as preferred by the individual, which would include having access to appropriate



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							exercise facilities.
Barnsley PCT	74		Surgery			The obesity surgery guidance from NICE 2002 has extra recommendations that have been excluded in the short document. Why is this?	The recommendations included in this guidance replace the NICE 2002 guidance. The proposed recommendations are based on updated evidence and the clinical expertise and judgement of the GDG.
Barnsley PCT	75		Surgery			Are recommendations going to be made about which people should be prioritised for obesity surgery in the event of insufficient surgical capacity locally. E.g. by specific conditions or BMI?	We drafted the recommendations so that they can be interpreted at local level, and that priorities can be determined in response to local need.
Barnsley PCT	76		Misc			What guidance is there on treating obese people with mild mental health problems or learning difficulties? This applies to a variety of interventions but particularly surgery.	We have noted throughout that the needs and the abilities of individuals should be considered throughout any care process.
Barnsley PCT	88		Lifestyle			Not sure why there is such emphasis on PSMF diets – will this mean anything to most practitioners? And where is the supporting evidence? I think this section is very confusing.	We have added clarity to the recommendations and the reviews in light of this and other comments to address your concern.
Barnsley PCT	90		Lifestyle	40	15	Consider using marketing experts to help	The specifics of implementation are outside the remit of this work. Furthermore, in this instance the evidence considered does not allow the provision of more specific guidance on these issues. The guidance allows professionals/clinicians to exercise their own clinical judgement as appropriate, and for local providers to interpret and

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							implement the guidance as appropriate to their situation.
Barnsley PCT	91		Lifestyle	42	2	Consider financial incentives to promote healthy choices	The specifics of implementation are outside the remit of this work. Furthermore, in this instance, the evidence considered does not allow the provision of more specific guidance on these issues. The guidance allows professionals/clinicians to exercise their own clinical judgement as appropriate, and for local providers to interpret and implement the guidance as appropriate to their situation.
Barnsley PCT	92		Drugs	P 43	8	Motivated individuals must be sought. Prescriptions are wasted on those who are ambivalent towards drug therapy; many people do not take the anti-obesity drugs as recommended.	We have recommended that willingness to change be included in any assessment.
Barnsley PCT	93		Surgery	P 44	3	Is there sufficient funding to be able to treat all those patients who are clinically eligible for bariatric surgery?	Funding is outside the scope. But please see Implementation and Costing sections for further information on this.
British Cardiovascular Society	4		Ident	10		BMI is implicit as the measurement of choice, yet waist measurement is considered a more suitable predictor of future ill health – p.35 refers.	Recommendation 1.2.2.4 reflects this evidence.
British Cardiovascular Society	14		Misc	33	1.2.1.1	The physical environment... Will there be funding to enable the provision of eg special seating /scales?	We cannot provide guidance on Funding issues. However, audit tools are currently being developed to aid the implementation of the guidance (see section 3 of the NICE version).

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British Cardiovascular Society	15		Ident	35	Lines 3–5	BMI should be used with caution in highly mesomorphic (muscular) adults.	We have added more detail to this recommendation.
British Cardiovascular Society	16		Ident	36	Table 1.2.2.10	Legend is not clear because BMI is not included in table. It needs cross reference to Table 1.2.2.7.	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
British Cardiovascular Society	17		Ident	37	Table 1.2.2.11	As above [British Cardiovascular Society comment 16]	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK

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							population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
British Cardiovascular Society	18		Lifestyle	39	1.2.4.1	Multicomponent interventions are the treatment choice..... Lifestyle interventions presently are taking place within the cardiac rehabilitation services nationwide. It would be more cost effective to direct obese patients (obesity being a risk factor for a number of chronic diseases) to enlist onto a cardiac rehabilitation programme. Lifestyle management eg diet/nutrition, smoking cessation, exercise, weight management, counselling, motivational techniques, psychological support is already provided within this setting. The expertise that is already available should be utilised.	We have not made service delivery recommendations as these are outside the remit of the guidance.
British Cardiovascular Society	19		Lifestyle	40	1.2.4.3	Patients could be risk assessed and included into the health promotion forum. The multi disciplinary team posses both the knowledge and skills.	We have tried to give generic advice, without specifying who should do what, to allow for local variation in practice and circumstances.
British Cardiovascular Society	20		Lifestyle	40	1.2.4.6	Care should be taken in the use of the term 'patient' as this may have certain implications for some people, especially children.	Noted. We have tried to use 'patient' only where appropriate in a clinical setting.
British	21		Lifestyle	42	1.2.4.11	Children could be given "exercise"	This was not an intervention

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Cardiovascular Society						homework – tasks that they need to achieve within the week – possibly during the evening, with family involvement.	reviewed in the identified evidence. However, the healthcare professional may use such a technique to facilitate the recommended level of activity.
British Cardiovascular Society	22		Lifestyle	42	1.1.4.13	We agree that a dietary approach alone should not be recommended – any work around obesity should always be looking at all the component parts – to include energy expenditure/self esteem etc.	Thank you for your comments.
British Cardiovascular Society	23		Drugs	45	Last line	'set up' not 'setup'	Noted and amended.
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	6	NICE	Misc	General		A specialist obesity service needs better definition. Health visitors can run weight loss clinics but this is not the same as a specialist clinic which should include an obesity specialist dietitian, physiotherapist (not health trainers as they are not trained to understand joint and other problems that affect the morbidly obese), behaviour modification counsellor and consultant physician..	We have used the Department of Health's document on specialised Services National definition set. For further details please refer to <a href="http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187&amp;chk=jAqaRv">http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187&amp;chk=jAqaRv</a>
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity	7	NICE	Misc	General		There also need to be separate clinics for children and adolescents	Any care and follow-up provided to young people should be co-ordinated around their individual and family needs and should comply with national core standards as defined in the NSF for Children, Young People and Maternity Services.

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Management BDA Specialist Group (DOM UK)							
British Dietetic Association Reviewers: Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	20	NICE	Drugs	9		Good to see guidance on making informed joint decisions about drug treatment and that concomitant support is vital.	Thank you for your comment.
British Dietetic Association Reviewers: Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	21	NICE	Drugs	9		Drugs should only be used with lifestyle approaches in place – important point	We have taken care to ensure that this is reflected in the recommendations.
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in	22	NICE	Misc	9	1 <sup>st</sup> bullet under children 1.2.1 table	These all apply to adults as much as children. Particularly in relation to family and social situation.	The recommendations were drafted specifically for each group, thus the GDG have decided after discussion that they will remain separate.

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Obesity Management BDA Specialist Group (DOM UK)							
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	54	NICE	Misc	33	1 <sup>st</sup> bullet under children 1.2.1 table	These all apply to adults as much as children. Particularly in relation to family and social situation.	The recommendations were drafted specifically for each group, thus the GDG have decided after discussion that they will remain separate.
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	55		Misc	33	Table 1.21	It is helpful to have emphasised practical points here such as the need for appropriate seating and weighing scales.	Thank you for your comment.
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians	56	NICE	Ident	34	1.2.2.2	Statements on measuring weight are confusing. Document promotes BMI as an identification tool and also promotes self monitoring. Needs to more clearly differentiate between initial assessment and ongoing monitoring. Also GMS contract	This section has been revised to address these and other concerns.

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Working in Obesity Management BDA Specialist Group (DOM UK)						incorporates BMI.	
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	57	NICE	Ident	34	1.2.2.1	It is unclear what is meant by 'routine' measurement in this context. Does this fit with the new GMS contract?	The GDG have decided to omit this recommendation, as it is not part of our remit to issue recommendations on population-based screening. However, the GDG consider that the revised recommendations on measurement do not conflict with the QoF in the new GMS contract.
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	58	NICE version	Assess	34	1.2.2.1	Would not say that routine weight and height measurements are NOT recommended- perhaps better to say that they are not necessary but can be carried out if so wished	This recommendation has been revised.
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including	60		Ident	36 & 37		The tables outlining risk for non-Asian and Asian adults are confusing, mainly due to the layout.	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered



Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)							that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
British Dietetic Association Reviewers: Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	61		Assess	39	1.2.3.5	It is good to see that it is acknowledged that it may take more than one consultation to fully explore treatment options and make a full assessment.	Noted. Thank you for your comment.
British Dietetic Association Reviewers: Registered Dietitians of the BDA including Dietitians Working in Obesity	62	NICE	Lifestyle	41	1.2.4.8	Include 'goal setting' for adults	Added.

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Management BDA Specialist Group (DOM UK)							
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	63		Lifestyle	41	1.2.4.8 & 1.2.4.9	Include 'goal setting' in recommendations for the components of behavioural interventions for adults The acknowledgement of the importance of having an appropriately trained individual to deliver a behavioural intervention is valuable.	Added.
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	64	NICE	Lifestyle	42	1.2.4.11	These are the recommendations for general population adults, the guidelines for obese adults are much greater than this. 45-60 minutes to prevent transition from being overweight to obese. 60-90 minutes per day to prevent weight re-gain. When referring to particular methods of physical activity within the document, i.e. walking; reference should be made to the NICE guidance on physical activity.	Noted and revised – thank you.
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in	65		Lifestyle	43	1.2.4.16	When using a 1000 calorie diet (food based) it is extremely difficult to achieve nutritional adequacy. It would be preferable to see guidance given on 1200-1600 Kcal/day as a low-calorie diet. Also the overall nutritional adequacy of diets is not given enough emphasis and that some may have	We have brought back this issue to the group and we have added more detail in to the dietary recommendations. Additionally, the GDG did feel that very low calorie diets (VLCDs) can be used in the short term (maximum of 12 weeks continuously, or used

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Obesity Management BDA Specialist Group (DOM UK)						special dietary needs in addition to weight loss.	intermittently with a low-calorie diet, for example for 2–4 days a week).
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	66		Lifestyle	43	1.2.4.16	Is 1000 calories not too low? Should this not be 1200 – 1600Kcals (sustainable & more likely to cover nutritional requirements). Also should be clear that this would not be appropriate for individuals with higher BMIs	The GDG did feel that VLCDs can be used in the short term (maximum of 12 weeks continuously, or used intermittently with a low-calorie diet, for example for 2–4 days a week).
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	67		Lifestyle	43	1.2.4.17	This is the most disappointing section – very little detail or clarification on other dietary options. Meal replacements are not mentioned – I think that they should be as a suitable alternative (NB with support). They have been shown to be AS effective as low calorie diets (Heymsfield 2003 – wonder why this meta analysis was not included in evidence?). VLCDs only under medical & dietetic supervision for those needing urgent weight loss. Difference between Meal Replacements (1200 – 1600 kcals) and Very Low Calorie Diets (less than 800 kcals) is not clarified. There is a clear difference, both practically and	We have considered the issue of meal replacements at length, and consider that the use of meal replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.  We have also clarified issues around VLCDs.

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						in relation to the evidence.	
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	68	NICE	Lifestyle	43	1.2.4.17	This is the most disappointing section – very little detail or clarification on other dietary options such as meal replacements and VLCD.	We have revised this section considerably in light of this comment and others. We consider the revised section satisfactorily addresses these concerns.
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	69	NICE	Lifestyle	43	1.2.4.17	This section is very brief. VLCDs are defined as diets < 1000 kcal. In other literatures they are defined <800 kcal /day e.g. review by (Mustajoki & Pekkarinen, Obesity Reviews, 2001, 2, 61-72). It is not stated that VLCDs need to be used under medical & dietetic supervision. Meal replacements are discussed in the full guidance but not in this section.	We have revised these recommendations following discussion with the GDG and given more detail where possible. We have considered the issue of meal replacements at length. We consider that the use of meal replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management	70	NICE	Lifestyle	43	1.2.4.16	Is there a danger in stating the use of 1000 kcals diets? Can this diet be properly monitored by a qualified individual in the community? Would it be better to say 'a tailored low calorie diet to suit the individual'	We have revised this section considerably in light of this comment and others. We consider the revised section satisfactorily addresses these concerns.

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BDA Specialist Group (DOM UK)							
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	71	NICE	Lifestyle	43	1.2.4.17	Could the term 'protein sparing modifying fasts' be misinterpreted?' Is it better to say high protein, low fat?	We have added in a definition to make it clearer.
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	72	NICE	Lifestyle	43	1.2.4.17	Needs to explain what they mean by 'protein sparing modified fast' or cross reference to full document	We have added in a definition to make it clearer.
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management	73	NICE	Lifestyle	44	1.2.4.18	Long term weight maintenance and the need for support needs to be included here.	We have a recommendation on the need for long-term support, and also added in more detail on the difference between weight loss and weight maintenance. We have also added in more linkage between the prevention and treatment recommendations.

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Management BDA Specialist Group (DOM UK)							
British Dietetic Association Reviewers: Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	74	NICE check scope	Drugs	44		Should there be reference to previous NICE documents on drugs for the treatment of obesity?	Clarification on the status of previous NICE guidance has been added.
British Dietetic Association Reviewers: Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	75		Drugs	46	1.2.5.15	Sibutramine is contra-indicated in mental illness	We have recommended that prescribers should refer to the summary of product characteristics for details when prescribing.
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in	76		Misc	47	1.2.6. 1	Needs to link with point above re VLCDs, making it clear that under specialist supervision only, whereas, MR can be safely used in community settings, with proper support. We need to be able to offer alternatives that work, to those who struggle with conventional low calorie	These recommendations have been revised in light of this and other comments.

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Obesity Management BDA Specialist Group (DOM UK)						diets NB: No emphasis is placed on the importance of nutritionally adequate diets esp with vulnerable groups & those with special dietary needs.	
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	79	NICE	CP	74	Clinical care pathway	Under assessment should include mental illness in addition to psychological problems	We consider that 'psychological problems' allows for mental health problems/illness to be considered.
British Dietetic Association <b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)	85	Full	Lifestyle	5b		As far as can be seen the difference between VLCDs (800 kcals or less) & Meal replacements (1200 – 1400 kcals) is not clarified. They seem to be treated as the same, which they are not. Heymsfield SB et al. International Journal of Obesity, 2003, 27(5): 537-49) meta analysis of meal replacements is not included in the evidence and the section in the full guidance relating to this has only cited 2 studies. We are concerned that PSMF diets are being advocated without sufficient evidence to support their use in clinical practice.	Noted; the recommendations and statements have been revised to clarify.
British Dietetic Association	86	Full	Lifestyle	5b		Not sure why there is such emphasis on PSMF diets – will this mean	We have clarified the recommendations and the

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<b>Reviewers:</b> Registered Dietitians of the BDA including Dietitians Working in Obesity Management BDA Specialist Group (DOM UK)						anything to most practitioners? And where is the supporting evidence? I think this section is very confusing.	reviews in light of this and other comments to address your concern.
British Geriatrics Society - Gastroenterology and Nutrition Special Interest Group	2		Surgery			2. I was astonished that the guidelines did not mention anything on the growing and successful method of treating obesity with Intra Gastric Balloon. This is currently used widely and successfully in Europe particularly Italy and the Netherlands as well as in America. There is a relatively new device which is being used and there has been several publications on thousands of patients with extremely little complications. It is also being used in certain parts of England such as London and Manchester.	It was advised that this is a short term intervention, and should therefore be outside the scope of the guideline.
British Geriatrics Society - Gastroenterology and Nutrition Special Interest Group	3		Surgery			3. The draft guidelines also did not mention the procedures of Gastric Pacing or Botox Injection of the stomach and their effect on weight loss. The draft guidelines also did not mention the procedures of Gastric Pacing or Botox Injection of the stomach and their effect on weight loss	The GDG considered that these were not appropriate interventions to be included in the updated surgery reviews.
British Geriatrics	1		Drugs			1. The draft guidelines have stated	No evidence matching our



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Society – Gastro-enterology and Nutrition Special Interest Group						<p>in the section of pharmacotherapy on both Orlistat as well as on Sibutramine, that the guidelines do not recommend using them in combination. I totally disagree with these statements and would like to make the following points:-</p> <p>(a) There is no scientific evidence that combining them can cause any harm to patients. As a matter of fact we are dealing with completely different class of therapy which act on completely different modality. I sincerely hope that this is not a cost driven statement!</p> <p>(b) This combination is being used in very selective patients who are morbidly obese and cannot have surgery in many obesity centres in North America and Europe as well as in a few patients attending our Blaenau Gwent Specialist Weight Management Clinic with success. This combination therefore can be adjuvant in carefully selected subjects.</p> <p>(c) I think combining the two drugs should only be done on the advice of a specialist obesity consultant.</p>	inclusion criteria was found that evaluated the effect of sibutramine and orlistat in combination.
British Heart Foundation	21	NICE version	Ident	35		Guidance on the measurement and classification of obesity should be stated earlier on in the document.	The recommendations do allow for both BMI and waist to be used in the assessment process.

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						<p>The BHF thinks that both body mass index and waist circumference should be considered and available to use as a measure.</p> <p>We would also like to note that the term 'obesity' is often rejected by patients which may make the guidance inaccessible for some people. We suggest it would be useful to acknowledge this and explain the reason the term is used throughout the document.</p>	<p>This document is evidence-based and therefore reflects terminology that is used in medical and social science literature. We do appreciate that it is a term that may have negative connotations for patients, and have highlighted this issue in the 'Patient-centred care' section.</p>
British Heart Foundation	22	NICE version	Ident	37		We would suggest that these charts are confusing in tabular form.	Noted, and we have asked for editorial input.
British Heart Foundation	23	NICE version	Lifestyle	42		The BHF would advise that adults needing to lose weight do at least 45-60 minutes physical activity on 6 or more days of the week, not 30 minutes.	Noted and revised – thank you.
British Heart Foundation	24	NICE version	Misc	47		We would like to stress that if a referrals to paediatricians or specialists are to be made on a large scale, adequate resources must be available to cope with demand.	We acknowledge that there is concern In regard to these matters, but detailed funding and service issues are outside the remit of NICE. Costing tools are currently being developed to aid the implementation of the guidance (see section 3 of the NICE version).
British Heart Foundation National Centre for Physical Activity & Health	8	NICE version	PCC	6	4/5	Respect individual's decision.	We have made a recommendation about what should be done when people are not able/willing to make changes.

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British Heart Foundation National Centre for Physical Activity & Health	9	NICE version	Misc	7	10	Vague – Primary Care needs more help with this – what kind/type of systems – what has worked? Case studies would be useful	The specifics of implementation are outside the remit of this work. NICE guidance does not include individual case studies or examples of best practice, but these may be contained in websites and documents reference d within the guidance (see appendix D in particular). Implementation tools are currently being developed – see section 3 of the NICE version for further information.
British Heart Foundation National Centre for Physical Activity & Health	17	NICE version	CP	9	6	Vague – what kind of behavioural treatments? What does the evidence say are the most effective interventions for physical activity? We know brief interventions work but professionals need training/skills and time to deliver these.	Please see recommendations for details.
British Heart Foundation National Centre for Physical Activity & Health	18	NICE version	CP	9	10	Agree, but how is this going to happen? – need specifics	Have added in as much detail as we consider appropriate. Also see Implementation section.
British Heart Foundation National Centre for Physical Activity & Health	19	NICE version	CP	9	21	Be consistent with message – exercise and/or physical activity have different meanings to people. One is seen as more structured and perhaps less achievable.	We have ensured that our messages are consistent throughout the document.
British Heart Foundation National Centre for Physical Activity & Health	20	NICE version	CP	9	26/27	Healthcare professionals need training to offer support and counselling for diet, physical activity and behavioural strategies – who is going to deliver/fund this training?	We have added an additional section on training to both versions, based on information already included throughout the guidance. The specifics of

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							implementation – including local training needs and the skill mix required – are outside the remit of this work. The guidance allows local providers to interpret and implement the guidance as appropriate to their situation. However, a number of recommendations highlight the type of skills that should be acquired by staff, as appropriate.
British Heart Foundation National Centre for Physical Activity & Health	21	NICE version	CP	10	2/3	Following surgery people need support to make long term changes in lifestyle, diet and physical activity.	See recommendations for details.
British Heart Foundation National Centre for Physical Activity & Health	56	NICE version	Assess	37	12– 4	This is fine but there needs to be some back-up to support individuals in making changes – systems need to be in place before assessments are undertaken.	Noted and revised where appropriate in the recommendations.
British Heart Foundation National Centre for Physical Activity & Health	57	NICE version	Lifestyle	39	13 – 17	Any care needs to be provided in a non-judgmental directive way – patient needs to feel in control of solutions.	We have revised the ‘Patient-centred care’ section to clarify the rights of the patient to accept/refuse care.
British Heart Foundation National Centre for Physical Activity & Health	58	NICE version	Lifestyle	39	21/22	What is meant by ‘some component of behaviour change’. More detail needed.	This is referenced to check further details on the section on ‘Behavioural interventions’.
British Heart Foundation National Centre for Physical	59	NICE version	Lifestyle	40	8/9	Who is going to provide funding for this training? Need quality assurance re. appropriate training.	National and local funding issues are outside the remit of NICE. However, audit tools are currently being developed to aid the

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Activity & Health							implementation of the guidance (see section 3 of the NICE version).
British Heart Foundation National Centre for Physical Activity & Health	60	NICE version	Lifestyle	42	4–24	Very narrow range of activities, leaves out a lot of informal types of activity.	We have taken these activities from the CMO report, and strengthened the choice of the individual as to the most appropriate/convenient/sustainable activity to be undertaken.
British Heart Foundation National Centre for Physical Activity & Health	61	NICE version	Misc	48	16 – 18	Intensive management in a specialist obesity service is a sound idea, however there is still no sign of such services being developed widespread. Who is responsible for funding/providing these services?	National and local funding issues are outside the remit of NICE. However, costing tools are currently being developed to aid the implementation of the guidance (see section 3 of the NICE version).
British Heart Foundation National Centre for Physical Activity & Health	62	NICE version	Misc	51	25	Struggle to see evidence of how 'raising awareness' has been addressed in this guidance . Provided little detail of how this has been done effectively or how it could be done in the future.	A rigorous evidence review was undertaken to consider the effectiveness of interventions to raise awareness – please see chapter 7 for evidence statements and methodology. All available evidence which met the agreed review parameters would have been included if available. The GDG were careful not to develop recommendations which overstep the evidence base. In this instance, the evidence considered does not allow the provision of more specific guidance on these issues.
British Obesity Surgery Patient	1	NICE version	Surgery	48/49		We recommend that all patients considering surgery should have	Noted and revised.

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Association						access to a patient support group where they can meet other patients who have already had the surgery – this enables them to understand the changes that surgery will make to their lives.	
British Obesity Surgery society, Dieticians group	3	Full	Surgery	485	12	Vertical gastric banding should read vertical banded gastroplasty (VGB)	Amended.
British Obesity Surgery society, Dieticians group	4	Full	Surgery	485	13	Should Biliopancreatic diversion and duodenal switch be included?	Amended.
British Obesity Surgery society, Dieticians group	5	Full	Surgery	485	19	VGB should read VBG	Amended.
British Obesity Surgery society, Dieticians group	6	Full	Surgery	485	21	Gastric banding should read gastric bypass	Amended.
British Obesity Surgery society, Dieticians group	7	Full	Surgery	485	22	Should the end of the sentence read 'reduces the absorption of nutrients'	Amended.
British Obesity Surgery society, Dieticians group	8	Full	Misc	483	20	What is the meaning of serious obesity-related comorbidities? Type 2 diabetes, CVD? Do these need defining as this could be open to interpretation.	Have added common comorbidities, but healthcare professionals should use clinical judgement to assess the most relevant.
British Obesity Surgery society, Dieticians group	9	Full	Surgery	627	13	VGB should read VBG	Amended.
British Obesity Surgery society, Dieticians group	10	Full	Surgery	627	16	Gastric banding should read gastric bypass and mainly restricts 'dietary' intake	Amended.
British Obesity Surgery society,	11	Full	Surgery	645	21	Should state 'registered dietitians'	Amended.

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Dieticians group							
British Obesity Surgery society, Dieticians group	12	Full	Surgery	645	23	Surgeons should be bariatric surgeons	Amended.
British Obesity Surgery society, Dieticians group	13	Full	Surgery	487	17	Should laparotomic read laparoscopic?	Amended.
British Obesity Surgery society, Dieticians group	14	Full	Surgery	General		As a specialist dietitian in bariatric surgery, I feel that there should be some references to the importance of regular post operative dietetic monitoring by a specialist registered dietitian in bariatric surgery, who is able to monitor and advise regarding the appropriate diet depending upon the bariatric procedure and monitor the patients micronutrient status, provide appropriate individualised nutritional supplementation, support and guidance to achieve long term successful weight loss and weight maintenance. References could be provided regarding evidence for nutritional deficiencies following bariatric surgery.	Noted and revised.
British Obesity Surgery Society, Patient Association	2	NICE version	Surgery	51	1.2.7.12	The surgeon and multidisciplinary team should also have access to a patient support group to provide post-op support and education to patients. BOSPA is willing and able to assist surgical teams with the establishment of these groups.	Noted and revised.
Cambridge Manufacturing Co Ltd	1	NICE	Lifestyle	General		'Dietary advice' throughout the document should clearly identify formula food options with the addition	We have considered the issue of meal replacements at length. We consider that the use of meal

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						of '..... and other formula food dietary options.'	replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.
Cambridge Manufacturing Co Ltd	2	NICE	Drugs	Page 9		<p>Adults:</p> <p>The use of LCD/VLCD programmes should also be considered before recommending pharmacological treatment.</p> <p>Suggest expanded wording such as '...only after dietary and exercise has been initiated and the appropriate use of LCD/VLCD programmes has been assessed'.</p> <p>(Ref: Capstick, F et al. VLCD: A useful alternative in the treatment of the obese NIDDM patient. Diabetes Res Clin Pract 1997: 36: 105-11)</p>	We have recommended that appropriate dietary, activity, and behavioural approaches should be tried before drug treatment is initiated and continued during drug treatment. This therefore allows the choice of dietary intervention to be determined by the healthcare professional and the patient.
Cambridge Manufacturing Co Ltd	3	NICE	Lifestyle	Page 33	1.1.7.5	<p>The wording in paragraph 1.1.7.5 relating to maximum weekly weight loss as one of the best practice criteria conflicts with p.43 (1.2.4.17) which refers to the use of VLCD for short term use, and which will inevitably lead to weight loss greater than kg/wk. Suggest amended wording as follows:</p> <p><i>'..... and expect to produce a weekly weight loss of more than 0.5- 1 kg (1- 2 lb) are not <b>normally</b> recommended,</i></p>	Noted but not amended. The current wording is appropriate for a recommendation to the public and reflects the BDA best practice.



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						<p><i>although for those who are obese a rate of weight loss greater than 1kg/wk in the early stages of dieting through the use of a nutritionally balanced and complete VLCD programme may also be compatible with good medical and nutritional practice.</i></p> <p>(NB: this wording is taken from the British Code of Advertising, Sales Promotion and Direct Marketing which itself was based on advice from the Association for the Study of Obesity (ASO).</p>	
Cambridge Manufacturing Co Ltd	5	NICE version	Drugs	Page 44	1.2.5.2	<p>The use of LCD/VLCD programmes should also be considered before recommending pharmacological interventions.</p> <p>Suggest extended wording in 1.2.5.2:</p> <p>'..... has been initiated. Evidence based research has established that the use of LCD/VLCD programmes can reduce or remove the need for medication for co-conditions to obesity and thus the need for pharmacological treatment for obesity'</p> <p>(Ref: The Re-Shape Study: The effectiveness of a commercial weight loss programme compared to usual care as delivered in a primary care environment. University of Teesside</p>	<p>We have recommended that appropriate dietary, activity, and behavioural approaches should be tried before drug treatment is initiated and continued during drug treatment. This allows the choice of dietary intervention to be determined by the healthcare professional and the patient.</p>

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						<p>School of Health &amp; Social Care 2004-5. Submitted to IJO)</p> <p>(Ref: 12 Month Interim Audit of the Cambridge Diet Program for Patients with Diabetes. Mid-Staffordshire General Hospitals NHS Trust Clinical Audit Department.)</p>	
Cambridge Manufacturing Co Ltd	6	NICE version	Misc	Page 47	1.2.6.1	<p>Paragraph 1.2.6.1 implies that a VLCD programme is an intervention at secondary or specialist care level and could be misleading. Whilst this can of course be the case, VLCD is also an option in appropriate circumstances before pharmacological or surgical options are considered, and can reduce or remove the need for such interventions (see p 43, 1.2.4.17)</p>	<p>These recommendations have been revised in light of this and other comments as appropriate.</p>
Cambridge Manufacturing Co Ltd	7	NICE version	CP	Page 74		<p>Clinical Care Pathway</p> <p>The management of overweight and obesity should also list formula LCD/VLCD programmes as an option.</p> <p>Suggest <i>Management</i> box is amended as follows:</p> <p><i>Intensity of management will depend on level of risk*, and may include</i></p> <ul style="list-style-type: none"> <li>- <i>diet</i></li> <li>- <i>physical activity</i></li> <li>- <i>behavioural interventions</i></li> <li>- <i>formula LCD/VLCD programmes</i></li> </ul>	<p>We consider that the wording is appropriate, and details of recommended dietary approaches can be found in the recommendations.</p>

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						<ul style="list-style-type: none"> <li>- <i>drug therapy</i></li> <li>- <i>surgery</i></li> </ul> <p><i>Weight loss goals should be agreed with the individual.</i></p>	
Cambridge Manufacturing Co Ltd	10	Full version	Lifestyle	Section 5b - pages 510-686		<p>The following papers should be considered when assessing appropriate intervention options for overweight and obesity:</p> <p><b>VLCD: a useful alternative in the treatment of the obese NDDIM patient</b> Capstick, F et al. Diabetes Res Clin Pract 1997; 36:105-111</p> <p>Conclusion:</p> <p>The short term use of a VLCD is very effective in rapidly improving glycaemic control and promoting substantial weight loss in obese patients with Type 2 diabetes. Moreover, a VLCD increases insulin secretion and reduces substrate for glyconeogenesis. This VLCD treatment may improve glycaemic control by factors more than calorific restriction alone.</p> <p><b>Very Low Energy Diets in the Treatment of Obesity</b> Mustajoki &amp; Pekkarinen, Peijas Hospital, Dept Medicine, Vantaa, Finland, Obesity Reviews 2001</p>	Noted; we have clarified our recommendations and statements on the use of VLCDs.

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						<p>Conclusion: VLEDs accomplish maximum initial weight loss and can be conducted safely in patients with obesity related diseases – diabetes, hypertension or other chronic diseases.</p> <p><b>Long Term Efficacy of Dietary Treatment of Obesity: A systematic review of studies published between 1931 and 1999</b></p> <p>Ayyad &amp; Anderson, Roskile County Hospital, Denmark</p> <p>Conclusion: VLCD was most efficacious if combined with behaviour modification and active follow-up. The literature on long-term follow-up of dietary treatment of obesity points to an overall median success rate of 15% and a possible adjuvant effect of group therapy, behaviour modification and active follow-up.</p> <p><b>Efficacy of Very Low Energy Diets and Meal Replacements in the Treatment of Obesity</b></p> <p>Jebb &amp; Goldberg. RC Dunn Clinical Nutrition Centre, Cambridge. J Human Nutrition &amp; Dietetics 1998</p> <p>Conclusion: VLEDs are a proven success in</p>	

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						<p>achieving significant short term reduction in body weight. There is evidence to suggest that meal replacements may make a contribution to the maintenance of weight loss in some individuals.</p> <p><b>Lessons from obesity management programmes: greater initial weight loss improves long term maintenance.</b></p> <p>Astrup &amp; Rossner. Obesity Reviews 2000</p> <p>Conclusion:</p> <p>Greater initial weight loss as the first step of weight management may result in improved weight maintenance.</p> <p><b>Very Low Calorie Diets and Sustained Weight loss</b></p> <p>Saris, Maastricht University. Obesity Research 9, Supp 4 Nov 2001</p> <p>Conclusion:</p> <p>VLCD with active follow-up treatment seems to be one of the better treatment</p> <p>Modalities related to long term weight maintenance success.</p> <p><b>An eight-year experience with very low calorie formula diet for control</b></p>	

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						<p><b>of major obesity.</b></p> <p>Kirschner et al. Newark Beth Israel Medical Centre, New Jersey. IJO 1988 12(1) pp 69-80</p> <p>Conclusion:</p> <p>Our 8-year experience strongly suggests that the VLCD approach using high quality protein supplement and multi-disciplinary counselling provides a reasonable success rate for achieving and maintaining weight loss in the morbidly obese population.</p> <p><b>Long term weight loss maintenance: a meta-analysis of US studies</b></p> <p>Anderson et al. American Society for Clinical Nutrition, 2001</p> <p>Conclusion</p> <p>Five years after completing structured weight-loss programme, the average individual maintained a weight loss of more than 3kg and a reduced weight of more than 3% of initial body weight. After VLEDs, or weight loss of more than 20kg, individuals maintained significantly more weight loss than after HBDs or weight losses of less than 10kg.</p>	
Child Growth Foundation and the National	1		Ident			The Child Growth Foundation, a co-opted member on in the NICE/Obesity GDG [Clinical Management], must	Thank you for your comments. We have made changes as appropriate, in line with these and

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Obesity Forum						take issue with several sections of the Draft for First Consultation {DfFC} as it relates to children. GDG should also consider this response as coming also from the National Obesity Forum on whose Board the Foundation is represented to oversee child obesity issues.	other comments.
Child Growth Foundation and the National Obesity Forum	2		Ident			We would both be particularly concerned with pages 189 197, “ 5.1.4 Evidence review on the classification of overweight and obesity “, and pages 216- 222, “ 5.2.1 Existing guidance and recommendations “ but there are other issues which we have addressed.	Thank you for your comments.
Child Growth Foundation and the National Obesity Forum	3		Ident	Pages 189 197 “5.1.4 Evidence review of the classification of overweight and obesity”		The Foundation/NOF deeply regrets that NICE is considering offering no guidance as to which of the 3 classifications of overweight/obesity currently in circulation the UK should adopt. The latest “ guidance “ on the subject, the 2 Department of Health [DH] booklets “Measuring Childhood Obesity: Guidance to PCTs ” [DH, Part 1, January & Part 2, May 2006], offer no guidance at all and virtually allow PCTs to pick whichever classification happens to suit them! The Foundation/NOF believes that it is not alone in expecting the DfFC to put an end to this nonsense and opt for a single measure. It has not done this. It has simply regurgitated the trio	The GDG did not consider that, in light of the available evidence, we could confidently support one sole definition of childhood overweight/obesity.  The GDG recommended that ‘Pragmatic indicators for action are the 91st and 98th centiles from the 1990 UK BMI charts.’

