

Surgery for morbid obesity

Framework for bariatric surgery in Victoria's public hospitals

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Executive summary

The prevention and management of obesity is a high priority for the Victorian Government. While its efforts to tackle rising rates of obesity are appropriately focused on promoting weight management through diet and exercise, there is strong evidence that weight loss (bariatric) surgery has a role in treating some morbidly obese people who have not been able to achieve long-term weight loss through more conservative means.

Growing demand for bariatric surgery in the public hospital system is driven by the increased prevalence of morbid obesity and community awareness of the effectiveness of surgery in producing weight loss.

It is important that the public health system can offer high quality bariatric surgery programs for carefully selected patients. However, bariatric surgery is a significant intervention with potential complications: and the provision of bariatric surgery should be targeted to patients for whom the advantages of surgery clearly outweigh the risks, and should be prioritised according to clinical need.

The Victorian Department of Human Services (the department), in collaboration with the bariatric surgery working group of the department's Advisory Committee on Access to Elective Surgery (ACAES),ⁱ has developed the *Framework for bariatric surgery in Victoria's public hospitals* to guide public health services that provide or plan to provide bariatric surgery programs.

The framework applies to adult patients aged 18 to 65 years. It aims to promote rational, consistent and equitable access to bariatric surgery, and safe, effective care for morbidly obese patients undergoing these procedures. It is expected that health services providing bariatric surgery will use the framework to develop specific policies and protocols for the surgery and related activities. The framework does not replace the need for clinical judgment in decision-making about the care of individual patients.

The framework for bariatric surgery described in this document reflects evidence reported in peer-reviewed literature and current best practice guidelines of a range of professional bodies. This evidence was summarised in a review commissioned by the Victorian Policy Advisory Committee on Clinical Practice and Technology (VPACT) in 2006. In 2007, ACAES noted the findings of the review and endorsed the establishment of a working group to assist the department in developing a bariatric surgery policy framework.

Part A of the document outlines background and contextual information about bariatric surgery, including current evidence relating to its clinical and cost-effectiveness.

Part B provides a framework for bariatric surgery programs that is consistent with the evidence reported in the VPACT review, more recently published information, and the input of the bariatric surgery working group. The framework is based on:

- careful patient selection in accordance with evidence-based criteria
- a patient care pathway that includes:
 - clear referral processes
 - comprehensive pre-surgical and perioperative patient assessment and monitoring
 - post-surgical follow-up and monitoring for early recognition of complications

i. ACAES ended its final term in June 2008. A new Ministerial Advisory Committee on Surgical Services was convened in November 2008. The bariatric surgery working group met between May and September 2008 and handed its recommendations directly to the Department of Human Services.

- input from a multidisciplinary treatment team and good linkages between bariatric surgery programs and community-based healthcare providers
- optimisation of nutrition and physical activity, and support for changed eating behaviour
- adequate health service infrastructure, including staffing and skill mix, facilities and equipment, and mechanisms for quality and outcome monitoring.

Bariatric surgery is a rapidly evolving and expanding field, and has implications for the lifelong management of patients. As described in Part C of this document, the Department of Human Services will work with health services to develop a limited number of bariatric surgery programs consistent with the framework and will commence a formal evaluation of the framework. The Department of Human Services also has roles in monitoring and contributing to the evidence base about bariatric surgery, and in supporting collaboration between health services and partners in the community to ensure effective lifelong care of patients following bariatric surgery.

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Part A: Background and context

Part A: Background and context

Obesity is one of the most important public health challenges of the 21st century: the World Health Organization has described it as an epidemic in developed nations and expressed concern about the cost of obesity to individual health and wellbeing, to health care systems, and economies generally.¹

Table 1 shows widely accepted weight classifications, based on body mass index (BMI).ⁱⁱ In this document, the term ‘morbid obesity’ is defined as a BMI greater than 40 or between 35 and 40 where there are other major medical conditions such as high blood pressure and diabetes. This is consistent with the definition of morbid obesity used in many national and international obesity studies.

Table 1: Weight classifications based on body mass index²

Classes	BMI	Risk of comorbidities
Underweight	Less than 18.5 kg/m ²	Low (although there may be other problems associated with being underweight)
Normal	18.5-24.9	Normal
Overweight	25-29.9	Increased
Obesity (Class 1)	30-34.9	Moderate
Obesity (Class 2)	35-39.9	Severe
Obesity (Class 3)	Above 40	Very severe

Prevalence of obesity

The *Australian Diabetes, Obesity and Lifestyle Study* (AusDiab) is the largest Australian population-based study of diabetes and associated risk factors. In the 1999–2000 baseline survey of 11,247 Australians aged 25 years and over, the prevalence rates for overweight and obesity were 39.0 per cent and 20.8 per cent, respectively, defined by BMI, and 30.5 per cent and 25.5 per cent by waist circumference.³ By either measure, approximately 60 per cent of the population was overweight or obese. The study reported that 1.7 per cent of its sample had a BMI of 40 or over and 4.1 per cent had a BMI of between 35 and 40.

In a 2005 follow-up of people who participated in the baseline AusDiab study, those aged less than 65 years showed an average weight increase of 1.8 kilograms over five years. Twice as many overweight people became obese as reverted to normal.⁴

Separate research (based on self-reported height and weight rather than actual measurement) found that the proportion of obese adults doubled over the fifteen years between 1989–90 and 2004–05.⁵

