### Managing adult obesity in primary care – a consensus algorithm

This publication, and the meeting upon which it is based, were sponsored by sanofi-aventis.

This is a report from a roundtable discussion that took place on 1 October 2008 at Nuthurst Grange, Birmingham. The panel received a standard honorarium. Representatives from sanofi-aventis were not present during the deliberation of the panel and reviewed this document for technical accuracy only. This article represents the views of the panel, with whom editorial control rests.

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### Introduction

Rates of obesity have dramatically increased in the UK over the past two decades. The ongoing Health Survey for England (HSE) provides data from a large nationally distributed random sample and highlights the increasing trend. In 1993, 13% of men and 16% of women were estimated to be obese (body mass index [BMI] >30 kg/m²; HSE, 1993). Just over a decade later the proportion of men and women classed as obese had increased to 24% for both sexes (HSE, 2004). In an effort to assist GP teams to provide consistent and high-quality care for obese people throughout the country, a panel of experts was convened to develop a clinical algorithm for the management of obesity in primary care. Details of the panel members and their institutional affiliations appear at the end of this report.

ata from the International Obesity Task Force show that few countries in Europe report obesity rates below 10% (International Association for the Study of Obesity, 2008). Prevalence rates rise to more than 20% in countries such as the UK, Malta, Lithuania and Greece. The most rapid increase is noted in the UK, where obesity rates have risen threefold from 1980 to 2001, with levels of extreme obesity (BMI >40 kg/m<sup>2</sup>) also increasing threefold among men and almost doubling among women during the 1990s (HSE, 2001). Readers are referred to Appendix 1 for information about where to access sites for regional, national and international obesity

prevalence data. Although this document is restricted to the management of adult obesity, prevalence rates in children and adolescents are also increasing. High levels of overweight and obesity among the young are likely to exacerbate the trend towards overweight and obesity in the adult population (Janssen et al, 2005). The Foresight report "Tackling Obesities: Future Choices", which was commissioned by the UK government, has estimated that if no action is taken, 60% of men, 50% of women and 25% of under-20 year olds will be obese by 2050 based on current trends (Foresight, 2007).

Obesity in adults is an important risk factor for a number of chronic diseases including hypertension,

coronary heart disease (CHD), stroke, type 2 diabetes and some cancers (Kopelman, 2007). Obesity is also directly related to increased mortality and lower life expectancy, with several prospective studies demonstrating a relationship between obesity and premature death from CHD, cancers and other diseases (Lee et al, 1993; Jousilahti et al, 1996; Calle et al, 1999; Adams et al. 2006). In the UK, it is estimated that obesity is responsible for more than 30 000 deaths each year (6% of all deaths in the UK; National Audit Office, 2001).

Evidence exists that weight loss in obese and overweight people produces a variety of health benefits (Avenell, 2004). Estimates of the favourable changes in risk factors associated per kilogram of weight loss are shown in Table 1 (Anderson and Konz, 2001). Clinical benefits include improvements in back and joint pain, symptoms of breathlessness and sleep apnoea (Goldstein, 1992) and a delay or prevention of type 2 diabetes in highrisk individuals (Knowler et al, 2002; Tuomilehto et al, 2001). Weight lossassociated reductions in risk factors would be expected to lead to a decreased risk of developing type 2 diabetes and cardiovascular disease. Prospective studies have shown reductions in mortality in overweight individuals with diabetes associated with intentional weight loss (Williamson et al, 2000; reviewed in: Aucott, 2008). Long-term weight loss after bariatric surgery for severe obesity has also been associated with decreased overall mortality (Adams et al, 2007; Sjöström et al, 2007).

Comprehensive guidance on the prevention and management of overweight and obesity in adults and children was published by NICE in 2006 (NICE, 2006). Recognising that our first priority should be to

prevent the gradual weight gain experienced by much of the population, the NICE guidance contains wideranging recommendations for the prevention of obesity, not just for the NHS, but also for schools, local authorities, employers and town planners, to encourage people to improve their diet and become more active. In addition to highlighting the importance and value of prevention, the recommendations provide evidence-based guidance to help primary care physicians identify and treat children, young people and adults who are overweight or obese. Diet changes and exercise, supported by behaviour change, are the first-line treatment for adults who are overweight or obese, followed by pharmacotherapy if lifestyle interventions alone are unsuccessful.