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						<p>listed by the DH and, in policy terms, no-one is any the wiser. We trust that the GDG will rectify this outstanding issue by November. [1]</p> <p>At a workshop hosted by the Foundation in June 2005, “ Annual BMI Checks in Schools “, and staged principally for the benefit of the DH and DfES, a DH representative announced that Ministers had chosen the 85<sup>th</sup>/95<sup>th</sup> centile classifications and that the decision was “ non negotiable “. The announcement was received with frank amazement by the workshop audience which subsequently voted that the 91<sup>st</sup>/98<sup>th</sup> classification should be the only one sanctioned [voting: 80% = 91<sup>st</sup>/98<sup>th</sup>, 10%= 85<sup>th</sup>/95<sup>th</sup>, 10% =IOTF]. Furthermore, the representatives from both Departments were emphatically told by leading clinical and public health doctors that to have more than one definition would be a hostage to fortune. NICE cannot ignore this warning and merely mouth what DH has decided.</p> <p>If GDG really does believe that the DH has got it right and that the classification should be “ obese above the 95<sup>th</sup> centile “ [see page 139 line 25 and elsewhere], so be it. GDG must realise however that by adopting</p>	



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						<p>the 85<sup>th</sup>/95<sup>th</sup> classification it will effectively increase percentage of UK children who are overweight/obese and will be advocating a h the GDG should be aware if/when it reviews Parts 1 &amp; 2 prior to issuing its final guidance in November. One of January's errors was mercifully corrected in the May publication but should never have been perpetratedclassification which does not even appear on the current UK paediatric " reference " BMI charts.</p> <p>[1] In the Foundation/NOF's opinion " Measuring Childhood Obesity " [MCO] has a number of other errors of which in the first place. MCO allowed its readers to believe that height measurements taken at school could be inaccurate and acceptable! By advising that data could be " rounded up or down to the nearest half-centimetre " [as opposed to being recorded to the last completed millimetre] it permitted 80% of UK children to be recorded as being taller or shorter than they really are!</p> <p>Other errors have yet to be redressed. An example is that MCO " discouraged " PCTs from informing parents/children what the school measurements actually were and thereby probably infringed the</p>	

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						<p>Freedom of Information Act. Amazingly, the MCO readily admits that parents have a right to know - but tries to put every obstacle in their way from obtaining the information.</p> <p>Further errors in the document need not be itemised here. Suffice it to say that " Measuring Childhood Obesity " does not deliver what it promises on its title page – i.e how to measure the height and weight of children between 4 and 11yrs. It is, all told, a bit of a dog's breakfast.</p>	
Child Growth Foundation and the National Obesity Forum	4		Ident	216– 222 "5.2.1 Existing guidance and recs"		<p>DfFC is quite inaccurate when stating that to state that there is no consensus on whether to regularly monitor or screen BMI, particularly in children. There is. " Health For All Children " [HFAC] {OUP January 2003} – the UK " bible " of child health care - states that a single, universal screen of children's height and weight at primary school entry should be undertaken and recommends that a BMI calculation for public health purposes is then put in hand. The " National Service Framework for Children [NSF/C] " {DH January 2005} repeats this recommendation and MCO stipulates that not only should growth be assessed in the Reception Yr but also should be repeated in Yr</p>	<p>Noted.</p> <p>Other issues:</p> <p>Second point. This is part of the evidence review, but the recommendation does support the use of the 1990 UK chart alone.</p> <p>This has been considered by the GDG and they are happy with the current recommendations.</p> <p>A link for the National Service Framework for Children (NSF/C) will be inserted.</p>

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						<p>6. The Foundation/NOF appreciates that the latter directive was published too late to feature in DfFC and trusts that GDG will highlight it in November. [2-3].</p> <p>The Foundation touched on the need that GDG recommended serial measurements when responding to its January 2006 draft recommendations document. We stated on Feb 7<sup>th</sup> that we fundamentally rejected the proposal that " health practitioners should use their clinical judgment to determine whether measuring the height and weight of an individual is appropriate ". They have been allowed to do just that since HFAC was first published in 1989 and its outcome is that the UK has such an overweight/obese problem today. Since no-one was advised to periodically assess children's growth, the yearly insidious rise of their unhealthy weight passed unnoticed. Even when the CMO in his 2002 Annual Report recommended action to pick up the early signs of obesity, no action was taken.</p> <p>Having now reviewed the DfFC, we are even more of the opinion that growth assessment at specific ages must be recommended. The House of Commons Select Health</p>	

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						<p>Committee advised HMG in May 2004 that the height and weight of every child should be measured every year in primary school and we are highly critical of the DH for dismissing that advice and whittling down the recommendation to only two occasions. Even the policy in Scotland to measure three times in primary school is not enough. The Foundation/NOF finds it somewhat ironic that Professor Sir David Hall, former President of the Royal College of Paediatrics &amp; Child Health [RCPCH] and principal author of HFAC, has amended his view from a single screen in Reception Year to three screens during a child's school career: he suggests that it would probably be [more] useful in formulating and monitoring local public health policy [Archives of Disease in Childhood 2006:91:283-286]!.</p> <p>HFAC and NSF/C both failed children by not addressing the need to measure height and weight pre-school years and the Foundation/NOF welcomes the DfFC's remit being extended to include 2yr old children. We believe, however, that it is vital to check BMI from infancy and would like to see GDG push the boundaries back even earlier in the child's life.</p>	

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						<p>Firstly, a BMI taken at approximately at 1yr will facilitate the RCPCH desire that children with severe and progressive obesity be referred to a paediatrician before age 2. Secondly, it would check that children were not progressively putting on larger than expected weight and were "growing into their weight" and, thirdly, we consider that BMI should be a feature of the infancy Life-Check [MoT]. This MoT was advocated in the White Paper "Our Health, Our Choice, Our Say" and though the DH was not explicit about the exact age at which it should be carried out, we believe it should be at approximately 1yr.</p> <p>[2] The Foundation/NOF are surprised that we cannot find any reference to HFAC in DfFC. We apologise of this is an oversight on our part. Although HFAC is now largely out-of-date in its coverage of growth assessment/obesity it should not be entirely forgotten</p> <p>[3] The Foundation/NOF cannot believe DfFC also omitted to list the NSF/C together with the other National Frameworks itemised [pages 188/9]. This is particularly surprising since NSF/C has, in essence, replaced HFAC.</p>	

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						<p>Neither can the Foundation/NOF understand why DfFC ignores the periodic monitoring of weight status recommended by so many non-UK based authorities, notably by two senior USA medical bodies, the AAP and the Institute of Medicine [Washington DC]. Their recommendations cannot be dismissed simply as “ no clear link to evidence or low quality: expert opinion “: The Foundation/NOF would remind GDG that Derek Wanless, whilst agreeing that interventions should be evidence-based, stated that “ the lack of conclusive evidence should not, where there is serious risk to the nation’s health, block action proportionate to that risk “ [Securing Good Health for the Whole Population, February 2004]. Childhood obesity is a serious risk to the nation’s health.</p> <p>OTHER ISSUES p134 lines 12-14 HMG TARGET</p> <p>Whether GDG deliberately omitted the “ target year “ in a gesture of goodwill to HMG, the omission of “ by 2010 “ stands out a mile. GDG will know how fatuous it was THAT HMG</p>	

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						<p>set 2010 as being the year by which the year-on-year rise of obesity in children under-11yrs could be halted. The date should be included as a statement of fact</p> <p>p 193 line 23 – p 194 line 3 These lines need to be re-written to state that the only UK 1990 chart used to assess the overweight or obesity of a child should be the 1990 BMI chart. The remainder of this section is superfluous.</p> <p>p 219 lines 13-14 Cost data for measurement for recording height/weight is, in fact, written up and will be published in the Autumn. An NHS Health Technology Assessment [HTA] research study undertaken by the Centre for Reviews and Dissemination, University of York has clearly indicated the potential utility and cost-effectiveness of growth monitoring. It indicates that more research is needed on its impact for obesity and the HTA has that in hand.</p>	
Child Growth Foundation and the National Obesity Forum	6		Ident			<p>AUDIT</p> <p>Both the Foundation/NOF recognise that the use of BMI as an audit tool may not have been within NICE's scope but we would like to emphasise that the periodic assessment of BMI to identify overweight/obesity etc is</p>	Noted. We accept these views; however, we consider that periodic BMI assessments constitute screening and are therefore outside our remit.

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						also, by definition, an audit. It would be foolhardy for any initiative to halt or manage obesity to go unchecked and periodic BMI assessments would be the simplest form of establishing whether or not the initiatives have borne. It has been put to the Foundation that the assessment of obesity is the touchstone for a National Health Intelligence Strategy.	
Child Growth Foundation and the National Obesity Forum	7		Ident			<p>BMI ON HOSPITALISATION</p> <p>In view of NICE's February 2006 guideline re malnutrition [and overfeeding is very much a form of malnutrition], the Foundation/NOF wonders why it appears from the DfFC that a BMI has also not been considered as an opportunistic measure at all hospital in-patient and first clinic appointments. This is already practised in many hospitals and should be rolled out nationally.</p>	We have revised our guidance and the GDG has decided to withdraw the recommendation that referred to opportunistic measuring as it is outside our remit to provide guidance on population-based screening.



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Child Growth Foundation and the National Obesity Forum	8		Ident			<p>.....AND, FINALLY: CHILDREN'S BMI/WAIST CIRCUMFERENCE CHARTS</p> <p>The Foundation/NOF would like the GDG to consider illustrating its final Guidance with a paediatric BMI chart or two. We believe that an illustration showing the distinctive pattern of children's BMI wouldn't come amiss as the reader ploughs through the complexities of its variations throughout childhood. As the charts' copyright holder, the Foundation would of course make reproduction free of charge!</p>	The GDG considered it inappropriate to insert paediatric BMI charts into the guidance.
Child Growth Foundation and the National Obesity Forum.	5		Misc	pp 469 – 508 BARIATRIC SURGERY AND DRUG THERAPY		<p>This response needs but a couple of paragraphs to congratulate GDG for recommending that both pharmaceutical and surgical intervention did have a place in the treatment of children who were so overweight that no other treatment might be successful. We would prefer that a specific age [e.g 12 yrs] was struck from GDG advice and that it made clear that no child should be considered for surgery until its growth had been completed. It seems to the Foundation/NOF to be good common sense that an 11yr old who has completed his/her growth and is morbidly obese should not have to wait until technically an adult [16 yrs] before receiving surgery.</p>	Thank you for your comments on the guidance. No specific age as a requisite for surgery has been proposed. Thus, the recommendation has been worded to stress that young people being considered for surgery should have reached or nearly reached physiological maturity.

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						<p>As far as pharmaceutical products are concerned we feel that treatment may well be warranted even if absolute final stature has not been achieved. Having taken advice from all of the family's medical specialists there could well be a trade-off between receiving orlistat or sibutramine and losing a centimetre or two of final height and not continuing being unhealthily fat.</p> <p>The Foundation/NOF is fully satisfied that GDG has listed all the rigorous conditions that must be complied with for either kind of treatment.</p>	
College of Occupational Therapists	3	NICE	Lifestyle		1.2.4.12	Include options for people with disabilities and wheelchair users	Noted and revised.
Community Practitioners and Health Visitors Association	2		PCC	5		Should it be patient centred with 50% population involved? Better not to use term patients. Part of medicalising people rather than addressing socio cultural issues. Suggest use term, people or clients medicalising people rather than addressing socio cultural issues. Suggest use term, people or clients	Noted and revised.
Community Practitioners and Health Visitors Association	3		PCC	5		Certain ethnic backgrounds may have different views about acceptability and even desirability of being large	Noted and revised.
Community Practitioners and	4		PCC	5		Suggest wording interventions rather than treatments	Noted and revised.

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Health Visitors Association							
Community Practitioners and Health Visitors Association	5		Misc		20	Issue of medicalising obesity/overweight	We have tried to use appropriate wording and approaches so not as to medical obesity or overweight.
Community Practitioners and Health Visitors Association	10		Misc	15/16	1.1.2	Important to have 'whole organisation approach' so also role of clinic assistants, nursery nurses, health care workers	Noted and joint working has been stressed throughout.
Community Practitioners and Health Visitors Association	14		Ident	35	1.2.2.8	<p>Sound communication and interpersonal skills are required by all health professionals working with those who are overweight/obese.</p> <p>This will be particularly the case for those working with groups where different definitions of overweight/obese (e.g. Asians), are in use, to avoid the perception of racism.</p>	This is reflected both in the Generic Principles of Care (1.2.1) and in the 'Patient centred care' section.
Department of Health (DH), Department for Education and Skills (DfES), and Department for Culture, Media and Sport (DCMS)	2	NICE/Full	Ident	General		<p><b>Measurement:</b></p> <p>The guidance states that "routine measurement of height and weight is not recommended for adults", and that "health care practitioners should use their clinical judgement to determine whether measuring the height and weight of an individual is appropriate" (draft recommendations 1.2.2.1 and 1.2.2.2).</p> <p>Under research recommendations,</p>	This section has been revised in light of this and other comments.

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						<p>NICE states further in relation to population trends in obesity and overweight, that "the continued, frequent, collection of detailed data on the prevalence of obesity at a national and regional level is strongly recommended" (section 4.2, pages 57 - 58).</p> <p>WE consider that the first two of these recommendations could be seen as contradictory to the requirements on the NHS to monitor performance on obesity, and would therefore be confusing to the NHS. Under current NHS performance management arrangements, all primary care trusts in England are required to submit NHS Local Delivery Plan (LDP) performance monitoring data on the obesity status of GP registered adults. The requirement to return LDP monitoring data on obesity was introduced by the Department of Health in 2005/06, with baseline data returned for the first time in March 2005.</p> <p>The two clinical recommendations on measurement of height and weight in adults appear to concern good practice in case identification at the individual level, rather than NHS</p>	

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						<p>performance monitoring or population prevalence monitoring. In reality, we believe that these clinical good practice recommendations should support rather than conflict with the requirement on the NHS to return LDP performance monitoring data on adult obesity status. We would appreciate it if consideration were given to clarifying the meaning of these recommendations by locating them in their proper policy context, and by clarifying the different purposes of measurement of obesity.</p> <p>In particular, we think it would be helpful to explain that the purpose of obesity measurement for the clinician is quite distinct from wider NHS performance management or strategic service planning purposes. We also suggest that NICE could consider reframing the recommendation in terms such as the following: "Periodic screening of height and weight is not recommended".</p> <p>These general points are further elaborated below.</p> <p>Tackling obesity is a key national priority of the White Paper "Choosing</p>	

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						<p>Health: making healthy choices easier". This is supported by the recommendations of the National Service Frameworks for Coronary Heart Disease and Diabetes, which recommend identification of those who are overweight in order to reduce the prevalence of coronary heart disease and diabetes and provide appropriate clinical interventions.</p> <p>The Quality and Outcomes Framework (QOF) and the National Service Frameworks (NSFs) for Coronary Heart Disease and Diabetes set out clear rationales for identifying obese individuals based on the increased risks of poor clinical outcomes including heart disease and diabetes.</p> <p>The draft recommendations on routine measurement of height and weight in adults concerns opportunistic identification of obesity in clinical settings. These recommendations do not appear to be balanced by other reasons for routine measurement of obesity, such as the wider public health population monitoring or the NHS performance management perspective, or management of chronic conditions,</p>	

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						<p>such as diabetes.</p> <p>The draft NICE guidance could be interpreted as precluding routine body mass index (BMI) measurement of individuals who might be eligible for entry on these registers. As it stands, this may therefore have implications for the implementation of national policy and the ability of health services to identify at risk individuals for the purposes of offering interventions / improving public health. Reliable local health information is needed by primary care trusts (PCTs) and local authorities to identify the needs and choices of communities and to monitor the impact of interventions. High quality local information is also needed so that services can accurately target diverse local communities.</p> <p>To support this, PCTs are required to submit local delivery plans to strategic health authorities (SHAs) as part of the 3-year planning cycle, showing the number of adults on the General Practice register, recorded as having BMI of 30 or greater in the last 15 months. PCTs are held to account for delivery of this as part of the Healthcare Commission's annual</p>	

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						<p>health check.</p> <p>It is the Department of Health's view that the NICE recommendation may be interpreted as conflicting with the requirements on the NHS to return Local Delivery Plan (LDP) monitoring data. It would also appear to conflict with the incentives included in the new Quality and Outcomes Framework (QOF) which, in line with policy, recommends development of registers of those with a BMI of 30 or over with measurement in a 15 month period.</p> <p>These recommendations are necessary in order to trigger early interventions, prevent complications and allow service planning / monitoring. Periodic height and weight assessment is necessary in order to populate these registers. The Quality and Outcomes Framework (QOF) envisages that the register will be populated by those identified as obese as part of <u>routine</u> care, but does not require screening.</p> <p>It would be helpful if the wording of the guidance were reviewed. It would be helpful if the guidance clarified what "routine versus periodic "</p>	



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						<p>measurement means. In particular, does the recommendation conflict with QOF and LDP measures that look at the number of adults on the GP register, recorded as having BMI of 30 or greater <u>in the last 15 months</u>, and if so, what would be considered appropriate?</p> <p>Under research recommendations, at Section 4.2, the draft guidance states that “the continued, frequent, collection of detailed data on the prevalence of obesity at a national and regional level is strongly recommended”, and that “All local action ... should be monitored and evaluated with the potential impact on health in mind.”</p> <p>The apparent discrepancy between the clinical recommendation on routine measurement of height and weight, and the research recommendation on population monitoring, could lead to confusion at local level, where approaches to obesity measurement and monitoring are still relatively under-developed.</p>	
Department of Health (DH), Department for Education and Skills (DfES), and	4	NICE/Full	Misc	General		<p>Prioritisation:</p> <p>Although the recommendations are graded in terms of the supporting evidence, we would appreciate it if</p>	We have listed key priorities for Implementation in the NICE version

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Department for Culture, Media and Sport (DCMS)						consideration were given to including a grading of priority, so that those implementing the guidance can be clear which aspects should be dealt with first.	
Department of Health (DH), Department for Education and Skills (DfES), and Department for Culture, Media and Sport (DCMS)	6	NICE/Full	Drugs	General		<p>Pharmaceutical recommendations:</p> <p>We are concerned that some of the recommendations could require prescribing outwith the existing licence . For example, currently neither Sibutramine nor Orlistat are recommended for use in children and yet the draft guidance appears to endorse their use in specialist settings. Although the draft guidance comments that the recommendations for primary care would be subject to licensing, to include any recommendation on prescribing in an unlicensed form may cause confusion.</p> <p>We would appreciate it consideration were given to the issues of confidentiality / data sharing around the recommendations to set up registers of patients on specific treatments.</p> <p>We believe the value of the final / implementation guidance would be strengthened by being explicit about how NHS organisations and health</p>	We do recognise that these are drugs that are not licensed for use in children. However, this is not dissimilar to many other pharmacological options that are not licensed and that are prescribed to children with other conditions. We do, however, ensure that the caveats for this use are reflected in added detail in the recommendations, and that these are to be given only in exceptional circumstances, if severe life-threatening comorbidities are present, by multidisciplinary teams with experience of prescribing in this age group.

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						professionals should deal with these issues.	
Department of Health (DH), Department for Education and Skills (DfES), and Department for Culture, Media and Sport (DCMS)	8	NICE/Full	Ident	General		<p><b>BMI / waist measurement recommendations especially for Asians:</b></p> <p>The World Health Organisation has recently published Growth Charts for children, and the Department of Health would encourage NICE to ensure that these are taken fully into consideration in the final guidance.</p> <p>The cut-offs for Asians appear stringent and there may be implications for clinical care. We recommend that the clinical implications should be taken fully into consideration in developing the final guidance. Additionally, should these more stringent levels be linked to co-morbidities? The recommendation on BMI in Asians is based on quality of evidence level 3 but has been translated into a recommendation grading of B. There is as yet no consensus on a commonly accepted cut-off. Given both of these, the Department of Health would appreciate it if the recommendations on BMI cut-offs for Asians were reconsidered.</p>	The guideline development group (GDG) were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same body mass index (BMI). However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Department of Health (DH), Department for	17	NICE	Misc	5		It would be helpful if you referred to consultation/ communication skills to ensure that this is understood by all	Noted, but throughout we stress the need for good communication.

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Education and Skills (DfES), and Department for Culture, Media and Sport (DCMS)						healthcare professionals rather than just medics.	
Department of Health (DH), Department for Education and Skills (DfES), and Department for Culture, Media and Sport (DCMS)	19	NICE	Misc	10	2	We have presumed this applies to adults only rather than everybody covered by the guidance. It would be helpful if the guidance could clarify this.	See detailed recommendations.
Department of Health (DH), Department for Education and Skills (DfES), and Department for Culture, Media and Sport (DCMS)	22	NICE	Lifestyle	33	Section 1.2.1. Lines 1.1.2, 1.1.3, 1.2.1.1	The choice of intervention is applied to adults only, whilst for children the approach is described differently. We believe that children also have a right to choose. Whilst this must reflect their maturity and capability, we would encourage NICE to give further consideration to the rights of children and particularly young people.	We have strengthened the 'Patient-centred care' section to reflect more the rights of both adults and children. In addition, we would expect that any care involving children would follow other guidance (e.g. NSF, legal requirements) and recommended best practice in paediatric/ adolescent clinical practice.
Department of Health (DH), Department for Education and Skills (DfES), and Department for Culture, Media and Sport (DCMS)	64	NICE	Misc	General / Page 9		It would be helpful if the message to decrease inactivity were turned into a more positive message in the final / implementation guidance.	We consider the wording to be appropriate.
Department of	65	NICE	Lifestyle	Page 41		Physical activity grid.	Noted and revised.

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Health (DH), Department for Education and Skills (DfES), and Department for Culture, Media and Sport (DCMS)						It would be helpful if the message on minutes of exercise were maintained as 30 minutes per day, 5 days a week, in line with the Chief Medical Officer's recommendations, rather than 150 minutes per week - as we consider that departing from the former may reduce the health benefits.	
Department of Health (DH), Scientific Advisory Committee on Nutrition	68	NICE version	PCC	Page 5		<p>How are healthcare professionals meant to acquire these consultation skills? There are few training courses available. This section also fails to recognise the clearly established biases which exist among health professionals towards obese people. Thus, before improving consultation skills there is a need to change attitudes. Has any thought been given to how long the consultation will take if all of the bullet points on page 5 are to be covered? If this is done for only 1/10<sup>th</sup> of the 55+% of the adult population who are overweight and obese it will swamp primary care.</p> <p>Patient-centred care needs to take account of the family context.</p>	<p>See other responses on training. Also assessment is meant to be based on clinical need, and not all done in one consultation.</p> <p>We have made recommendations about the importance of the family setting, specifically with regard to children.</p>
Department of Health (DH), Scientific Advisory Committee on	70		Drugs	9		<p>Minor point: "Pharmacological treatment should usually be recommended only after dietary and exercise advice have been initiated."</p>	We have revised the wording to clarify this point.

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Nutrition						Would it not be better to wait until the dietary and exercise advice has been given a chance to work, rather than simply 'initiated'. Otherwise it is not clear why pharmacological treatment should be provisional on the use of diet/exercise.	
Department of Health (DH), Scientific Advisory Committee on Nutrition	74		Misc	Page 15-20	Sec 1.1.2	"NHS Professionals". Please estimate the size of the workforce a). currently trained and b). required to deliver each recommendation (see also re: page 63 and 687).	The specifics of implementation – including local training needs and the skill mix required - are outside the remit of this work. The guidance allows local providers to interpret and implement the guidance as appropriate to their situation. However, a number of recommendations highlight the type of skills that should be acquired by staff, as appropriate.
Department of Health (DH), Scientific Advisory Committee on Nutrition	81		Ident	33	Sec 1.2	<p>It is a mistake to tie up children and adults in the same text. Approaches to assessment and management are quite different</p> <p>Guidance about the management of childhood obesity should be dealt with entirely separate to adults - it is confusing as it stands.</p> <p>There is no mention about the identification and management of associated medical risks. Health professionals are at fault when focusing on overweight and obesity</p>	<p>After further discussion, the GDG considered that these sections could remain together, but different recommendations for each group have been made.</p> <p>Identification of these has been recommended, but management of associated comorbidities is not part of the scope of the guidance.</p>

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						<p>and ignoring treatment of hypertension, dyslipidaemia, type 2 diabetes etc. There is but a brief mention in section 1.2.3</p> <p>The sections on opportunistic identification/classification are confusing and the tables difficult to follow. Given that INTERHEART applied waist: hip ratio why has this been ignored?</p>	<p>We have clarified this section. The Interheart study only looked at risk of myocardial infarction (MI), and not overall cardiovascular (CV) risk. The evidence review does acknowledge, therefore, that different measures may reflect different risks.</p>
Department of Health (DH), Scientific Advisory Committee on Nutrition	82		Ident	34	1.2.2.1	<p>Routine height and weight measurement is not recommended for adults. Why not as the people themselves are advised to regularly check their weight (1.1.1.3)?</p>	<p>We have withdrawn recommendation 1.2.2.1 to avoid misinterpretations. However, it is still recommended that healthcare professionals should use opportunities to measure height and weight as appropriate.</p> <p>We also recommend in the public health section that people should be encouraged to monitor their weight.</p>
Department of Health (DH), Scientific Advisory Committee on Nutrition	83		Ident	34	1.2.2.3	<p>BMI is not a measure of adiposity, it is a measure of overweight.</p>	<p>Noted and revised as appropriate.</p>
Department of Health (DH), Scientific Advisory	84		Ident		1.2.2.4	<p>What is the evidence concerning these false negative assessments of abdominal obesity? To what extent is it caused by poor measurement</p>	<p>We have revised evidence statements and recommendations to address this.</p>

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Committee on Nutrition						techniques?	
Department of Health (DH), Scientific Advisory Committee on Nutrition	85		Assess	35	1.2.2.8	Where is the evidence supporting these Asian specific cut-offs? The main report makes it clear that within the populations listed, there are a variety of different groups with markedly different BMI ranges. The present WHO worldwide standards are appropriate for some of these groups and may not be for others. One major problem in the UK is knowing the definite ethnic origin of such Asian groups.	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. Thus, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. However, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Department of Health (DH), Scientific Advisory Committee on Nutrition	86		Assess	38	1.2.3.2	What is meant by genetic tests? This is not a routine lab investigation and requires tertiary referral.	We have revised this recommendation to ensure that it is clear that genetic tests are examples of what can possibly be undertaken. Genetic tests include some that are routinely available, e.g. for Prader-Willi syndrome, as well as those that are specialist. Those with severe early onset obesity should be under specialist care, and most paediatricians are probably aware of the genetic tests available on the NHS and as



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							research tools.
Department of Health (DH), Scientific Advisory Committee on Nutrition	87		Lifestyle	40	1.2.4.4	This is vital but urgently needs to be supported by a recommendation addressed to Colleges and providers of education (including Postgraduate Deans and medical schools) to define curricula and institute educational programs which include assessment of competence.	<p>We have added an additional section on training to both versions, based on information already included throughout the guidance.</p> <p>The specifics of implementation – including local training needs and the skill mix required – are outside the remit of this work. The guidance allows local providers to interpret and implement the guidance as appropriate to their situation. However, a number of recommendations highlight the type of skills that should be acquired by staff, as appropriate.</p>
Department of Health (DH), Scientific Advisory Committee on Nutrition	88		Lifestyle	41	1.2.4.10	<p>Behavioural interventions - this section is unhelpful. A list of measures provides little guidance and uncertain of the evidence base for many of the items listed. Moreover, behaviour therapy is resource intensive - where is the cost benefit?</p> <p>Activity -- there is no mention of accessibility which is the key issue, particularly when considering social inequalities.</p>	<p>We have listed the behavioural techniques as evaluated in the trials reviewed. However, there is a lack of evidence on which technique is most effective.</p> <p>Re health economics – please see the section on 'Health economics' in the full guideline for a discussion of this issue.</p> <p>Accessibility – we have stressed throughout that individual circumstances should be taken into account, including issues around social inequalities and barriers.</p>

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Department of Health (DH), Scientific Advisory Committee on Nutrition	89		Lifestyle	42	1.2.4.11	The CMO's report highlights the likely need for those who are obese need 45 mins of activity each day.	Noted and revised.
Department of Health (DH), Scientific Advisory Committee on Nutrition	90		Lifestyle	Page 43	1.2.4.15	The dietary guidance is inadequate - this is an important section that needs to address more critically low carbohydrate diets, meal supplements and VLCD.	We have revised this section in light of this comment, and others received.
Department of Health (DH), Scientific Advisory Committee on Nutrition	91		Drugs	Page 44	1.2.5.2 – 1.2.5.3	Neither orlistat nor sibutramine are licensed in Europe for use in children. There is no mention of this. Given that other drugs are in the pipeline, suggest that recommendations for drug use should be generic with reference to specific drugs given in an annex.	We do recognise that these are drugs that are not licensed for use in children. However, this is not dissimilar to many other pharmacological options that are not licensed and that are prescribed to children with other conditions. We do, however, ensure that the caveats for this use are reflected in added detail in the recommendations, and that these are to be given only in exceptional circumstances if severe life-threatening comorbidities are present, by multidisciplinary teams with experience of prescribing in this age group.  We were asked to review the evidence on orlistat and

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							sibutramine only, and the GDG have made recommendations both about general prescribing, and prescribing for these specified drugs.
Department of Health (DH), Scientific Advisory Committee on Nutrition	92		Drugs	Page 46	1.2.5.13	Should be 'Fat soluble vitamin supplementation'	This recommendation has been revised.
Department of Health (DH), Scientific Advisory Committee on Nutrition	93		Misc	Page 47	1.2.6	<p>The role of secondary and specialist care needs to be clearly defined in a changing health service.</p> <p>The surgical section is too superficial. There needs to a risk-benefit analysis included in the text as well as information about the potential weight loss and risks associated with particular surgical techniques. The major benefit of surgery is prevention or management of medically associated complications and there is no mention of this. again, what is meant by "genetic screening".</p> <p>The frequency of obesity in the population inevitably means that it is not affordable to treat all - the guidance should include a section on health economics and priorities for treatment. There is no mention of type</p>	<p>We have used the Department of Health's document on specialised Services National definition set. For further details please refer to <a href="http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187&amp;chk=jAqaRv">http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187&amp;chk=jAqaRv</a></p> <p>We have revised the surgical recommendations in light of this and other comments.</p> <p>A rigorous evidence review was undertaken as part of the development of this guidance. All available evidence which met the agreed review parameters would have been included if available.</p>

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						<p>2 diabetes where surgical treatment may be particularly successful.</p> <p>The notes on the scope of guidance identifies the need for additional research. Much of the available research and guidance do not appear to have been applied in the most coherent way.</p>	
Department of Health (DH), Scientific Advisory Committee on Nutrition	96	Full version	Assess			<p>One issue which should be addressed, both here and in the NICE version, is the impact of obesity per se on cardiovascular disease risk.</p> <p>The newly produced risk calculation nomograms continue to omit BMI – the reason is said to be that once BP, diabetes, smoking and cholesterol have been taken into account there is no additional effect of obesity. This is clearly not true, because someone with hypertension, elevated cholesterol and who smokes has their risk of an early cardiac event increased from 32 to 64 fold if they are also obese.</p> <p>The Main report and NICE version should clearly indicate the disease risk directly attributable to obesity, as well as that associated with the co-morbidities.</p>	<p>We have noted in the introduction to the full guideline the impact of obesity on CV risk.</p> <p>Furthermore, we have recommended that any assessment of people who are overweight or obese should include an assessment of CV risk.</p> <p>It is, however, outside the scope of this guideline to develop risk/ scoring tools to measure CV risk. The question of modifying current risk factor scoring tools (e.g. Framingham) for risk factors not currently used in the equation is being considered by the NICE lipid modification guideline development group.</p>
Department of Health (DH), Scientific Advisory Committee on	99		Ident	Section 2		<p>One issue about the various expert recommendations concerning waist circumference as a risk factor is the extent to which they are independent recommendations (each having used</p>	Noted.

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Nutrition						different datasets), or all simply drawing the same conclusions based on the same data?	
Department of Health (DH), Scientific Advisory Committee on Nutrition	103		Ident	35		There is no consensus on the ethnic group specific cut-offs. The variation described within countries makes such cut-offs very difficult to develop and apply.	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Department of Health (DH), Scientific Advisory Committee on Nutrition	104		Lifestyle	40	8	System for grading guidance not yet defined in document, nor cross-referenced for reader (indicative of a general editorial problem).	Recommendations are no longer graded under the NICE process.
Department of Health (DH), Scientific Advisory Committee on Nutrition	105		Ident	Page 42	24/25	What does interpret BMI “with caution” actually mean? What further information is useful?	This has been revised.

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Nutrition							
Department of Health (DH), Scientific Advisory Committee on Nutrition	106		CP	Page 45	Flow Chart	No explanation of how to interpret BMI; indeed it now seems to be used without qualification to define "obesity", far from requiring interpretation "with caution".	Noted and revised.
Department of Health (DH), Scientific Advisory Committee on Nutrition	107		Surgery	Page 48		Lower limit of "pre school" needs defining	It is age 2.
Department of Health (DH), Scientific Advisory Committee on Nutrition	108		Surgery	Page 49		Diagram unhelpful	Noted.
Department of Health (DH), Scientific Advisory Committee on Nutrition	121		Ident	Page 181	6–8	<i>"Adiposity is defined as the amount of body fat expressed as either the absolute fat mass (in kilograms) or as the percentage of total body mass".</i> This problem deserves further exploration as % fat and fat mass can give very different estimates in the same individual; the first is relative (to other body components) and the second absolute (2).	In the guidance this is used to distinguish 'fatness' from BMI.
Diabetes UK	3		PCC	5		Would benefit from a definition of patient centred care	This is a standard NICE section.
Diabetes UK	4		PCC	5	6	"Stressing that obesity is a clinical term with specific health implications ...." This makes the assumption that	This point is specific to the definition of obesity – that is, it is based on health risk, rather than

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						health risk is the main motivator for change in most people. However, other motivators may carry greater weight in a decisional balance.	being a definition based on looks.
Diabetes UK	5		PCC	6	last	“explain that their obesity will be discussed again in the future” This is linked to the point that consultations would benefit from “assessing readiness for change” (P5) and would benefit from expansion on strategies for the various stages of readiness for change.	We have made recommendations about willingness and readiness to change throughout in assessment and interventions. However, there is a NICE review of behaviour change currently being developed, and we have asked for this to be signposted.
Diabetes UK	7		Lifestyle	9		Highlight here that interventions should be tailored to the individual	This is stressed throughout the guidance.
Diabetes UK	19		Misc	33	First para	In earlier text references talking to health visitor, school nurse - ? should be included here too	Not sure to what this is referring.
Diabetes UK	20		Misc	33	1.2	At this stage of the document the term young adult is lost – a little ambiguous as to where they may fit in the recommendations	Noted and revised as appropriate.
Diabetes UK	21		Misc	33 onwards	1.2	Format – unclear as to reason for some recommendations being in boxes and others not.	We have chosen to put recommendations that are similar in nature side by side in boxes, whilst the recommendations that are more specific to adults or children remain outside.
Diabetes UK	22		Misc	33	1.2.1.1	The child principle of “The overall aim is to create a supportive environment .....” is relevant for adults too.	The recommendations were drafted specifically for each group, thus the GDG have decided after discussion That they will remain separate.
Diabetes UK	23		Misc	33	1.2.1.2	Adult: should also include point made in child principle that there “should be	The recommendations were drafted specifically for each

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						a process of agreement of goals and actions tailored to the individual”	group, thus the GDG have decided after discussion That they will remain separate. However your point is stressed throughout the recommendations.
Diabetes UK	24		Ident	36	1.2.2.10	Table not very user friendly - ? benefit from shading or addition of word “risk” after “increased, high etc”	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Diabetes UK	25		Ident	37	1.2.2.11	Table not very user friendly - ? benefit from shading or addition of word “risk” after “increased, high etc”	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly



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							populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Diabetes UK	26		Assess	39	1.2.3.5	"if care cannot be provided by the same healthcare professional, it is important that record keeping is clear and consistent." – implies that clear and consistent record keeping is only applicable to these cases. It is important in all cases.	We have revised the recommendation to make this clearer.
Diabetes UK	27		Lifestyle	40	1.2.4.7	Information about health risks associated with obesity/overweight should be included especially re risk of Type 2 diabetes.	Noted and added.
Diabetes UK	28		Lifestyle	42	1.2.4.13	This point applies to adults too.	We have discussed this with the GDG and have decided to keep it solely for children, to emphasise its importance in children. However, we do highlight that a multicomponent intervention is the treatment of choice for adults and children.
Diabetes UK	29		Lifestyle	43	1.2.4.17	This point aimed at the "child" applies to adults too.	We do not think that the evidence supports this as applied to children.
Diabetes UK	30		Lifestyle	44	1.2.4.18	This point aimed at the "child" applies to adults too.	Noted and revised.
Diabetes UK	31		Drugs	45	1.2.5.8	This needs to be more specific and	The evidence is presented in

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						should be referenced with evidence.	Section 5 of the full guideline (evidence is not generally presented in the recommendations).
Diabetes UK	32		Drugs	46	1.2.5.15	Typo – Type 2 diabetes not type 2 diabetes	Amended
Disability Rights Commission	1		Misc	General		The document needs to recognise more fully the role of anti-psychotics in causing obesity and to identify more effective measures to mitigate their effects. NICE guidance already exists in relation to the management of schizophrenia, as does an array of other clinical guidance. It remains the case, though, that the effects of anti-psychotics in causing obesity are not being sufficiently well monitored, alternative medication or non-psychopharmacological treatments are not always considered, and the balance between the control of psychotic symptoms and side-effects such as obesity is not sufficiently discussed between clinicians and patients. Many patients wish to come off anti-psychotic medication because of the physical side-effects but some clinicians refuse to consider alternatives or to provide support. As a result, some patients attempt to come off such medication against clinicians' advice or without advising them. The document must identify effective ways of addressing current poor practice, which continues	Noted, and we have recommended that causes of obesity be fully assessed and referral considered if appropriate.