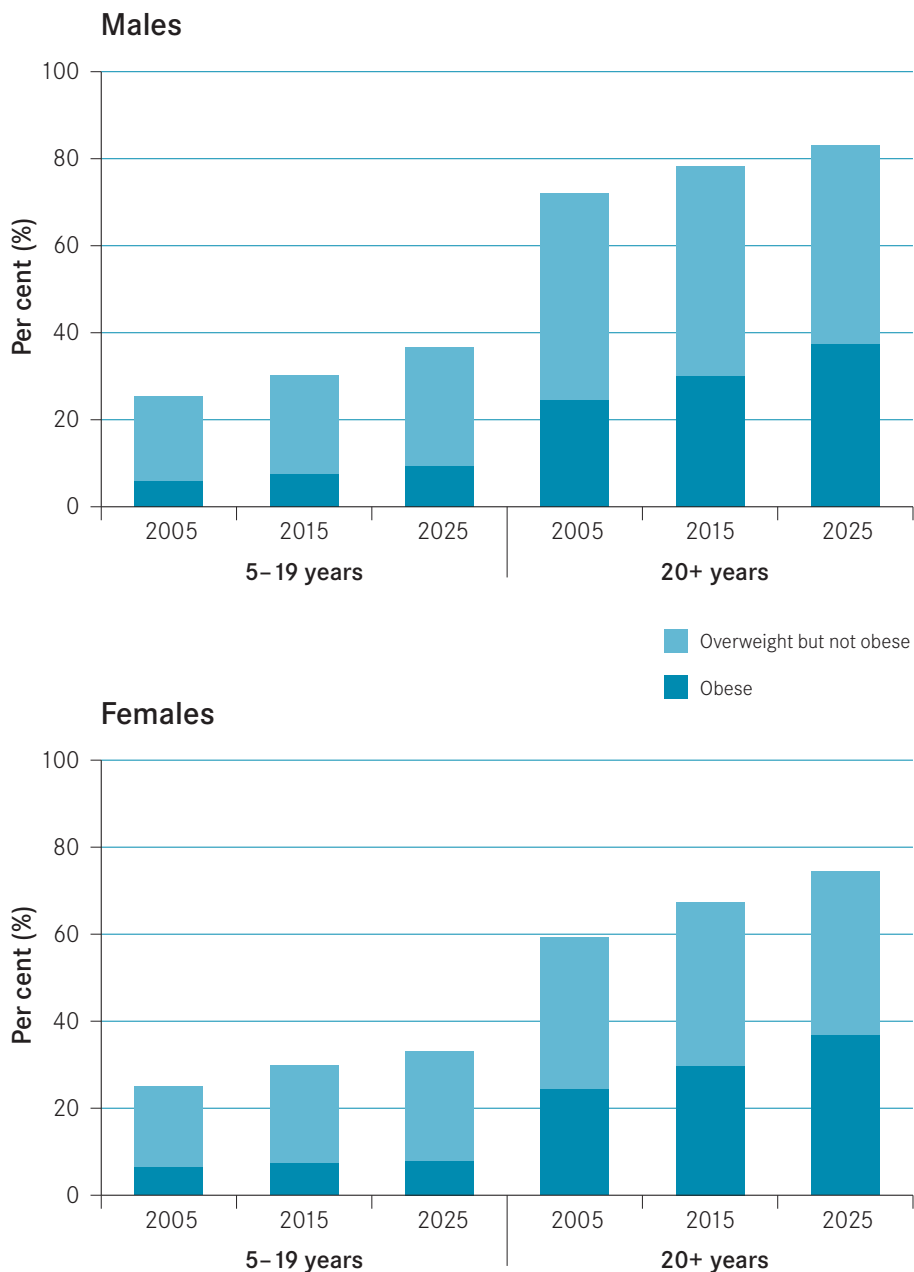
A study by Access Economics on the economic costs of obesity (excluding people defined as ‘overweight’) estimated that the burden of obesity on the health system, as well as lost productivity, welfare payments and carers’ costs, is more than \$58 billion a year—up from an estimated \$21 billion in 2005. This jump reflects new data on the incidence of weight-related diabetes, heart disease and cancer.⁶

ii. Body mass index is calculated by dividing a person’s weight in kilograms by the square of his or her height in metres (kg/m²). There are differing opinions about the reliability of BMI for setting weight standards because it does not take into account the individual’s frame size, whether the weight is fat or muscle, or other factors—such as waist circumference—that are important in establishing health risks. Despite these limitations, there is evidence that BMI accurately identifies adults at increased risk for mortality and morbidity due to being overweight or obese. For individuals with a BMI over 35, additional measures do little to improve the risk rating offered by BMI.

Research by the Department of Human Services predicts that prevalence of obesity and overweight in Victoria will continue to increase at an alarming rate (see Figure 1).⁷ If current trends continue and no effective interventions are put in place, 83 per cent of males and 75 per cent of females aged 20 and over are expected to be overweight or obese by 2025, up from 72 per cent of males and 59 per cent of females in 2005.

The department’s study also suggests that one third of 5–19 year olds will be overweight or obese by 2025, compared with 25 per cent in both males and females in 2005. Many experts believe that the present generation of young people will be the first to suffer a decline in life expectancy because of obesity.

Figure 1: Predicted future prevalence of overweight and obesity



Obesity comorbidities

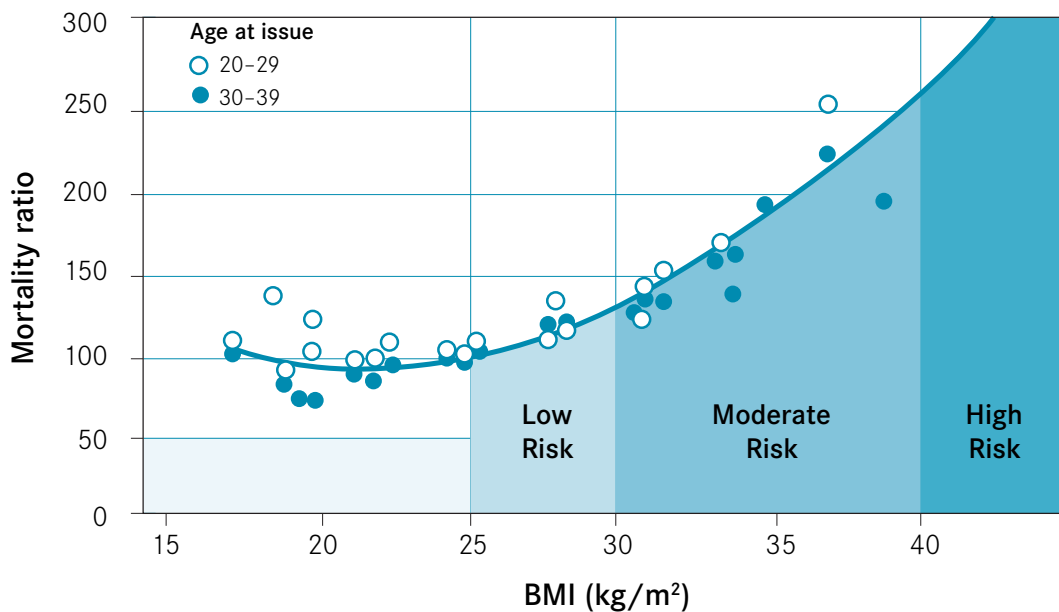
Obesity is a major cause of preventable health problems and mortality. It is strongly linked to type 2 diabetes and is a risk factor for many other chronic conditions such as hypertension, cardiovascular disease, some cancers and arthritis. Table 2 shows the health conditions associated with being obese, including problems that result from the metabolic consequences of obesity and those directly related to excess weight. The level of risk increases sharply with a BMI above 35.

Morbid obesity is a medical disorder associated with greatly increased risk of disease and death. Figure 2 shows mortality risk in relation to BMI.

Depression, low self-esteem, social prejudice, and reduced work opportunities can add to the burden of people who are obese.

Table 2: Diseases and conditions associated with obesity⁸

Relative risk	Associated with metabolic consequences	Associated with excess weight
Greatly increased	Type 2 diabetes Gall bladder disease Hypertension Dyslipidaemia Insulin resistance Non-alcoholic fatty liver disease (steatohepatitis)	Sleep apnoea Breathlessness Asthma Social isolation and depression Daytime sleepiness and fatigue
Moderately increased	Coronary heart disease Stroke Gout/hyperuricaemia	Osteoarthritis Respiratory disease Hernia Psychological problems
Slightly increased	Cancer (breast, endometrial, colon and others) Reproductive abnormalities Impaired fertility Polycystic ovaries Skin problems Cataracts	Varicose veins Musculoskeletal problems Back problems Stress incontinence Oedema/cellulitis

Figure 2: Body mass index and mortality risk⁹

Causes of obesity

Sedentary lifestyles and ready availability of energy dense food have contributed to the obesity epidemic, but obesity for any individual results from a complex interplay of genes, environment, behaviour and psychosocial factors.