Within the NHS, most contact with overweight and obese people occurs in general practice. Many general practitioners and practice nurses provide valuable services in identifying those at risk from weight gain and offering advice and support, but many remain uncertain about which interventions are the most effective in

preventing and treating obesity, and as a consequence there is significant variability nationwide in how people are managed. NICE has undertaken detailed, evidence-based evaluations of the health benefits, costs and risks of all agents currently available in the UK for the treatment of overweight and obese adults. While the first-line strategy for weight loss and its maintenance is a combination of diet, exercise and behaviour modification, there is increasing awareness of the potential value of anti-obesity drug therapy as a useful adjunct for people who cannot achieve sufficient weight loss through lifestyle and behavioural modification

With appropriate training, obesity and overweight can be managed in primary care by a motivated, well-informed, multi-professional team. The aim of treatment is to achieve and maintain weight loss by promoting sustainable changes in lifestyle. In an effort to assist primary care professionals to provide consistent and high quality care throughout the country, a panel of experts was convened to develop a clinical algorithm for the management of

Table 1. Percentage improvements in risk factors estimated to occur for every kilogram of weight loss (adapted from Anderson and Konz, 2001)

Risk factor	Percentage improvement (%)
Fasting serum cholesterol	-1.0
LDL-cholesterol	-0.7
Triglycerides	-1.9
HDL-cholesterol	+0.2
Systolic blood pressure	-0.5
Diastolic blood pressure	-0.4
Blood glucose	-0.2mM

obesity in primary care. It is intended to complement the NICE recommendations by providing a concise and practical guide to obesity management from a panel with expertise and first-hand experience of managing obesity in primary care. The algorithm developed at the meeting is presented in *Figure 1*.

### Step 1: Determine degree of overweight or obesity

Many people may feel uncomfortable about raising and discussing the issue of body weight and it may fall to the clinician to broach the subject. However, obesity is an important health concern that needs to be raised in a sensitive manner. People should ideally be managed by a multi-professional team. In addition to the clinician, practice nurses and health trainers play a valuable role assisting with goal setting, and providing motivation and important one-to-one support.

Initial discussion with the person should be in relation to health rather than weight, for example, "What do you think you could do to help improve your health?" Addressing issues associated with an unhealthy lifestyle will inevitably also have an impact on a person's weight. Assuming that the individual knows that he or she is overweight, linking weight to an existing medical concern with an approach that is meaningful to the person may be an opportunity to raise the issue of weight management,

for example, "How would you feel about adopting a healthier lifestyle and losing a little weight? Then you may not need a tablet for your blood pressure."

Listening carefully to the response given by individuals when invited to consider a weight management programme will provide insight into their ability and commitment to lose weight. If a person does not express interest at this point the most suitable strategy is to ensure that the door is left open to revisit this discussion at some point in the future. It is important to try to emphasise the benefits of being healthy without adopting too much of a weight-centric approach, although individuals should be encouraged to minimise any further weight gain.

If a person expresses interest in adopting a healthy lifestyle and losing weight, the first step is the measurement of his or her height, weight, and waist circumference to establish BMI and the degree of central adiposity. The algorithm shows the weight classifications by BMI defined by NICE (NICE, 2006). People are classified as overweight if they have a BMI of  $25.0-29.9 \text{ kg/m}^2$  and obese if their BMI is  $\geq 30 \text{ kg/m}^2$ . These cut-off points are based on epidemiological evidence of the link between mortality and BMI in adults.

Waist circumference is also an important indicator of risk from excess fat and should be used in addition to BMI. It is measured at the midpoint between the upper edge of the

hip bone (iliac crest) and the lower edge of the lowest rib. Central obesity is defined as a waist circumference ≥94cm in men and ≥80cm in women (International Diabetes Federation [IDF], 2006). If BMI is  $\geq 35 \text{ kg/m}^2$ , central obesity can be assumed and waist circumference need not be measured. Adults of certain ethnic origins have higher cardiovascular risk factors at lower BMI and waist circumference values than Western populations. The ethnic-specific values for waist circumference shown in the algorithm are recommended by the IDF (2006).

If a person's BMI is  $\ge 25 \text{ kg/m}^2$  or waist circumference is above cut-off, risk assessment and screening should be conducted. A recent prospective analysis conducted in over 350 000 subjects with a mean followup of nearly 10 years reported that both general adiposity and abdominal adiposity are associated with the risk of death (Pischon et al, 2008). For every 5cm increase in waist circumference the study demonstrated a 17% increased relative risk of death for men and 13% for women that was independent of BMI. The results emphasise the need to measure waist circumference in addition to BMI, particularly in those with lower BMI values, when assessing a person's level of risk.