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						<p>despite a wealth of research evidence and clinical guidance.</p> <p>The use of anti-psychotics for people with learning disabilities is a specific issue of concern. Studies have estimated that between 20% and 66% of people with learning disabilities are given psychotropic medication (Linehan et al 2004). However, it is often used as a form of chemical restraint for behaviour management rather than to treat mental health problems (Ahmed et al 2000, Holden and Gitlesen 2004, Matson et al 2000, Stolker et al 2002). Its effectiveness in addressing challenging behaviour is questionable (Brylewski and Duggan 1998) and there are strong arguments for stopping or reducing its use for many people (Ahmed et al 2000). Doing so would make a major contribution to reducing the very high obesity rates among people with learning disabilities (who comprise 2% of the population).</p>	
Faculty of Public Health	7	NICE	PCC	5-6		Patient-centred care: this section seems misplaced. It should come later in the document, perhaps as an appendix.	This is standard NICE format, but we have revised the guidance and recommendations within this section.
Faculty of Public Health	11	NICE	Misc	9		Children, first bullet: this could be re-written to emphasise the need for family-based approaches	After discussion we have decided to keep this recommendation the same, as by stating interventions must address lifestyle changes within family we are emphasising

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							the need for family based approaches.
Faculty of Public Health	12	NICE	Drugs	9		Adults, first bullet, line 2: suggest replacing 'initiated' with 'followed for at least a month' (as per orlistat prescribing information)	These are general recommendations; for more detail, please see specific recommendations.
Faculty of Public Health	21	NICE	CP	73		Children's pathway: in Management box mention family-based approach	We have noted in the detail of the recommendations that family or individual approaches should be used as appropriate.
Faculty of Public Health	22	NICE	CP	74		Adults' pathway: consideration of referral seems to come too soon (ie. before trial of lifestyle changes in primary care. Early referral is only justifiable in complex cases, cases with urgent co-morbidities or very severe obesity.	The details in the referral box outline that referral <u>is</u> only suitable for specific groups, including those in whom management in primary care has failed.
Fitness Industry Association (FIA)	1	NICE	Misc	5		The report states that all healthcare professionals should have a high standard of consultation skills. Given the range and depth of advice that would need to be given in differing situations and to individuals with a variety of needs, there may be no one healthcare professional qualified in all necessary areas. The fitness industry for example have a vast range of skilled and experienced exercise professionals who would be capable of delivering part of the necessary advice related to physical activity and improved health.	Thank you, and because of the wide range of professionals who may be able to deliver interventions, or components of them, we have recommended only that anyone involved in delivery be appropriately trained.
Food and Drink Federation	17	Full version	Lifestyle	781–784		FDF agrees that further research is needed on how best to prevent and manage obesity. Examples of	Thank you for these suggestions. Research recommendations are included in the NICE guidance,

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						<p>research needs include:</p> <ul style="list-style-type: none"> <li>• How knowledge can be translated into action; Experience shows that education on healthy diet and lifestyle does not automatically lead to change in behaviour.</li> <li>• How to successfully lose weight and keep it off and the cognitive aspects of this problem.</li> <li>• Why do some people eat more than they need?</li> <li>• What are the attitudes to increased body weight in adults?</li> <li>• When are the critical periods for weight gain and how to stop weight gain at these times?</li> <li>• What are the lifestyle habits of adults on an individual basis, which cause them to continue to gain weight?</li> <li>• Why are some dieters successful, yet others seem to fare even worse once they try to 'go on a diet'?</li> </ul>	and the GDG has made some recommendations, but we agree that other research is needed in this area.
Greater Peterborough Primary Care Partnership	1	NICE version	PCC	5		<p><i>Taking fully into account their race, culture,.... Suggest you add socio-economic factors</i></p> <p>Certain groups are known to be more at risk of obesity than others. These differences may be the consequence of genetic, cultural or socio-economic factors or more likely, some combination of all three.</p>	Noted and revised.
Greater	2	NICE version	PCC	6		Empowerment and choice	Noted and revised in light of this

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Peterborough Primary Care Partnership						For patients who do not want to do anything at the time of discussion – in addition to explaining to them that it will be discussed in the future – provide access/contact details so that they can initiate contact should they change their mind	and other comments.
Greater Peterborough Primary Care Partnership	4	NICE version	CP	9		Adults Include statement on assessing health related risk of obesity using a combination of BMI, waist circumference and ethnicity.  Leading with a statement on pharmacological treatment may distract from a focus on first-line management . priorityu should be placed on primary care interventions that help a patient to reduce calorie intake; increase physical activity while reducing sedentary behaviours; and increase self-awareness about day-to-day behaviours that affect intake and activity levels.	These are Key Priorities for Implementation, and should be read in the context of all the recommendations.
Greater Peterborough Primary Care Partnership	5	NICE version	Surgery	10 and 47	Also 1.2.6.1	Surgery. Include specialist obesity service description as access to a specialist dietitian, physical activity specialist and relevant advice on behavioural change to complete the sentence rather than as a footnote. We recommend that the guidance should incorporate the current NICE guidelines for surgery (BMI 40 or 35 with serious co-morbidities). We do	This guidance replaces current NICE guidance on surgery.

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						not support the recommendation of surgery as first line treatment for suitable patients with a BMI > 50. Many centres within the US consider that there is inadequate research on effective non-surgical management of morbid obesity, we should be contributing to the development of the evidence base of best practice rather than going directly to surgery.	
Greater Peterborough Primary Care Partnership	11	NICE version	Misc	33	1.2.1.1.	Include measuring equipment	Noted. Has been revised as appropriate.
Greater Peterborough Primary Care Partnership	12	NICE version	Ident	36–37	1.2.2.10 & 1.2.2.11	Layout of charts is confusing	Noted and revised.
Greater Peterborough Primary Care Partnership	13	NICE version	Misc	47		No definition of what specialist care / service means – need to clarify.	We have used the Department of Health's document on specialised Services National definition set. For further details please refer to <a href="http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187&amp;chk=jAqaRv">http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187&amp;chk=jAqaRv</a>
Greater Peterborough Primary Care Partnership	14	NICE version	Ident	34	1.2.2.1	Suggest all routine medicals should require measurement of height and weight (new patient, insurance medical, annual check of co morbid patients i.e. hypertensive, diabetics, dyslipidaemia etc)	The GDG have decided to omit this recommendation. However, the GDG consider that the recommendations on measurement do not conflict with the QoF of the new GMS contract.

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Hampshire Partnership NHS Trust	2	NICE	Misc	General		Paucity of research in this area, what are effective interventions for the treatment of obesity. Raises questions around funding, research opportunities, who would be in a multidisciplinary team, training needs.	Noted.
Hampshire Partnership NHS Trust	3	NICE	Misc	General		Risk of developing eating disorders for those vulnerable adults who see weight loss as a panacea for all that is wrong in their lives	We have recommended that eating behaviour be assessed, along with any psychological issues.
Heart of England NHS Foundation Trust	1	General	Surgery	48		Although there is mention of bariatric surgery and its indications, I feel that there should be some further guidance on relative and absolute contra-indications to bariatric surgery. Patients with eating disorders, major psychiatric illness, alcohol or drug addiction, or endocrine/genetic causes for their obesity may not be suitable for bariatric surgery.	Noted, but the recommendations do allow for comprehensive assessment of any factors that may affect the choice and outcomes of surgery.
Hyperlipidaemia Education And Research Trust (UK)	1	NICE	Misc	4		There is a need for secondary care facilities for management of obesity and its allied complications including dyslipidaemia. This is lacking in many parts of the UK.	Noted.
Hyperlipidaemia Education And Research Trust (UK)	3		Surgery	10	Bullet 6	Surgery may be appropriate at lower BMI cut-off than 50 for high –risk patients with complications of obesity e.g. sleep apnoea, diabetes, renal failure, lymphoedema	Surgery is recommended for people with severe obesity i.e. <50BMI. But we have recommended that for people with a BMI>50, surgery is considered as first line.  This group will probably have comorbidities (possibly severe and multiple), and weight loss



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							using lifestyle changes and drugs are very unlikely to achieve a clinically significant benefit.
Hyperlipidaemia Education And Research Trust (UK)	4		Assess	1.1.2.7		There is a need for secondary care facilities for management of obesity and its allied complications including dyslipidaemia. This is lacking in many parts of the UK and needs to be integrated into the primary care strategy. Facilities required include appropriate laboratory and physiological investigations.	It is not part of our remit to Issue guidance on the management of obesity-related comorbidities. It is also outside our remit to provide guidance on service arrangements and delivery. However, audit tools are currently being developed to aid the implementation of the guidance (see section 3 of the NICE version).
Hyperlipidaemia Education And Research Trust (UK)	5		Ident	1.2.2.1		This view is at –odds with the recommendation of the National Screening Committee (Muir Gray) which has recommended opportunistic screening for lipids, glucose and blood pressure at age 40 and includes the identification of metabolic syndrome by waist circumference (or BMI) as a relevant cardiovascular and future diabetes risk factor.	Noted.  We have decided to withdraw this recommendation on the grounds that population-based screening programmes are outside our remit.  We do, however, still recommend that healthcare professionals should use opportunities to measure height and weight, if this is deemed appropriate.
Hyperlipidaemia Education And Research Trust (UK)	6		Ident	1.2.2.4		Waist circumference is valuable (indeed a defining major part of the International Diabetes Federation [IDF] definition) for the identification of metabolic syndrome and its attendant risks of diabetes or cardiovascular disease, It is of equal vale to BMI in our view and the current phrasing is	Most, if not all, people with BMI >35 will have high waist circumference, hence there is no added value for this group.

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						too negative and applies only to BMI > 35 kg/m2.	
Hyperlipidaemia Education And Research Trust (UK)	7		Ident	1.2.2.10		This table uses data derived from the US National Cholesterol Education Program ATP-3 definition. Rates of obesity are far greater in the USA and there is a discrepancy between data in table 1.2.2.7 as in the WOSCOPS study BMI 30 was equivalent to waist 100 cm. It might be more appropriate to use the IDF definition based on a 95 cm cut-off for Caucasian men allied with IDF adjusted values for other major ethnic groups in comparison to the lack of such data in ATP3 defined populations where values are derived post facto and not compared with the original US data sets.	Noted. See the details of the evidence review for the source.
Hyperlipidaemia Education And Research Trust (UK)	8		Ident	1.2.2.11		The Asian definition given here does not agree with values derived from native Indians (Chennai study). Also other ethnic groups e.g. Chinese, Filipinos have their own defined values for waist. Similarly there is no mention of Africans but some evidence (but not all) suggest that they may not be as insulin resistant as Caucasians at 102cm.	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how

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							different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Hyperlipidaemia Education And Research Trust (UK)	9		Assess	1.2.3.1		We would recommend complete cardiovascular risk assessment including a fasting full lipid profile. Liver function test should also be measured to identify non-alcoholic steatotic hepatitis – a common cause of cirrhosis in the obese. There may also be a case for measurement of plasma insulin and /or microalbuminuria in line with some definitions of the metabolic syndrome (WHO/EGIRS)	We have given some examples of appropriate investigations for adults in 1.1.3.1. However, we cannot recommend on further specific details of the testing, as this is down to clinical judgement based on the patient (history, examination, results of other tests).
Hyperlipidaemia Education And Research Trust (UK)	10		Assess	1.2.3.2		We fail to see why adults should be assessed differently to children (see above) as some primary genetic cases of obesity with a mild phenotype may present in adult hood. This especially applies to the promelanocortin mutations. .	However, this is implicit in recommendation 1.2.3.1. And it is particularly vital to assess genetic causes for severe, early onset obesity in children ... so we have specified this for children, but do not exclude such testing for adults, as clinically appropriate.
Hyperlipidaemia Education And Research Trust (UK)	11		Drugs	1.2.5		The imminent launch of rimonabant as an additional therapy for obesity needs to be considered.	Rimonabant is outside the scope of this guidance.
Hyperlipidaemia Education And Research Trust (UK)	12		Surgery	1.2.7.3		Given the high rate of complications following bariatric surgery in patients with sleep apnoea syndrome access to a high dependency unit before and after surgery is mandatory in such patients. There may be a case for all	We consider that pre-op assessment would include all the relevant/required investigations, including oximetry studies.

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						patients due to undergo bariatric surgery to undergo pre-operative oximetry studies.	
Hyperlipidaemia Education And Research Trust (UK)	13		Surgery	1.2.7.3		The availability of bariatric surgery is very limited, subject to vast (unofficial) waiting lists and also wide postcode effects. Denial of surgery for financial reasons is (unacceptably and scandalously) routine in many primary care Trusts.	Noted. Please see the implementation section for further details.
Hyperlipidaemia Education And Research Trust (UK)	14		Surgery	1.2.7.3		Many centres do not have facilities for the super-obese who require management at a regional centre. Other patients are anaesthetically unfit for bariatric surgery. An alternative option producing a 15% weight loss- endoscopic intra-gastric balloon insertion should be available to these patients.	Gastric balloons were not considered in the evidence reviews for this guideline.
Hyperlipidaemia Education And Research Trust (UK)	15		Surgery	1.2.7.4		Surgery may be appropriate at lower BMI cut-off than 50 for high –risk patients with complications of obesity e.g. sleep apnoea, diabetes, renal failure, lymphoedema. Some units use >45 with complications and >50 without as cut-offs.	<p>Surgery is recommended for people with severe obesity i.e. &lt;50BMI. But we have recommended that for people with a BMI&gt;50, surgery is considered as first line.</p> <p>This group will probably have comorbidities (possibly severe and multiple), and weight loss using lifestyle changes and drugs are very unlikely to achieve a clinically significant benefit.</p>
Infant and Dietetic Foods Association	1	Full version	Lifestyle	General		<b>Meal Replacements</b> Meal replacements, while being noted in the Scope as a non-	We have considered the issue of meal replacements at length. We consider that the use of meal

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						<p>pharmacological intervention, have had limited review in the Draft Guidance – this is partly because the better papers were omitted from examination (omitted references are listed in the next point) but also, it appears, because of a misunderstanding about the nature of Meal Replacements.</p> <p>Meal replacements for weight control have a special regulatory position as the only products specifically designed as meal replacements to meet the nutritional requirements of weight loss<sup>(2)</sup>.</p> <p>Their composition was determined following study by the Scientific Committee for Foods to the European Commission on the nutritional needs of dieters. Their legislative status is the same as Foods for Special Medical Purposes (FSMPs). They should never be confused with normal foods promoted for weight loss on the basis of being calorie controlled, low fat, etc. They are nutritionally complete meals for use in weight management and are closely regulated as such.</p> <p><b>The Legislation</b> Meal Replacements for Weight Control is a legal category<sup>(1)</sup> of</p>	<p>replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.</p>

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						<p>formula foods for weight loss covered by Directive 96/8/EC, a specific directive within Directive 89/398/EEC on Foods for Particular Nutritional Uses (PARNUTS), implemented in the UK as The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations <a href="http://www.opsi.gov.uk/si/si1997/97218201.htm">http://www.opsi.gov.uk/si/si1997/97218201.htm</a></p> <p>PARNUTS foods are  <i>'foodstuffs which, owing to their special composition....are suitable for their claimed nutritional purposes'</i>  and they must  <i>'fulfil the particular nutritional requirements .....  of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs'</i></p> <p>The composition of PARNUTS foods for weight control was defined after examination by the Scientific Committee for Foods to the European Commission assessing need, safety and efficacy. Under PARNUTS definitions the overweight and obese 'are in a special physiological condition'.</p>	

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						<b>Objective : Understanding of the unique legal status of Meal Replacements – they must not be confused with ‘normal’ foods</b>	
Infant and Dietetic Foods Association	2	Full version	Lifestyle	General		<p>As noted in the previous comment, the following references were omitted in error from the original consultation – listed here as requested by Leicester AC:</p> <p>Ditschuneit. HH., Flechtner-Mors. M., Johnson. TD., Adler. G Metabolic and weight loss effects of a long term dietary intervention in obese patients. Am J Clin Nutr. 1999;69;198-204 (RCT – 2 years)</p> <p>Flechtner-Mors, M., Ditschuneit, HH., Johnson, TD., Suchard, MA, Adler, G. Metabolic and weight-loss effects of long-term dietary intervention in obese patients: Four-Year results. Obesity Research 2000;8;399-402 (Follow up to previous study – 4 year data)</p> <p>Ditschuneit. HH., Frier, HI., Flechtner-Mors, M. Lipoprotein responses to weight loss and weight maintenance in high-risk obese subjects. European Journal of Clinical Nutrition. 2002;56;264-270 - (RCT – 4 years)</p> <p>Anderson, JW. Combination approaches to weight management.</p>	We have considered the issue of meal replacements at length. We consider that the use of meal replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.

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						<p>Medscape Diabetes &amp; Endocrinology 6(2), 2004, posted 08/31/2004 (Analytical Review)</p> <p>Dhindsa. P., Scott. AR., Donnelly, R. Metabolic and cardiovascular effects of very-low-calorie-diet therapy in obese patients with type 2 diabetes in secondary failure: outcomes after 1 year. Diabetic Medicine. 2003; 20; 319-324 (UK Clinical Setting – 12 months)</p>	
Infant and Dietetic Foods Association	3	Full version	Lifestyle	46	Box	<p><b>Box Heading</b> – Management  “Intensity of management will depend on level of risk and may include</p> <ul style="list-style-type: none"> <li>◦ Diet</li> <li>◦ Physical activity</li> <li>◦ Behavioural interventions</li> <li>◦ <b>FORMULA FOODS FOR WEIGHT CONTROL (MEAL REPLACEMENTS AND TOTAL DIET REPLACEMENTS INCLUDING VERY LOW CALORIE DIETS – VLCD’s)</b></li> <li>◦ Drug therapy</li> <li>◦ Surgery”</li> </ul> <p><b>Recommended addition in caps</b></p> <p><b>Objective : Clarify that PARNUTS Foods (i.e. Meal Replacements and VLCDs) may be suitable interventions prior to pharmacotherapy and/or surgery for some patients.</b></p>	We have revised the recommendations in light of this and other comments.



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Infant and Dietetic Foods Association	14		Lifestyle	524	8-11	<p>All RCTs of dietary interventions in adults with a BMI of 28 or more were included. The duration of the trials had to be for 52 weeks or more. The main outcome was weight change in kg at 12 months follow-up.</p> <p><b><i>Please note papers from Ditschuneit &amp; Flechtner-Mors listed above (RCTs 12+ months reporting outcome of weight change in adults) omitted from original review</i></b></p>	We have considered the issue of meal replacements at length. We consider that the use of meal replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance, but we have also clarified the use of VLCDs.
Infant and Dietetic Foods Association	15		Lifestyle	524 525	12-15 1-11	<p>"The diets were classified as follows</p> <ul style="list-style-type: none"> <li>◦ Healthy eating advice</li> <li>◦ 600kcal/day deficit or low fat diet</li> <li>◦ Low calorie diets (1000-1600kcal/day)</li> <li>◦ <b>MEAL REPLACEMENTS FOR WEIGHT CONTROL</b></li> <li>◦ Very low calorie diet (&lt;100kcal/day)</li> <li>◦ Protein sparing modified fast (PSMF)</li> <li>◦ Low carbohydrate high monounsaturated fat diet</li> <li>◦ Salt restriction</li> </ul> <p>Due to reporting issues healthy eating advice and 600 kcal/day deficit or low fat diets were classified together, along with diets where the fat or calorie restriction was not stated or could not be estimated.</p> <p>We used the definitions as above</p>	We have considered the issue of meal replacements at length. We consider that the use of meal replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.

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						<p>when classifying diets. Because of some concerns about the definitions , we have tried to be explicit (that is, include as much detail as possible about the dietary content) in both the evidence tables and the evidence statements.”</p> <p><b><i>Recommended addition in caps</i></b></p> <p>Objective : Inclusion of meal replacements in ‘Clinical Management Section’ and understanding of the unique legal status of Meal Replacements – they must not be confused with ‘normal’ foods</p> <p>This becomes particularly important when including in this section diets such as ‘low fat’, ‘salt restriction’, ‘low carbohydrate’, etc. Such diets are followed using written advice or altered ‘normal foods’. Unlike PARNUTS foods they do not contain the complete nutritional requirements of dieters, have not been submitted to any regulatory review, and have no specific legal status. To restate: PARNUTS foods are  <i>‘foodstuffs which, owing to their special composition ... are suitable for their claimed nutritional purposes’</i>  and they must  <i>‘fulfil the particular nutritional</i></p>	

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						<p><i>requirements .....  of certain categories of persons  who are in a special physiological  condition and who are therefore  able to obtain special benefit from  controlled consumption of certain  substances in foodstuffs'</i></p> <p><b>They must be distinguished at all  times from 'normal foods'.</b></p>	
Infant and Dietetic Foods Association	16		Lifestyle			<p>1. Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22).</p> <p>2. Note that two other categories are identified as PARNUTS formula foods for weight loss – low calorie diets for the sole source of nutrition (800 – 1200kcal) and very low calorie diets for the sole source of nutrition (400 – 800kcal)</p>	Thank you for your comment.
Johnson & Johnson Medical Ltd	1	NICE	Surgery	10	-	<p>The summary has combined two separate recommendations into one, which results in a very different and unintended meaning.</p> <p>The final bullet point was intended as an <b>additional</b> indicator for surgery and therefore should be identified as such. Without amendment, it could be interpreted as surgery only being indicated for patients with BMI &gt;50 kg/m<sup>2</sup>. We suggest the following amendment (<b>additions in bold and</b></p>	Noted and revised.

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						<p><b><u>underlined</u></b>):</p> <p><b><i>Text currently reads:</i></b>  Surgery is recommended as a treatment option for severely obese people provided all the following criteria are fulfilled.</p> <ul style="list-style-type: none"> <li>- There is evidence that all appropriate non-surgical measures have been tried but have failed to achieve/maintain adequate clinically beneficial weight loss for at least 6 months.</li> <li>- The person has been receiving intensive management in a specialist obesity service.</li> <li>- The person is generally fit for anaesthesia and surgery.</li> <li>- The person commits to the need for long-term follow-up.</li> </ul> <p><b><u>In addition,</u></b> Bariatric surgery is <b><u>also</u></b> recommended as a first-line option for people with a BMI greater than 50 kg/m<sup>2</sup>, and in whom surgical intervention is considered appropriate.</p>	
Johnson & Johnson Medical Ltd	2	NICE	Surgery	48	1.2.7.1	<p>This paragraph indicates that the BMI limits used to guide patient selection for suitability for surgery recommended by technology appraisal no. 46 have been removed, and replaced by the requirement to meet the four criteria listed below:</p> <ul style="list-style-type: none"> <li>- There is evidence that all</li> </ul>	Noted. Thank you for your comments.

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						<p>appropriate non-surgical measures have been tried but have failed to achieve/maintain adequate clinically beneficial weight loss for at least 6 months.</p> <ul style="list-style-type: none"> <li>- The person has been receiving intensive management in a specialist obesity service.</li> <li>- The person is generally fit for anaesthesia and surgery.</li> <li>- The person commits to the need for long-term follow-up</li> </ul> <p>We endorse this recommendation.</p>	
Johnson & Johnson Medical Ltd	3	NICE	Surgery	49	1.2.7.3	We support the recommendations made regarding the requirements of multidisciplinary teams undertaking surgery for obesity	Thank you for your comments.
Johnson & Johnson Medical Ltd	4	NICE	Surgery	49	1.2.7.4	<p>The wording of this recommendation and its proximity to the previous recommendations may lead to the guideline being misinterpreted. This is considered likely as the original technology appraisal had surgery indicated by BMI (mentioned above), so providers 7 commissioners maybe looking for similar recommendations. We therefore recommend the GDG amend the start of the paragraph to explicitly identify it as a separate recommendation, such as:</p> <p><b><u>In addition</u></b>, Bariatric surgery is <b><u>also</u></b> recommended as a first-line</p>	Noted and some revisions made.

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						<p>option for people with a BMI &gt; 50 kg/m<sup>2</sup>, and in whom surgical intervention is considered appropriate. (Adult)</p> <p>Alternatively, paragraphs 12.7.4 &amp; .5 could be separated by a sub-heading specific for patients with BMI &gt; 50 kg/m<sup>2</sup>.</p> <p>We endorse the recommendation of surgery as a first line option for patients with a BMI &gt; 50 kg/m<sup>2</sup> as these are small but specific group who could be considered in need of more immediate weight-loss assistance.</p>	
Leeds Teaching Hospitals NHS Trust	1		Surgery			<p>The comments below are the combined comments of members of the Trust's Obesity MDT (adults) and paediatrician. The Obesity MDT consists of both medical and surgical representatives, dietitian and the project lead for obesity (a dietitian from NW PCT.) The MDT is working across primary and secondary care boundaries to improve the obesity patient pathway for adults. (NB The Trust dietitian has not put forward views on the NICE guidance as she is a member of the NICE guidance group.) The paediatrician works in the Trust, the East Leeds PCT and the University of Leeds.)</p>	Thank you for your comments.
Leeds Teaching	2	NICE	Misc	General		The layout of the tables is confusing.	Noted, and editorial input has

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Hospitals NHS Trust						It would aid presentation and understanding if the adult's and children's tables were separate.	been accessed.
Leeds Teaching Hospitals NHS Trust	4	NICE	Misc	5	general	There is a significant time implication to primary care staff to be able to cover the patient assessment and give information as indicated.	Noted but we have highlighted that not all the assessment and information need be delivered in one consultation, but should be appropriate to need.
Leeds Teaching Hospitals NHS Trust	5	NICE	Drugs	9		A definition of an appropriate health professional would be useful to provide clarity on what arrangements need to be made to support a patient on medication	We do recommend that any healthcare professional involved in the delivery of interventions for weight management must have the relevant competencies. However, to issue guidance on the specific set of competencies is outside our remit. We have added an additional paragraph/section on training, based on information already included throughout the guidance. The specifics of implementation – including local training needs and the skill mix required – are outside the remit of this work. The guidance allows local providers to interpret and implement the guidance as appropriate to their situation. However, a number of recommendations highlight the type of skills that should be acquired by staff, as appropriate.
Leeds Teaching Hospitals NHS Trust	6	NICE	Surgery	10		Clarity on what a clinically beneficial weight loss is would be useful –is this 10% of body weight?	Yes, but we have not specified this so as to allow for clinical judgement as appropriate.
Leeds Teaching	7	NICE	Surgery	10		What should long term follow up entail	This should be as needed by the

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Hospitals NHS Trust						– what level of input, how regularly?	individual.
Leeds Teaching Hospitals NHS Trust	13	NICE	Assess	34	1.2.2.1	Why not measure height and weight routinely? Whilst it may be obvious that someone is morbidly obese, it is not obvious that someone is overweight. How can changes in BMI be tracked?	We have decided to withdraw this recommendation on the grounds that population-based screening programmes are outside our remit.  We do, however, still recommend that healthcare professionals should use opportunities to measure height and weight if this is deemed appropriate.
Leeds Teaching Hospitals NHS Trust	14	NICE	Ident	35 36	1.2.2.5 1.2.2.10	1.2.2.5 and 1.2.2.10 contradict. 1.2.2.5 says that waist-hip is not a measure of central adiposity whilst 1.2.2.10 suggests that it should be taken into account in the risk assessment.	1.2.2.10 refers to the measurement of waist circumference and not waist to hip ratio.
Leeds Teaching Hospitals NHS Trust	15	NICE	Lifestyle	36	1.2.2.10	It would be helpful to insert a reference to paragraph 1.2.3.2 here so it is clear what the assessment should include	Noted and revised.
Leeds Teaching Hospitals NHS Trust	16	NICE	Lifestyle	40	1.2.4.4	Need more information on what the relevant competencies referred to are.	It is outside our remit to give specific detail on which are the relevant competencies. However, we have expanded the section on training to ensure that the need for training is given appropriate emphasis.
Leeds Teaching Hospitals NHS Trust	17	NICE	Lifestyle	41	1.2.4.9	Needs clarity on what an appropriate level of training is	We have added an additional paragraph/section on training, based on information already included throughout the guidance.  The specifics of implementation –



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							including local training needs and the skill mix required – are outside the remit of this work.  The guidance allows local providers to interpret and implement the guidance as appropriate to their situation. However, a number of recommendations [highlight the type of skills that should be acquired by staff, as appropriate.
Leeds Teaching Hospitals NHS Trust	18	NICE	Drugs	44	1.2.5	Guidance on pharmacological treatment for children is very welcome	Thank you for your comment.
Leeds Teaching Hospitals NHS Trust	19		Drugs	44	1.2.5.3	Needs clarity on appropriate health care professional to give advice to support pharmacological interventions	We have not specified who should give advice, but have recommended that anyone delivering such interventions (including advice) should have the relevant competencies etc. – see 1.1.4.4.
Leeds Teaching Hospitals NHS Trust	20	NICE	Drugs	45	1.2.5.9 (paeds)	The recommendation of a registry on the use of orlistat and sibutramine is important. These medications are experimental in the paediatric age range, and a register would help insure that the paediatric community is informed of both benefits and harms	In the research recommendations we have given as much detail as we could in regard to the creation of a registry.
Leeds Teaching Hospitals NHS Trust	21	NICE	Misc	47	1.2.6	Need to define what is meant by secondary and specialist care	We have used the Department of Health's document on specialised Services National definition set. For further details please refer to <a href="http://www.dh.gov.uk/PolicyAndG">http://www.dh.gov.uk/PolicyAndG</a>

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							<a href="https://www.nice.org.uk/guidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187&amp;chk=jAqaRv">uidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187&amp;chk=jAqaRv</a>
Leeds Teaching Hospitals NHS Trust	22	NICE	Misc	47	1.2.6	The section on referral to secondary and specialist care is important, and I suspect will be open to comment. It needs some further clarity, as services at present are not widely available and the potential numbers of children requiring paediatric care is enormous.	Noted.
Leeds Teaching Hospitals NHS Trust	23	NICE	Misc	47	1.2.6.1	It is clear that children with comorbidity need paediatric input, but as most of the comorbidity is subclinical, children will only be identified if they undergo investigations for liver dysfunction, hyperlipidaemia and glucose impairment, (and blood pressure is measured). Professionals in primary care will require some guidance as to who to investigate. (This will be hard as the evidence base indicates that severity of obesity is not a consistent predictor. Perhaps family history and ethnicity can form part of the guidance, as has been adopted by the American Academy of Peds).	We have tried to be clear about investigation and assessment in children for these reasons.
Leeds Teaching Hospitals NHS Trust	24	NICE	Surgery	48	1.2.7.1	"Specialist obesity service". We welcome the fact that patients are not required to attend a hospital obesity clinic prior to surgery, assuming that the surgery service is fully NICE	Noted –see also the Implementation section.

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						compliant. However, we are concerned that many PCTs do not have a specialist obesity service and that this once again will be seen as a reason not to refer a patient for surgery.	
Leeds Teaching Hospitals NHS Trust	25	NICE	Surgery	49	1.2.7.5	Need to read "Drug therapy is not necessarily recommended as first-line treatment for people with a <i>BMI greater than 50</i> who are considered suitable for surgery.	Noted, but wording considered appropriate.
Leeds Teaching Hospitals NHS Trust	26	NICE	Surgery	50	1.2.7.7	Patients with binge eating disorders may benefit prior to surgery with input from a psychologist. After surgery, the psychologist may be able to help with life style adjustments. It may be that with improved follow-up from the multidisciplinary team that the support following surgery can be given by an experienced dietitian and nurse with the appropriate skills.	We have recommended that psychological support is given before and after surgery (but have not defined who should do this).
Leeds Teaching Hospitals NHS Trust	27	NICE	Surgery	51	1.2.7.12	The surgeon should be an upper GI surgeon	Noted but we consider the current wording to be appropriate.
Leeds Teaching Hospitals NHS Trust	28	NICE	CP	73		The clinical pathway for children is important to include, however I have some concerns as follows: 1. There is a feedback loop so that all children who do not attain successful weight control are referred to a paediatrician. This is not likely to be helpful, and it would certainly block referral pathways to no benefit 2. The biochemical tests for comorbidity can as well be carried out	Thank you.  We have only recommended that referral be considered.  The GDG considered that such tests in children should be

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						<p>in primary care</p> <p>3. Some specification needs to be made that the paediatrician should work with the support of dietetic, sport and CAHMS professionals. A lone paediatrician is unlikely to be helpful</p> <p>4. The specialist management box needs to emphasise that paediatric care MUST be in the context of a multidisciplinary team (as mentioned earlier in the document)</p>	<p>undertaken in secondary care.</p> <p>It is anticipated that paediatricians will be working in teams/structures as outlined in the NSF for children.</p>
Leeds Teaching Hospitals NHS Trust	29		CP	74	Pathway adults	<p>Management box- Needs to indicate that weight management should include all the bullet points listed. This would be multifaceted and in line with the rest of the document. Some indication of where the management interventions will take place (i.e. primary care? / Community settings? etc) would be useful to help visualise the pt journey.</p>	<p>We have provided details on which components are appropriate for different degrees of risk. Also service delivery is outside our remit, but we have written the guidance so that professionals/clinicians can exercise their own clinical judgement as appropriate, and for local providers to interpret and implement the guidance as appropriate to their situation.</p>
Leeds Teaching Hospitals NHS Trust	30		CP	74	Pathway adults	<p>Needs some guidance on desired weight loss, i.e. 10% and in what time period?</p>	<p>Noted and added details to the pathway.</p>
Leeds Teaching Hospitals NHS Trust	31		CP	74	Pathway adults	<p>Needs greater clarity on how many times a patient would go round the loop from assessment to management to determine when a referral to specialist obesity services is appropriate. If all pts who are deemed to have failed with conventional treatment in primary</p>	<p>We have not provided details of 'how many times' as we have written the guidance so that professionals/clinicians can exercise their own clinical judgement as appropriate.</p>

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						care are referred to specialist centres (as cited), services will very quickly reach capacity, bearing this in mind they may then be unable to provide the intensity of support recommended to those requiring surgery.	
Leeds Teaching Hospitals NHS Trust	32		CP	74	Pathway adults	Not clear where patients go post discharge from specialist services. The document highlights patients need to commit to long term follow up but this is not reflected in the pathway.	There is a link from 'Consider referral' to 'Management'. Management could therefore happen in any setting as appropriate to the individual.
Leeds Teaching Hospitals NHS Trust	34	Full section 5b	Lifestyle	General		We noted a number of non UK studies that advocated very low energy intakes or an Atkins-type regimen. Whilst these studies achieved good results, we believe these outcomes would be short-term, the diets are not sustainable and would not achieve long term successful weight control.	We have phrased the recommendations so that any diet considered in the longer term should be sustainable, and in line with current guidelines on healthy eating.
Leeds Teaching Hospitals NHS Trust	35	Full section 5b	Misc	General		We are unable to comment on surgical interventions and anti-obesity medication in children.	Noted.
Leeds Teaching Hospitals NHS Trust	36	Full section 5b	Lifestyle	General		We support the recommendation that weight reduction programmes should comprise ALL of the following: A multi-disciplinary approach Advice on nutrition and physical activity Behavioural treatment Decreasing sedentary activities and increasing lifestyle activities. Social and / or psychological	We have attempted to capture these key points in all the recommendations that are related to the management of obesity in children and young adults. We do briefly mention some of the issues in the barriers section; however, we will try to give more emphasis to this in the 'Patient-centred care' section.