A great deal of current research is focused on the causes of obesity—looking beyond the obvious to try to find out why some people seem predisposed to large weight gains. Not everyone becomes obese when placed in an obesogenic environment, and there is evidence that genetic predisposition is important in the development of obesity. Studies on identical and non-identical twin pairs either reared together or reared apart suggest that approximately 70 per cent of the influence on body weight is genetic while approximately 30 per cent is environmental.¹⁰ Adoption studies have shown that adoptees resemble their biological parents in body size and have very little resemblance to their adopted parents.¹¹ Some of the genes that could predispose people to obesity have been identified¹² but there are likely to be many more as yet undiscovered. Of considerable interest is that all the genes discovered so far that can cause obesity do so by increasing hunger.

There is now evidence that weight is both regulated and defended. There is a vigorous reaction to weight loss (called the starvation response), which explains why many obese people fail to maintain weight lost by dieting (see page 10). The mechanisms of the starvation response are now starting to be unravelled. It has been known for many years that, after weight loss, thyroxine is converted more to the inactive reverse tri-iodothyronine than the metabolically active tri-iodothyronine,ⁱⁱⁱ leading to a drop in energy expenditure. In addition, it has been shown that after weight loss the hormone that stimulates hunger, ghrelin, increases in the blood¹³ while hormones that inhibit food intake, including leptin¹⁴ and cholecystokinin,¹⁵ decline. Hence, after dieting and weight loss, people are hungrier and have a lower metabolic rate than when they were at their stable high weight.

iii. This is a hormone from the thyroid gland that among other actions stimulates metabolism.

Obesity prevention and management

The government's efforts to tackle rising rates of obesity in the community will continue to focus on promoting healthy lifestyles and weight management through diet and exercise. However, weight loss surgery has a role in treating some severely obese people who have not been able to achieve long-term weight loss through more conservative means and whose health is severely compromised.

The prevention of weight gain, beginning in childhood, offers the most effective means of achieving healthy weight in the population and reducing the burden of disease associated with obesity. Governments at all levels—local, state and federal—are increasingly investing in initiatives to help people adopt healthy lifestyles and maintain healthy body weights. These approaches aim to educate the community about diet, nutrition and exercise, to improve understanding of food labelling and advertising information, and to create environments that support physical activity. Recognising that effective preventive approaches must address the underlying environmental and lifestyle causes of weight gain, action is occurring across a wide range of government areas, such as health, education, family and community services, transport, sport and recreation, infrastructure and planning. Private and non-government agencies are often involved as key partners in these initiatives. The Victorian Government's 'Go for your life' initiative¹⁶ is an example of a whole-of-government and community strategy that brings together a range of programs to encourage people to adopt healthier and more active lifestyles.

For people who are already overweight, weight loss strategies need to address modifiable causes of weight gain such as inappropriate diet and sedentary lifestyle. Many overweight or obese people self-manage their weight loss regimes or seek support—such as dietary advice, exercise programs, counselling, and behavioural modification therapies—from private organisations, general practitioners or other primary care providers. Pharmacological therapies (which include appetite suppressants and drugs to reduce the absorption of fats) and behavioural or cognitive therapies may be needed to maximise the individual's capacity to benefit from healthier lifestyle choices. In some cases, referral to specialist weight management clinics will need to be considered. Appendix 1 provides a list of current clinical guidelines for managing overweight and obese patients.

The Commonwealth Government has signalled its commitment to making obesity a national health priority and working with states and territories to tackle Australia's obesity epidemic.¹⁷ In addition to opportunities for promotion of healthy lifestyles and obesity prevention, there is significant scope for better management of established obesity in community-based settings. For example, while the Commonwealth Government's Enhanced Primary Care Program allows general practitioners (GPs) to access Medicare rebates to manage the health care of patients with chronic medical conditions, morbid obesity is not listed as a chronic disease within the program, meaning patients are unable to access Medicare support for multidisciplinary care.

Better coordination between privately provided GP and allied health services and community health programs provided by state and local governments is important in ensuring more effective community-based management of obesity and its comorbidities. Primary Care Partnerships are working to improve the coordination of services across agencies, and have a focus on integrated chronic disease management. Relevant programs provided by the Victorian Government include allied health programs provided by community health services, the Early Intervention in Chronic Disease Program,¹⁸ the Diabetes Self Management Program,¹⁹ and WorkHealth initiative,²⁰ which targets Victorian workplaces.

Government efforts to tackle rising rates of obesity in the community will continue to focus on promoting healthy lifestyles and weight management through diet and exercise. However, as discussed on page 10, there is considerable research evidence that some people who are severely obese have poor long-term outcomes from diet, exercise and drug therapies, even with intensive support. There is now strong evidence that bariatric surgery, which reduces the intake of calories by modifying the anatomy of the gastrointestinal tract, offers the best chance of significant and sustained weight loss—and resolution or improvement of associated health problems—for severely obese people who have not been able to lose weight through more conservative means. Therefore, although surgery has a relatively minor role in the overall fight against obesity, it does need to be considered for a small segment of the population whose health is seriously compromised by morbid obesity.

Bariatric surgery

There has been a continued evolution and modification in bariatric surgical techniques in the past few decades. Appendix 2 describes commonly used bariatric procedures. In summary the main bariatric techniques are:

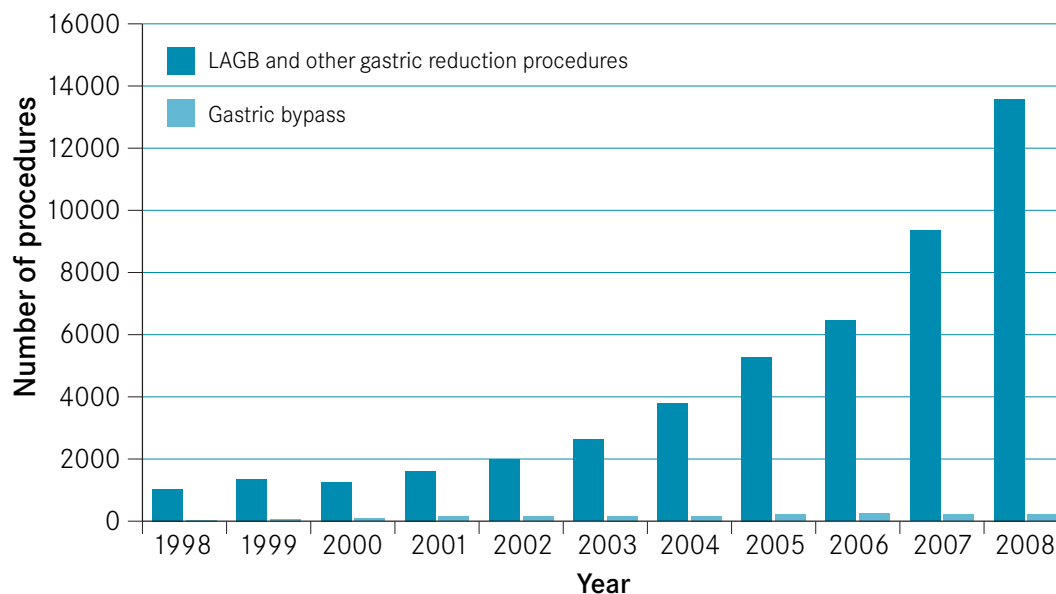
- restrictive procedures, which reduce the amount of food the stomach can hold but do not interfere with normal digestion. Restrictive procedures limit intake by creating a small gastric reservoir with a narrow outlet to delay emptying. These procedures include vertical banded gastroplasty (VBG) and laparoscopic gastric banding (LAGB)
- malabsorptive procedures, which shorten the digestive tract to limit the calories and nutrients that can be absorbed. These procedures include various forms of gastric bypass and gastric reduction, including jejunioileal bypass, biliopancreatic diversion (BPD) and biliopancreatic diversion with duodenal switch (BPD/DS)
- combined restrictive and malabsorptive procedures, which include roux-Y gastric bypass (RYGB) and, more recently, sleeve gastrectomy.