### Step 2: Conduct risk assessment and screening Having established the degree of overweight, the next

part of the assessment is to determine the individual's absolute risk status in terms of comorbid conditions or risk factors for cardiovascular disease. A comprehensive history relevant to the individual's adiposity should be obtained. This will include information on lifestyle factors such as dietary habits, eating patterns and physical activity; psychosocial factors including prejudice and discrimination; presence of depression and other mood disorders; sleep disorders, menstrual irregularities; an assessment of the previous weight loss methods that the person has tried; and motivation and willingness to change. A detailed alcohol history is also necessary as excessive alcohol intake can be a major contributor to weight gain. People aiming to stop smoking at the same time as losing weight will need specific and regular support.

A physical examination should be conducted to assess for the presence of obesityrelated comorbidities and risk factors including:

- Type 2 diabetes.
- Impaired glucose tolerance.
- Hypertension.
- Cardiovascular disease (CVD) or CVD risk factors.
- Osteoarthritis.
- Obstructive sleep apnoea (Epworth Sleepiness Scale; neck circumference).
- Non-alcoholic fatty liver disease (NAFLD).
- Polycystic ovary syndrome. People with these conditions are classified as being at high

risk for disease complications.

Laboratory investigations that should be considered in the assessment of an obese person include:

- Oral glucose tolerance test (measured after an overnight fast).
- Fasting lipid profile.
- Thyroid function tests.
- Renal and liver function tests.

The majority of obese people can be managed successfully by the primary healthcare team with only a very few requiring referral for specialist help. Circumstances in which specialist referral may be required are when previous attempts in primary care have not succeeded, when surgery is being considered, or when NICE criteria for bariatric surgery are met (referral to specialist obesity services), and when obstructive sleep apnoea is suspected.

### Step 3: Define who needs treatment

When assessing a person as a candidate for weight loss therapy, it is important to consider their BMI, waist circumference, and overall risk status. NICE has issued guidance for deciding the initial level of intervention to discuss with the person (NICE, 2006). When obesity-related risk factors are present, people have a high risk for type 2 diabetes, hypertension and CVD relative to individuals with healthy weight and waist circumference and will require a greater level of intervention. For all people, lifestyle changes, centred

around improvements in diet and physical activity, are the mainstay of obesity management and should be continued even when drugs are prescribed.

Obesity is a chronic condition. Management is not simply helping a person to lose some unwanted weight, but a long-term approach to change attitude, habits and values for the rest of that person's life. A 10% weight loss has demonstrated health benefits (Jung, 1997; Goldstein, 1992). At a minimum the general goals of weight loss and management are to prevent further weight gain, to reduce body weight, and to maintain a lower body weight over the long term.

### Step 4: Tailored management Lifestyle advice

The World Health Organization (WHO) report on obesity states that sedentary lifestyle and consumption of highfat, energy-dense diets are fundamental causes of the obesity epidemic (WHO, 1998). Whenever possible, weight loss intervention should therefore employ the combination of lowcalorie or low-fat diets, increased physical activity and behaviour modification so that total energy intake is less than energy expenditure. Lifestyle changes should be tailored to the individual. Encouraging people to make small, manageable changes to their lifestyle is likely to be more successful than attempts to radically alter their diet

and physical activity.

Unless there is documented evidence of previous dietary intervention, people should begin a 3-month weight loss trial with lifestyle interventions. Weight loss targets should be individualised, but may be lower in people with type 2 diabetes.

### Diet

Diets should be tailored to the individual's food preferences. In most people, avoiding unhealthy food options will improve weight loss efforts greatly. Diets that have a 600 kcal/day deficit below a person's daily requirement, as predicted by the modified Harris-Benedict equation, or that reduce calories by lowering the fat content (lowfat diets), or carbohydrate, in combination with support and follow-up, are recommended for sustainable weight loss (NICE, 2006). The panel agreed that with strict expert medical and dietetic supervision a number of other weight loss diets may be considered. Low-calorie diets restrict calories to 1000-1600 kcal/day. Verylow-calorie diets (VLCDs; less than 1000 kcal/day) are an option for some overweight and obese people, but should only be used under supervision if the person is on medication or has a medical condition. The short-term use of a VLCD is very effective in rapidly improving glycaemic control and promoting substantial weight loss in obese people with type 2 diabetes (Capstick et al,

1997). NICE recommends they are used for a maximum of 12 weeks continuously, or intermittently with a low-calorie diet (for example for 2-4 days a week), by people who are obese and have reached a plateau in weight loss (NICE, 2006). Meal replacements provide a suitable option for some people. These are structured diet plans normally involving the consumption of two meal replacement drinks per day, plus a self-prepared evening meal, fruit and vegetables, totalling approximately 1200-1400 kcal/day. Lowcarbohydrate diets have also become increasingly popular for weight loss and appear to be at least as effective as low-fat, energy-restricted diets in inducing weight loss for up to 1 year (Nordmann et al, 2006).