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						<p>support provided by appropriately trained individuals.</p> <p>The Leeds "WATCH IT" programme for children above 8 years of age is run along similar lines. However we understand some difficulties in recruitment have been experienced as a result of a negative attitude held by parents and children to such programmes. A further barrier to children embarking on a weight reduction regimen is a failure by some parents to recognise and accept that their children are overweight/ obese. Both these issues need to be addressed to allow greater numbers of children to benefit from such programmes</p>	
Leeds Teaching Hospitals NHS Trust	37	Full section 5b	Lifestyle	General		<p>We are in support of programmes, where children can be seen without their parents. This provides an opportunity for children to disclose reasons behind over eating or underlying issues that may be related e.g. family conflict, parental separation.</p>	<p>A valuable point. We do not have evidence to support this; however, we would consider this as part of usual clinical practice if such issues were suspected.</p>
Living Streets	2		PCC	6		<p>We support the recommendation that there should be agreed goals and actions for the patient. It is important that treatment is not imposed and that changes can be adapted to the patient's circumstances and build on exercise, such as walking, that the patient already does.</p>	<p>We have stressed throughout the importance of recognising that people may refuse treatment/intervention for many reasons, and that any changes that are agreed should be in partnership, and build on the skills of the individual.</p>
Medtronic	1	Full version	Surgery	43	14-16	<p>Pre-requisite for surgery: not clear if</p>	<p>Noted and clarified.</p>

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International Trading Sarl						the "for at least 6 months" refers to the length of time the non-surgical interventions have to have been tried or the period during which weight loss has to be maintained (with these interventions)	
Mend Central Ltd	3	NICE	Lifestyle	9	Clinical – children and adults	Multicomponent interventions should also improve self-esteem and confidence in obese children who often suffer with low self-esteem, depression and even have higher levels of suicide than healthy weight children.	We have revised this recommendation in light of the stakeholder comments.
Mend Central Ltd	4	NICE	Ident	9	Children – 2nd bullet point	If BMI is not a direct measure of adiposity then why is it being used in isolation? Use of waist circumference is imperative in order to distinguish between children who may be stocky or muscular and those with obesity. Considering the scarce NHS resources available, surely identifying those with the highest negative health risk would be an advantage? If waist circumference is used in conjunction with BMI, those at most risk of poor future health could be identified and preference given to them in terms of treatment.	We do agree with the comments, and recommendation 1.2.2.4 does state that waist circumference can be used as additional information, when appropriate.
Mend Central Ltd	5	NICE	Assess	9	3rd bullet point	Must be made clear that only those children who are obese AND have significant complications or are at risk of significant comorbidity should be referred to a paediatrician. Children with simple obesity do not need to be referred to paediatricians as this	We agree with these comments; however, we think that this is clear in the recommendation.

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						medicalises the problem. Treating them in community settings is the most ideal setting for children with simple obesity. It also swamps paediatricians unnecessarily.	
Mend Central Ltd	28	NICE	Lifestyle	33	Recommendations for the public	..... applies to adults only..... Explain why – because diets are NOT recommended for children. This should be stated more strongly, transparently rather than inferred.	The recommendations have been revised with the GDG and they were content with the wording.
Mend Central Ltd	29	NICE	Lifestyle	33	1.2.1.2	Collaborative between who? Parent and child, child or doctor?	This has been revised.
Mend Central Ltd	31	NICE	Ident	35	1.2.2.4	Waist circumference is a good predictor of heart disease and diabetes and therefore should be routinely measured in all obese children. It is also extremely useful to differentiate those who are stocky/muscular from those with abdominal adiposity. BMI and waist circumference should be measured together to give a clear clinical picture.	We acknowledge the value of waist circumference and have thus recommended that it can be used alongside BMI.
Mend Central Ltd	32	NICE	Assess	39	1.2.3.3	.....when they are ready to make lifestyle changes and should be informed or made fully aware of the risks involved in not doing so.	The recommendation has been revised in light of this and other comments.
Mend Central Ltd	33	NICE	Lifestyle	43	1.2.4.15	As children are still growing, dietary advice needs to be consistent with healthy eating advice which will promote weight loss or maintenance. It also must be easy to adhere to and promote linear growth. In addition, the dietary recommendations should be acceptable to individual tastes and	Throughout the dietary interventions section we have stressed the importance of tailoring the diet to the child and family, and for such interventions being delivered by professionals with the appropriate training.



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						<p>habits, ethnically appropriate and favour long lasting patterns of food intake.</p> <p>Dietary advice needs to be customised for obese children taking into account children's portion sizes and dietary recommendations. Please make it clear that healthy eating advice is only suitable for children above 5 years of age unless done under the care of a paediatric dietitian.</p>	
Mend Central Ltd	34	NICE	Lifestyle	43	1.2.4.16	Please make clear that this recommendation is for adults only.	The recommendation is already annotated as for adults only, but this will be made clearer in the final version.
Mend Central Ltd	35	NICE	Lifestyle	43	1.2.4.17	Dietary advice cannot be individualised for all children. Dietary advice given to groups of obese children has been shown to reduce intake of macronutrients and increase intake of fruit and vegetables. Giving individualised dietary advice is very time consuming, expensive and unnecessary when teaching healthy eating.	This recommendation relates to care in the clinical setting, where care will usually be delivered to those who are obese/overweight on a one-to-one basis. In such circumstances it is correct for the child to be offered individualised advice.
Mend Central Ltd.	6	NICE	Drugs	9	Adults	Remove "usually" in 1st line. Drugs should only be recommended after dietary and exercise advice has been tried and found to be ineffective. The MEND Programme could be offered to families when there are obese children as often there will also be obese adults. If the parents do not	Noted and revised. We have also added more detail in this recommendation in light of the stakeholder comments.

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						succeed in losing weight then drug treatment could be recommended. By not offering the whole family the opportunity to take part in a multicomponent intervention, the root causes of the obesity will not be addressed and the chance of the long-term success will be much less than if they attended a multicomponent programme	
Mend Central Ltd.	30	NICE	Misc	34	1.2.1.5	Regular long-term follow up ..... this is very difficult to provide with no funding or advice on prioritisation. Good record keeping is essential but more important is clear ownership/leadership by one or more of the team not continual passing of responsibility.	Noted.
Mend Central Ltd.	36	NICE	Drugs	44	1.2.5	<p>Prescription of weight loss medication for children should not be allowed unless they have been on a multicomponent, community, lifestyle intervention beforehand. If they are prescribed the medication, it should be a requirement that they attend a multicomponent lifestyle intervention to ensure that their diet is improved and that they increase their physical activity levels.</p> <p>Prescription of weight loss medication without the above provisions is totally unacceptable from a child health point of view.</p>	We have considered this and other comments from stakeholders and we have revised the recommendation.
Mend Central	37	NICE	Surgery	48	1.2.7	Bariatric surgery for children should	Has been clarified.

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Ltd.						not be allowed unless they have been on a multicomponent, community, lifestyle intervention beforehand. Before surgery is even considered, it should be a requirement that they attend a multicomponent lifestyle intervention to ensure that their diet is improved and that they increase their physical activity levels.	
Merck Sharp & Dohme Ltd	2	NICE	Drugs	General		A new class of pharmacological interventions, the Cannabinoid Receptor Antagonists, is expected to be licensed and available to physicians before this guideline is reviewed in 2010. Indeed, we understand that the CHMP has already issued a positive opinion for the first treatment in this class, rimonabant. These look to be a new generation of effective treatments and seem to be well tolerated. Although we recognise that the scope states that only orlistat and sibutramine will be considered specifically, we feel that there should be a forward-looking statement of some kind included in the guideline, along the lines of; 'New pharmaceutical interventions indicated for the treatment of overweight and obesity may become available in England and Wales prior to this guideline being reviewed. Physicians should take note of local guidance and protocols regarding the use of these medicines and refer to	These drugs are outside the scope, but prescribers should and will be aware of new developments.

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						the Summary of Product Characteristics when considering them as treatment options.'	
Merck Sharp & Dohme Ltd.	1	NICE		General		<p>We feel that there is insufficient prominence granted to pharmaceutical interventions within the guideline. The interventions are evidence-based and have been shown to be cost effective in the guideline. Whilst currently available treatments are not without their limitations we regard them to be an important clinical tool for treating obese and overweight patients, and anticipate that pharmaceutical agents will have an important role to play alongside dietary and lifestyle interventions in the future.</p> <p>Newer pharmacological interventions that can provide greater weight loss together with reductions in CV risk factors would be a suitable advance, and research in this area should be supported and encouraged by the NHS and the Department of Health.</p>	<p>We have sought to give equal importance to all types of intervention based on the evidence, and consider that the role of drugs within a comprehensive management programme is well covered. Drugs other than orlistat and sibutramine are outside the remit of this guidance.</p>
Merck Sharp & Dohme Ltd.	3	NICE	Drugs	45	1.2.5.9	<p>We endorse the recommendation to set up a registry to track prescribing of pharmaceutical interventions for obesity in young people, and believe that such a registry should be transparent and accessible to parties such as patient groups and the pharmaceutical industry. Ideally this registry would be owned by a third party rather than the NHS or</p>	<p>Thank you for your comment.</p>

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						Department of Health, an appropriate patient organisation, for example.	
Merck Sharp & Dohme Ltd.	4	NICE	Misc	General		We recommend that a number of regional managed clinical networks be established regarding obesity, similar to those for diabetes, psychiatric care, etc. This would enable primary care professionals to work in close collaboration with secondary care colleagues, whilst at the same time being able to access other non-NHS support and resource, such as dietary advice, physical activity initiatives, community weight management programmes, local government, local schools, etc. to implement the guideline's recommendations.	Noted. However, such service specification is outside the scope.
MHRA	1	NICE	Drugs	9	21	<p>Adults- Pharmacological Treatment</p> <p>The weight loss induced by pharmacological agents, such as orlistat or sibutramine, is in the order of 2.5 - 5 kg. Such weight loss may be of cosmetic benefit, but it is insignificant in terms of health benefit.</p> <p>For reviews please see: Warren J. Obesity - weighing the evidence before prescribing. BrJ Clin Pharmacol 2004;59:259-261 and Reidenburg MM. Are we treating health or physical appearance when we prescribe drugs for obesity? Clin Pharm &amp; Therapeutics 2000;67:193-</p>	<p>We have reviewed a lot of very convincing evidence that shows benefit (other than cosmetic alone) may be achieved: for example, prevention of diabetes, and remission of other conditions.</p> <p>Throughout we have emphasised the need for lifestyle change and healthy eating, rather than viewing pharmacological treatment as a single-component intervention.</p>

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						195.	
MRC Centre of Epidemiology for Child Health, Institute of Child Health, University College London	6	NICE version	Drugs	General		Although details have been provided regarding drug treatments, there is limited information available on behavioural interventions. Clearer guidance, such as protocols, for effective behavioural interventions is needed by practitioners (p. 41).	We have revised the recommendations on behavioural interventions in light of this and other comments. However, the evidence on such interventions is much more diverse (in terms of interventions), and therefore the GDG considered that the recommendations reflect the evidence, and allow local services to be developed based on need and circumstances.
MRC Centre of Epidemiology for Child Health, Institute of Child Health, University College London	7	NICE version	PCC	p. 5		Patient-centred care: Although this section focuses on the role of clinicians to treat obesity, it does not emphasise their role in prevention. Since the new physical activity guidelines recommend assessing patient's physical activity levels, it would be important for the obesity guidelines to also support the role of clinicians in obesity prevention through monitoring patient's (adults and children) weight, physical activity levels, and diet. [Although this is also discussed on page 16, it would seem appropriate to highlight prevention at the beginning of the document].	An additional section on prevention has been added.
MRC Centre of Epidemiology for Child Health, Institute of Child Health, University College London	14	NICE version	Lifestyle	p. 42	1.2.4.11	This section includes the physical activity recommendation for adults, but does not in the physical activity recommendation for children (at least 60 minutes of at least moderate physical activity daily; Chief Medical	This has been discussed with the GDG and a new recommendation has been added.

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						Officer Annual Report, 2004).	
MRC Collaborative Centre for Human Nutrition Research (HNR)	3	NICE version	CP	9	Line 7	Children and Adults - What is “an improved eating behaviour”? We suggest the sentence is rephrased to: ..decrease inactivity, improve quality of the diet and make changes in eating behaviour in support of dietary goals.	We took back these and other issues to the guideline development group, which considered that the wording was appropriate.
MRC Collaborative Centre for Human Nutrition Research (HNR)	5	NICE version	CP	9	Line 16	We agree that BMI charts need to be interpreted with caution as it is not a direct measure of adiposity but why not measure body fatness with a simple measure such as bioelectrical impedance?	We have reviewed literature on this and the evidence did not support the use of bioelectrical impedance as opposed to BMI.
MRC Collaborative Centre for Human Nutrition Research (HNR)	10		Misc	General		Currently health professionals receive limited training for the treatment of obesity. More information is required on the specific training health professionals should undergo including undergraduate, postgraduate and continuing professional development opportunities. This raises resource implications for training that are not addressed.	We have added additional paragraph/section on training, based on information already included throughout the guidance. The specifics of implementation – including local training needs and the skill mix required - are outside the remit of this work. The guidance allows local providers to interpret and implement the guidance as appropriate to their situation. However, a number of recommendations highlight the type of skills that should be acquired by staff, as appropriate.
MRC Collaborative Centre for Human Nutrition Research (HNR)	15	NICE version	Ident	34	1.2.2.1	Routine measurement of height and weight is not recommended for adults. Why not? If we want to prevent overweight and obesity in adults it is important to monitor weight trends. Early intervention is vital. If only	We have withdrawn recommendation 1.2.2.1 to avoid misinterpretations. However, it is still recommended that healthcare professionals should use opportunities to measure height

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						overweight and obese people should be weighed how do you decide who to weigh and who not to weight? Routine weighing also identifies other problems associated with involuntary weight loss.	and weight as appropriate.  We also recommend in the public health section that people should be encouraged to monitor their weight.
MRC Collaborative Centre for Human Nutrition Research (HNR)	16	NICE version	Ident	35	1.2.2.6	"Bioimpedance is not recommended as a substitute for BMI". Why not since it gives a better measure of adiposity than BMI.	There was no evidence that compared the use of bioimpedance to BMI, which is the question that was asked by the GDG.
MRC Collaborative Centre for Human Nutrition Research (HNR)	17	NICE version	Ident	36	1.2.2.9	What is the evidence for different BMI cut offs for older adults?	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
MRC Collaborative Centre for	18	NICE version	Assess	38	1.2.3.2	Specific guidance on the interpretation and management following the results of endocrine	It is outside our remit to provide further guidance on specific details of the investigations, as



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Human Nutrition Research (HNR)						investigations and the use of genetic tests should be provided.	these relate to management of specific clinical conditions, which are outside our remit.
MRC Collaborative Centre for Human Nutrition Research (HNR)	19	NICE version	Lifestyle	40	1.2.4.4	<p>“..have the relevant training and competencies” What is relevant training and what competencies are needed and who is going to provide this?</p> <p>Knowledge of nutrition, physical activity and health behaviour is important.</p>	It is outside our remit to give specific detail on which are the relevant competencies. We have added an additional paragraph/section on training, based on information already included throughout the guidance. The specifics of implementation – including local training needs and the skill mix required – are outside the remit of this work. The guidance allows local providers to interpret and implement the guidance as appropriate to their situation. However, a number of recommendations highlight the type of skills that should be acquired by staff, as appropriate.
MRC Collaborative Centre for Human Nutrition Research (HNR)	20	NICE version	Lifestyle	40	1.2.4.7	Healthy eating advice should be added to this list. In addition, guidance should be given on the appropriate sources for credible and accurate information from authoritative sources.	Noted and added.
MRC Collaborative Centre for Human Nutrition Research (HNR)	21	NICE version	Lifestyle	42	1.2.4.13	Nowhere within the consultation does it acknowledge that physical activity alone is not recommended. This should be included. Also it ignores or undervalues the health benefits of dietary changes independent of weight loss.	We have added a recommendation on how single-component interventions are not recommended and on the importance of improving the diet. Throughout we have stressed the importance of multicomponent interventions, rather than single-

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							strategy approaches.
MRC Collaborative Centre for Human Nutrition Research (HNR)	22	NICE version	Lifestyle	43	1.2.4.16	There is little evidence that a low-fat diet would produce weight loss in itself. Low fat diets are only effective for weight loss as a method to reduce energy intake.	We have added in a definition of 'low fat' that should address your concern.
MRC Collaborative Centre for Human Nutrition Research (HNR)	23	NICE version	Drugs	44	1.2.5.2	Children with established weight problems at 12 years need specialist interventions. Drugs can only be an adjunct to more fundamental changes in diet and physical activity habits. More formal protocols need to be developed particularly for the use of medication and surgery options. Issues of medical responsibility need to be addressed especially in the case of drug reactions which do not currently have a product licence for children.	Noted. We have emphasised the need for multicomponent interventions. Detailed protocols on drug and surgery use are outside the remit of the guidance.
MRC Collaborative Centre for Human Nutrition Research (HNR)	24	NICE version	Drugs	45	1.2.5.4	Diet is missed out in the list. Drugs are an adjunct to diet, not an alternative.	Noted and revised.
MRC Collaborative Centre for Human Nutrition Research (HNR)	25	NICE version	Drugs	45	1.2.5.8	Clarification is required on the less strict goals of weight loss	The group felt that the current recommendation was adequate as it stands.
MRC Collaborative Centre for Human Nutrition Research (HNR)	26	NICE version	Drugs	46	1.2.5.9	What details should be in this registry?	We have given as much detail as possible as we feel appropriate in a clinical guideline in regard to the creation of a registry in the research recommendations.
MRC	27	NICE version	Drugs	46	1.2.5.10	The individual plan should include	We have emphasised throughout

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Collaborative Centre for Human Nutrition Research (HNR)						individualised recommendations on diet and physical activity	the importance of taking an individualised approach.
MRC Collaborative Centre for Human Nutrition Research (HNR)	28	NICE version	Drugs	46	1.2.5.13	What vitamin supplementation and what doses?	Recommendation has been revised.
National Obesity Forum	1	NICE version	PCC	5		Patient centred care – we suggest that it is made clear that the following items are covered in the 'initial consultation' rather than any consultation. Experience from HCP within the NOF is that patients disbelief is often routed in lack of awareness that that they themselves maybe obese, and therefore at the first consultation they may not even be in the pre-contemplation stage.	We have not stated which items should be covered at which consultation as we consider that each consultation should be tailored to the individual, and allow for different items to be addressed at the appropriate time, which may be at the initial or subsequent consultations. However, we do note the issue about lack of awareness and have made recommendations to address this.
National Obesity Forum	2	NICE version	PCC	6		For patients who are not yet ready to change expand guidance to include providing contact / access information to return the services when ready.	Noted and added.
National Obesity Forum	7	NICE version	Drugs	9, 44	1.2.5.3	Adults – suggest restructure first sentence to reflect diet & physical activity as first line treatment and pharmacotherapy as second line. Also should include measures to be used to assess adiposity e.g. BMI/ Waist. Suggest expanding the 'specific concomitant advice' to include	We have revised the recommendations to reflect this and other concerns.

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						associated and appropriate patient support programmes provided by pharmaceutical companies to improve patient concordance, as recommended in the DH Care Pathway. For example Xenical-MAP and Reductil-Change for Life.	
National Obesity Forum	8	NICE version	Surgery	10, 49		<p>Surgery. We notice that this guidance does not incorporate the current NICE guidelines for surgery. It is our view that there is lack of research evidence for long term outcomes of non-surgical interventions in the super obese patient population. Therefore it is our belief that it is an unsafe recommendation to have surgery as first line.</p> <p>We suggest the guidance prioritises the provision of ongoing structured support by stating that it 'is essential that provision is made for life-long post operative support is in place prior to surgery'.</p>	<p>This guidance replaces current NICE guidance on surgery.</p> <p>Support should be as needed by the individual, but we have recommended that follow-up be long-term.</p>
National Obesity Forum	19	NICE version	Misc	33	1.1.7.5	Evidence for Meal replacements, LCDs and VLCDs is good in appropriate circumstances, even though not fulfilling 'balanced diet' Many programmes include behavioural change counselling as part of the scheme, and should be encouraged for certain patients	We have revised these recommendations in light of this and other comments.
National Obesity Forum	20		Misc	33	1.2.1.1.	Suggest expand to 'Appropriate seating, adequate weighing equipment, large blood pressure cuffs and tape measures in a non-	Noted and revised as appropriate.

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						discriminative, culturally sensitive environment.'	
National Obesity Forum	21	NICE version	Ident	34	1.2.2.2	And waist	The GDG did not consider that we should refer to waist in this recommendation.
National Obesity Forum	22	NICE version	Ident	35	1.2.2.4	Waist is now generally accepted as being directly proportional to visceral fat, hence risk. BMI is flawed, because it doesn't take into account body fat distribution. It is also an abstract figure, as is waist: hip ratio, and involve a calculation, whereas waist is a tangible figure, easily measured and understood by patients	Noted. We have recommended that waist be used as appropriate.
National Obesity Forum	23	NICE version	Ident	35	1.2.2.6	This statement would benefit from a bit more qualification. It reads as slightly confusing in the existing text. Also it the rational for this based on issue of correctness of measurement or feasibility of measurement?	There was no evidence that compared the use of bioimpedance to BMI, which is the question that was asked by the GDG, and the recommendation states 'as a substitute for BMI'.
National Obesity Forum	24		Assess	36–37	1.2.2.10 & 1.2.2.11  1.2.3.1	Layout of charts so confusing almost impossible to read. What is meant by assess co morbidity in children? No GP will measure BP in kids, as they do not have the necessary cuffs or tables with which to interpret values. Bloods are rarely taken in children. Adult assessment is completely inadequate. See NOF guidelines. Blood tests should be fasting, and should include LFTs for NASH, and should lead to further tests as appropriate including GTT, HbA1c	We have given some examples of appropriate investigations for adults in 1.1.3.1 and also for children. However, we cannot recommend on further specific details of the testing, as this is down to clinical judgement based on the patient (history, examination, results of other tests).

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						CXR etc. Direct questioning should exclude other co-morbidities, eg chest pain, sleep apnoea etc.	
National Obesity Forum	25	NICE version	Assess	39	1.2.3.4	This doesn't sit well with the childhood obesity monitoring which PCTs are currently being asked to undertake, where there are explicit instructions to take height and weight but not calculate BMI or feed back any results or meaning of results to parents.	Population monitoring (within clinical settings) is outside the remit of this guidance.  This is not done in primary care.
National Obesity Forum	26		Lifestyle	40	1.2.4.4	Not enough to state appropriate training needs to specify training by specialist practitioners who they themselves are qualified. nb currently most primary care practitioners do not have any obesity training.	We have revised recommendation 1.1.4.4 to address comments from stakeholders. We have added an additional paragraph/section on training, based on information already included throughout the guidance. The specifics of implementation – including local training needs and the skill mix required – are outside the remit of this work. The guidance allows local providers to interpret and implement the guidance as appropriate to their situation. However, a number of recommendations highlight the type of skills that should be acquired by staff, as appropriate.
National Obesity Forum	27		Lifestyle	40	1.2.4.5	Expand 'culture' to specify cultural needs and sensitivities What about ethnicity, deprivation, social class and health inequalities? What about physical and mental	This recommendation has been revised as appropriate.

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						disabilities?	
National Obesity Forum	28	NICE version	Lifestyle	44	1.2.4.5	There is an important capacity issue here. The default option is that the practice nurse, the GP, and possibly a dietitian provide the multidisciplinary team. The obvious omission here is a physical activity specialist who should have the equivalent specialist technical knowledge, as well as knowledge of behavioural interventions, as an experienced primary care dietitian has. A useful descriptor which is being used amongst the exercise industry is Clinical Exercise Practitioner. Reference to the Register of Exercise Professionals (REPS) as a means of regulation based on knowledge, experience, and a commitment to professional development, should be made	Noted. We have not made service delivery recommendations as these are outside the remit of the guidance.
National Obesity Forum	29		Misc	47	1.2.6.1	Copy & paste referrals criteria from NOF children's guidelines No definition of what specialist care / service means – need to clarify.	We have added in our recommendations: Surgical care and follow-up provided to young people should be co-ordinated around their individual and family needs and should comply with national core standards as defined in the NSF for Children, Young People and Maternity Services. We have used the Department of Health's document on specialised Services National definition set. For further details please refer to

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							<a href="http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187&amp;chk=jAqaRv">http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187&amp;chk=jAqaRv</a>
National Obesity Forum	30		Surgery	49	1.2.7.5	Very confusing and unclear. Clinical guidelines should not depend on waiting list times.	Noted, but the GDG considered this an important recommendation on the use of drugs in people considered suitable for surgery.
National Obesity Forum	31	NICE version	Surgery	50	1.2.7.7	Specific mention of eating disorders; BED and NES as being contraindications for surgery, and needed specific interventions.	We have recommended a comprehensive assessment and added cross referencing to the Eating Disorders guideline as appropriate.
National Obesity Forum	32		Assess	34, 70	1.2.2.1 & 1.2.2.2 Public Health Map	Suggest all routine medicals should require measurement of height and weight (new patient, insurance medical, annual check of co morbid patients i.e. hypertensive, diabetics, dyslipidaemia etc) We also suggest Public health map is updated to include additional bullet point in 'NHS: primary care – adults' box proactive measurement of all patients during routine medicals and annual proactive screening of high risk patients (i.e. those with co morbidity)	We have decided to withdraw this recommendation as population-based screening programmes for overweight or obesity are outside the remit of this work, and could therefore conflict with this. We did, however, expand the following recommendation as to when healthcare practitioners should use their clinical judgement to use opportunities to measure height and weight. The public health section will address this final point.
National Obesity Forum	34		CP	73-74		NOF supports the use of care pathways and algorithms, and would like to submit the NOF Care Pathway as a gold standard example. The NOF Care Pathway and pharmacotherapy algorithm has been	We have revised our recommendations in light of the comments from stakeholders and these will be incorporated into the Care pathway.



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						<p>developed by a multidisciplinary team of HCP and is evidence based. Specific suggestions to improve the clarity of the NICE clinical care pathway include the following:</p> <ul style="list-style-type: none"> <li>- Under assessment – specify fasting blood tests</li> <li>- Under management – suggest drug therapy is replaced with ‘anti-obesity medication i.e. orlistat and sibutramine’</li> <li>- Under referral to specialist services – ‘underlying causes of obesity needs to be assessed (such as .... Drug treatment)’ – there is a wide range of drug treatments which are known to lead to weight gain, the vast majority of these can be effectively managed in primary care without referral to specialist obesity service.</li> <li>- The risk categories are confusing particularly with relation to Asian population, and are inconsistent with evidence and existing NICE guidance on use of pharmacotherapy</li> <li>- We recommend NICE produce an additional algorithm detailing the use of the anti-obesity medication as a quick reference diagrammatic form of the final guidelines on pharmacotherapy use.</li> </ul>	<p>Please note that this guidance replaces previous technology appraisal NICE guidance on drugs and surgery.</p> <p>We feel that practitioners can refer to the drug recommendations as needed, but this algorithm aims to show the overall pathway of care.</p>

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National Public Health Service for Wales (NPHS)	6	NICE version	CP	9		Reading the 'adult' section – would have expected a brief mention of need to address to physical activity and dietary advice before the section on drug interventions. The long term approach should be based on tackling the obesogenic environment	These are Key Priorities for Implementation, and should be read in the context of all the recommendations.
National Public Health Service for Wales (NPHS)	7	NICE version	CP	9		<ul style="list-style-type: none"> <li>The definitions for obesity should be given earlier in the document to avoid confusion and incorrect guidance use.</li> <li>Criteria for surgery – 6 months maintenance is perhaps shorter than expected.</li> <li>Footnote relates only to England - and yet this is part of clinical section therefore relevant to Wales?</li> </ul>	Thank you for your comments.
National Public Health Service for Wales (NPHS)	13	NICE version	Lifestyle	Page 39–41		Sections on behavioural and lifestyle interventions are very brief and do not give reader information about key criteria in running programmes. Does not discuss one to one versus group interventions or the optimum number of sessions, duration or gap between sessions for the behavioural approach to be most effective. Would benefit from cross referencing to relevant section of full guidance document	Because of the heterogeneity of the evidence, we have not been prescriptive about the details of the programmes to be delivered. However, we emphasise that any intervention should be based on the preference of the individual, the competencies of the healthcare delivering the intervention, and local service provision.
National Public Health Service for Wales (NPHS)	19	NICE version	Misc	33-34 and onwards		The tables are presented in a confusing manner. Hopefully this can be tightened up before final publication.	Noted.
National Public	20	NICE version	Lifestyle	41	1.2.4.8	The list of interventions will need	We have recommended that only

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Health Service for Wales (NPHS)						'translation' and interpretation for many professionals, who are not specialists in the field.	healthcare professionals with appropriate skills deliver such interventions; therefore the expectation would be that these terms would be understood by the practitioners concerned. In addition, the glossary offers definitions of technical terms.
National Public Health Service for Wales (NPHS)	21	NICE version	Lifestyle	Page 43	1.2.4.16 and 1.2.4.17	These are confusing tables and sections at first sight, and terms need fuller explanation: e.g. protein sparing modified fasting' diet	We have revised these recommendations in light of this and other comments.
National Public Health Service for Wales (NPHS)	22	NICE version	CP	69 onwards	The algorithms	The information is useful, however the presentation is very busy, and could prove confusing. Again we would urge you to consider the presentation and suggest simplification where possible.	Noted.

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NCC-AC		NICE	Drugs	46/80	1.2.5.3.13	<p>Please note in the nutrition support guideline we provide a recommendation on the indications for micro-nutrient supplementation – see below. It would be good if we could become consistent in our message. Please note also that if someone is deficient in vitamin intake there is also a significant chance that their dietary intake could also be inadequate for micronutrient intake. For example in the Nutrition Support guideline: ‘If there is concern about the adequacy of micronutrient intake, a complete oral multivitamin and mineral supplement providing the reference nutrient intake for all vitamins and trace elements should be considered by healthcare professionals with the relevant skills and training in nutrition support who are able to determine the nutritional adequacy of a patient’s dietary intake. D(GPP) ‘</p> <p>Perhaps we could suggest that your recommendation numbered 1.2.5.13 is reworded to say</p> <p>‘If there is concern about the adequacy of vitamin/ micronutrient intake, a complete oral multivitamin and mineral supplement providing the reference nutrient intake for all vitamins and trace elements should be considered, particularly for</p>	Have revised recommendation as suggested.

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						individuals in vulnerable groups such as older people or young people’.	
NCC-AC	3	NICE	Ident	34/80	1.2.2.1	<p>‘Routine measurement of height and weight is not recommended for adults’ Please note this conflicts slightly with the nutrition support guideline – where we specifically recommend that certain groups should be screened for malnutrition or risk of malnutrition. Please note that screening potentially involves measuring weight and height.</p> <p>A suggestion for altering your recommendation could be??</p> <p>‘Routine measurement of height and weight is not recommended for adults who are overweight and or obese’.</p>	<p>After discussion with the GDG we have decided to withdraw this recommendation as screening is not part of our remit.</p> <p>We do still recommend that healthcare professionals use opportunities to measure height and weight if deemed appropriate.</p>
North Central London Strategic Health Authority	2	NICE version	Misc	P34	1.2.2.1	Does this conflict with the PSA target: ‘Obesity status amongst the GP registered population aged 15 to 75 years’? This may distort the overall figures/results for the adult obesity target.	The revised recommendation is not in conflict with this.
North Central London Strategic Health Authority	5	NICE version	CP	P73		The clinical pathway for children lacks detail and clarity at a number of levels, as discussed below:	There is more detail in the recommendations but this aims to give an outline of the care process.
North Central London Strategic Health Authority	6	NICE version	CP	P73		It is not clear what age range/definition is being used for children and young people and cut off points associated with this.	<p>We have used age-specific recommendations where appropriate, and see glossary for general definitions.</p> <p>The GDG did not feel that in light of the available evidence we could confidently support one</p>

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							sole definition of childhood overweight/obesity. The GDG recommended that 'Pragmatic indicators for action are the 91st and 98th centiles.'
North Central London Strategic Health Authority	7	NICE version		P73		It does not specify the context/setting beyond primary care. Therefore, it is not clear which health care professionals should be providing interventions at different levels of the pathway. Schools are not cited as a setting and its not clear whether the pathway is a tool for school nursing	The specifics of implementation are outside the remit of this work. However, we consider that the pathway shows the options (in brief) for children. See the public health pathway for interventions for prevention in schools.
North Central London Strategic Health Authority	8	NICE version	CP	P73		It is unclear where a child is referred to post further assessment/specialist management	There is a double arrow between these, but have revised for clarity.
North Central London Strategic Health Authority	9	NICE version	CP	P73		The pathway does not specify length of time between interventions and with regard to follow up.	We have not provided details of 'how many times' as we have written the guidance so that professionals/clinicians can exercise their own clinical judgement as appropriate. Also details of follow-up are noted as something that needs to be negotiated.
North Central London Strategic Health Authority	10	NICE version	CP	P74		Clinical pathway for adults –lacks clarity and specificity but too detailed in other areas:	Noted.
North Central London Strategic Health Authority	11	NICE version	CP	P74		Health care professionals are not identified.	We have not specified which healthcare professional, but have recommended that any healthcare professional delivering interventions should have the appropriate competencies.
North Central	12	NICE version	CP	P74		The assessment stage is too detailed	Noted, and see full

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London Strategic Health Authority						and complex for all health care professionals to complete.	recommendations for additional detail.
North Central London Strategic Health Authority	13	version	CP	P74		'Desired weight loss' – lacks detail – e.g. previous evidence states that weight loss should be greater than 5% at 3 months – need some guidance as to safe and efficient weight loss goals.	Noted and added detail.
North Central London Strategic Health Authority	14	NICE version	CP	P74		The Grading of interventions table provides a useful and practical tool especially when complete list of co-morbidities is complete and intervention level finalised.	Thank you.
Obesity Management Association [OMA]			Drugs			<p>The Commission reviewed the following;</p> <ul style="list-style-type: none"> <li>-Public Safety</li> <li>-Safety profile of centrally acting appetite suppressants</li> <li>-Possible occurrence of addiction</li> <li>-Effectiveness of the medicines</li> </ul> <p>The Commission concluded the following;</p> <p>Public Safety  Insufficient evidence of significant harm.  Safety profile of centrally acting appetite suppressants  Side effects are generally minor, self-limiting and of no serious consequences.  Possible occurrence of addiction  No evidence was presented to substantiate this concern.</p>	This class of drugs was outside the scope of the guideline.