Other surgical procedures and techniques for the treatment of morbid obesity, such as intra-gastric balloon insertion and implantable gastric stimulators, are being investigated locally and internationally.

Most bariatric surgery can be performed laparoscopically. While this requires specialised surgical skills and equipment, it creates less tissue damage, leads to earlier discharges from the hospital and has fewer complications, especially post-operative hernias. However, not all patients are suitable for laparoscopy. Patients who are extremely obese, who have had previous abdominal surgery, or have complicating medical problems may require the open approach.

Figure 3 shows the rapid growth in the annual number of bariatric procedures performed in Australia between 1998 and 2008. This information is based on health insurance data collected by Medicare Australia and therefore does not include bariatric surgery performed on public patients in public hospitals.

Figure 3: Annual number of bariatric procedures performed in Australia, 1998–2008²¹



Note: Based on Medicare Benefits Schedule (MBS) item numbers 30511 (laparoscopic adjustable gastric banding and other gastric reduction procedures) and 30512 (gastric bypass procedures).

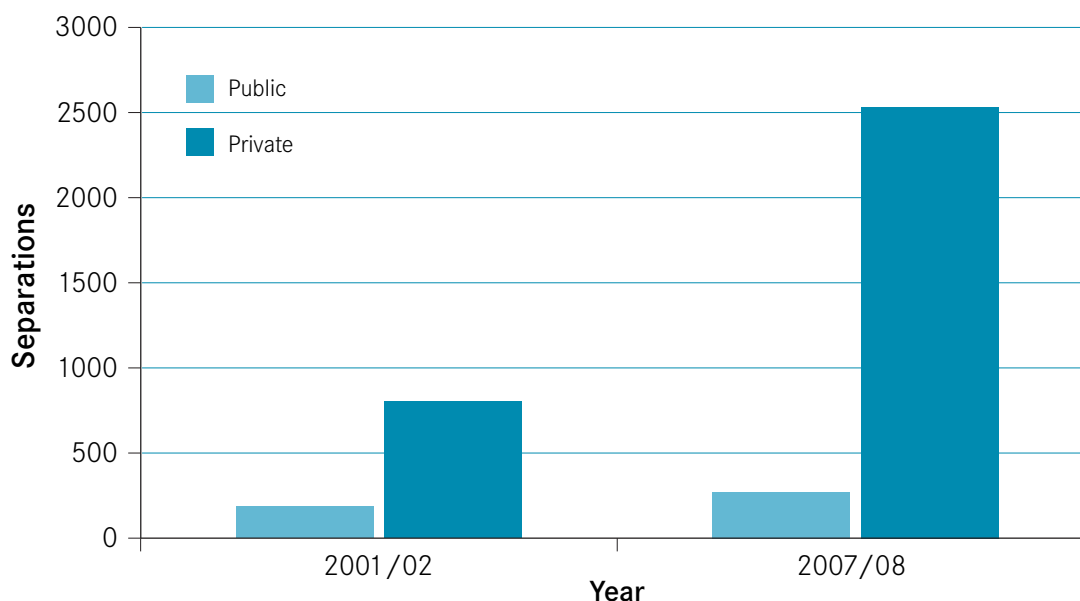
Survey data from 2002 and 2003 indicate that gastric bypass is the most frequently performed weightloss surgery worldwide, comprising 65 per cent of bariatric procedures performed at that time.²² However, laparoscopic gastric banding is the preferred procedure in Australia, accounting for the vast majority of bariatric surgery procedures performed.²³

While other procedures may lead to greater weight loss, as discussed on page 11, the following features of laparoscopic gastric banding have led to its greater acceptance in Australia:

- overall effectiveness in producing weight loss (see page 10)
- safety (the lower level of serious post-operative complications and mortality compared with other procedures – see page 13)
- adjustability
- complete reversibility.

Bariatric surgery in Victoria

In line with the Australia-wide trends, there has been a sharp increase in the number of bariatric procedures performed in Victoria in recent years. Figure 4, which is based on the Victorian Admitted Episodes Dataset (VAED), shows that the number of procedures has more than doubled for both public and private patients. Figure 4 also shows that most bariatric surgery is performed on private patients. As in other states and territories, there is comparatively limited access to bariatric surgery in Victorian public hospitals.

Figure 4: Bariatric surgery separations in Victoria in 2001–02 and 2007–08

In 2007–08, patients aged between 20 and 64 years accounted for over 95 per cent of bariatric surgery separations at public and private hospitals in Victoria. In the same period, 2.8 per cent of public separations and 1.1 per cent of private separations were for patients under 20 years, while 1.6 per cent of public and 2.3 per cent of private separations were for patients aged 65 years and over. Overall, most bariatric surgery patients were female, with females accounting for 79.4 per cent of public hospital separations and 78.0 per cent of private hospital separations.

The data also shows that the length of stay in hospital for patients undergoing bariatric surgery has declined markedly for both public and private patients. In 2007–08, the median length of stay for public and private bariatric surgery patients was one night, compared to three nights in 2001–02. The majority of separations for bariatric surgery were overnight admissions in 2007–08 (see figure 5). Only a small proportion of bariatric surgery separations were recorded as same-day admissions.

Table 3 shows the type of bariatric surgery performed in the public and private sectors in 2007–08. The list includes the major bariatric surgical procedures for the treatment of morbid obesity and two related procedures: revision of gastric band and surgical reversal of procedure for morbid obesity. As noted previously, laparoscopic gastric reduction was the most frequently performed procedure. There were not inconsiderable numbers of surgical reversals of morbid obesity procedures and revisions of gastric bands. There is no available data on the reasons for these reversals or revisions. The need for careful patient selection and preparation, and monitoring and evaluation of bariatric surgery outcomes, is discussed in parts B and C of this document.