### Physical activity

Although food restriction is key to weight loss, physical activity is thought to be key to the maintenance of weight loss (Hill et al, 2005). The current government recommendation is for a minimum of 30 minutes of moderate intensity physical activity on at least 5 days per week for general health (NICE, 2006). For weight loss or maintenance of reduced weight, physical activity should be increased to 60-90 minutes on at least 5 days per week (NICE, 2006).

This level of activity will not be immediately possible for all people and an acceptable and achievable level of activity should be agreed on that can progressively be increased. Understanding the individual's interests is essential as physical activity that is not enjoyable is less likely to be sustained. People who prefer objective measures of their activity can use pedometers to gradually improve their walking activity. People should not be encouraged to join a gym unless motivated sufficiently to maintain attendance, but provision of information on local physical activity initiatives is recommended. In addition to planned activity, increasing the activities of daily living may also make a valuable contribution, for example, using the stairs instead of the lift. Enquiry should be made into sedentary activities such as television viewing. People may complain that they don't have any time to be active when they are spending a significant amount of time watching TV!

### Behaviour therapy

Behaviour therapy involves changing diet and physical activity patterns and habits to new behaviours that promote a healthy lifestyle, thereby overcoming barriers to dietary therapy or physical activity. Behavioural therapy strategies for weight loss and maintenance include: recording diet and exercise patterns in a diary; identifying high-risk situations (such as having high-calorie foods in the house), and consciously avoiding them; and changing unrealistic goals and false beliefs about weight loss and body image to realistic and positive ones. When used in combination with other weight loss approaches, behaviour therapy provides additional benefits in assisting people to lose weight (Shaw et al, 2005).

### Pharmacotherapy

Pharmacotherapy should be considered as part of a comprehensive strategy of obesity management. There are currently two agents available for the treatment of obesity in the UK: orlistat (Xenical; Roche, Welwyn Garden City) and sibutramine (Reductil; Abbott, Maidenhead).

Adding drug treatment to lifestyle approaches may be considered for people who have not reached their target weight loss, or for those who have reached a plateau with dietary, physical activity and behavioural changes alone (NICE, 2006). NICE has issued guidance on the use of both orlistat and sibutramine (NICE, 2006). The drugs should be used as a means of reducing health risk in those with a BMI of  $\geq 30 \text{ kg/m}^2$ . NICE guidance is also given on the use of drugs at a lower BMI  $(27-30 \text{ kg/m}^2)$  when obesity-related co-morbidities are present.

The choice of drug should be based on careful consideration of the potential risks and benefits of each agent in individual people to achieve tailored, individualised treatment. A person's dietary habits may also influence treatment. For example, orlistat may be preferred for individuals who eat three large meals each day, particularly if high in fat, while sibutramine may be more suitable for individuals who snack between meals as it suppresses appetite throughout the day. The drugs should be used according to their licensed indications and restrictions. According to license these two anti-obesity medications are not recommended for coprescribing.

The efficacy of pharmacotherapy should be evaluated after the first 3 months. NICE suggests the adult target for weight loss is to lose 5-10% of original weight (NICE, 2006). The panel agreed that a weight loss aim of at least 5% of baseline body weight was appropriate, but that individualised targets may well be less. For example, in people with type 2 diabetes in whom rates of weight loss may be slower, possibly because of the underlying disease state or because medications used to treat diabetes tend to increase weight. In such people the panel noted that therapeutic success may be weight maintenance. If the weight loss achieved is satisfactory, treatment should be continued. Treatment should be reviewed regularly to monitor for effectiveness. adverse effects and adherence, and lifestyle advice should be reinforced at the same time. Treatment should be discontinued in nonresponders.

### Orlistat

Orlistat is a gastrointestinal lipase inhibitor which prevents absorption of around 30% of dietary fat (Xenical Summary of **Product Characteristics** [SmPC], 2008). It is taken orally with meals and should be prescribed only as part of an overall plan for managing obesity in adults who meet one of the following criteria: a BMI of 28.0 kg/m<sup>2</sup> or more with associated risk factors, or a BMI of 30.0 kg/m<sup>2</sup> or more (Xenical SmPC, 2008). The product licence for orlistat does not specify a maximum duration of treatment, but advises that the decision to use orlistat for longer than 1 year (usually for weight maintenance) should be made only after discussing its risks and benefits with the person.