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						No pharmacological connection to amphetamine. Effectiveness of the medicines Several major studies substantiated the claims for efficacy of these drugs.	
Obesity Management Association [OMA]	1	NICE	Drugs	44	1.2.5.4	NICE guidelines on obesity make no reference to Diethylpropion or Phentermine	These drugs are specifically outside the scope of the guidance.
Obesity Management Association [OMA]	3	NICE	Drugs			Both have been used safely and successfully in the United Kingdom for more than 40 years.	These drugs are outside the guidance scope.
Obesity Management Association [OMA]	4	NICE	Drugs			Both have similar side effect profile to Sibutramine which NICE is recommending and both require similar monitoring.	These drugs are outside the guidance scope.
Obesity Management Association [OMA]	5	NICE	Drugs			Both are available at 10-15% of the price of Sibutramine.	These drugs are outside the guidance scope.
Obesity Management Association [OMA]	6	NICE	Drugs			Both have been cleared by The European Court as being safe and effective.	These drugs are outside the guidance scope.
Obesity Management Association [OMA]	7	NICE	Drugs			In November 2002, The European Court overturned European Commission [EU] decision to withdraw marketing authorisations on anorectics.	These drugs are outside the scope of this guidance.
Obesity Management Association	8	NICE	Drugs			The court stated;  "The Commission was not competent	These drugs are outside the guidance scope.



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[OMA]						<p>to take these decisions; the decisions were invalid because they were not based on new clinical data.</p> <p>“The EU had no power to remove Diethylpropion and Phentermine from the UK market because these authorisations were issued originally by the United Kingdom’s Medical Control Agency [MCA] and not by EU.</p> <p>The court found that the EU had not proven their allegation of lack of efficacy.</p> <p>Efficacy had been proven when the MCA originally registered these medicines.</p>	
Obesity Management Association [OMA]	9	NICE	Drugs			The court also found that no new safety concerns had been proven since the EU review of the safety data in 1996.	These drugs are outside the guidance scope.
Obesity Management Association [OMA]	10	NICE	Drugs			<p>These decisions cannot be ignored because the confirm:-</p> <ol style="list-style-type: none"> <li>1. That Diethylpropion and Phentermine are safe in normal use.</li> <li>2. That Diethylpropion and Phentermine are effective in normal use.</li> <li>3. That Diethylpropion and Phentermine are a low cost, safe and effective alternative to the more expensive Orlistat and Sibutramine.</li> <li>4. The NHS should add Diethylpropion and Phentermine to its list of</li> </ol>	These drugs are outside the scope of the guidance.

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						anorectics so that they are available to more obese patients resulting in large savings to the NHS budget.	
Obesity Management Association [OMA]	11	NICE	Drugs			In 1995, The Medicines Commission conducted a consultation into alleged safety hazards arising from the use of anorectic agents.	These drugs are outside the scope of this guidance.
Patient and Carer Network, Royal College of Physicians	106					<p><b>Respondent 3</b></p> <p>Patient Centred Care p.5</p> <p>Under this heading although there is guidance about consultation on obesity it might be worth adding that such advice might also be given to patients in consultations when other health problems may be discussed rather than an appointment specifically to discuss obesity, which might never arise. In other words on an 'opportunistic' basis which is used as an approach to promote immunisation in children whenever a child is seen. In the same way healthy eating and obesity could be picked up as a topic, if done with sensitivity. This is picked up on page 16 but mentioned only in the context of pharmacy assistants.</p> <p>p.12 under 1.1.1. Recommendations for the Public</p> <p>'A person needs to be in 'energy</p>	<p>We have not stated what the main reason for the consultation may be, however, we have recommended that healthcare professionals use opportunities including registration with a GP practice, consultation for related conditions (including diabetes, cardiovascular disease for example), or other routine health checks.</p> <p>A definition of healthy weight has</p>

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						<p>balance' to maintain a healthy weight' - does not then go on to clarify what is a healthy weight and how this can be assessed, which would have been helpful, for the public, although the use of BMI is mentioned under Clinical Recommendations further on.</p> <p>General Points The aspects of prevention by all agencies are very comprehensively covered but with some repetition. Much of this health promotion work has been going on for some years but with minimal evidence of effectiveness for more deprived groups of the population. It will be essential for all front line workers to be well informed about a healthy diet and factors in preventing obesity and to find the time to discuss these areas when other more pressing health and social matters may threaten to take priority. This may also depend on staffing levels and local resources, for example, Practice nurses may be too busy with more urgent health issues and give less time to obesity matters, the same may follow for doctors in A&amp;E departments who have the opportunity to give advice but not the time perhaps.</p> <p>I feel that this document is useful in raising and maintaining the profile of</p>	<p>been included in the glossary.</p> <p>We have inserted a section on training that explains the importance of front line workers receiving training in the issues around prevention and management of obesity. In terms of service delivery and how this is delivered this is outside the remit of NICE guidance.</p> <p>This may be considered when the implementation guidance is</p>

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						<p>the management of obesity for all agencies. However I feel that there could be more mention of the need for consumers to take note of food labelling in supermarkets and be educated about for example the high fat content of many foods in supermarkets and food outlets.</p> <p>The issue of the psychological aspects of eating a healthy diet is mentioned but could be expanded on.</p> <p>The paucity of UK evidence on the effectiveness of interventions among key 'at risk' groups should be a major area for resources and monitoring of further research.</p> <p>On Appendix D I presume that this will be made more user friendly for consumers in the final version. On p.76 the diagram could be better expressed by the addition of the model used by the Mayo Clinic USA of the pyramid to show the balance of what should be eaten during the course of a week.</p>	<p>developed.</p> <p>We feel this has been adequately addressed in the document.</p> <p>This will be considered in the research recommendations.</p> <p>Your point will be considered before the guideline is published. A number of versions of the guideline will be produced including the information for the public, a quick reference guide a short version and the full version.</p>
Plymouth Hospitals NHS Trust	1	NICE	Lifestyle	5		<p>These recommendations are, in my view, largely platitudes that have failed repeatedly in the past. Stages of change are crucial to patient compliance, and questionnaires are widely available to assess the preparedness of the subject to</p>	<p>We will not be covering detailed issues of stages of change, as there will be forthcoming NICE guidance on behavioural change in 2007. However, we have made reference to the need to consider the level of willingness of the</p>

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						change from externalising to internalising his/her locus of control. Until the latter is reached, there seems little or no point in offering advice or treatment. The vast majority of weight management failures are simply not at the appropriate stage when treatment is offered.	individual, and their right to accept/refuse treatment.
Plymouth Hospitals NHS Trust	3	NICE	Ident	9		Children – the correlation between adult BMI and BMI at primary school is poor and, with the ground shifting so rapidly, there is a real problem with period effects. There is no truly longitudinal evidence to link early BMI with adult metabolic health (Voss LD Int J Obesity 2006;30:606-9).	The first bullet relates more to behavioural changes that need to be addressed in the family context.
Plymouth Hospitals NHS Trust	4		Ident	9		Children – WHO is now recommending breast-fed weight charts. The 1990 charts incorporate a proportion of the weight gain (and metabolic risk) that has accrued over the past 40 years.	We accept that there may be some problems with the UK 1990 charts, but consider them to be the most appropriate tool at present.
Plymouth Hospitals NHS Trust	5		Lifestyle	9		Children – reference might be made to the parent as the key partner (and sometimes obstacle) in reaching the individual child. Evidence suggests that parents are largely unaware and unconcerned about their child's weight – a serious issue (Jeffery AN BMJ . 2005 1;330:23-4)	Noted. This is a valuable point and we have tried to capture this in the 'Patient-centred care' section.
Plymouth Hospitals NHS Trust	6		Surgery	10		Surgery – there is little evidence that dietary management offers long-term benefit to more than 20-25% of all-comers to weight management (see comments on stages of change	Noted.  We have drafted the recommendations to support the use of surgery in people for whom

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						above) and none that it is worth considering in people of BMI >40. Bariatric surgery is one of the (if not the) most cost-effective treatments of all time, given the expense of managing the co-morbidities that otherwise arise. Surgery is safe in practised hands and, in my view, should not be relegated to a back seat. Laparoscopic bariatric surgery is already a day-patient procedure.	this would be appropriate.
Roche	2	NICE version	CP	73-74	NA	<p>Roche fully support the use of algorithms as provided in Appendix C, as a way of presenting the guideline recommendations for implementation within the NHS:-</p> <ul style="list-style-type: none"> <li>We suggest that the wording around assessment of co-morbidities and risk factors within the Clinical Care Pathway for Adults is amended. Random measurement of lipids/glucose can be misleading and it is now accepted that such tests should be done after fasting. We therefore recommend that “fasting lipid profile/glucose” is specified.</li> <li>We suggest that the need for “drug treatment” to be assessed as an underlying cause of obesity, as referred to within the referral box of the Clinical Care Pathway for Adults is potentially unclear and may benefit from further</li> </ul>	<p>Thank you.</p> <p>We have revised our recommendations in light of the comments from stakeholders and these will be incorporated into the Care pathway.</p> <p>We consider that the wording is appropriate within the pathway.</p>

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						<p>clarification. The reason for this view is that a wide range of commonly used medicines can lead to weight gain and so referral to specialist services purely to assess this aspect of causality may not be appropriate.</p> <ul style="list-style-type: none"> <li>• We suggest that the wording around drug use within the two Clinical Care Pathways is further specified for clarity, ie; replace “drug therapy” with “therapy with anti-obesity drugs (ie; orlistat or sibutramine)”.</li> <li>• We also suggest that an additional algorithm relating specifically to the recommendations on pharmacological intervention (section 1.2.5.4 for adults, and sections 1.2.5.10 – 1.2.5.18) would further aid understanding and ease of use of these recommendations.</li> </ul>	<p>We feel that practitioners can refer to the drug recommendations as needed, but this algorithm aims to show the overall pathway of care.</p>
Roche	3	NICE version	Misc	74, 44-47, 34-37		<p>The guidance on management intensity based on level of risk as explained within the Clinical Care Pathway for Adults and with reference to the classification of overweight and obesity (section 1.2.2) is understandably somewhat complex. However, it does appear that this guidance may be unnecessarily confusing, by being overly complex and/or not evidence based with</p>	<p>Noted, but the table does include consideration for these groups.</p>

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						<p>regard to its implications for the suggested point at which drug therapy should be considered:-</p> <ul style="list-style-type: none"> <li>• Both orlistat/sibutramine are recommended for patients who either have a BMI of 28/27 kg/m<sup>2</sup> (ie; overweight) with risk factors, or a BMI of 30 kg/m (ie; obesity 1) or more. Waist circumference is not an additional criterion for pharmacological intervention (section 1.2.5).</li> <li>• Therefore, we suggest that the table on page 74 be amended to indicate that for patients who are obese (rather than overweight), drug therapy should be considered regardless of other factors such as low waist circumference.</li> <li>• If waist circumference is retained as a marker of risk, then the categories low/high/very high need to be more clearly explained (section 1.2.2).</li> </ul>	
Roche	4	NICE version	Drugs	9, 44-45		<p>The recommendations on pharmacological intervention stress the importance of providing periodic concomitant advice, support and counselling on diet, physical activity and behavioural strategies. Roche would like to highlight the availability of our 'Motivation, Advice and Pro-active support (MAP)' programme:-</p>	<p>Have added reference to patient support programmes.</p>



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						<ul style="list-style-type: none"> <li>MAP is an integrated patient support programme which was conceived to support patients through their orlistat weight loss by helping them make informed choices about their food intake, physical activity levels and weight loss goals. MAP has been developed in conjunction with healthcare professionals from around the UK and is staffed by independent healthcare professionals (registered nurses, dieticians and psychologists). Patients receive regular telephone calls and written materials designed to complement the advice they receive from their own prescribers. Further information is available on this website: <a href="http://www.medicines-partnership.org/projects/mp-projects/map-programme">http://www.medicines-partnership.org/projects/mp-projects/map-programme</a>. The MAP contact number is 0800 731 7138. Online support is at <a href="http://www.xenicalmap.co.uk">www.xenicalmap.co.uk</a>".</li> </ul>	
Roche	5	NICE version	Drugs	9, 44		<p>The recommendations on pharmacological intervention indicate that the choice of drug should involve consideration of adverse events and monitoring requirements.</p> <ul style="list-style-type: none"> <li>Roche would like to highlight the fact that orlistat and sibutramine</li> </ul>	We consider that prescribing of any drug requires consideration of the potential for side effects and any monitoring required, and have reflected this in the recommendation.

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						<p>have fundamentally different modes of action, which have an impact on their adverse event profiles. Whereas sibutramine is a centrally-acting agent, orlistat is not; orlistat consequently is not associated with adverse events caused by action on the CNS. For example, dry mouth, insomnia, light-headedness, and paraesthesia are all listed as CNS effects within the sibutramine licence but not in the equivalent section of the orlistat licence.</p> <ul style="list-style-type: none"> <li>• This guidance on adverse events within the orlistat licence has recently been supported by an independent study by the Drug Safety Research Unit (DSRU) in Southampton. The report from this study, which has been peer-reviewed and published, concludes that "...orlistat is fairly well tolerated. The safety profile of orlistat was similar to the prescribing information and experience reported in the literature." In particular, CNS effects were not evident as frequently reported events. Reference: Acharya et al 'Safety profile of orlistat: results of a prescription-event monitoring study' International Journal of Obesity</li> </ul>	

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						<p>(2006) 1-8.</p> <ul style="list-style-type: none"> <li>We therefore suggest that the guidance draws attention to this difference, and thereby recommends that the drugs' mode of actions be added as an additional consideration in the choice of drug treatment.</li> </ul>	
Roche	6	NICE version	Drugs	44		<p>The recommendations on pharmacological intervention include guidance on drug treatment for children aged 12 years and older (section 1.2.5.3 for children) and for children of unspecified age (sections 1.2.5.4, 1.2.5.5, 1.2.5.6, 1.2.5.9). However, the recommendations do not currently distinguish between orlistat and sibutramine with regard to the evidence base and licencing status for use in adolescents:-</p> <ul style="list-style-type: none"> <li>There is a significantly larger body of evidence to support the adolescent use of orlistat compared to sibutramine. Five clinical studies assessing the use of orlistat in over 600 adolescents have been conducted including the very large randomised control clinical trial by Chanoine et al (Ref 62). Adolescent clinical data for sibutramine is limited to just the two small trials by Berkowitz et al (Ref 71) and Godoy-Matos et al (Ref 70) which include 60 and 82</li> </ul>	<p>Thank you. We note the evidence base regarding the use of both orlistat and sibutramine in adolescents and we have referred to this data when it meets our study inclusion criteria.</p> <p>It is NICE policy that health practitioners should refer to the licensing status as set out in the summary of product characteristics when considering prescribing of both orlistat &amp; sibutramine.</p>

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						<p>subjects respectively.</p> <ul style="list-style-type: none"> <li>• Chanoine et al concluded in their study that the use of orlistat for 1 year in their adolescent population did not raise major safety issues. In contrast, Berkowitz et al expressed their concern regarding the rise in BP and pulse rate in sibutramine treated adolescents and recommended close monitoring of vital signs in this patient group. Similarly, Godoy-Matos et al recommended that larger placebo-controlled randomised studies in adolescents are carried out to ensure the safety of sibutramine in this age group.</li> <li>• The use of sibutramine in adolescents less than 18 years old is contraindicated within the sibutramine licence. However data concerning the use of orlistat in adolescents is included in section 5.1 of the orlistat licence.</li> </ul> <p>We therefore suggest that accordingly, clear differentiation should be made between these two treatments in the recommendations on pharmacological intervention.</p>	
Royal College of Midwives	1	NICE	Misc	general		The RCM is pleased to offer some comment on the obesity guidelines and appreciate the significant impact that overweight and obesity has on the health of the population.	Thank you for your comment.

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						Improvements in diet and lifestyle are not simply the domain of healthcare professionals and the guideline appropriately reflects this. The language used is positive and supportive e.g. assisting people with "weight management"	
Royal College of Midwives	2		PCC	5		The bullet points appear to be based on a health promotion model, which is positively presented It may be beneficial to see a stronger emphasis on the benefits of sitting with clients/patients and the support needed to provide a tailored care plan. The benefits of a tailored plan for women and young families could have been more strongly presented.	We have emphasised throughout the importance of tailoring care, and providing the appropriate levels of support.
Royal College of Midwives	5		Misc	9		The College hoped that the guideline would address breast feeding.	While it is recognised that this is an important area, as outlined in the scope, the guidance covers children aged 2 onwards. Pregnancy/breastfeeding / weaning/under 2 are outside the remit of this work. However, NICE is currently developing <i>Guidance for midwives, health visitors, pharmacists and other primary care services to improve the nutrition of pregnant and breastfeeding mothers and children in low income households</i> , due to be published May 2007. For further information see

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							<a href="http://www.nice.org.uk/page.aspx?o=MaternalandChildNutritionMain">www.nice.org.uk/page.aspx?o=MaternalandChildNutritionMain</a>
Royal College of Midwives	6		Surgery	10		The criteria for surgery appear appropriate; however, it could be clearer that surgery should only be considered when all other options have been tried.	Noted.
Royal College of Midwives	13		Ident	33–36	1.2.1	The generic principles are clear. It is reassuring to see that the different needs of Asian populations are identified	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Royal College of Midwives	14		Lifestyle	41	1.2.4.10	In the pages dealing with giving children (and adults exercise) the problems for these children is not really explicit. An obese child may find doing this exercise both challenging in itself, but also may be very self conscious and uncomfortable.	We have reflected both the evidence and the views of experts on the GDG on this issue. We consider that this is taken into account in these recommendations. The recommendations have subsequently been revised.

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Royal College of Nursing	2	NICE	PCC	5		Pleased that a patient-centred approach is emphasised and patient preference taken into account	Thank you.
Royal College of Nursing	4	NICE	Drugs	9		Good it says Drugs should only be used with lifestyle approaches in place	Thank you for your comment.
Royal College of Nursing	12	NICE	Lifestyle	33	1.1.7.5	Good to guidance on weight loss (1 – 2 lbs)	Thank you for your comment.
Royal College of Nursing	13	NICE	Ident	34	1.2.2.1	Routine Ht/Wt is NOT recommended – how does this fit in with GMS contract? What does 'routine' mean? needs to be clearer.	The GDG have decided to omit this recommendation, as it is not part of our remit to issue recommendations on population-based screening. However, the GDG consider that the recommendations on measurement do not conflict with the QoF of the new GMS contract.
Royal College of Nursing	14	NICE	Ident	35		Glad to see BMI still considered important & that waist is put in context.	Thank you for comment.
Royal College of Nursing	15	NICE	Assess	36	1.2.2.9	Good to see BMI for older adults included	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised

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							recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Royal College of Nursing	17	NICE	Lifestyle	41	1.2.4.8 1.2.4.9	Include 'goal setting' for adults Like the emphasis on appropriately trained Healthcare professional in BC skills	Added. Thank you for your comment.
Royal College of Nursing	18	NICE	Lifestyle	43	1.2.4.16	Is 1000 calories not too low? Would prefer to see this as 1200 – 1600Kcals	We have brought back this issue to the group and we have added more detail in to the dietary recommendations. Additionally, the GDG did feel that VLCDs can be used in the short term (maximum of 12 weeks continuously, or used intermittently with a low-calorie diet, for example for 2–4 days a week).
Royal College of Nursing	19	NICE	Lifestyle	43	1.2.4.17	This is the most disappointing section – very little detail or clarification on other dietary options. Meal replacements are not mentioned – consider that they should be as a suitable alternative (NB with support). VLCDs only under medical & dietetic supervision for those needing urgent weight loss. They do not distinguish between VLCDs (which are classified as 800kcal or less) and Meal Replacements (which are 1200 – 1600kcal)	We have considered the issue of meal replacements at length. We consider that the use of meal replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.  However, the dietary recommendations have been revised in light of this and other comments.



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						In the full version, why is the meta analysis by Heymsfield (2003) not included?	
Royal College of Nursing	20	NICE	Misc	47	1.2.6. 1	Needs to link with point above re VLCDs, making it clear that under specialist supervision only, whereas, MR can be safely used in community settings, with proper support. We need to be able to offer alternatives that work, to those who struggle with conventional low calorie diets NB: No emphasis is placed on the importance of nutritionally adequate diets especially with vulnerable groups & those with special dietary needs.	Noted, and recommendations revised in light of this and other comments
Royal College of Nursing	22	NICE	Lifestyle	Full version		It seems the difference between VLCDs (800 kcals or less) & Meal replacements (1200 – 1400 kcals) is not clarified. They seem to be treated as the same, which they are not.  Also, not sure why there is such emphasis on PSMF diets – will this mean anything to most practitioners? This section is very confusing.	Noted, and clarified in the recommendations and the statements.
Royal College of Paediatrics and Child Health	2	NICE	Misc	General		The document fails to adequately separate issues for children or adolescents from those of adults. The document appears to be missing an over-arching statement that children and adolescents should not be treated in adult obesity programmes using adult approaches,	Noted and revised as appropriate.

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						be it either lifestyle modification or other treatment. This is essential – the NSF is clear that children and adolescents must not be treated in adult programmes. The importance of growth and puberty in the development and perpetuation of puberty is not considered.	
Royal College of Paediatrics and Child Health	3	NICE	Lifestyle	General		Treatment, both physically (in terms of diet, fat requirements, caloric requirements) and psychologically (in terms of family involvement) are quite different for growing children (i.e. before and at peak growth velocity) and adolescents. There is minor recognition of this.	We have recommended that any intervention/assessment consider the age/growth status/situation of the child/young adult.
Royal College of Paediatrics and Child Health	4	NICE	Misc	General		Education and training implications for the whole of this guidance need to be considered urgently because there are currently no national validated generic courses for all the people who will need to be trained. Dieticians have specific courses, and the current DH directory of courses illustrates how sparse training is for other health professionals and anyone else who would need high quality training as a result of this guidance.	We have added additional paragraph/section on training, based on information already included throughout the guidance. The specifics of implementation – including local training needs and the skill mix required – are outside the remit of this work. The guidance allows local providers to interpret and implement the guidance as appropriate to their situation. However, a number of recommendations highlight the type of skills that should be acquired by staff, as appropriate.
Royal College of Paediatrics and Child Health	7	NICE	Misc	General		The documents do not seem to offer very much guidance on how to approach children or families who do not accept that they have a problem	We do however highlight the Importance of addressing lifestyle changes within the family to create supportive environments

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						with obesity or are uncooperative in other ways, yet these children and families are the critical points in so much management: getting subjects and families to take up advice and put it into practice.	that facilitate this.
Royal College of Paediatrics and Child Health	8	NICE	Lifestyle	General		The document is lacking in detail about the management of childhood obesity other than emphasizing "multi-component interventions" without really going into depth of what this means for the average clinician or commissioning organisation. Perhaps this is because there isn't much published evidence anyway. The WATCH-IT programme in Leeds does indicate some success and could be reported in depth. Otherwise someone picking up this guidance still would not have much idea about what to actually do.	<p>We have tried to reflect the existing evidence, which for children and adolescents is very limited.</p> <p>The GDG considered that the recommendations both reflected the (limited) evidence and were general enough to fall within the remit of the guidance. More specific recommendations specifying which healthcare professional should deliver which interventions is a service delivery issue and outside the remit of the guidance.</p>
Royal College of Paediatrics and Child Health	9	NICE	Lifestyle	General		The document emphasises the importance of behavioural interventions. However, whereas there is some concrete detail about drug treatments, such detail is lacking for behavioural interventions. We would welcome much clearer guidance, including specific tried and tested behavioural programmes. This is what people in the field need.	Because of the heterogeneity of the evidence on this type of intervention (as compared to drugs), we have not been prescriptive about the details of the programmes to be delivered. However, we emphasise that any intervention should be based on the preference of the individual, the competencies of the healthcare professional delivering the intervention, and local service provision.

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Royal College of Paediatrics and Child Health	15	NICE	Ident	9		In the Clinical paragraph, section on children, the children's BMI chart is recommended as the measure for obesity in children, but its use is dependent on the health care practitioner recognising the weight problem in the first place. We are bad at doing so visually and, therefore, the first step is measuring height and weight and plotting these on the UK1990 growth charts. If the child's weight is greater than 2 centile bands above the height centile, then the child is clinically obese, this being equivalent to the 98th centile on the BMI charts. The use of growth charts should be recommended as the first step in the assessment of obesity in children.	The GDG did not consider that it was appropriate to recommend the use of the UK 1990 growth charts to identify and assess obesity. It recommends the use of BMI.
Royal College of Paediatrics and Child Health	32	NICE	Misc	34	1.2.2	It is not clear to me how many children are likely to get referred to paediatricians with obesity using the criteria in section 1.2.2, and most paediatric units are just not resourced to deliver an effective care package to children referred with obesity. What are we as paediatricians to do if we get a large influx of obesity referrals?	We acknowledge that the recommendations will have an impact on the delivery of care and that services are constrained by both financial and facility resources. However, our recommendations aim to reflect the evidence to support best practice. It is intended that the guidelines should drive up standards relating to service delivery issues, although they cannot make recommendations in this area directly.
Royal College of Paediatrics and	33	NICE	Misc	33 on		We think it is a mistake to tie up children and adults in the same text.	Noted, but the GDG considers the format appropriate.

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Child Health						Approaches to assessment and management are quite different	
Royal College of Paediatrics and Child Health	34	NICE	Misc	33	1.2	We find the tables in the section on clinical recommendations very hard to follow and not helpful. We think the advice for children should be separated from that for adults and then consolidated. It is difficult to read in this format, difficult to interpret, and confusing (e.g. tables on adult waist circumferences in the middle of charts which involve both children and adults).	Noted, and editorial input has been accessed.
Royal College of Paediatrics and Child Health	35	NICE	Ident	34	1.2.2.3	Regarding the use of BMI, the document correctly counsels caution but appropriately suggests that BMI is useful in assessing overweight children and adolescents. However, the guidance as it stands is incorrect; the BMI centile (or SD score) rather than the BMI itself should be used as a measure of adiposity. It is important to note this here. This is mentioned briefly in Section 1.2.2.7, but should be made clear here.	We have revised the recommendation accordingly.
Royal College of Paediatrics and Child Health	36	NICE	Ident	35	1.2.2.4	We disagree with the statement that waist circumference should not be a routine measure. Population-based centile charts for waist circumference exist. There is increasing evidence in children that different phenotypes of obesity exist, and the waist circumference is important in distinguishing those with abdominal	We appreciate the value of these comments.  There are lower-quality studies that indeed propose cut-offs for waist circumference in children, but the GDG did not feel that, in light of the evidence, we could support the use of specific cut-

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						rather than generalised obesity.	offs for waist circumference.
Royal College of Paediatrics and Child Health	37	NICE	Ident	35	1.2.2.7	NICE has clearly decided not to recommend a definition of childhood obesity, other than to recommend that children $\geq 98^{\text{th}}$ BMI centile should be “considered for assessment of co-morbidity” (Section 1.2.2.10, p36). While NICE correctly recognises the lack of evidence to recommend one definition above another, the current guidance does not help clinicians to decide which children and adolescents to treat. By default clinicians will use the 98 <sup>th</sup> centile that, however, was only recommended for assessment of comorbidity. We understand the rationale for undertaking this approach, however we believe it will lead to confusion.	The GDG did not feel that in light of the available evidence we could confidently support one sole definition of childhood overweight/obesity.  The GDG recommended that ‘Pragmatic indicators for action are the 91st and 98th centiles.’
Royal College of Paediatrics and Child Health	38	NICE	Lifestyle	36	1.2.2.10	It would be helpful to insert a reference to paragraph 1.2.3.2 here so it is clear what the assessment should include.	Noted and revised.
Royal College of Paediatrics and Child Health	39	NICE	Lifestyle	39–40	1.2.4	The guidance suggests that multi-component interventions are the treatment of choice, encompassing behavioural treatments around activity and diet. We support this strongly for children. We would argue that NICE should go much further and recommend that for children, single component interventions should not be implemented as there is little evidence that they are effective. The	We have inserted a new recommendation in light of this and other comments from stakeholders.  See general recommendations for lifestyle.

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						<p>document does state this for dietetic interventions (Section 1.2.4.13, p. 42), noting that a dietary approach alone is not recommended.</p> <p>However, the same issue exists for single component exercise interventions: while these may be effective in the short term, there is little or no evidence of long-term benefit. Clinically, single component interventions can be tempting to health professionals working in isolation, as is often the case where dedicated childhood obesity services have not been set up. For example, many obese children are referred to paediatric dieticians, who generally work in isolation from physiotherapists. Some children are referred to psychologists or other mental health professionals in CAMHS services, who again do not routinely see these patients with dieticians or physiotherapists. Despite the excellent evidence for the importance of behavioural modification in multi-component programmes, there is no evidence that individual psychological work with obese children is effective.</p> <p>In essence, both single component programmes and individual treatment of obese children within isolated</p>	

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						dietetic, physical therapy or psychological services are likely to be waste of scarce resource. We believe that these recommendations should be greatly strengthened to recommend against resource wastage through single component interventions of any type.	
Royal College of Paediatrics and Child Health	40	NICE	Misc	40	1.2.4.4	This is vital but urgently needs to be supported by a recommendation addressed to Colleges and providers of education (including Postgraduate Deans and medical schools) to define curricula and institute educational programs that include assessment of competence.	Noted and more detail on training has been added.
Royal College of Paediatrics and Child Health	41	NICE	Lifestyle	43	1.2.4.14	Regarding age-appropriate dietary advice, this is correct. However, low-fat diets are generally inappropriate in children. Section 1.2.4.18 (Page 44) does suggest that restrictive and unbalanced diets should not be used in children. However, we believe NICE must be much clearer if these recommendations are to be easily implemented by clinicians. NICE should recommend against both low fat and low carbohydrate diets in children and adolescents.	We have revised this recommendation in light of this and other comments from stakeholders.
Royal College of Paediatrics and Child Health	42	NICE	Misc	47	1.2.6	This section requires further clarity, as services at present are not widely available and the potential numbers of children requiring paediatric care are enormous.	Noted, and implementation and costing tools have been produced.



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Royal College of Paediatrics and Child Health	43	NICE	Misc	47	1.2.6.1	Huge numbers of children could be referred. We would suggest this be defined in terms of BMI cut offs and conditions suitable for referral.	The GDG did not feel that in light of the available evidence we could confidently support one sole definition of childhood overweight/obesity. The GDG recommended that 'Pragmatic indicators for action are the 91st and 98th centiles.'
Royal College of Paediatrics and Child Health	44	NICE	Misc	47	1.2.6.1	It is clear that children with comorbidity need paediatric input, but as most of the comorbidity is subclinical, children will only be identified if they undergo investigations for liver dysfunction, hyperlipidaemia and glucose impairment (and blood pressure is measured). Professionals in primary care will require some guidance as to who to investigate. This will be challenging as the evidence base indicates that severity of obesity is not a consistent predictor. Perhaps family history and ethnicity can form part of the guidance, as has been adopted by the American Academy of Pediatrics?	We have tried to be clear about investigation and assessment in children for these reasons.
Royal College of Paediatrics and Child Health	45	NICE	Surgery	48	1.2.7.1	Where is the evidence for this, and is it linked with current NICE guidance?	From expert opinion. See page 483 of the full guideline.  This guidance replaces existing NICE guidance.
Royal College of Paediatrics and Child Health	46	NICE	Surgery	48	1.2.7.2	We strongly oppose the suggestion that current bariatric surgery in children should be done in adult centres with specialist paediatric	Noted and revised.

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						support. This is contrary to well-established models of paediatric specialist surgery, in which adult surgeons operate jointly with paediatric surgeons within paediatric settings. This suggestion is also directly contrary to the NSF for Children & Young People, which directs that children must be treated within child-friendly environments by trained paediatric staff.	
Royal College of Paediatrics and Child Health	47	NICE	Assess	49–50	1.2.7.3, 1.2.7.7	We support the recommendation that assessment and treatment teams include psychological assessment. However, generic child and adolescent mental health professionals are unlikely to have the skills to undertake this work. We suggest that NICE should include a recommendation that teams undertaking adolescent bariatric surgery include a psychologist or psychiatrist with specialist child and adolescent eating disorder expertise.	Noted.  It is an important principle that the guideline should specify, when appropriate, the necessary psychological assessment and the need for the individual delivering this to be appropriately trained. The GDG consider this has been addressed in this case.
Royal College of Paediatrics and Child Health	48	NICE	Surgery	49	1.2.7.3	In reference to surgery for children, a BMI cut off point for when surgery should be considered and the different ages is not included. Should this be considered?	We are not recommending surgery for children, but adolescents who have reached physiological maturity.
Royal College of Paediatrics and Child Health	49	NICE	CP	73		The clinical pathway for children is important to include, however we have some concerns as follows: 1. There is a feedback loop so that all children who do not attain successful weight control are referred to a	Thank you.  We have only recommended that referral be considered.

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						<p>paediatrician. This is not likely to be helpful, and it would certainly block referral pathways to no benefit.</p> <p>2. The biochemical tests for comorbidity can as well be carried out in primary care.</p> <p>3. Some specification needs to be made that the paediatrician should work with the support of dietetic, sport and CAHMS professionals. A lone paediatrician is unlikely to be helpful.</p> <p>4. The specialist management box needs to emphasise that paediatric care MUST be in the context of a multidisciplinary team.</p>	<p>The GDG considered that such tests in children should be undertaken in secondary care.</p> <p>It is anticipated that paediatricians will be working in teams/structures as outlined in the NSF for children.</p>
Royal College of Paediatrics and Child Health	63	Full	Ident	181	6-8	This problem deserves further exploration as % fat and fat mass can give very different estimates in the same individual; the first is relative (to other body components) and the second absolute (2)	In the guidance this is used to distinguish 'fatness' from BMI.
Royal College of Paediatrics and Child Health	65	Full	Ident	190		It would be desirable to include mention of the new WHO charts for BMI which describe desirable growth patterns, even if these are not assessed in detail yet.	Noted.
Royal College of Physicians	5	NICE	Misc	General		There is an assumption that doctors, nurses and health professionals are trained to manage obesity - this is simply not the case. there needs to be recommendations about undergraduate, pre-registration, postgraduate and post-registration training.	Added additional paragraph / section on training, based on information already included throughout the guidance.