Figure 5: Length of stay for public and private bariatric surgery patients, 2007–08

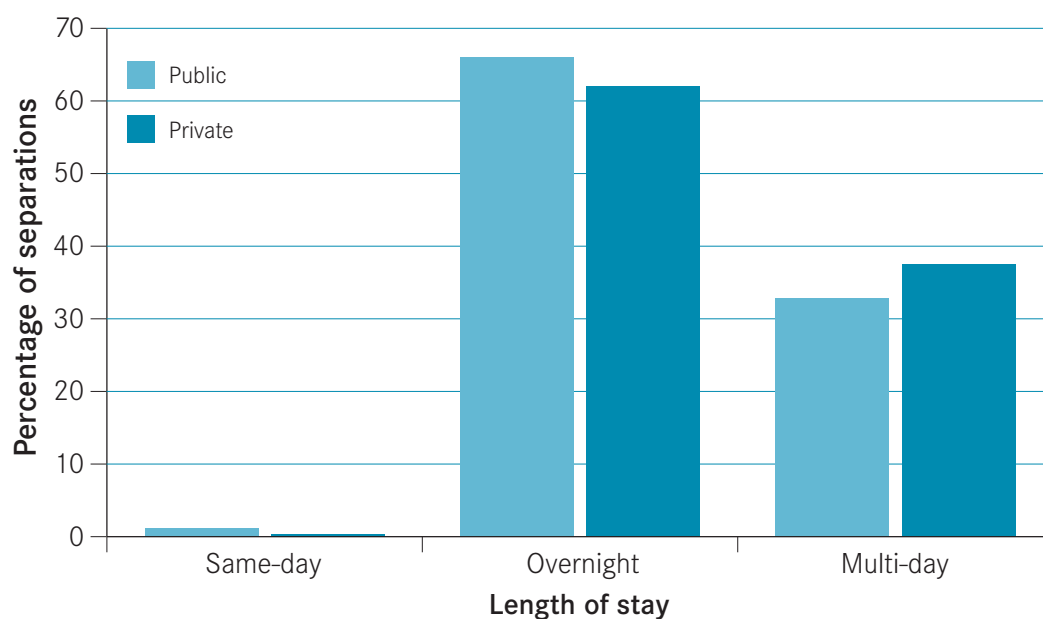


Table 3: Type of bariatric surgical procedures Victoria in 2007-08

		Public hospital patients	Private hospital patients
Major obesity procedures	Gastric bypass	6	9
	Gastric reduction	38	107
	Laparoscopic gastric reduction	230	2510
Procedures related to bariatric surgery	Revision of gastric band	117	341
	Surgical reversal of procedure for morbid obesity	51	301

Demand for bariatric surgery in public hospitals

As suggested by the above data, there is growing demand for bariatric surgery in the public hospital system: this is driven by the rising incidence of morbid obesity and increased community awareness of the potential effectiveness of surgery as an aid to weight loss. There have been several highly publicised cases of celebrities who have lost large amounts of weight following bariatric surgery. However, much of the information in the public domain is misleading, causing people who are mildly or moderately overweight to seek surgery as an 'easy' solution to their weight loss problems.

While there is strong interest in bariatric surgery, it remains controversial in both the medical and general communities. Reflecting the limited community understanding of morbid obesity and its consequences, some sections of the media have criticised the use of public money (through the Medicare or public hospital systems) to provide surgery for people who are regarded as having created their own problems. There has also been recent media coverage of the risks involved in bariatric surgery, including publicity about cases where the surgery has caused death or disability. The possible complications of bariatric surgery are described on page 13.

It should be noted that not all people who are morbidly obese will be suitable candidates for surgery and not all will want it. According to a recent Victorian survey, 90 per cent of obese people do not wish to undergo surgery as they see this as a last resort.²⁴ In a comprehensive analysis of the need for bariatric surgery in the United Kingdom's health care system, the National Institute for Health and Clinical Excellence (NICE)²⁵ estimated the demand for the surgery to be between two and four per cent of the morbidly obese population. (This informed the development of NICE guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children).²⁶

Effectiveness of bariatric surgery

There is evidence to suggest that no other currently available therapies are as effective as surgical management in achieving weight loss and improving obesity-related diseases in morbidly obese individuals.

Non-surgical intervention should be the first line approach for managing any form of obesity. However, these modalities have been found to be only minimally effective for many patients with established morbid obesity²⁷ and there is strong evidence that most obese individuals do not maintain weight loss in the long term.²⁸ A number of studies have suggested that the reasons for non-maintenance of weight loss are biological rather than social.²⁹

The study commissioned by VPACT provided a comprehensive review of the pre-2007 literature relating to effectiveness of bariatric surgery for the treatment of morbid obesity.³⁰ The following summary of evidence on the effectiveness of bariatric surgery draws on the VPACT review, and informal review of more recent literature conducted by members of the department's bariatric surgery working group.

Effectiveness of bariatric surgery in producing weight loss

There is extensive literature on the effectiveness of bariatric surgery in producing weight loss. This clearly demonstrates that morbidly obese patients receiving surgical interventions show greater and more sustained weight loss than those receiving non-surgical interventions.³¹ There is systematic review evidence of maintenance of post-surgical weight loss in studies that have monitored patients for up to ten years after surgery.³²

Differences between procedures

Malabsorptive procedures tend to lead to more weight loss than restrictive procedures. The VPACT review reported comparative studies of weight reduction outcomes suggesting weight losses ranging from 40 per cent to 64 per cent of excess body weight for LAGB, 33 per cent to 87 per cent for VBG, and 59 per cent to 90 per cent for RYGB.

The Swedish Obese Subjects study, the largest prospective study on the effects of operative treatment for obesity reported that maximum weight losses occurred one to two years post-surgery: patients treated with different bariatric procedures had mean overall weight loss as follows: gastric bypass, 32 per cent; VBG, 25 per cent and LAGB, 20 per cent. (A control group of patients matched for sex, age, BMI, clinical site and comorbidities lost an average of only 0.5 kilograms). After ten years, the surgical patients' weight losses from baseline were stabilised at 25 per cent, 16 per cent and 14 per cent, respectively.³³

A relatively new bariatric procedure, sleeve gastrectomy (SG), is a partial gastrectomy where most of the stomach is resected to reduce its size. While the VPACT review did not specifically consider sleeve gastrectomy, recent clinical studies demonstrate that SG is capable of inducing substantial weight loss compared to LAGB.³⁴ While SG is considered a restrictive procedure, it may have hormonal effects as well. During SG the gastric fundus and the greater curvature (both key sites of ghrelin production) are completely resected, resulting in significantly decreased plasma ghrelin levels: this might reduce the patient's appetite and explain the superior weight loss outcomes of SG compared to LAGB.³⁵

As noted in the VPACT review, the most appropriate form of bariatric surgery depends on the available clinical skill set and supports, the clinical needs of the patient, and consideration of the relative risks and possible complications (as discussed on page 13).

Resolution of comorbidities

The association between bariatric surgery and improvement in obesity-related comorbidities has been well documented.