Side effects of orlistat are related to its mechanism of action and include: fatty or oily stools, faecal urgency and oily spotting with 15-30% of people experiencing each of these effects in most studies (Rucker et al, 2007). While these problems are minimised by a low-fat diet, fat malabsorption does increase the risk of vitamin D, E and beta-carotene deficiency. Daily fat soluble vitamin supplementation is therefore recommended and supplements should be taken between meals (2 hours before and after orlistat ingestion).

Data from a recent metaanalysis of 16 randomised, placebo-controlled trials of approved anti-obesity drugs used in adults (age over 18 years) for 1 year or longer reported that orlistat (n=10631) reduced weight by 2.9 kg (95% confidence interval [CI] 2.5kg to 3.2kg; 15 studies) more than placebo and increased the absolute percentage of participants achieving 5% and 10% weight loss thresholds by 21% (54% vs. 33%; 95% CI 18% to 24%; 14 studies) and 12% (26% vs. 14%; 95% CI 9% to 14%; 13 studies), respectively (Rucker et al, 2007). These results are consistent with those of previous reviews, such as those included in NICE clinical guidelines, which reported that orlistat reduced weight by 3.3 kg (95% CI 3.0 kg to 3.6 kg; 15 studies) more than placebo and increased the absolute percentage of participants achieving 5% weight loss thresholds by 33% (95% CI 28% to 37%; 14 studies; NICE, 2006).

Four randomised controlled trials looked at weight maintenance in the second year and found that the initial difference in weight loss between orlistat and placebo was maintained, although both groups regained the same amount of weight (Rucker et al, 2007).

Analysis of secondary endpoint data found that taking orlistat was associated with statistically significant reductions in total cholesterol, LDL-cholesterol, blood pressure, fasting plasma glucose, HbA<sub>1c</sub>, BMI and waist circumference, although concentrations of HDL-cholesterol were slightly lowered (Rucker et al, 2007).

### Sibutramine

Sibutramine is a centrally acting reuptake inhibitor of noradrenaline, serotonin and to a lesser extent dopamine (Nisoli and Carruba, 2000). It increases satiety and the feeling of fullness and at higher doses a mild increase in energy expenditure may also contribute (Hansen et al, 1999). It should be prescribed only as part of an overall plan for managing obesity in adults who meet one of the following criteria: a BMI of 27.0 kg/m<sup>2</sup> or more with other obesity-related risk factors such as type 2 diabetes or dyslipidaemia, or a BMI of 30.0 kg/m<sup>2</sup> or more (Reductil SmPC, 2007). Treatment is not currently recommended beyond the licensed duration of 12 months.

The most common adverse effects occurring with sibutramine are insomnia, nausea, dry mouth and constipation, reported in 7-20% of people taking sibutramine in randomised controlled trials (Rucker et al, 2007). In addition, compared with placebo, sibutramine is associated with increases in heart rate and blood pressure. A recent meta-analysis reported a mean increase in systolic blood pressure of 1.7 mmHg, in diastolic blood pressure of 2.4 mmHg and in pulse rate of 4.5 beats per minute at 1 year (Rucker et al, 2007). The product licence for sibutramine recommends that blood pressure and pulse rate are monitored in all people on sibutramine (twice monthly for the first 3 months) as it may cause clinically relevant

# Managing obesity in primary care – a consensus algorithm

# 1. Determine degree of overweight or obesity

Calculate BMI and measure waist circumference. Cut-off points differ for some ethnic groups. BMI classifications below suggested by NICE (2006).

	$BMI (kg/m^2)$
Healthy weight	18.5–24.9
Overweight	25.0–29.9
Obesity I	30.0–34.9
Obesity II	35.0–39.9
Obesity III	> 40.0

If BMI >25 kg/m<sup>2</sup> or waist circumference above cut-off

# 2. Conduct risk assessment and screening

# Patient history to include information about:

- Sleep disorders (obstructive sleep apnoea).
- Psychosocial factors.
- Depression and mood disorders.
- Menstrual irregularities.

### Conduct physical examination to assess Laboratory investigations to include:

# Oral glucose tolerance test.

- Fasting lipid profile.
  - Thyroid function.
- Liver function.

Osteoarthritis.

Comorbidities include:

- Sleep apnoea.
- Non-alcoholic fatty liver disease (NAFLD).
  - Polycystic ovary syndrome.

# Specialist referral criteria:

CHD and/or CHD risk factors.

• Glucose intolerance. • Type 2 diabetes.

• Hypertension.

- If complex comorbidities present.
- If suspected obstructive sleep apnoea on Epworth scale.
- If NICE criteria for bariatric surgery are met and person is suitable and motivated.