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Royal College of Physicians	6	NICE	Assess	General		There is no attempt to risk assess patients - it is unrealistic to assume that hard pressed health professionals will be able to manage every overweight or obese individual. Moreover, guidance about who is at particular risk is crucial in defining management approaches.	We disagree with this observation. Recommendation 1.1.2.10 clearly sets out that BMI and waist circumference can be used to risk-assess patients.
Royal College of Physicians	7	NICE	Assess	General		We are very surprised that there is no mention about the identification and management of associated medical risks. Health professionals are at fault when focusing on overweight and obesity and ignoring treatment of hypertension, dyslipidaemia, type 2 diabetes etc. There is but a brief mention in 1.2.3.	We appreciate the importance of this, but it is outside our remit to provide guidance on the management of related comorbidities. However, we have added a statement to address this issue.
Royal College of Physicians	8	NICE	PCC	5		Patient-centred care needs to take account of the family context.	Noted and revised as appropriate.
Royal College of Physicians	21	NICE	Misc	33	1.2	Guidance about the management of childhood obesity should be dealt with entirely separate to adults - it is confusing as it stands.	The GDG considers the format to be appropriate.
Royal College of Physicians	22	NICE	Ident	34–35	1.2.2	The sections on opportunistic identification/classification are confusing and the tables difficult to follow. Given that Interheart applied waist: hip ratio why has this been ignored?	We have clarified this section. The Interheart study only looked at risk of MI, and not overall CV risk. The evidence review does acknowledge, therefore, that different measures may reflect different risks.
Royal College of Physicians	23	NICE	Ident		1.2.2.4	This is wrong. Waist circumference in adults is not primarily a measure of “central adiposity”. It is the primary measure of total body fat and thus of general adiposity. It correlates more	Noted and revised as appropriate.

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						strongly than body mass index with total body fat (Lean et al, AJCN 1996). For people with a BMI less than 30 kg/m <sup>2</sup> , a high waist circumference indicates a predominantly intra-abdominal fat accumulation.	
Royal College of Physicians	24	NICE	Ident		1.2.2.5	This is in direct conflict with the statement in 1.2.2.4.	We have withdrawn this recommendation.
Royal College of Physicians	25	NICE	Ident		1.2.2.6	Once again the waist is a better measure of general adiposity than body mass index (Lean et al, AJCN 1996).	We have revised the terminology to be clearer, and the recommendations do allow for the use of waist circumference as appropriate.
Royal College of Physicians	26	NICE	Assess	38	1.2.3.2	What is meant by genetic tests? This is not a routine lab investigation and requires tertiary referral.	We have revised this recommendation to ensure that it is clear that genetic tests are examples of what can possibly be undertaken. Genetic tests include some that are routinely available, e.g. for Prader-Willi syndrome, as well as those that are specialist. Those with severe early onset obesity should be under specialist care, and most paediatricians are probably aware of the genetic tests available on the NHS and as research tools.
Royal College of Physicians	27	NICE	Lifestyle	41	Behavioural interventions	This section is unhelpful. A list of measures provides little guidance and we are uncertain of the evidence base for many of the items listed.  Moreover, behaviour therapy is	We have listed the behavioural techniques as evaluated in the trials reviewed. However, there is a lack of evidence on which technique is most effective.  Health economics – please see

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						resource intensive - where is the cost benefit?	the section on 'Health economics' in the full guideline for a discussion of this issue.
Royal College of Physicians	28	NICE	Lifestyle	41	1.2.4.10	Physical activity - there is no mention of accessibility which is the key issue. particularly when considering social inequalities.	We have stressed throughout that individual circumstances should be taken into account, including issues around social inequalities and barriers.
Royal College of Physicians	29	NICE	Lifestyle	42	1.2.4.11	The CMO's report highlights the likely need for those who are obese to need 45 mins of activity each day.	Noted and revised – thank you.
Royal College of Physicians	30	NICE	Lifestyle	43	1.2.4.15	The dietary guidance is inadequate - this is an important section that needs to address more critically low carbohydrate diets, meal supplements and VLCD.	This section has been considerably revised in light of this comment and others.
Royal College of Physicians	31	NICE	Drugs	44-45	1.2.5.2– 1.2.5.3	Neither orlistat nor sibutramine are licensed in Europe for use in children. There is no mention of this.	We do recognise that these are drugs that are not licensed for use in children. However, this is not dissimilar to many other pharmacological options that are not licensed and that are prescribed to children with other conditions. We do, however, ensure that the caveats for this use are reflected in added detail in the recommendations, and that these are to be given only in exceptional circumstances if severe life-threatening comorbidities are present, by multidisciplinary teams with experience of prescribing in this age group.

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Royal College of Physicians	32	NICE	Drugs	44-45	1.2.5.2– 1.2.5.5	Given that other drugs are in the pipeline, we suggest that recommendations for drug use should be generic with reference to specific drugs given in an annex.	We were asked to review the evidence on orlistat and sibutramine only, and the GDG have made recommendations both about general prescribing and prescribing for these specified drugs.
Royal College of Physicians	33	NICE	Drugs		1.2.5.12	This is a very curious statement. Orlistat or any other treatment is used for weight maintenance whenever weight loss has finished. In exactly the same way an anti-hypertensive drug is used for maintaining a lower blood pressure once the falling of the blood pressure has finished. There is no reason to pick on a time of 12 months. For the majority of patients, weight loss has finished at about 3 or 4 months. A minority continue to lose weight up to 6 months. It is exceptionally rare to continue to lose weight beyond that, therefore obesity or any other treatment for obesity is mainly being used for weight maintenance beyond about 3 months not 12 months.	We have revised the recommendations on when treatment should be prescribed in light of this and other comments.
Royal College of Physicians	34	NICE	Misc	47	1.2.6	The role of secondary and specialist care needs to be clearly defined in a changing health service.	We have used the Department of Health's document on specialised Services National definition set. For further details please refer to <a href="http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187">http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187</a>

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							<a href="#">&amp;chk=jAqaRv</a>
Royal College of Physicians	35	NICE	Surgery	48	1.2.7	The surgical section is too superficial. There needs to a risk-benefit analysis included in the text as well as information about the potential weight loss and risks associated with particular surgical techniques. The major benefit of surgery is prevention or management of medically associated complications and there is no mention of this. again, what is meant by "genetic screening"?	Noted and revised in light of this and other comments.
Royal College of Physicians	36	NICE	Surgery	48	1.2.7	The frequency of obesity in the population inevitably means that it is not affordable to treat all - the guidance should include a section on health economics and priorities for treatment. We are particularly disappointed that there is no mention of type 2 diabetes where surgical treatment may be particularly successful.	We would consider that the guidance allows for local priorities to be set, to meet local needs.
Royal College of Physicians	37	NICE	Misc	51	2 Notes on scope of the guidance	These Notes identify the need for additional research. Our disappointment with the present guidance is that much of available research and guidance do not appear to have been applied in the clearest and most coherent way. We suspect that many physicians will be disappointed with this document - we had been led to believe that the guidance would provide practical and evidence based approaches to managing obesity. Our comments	We have tried to apply evidence as clearly as possible, but there is a paucity of good evidence in many areas. However, recommendations have been revised in light of your comments, and all stakeholder comments.



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						make it clear that this has not been achieved. The College would like to offer assistance with the revision of the guidance in an attempt to achieve this.	
Royal College of Physicians	47	Full	Assess	457	3	Genetic Tests. This must be spelt out – ie screening for genetic causes of obesity. The question is how and where? PWS is available through Regional Genetics, but screening for rare monogenic disorders is still a research procedure – in this country localised to Cambridge. We agree with the appropriateness of the advice, but NICE will then need to recommend establishment of such services.	We have revised this recommendation to ensure that it is clear that genetic tests are examples of what can possibly be undertaken. Genetic tests include some that are routinely available, e.g. for Prader-Willi syndrome, as well as those that are specialist. People with severe early onset obesity should be under specialist care, and most paediatricians are probably aware of the genetic tests available on the NHS and as research tools.
Royal College of Physicians	67	Full	Ident	179	No. 4	See comments above re age-related definitions. This statement is acceptable – it states facts but does not redefine overweight.	Noted. Thank you for your comment.
Royal College of Physicians	68	Full	Ident	179	6 and 7	Should qualify this applies to Caucasians.	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK

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							population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Royal College of Physicians	69	Full	Ident	179	8	Not sure it is less accurate but for sure it does not alter (much) with weight loss. See comments re Interheart above.	We have revised the evidence statement.
Royal College of Physicians	70	Full	Surgery	185		<p>We have inserted comments here about the term 'excess body weight' that is used by bariatric surgeons. It is a term that snuck into the field and is widely used.</p> <p><b>Excess weight</b> Difference between actual weight and normal weight (or ideal weight) before surgery</p> <p><b>Excess weight loss (EWL)</b> Is treated as a reference value to measure the success of treatment as a percentage (% EWL) in international literature <a href="http://www.surgery.ch/en/default.asp?ID=27545">http://www.surgery.ch/en/default.asp?ID=27545</a></p> <p>Thus the definition of EWL depends upon defining ideal body weight and this is undefined. Indeed the development of BMI was specifically in part to overcome the limitations of</p>	Thank you for your comment. We accept the limitations of EWL, but this is most often reported in the surgical literature. However, we have added details of the change in BMI to the evidence statements (as were already in the evidence tables).

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						<p>the concept of Ideal Body Weight (based as it was on the Metropolitan Life Tables). Only surgical series report results in terms of EWL, but they rarely give details as to how this was calculated. For an example:</p> <p><b><i>International Journal of Obesity</i></b>  <b>advance online publication</b>  <b>14 February 2006; doi:</b>  <b>10.1038/sj.ijo.0803247. Resting energy expenditure and fuel metabolism following laparoscopic adjustable gastric banding in severely obese women: relationships with excess weight lost. F Galtier<sup>1</sup>, A Farret<sup>1</sup>, R Verdier<sup>3</sup>, E Barbotte<sup>3</sup>, D Nocca<sup>4</sup>, J-M Fabre<sup>4</sup>, J Bringer<sup>2</sup> and E Renard<sup>2</sup></b></p> <p>Subjects lost 22% of BW at 1 yr, and 32.5% of Excess weight</p> <p>Excess weight calculated from very old Lorentz formula: eg patient 120 kg @ 175 cm  Lorentz IBW = 175 – 75- 12.5 = 62.5  <u>This corresponds to a BMI of 20.4</u></p> <p><b>Obesity Surgery, 8, 487-499. Bariatric Analysis and Reporting Outcome System (BAROS). Horatio E. Oria, MD; Melodie K. Moorehead, PhD2</b></p>	

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						<p>In this paper that developed concept of EWL IBW comes out at a BMI of 22. Not defined how this was determined but we suspect this corresponds to the midpoint of the medium frame Metropolitan Weight Tables.</p> <p>We think this is a very important issue as regards all of the surgical evidence – are you sure that you know how EWL was calculated? The ‘success’ will be biased as to whether the IBW is defined as 20.2, 22 or as is also often used we believe 25. Furthermore this makes results of surgery non-comparable with drugs or lifestyle.</p>	
Royal College of Physicians	71	Full	Ident	208	Table	Rather confusing – we are not sure we understand - are there are 3 columns for men or is it 2 and 2? Even so, why the groupings?	This table has been deleted.
Royal College of Physicians	73	Full	Lifestyle	436	21–24	We are unclear whether this section is NICE speaking or existing guidelines of NHMRC. Should not thyroid status be tested? Although a rare cause for obesity, it is relatively common and insidious and may not have ‘specific’ evidence of endocrine disease esp in children.	<p>We have endorsed the NHMRC proposals of tests that could be carried out, based on clinical judgement. The list is not intended to be comprehensive, but gives examples of some appropriate tests to consider.</p> <p>Regarding thyroid status in adults, it is important the guideline does not impede clinical judgement – a practitioner may choose to</p>

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							undertake thyroid status tests if the history/examination suggest this should be considered in the differential diagnosis.
Royal College of Physicians	74	Full	Misc	447	11-12	While high drop-out rates do make interpretation more complex they are a fact of life and what really matters is how drop-outs are treated in the analysis and how this is translated ultimately into an NNT. This issue relates also to non-lifestyle interventions esp drugs. The biggest issue we think in many of these behaviour studies is their translatability. Many are carried out in highly selected small numbers of children, in 'intense' and 'intensive' academic units, using health professionals whose skills and experience is not generally available. In many of the studies only children with families willing to be included were considered eligible, ie selecting out the, we suspect, more common social setting where the family are relatively uninterested.	We recognise the importance of these comments. We decided to include the listing of levels of drop-outs for the trials for Information purposes. In regard to the translatability of the trials, we did highlight the fact that because these studies were undertaken in such highly specialised centres that the validity and generalisability of the conclusions remains unclear.
Royal College of Physicians	75	Full	Lifestyle	450	?	What is meant by 'large increments'? We realise not NICE speaking here or below.	As you note, this phrase is taken directly from the source document.
Royal College of Physicians	76	Full	Lifestyle	450		Energy intake rather than calorie intake.	This is taken from the source document, so has not been revised.
Royal College of	77	Full	Surgery	479	Item 8	Excess weight loss – see earlier	Thank you for your comment. We

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Physicians						comments. These are particularly appropriate to adolescents where ideal body weight is even less well-defined than for adults.	accept the limitations of EWL, but this is most often reported in the surgical literature. However, we have added details of the change in BMI to the evidence statements (as were already in the evidence tables).
Royal College of Physicians	78	Full	Surgery	486	2	<p>JI bypass in fact reduced food intake as its main method of maintaining weight loss Pilkington et al, Br Med J 1986. We think that somewhere the issue of the effects of RNY,BPD,DS on food intake and appetite should be mentioned albeit that it is still a matter of active research. Sleeve gastrectomy, either as a first stage for super-obese, or increasingly as a definitive procedure should be considered – perhaps later in adult section.</p> <p>Sleeve gastrectomy and gastric banding: effects on plasma ghrelin levels. Langer FB, Reza Hoda MA, Bohdjalian A, Felberbauer FX, Zacherl J, Wenzl E, Schindler K, Luger A, Ludvik B, Prager G. Obes Surg. 2005 Aug;15(7):1024-9.</p> <p>Nguyen NT, Longoria M, Gelfand DV, Sabio A, Wilson SE. Staged laparoscopic Roux-en-Y: a novel two-stage bariatric operation as an alternative in the super-obese with massively enlarged liver. Obes Surg. 2005 Aug;15(7):1077-81.</p>	Noted and revised. Staged surgery is also reviewed.

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Royal College of Physicians	79	Full	Lifestyle	512	Table item 1	Weight loss and weight loss maintenance (WLM). We have only just realised at this point that weight loss is a used term. In terms of benefit the focus must be on WLM. Clearly WLM can only be achieved if WL is first achieved.	Noted, and the evidence statement has been revised.
Royal College of Physicians	80	Full	Lifestyle	518	Table item 1	Again there appears to be no appreciation that the aim of obesity management is WLM. To say that WL requires an energy deficit (again – why the use of calorie which is an outdated measure of energy?) but fail to mention that a permanently lowered EI or increased EE is needed to maintain weight loss betrays a misunderstanding of treatment goals. NICE must address the issue of WLM – if only to point out somewhere that all trials of >6m by definition include both WL and WLM. If you want to talk about WL don't restrict your search to 6m or longer studies.	We have added cross references to the 'Prevention' section as appropriate to address the issue of weight maintenance in adults.
Royal College of Physicians	81	Full	Lifestyle	525	1	We think that in section 1 you defined VLCD as <800 kcals. See our earlier comments about LCLD. Have you referenced EU SCOOP report on VLCLDs?	We have clarified our recommendations on this, but have used definitions from the original health technology appraisal review.
Royal College of Physicians	82	Full	Lifestyle	526	12	Are not the placebo arms of drug RCTs useful data to consider? We appreciate that these studies do not include a non-intervention arm, but they do provide corroborative data on what diet +/- behavioural intervention can achieve.	We consider that, as RCT evidence is available, lower levels of evidence (such as the placebo arms of drug trials) is not appropriate. Also, we would not be able to calculate the placebo drug effect, which may influence

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							the results. Details of the placebo arms of the drug trials are, however, reported in the drug reviews.
Royal College of Physicians	83	Full	Lifestyle	527	5	Abbreviations in table not defined – eg HOT, TAIM, HPT.	Noted – these should refer to the narrative and evidence tables.
Royal College of Physicians	84	Full	Drugs	595	Table 1, para 2	The word risk for HT and DM subjects is inappropriate – the outcome is what is wanted!	Noted and revised.
Royal College of Physicians	85	Full	Drugs	597	Table 10,11,12,13,14	Lowering may be a better term than improving. Not all the subjects had 'abnormal' LDL-C levels so 'improving' implies an inappropriate clinical judgement	Noted and revised.
Royal College of Physicians	86	Full	Drugs	599	19,20,21	As above for BP	Noted and revised as appropriate.
Royal College of Physicians	87	Full	Drugs	601	25	We think the term 'statistically independent' should be used. These studies were not designed specifically to test true 'independence' and the findings are from post hoc statistical techniques that are, in our view, hypothesis generating and suggestive, but not proving. Only one study has specifically been designed to look at the issue of independent effects of orlistat – in relation to TGs and insulin resistance – <a href="#">Kelley DE</a> , <a href="#">Kuller LH</a> , <a href="#">McKolanis TM</a> , <a href="#">Harper P</a> , <a href="#">Mancino J</a> , <a href="#">Kalhan S</a> . Effects of moderate weight loss and orlistat on insulin resistance, regional adiposity, and fatty acids in type 2 diabetes. Diabetes Care. 2004 Jan;27(1):33-40.	Noted and revised.
Royal College of	88		Drugs		End	There are no considerations of recent	Zelber 2006 is outside our



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Physicians						<p>papers on orlistat and NASH, PCOS <a href="#">Zelber-Sagi S, Kessler A, Brazowsky E, Webb M, Lurie Y, Santo M, Leshno M, Blendis L, Halpern Z, Oren R.</a>A Double-Blind Randomized Placebo-Controlled Trial of Orlistat for the Treatment of Nonalcoholic Fatty Liver Disease. Clin Gastroenterol Hepatol. 2006 Apr 17</p> <p><a href="#">Jayagopal V, Kilpatrick ES, Holding S, Jennings PE, Atkin SL.</a>Orlistat is as beneficial as metformin in the treatment of polycystic ovarian syndrome.J Clin Endocrinol Metab. 2005 Feb;90(2):729-33. Epub 2004 Nov 9.</p>	<p>searches cut-off date (Dec 2005).</p> <p>Jayagopal 2005 – the aim of this trial was to evaluate and compare the effect of treatment with orlistat vs. metformin on the hormonal and biochemical features of patients with polycystic ovarian syndrome, not primarily to reduce weight. The treatment of PCOS was outside our scope.</p>
Royal College of Physicians	89		Drugs	603	31	Or vice versa since those attending hospital/specialist clinics, or participating in trials may be more resistant than patients seen in primary care.	Noted and revised.
Royal College of Physicians	90		Drugs	610	1	An important methodological issue is that most/all of these trials included a 4 week active dietary run-in. Weight loss during this period is excluded from the outcome analysis. Also the true baseline for biochemical parameters in my view is from start of study, not randomisation. It clearly is neither possible nor appropriate to re-analyse data but a statement that such study design may underestimate	Thank you for this comment – the point is acknowledged.

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						the benefits of the 'total' intervention would be worthwhile. Thus if BP falls by 3-4 mm during the 4-week run-in, it is in effect 'lost' from the randomised part of the trial even though in real world clinical practice one would consider the benefits (or otherwise) of the whole intervention – run-in + active therapy. This holds true for sibutramine trials too. The only parameter where this effect works in an opposite direction is in relation to HDL-C levels which might be expected to fall during the 4 week run-in, thus 'artificially' lowering the apparent 'baseline' level.	
Royal College of Physicians	91		Drugs	613	6	This is an odd conclusion. How can you overestimate a success rate in WLM in subjects who have not lost weight? The trial outcomes describe accurately the clinical scenario. We disagree that it could overestimate the results.	Evidence statement has been revised.
Royal College of Physicians	92		Drugs	613	8	Elevating this conclusion to an evidence-based statement seems odd. We are not sure why negative findings are in this category. Thus, for example, you do not have a similar statement re HDL-C for orlistat. We are not aware of any claim that sibutramine does alter total Cholesterol levels.	Noted and revised.
Royal College of Physicians	93		Drugs	617	16	Exclusively in the UK. Other studies were conducted, in part in the UK.	This has been revised.
Royal College of	94		Surgery	621/2	Table 2	See earlier comments on EWL. It	Noted and added to evidence

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Physicians						would be helpful to have actual weight loss figures as well as the spurious EWL figures	statements where possible.
Royal College of Physicians	95		Surgery	621/2	Table 2	See earlier comments on EWL. It would be helpful to have actual weight loss figures as well as the spurious EWL figures	Noted and added to evidence statements where possible.
Royal College of Physicians	96		Misc	655	6	We wonder if some statement about the failure of SHAs and PCTs to implement NICE Guidance 46 is warranted here, using Dr Foster report as evidence. While this has a 'political' tint to it, it is a clear demonstration of the reluctance of Health Care Purchasers/providers to implement NICE guidance.	Noted, and there is additional work on the implementation to be published to support this guidance.
Royal College of Physicians of Edinburgh	2	NICE	Ident	35	1.2.2.4	Waist circumference in adults is not primarily a measure of "central adiposity". It is the primary measure of total body fat, and thus of "general adiposity". It correlates more strongly than body mass index with total body fat (Lean et al, AJCN, 1996). For people with a BMI less than 30 kg/m <sup>2</sup> , a high waist circumference indicates a predominantly intra-abdominal fat accumulation.	Noted and revised as appropriate.
Royal College of Physicians of Edinburgh	3	NICE	Ident	35	1.2.2.5	This conflicts with the statement in 1.2.2.4.	We have withdrawn this recommendation.
Royal College of Physicians of Edinburgh	4	NICE	Ident	35	1.2.2.6	As for [our comment on] 1.2.2.4.	The GDG considered that this recommendation does not conflict with recommendation 1.2.2.4.
Royal College of Physicians of	5	NICE	Ident	37		Welcome limitation of waist circumference to less than BMI 35,	The GDG were aware of the evidence that black and minority

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Edinburgh						but its use in Asian population is needed to stratify risk as highlighted on page 35.	ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Royal College of Physicians of Edinburgh	6	NICE	Drugs	44	1.2.5.2	Advice to introduce pharmacological intervention 'after dieting and exercise advice has been initiated' is vague and could be misinterpreted. Surely these agents which can have side effects should be advised AFTER a reasonable period (RCP SIGN and RCPL said 3m in their guidance) of assessment of diet, exercise and behavioural adaptation. Otherwise, diet and exercise will be advised on day 1 and drugs on day 2. Otherwise, drug advice is appropriate	Noted and revised as appropriate.
Royal College of Physicians of Edinburgh	7	NICE		46	1.2.5.12	Orlistat or any other treatment is used for weight maintenance whenever weight loss has finished, in the same way as an anti-hypertensive drug is	The recommendations have been revised to reflect this and other concerns.

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						<p>used for maintaining a lower blood pressure once the falling of the blood pressure has finished.</p> <p>There is no reason to select a time of 12 months. For the majority of patients, weight loss has finished at about 3 or 4 months. A minority continue to lose weight up to 6 months. It is exceptionally rare to continue to lose weight beyond that, therefore orlistat or any other treatment for obesity is mainly being used for weight maintenance beyond about 3 months, not 12 months. In addition, the licence for orlistat is now longer than 12 months, so why restrict usage to 12 months if weight benefit is continuing?</p>	
Royal College of Physicians of Edinburgh	8	NICE	Drugs	Gen		<p>There is no advice regarding drugs for obesity and pregnancy, or for women who have high likelihood of pregnancy, especially those referred for weight loss who desire fertility and where weight loss is advocated. Orlistat and sibutramine have no licence for use in pregnancy and in theory should not be used. However, orlistat maker Roche does have evidence of no teratogenicity so far on orlistat, so possibly some comment by NICE on this risk is required. There is no evidence on sibutramine, as far as we know.</p>	<p>We have noted that prescribers should refer to current summary of product characteristics for prescribing details. Weight management in pregnancy is also being considered by the NICE Maternal and Child Nutrition guidance.</p>
Royal College of Physicians of	9	NICE	Misc	47	1.2.6.1	<p>Why do those with BMI &gt;50 need referred to secondary sector for anti-</p>	<p>This group are not included in most, if not all, drug trials so the</p>

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Edinburgh						obesity drugs?	evidence is therefore limited. We have recommended that surgery be a first line option for these people.
Royal College of Physicians of Edinburgh	10	NICE	Surgery	48	1.2.7.1	There is need for better definition of what is meant by severe obesity when referring for bariatric surgery. Most state BMI 40 or higher, but BMI of 35 if patients have concomitant associated severe morbidity, not able to be treated by appropriate medicines, and therefore weight loss is imperative.	Noted, and please refer to the definition of severe obesity in the Identification sections.
Royal College of Physicians of Edinburgh	11	NICE	Surgery	49	1.2.7.3	There are concerns about the recommendations for bariatric surgery in young women of reproductive potential. The literature indicates that vitamin and mineral deficiencies after surgery, especially Malabsorptive techniques, can result in foetal damage in pregnancy, in some series as high as 25%. Granted, correction of deficiencies does reduce this, but the risk is still apparent and real. Therefore, some do not advocate Malabsorptive surgery and some avoid bariatric surgery in such young women, especially if requested for cosmetic rather than medical reasons.	We would consider this to be part of the comprehensive assessment.
Royal College of Physicians of Edinburgh	12	NICE	Surgery	49	1.2.7.4	The College is concerned that bariatric surgery should be included as a first line option for patients with BMI >50. Such patients can respond to specialist approaches of diet, behavioural, exercise and anti-obesity	Wording of this recommendation is considered appropriate, as there is little evidence on the effectiveness of other options in this group.

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						<p>drugs. In any case, operating is a major risk in such patients as they often have co-morbidity conditions, and respiratory problems after surgery can require ICU bed and ventilation. It would be preferable to improve metabolic and lung function by weight loss before contemplating bariatric surgery to sustain weight loss and prevent weight regain. There is poor emphasis in this document on preventing weight regain in those who are severely obese and who are initially successful on conventional therapy.</p>	<p>In addition, this group will probably have comorbidities (possibly severe and multiple), and weight loss using lifestyle changes and drugs are very unlikely to achieve a clinically significant benefit.</p>
Salford PCT	7	NICE	Misc	General		<p>There is nothing on weight maintenance. What happens after someone has lost say 5-10%? What should be in a weight maintenance programme?</p>	<p>We have recommended that weight maintenance be part of the overall programme, and where appropriate, people refer to the prevention guidance for weight maintenance.</p>
Salford PCT	8	NICE	Misc	General		<p>What if someone has tried to lose weight and failed. Should they try again? When?</p>	<p>We have recommended that previous attempts at weight loss be explored, and have not been prescriptive as to time periods, but would anticipate that this is done when the individual is willing and able to make changes.</p>
Salford PCT	9	NICE	Lifestyle	General		<p>What is best, group based or individual?</p>	<p>Assuming this relates to group/individual interventions, we have recommended that both strategies can be effective, and the choice should be determined by the preference of the individual and local circumstances.</p>

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Salford PCT	10	NICE	Misc	General		Are brief interventions worthwhile?	We did not retrieve any evidence that supported such Interventions for weight loss specifically.
Sanofi-aventis	1	NICE	Misc	General		The remit of this clinical guideline is to provide information on the prevention and management of both overweight and obesity, and whilst it may be considered efficient to refer only to obesity throughout the document, we feel it is prudent to remind the reader where recommendations relate to both categories of unhealthy individuals, and that both overweight and obesity are the subject of attention.	Noted, and we have tried to use both terms appropriately.
Sanofi-aventis	2	NICE	Misc	General		Throughout the document the word(s) 'risk' or 'at risk' are used but no definitions are provided in most instances. The use of the word risk therefore requires qualification where it is applied, since it might refer to risk of obesity, risk of cardiovascular disease, risk of diabetes etc. (e.g. Table in section 1.2.2.8)	Noted and tried to clarify as appropriate.
Sanofi-aventis	3	NICE	Misc	General and Page 4		Apart from a limited quote from the Wanless report, it is not clearly stated how overweight and obesity contribute to ill-health, or that the likely consequences of long-term overweight and obesity are specifically diabetes, dyslipidaemia, and cardiovascular disease. These conditions should be highlighted throughout the document to reinforce the importance of intervention.	Noted and we have recommended that such consequences are assessed as appropriate.



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Sanofi-aventis	4	NICE	Misc	General		Little cross-referencing with existing guidelines or NSFs is presented. Incorporating these references and placing them in context will demonstrate where interdependencies exist and this will aid implementation.	Noted and some cross referencing added.
Sanofi-aventis	5	NICE	Misc	General		The guideline should adopt an holistic approach to screening and management, to which treatment options are tried and adapted as necessary. The narrative of the current guideline does not convey the care pathway clearly, so we would suggest bringing the diagram forwards from the appendix.	The format is as for NICE clinical guidelines.
Sanofi-aventis	6	NICE	Misc	Page 5 Para 2		The statement indicates obesity has specific health implications, but these are not defined. We recommend that more information is provided.	We have recommended that these be discussed with the individual using clinical judgement to address the most relevant.
Sanofi-aventis	11	NICE	Misc	Page 33		There is a typo in the section "Recommendations for the public". The following sentence requires an 'a'. "The following recommendation applies to adults only. Children and young adults concerned about their weight should speak to a nurse or GP".	Revised.
Sanofi-aventis	12	NICE	Ident	36		We suggest deleting the rows in the tables in sections 1.2.2.7 and 1.2.2.8. that refer to 'underweight', since this is not relevant in the classification of overweight or obesity.	Noted and revised.
Sanofi-aventis	13	NICE	Ident	35-36	Tables	The tables presenting the levels of	The GDG were aware of the

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						'risk' associated with combinations of BMI with Waist circumference are not clear and can be confusing. For example, the table in section 1.2.2.11 indicates that Asian people with BMI levels 'At risk' (23 -24.9 BMI) are at moderate or increased risk, whereas people who are underweight can be at low risk, but at increased risk for other clinical problems? It is not clear how 'risk' is being used here, and what the levels of risk (i.e. low, average, increased, moderate, severe, and very severe) actually refer to. The footnote indicates that the WHO report definitions apply, for some of these definitions, but it is not clear without cross-reference what is being communicated here.	evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
Sanofi-aventis	14	NICE	Assess	Page 37		Footnote 8 on this page does not contain some of the important comorbidities such as dyslipidaemia, and sleep apnoea.	The list has been extended, but cannot be comprehensive and includes the most common comorbidities.
Sanofi-aventis	15	NICE	Lifestyle	Page 37		In section 1.2.3.1 we suggest the addition of 'blood' to the glucose measure.	This has been revised.
Sanofi-aventis	16	NICE	Lifestyle	Page 40		In section 1.2.4.7, we recommend including in the list of information for individuals and their families/carers the details on the various consequences of obesity.	Noted and revised.
Sanofi-aventis	17	NICE	Lifestyle	Page 43 1.2.4.16		Does expert support refer to Dietician support? If so Dieticians should be identified as the appropriate care-givers in relation to this specialised	We have not specified which healthcare professional should deliver each intervention (except in a few very specific cases,

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						support service.	mainly surgery), but we have emphasised the need for any healthcare professional delivering interventions to have the appropriate competencies.
Sanofi-aventis	18	NICE version	Lifestyle	Page 44 1.2.4.18		We question why this section only applies to Children. It would seem entirely appropriate that adults should also be encouraged to abstain from 'unbalanced diets'.	Noted and revised.
Sanofi-aventis	19	NICE version	Drugs	Page 46		<p>The presentation in the guideline of the role of pharmacotherapy highlights two products that have previously been the subject of NICE Technology appraisals. The NICE Guideline does not currently make any recommendations about how later Technology Appraisals should be considered in relation to this guideline.</p> <p>We recommend a statement is made in sections relating to pharmacotherapy that indicate the Guideline should be flexible with respect to specific technologies, and the user of the guideline be advised to consider the use of other technologies reviewed by NICE.</p>	It would be expected that prescribers are aware of advice from NICE on newer drugs, so we have not made specific reference to this. We will also clarify that these recommendations replace the previous guidance.
Sanofi-aventis	20	NICE version	Drugs	General		References made to pharmacotherapy throughout the document should not refer to specific interventions unless those technologies are being reviewed directly. The user should understand	The guidance was charged with reviewing evidence on orlistat and sibutramine. However, we would expect that as new drugs are licensed, prescribers are aware of this, and any related NICE

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						the role of pharmacotherapy, per se, rather than the role of named products, since this list may not always be exhaustive.	guidance.
Sanofi-aventis	23	NICE version	Misc	Page 59		We recommend that the section on related guidance should be re-written, since the three Technology Appraisals referred to will be obsolete, and withdrawn at the publication of these guidelines. We further suggest that Technology Appraisals expected to be included in future waves should be included.	Noted and revised. However, we are not able to add topics that may/may not be addressed in future waves.
Sanofi-aventis	24	NICE version	CP	Page 74		The patient care algorithm includes a table describing the level of treatment intensity dependent on level of risk. This diagram suffers from the same limitations described above in relation to the usability of the table.	Thank you for your comments.
School Food Trust	10		Lifestyle	13;28		The SFT endorses the guidance relating to diet and supports its implementation in all aspects of school activities. Similarly, it endorses the recommendations that children eat in “a supportive, social environment free from other distractions.” The words “unhurried and pleasant” should be added. Teachers should not only eat regularly with pupils but should consume consuming similar (healthier) foods.	Noted but not amended as suggested. The wording of this recommendation has already been amended for clarity.
Sheffield South West PCT	1	Full and NICE version	Lifestyle	General		Thank you. We welcome this ambitious guidance and recognise the immense work that has gone into	Thank you. We will not be covering detailed issues of stages of change, as there will be

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p>preparing it.</p> <p>The following general comments relate specifically to the clinical management of obesity in adults.</p> <p>We acknowledge the suggested guidance is informed by a review of the evidence base (such as it is) on obesity management. We are concerned, however, that it has omitted to address the evidence base concerning:</p> <ul style="list-style-type: none"> <li>(i) factors that influence individual health behaviours and experience</li> <li>(ii) The most appropriate means of providing interventions to support attitude and behaviour change at primary care level.</li> </ul> <p>We believe this omission has implications for the robustness of the implementation recommendations, specifically with respect to the <i>process</i> of delivering the care pathway and ultimately health outcomes.</p> <p>We are aware that <i>NICE Public Health Programme Guidance on Health Behaviour Change</i> (HBC) is not due until 2007, but that the final scope specifically includes (i) and (ii) above. We would therefore recommend consideration be given to inviting a representative of the <i>NICE</i></p>	<p>forthcoming NICE guidance on behaviour change in 2007. However, we have made reference to the need to consider the level of willingness of the individual, and their right to accept/refuse treatment. The GDG considered that the use of 'willing' was appropriate for this guidance.</p> <p>We have also strengthened the 'Patient-centred care' section to reflect more the rights of adults and children.</p>

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p><i>Health Behaviour Change GDG</i>, familiar with the HBC evidence base, to contribute to writing the final version of the <i>NICE Obesity Guidance</i> . We believe this is important to ensure that the complexity of the issues involved (or patients and clinicians) in relation to obesity management/lifestyle change, is reflected within the language used in the NICE guidance. (We would, for example, avoid the use of the word 'willingness' (NICE, pg 5), to describe a patient's response in relation to change. 'Unwillingness to change' implies a lack of cooperation on the patient's part - whereas this may be a reflection of resistance arising from the manner in which the issue was raised by a clinician, or stem from other factors (such as competing priorities; the absence of the necessary internal or external resources to consider/embark on change at this particular point in time.)</p>	
Sheffield South West PCT	2	NICE	PCC	General		<p><i>Consent and patient preference</i> We would recommend more explicit reference to the importance of obtaining informed patient consent, and the role of patient choice, at all points in the care pathway.</p> <p>DoH: <i>Learning from Bristol: The Department of Health's Response to</i></p>	Standard NICE recommendations on this have been added, and also specific recommendations have been revised in light of this and other comments.