Surgery has been shown to dramatically ameliorate type 2 diabetes: for example, an Australian study investigated gastric banding in 60 obese patients diagnosed with type 2 diabetes. Half were given conventional diabetes therapy, including a calorie-controlled diet and exercise program, and half were given conventional therapy plus weight-loss surgery. After two years, 13 per cent of the conventional therapy group were in remission from their diabetes, and had shed on average 1.7 per cent of their body weight. In contrast, 73 per cent of the surgery group were in remission, and lost an average 20.7 per cent of their body weight.³⁶

Studies have also demonstrated improvements or reversal of:

- obstructive sleep apnoea³⁷
- polycystic ovarian syndrome³⁸
- hypertension³⁹
- dyslipidaemia⁴⁰
- cardiovascular risk⁴¹
- asthma⁴²
- non-alcoholic steatohepatitis⁴³
- life expectancy.⁴⁴

It appears that weight loss per se is the major factor in the improvement in health, and there is little evidence that any particular type of bariatric surgery is inherently better at resolving comorbidities than any other. The only exception may be the rise in glucagon-like peptide-1 (GLP-1)^{iv} following bypass procedures: this increase in GLP-1 may boost insulin-producing beta cells and thus have a better chance of reversing more advanced forms of type 2 diabetes.⁴⁵

Effect on quality of life and psychosocial wellbeing

In a review of the outcomes of bariatric surgery, the National Health and Medical Research Council reported evidence that quality of life is improved in the majority of patients following bariatric procedures: this improvement in psychosocial functioning is well maintained at two years post-surgery and self-image, state of happiness, social interaction, and employment opportunities are increased three years after surgery compared with before the operation.⁴⁶ Other recent studies have reported positive effects of surgery on quality of life⁴⁷ and psychological health.⁴⁸ While most of these studies are from overseas, Australian research has also reported improved quality of life after bariatric surgery.⁴⁹

Studies such as these highlight the adverse effect obesity has on quality of life: even when bariatric surgery causes significant discomfort or lifestyle restrictions (including limitations on food intake and the need for major changes in eating habits), the improvement in quality of life is enough to overshadow any ill effects of the operation.

In contrast to these positive assessments, some studies have suggested that some patients experience a negative psychological response post-operatively, and that improvements in psychosocial status wane with time. Sarwer and colleagues⁵⁰ have comprehensively reviewed the research on quality of life and psychosocial wellbeing following bariatric surgery, including studies indicating possible negative impacts for some patients. A recent article by this research group concludes that while the vast majority of patients have improvements in psychological functioning, a minority struggle with post-operative psychological issues such as depression, disordered eating, body image dissatisfaction and suboptimal weight loss.⁵¹

Cost-effectiveness

The VPACT review found that there was a relative paucity of data, especially from the Australian context, to determine the cost-effectiveness of bariatric surgery. Most published economic evaluations of cost-effectiveness have significant limitations in study design and selection of data points. Few studies have evaluated cost-effectiveness over the longer term and few have taken into account the full range of potential costs (including surgery-related adverse events and the need for abdominoplasty or other additional surgery) and savings (such as obesity-related non-medical costs).

Nevertheless, the available evidence suggests that bariatric surgery is a cost-effective treatment for people who have morbid obesity compared with no treatment or conservative management.⁵² There is strong evidence that gastric bypass surgery is more cost-effective than restrictive procedures. However a recently published Canadian review, which specifically examined the clinical and economic effectiveness of LAGB, concluded 'the economic research, while limited, suggests that LAGB may lower total future health care costs by lowering the severity and incidence of obesity-related comorbidities and associated costs'.⁵³

iv. This is a hormone from the lower small bowel that has many actions including suppression of food intake, slowing of stomach emptying, stimulation of insulin secretion and inhibition of glucagon secretion.

Complications of bariatric surgery

Surgical interventions for morbid obesity carry some risk, but these are significantly less than the health risks associated with morbid obesity.

Surgery to aid weight loss can cause side effects both at the time of the operation and in the long term. Potential complications include nausea, vomiting, diarrhoea, heartburn and nutritional deficiencies. Problems can also occur as a result of having had surgery: these include infections in the wound, slippage or breakage of the band or staples, and ulcers forming around the band or staples. Newly published research has found that bariatric surgery can lead to bone loss, and suggests that patients undergoing this surgery may need to increase their intake of calcium and vitamin D.⁵⁴

There are different risks and potential complications for the various bariatric surgery methods. The VPACT review reported that overall morbidity rates, including short-term (post-operative) adverse events, are lower with LAGB compared with RYGB and VBG. Medium to longer-term adverse events and associated re-operation following LAGB occurred more frequently compared to RYGB, but tended to be of a less serious nature. Unlike gastric bypass procedures, LAGB is not associated with an increased chance of abdominal sepsis, bowel obstruction, or other abdominal catastrophes that can result in death if not rapidly treated.⁵⁵ Most LAGB complications can be managed by a simple procedure under local anaesthesia or by band deflation. There has been a reduction in the reported incidence of surgical complications associated with LAGB over time.

A recent report on sleeve gastrectomy, prepared for the Australian Government's Health Policy Advisory Committee,⁵⁶ noted that despite some studies showing that SG has comparable or even lower complication rates relative to gastric banding, SG is irreversible and substantially more invasive. At least one study has reported more severe complications after this procedure. (Anecdotal information from surgeons in Victoria and Western Australia suggests that SG is associated with significantly more complications in the immediate post-operative period, but may have fewer complications than LAGB in the longer term). Further studies with larger patient cohorts and long-term data are required before the safety and efficacy of SG relative to established bariatric procedures can be determined.

Appendix 2 provides further information on the complications associated with different bariatric surgery methods.

In summarising the literature on the risks of bariatric surgery, the VPACT-commissioned review noted:

- There is wide variation in adverse events rates reported in the literature. Reported adverse event rates range from 1.1–18 per cent for LAGB, 0.1–70 per cent for RYGB and 1.0–30.4 per cent for VBG.
- The mortality rate reported by systematic reviews was 0.05 per cent for LAGB, 0.5 per cent for RYGB and 0.3 per cent for VBG.

Relationship of surgical volume and mortality/morbidity

While there is no comparable Australian research, studies in the United States have demonstrated that the likelihood of post-operative complications is significantly associated with the level of experience of both surgeons and the hospitals that host the operations. The risks are greatest when surgeons perform fewer than 25 operations and hospitals host fewer than 50 operations per year.⁵⁷ In discussing the relationship between surgical volume and mortality/morbidity, a practice guideline from the American College of Physicians⁵⁸ reports findings from several different studies of bariatric surgery, all of which indicated a strong inverse relationship between surgeon experience and the rate of complications.

While these studies generally refer to the more complex gastric bypass operations, recent evidence suggests that there is an important learning curve associated with LAGB. A 2007 Californian technology assessment of this procedure reported that both open and laparoscopic gastric banding had satisfactory results in the United States and Europe, but noted that the procedures are technically demanding and that results among patients treated at high volume centres improve over time: *'after several hundred implantations the procedures usually have far fewer associated complications than those of the first 50–100 cases.'*⁵⁹ (The report does not provide exact figures on the relationship between complication rates and surgical volume).