# 3. Define who needs treatment

	Waist ci	Waist circumference (cm)	(cm)	Comorbidities present
	Low	High	Very high	•
	Men: <94	94–102	>102	
	Women: <80	88-08	>88	
Overweight	General advice	Dietan	Diet and physical	Diet and physical
Obesity I		activity		activity; consider drugs
Obesity II	Diet and physical activity; consider drugs	activity; consic	der drugs	
Obesity III	Diet	and physical	activity; consider d	Diet and physical activity; consider drugs; consider surgery

# Management notes

Ethnic specific values for waist circumference denoting central obesity (International Diabetes Federation, 2006)

editerranean Male ≥94 cm	Female >80 cm	outh and Male ≥90 cm
Europid, Sub-Saharan African, Eastern M	ınd Middle East (Arab) populations	South Asians, Chinese, Japanese, Ethnic South and

If BMI is ≥35 kg/m², central obesity can be assumed and waist circumference need not be measured.

Female ≥80 cm

Central Americans

- Lifestyle factors (diet and exercise).

- Motivation and willingness to change.

Initial level of intervention to discuss, as recommended by NICE (2006).

	Waist ci	Waist circumference (cm)	(cm)	Comorbidities present
	Low	High	Very high	
	Men: <94	94–102	>102	
	Women: <80	88-08	>88	
Overweight	General advice	Dietan	Diet and physical	Diet and physical
Obesity I		activity	r Fris oreas	activity; consider drugs
Obesity II	Diet and physical activity; consider drugs	activity; consic	ler drugs	
Obesity III	Diet	and physical a	ctivity; consider d	Diet and physical activity; consider drugs; consider surgery

# 4. Tailored management

With appropriate team supervision the following weight loss diets may be

Meal replacement.Low carbohydrate.

considered:Low calorie.Very low calorie.

### a) Lifestyle advice

Initiate 3-month trial with individualised weight targets, unless documented evidence of previous dietary

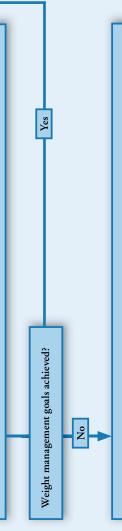
- Dietary change (for weight loss and health)
- Increase physical activity (30 minutes moderate activity 5 days per week for general health, 60–90 minutes for weight loss or maintenance of reduced weight; NICE, 2006)
- Behavioural change programmes (to help people who are motivated to change become more active, e.g. by walking or cycling instead of driving; NICE, 2006).

### 5. Consider programmes to encourage weight maintenance and prevent weight regain Regular monitoring of weight, BMI, waist circumference. • Reinforce healthy eating and physical activity advice Monitor and address other risk factors. Yes Weight management goals achieved? °N

# b) Pharmacotherapy (tailored - see text)

Aim is 5% weight loss, but individualised targets may be less

- Prescribed as adjunct to diet and lifestyle modifications in adults who meet one of the following criteria (NICE, 2006):
- BMI >30 kg/m<sup>2</sup> or
- BMI ≥27 kg/m² + risk factors (sibutramine)
  - BMI ≥28 kg/m<sup>2</sup> + risk factors (orlistat).
- Treatment should be reviewed regularly to monitor for effectiveness, adverse effects and adherence, and lifestyle advice should be reinforced at the same time (NICE, 2006).



### c) Bariatric surgery

- Bariatric surgery can be very successful and is indicated for people with a BMI ≥40, or ≥35 kg/m² with comorbidities (NICE, 2006).
- Oonsider if other weight loss attempts have failed; requires careful multi-professional team assessment and lifelong medical monitoring for cardiometabolic risk and side-effects relating to the procedures.

## Pharmacotherapy:

Two agents are licensed for the management of people with obesity. Drugs should be used according to their licensed indications and restrictions.

### Orlistat (Xenical)

- Therapy to be continued beyond 3 months only if the person has lost ≥5% of their initial body weight since starting drug treatment (NICE, 2006).
- Decision to use drug treatment for >12 months should be made after discussing potential benefits and limitations with the person (NICE, 2006).
- Possibility of experiencing gastrointestinal adverse reactions may increase when ordistat is taken with a diet high in fat.

# Sibutramine (Reductil)

- Therapy to be continued beyond 3 months only if the person has lost ≥5% of their initial body weight since starting drug treatment (NICE, 2006).
- Sibutramine should only be given for periods of up to 1 year.
- Blood pressure and pulse rate should be monitored (twice monthly for first 3 months) as sibutramine may cause clinically relevant increases in blood pressure in some people.

increases in blood pressure in some (Reductil SmPC, 2007).