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						<p><i>the Report of the Public Inquiry into children's heart surgery at Bristol Royal Infirmary 1984-1995</i>. London. Stationary Office. 2002.</p> <p>Habiba M, Jackson C, Akkad A, <i>et al</i>. Women's accounts of consenting to surgery: is consent a quality problem? <i>Qual Saf Health Care</i> 2004;13:422-7.</p>	
Sheffield South West PCT	3	NICE	Misc	General		<p><i>Binge eating disorder (BED)</i></p> <p>We note that BED was considered to be outside the scope of this obesity guidance, but that it was intended that reference would be made to the <i>NICE Eating Disorders (ED) Guidelines</i> as appropriate. This is currently omitted.</p> <p>We regard explicit reference to the <i>ED Guidelines</i> within the <i>Obesity Guidelines</i> as essential:</p> <ul style="list-style-type: none"> <li>• in the interests of delivering integrated, flexible care, in line with '<i>Our health, our care, our say: a new direction for community services</i> (2006) DoH</li> <li>• ensuring patients are offered or referred for the treatment appropriate for their condition</li> <li>• Facilitating integrated training for primary health care professional in management of people who are overweight/obese.</li> </ul> <p>It has been estimated that 8.8% of people with obesity have binge eating disorder (Kinzl et al, 1999, cited in</p>	Noted and added cross references as appropriate.

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p>NCCMH <i>Second draft: Eating Disorders Consultation</i>, commissioned by NICE, 2003). For some overweight/obese patients entering a consulting room, the <i>NICE ED Guideline</i> will be more/as applicable as the NICE Obesity Guideline.</p> <p>(We note the following from <i>Choosing Health</i>: "It is difficult to separate cause from effect in the relationship between obesity and psychological disorders. Whilst mental well being may suffer as a result of pressures associated with being obese, psychological problems may equally contribute to the type of behaviours, such as emotional eating and binge eating, that can result in the onset of obesity " (Appendix 5, Para 13 <i>National Audit Office Report</i>. Quoted pg 138, <i>Choosing Health</i>)</p>	
Sheffield South West PCT	4	NICE	PCC	5		<p><b>Patient centred care</b>  We welcome the inclusion of this section early in the guidance – however, we would suggest that it focuses exclusively on <i>processes</i> of care and the <i>context</i> in which care is offered. We would suggest transferring paragraph three, (which looks at the content of the consultation) to assessment section of the implementation section (pg 37). We would omit the final paragraph of</p>	This section has been modified in light of this and other comments.



Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						this section.	
Sheffield South West PCT	5	NICE	PCC	5		<p><b>Patient centred care</b></p> <p>We would recommend that all health professionals have specific training in health behaviour change counselling skills, over and above core consultation skills.</p> <p>Our rationale for this is:</p> <p>(a) Research documenting reticence among health professionals about raising the issues of obesity, lack of necessary skills to deal with obese patients. E.g.: Report to the DoH: Attitudes towards and practice of prevention in primary care : a qualitative study, <i>OLR</i>, June 2004, cited in <i>Choosing Health</i></p> <p>(b) Raising the subject of obesity and the assessment process are integral parts of the <i>intervention</i> – skilfully conducted, these initial stages have the potential to help patients move along a continuum of change. Conversely, unskilful early interventions have the potential to inadvertently increase resistance. (Research has demonstrated that ambivalence to healthy options leads to close scrutiny of health messages – well intended messages can backfire, and inadvertently increase resistance to change.) (ref: ESRC Seminar Series: <i>Tackling Obesity: Changing Behaviour</i>. 2004)</p> <p>(c) The importance of early, stepped</p>	We have made a recommendation that any healthcare professional delivering interventions should have the appropriate competencies.

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						care intervention with the least intrusive, most cost effective intervention early on – including the minimisation of the number of patients needing to be considered for invasive surgery due to a lack of appropriate early intervention.	
Sheffield South West PCT	6	NICE	PCC	5		<p><b>Patient centred care</b>  Social psychological research has amassed considerable evidence that prejudice and discrimination against obese people is a very important social problem in its own right. (See ESRC ref above). We would suggest that paragraph 2 refers to the evidence base on the psychosocial impact of obesity on individuals<sup>R</sup> (for example: shame, low self esteem, guilt and embarrassment, stigmatisation) – and states the importance, therefore, of maintaining a supportive, non judgemental approach, focusing on engagement and recognising ambivalence (as addressed within <i>NICE ED Guidance</i>)</p> <p><sup>R</sup>Wadden TA, Womble LG et al. <i>Psychosocial consequence of obesity and weight loss. In Handbook of Obesity Treatment</i>, TA Wadden, AJ Stunkard (eds). New York; Gilford Press. 2002.</p>	Throughout the guidance we have stressed the importance of a non-judgemental approach and the need to explore any psychosocial distress.
Sheffield South West PCT	7	NICE.	Misc	39		<p><i>Continuity of care</i>  We welcome the fact this important issue is addressed.</p>	We have noted the importance of continuity of care, and that this should be in a form most

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p>We wonder how best to address the fact that some patients have multiple consultations with different clinicians over a relatively short time frame<sup>+</sup>. In this context, uncoordinated implementation of the obesity care pathway may be counter productive<sup>++</sup>, conversely – coordinated implementation may enhance both long term effectiveness and acceptability.</p> <p>We suggest the following:  <i>Thought is required to ensure that, where necessary - and with the patient's consent, weight management assessments and interventions are coordinated between clinicians/across services, and consideration be given to identifying a named clinician to lead on this with respect to an individual patient"</i></p> <p><sup>+</sup> A recent local report noted one patient saw 40 different hospital and community midwives across the course of three pregnancies  <sup>++</sup>From clinical experience, we know patients who have successfully reduced their BMI by 5-10%, only to be further advised by a new clinician (unaware of previous progress) of the need to lose weight – thereby losing an opportunity for a constructive</p>	<p>appropriate for the individual, which may/may not include a named healthcare professional.</p>

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						intervention focusing on the importance of weight <i>maintenance</i> – before any consideration of further <i>weight loss</i> .	
Sheffield South West PCT	8	NICE	CP	46		<p><b>Adult clinical care pathway</b> Following on from our general comments, suggested additions to pathway are outlined below:</p> <p>Box 2</p> <div style="border: 1px solid black; padding: 5px;"> <p>[Add] <i>Seek permission to</i></p> <ul style="list-style-type: none"> <li>• Determine degree of overweight/obesity BMI waist circumference</li> <li>• [Add] <i>Discuss in context of individual's health, informed by knowledge of any other recent/concurrent health care interventions in respect of weight management</i></li> </ul> </div> <p>Add new box (connected with arrows to overweight/obese adult box; box 2; assessment box and management box)</p> <p>Add new box (a)</p> <div style="border: 1px solid black; padding: 5px;"> <p><i>Offer generalised/personalised information on weight management/weight maintenance</i></p> </div>	<p>The whole of the care pathway is within the 'Patient-centred care' framework (See NICE version for details).</p> <p>Eating disorders were outside the remit of the guidance, but we do provide signposting to the Eating Disorders guideline in the NICE version.</p>

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p>Assessment box</p> <div style="border: 1px solid black; padding: 5px;"> <p>Add, after other bullet points</p> <ul style="list-style-type: none"> <li>• <i>Presence of binge eating disorder (BED)</i></li> </ul> </div> <p>Add arrow from BED bullet point in assessment box to a <i>new box</i> (with arrow from new box to both assessment and management box)</p> <p>Add new box (b)</p> <div style="border: 1px solid black; padding: 5px;"> <p><i>Follow NICE Eating Disorder Guideline 9, including</i></p> <ul style="list-style-type: none"> <li>• <i>Encourage individual to follow an evidence based self help programme for BED</i></li> <li>• <i>Consider referral for CBT for BED</i></li> <li>• <i>Inform pt that all psychological treatments for BED have a limited effect on body weight</i></li> </ul> </div> <p>Management box</p> <div style="border: 1px solid black; padding: 5px;"> <p>Intensity of management will depend on level of risk [suggest add] <i>"informed patient choice,"</i> and may include...</p> </div>	
Sheffield	1	Full	Surgery	485	12	Vertical gastric banding should read	Amended.

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
Teaching Hospitals NHS Foundation Trust						vertical banded gastroplasty (VGB)	
Sheffield Teaching Hospitals NHS Foundation Trust	2	Full	Surgery	485	13	Should Biliopancreatic diversion and duodenal switch be included?	Amended.
Sheffield Teaching Hospitals NHS Foundation Trust	3	Full	Surgery	485	19	VGB should read VBG	Amended.
Sheffield Teaching Hospitals NHS Foundation Trust	4	Full	Surgery	485	21	Gastric banding should read gastric bypass	Amended.
Sheffield Teaching Hospitals NHS Foundation Trust	5	Full	Surgery	485	22	Should the end of the sentence read 'reduces the absorption of nutrients'	Amended.
Sheffield Teaching Hospitals NHS Foundation Trust	6	Full	Misc	483	20	What is the meaning of serious obesity-related comorbidities? Type 2 diabetes, CVD? Do these need defining as this could be open to interpretation.	Noted and added footnote, but clinical judgement should be used to assess the most relevant.
Sheffield Teaching Hospitals NHS Foundation Trust	7	Full	Surgery	627	13	VGB should read VBG	Amended.
Sheffield Teaching Hospitals NHS Foundation Trust	8	Full	Surgery	627	16	Gastric banding should read gastric bypass and mainly restricts 'dietary' intake	Amended.
Sheffield Teaching	9	Full	Surgery	645	21	Should state 'registered dietitians'	Amended.

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
Hospitals NHS Foundation Trust							
Sheffield Teaching Hospitals NHS Foundation Trust	10	Full	Surgery	645	23	Surgeons should be bariatric surgeons	Amended.
Sheffield Teaching Hospitals NHS Foundation Trust	11	Full	Surgery	487	17	Should laparotomic read laparoscopic?	Amended.
Sheffield Teaching Hospitals NHS Foundation Trust	12	Full	Surgery			As a specialist dietitian in bariatric surgery, I feel that there should be some references to the importance of regular post operative dietetic monitoring by a specialist registered dietitian in bariatric surgery, who is able to monitor and advise regarding the appropriate diet depending upon the bariatric procedure and monitor the patients micronutrient status, provide appropriate individualised nutritional supplementation, support and guidance to achieve long term successful weight loss and weight maintenance. References could be provided regarding evidence for nutritional deficiencies following bariatric surgery.	Noted and added.
Slim Fast Foods - Unilever	2	NICE	CP	74		<b>Box Heading</b> – Management “Intensity of management will depend on level of risk and may include <ul style="list-style-type: none"> <li>◦ Diet</li> <li>◦ Physical activity</li> <li>◦ Behavioural interventions</li> </ul>	We consider that the wording is appropriate, and details of recommended dietary approaches can be found in the recommendations.

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<ul style="list-style-type: none"> <li>◦ <b>FORMULA FOODS FOR WEIGHT CONTROL (MEAL REPLACEMENTS AND TOTAL DIET REPLACEMENTS INCLUDING VERY LOW CALORIE DIETS)</b></li> <li>◦ Drug therapy</li> <li>◦ Surgery”</li> </ul> <p><b><i>Recommended addition in caps</i></b></p> <p><b><i>Objective : Clarify that PARNUTS Foods (i.e. Meal Replacements and VLCDs) may be suitable interventions prior to pharmacotherapy and/or surgery.</i></b></p>	
Slim Fast Foods - Unilever	20	Full	Drugs	619	19-20	<p>Sibutramine with a combination lifestyle intervention versus sibutramine, low calorie diet and activity</p> <p>Comment : Please note that the most successful arm of this study involved the inclusion of Meal Replacements as part of combination therapy.</p>	We have recommended that appropriate dietary, activity, and behavioural approaches should be tried before drug treatment is initiated and continued during drug treatment. This therefore allows the choice of dietary intervention to be determined by the healthcare professional and the patient.
Slim Fast Foods - Unilever	21	Full	Misc	648	1	<p>“Evidence review on interventions delivered in a UK clinical setting”</p> <p><b><i>Comment : No assessment of the following paper using Meal Replacements by Dhindsa and submitted as evidence - please could it be evaluated.</i></b></p> <p>Dhindsa. P., Scott. AR., Donnelly, R.</p>	We have reviewed the evidence and we do not feel that it meets our inclusion criteria.



Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<b>Metabolic and cardiovascular effects of very-low-calorie-diet therapy in obese patients with type 2 diabetes in secondary failure: outcomes after 1 year.</b> Diabetic Medicine. 2003; 20; 319-324	
Slim Fast Foods - Unilever	24	Full	Misc	2372  2373	2-3	<p>Excluded Studies            "1.10 Effectiveness of brief interventions in primary care and other general clinical settings in improving outcomes for people who are overweight and obese            Ashley JM, St Jeor ST, Schrage JP, Perumean-Chaney SE, Gilberston MC, McCall NL et al. Weight control in the physician's office. Arch.of Internal Medicine 2001; 161(13):1599-1604            Not relevant to KCQ"</p> <p><b><i>Comment : No explanation of what 'not relevant to KCQ means' – please either explain or re-evaluate this study in the appropriate section.</i></b></p>	Have clarified reason for exclusion, as it was not a brief Intervention.
Slim Fast Foods – Unilever	3	Full	Lifestyle	General		<p><b><i>Meal Replacements - misunderstandings</i></b>            We are sorry to see that throughout the document there appears to be a misunderstanding about the form and role of meal replacements. They appear to be either included with 'low calorie' foods or with VLCD (very low calorie diets) or completely disregarded. They are a distinct legal</p>	We have considered the issue of meal replacements at length. We consider that the use of meal replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance, but we have added more clarity around the use of VLCDs.

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						category.  Clarification on the nature of meal replacements is in the following point.	
Slim Fast Foods – Unilever	4	Full	Lifestyle	General		<b>Meal Replacements – omission of evidence</b> Meal replacements, while being noted in the Scope as a non-pharmacological intervention, have had limited review in the Draft Guidance – this is partly because the better papers were omitted from examination (omitted references are listed in the next point)	We have considered the issue of meal replacements at length. We consider that the use of meal replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.
Slim Fast Foods – Unilever	5	Full	Lifestyle	General		<b>Meal Replacements – nutritional status and legislative position</b> Meal replacements for weight control have a special regulatory position as the <b>only</b> products specifically designed as <b>meal replacements to meet the nutritional requirements of weight loss<sup>(2)</sup></b> .  The composition of Meal Replacement for Weight Control was determined following study by the Scientific Committee for Foods to the European Commission on the nutritional needs of dieters. Their legislative status is the same as Foods for Special Medical Purposes (FSMPs).  <b>They should never be confused with normal foods promoted for</b>	We have considered the issue of meal replacements at length. We consider that the use of meal replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p><b>weight loss on the basis of being calorie controlled, low fat, etc. They are nutritionally complete meals for use in weight management and are closely regulated as such. Their purpose is to replace one or more meals in the day with a high nutrition low calorie composition including 25-50% en Protein, &lt;30% fat, essential fatty acids, minimum 30% 23 micronutrients.</b></p> <p>Meal Replacements for Weight Control is a legal category<sup>(1)</sup> of formula foods for weight loss covered by Directive 96/8/EC, a specific directive within Directive 89/398/EEC on Foods for Particular Nutritional Uses (PARNUTS), implemented in the UK as The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations <a href="http://www.opsi.gov.uk/si/si1997/97218201.htm">http://www.opsi.gov.uk/si/si1997/97218201.htm</a></p> <p>PARNUTS foods are  <i>'foodstuffs which, owing to their special composition...are suitable for their claimed nutritional purposes'</i>  and they must  <i>'fulfil the particular nutritional requirements ...  of certain categories of persons</i></p>	

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p><i>who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs'</i></p> <p>The composition of PARNUTS foods for weight control was defined after examination by the Scientific Committee for Foods to the European Commission assessing need, safety and efficacy. Under PARNUTS definitions the overweight and obese 'are in a special physiological condition'.</p> <p><b>Objective : Understanding of the unique legal status of Meal Replacements – they must not be confused with 'normal' foods</b></p>	
Slim Fast Foods – Unilever	6	Full	Lifestyle	General		<p>As noted in the previous comment, the following references were omitted in error from the original consultation – listed here as requested by Leicester AC:</p> <p>Ditschuneit. HH., Flechtner-Mors. M., Johnson. TD., Adler. G <b>Metabolic and weight loss effects of a long term dietary intervention in obese patients.</b> Am J Clin Nutr. 1999;69;198-204 (RCT – 2 years)</p> <p>Flechtner-Mors, M., Ditschuneit, HH., Johnson, TD., Suchard, MA, Adler, G. <b>Metabolic and weight-loss effects</b></p>	<p>We have considered the issue of meal replacements at length. We consider that the use of meal replacements (as available over the counter) is not considered to be a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.</p>

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p><b>of long-term dietary intervention in obese patients: Four-Year results.</b> Obesity Research 2000;8;399-402 (Follow up to previous study – 4 year data)</p> <p>Ditschuneit. HH., Frier, HI., Flechtner-Mors, M. <b>Lipoprotein responses to weight loss and weight maintenance in high-risk obese subjects.</b> European Journal of Clinical Nutrition. 2002;56;264-270 - (RCT – 4 years)</p> <p>Anderson, JW. <b>Combination approaches to weight management.</b> Medscape Diabetes &amp; Endocrinology 6(2), 2004, posted 08/31/2004 (Analytical Review)</p> <p>Dhindsa. P., Scott. AR., Donnelly, R. <b>Metabolic and cardiovascular effects of very-low-calorie-diet therapy in obese patients with type 2 diabetes in secondary failure: outcomes after 1 year.</b> Diabetic Medicine. 2003; 20; 319-324 (UK Clinical Setting – 12 months)</p>	
Slim Fast Foods – Unilever	17	Full	Lifestyle	524	8–11	<p>“All RCTs of dietary interventions in adults with a BMI of 28 or more were included. The duration of the trials had to be for 52 weeks or more. The main outcome was weight change in kg at 12 months follow-up.”</p>	<p>We have considered the issue of meal replacements at length. We consider that the use of meal replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the</p>

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p>Please note papers from Ditschuneit &amp; Flechtner-Mors listed above (RCTs 12+ months reporting outcome of weight change in adults) appearing to meet the criteria but omitted from original review – listed here again for ease of reference:</p> <p>Ditschuneit. HH., Flechtner-Mors. M., Johnson. TD., Adler. G <b>Metabolic and weight loss effects of a long term dietary intervention in obese patients.</b> Am J Clin Nutr. 1999;69;198-204 (RCT – 2 years)</p> <p>Flechtner-Mors, M., Ditschuneit, HH., Johnson, TD., Suchard, MA, Adler, G. <b>Metabolic and weight-loss effects of long-term dietary intervention in obese patients: Four-Year results.</b> Obesity Research 2000;8;399-402 (Follow up to previous study – 4 year data)</p> <p>Ditschuneit. HH., Frier, HI., Flechtner-Mors, M. <b>Lipoprotein responses to weight loss and weight maintenance in high-risk obese subjects.</b> European Journal of Clinical Nutrition. 2002;56;264-270 - (RCT – 4 years)</p>	clinical guidance.
Slim Fast Foods – Unilever	18	Full	Lifestyle	524 525	12–15 1–11	<p>“The diets were classified as follows</p> <ul style="list-style-type: none"> <li>◦ Healthy eating advice</li> <li>◦ 600kcal/day deficit or low fat diet</li> <li>◦ Low calorie diets (1000-</li> </ul>	We have considered the issue of meal replacements at length. We consider that the use of meal replacements (as available over

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p>1600kcal/day)</p> <ul style="list-style-type: none"> <li>◦ <b>MEAL REPLACEMENTS FOR WEIGHT CONTROL</b></li> <li>◦ Very low calorie diet (&lt;100kcal/day)</li> <li>◦ Protein sparing modified fast (PSMF)</li> <li>◦ Low carbohydrate high monounsaturated fat diet</li> <li>◦ Salt restriction</li> </ul> <p>Due to reporting issues healthy eating advice and 600 kcal/day deficit or low fat diets were classified together, along with diets where the fat or calorie restriction was not stated or could not be estimated. We used the definitions as above when classifying diets. Because of some concerns about the definitions, we have tried to be explicit (that is, include as much detail as possible about the dietary content) in both the evidence tables and the evidence statements.”</p> <p><b><i>Recommended addition in caps</i></b></p> <p>This becomes particularly important when including in this section diets such as ‘low fat’, ‘salt restriction’, ‘low carbohydrate’, etc. Such diets are followed using written advice or altered ‘normal foods’. Unlike PARNUTS Meal Replacements they</p>	<p>the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.</p>

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						<p>do not contain the complete nutritional requirements of dieters, have not been submitted to any regulatory review, and have no specific legal status. To restate:  PARNUTS foods are  <i>'foodstuffs which, owing to their special composition....are suitable for their claimed nutritional purposes'</i>  and they must  <i>'fulfil the particular nutritional requirements ...  of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs'</i>  <b><i>They must be distinguished at all times from 'normal foods'.</i></b></p> <p><b><i>Objective : Inclusion of Meal Replacements in 'Clinical Management Section' and understanding of the unique legal status of Meal Replacements – they must not be confused with 'normal' foods</i></b></p>	
Slim Fast Foods – Unilever	19	Full	Lifestyle	524	15	<p>"low calorie diet (1000-1600 kcal/day)"</p> <p>Comment : The lower level of 1000 kcal/day is widely acknowledged to be too low for people selecting from</p>	We have taken back this issue to the group and they have decided that diets with less than 1000 kcal can be used in the short term (maximum 12 weeks continuously, or used



Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p>'normal' foods to achieve sufficient nutrition. People following such low calorie levels require nutritional supplementation such as Meal Replacements. This is the type of intervention for which Meal Replacements were designed. We hope that this will be acknowledged by the inclusion of Meal Replacements in the diet classification list on page 524 line 12.</p> <p>Objective : Inclusion of Meal Replacements in 'Clinical Management' Section.</p>	<p>intermittently with a low-calorie diet, for example for 2–4 days a week).</p> <p>We have considered the issue of meal replacements at length. We consider that the use of meal replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.</p>
Slim Fast Foods – Unilever	22	Full	Lifestyle	2327	1	<p>1.3 Diet Interventions Excluded Studies  “JM Ashley, ST St Jeor, S Perumean-Chaney, J Schrage and V Bovee. Meal replacements in weight intervention. Ob REs 9 Suppl 4:312S-320S, 2001  Source – Searches  Evaluates two comparable diets, but uses MR in one group. MR assessed in PH reviews”</p> <p>Comment : This paper is not assessed in the PH Review – please could it be re-evaluated in the appropriate section.</p>	<p>We have considered the issue of meal replacements at length. We consider that the use of meal replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.</p>
Slim Fast Foods – Unilever	23	Full	Lifestyle	2328		<p>In section 1.3 Diet Interventions Excluded Studies  “Ditschuneit &amp; Flechtner Mors. Value</p>	<p>We have considered the issue of meal replacements at length. We consider that the use of meal</p>

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p>of structured meal for weight management: risk factors and long-term weight maintenance. Ob Res 9 Suppl 4:284S-289S, 2001 Source – Searches Evaluates two comparable diets but uses MR in one group. See PH Review.”</p> <p>Comment : This paper is not assessed in the PH Review – please could it be re-evaluated in the appropriate section.</p>	<p>replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.</p>
Slim Fast Foods – Unilever	25	Full	Lifestyle	2378	1	<p>Papers for inclusion:</p> <p>Please include the following papers in the further assessment:</p> <p>Redmon JB, Dristell P, Raatz, S, et al. <b>Two Year outcome of a combination of weight loss therapies for Type 2 Diabetes</b> Diabetes Care 2005; 28(6); 1311-1315</p> <p>Mattes RD. <b>Feeding behaviours and weight loss outcomes over 64 months.</b> Eating Behaviors 2 (2002) 191-204</p> <p>Poston WSC, Haddock CK, Pinkston MM et al. <b>Weight loss with meal replacement and meal replacement plus snacks: A randomised trial</b> Int J Obes 2005; 29: 1107-1114</p>	<p>We have considered the issue of meal replacements at length. We consider that the use of meal replacements (as available over the counter) is not a clinically prescribed intervention, and as such is outside the scope of the clinical guidance.</p>

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						<p>For assessment under section 1.10</p> <p>1.10 Effectiveness of brief interventions in primary care and other general clinical settings in improving outcomes for people who are overweight and obese:</p> <p>Li Z, Huerta S, Heber D. <b>Feasibility of a partial meal replacement plan for weight loss in low-income patients</b> Int J Obes 2004; 28: 1575-1579</p> <p>Anderson JW, Luan J, Hoie LH <b>Structured Weight Loss Programs: Meta analysis of weight loss at 24 weeks and assessment of effects of intervention intensity.</b> Advances in Therapy 2004; 21(2): 61-75.</p> <p>1. Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22).</p> <p>2. Note that two other categories are identified as PARNUTS formula foods for weight loss – low calorie diets for the sole source of nutrition (800 – 1200kcal) and very low calorie diets for the sole source of nutrition (400 – 800kcal)</p>	

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						TP 110506	
Slimming World	7	NICE	Misc	P7	Public Health. NHS	Should this bullet not say ...interventions to prevent <b>'and treat'</b> obesity rather than just prevent?	Noted but not amended.
Slimming World	8	NICE	Drugs	Page 9	Clinical. Adults.	As this section starts with pharmacological interventions it suggests that this is the first line treatment. Should there not be a paragraph to discuss lifestyle interventions first? This would better reflect the full version.	We have presented the recommendations, so that lifestyle is presented first, but also have clarified the recommendations on drug initiation to address this and other similar concerns.
Slimming World	9	NICE		P10	Clinical. Adults Surgery	<p>Section on surgery.</p> <p>Further suggestions to the list of criteria that should be fulfilled before surgery is recommended as an option:</p> <p>a) In the first criteria it is suggested that non-surgical measures have been tried but failed to achieve/maintain clinically significant beneficial weight loss for at least 6 months. This should be defined i.e. is it referring to a 10% weight loss as being clinically beneficial. Also, is a period of weight maintenance required or can surgery be considered following just a period of weight loss and if a period of maintenance is required, for how long?</p> <p>b) The second criteria suggests that the person should have been</p>	This section has been revised in light of these comments and others. Thank you.

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						<p>receiving 'intensive' management. Is there a definition for intensive? Also, how is this to be provided given the number of obese and the lack of provision for this service e.g. the limited number of dietitians as identified in the Dr Foster report.</p> <p>c) 5<sup>th</sup> criteria suggests bariatric surgery is recommended as a first line option for people with BMI &gt; 50. Why is this a first line option rather than only after other non-surgical options have been attempted. Case studies of numerous people of BMI &gt; 50 can be provided by lifestyle interventions such as the Slimming World programme which show that at least clinically beneficial weight loss can be achieved and maintained by this population group without the need for surgical intervention.</p> <p>In fact the evidence for gastric banding seems to be for people with a starting BMI less than 50.</p>	<p>The recommendation that surgery is first line for people with BMI &gt; 50 is based on the evidence, and the lack of evidence for drugs and lifestyle interventions for this group.</p> <p>In addition, this group will probably have comorbidities (possibly severe and multiple), and weight loss using lifestyle changes and drugs are very unlikely to achieve a clinically significant benefit.</p>
Slimming World	25	NICE	Ident	Page 34		1.2.2.3. It is stated that BMI is recommended as an estimate of adiposity in children but needs to be interpreted with caution. This is not clear in terms of exactly what the health professional should do to estimate adiposity. Will further guidance be given on how to interpret the results?	We have outlined the problems with BMI in children in the full review, but we have also provided more detail about when action should be considered in children.
Slimming World	26	NICE	Ident	Page 35		1.2.2.4. Has waist for height been	Waist for height was not included

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						considered as a measure of adiposity in adults? Why is waist only recommended in BMI less than 35? The evidence for this is not particularly clear in the full report	in the evidence reviews.  Waist (circumference) is only recommended in BMI<35, as above this cut-off, waist in addition to BMI does not add any more information on the absolute risk (see NHMRC 2003).
Slimming World	27	NICE	Ident	Page 35		1.2.2.7. Is the definition of a healthy weight range being between 18.5 and 25 kg/m2 in line with the conclusions of the FULL version?	The accepted definition of healthy weight is 18.5–25, but the GDG accepts that reaching this target may not apply (and may not be realistic) for individuals with a very high BMI. A note has been added to the recommendations to clarify this.
Slimming World	28	NICE	Lifestyle	Page 39 & 41		1.2.4.1.&1.2.4.9 It should also be stressed that weight management programmes should also provide frequent and ongoing support as part of best practice which has been shown to improve outcomes.	Noted and revised.
Slimming World	29	NICE	Lifestyle	Page 42		1.2.4.1.1. States that individuals should be encouraged to do at least 30 minutes of physical activity. It should be highlighted that individuals should be encouraged to 'build up' to 30 minutes therefore acknowledging that not all people, especially those who are currently sedentary, will be able to, or should be expected to, immediately participate in 30 minutes of moderate intensity activity a day and are likely to require a lot of support, encouragement and help in	Noted and revised.

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						starting an activity programme. Many people may be put off from becoming more active if it is not made clear that a stepwise approach can be taken to reach this level and it is not an 'all or nothing' target.	
Slimming World	30	NICE	Lifestyle	Page 43		1.2.4.17 The recommended length of use of VLCDs requires definition. Short term should be defined.	We have revised this recommendation in light of the stakeholder comments, and added further detail.
Slimming World	31	NICE	Drugs	Page 44		1.2.5.3 It would be important to provide regular and long-term support whilst prescribing pharmacological treatments. The commercial organisations could be considered as a setting for providing this ongoing support as they are already established in providing regular support.	We have added details to the recommendations that support should be offered, and added details of patient support programmes.
Slimming World	32	NICE	Surgery	P48		1.2.7.1 Should the same list of bullets given for adults in this table not also apply to the child? It should be made clear that surgery should only be considered an option for children after fist line lifestyle interventions have been attempted.	The intention is that the indications apply to all being considered for surgery – wording revised to make this clearer.
Slimming World	41	Full	Ident	201	1-8	Text and table are not consistent regarding the healthy weight range. It is not clear which is recommended for use in this guidance 20-25 or 18.5-25?	Noted and revised.
Slimming World	43	Full	Misc	661	4-11	This is not an accurate reflection of this piece of cited work. The summary could be interpreted as implying that because the subject sample was	We have reviewed the evidence and we do not feel that it meets our inclusion criteria.

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						taken from members of a commercial slimming group, this organisation was not providing an adequate level of motivational support, mentioned as a conclusion. It should be made clear that the barriers that had previously prevented people from taking action to manage their weight had come from previous experiences in NHS and other commercial settings. The key points reported in this paper were that health professionals should be aware of patients' vulnerability, approaching patients at the right time in the right way and ensuring services do not respond with judgement or blame but provide adequate motivation and support required by patients. In fact it was concluded that given the restraints on health services and staff limiting their ability to provide this level of support, the NHS should work in partnership with commercial weight loss services who may be better placed to provide the large component of motivational support required.	The guidance is based on a rigorous evidence review. Within the full version of the guidance clear links are made between each recommendation, the relevant evidence statement(s) and specific reference(s). The full version of the guidance clearly states where recommendations are the opinion of the GDG – these are the minority of recommendations. The status of the guidance is highlighted within sections 3.1 and 5.2 within the NICE version. Standard phrasing of NICE recommendations is adhered to (or will be adhered to with further editing).
South West Peninsula Strategic Health Authority	3	NICE	Lifestyle	9		There may need to be a subdivision of interventions for children reflecting different age groups and the impact this has on the control and responsibility they have for their own eating behaviours, etc.	We have emphasised that the age and the preferences of the child should be considered when making the choice of interventions.
South West Peninsula	4	NICE	Lifestyle	9	Childre n – first	This is not entirely consistent with the last bullet point of 1.1 2.10 on page	Pragmatically, we think that the recommendations do not clash.



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Strategic Health Authority				34	bullet point 1.2.1.3	18 which is more flexible, taking into account the age and maturity of the child.	
South West Peninsula Strategic Health Authority	11	NICE	Misc	34	1.2.2.1	<p>Whilst perhaps of less concern to NICE in relation to the scope of its work, it should be noted that PCTs, under their LDP requirements, and GPs, under their QOF contracts, are required to increase the number of BMIs recorded routinely for adults aged 16 – 74 years. We clearly would wish most emphasis to be placed on delivering effective interventions, but do have local evidence that the information provided by routine recording is helpful in targeting/prioritising interventions – particularly to ensure inequalities are addressed.</p> <p>From a slightly different perspective we note the need to continue to monitor prevalence at regional and local levels (page 57 4.1.4). We would like further clarity on whether this could be more effectively undertaken by use of the GP data already collected where it does at least avoid problems of individuals under-reporting their weight and provide GPs with opportunities for opportunistic advice and interventions.</p> <p>We also wonder whether consideration has been given to recommending that GPs develop 'at</p>	Noted, but the rec on routine assessment has been removed.

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						risk' registers for overweigh and obese people with other risk factors (eg diabetes, CHD).	
South West Peninsula Strategic Health Authority	12	NICE	Ident	36	1.2 2.9/11	There will need to be discussions with the DH to ensure that BMI calculations of overweight and obese older adults and Asian adults for LDP purposes are consistent with those set out in NICE guidance – this is not currently the case.	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
South West Peninsula Strategic Health Authority	13	NICE	Drugs	48		We recognise that this draft obesity guidance is in line with the NICE guidance on pharmacotherapy for obesity. We would however welcome clarification on when the pharmacotherapy guidance is due for review, as we remain concerned (particularly given the current scale of obesity) that the thresholds for initiating medication for those without risk factors may be too low. Some evaluation of the effectiveness of	This guidance supersedes the previous NICE guidance on obesity.  Comments on thresholds noted, this has been expanded in the research recommendations.