These findings highlight the importance of clinical governance in health services providing bariatric surgery, including the need for robust systems for surgeon credentialling, defining the scope of clinical practice, audit of surgical outcomes, peer review and clinical supervision. These issues are discussed in part B of this document.

Part B: Framework for bariatric surgery programs

Part B: Framework for bariatric surgery programs

It is important that the public health system can offer a high quality weight loss (bariatric) surgery program for carefully selected patients.

The published evidence suggests that important issues in the delivery of best practice care for bariatric surgery patients include:

- careful patient selection in accordance with evidence-based criteria
- a patient care pathway that includes:
 - clear referral processes
 - comprehensive pre-surgical and perioperative patient assessment and monitoring
 - post-surgical follow-up and monitoring for early recognition of complications
- input from a multidisciplinary treatment team, and good linkages between bariatric surgery programs and community-based healthcare providers
- optimisation of nutrition and physical activity, and support for the required changes in eating behaviours
- adequate health service infrastructure, including staffing and skill mix, facilities and equipment, and mechanisms for quality and outcome monitoring.

The following guidelines for provision of bariatric surgery in Victoria's public hospitals apply to adult patients aged 18 to 65 years. They are drawn from published research and professional statements on bariatric surgery and from the advice of clinical experts on the department's bariatric surgery working group.

It is expected that health services providing bariatric surgery will use these guidelines to develop specific policies and protocols for the surgery and related activities.

The guidelines do not replace the need for clinical judgment in decision-making about the care of individual patients. Health services should have defined processes for consideration of bariatric surgery for patients who do not fit the criteria specified in this framework.

Health services are also responsible for balancing the demand for bariatric surgery with competing priorities for surgical care.

Patient selection

Careful selection of candidates for bariatric surgery is very important. Health services should have in place a screening protocol to ensure that prioritisation for bariatric surgery is based on clinical need and the potential for a successful long-term outcome.

Key criteria that should be considered in the selection of bariatric surgery patients are outlined below. Within these guidelines, the decision to select surgical treatment should be based on careful assessment of the risks and benefits for each individual.

Degree of obesity and comorbid conditions

Suitable candidates for bariatric surgery are those with a BMI of more than 40 and those patients with a BMI of more than 35 with medically important obesity-related comorbid conditions that could be improved by weight loss.⁶⁰

Priority should be given to patients with significant chronic diseases that are currently not well treated but which are known to respond well to weight loss. These conditions include:

- hypertension requiring medication
- diabetes mellitus type 2
- obstructive sleep apnoea
- pulmonary hypertension
- obesity hypoventilation syndrome
- obesity-related cardiomyopathy
- non-alcoholic steatohepatitis
- polycystic ovary syndrome.

Some experts have suggested that diabetic patients with a BMI over 35 are a prime target group for bariatric surgery as studies have shown resolution of type 2 diabetes in a large proportion of patients (see page 11).

History of weight loss attempts

For a person to be eligible for bariatric surgery, all appropriate non-surgical measures should have been tried but failed to achieve or maintain adequate, clinically beneficial weight loss.

There should be written documentation by a health care professional, preferably by a dietitian, of the person's efforts to lose weight: the documentation should include details of the health interventions prescribed, the person's progress towards their weight loss goal, and perceived obstacles to sustained weight loss.

Age

The framework presented in this document applies specifically to patients aged 18–65 years.

There is limited evidence on the effectiveness of bariatric surgery in people aged under 18 years. While there is some evidence of good clinical outcomes and cost-effectiveness,⁶¹ some experts have expressed concerns about the use of bariatric procedures in this age group.⁶² Most guidelines do not recommend the surgery for people aged under 18 years, as it is more appropriate to address lifestyle issues within the family and social settings.

Similarly, there is little data on the effectiveness of bariatric surgery for people aged over 65 but expert opinion suggests poorer outcomes and a higher rate of complications in older people.

However, as noted on the previous page, this framework does not replace the need for clinical judgment in decision-making about the care of individual patients and therefore it does not preclude surgery for patients outside the 18–65 year age group if—on the basis of expert clinical advice—a health service considers it necessary for a particular individual.

Surgical risk

As many morbidly obese patients will have some specific operative risks, the decision to perform bariatric surgery will require detailed consideration of whether the benefits outweigh the potential complications of the surgery.

There may be medical contraindications to bariatric surgery—for example, severe gastrointestinal disease, active cancer, unstable heart or lung disease, advanced liver disease with portal hypertension, uncontrolled obstructive sleep apnoea with portal hypertension, and serious blood or autoimmune disorders. Female patients should not be pregnant at the time of surgery.

Mental health and cognitive status

The psychological evaluation of candidates for bariatric surgery is one of the most important and difficult elements of the screening process. The ideal candidate for bariatric surgery has realistic expectations about the surgery, is well informed about the risks and benefits, and is prepared and able to commit to dietary and lifestyle changes. Clinicians should consider whether the patient has the motivation and capacity to make the changes needed for a successful long-term outcome from the surgery.

The high rate of mental health problems among people who are morbidly obese is well documented, although the cause and effect relationships may be unclear.⁶³ While patients with psychological problems should not be excluded from surgery, clinicians should take into account the fact that people with diagnosed schizophrenia, bipolar disorder and/or personality disorders are reported to have sub-optimal surgical outcomes.⁶⁴

Patients must be able to give fully informed consent to bariatric surgery and commit to post-operative care plans. Therefore, bariatric surgery should not be performed on patients who have:

- active psychosis or unstable psychiatric disorder
- severe untreated depression
- binge eating disorders
- current alcohol dependence or illicit substance use disorder
- significant intellectual impairment
- cognitive or behavioural disorders affecting decision-making, impulse control or ability to adhere to behavioural modification (dietary and other requirements) post-surgery
- unrealistic expectations of the procedure (either in terms of weight loss or in terms of the impact on life in general).

Screening of bariatric surgery candidates for severe depression, untreated or undertreated mental illnesses associated with psychoses, active alcohol substance abuse, and bulimia nervosa is necessary to help avoid adverse post-operative outcomes.

Patient care pathway

Patients undergoing surgically induced weight loss require programs that address pre-surgical evaluation and counselling, perioperative care and long-term management.

Surgery to aid weight loss for people with morbid obesity should be considered only following a comprehensive assessment and only when arrangements are in place for appropriate healthcare professionals to provide pre-operative education and counselling, high quality perioperative care, and post-surgical support and monitoring.

Key elements of the patient care pathway are described in the following pages.

Referrals to bariatric surgery programs

Referrals of individuals requiring assessment of their suitability for bariatric surgery will come from general practitioners or medical specialists.

Health services providing a bariatric surgery program should develop written information about the program for potential referrers, including details of the referral criteria.

Pre-surgical medical assessment

After making an initial assessment of the person's suitability for bariatric surgery, clinicians should use their professional judgment to investigate comorbidities (and other factors that may affect the outcome of the surgery) in an appropriate level of detail, depending on the degree of obesity and the person's age and medical history, and the results of previous assessments.

Secondary causes of obesity should be considered if these have not been examined previously. A medication history should be obtained, particularly in respect of drugs that can be associated with weight gain.