In a meta-analysis of 10 randomised controlled trials (n=2623) of sibutramine, eight looked at the effects of sibutramine on weight loss at 1 year and found that recipients lost 4.2 kg (95% CI 3.6 to 4.7 kg) more than those taking placebo (Rucker et al, 2007). This is similar to the weight loss seen in previous metaanalyses of sibutramine and to that reported in the NICE guidance (NICE, 2006; Avenell et al, 2004; Arterburn et al, 2004). In addition, sibutramine increased the absolute percentage of participants achieving 5% and 10% weight loss thresholds by 32% (55% vs. 27%; 95% CI 27% to 37%; seven studies) and 18% (28% vs. 10%; 95% CI 11% to 25%; seven studies), respectively (Rucker et al, 2007).

Three randomised controlled trials that assessed the effects of sibutramine in maintaining weight loss for up to 18 months found that between 10 and 30% more people on sibutramine than placebo maintained at least 80% of their initial weight loss (*P*<0.05 compared with placebo in all three studies; Apfelbaum et al, 1999; James et al, 2000; Mathus-Vliegen et al, 2005).

Sibutramine was associated with statistically significant reductions in BMI, waist circumference and triglyceride concentrations, and increased concentrations of HDL-cholesterol (Rucker et al, 2007). The potential benefits

of weight management with sibutramine on cardiovascular outcomes in overweight and obese people who are at high risk of cardiovascular events are currently being evaluated in the landmark (SCOUT) Sibutramine Cardiovascular Outcomes study (James, 2005).

### Bariatric surgery

Bariatric surgery is the collective name for operations intended to induce weight loss. Although surgical treatment of obesity can achieve significant sustained weight loss, it is just beginning to be accepted as a viable treatment option. The two most popular bariatric procedures are laparoscopic adjustable gastric banding and gastric bypass (Roux-en-Y). The panel was in agreement with the accepted clinical indications for surgery defined by NICE, which recommend bariatric surgery as a treatment option for adults with obesity if all of the following criteria are fulfilled (NICE, 2006):

- They have a BMI of (≥40 kg/m², or a BMI of 35–40 kg/m² and other significant disease [e.g: type 2 diabetes or high blood pressure] that could be improved if they lost weight.
- All appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months.
- The person has been receiving or will receive intensive management in a specialist obesity service.
- The person is generally fit for anaesthesia and surgery.

 The person commits to the need for long-term followup.

NICE also recommends bariatric surgery as a firstline option (instead of lifestyle interventions or drug treatment) for adults with a BMI of  $\geq 50 \text{ kg/m}^2$  in whom surgical intervention is considered appropriate. This recommendation, however, does not equate to inadequate assessment and preparation of a person by a multiprofessional team. In addition, individuals should be able to demonstrate that they can adhere to the lifestyle changes that accompany bariatric surgery (Taheri et al, 2009).

In the panel's opinion, results with laparoscopic gastric bypass are superior to laparoscopic gastric band surgery, a position supported by the literature (Tice et al, 2008). The choice of bariatric procedure will depend on the individual's preference and several factors including degree of adiposity, presence of co-morbidities and dietary habits. Weight loss achieved with bariatric surgery is also accompanied by significant improvements in obesity-related comorbidites including the resolution of type 2 diabetes in a substantial number of people and improves quality of life (Tice et al, 2008). The improvement in diabetes is often achieved within 3-14 days, and is therefore not merely a result of weight loss, but rather an unidentified metabolic sequel of bypassing part of the small bowel. The panel noted that long-term follow-up in

primary care is important after any bariatric surgical procedure as people who have undergone such a procedure are still at higher risk than those of the same weight who have not undergone surgery and must therefore be carefully managed with respect to cardiometabolic risk.

For those who have undergone gastric bypass, nutritional supplementation including vitamin B12 is essential (Fujioka, 2005). For people who have undergone gastric banding, monitoring is essential to exclude side-effects including malnutrition and to diagnose mechanical side-effects.

### What happens if weight management goals are not achieved?

If weight management goals are not achieved, the clinician should sensitively revisit the reasons why the individual has not succeeded in their weight loss efforts. Identifying individual circumstances and barriers, and readiness to change are essential.

### How many times can people retry pharmacotherapy?

Before deciding to retry a person on pharmacotherapy, it is important to determine whether the person had been ready for pharmacotherapy in their previous trial, and if not whether they are now more motivated. It is also important to determine whether the individual followed all the advice they were previously given. If adjunctive support was not

offered alongside the original pharmacotherapy, a re-trial with the same agent may be suggested with appropriate support. In motivated people who have not achieved weight management goals with one agent, a trial with the alternative agent may be worthwhile.