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						existing thresholds could usefully be incorporated into the areas highlighted for further research – if this information is not readily available.	
The National Centre For Eating Disorders	2	Full	Lifestyle	512	20 21	We point to reference that the presence of binge eating and dis-inhibition behaviours will derail weight loss efforts see third row for significance	We have recommended that eating behaviour be assessed.
The National Centre For Eating Disorders	3	Full	Lifestyle	513	7 (IN TABLE)	Ditto	We have recommended that eating behaviour be assessed.
The Obesity Awareness & Solutions Trust (TOAST)	1	NICE version & Full version	Misc	General		<p>The guideline should also include:</p> <ul style="list-style-type: none"> <li>Assessment that addresses the underlying causes of the eating behaviours. The assessment process should be holistic and cover all the various aspects including physiological, psychological, social, environmental and educational aspects</li> </ul> <p>Resources should include personal development and lifestyle management tools. These tools should be</p> <ul style="list-style-type: none"> <li>Localised</li> <li>Needs led</li> <li>Accessible</li> <li>Affordable</li> </ul>	Noted, and assessment of eating behaviour has been recommended with cross reference to the Eating Disorders guideline as appropriate.
The Obesity Awareness &	2	NICE version &	Assess	Nice version:		Assessment of obesity:	We agree with the issues that have been raised here, and we

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Solutions Trust (TOAST)		Full version		page 37  Full version: page 431 and 511		<p>It is very important to get things right at the assessment stage as this is crucial to engage people and to signpost them appropriately.</p> <p>It is important to identify the cause of overweight and obesity, i.e. to identify when for example certain eating patterns and behaviours developed in order to find practical and effective solutions.</p> <p>It is vital to think outside the box and not just see the weight as the issue. A person may benefit more for example by having a carer's assessment if the pressure they are under is caused by caring for a disabled relative. Or a person could benefit from debt advice if the stress is caused by financial pressure. Once people have been signposted appropriately and these types of underlying issues have been addressed, they may then be in a better position to address their own health.</p> <p>During the consultation it would be beneficial to illustrate the change cycle and to discuss with people where they may be in this process i.e. pre-contemplation, contemplation, planning, action, etc.</p> <p>It may also be helpful to look at</p>	<p>have recommended that issues other than medical ones be considered in the assessment, including eating behaviour.</p> <p>Stages of Change will be covered in the upcoming NICE guidance on Behaviour Change in 2007. In addition, we have reviewed evidence that looked at existing barriers in the clinical consultation for those who are overweight/obese. Please refer to section 15.3.8 of the full version. The section 'Patient-centred care' also expands on issues related to your comments.</p>

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						<p>barriers to change using a proforma such as:</p> <ul style="list-style-type: none"> <li>• Identifying Barriers</li> <li>• What is it that I want to change?</li> <li>• What happens if I change this?</li> <li>• What happens if I don't change this?</li> <li>• What makes it harder to make changes?</li> <li>• What makes it easier to make changes?</li> </ul>	
The Obesity Awareness & Solutions Trust (TOAST)	6	NICE version	CP	Page 9		<p>Clinical: Any interventions should take account of social, psychological and environmental issues and include areas of lifestyle and personal development such as decision making tools, problem solving, motivation etc</p>	<p>We have revised our recommendations in light of these comments and those of other stakeholders.</p>
The Obesity Awareness & Solutions Trust (TOAST)	7	NICE version	CP	Page 9		<p>Children: Need to think outside the box: obesity is not just about diet and exercise.</p> <p>Should also address the emotional and psychological aspects.</p> <p>What services are there? What services are available locally?</p>	<p>We have noted that behavioural strategies should be used, and healthcare professionals should refer to the detailed recommendations for guidance.</p> <p>The specifics of service organisation are outside our scope.</p>
The Obesity Awareness & Solutions Trust (TOAST)	8	NICE version	CP	Page 9 adults		<p>Adults: Appropriate support is needed whatever the intervention.</p> <p>All interventions need to have appropriate assessment processes in place that include social,</p>	<p>These are Key Priorities for Implementation, and should be read in the context of all the recommendations.</p>

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						environmental, psychological and physiological aspects as well as personal development issues such as attitude, motivation, change cycle, risk taking, how to get out of your comfort zone etc.	
The Obesity Awareness & Solutions Trust (TOAST)	9	NICE version	Surgery	Page 10		<p>Criteria for surgery:</p> <p>Local obesity resources should also be considered before surgery is recommended.</p> <ul style="list-style-type: none"> <li>• What local obesity resources are there?</li> <li>• Who delivers these?</li> <li>• Where are they?</li> <li>• What is the cost?</li> <li>• What other support is there?</li> </ul>	Please see the Implementation section for details.
The Obesity Awareness & Solutions Trust (TOAST)	26	NICE version	Misc	Page 33	1.2.1.1	It should also be ensured that gowns, cuffs for blood pressure, changing area, toilets, wheelchairs and beds etc are all suitable for very obese people.	Noted and revised.
The Obesity Awareness & Solutions Trust (TOAST)	27	NICE version	Assess	Page 39	1.2.3.3	<p>The following model of change could be helpful to help people to identify where they are stuck.</p> <ul style="list-style-type: none"> <li>• If people are unwilling to engage ask why?</li> <li>• Is it negative experiences from the past i.e. feeling like a dieting failure?</li> <li>• What is the fear behind change?</li> <li>• Is it fear of failure?</li> </ul>	Stages of Change will be covered in the upcoming NICE guidance on Behaviour Change in 2007. In addition, we have reviewed evidence that looked at existing barriers in the clinical consultation for those who are overweight/obese. Please refer to section 15.3.8 of the full version. The section 'Patient-centred care' also expands on issues related to your

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						<p>Use barriers to change questions such as:</p> <ul style="list-style-type: none"> <li>• Identifying Barriers</li> <li>• What is it that I want to change?</li> <li>• What happens if I change this?</li> <li>• What happens if I don't change this?</li> <li>• What makes it harder to make changes?</li> <li>• What makes it easier to make changes?</li> </ul>	comments.
The Obesity Awareness & Solutions Trust (TOAST)	28	NICE version	Assess	Page 39	1.2.3.3	Should also include self /personal development aspects i.e. personal responsibility, decision making, problem solving, time management, prioritising, how to have high self esteem and self confidence, assertiveness, etc.	Throughout the guidance we stress the importance of behaviour change (see also 'Patient-centred care' and 'Lifestyle interventions').
The Obesity Awareness & Solutions Trust (TOAST)	29	NICE version	Lifestyle	Page 40	1.2.4.7	<p>It is important to remember to "think outside the box" in terms of the types of information and the way that it is presented and made available to people who are overweight and obese.</p> <p>Based on the calls to the TOAST help and information line the issues are varied. There is no one size fits all solution because the reasons why and how people gain weight are very different and therefore solutions must reflect this. For example if a person starter to gain weight when their</p>	Noted and some revisions made. Throughout the guideline we have emphasised the need to take the specific circumstances of the individual into account, and hope that this addresses your concerns.

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						<p>partner died it may be that the issue would be resolved in part by bereavement counselling. Therefore it is important that the range of organisations that people are signposted to reflect their different needs.</p> <p>Should also include process of change, how we learn, barriers to change, risk taking and comfort zones etc</p> <p>In terms of setting targets, some of these should also be quality of life driven not just weight related.</p>	
The Obesity Awareness & Solutions Trust (TOAST)	30	NICE version	Drugs	Page 44	1.2.5.2	All interventions should include appropriate level of support for both adults and children.	We agree and consider that this is reflected in the revised recommendations 1.1.5.2 and 1.1.5.3
The Obesity Awareness & Solutions Trust (TOAST)	31	NICE version	Surgery	Page 50	1.2.7.7	Adults need a holistic, full and comprehensive needs led assessment before making a decision to have surgery.	Recommendation revised.
The Obesity Awareness & Solutions Trust (TOAST)	32	NICE version	Surgery	Page 50	1.2.7.9	The long term effects of obesity surgery on young people should also be considered?	Noted, but we have recommended that long term issues be considered.
Tissue Viability Nurses Association	1	NICE	Misc	Page 33	1.2.1	For example adequate weighing facilities, specialist seating, bed frames and mattresses to ensure the person can remain as active as possible and so prevent complications of immobility such as pressure ulceration.	Noted and revised.



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Tissue Viability Nurses Association	2	NICE	Surgery	page 34	1.2.2.2.	This will be particularly important when determining the need for specialist pressure relieving mattresses or wide bed frames because if a person is relatively short but overweight then their weight will not be evenly distributed over the mattress and they may need a wider bed frame and a more supportive mattress	Noted.
Tissue Viability Nurses Association	3	NICE	Surgery	page 49	1.2.7.3.	access to suitable equipment including scales, theatre table, mortuary tables, zimmer frames, commodes, hoist, bed frames, pressure relieving mattresses and seating all suitable for the bariatric patient and staff trained to use them	Noted and revised.
Tissue Viability Nurses Association	4	NICE	Surgery	page 50	1.2.7.9	the facilities and bariatric equipment available and staff trained to use them	Noted and revised.
University College London Hospitals NHS Trust	15		Drugs	44	Section 1.2.5.1	I support the recommendation that drug treatment is generally not recommended for children under 12 years.	Thank you for your comment.
University College London Hospitals NHS Trust	9		Ident	34	Section 1.2.2.3	Use of BMI. The document correctly counsels caution but appropriately suggests that the BMI is useful in assessing overweight in children and adolescents. However, the guidance as it standards is incorrect, as the BMI centile (or SD score) rather than the BMI itself should be used as a measure of adiposity. It is important to note this here. This is mentioned briefly in Section 1.2.2.7, but should	We have revised this recommendation accordingly.

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						be made clear here.	
University College London Hospitals NHS Trust	10		Ident	35	1.2.2.4	Re waist circumference. I strongly disagree with the statement that waist circumference not be a routine measure. Population-based centile charts for waist circumference exist. There is increasing evidence in children that different phenotypes of obesity exist, and the waist circumference is important in distinguishing those with abdominal rather than generalised obesity.	<p>We appreciate the value of these comments.</p> <p>There are lower-quality studies that propose cut-offs for waist circumference in children, but the GDG did not consider that, in light of the evidence, we could support the use of a specific cut-off for waist circumference.</p>
University College London Hospitals NHS Trust	11		Ident	35	Section 1.2.2.7	NICE has clearly decided not to recommend a definition of childhood obesity, other than to recommend that children $\geq 98^{\text{th}}$ BMI centile should be “considered for assessment of comorbidity” (Section 1.2.2.10, p36). While NICE correctly recognises the lack of evidence to recommend one definition above another, the current guidance does not help clinicians to decide which children and adolescents to treat. By default clinicians will use the 98 <sup>th</sup> centile, which, however, was only recommended for assessment of comorbidity. I understand the rationale for undertaking this approach, however I believe it will lead to confusion.	<p>The GDG did not feel that, in light of the available evidence, we could confidently support one sole definition of childhood overweight/obesity.</p> <p>The GDG recommended that ‘Pragmatic indicators for action are the 91st and 98th centiles.’</p>
University College London Hospitals NHS Trust	12		Lifestyle	38	Section 1.2.3.2	Re blood tests for assessment of comorbidity in children – I concur with this suggestion.	Noted. Thank you for your comment.

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University College London Hospitals NHS Trust	13		Lifestyle	39-40	Section 1.2.4	<p>Re lifestyle interventions: The guidance suggests that multi-component interventions are the treatment of choice, encompassing behavioural treatments around activity and diet. I support this strongly for children. I would argue that NICE should go much further and recommend that for children, single component interventions should not be implemented as there is little evidence that they are effective. The document does state this for dietetic interventions (Section 1.2.4.13, p. 42), noting that a dietary approach alone is not recommended.</p> <p>However the same issue exists for single component exercise interventions: while these may be effective in the short term, there is little or no evidence of long-term benefit. Clinically, single component interventions can be tempting to health professionals working in isolation, as is often the case where dedicated childhood obesity services have not been set up. e.g. many obese children are referred to paediatric dieticians, who generally work in isolation from physiotherapists. Some children are referred to psychologists or other mental health professionals in CAMHS services, who again do not</p>	<p>We have inserted a new recommendation in light of this and other comments from stakeholders.</p> <p>See general recommendations for lifestyle.</p>

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						<p>routinely see these patients with dieticians or physiotherapists. Despite the excellent evidence for the importance of behavioural modification in multi-component programmes, there is no evidence that individual psychological work with obese children is effective.</p> <p>In essence, both single component programmes and individual treatment of obese children within isolated dietetic, physical therapy or psychological services are likely to be waste of scarce resource.</p> <p>I believe that these recommendation should be greatly strengthened to recommend against resource wastage through single component interventions of any type.</p>	
University College London Hospitals NHS Trust	14		Lifestyle	43	Section 1.2.4.14	<p>Re age-appropriate dietary advice. This is correct, however, the point made above under General comments pertains again. Low-fat diets are generally inappropriate in children. Section 1.2.4.18 (Page 44) does suggest that restrictive and unbalanced diets should not be used in children. However I believe NICE must be much clearer if these recommendations are to be easily implemented by clinicians. NICE should recommend against both low fat and low carbohydrate diets in</p>	<p>We have revised this recommendation in light of this and other comments from stakeholders.</p>

Organisation	Order No.	Document	Section	Page No.	Line No.	Comment	Response
						children and adolescents.	
University College London Hospitals NHS Trust	16		Drugs	44	Section 1.2.5.3	I support the use of Orlistat or Sibutramine for adolescents over 12 years only within specialist settings with experienced teams. I concur that drug treatment should only be initiated in specialist care, but could be continued in primary care (Section 1.2.5.5, p. 45)	Thank you for your comment.
University College London Hospitals NHS Trust	17		Drugs	45	1.2.5.6	I agree that a 6 month trial of drug treatment followed by re-evaluation is appropriate in children.	Thank you for your comment.
University College London Hospitals NHS Trust	18		Misc	47	Section 1.2.6.1	I support the recommendations for referral to secondary care.	Thank you for your comment.
University College London Hospitals NHS Trust	19		Surgery	48	Section 1.2.7	<p>I support the restriction of bariatric surgery to adolescents who have largely completed their growth. I support the comments about restriction of surgery to specialist centres.</p> <p>I support the recommendation (Section 1.2.7.3 and 1.2.7.7) that assessment and treatment teams include psychological assessment. However, generic child and adolescent mental health professionals are unlikely to have the skills to undertake this work. I suggest that NICE should include a recommendation that teams undertaking adolescent bariatric</p>	Noted and revised.

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						surgery include a psychologist or psychiatrist with specialist child and adolescent eating disorder expertise.	
University College London Hospitals NHS Trust	20		Surgery	48	Section 1.2.7.2	I strongly oppose the suggestion that current bariatric surgery in children should be done in adult centres with specialist paediatric support. This is contrary to well-established models of paediatric specialist surgery, in which adult surgeons operate jointly with paediatric surgeons within paediatric settings. This suggestion is also directly contrary to the NSF for Children & Young People, which directs that children must be treated within child-friendly environments by trained paediatric staff.	Noted and revised.
University College London Hospitals NHS Trust Nutrition and Dietetics	22		Ident	436	3-4	Waist circumference- relevance if no cut off points? MUAC instead?	Despite no cut-off points being recommended, it is still of value to consider use of this measure.
University College London Hospitals NHS Trust Nutrition and Dietetics	23		Misc	437	15	Artificial feeding – increase in obesity – obesity message needs to be re-enforced through breast feeding promoting initiatives	Breast feeding is not part Of our remit. However, NICE is currently developing guidance for midwives , health visitors, pharmacists and other primary care services to improve the nutrition of pregnant and breastfeeding mothers and children in low income households, due to be published May 2007. For further information see

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							<a href="http://www.nice.org.uk/page.aspx?o=MaternalandChildNutritionMain">www.nice.org.uk/page.aspx?o=MaternalandChildNutritionMain</a>
University College London Hospitals NHS Trust Nutrition and Dietetics	24		Misc	438	10	Catch up growth can lead to obesity – again, this needs to be highlighted/awareness of in artificial feeding policies	Breast feeding is not part Of our remit. However, NICE is currently developing guidance for midwives , health visitors, pharmacists and other primary care services to improve the nutrition of pregnant and breastfeeding mothers and children in low income households, due to be published May 2007. For further information see <a href="http://www.nice.org.uk/page.aspx?o=MaternalandChildNutritionMain">www.nice.org.uk/page.aspx?o=MaternalandChildNutritionMain</a>
University College London Hospitals NHS Trust Nutrition and Dietetics	25		Lifestyle		General	“Red foods/green foods” – is this a concept which will be easily understood by all primary care providers/patients and carers? Is it recognised that this concept of “red/amber/green” foods is going to continue to be used in healthy eating programs/initiatives.	This is reiterated throughout the literature, and appears to be a simple way of labelling food from a specific diet called the ‘traffic light diet.
University College London Hospitals NHS Trust Nutrition and Dietetics	26		Drugs	469	2–3	Needs to be made clear to all concerned if this should not be used as a recommendation – generally people on orlistat treatment would assume that they would try to limit their dietary intake, i.e. hypocaloric diet – as opposed to the recommendation	Not clear what this relates to - the page number is from the ‘Behavioural’ section.
University College London Hospitals NHS Trust	27		Misc	494	26-27	VLCD – what are the criteria for identifying a “specialised centre”, ? suggested duration of VLCD	These have been revised in light of this and other comments.

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Nutrition and Dietetics							
University College London Hospitals NHS Trust Nutrition and Dietetics	28		Lifestyle	513	7	Medical evaluation should also include patient's willingness to change lifestyle habits in order to lose weight	We have recommended that willingness to change be assessed.
University College London Hospitals NHS Trust Nutrition and Dietetics	29		Lifestyle	526	3	The standard BMI eg < 25 kg/m does not fit everyone. A different BMI is required for different ethnic and age groups eg. A lower BMI for Asians, higher for African/Afro Caribbeans and the elderly	This cut-off was used in the review cited.
University College London Hospitals NHS Trust Nutrition and Dietetics	30		Lifestyle		General	Should definite recommendations be made on the minimum amount of appointments that should be offered to a patient in secondary setting in order to have positive results, and ideally how often these pts should be seen.	It is outside our scope to provide recommendations on the specifics of service delivery.
University of Leeds	4	NICE	Lifestyle	36	1.2.2.10	It would be helpful to insert a reference to paragraph 1.2.3.2 here so it is clear what the assessment should include	Noted and revised.
University of Leeds	5	NICE	Drugs	44	1.2.5	Guidance on pharmacological treatment for children is very welcome	Thank you for your comment.
University of Leeds	6	NICE	Drugs	45	1.2.5.9	The recommendation of a registry on the use of orlistat and sibutramine is important. These medications are experimental in the paediatric age range, and a register would help	Thank you for your contribution.



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						insure that the paediatric community is informed of both benefits and harms	
University of Leeds	7	NICE	Misc	47	1.2.6	The section on referral to secondary and specialist care is important, and I suspect will be open to comment. It needs some further clarity, as services at present are not widely available and the potential numbers of children requiring paediatric care is enormous.	We have used the Department of Health's document on specialised Services National definition set. For further details please refer to <a href="http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187&amp;ch=JAqaRv">www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SpecialisedServicesDefinition/SpecialisedServicesDefinitionArticle/fs/en?CONTENT_ID=4002187&amp;ch=JAqaRv</a> We are also unable to provide guidance on details of service delivery arrangements, as this is up to local priorities and resources.
University of Leeds	8	NICE	Misc	47	1.2.6.1	It is clear that children with comorbidity need paediatric input, but as most of the comorbidity is subclinical, children will only be identified if they undergo investigations for liver dysfunction, hyperlipidaemia and glucose impairment, (and blood pressure is measured). Professionals in primary care will require some guidance as to who to investigate. (This will be hard as the evidence base indicates that severity of obesity is not a consistent predictor. Perhaps family history and ethnicity can form part of the guidance, as has been adopted by the American Academy of Peds).	We have tried to be clear about investigation and assessment in children for these reasons.
University of	9	NICE	CP	73		The clinical pathway for children is	Thank you.

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Leeds						<p>important to include, however I have some concerns as follows:</p> <p>1. There is a feedback loop so that all children who do not attain successful weight control are referred to a paediatrician. This is not likely to be helpful, and it would certainly block referral pathways to no benefit</p> <p>2. The biochemical tests for comorbidity can as well be carried out in primary care</p> <p>3. Some specification needs to be made that the paediatrician should work with the support of dietetic, sport and CAHMS professionals. A lone paediatrician is unlikely to be helpful</p> <p>4. The specialist management box needs to emphasise that paediatric care <b>MUST</b> be in the context of a multidisciplinary team (as mentioned earlier in the document</p>	<p>We have only recommended that referral be considered.</p> <p>The GDG considered that such tests in children should be undertaken in secondary care.</p> <p>It is anticipated that paediatricians will be working in teams/structures as outlined in the NSF for children.</p>
Wandsworth PCT – Public Health and Community Nutrition and Dietetics department	41		Ident	34	1.2.2.3	Adults should include a mention of the considerations when interpreting BMI.	We have added in more detail to alert healthcare professionals.
Weight Concern	4	NICE version	PCC	p. 5		<p><b>Patient-centred care</b> Terminology change: The wording “assess the patient’s <b>‘feelings’</b> about their weight and diagnosis” etc. would be better phrased as; “assess the patient’s <b>‘thoughts’</b>”. A behavioural approach</p>	Noted and revised.

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						attempts to change thought processes or thinking patterns as feelings can not be changed.	
Weight Concern	7	NICE version	Ident	Page 34	1.2.2.1 & 1.2.2.2	<p><b>Opportunistic identification</b></p> <p>We would recommend that routine measurement of weight and height is appropriate with suitable clinical judgement. If it is specifically 'not recommended' and left to clinical judgement to determine the suitability of measuring any given patient at a given opportunity, the decision to measure will be dependent on the doctor-patient relationship, the doctor's interest in and understanding of obesity, and issues relating to time management. This could lead to patients with degrees of overweight and obesity progressing unidentified, which could make their condition more complex to treat once addressed at a later stage. The Department of Health has recently launched a tool to aid clinicians in 'raising the issue of weight' in a sensitive way and Weight Concern was centrally involved in the development of this tool.</p>	We have withdrawn recommendation 1.2.2.1 and have strengthened recommendation 1.2.2.2, to try to address these and other concerns.
Weight Concern	8	NICE version	Ident	Page 35	1.2.2.4	<p><b>Waist Circumference</b></p> <p>Due to the difficulty and degree of error in measuring waist circumference accurately, it could be beneficial to mention that health professionals should have appropriate training in how to measure waist</p>	It is outside our remit to provide guidance on the specifics of certain training issues. We will be providing a brief section on what our guidance can refer to in regard to training matters.

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						circumference.	
Weight Concern	9	NICE version	Ident	Page 35	1.2.2.7	<p><b>BMI in children and young people</b>  There is increasingly widespread usage of the IOTF international cut-off points for BMI (overweight and obesity) in children. It is a shame that there is no reference to these in the guidelines. Although we appreciate they are for use in epidemiological data, there is also a significant benefit from using them in a clinical setting.</p>	<p>The GDG did not consider that, in light of the available evidence, we could confidently support one sole definition of childhood overweight/obesity.</p> <p>The GDG recommended that 'Pragmatic indicators for action are the 91st and 98th centiles from the 1990 UK BMI charts.'</p>
Weight Concern	10	NICE version	Lifestyle	p. 42	1.2.4.11	<p><b>Physical activity – children and young people</b>  The addition of the recommendation that children should undertake at least 60 minutes of at least moderate intensity physical activity each day for general health benefits would be helpful here as a guide, rather than merely including a mention in Appendix D p.77. If a figure is not stated clearly, it will be difficult for health professionals to quantify the amount of exercise for a child to aim for when delivering the recommendation. This could lead to figures from the adult guidance being used instead in confusion.</p>	<p>This has been discussed with the GDG and a new recommendation has been added.</p>
Weight Concern	11	NICE version	Lifestyle	p. 43	1.2.4.17	<p><b>Protein Sparing Modified Fasts of 1000 kcal/day or less</b>  The reference to the use of low carbohydrate VLCD's is concerning. Is the quality of evidence good enough to include reference to this? Is the evidence not better for the net</p>	<p>The guidance is based on a rigorous evidence review. Within the full version of the guidance clear links are made between each recommendation, the relevant evidence statement(s) and specific reference(s).</p>

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						energy restriction of the VLCD (e.g. <1000 kcals) rather than the diet composition? Please consider this.	We have revised this recommendation in light of the stakeholder comments.
Weight Concern	12	NICE version	Surgery	p. 48	1.2.7.1	<b>Young people and bariatric surgery</b> We strongly feel it should be clearly stated as the first point in the table (similar to that in the recommendation for adults) that surgery for young people should only ever be considered if there is evidence that treatment of non-surgical measures have failed in primary and secondary care. Clarification is needed that it is not first line treatment.	Noted and altered to clarify.
Weight Concern	13	NICE version	CP	p. 74		<b>Clinical care pathway for adults</b> The risk assessment table would be more user-friendly at a clinical level if BMI figures were also stated for levels of obesity, although it is appreciated these differ between Asians and non-Asians. BMI figures are more widely used in a clinical setting rather than the levels of obesity I, II, or III.	Noted, but we consider that the table is useful and clear, and that adding such level of detail may detract from the readability.
Weight Watchers	6	Full version	Drugs	43	9–11	Lifestyle advice in conjunction with anti-obesity medication: We note with some concern that the specific wording of the recommendations about the supporting lifestyle advice (diet, physical activity and behavioural support) to be offered in conjunction with anti-obesity medication appear to suggest that such advice should be offered specifically by a health professional. We would strongly	In the 'Management in non-clinical settings' section, we have made recommendations for individuals and healthcare professionals when considering the use of commercial slimming programmes (using any mode of delivery – books, clubs, internet etc.).

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						<p>suggest a role here for commercial slimming organisations such as Weight Watchers, which can offer weekly contact and support on a hugely cost-effective basis. (Through PCTs appropriate patients can attend a 12 week course at Weight Watchers for a price [to the PCT] of £35.) The complementary effect of group behavioural counselling when used with anti-obesity medication was described by Tom Wadden and colleagues last year; Wadden T.A et al, Randomised trial of lifestyle modification and pharmacotherapy for obesity. New Engl J Med (2005) 353; 20: 2111-2120.</p> <p>With the imminent arrival of rimonobant it is likely that the volumes of patients needing such support with lifestyle change will be unmanageable with the present resource and skill level of health care practitioners. Weight Watchers has a readily available and accessible service which is quality assured, operates totally in line with clinical practice and is evidence based.</p>	
Welsh Assembly Government	11		Ident	15, 22 etc		reference is made to PCTs and not the Welsh equivalent of local health boards	Noted and revised.
West Gloucestershire PCT	2	NICE version		5	Under heading 'Patient-	<ul style="list-style-type: none"> <li>• Comment 'Stressing that obesity is...mitigate this.' Is not helpful. We should not assume that people are</li> </ul>	This point is specific to the definition of obesity – that is, it is based on health risk, rather than

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					centred care'	<p>motivated by health concerns over cosmetic ones – in many instances the opposite is true. The skill is to be patient-centred, ask the right questions and clue into the factors that are important to the individual. It is not helpful or consistent with a patient-centred approach to include this remark</p> <ul style="list-style-type: none"> <li>• Under 'During the consultation it would be helpful to:'</li> <li>- Do not agree that exploring eating /activity patterns will help – it is well documented that patients have a poor perception of these and that they may lie – this puts the patient on the back foot from the start. People need to develop their <b>own</b> awareness of their eating /activity patterns – this will occur during treatment through developing self monitoring skills</li> <li>- Add 'avoid making dangerous assumptions – i.e. about what patient thinks, feels, needs, knows and wants</li> <li>- Add, under 'find out what, if anything ... ' it more important to find out <b>what they learned</b> from these attempts rather than 'why it didn't work' – subtly but very significantly different</li> <li>- Add – be mindful of the fact that most patients know they are overweight and that they 'should'</li> </ul>	<p>being a definition based on looks.</p> <p>We have recommended that eating behaviour also be assessed, and then addressed using behavioural techniques such as self-monitoring.</p> <p>We would consider that having a high standard of consulting skill would include this.</p> <p>Noted and added.</p> <p>Again, we have stressed that people may not be able to commit to losing weight at that time, but</p>

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						<p>do something about it – but it may not be a high enough priority for them to be able to commit the time and effort needed</p> <ul style="list-style-type: none"> <li>- Add – be mindful of the fact that many people lack the resources needed to make major behaviour changes i.e. self-esteem, self-efficacy etc and that in some cases it is more appropriate to work on developing these than to forge ahead with weight management</li> <li>- Add – be mindful of the fact that half hearted attempts to manage weight will fail – ensure the patient is really ready to commit to this</li> </ul>	<p>may wish to at a later date.</p> <p>We have stressed that appropriate support needs to be available.</p> <p>This is part of working with individuals to ensure that goals and actions are agreed and understood.</p>
West Gloucestershire PCT	3	NICE version	PCC	6	Under heading 'Patient-centred care'	Re: comment ending 'obesity will be discussed again in the future'. This is <b>not</b> being patient-centred. Instead should read something like 'does not want to do anything at this time, ask if its okay to raise the issue again in the future and explain that there is an open-door policy whereby they may return at any time in the future if they feel like would like to be supported to manage their weight'	We have revised this in light of this and other comments.
West Gloucestershire PCT	8	NICE version	CP	9	Heading 'Adults'	Giving 'dietary and exercise <b>advice</b> ' <b>is not</b> a patient-centred approach. Should read something like '...only after support to make concurrent lifestyle changes has been initiated'. Also need to be consistent with use of terms i.e. use 'physical activity' instead of 'exercise'	These are Key Priorities for Implementation, and should be read in the context of all the recommendations.



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West Gloucestershire PCT	9	NICE version	CP	10	Heading 'Adults'	Surgery was formerly recommended for 'morbid obesity with a BMI of > 40 (or > 35 with associated comorbidity)' – has the NICE guidance on this been updated? See also page 49 under line 1.2.7.4	This guidance replaces previous NICE guidance on drugs and surgery.
West Gloucestershire PCT	26	NICE version		33	1.2.1	Under generic principles of care there needs to be a clear statement about weight maintenance being the aim of treatment for most children	Has been included under the lifestyle recommendations section.
West Gloucestershire PCT	27	NICE version	Ident	34	1.2.2.3	For children the use of BMI needs to be qualified as BMI percentile using age / gender specific growth charts. Also some reference to the effect of different pubertal stages on BMI in children of the same age and gender	The recommendation has been revised.
West Gloucestershire PCT	28	NICE version	Ident	36	1.2.2.10	The adult section of this table is really confusing as it stands as its got too many variables – this would make more sense (TABLE REMOVED FOR READABILITY)	Noted, and we have asked for editorial input.
West Gloucestershire PCT	29	NICE version	Assess	37	1.2.2.11	Suggest same format for table as above	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised

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							recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.
West Gloucestershire PCT	30	NICE version	Assess	38	1.2.3.1	Amend final bullet point to: - Willingness and motivation of family to change	The GDG were happy with the current wording.
West Gloucestershire PCT	31	NICE version	Assess	39	1.2.3.3	Please add 'without being judged' to the end of this point	We have considered this suggestion alongside others and have revised the recommendation.
West Gloucestershire PCT	32	NICE version	Assess	39	1.2.3.5	Should read that 'continuity of care is highly important...'	This has been included.
West Gloucestershire PCT	33	NICE version	Lifestyle	39	1.2.4.1	There needs to be a note here stating that in treating obese children treatment should be principally aimed at parents in under-12s and at the child when they reach adolescence – though still acknowledging the need for family support.	See 1.2.1.4.
West Gloucestershire PCT	34	NICE version	Lifestyle	40	1.2.4.4	Need a national competencies framework for weight management – and competencies need to be defined within this document	We have added an additional paragraph/section on training, based on information already included throughout the guidance. The specifics of implementation – including local training needs and the skill mix required – are also outside the remit of this work.
West Gloucestershire	35	NICE version	Lifestyle	41	1.2.4.7	Add to bullet points: The distinction between losing weight	Added.

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PCT						and maintaining lost weight and the importance of developing skills for both	
West Gloucestershire PCT	36	NICE version	Lifestyle	41	1.2.4.8	Amend adult side of table since there is some overlap and some key aspects missing. Should read: <ul style="list-style-type: none"> <li>- Self-monitoring of behaviour and progress</li> <li>- Stimulus control</li> <li>- Formalising eating, and slowing rate</li> <li>- Goal setting including pacing</li> <li>- Planning</li> <li>- Problem-solving</li> <li>- Assertiveness</li> <li>- Cognitive restructuring (particularly moving away from 'all or nothing' thinking around weight and its management)</li> <li>- Reinforcement of changes</li> <li>- Social support</li> <li>- Lapse management</li> <li>- Strategies for maintaining lost weight</li> <li>- Solution focused strategies</li> </ul>	We have made some revisions in light of this comment and others.
West Gloucestershire PCT	37	NICE version	Lifestyle	43	1.2.4.15	Adult side of table. Useful to add the point that this can be achieved by reducing the energy density of the diet rather than the absolute volume of food consumed	The GDG considered that the wording was appropriate, so revisions have not been made.
West Gloucestershire PCT	38	NICE version	Lifestyle	43	1.2.4.16	Why 600kcal and not 500kcal as generally quoted (and more realistic to sustain)	This was based on the definitions used in the original health technology appraisal Avenell

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							2004.
West Gloucestershire PCT	39	NICE version	Lifestyle	43	1.2.4.16	Rarely would a 1000kcal diet be recommended since it is so difficult to stick to. Would be more appropriate to pitch this at 1200-1800kcal per day and to qualify it by saying the taller / heavier / more active the person the higher their energy requirement	We have taken back this issue to the group and they have decided that diets with less than 1000 kcal can be used in the short term (maximum 12 weeks continuously, or used intermittently with a low-calorie diet, for example for 2–4 days a week).
West Gloucestershire PCT	40	NICE version	Lifestyle	43	1.2.4.17	Adult side – Be more specific about this – what do you mean by short term – no more than two weeks. Would prefer that these are only used under clinical supervision since, and with support to maintain weight lost otherwise there is a danger that they perpetuate the whole ‘all or nothing’ dieting mentality that we know to be part of the problem	We have revised this recommendation to address these and other stakeholder concerns.
West Gloucestershire PCT	41	NICE version	Lifestyle	44	1.2.4.18	This comment should apply to adults as well as children	Noted and revised.
West Gloucestershire PCT	42	NICE version	Drugs	45	1.2.5.6	Adult side – Add ‘support upon withdrawal of drug in order to help maintain weight lost, since patient confidence and self-efficacy likely to be low at this point’	Noted and revised.
West Gloucestershire PCT	43	NICE version	Drugs	47	1.2.5.17	Need to be more explicit about longer-term use of medication – major implications for prescribing budget	The recommendations on drugs have undergone some revision, to reflect this and other concerns.
West Gloucestershire	44	NICE version		47	1.2.6.1	Child side - This differs from NOF/RCP guidance which only	We have discussed the issues arising from stakeholders

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PCT						suggest referring those who are over 99.6 <sup>th</sup> centile unless significant comorbidity, complex needs or possible underlying pathology	regarding the Identification of children with the GDG. However they feel that in light of The current evidence, that we could not confidently support one sole definition of childhood overweight/obesity. The GDG recommended that 'Pragmatic indicators for action are the 91st and 98th centiles.'
West Gloucestershire PCT	45	NICE version		47	1.2.6.1	Adult side – Add to list of criteria – patient is committed to actively engaging in treatment	We have stressed throughout the need for people to be willing and able to make changes.
West Gloucestershire PCT	46	NICE version	Drugs	49	1.2.7.5	Be more specific in comment about using Orlistat or Sibutramine 'if the waiting time for surgery is considered to be excessive'	We consider that this is a more specific service delivery issue and the group felt that they were happy with the wording.
Wolverhampton PCT	1	NICE version	PCC	P.5	1 <sup>st</sup> paragraph	Good but need to recognise that this will potentially require additional training for some staff	Noted and section on training added.
Wolverhampton PCT	4		PCC	6	2 <sup>nd</sup> para	A flagging up system could be adopted in patient notes so that whoever picks up the notes knows that the patient expects to be asked again about their weight and this won't get overlooked in future consultations	This is part of implementation, but we have recommended that high quality record keeping is important.
Wolverhampton PCT	14			33	Section 1.2	This section is not easy to follow. There is too much of a mix of styles – some information in boxes, some in statements. It may be better to separate the recommendations more clearly into those for children and then those for adults.	Noted, and editorial input has been provided.

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Wolverhampton PCT	15		Ident	37	Section 1.2.2.11	The table for risk assessment in Asian adults is not at all clear or easy to follow.	The GDG were aware of the evidence that black and minority ethnic populations may have differing health risks from overweight/obesity at the same BMI. However, they considered that there was insufficient current evidence to allow the recommendation of specific BMI cut-offs for Asian and elderly populations as these have yet to be validated for use in the UK population. Thus, the GDG adopted a revised recommendation that highlights the limitations of BMI and how different populations may have different risks at the same BMI, but allows for the exercise of clinical judgement.