### Motivation

Motivation is the key to successful weight loss. Receiving advice from a healthcare professional to adopt a healthier lifestyle and lose weight is an important motivating factor in getting someone to begin a weightloss program. An important way to motivate people is to offer them the options and resources they need to take the first step in managing their weight. These may be introduced by saying, "There are a number of ways to work toward a healthier lifestyle and prevent further weight gain." A good way to start is by asking the person to make a plan for how they would accomplish their lifestyle modifications, rather than simply demanding that it occur. Such implementation intentions have been shown to significantly increase people's motivation to achieve a task (Armitage et al, 2006). As such, the importance of care planning – the process by which individuals are offered active involvement in deciding and agreeing how their condition is managed - should not be underestimated.

Support is important for successful weight loss and this

will involve a specific diet, physical activity and behaviour modification plan tailored for each individual based on their knowledge and level of motivation. Ideally individuals will be able to receive this from a dedicated team by attending a healthy lifestyle or weight management clinic where regular visits will review nutrition, physical activity, emotional state and motivation as well as medical treatment if initiated. In addition to providing people with emotional support, the tailored plan provides individuals with information on how to adapt diets to healthier options and institute physical activity into their daily routine. It is important to remind people that even a small weight loss can have a positive impact on their health.

A person will be more likely to succeed with their lifestyle and weight loss goals if they have the help and support of friends and family. If other members of the family could also benefit from eating a more healthy diet and exercising more it may be more appropriate to manage the family as a whole.

### 5. Weight maintenance

Like other agents for chronic conditions, weight loss agents only succeed while the drug is being continued. Weight regain occurs promptly when treatment is stopped unless sustainable lifestyle changes have occurred while the people were on medication. In STORM (the Sibutramine Trial of Obesity Reduction

and Maintenance), subjects who lost 5% of their body weight after 6 months of sibutramine therapy were randomised to either continuous sibutramine therapy or placebo for an additional 18 months (James et al, 2000). On average, placebo-treated subjects steadily regained weight, maintaining only 20% of their 6-month weight loss at the end of the trial. In contrast, subjects treated with sibutramine maintained 80% of their initial weight loss at the end of 2 years.

In the panel's opinion, weight maintenance efforts should begin after 6 months of weight loss. Programmes to encourage weight maintenance and prevent weight regain should include regular monitoring of weight, BMI and waist circumference; reinforcing the importance of changes in lifestyle including eating a healthy diet and performing regular physical activity; and monitoring and addressing other risk factors. For weight maintenance, the combined modalities of therapy (dietary therapy, physical activity, and behaviour therapy) must be continued indefinitely; otherwise, excess weight is likely to be regained. Observation, monitoring, and encouragement of people who have successfully lost weight should be continued on a long-term basis in order to help prevent weight regain.

Data from the US National Weight Control Registry, which is the largest prospective investigation of long-term successful weight loss maintenance, report that most of those who are successful with weight maintenance continue to maintain a low-calorie, low-fat diet combined with high levels of activity: 78% eat breakfast every day, 75% weigh themselves at least once a week, 62% watch less than 10 hours of television per week, and 90% exercise, on average, about 1 hour per day (National Weight Control Registry, 2009).

### Conclusions

Rates of obesity and overweight continue to rise and substantially increase the risk of morbidity and mortality from type 2 diabetes, CHD and stroke. Obese people unable to achieve significant weight loss with lifestyle changes alone may require drug therapy. Treatment methods and goals should be decided for each individual after careful assessment of the degree of overweight and any associated comorbidities. Both orlistat and sibutramine are effective in reducing body weight, but by different mechanisms. Their use must be combined with lifestyle changes for people to achieve the full benefits. Obesity should be treated chronically and prevention of weight regain must be part of all obesity treatment programmes.

### Contributors

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### Appendix. Web links for sources of regional, national and international obesity prevalence data.

### Foresight

Tackling Obesities: Future Choices – Modelling. Future Trends in Obesity & Their Impact on Health http://www.foresight.gov. uk/Obesity/14.pdf

### International Obesity Task Force

Trends in obesity prevalence in UK by local health authority http://www.iotf.org/database/documents/trendsinobesity inUK byStrategicHealth Authoritypdf.pdf

Trends in adult obesity prevalence in Europe http://www.iotf.org/database/ TrendsEuropean adultsthroughtimev3.htm