Any comorbidities should be managed when they are identified, rather than waiting until the person has lost weight. If obesity-related disease stabilisation is required before surgery, patients may need to be referred to the appropriate specialists (for example, cardiologist, respiratory physician, and endocrinologist).

Consideration should be given to requiring an achievable pre-operative weight loss (for example, five per cent of total body weight) and cessation of smoking, if relevant, in order to reduce operative risks and to demonstrate the patient's ability to modify unhealthy habits.

Appendix 3 outlines specific medical assessments that may be necessary for bariatric surgery candidates, and interventions to address common medical risks.

Pre-surgical evaluation and counselling

Surgery should be undertaken only after there has been a comprehensive evaluation of any psychosocial or other factors that may affect adherence to post-operative care requirements.

The pre-operative phase should also be used to provide information and support to patients and, if appropriate, members of their families. Pre-operative education is particularly important in improving the patient's understanding of the procedure and ensuring they have realistic expectations about the outcomes. Information should include details about the potential benefits of surgery, dietary and lifestyle implications and the associated risks, including complications and perioperative mortality rates. Some bariatric surgery programs provide an option for the patient to receive peer support from people who have already had the operation.

As discussed on page 22, pre-operative care for patients undergoing bariatric surgery requires patients to receive dietary advice from a dietitian and, where appropriate, support to help them change their eating habits and prevent complications from surgery. This should include advice about pre-operative dietary requirements (for example, instruction on the use of Optifast as described in Appendix 3). Group education alone is not sufficient: patients should receive individualised preparation for surgery.

Any mental health treatment indicated by the screening process (see page 18) should be available.

The patient's informed consent to surgery should reflect that:

- the patient fully understands the potential benefits, risks and long-term consequences associated with the procedure
- the choice of surgical intervention was made jointly by the patient and the healthcare professionals responsible for treatment, following detailed individualised assessment and discussion of risks and benefits
- the patient is motivated to make necessary dietary and lifestyle changes
- the patient commits to long-term follow-up after surgery.

Perioperative care

Health services, in consultation with clinical experts, should establish standardised approaches to risk assessment and patient care planning for morbidly obese patients undergoing bariatric surgery. It is advisable to have pre-operative, intraoperative, and post-operative written protocols. These should specify any special equipment and patient care needs during ward admission, surgery, recovery and ward stay.

The bariatric surgeon must be able to manage, and have coverage to manage, the post-operative patient and any problems and complications that may occur. Expert anaesthetist support, knowledgeable in the specific problems of the bariatric patient, is necessary, and the patient should see the anaesthetist before the operation. Availability of a full spectrum of expert consultants (for example, cardiologists, respiratory physicians and psychiatrists) is also necessary.

Individualised patient management plans should be put in place prior to admission to ensure optimal management of known risks during the patient's stay in hospital. For example, obstructive sleep apnoea is associated with difficult intubation and post-operative respiratory problems: medical and nursing staff should be prepared to deal with these problems.

Detailed clinical guidelines for perioperative management of patients undergoing weight loss surgery are available.⁶⁵ These emphasise the need for the surgeon to have support from anaesthetists, nurses and other clinicians who have expertise in managing the specific problems of patients undergoing bariatric surgery.

Many guidelines draw attention to the need for hospital staff to provide a positive and supportive environment for patients undergoing bariatric procedures. Patients requiring bariatric surgery often carry a psychological burden as a result of their obesity and may have had past negative experiences with health care professionals.

Post-surgical follow-up

Discharge planning should include the development of a post-admission care plan and written patient information, and liaison with general practitioners and other community providers that will be involved in the patient's care. As noted below under 'multidisciplinary input', it is important that bariatric surgery teams work with community-based providers, as these services have a key role in reinforcing and supporting patients' post-surgical dietary requirements (including vitamin, mineral, and possibly liquid protein supplementation) exercise and lifestyle changes.

There is evidence of sub-optimal outcomes for bariatric surgery patients who do not have good post-operative care.⁶⁶ All current clinical guidelines indicate that bariatric patients should be regularly evaluated after surgery and that a long-term commitment from both the patient and the bariatric surgical team is required.

The VPACT-commissioned review of bariatric surgery literature examined post-operative care guidelines from a number of organisations and clinical experts,⁶⁷ including the European Association of Endoscopic Surgery and the American Society for Bariatric Surgery. These agree that care of the bariatric surgery patient is required for the lifetime of the patient, but provide varying recommendations about the frequency of follow-up.

In practice, the frequency of follow-up visits should be adapted to the procedures, the patient weight loss time, the probability of complications, and the condition of the patient.

The department's bariatric surgery working group offered the following suggestions about follow-up of LAGB patients by the bariatric surgery team in the first six months after surgery. These should be taken as a guide rather than a hard and fast rule:

- An appointment with a dietitian 2-3 weeks post-surgery. This is the transition period between a liquid diet and the re-introduction of solid food, and dietician input is critical at this time.
- An appointment with the surgeon four weeks post-surgery to make the first adjustment to the band.
- Appointments every four weeks for the next six months.

Some patients may require emotional support through the post-surgical changes in body image and personal relationships. Given evidence that a small minority of patients struggle with post-surgical psychological issues, as discussed on page 18, patients should be screened for problems such as depression, disordered eating and body image problems: post-operative counselling and mental health support should be available if required.

Post-surgical care may include providing information on, or planning for, reconstructive operations (such as apronectomy) after weight stabilisation for certain patients.

Multidisciplinary input

Although there is limited evidence on the most clinically and cost-effective models of care for patients undergoing bariatric surgery, there is general consensus about the need for multidisciplinary assessment and treatment.⁶⁸ Available evidence and clinical guidelines for bariatric surgery suggest that a best practice care model should be based on a multidisciplinary team comprising the following professionals:

- an experienced and accredited bariatric surgeon
- a nurse or nurse practitioner
- a physician with special interest in obesity
- a dietitian
- a psychologist or licensed mental health care provider
- an anaesthetist.

The treatment team also requires access to the full range of expert consultants (cardiologists, respiratory physicians, plastic surgeons) and diagnostic services (pathology, imaging) necessary for management of comorbidities and complications.

As well as medical and nursing expertise, input from dieticians and mental health clinicians is required to ensure patients receive adequate preparation, education and support, both before and after the surgery. Some experts recommend that patients also be given the option of attending a support group with other people who have had the surgery.⁶⁹

Multidisciplinary input to the care of the patient requiring bariatric surgery may be provided from within the health service or on a purchased basis from external providers. In either case, the bariatric surgery program should be responsible for:

- clearly defining and communicating the roles and responsibilities of the various members of the treatment team
- coordinating care between different members of the bariatric surgery team
- communicating patient information to other service providers involved in the patient's care.

Linkages with primary care

General practitioners and other primary care providers have a key role in the follow-up of bariatric surgery patients: they can support adherence to dietary and exercise programs and monitor the patients for longer-term complications. Coordination of care with the patient's general practitioner is associated with better long-term outcomes from bariatric surgery.

The development of good linkages between bariatric surgery programs and general practitioners, and other community-based providers if applicable, is also important in regard to the effective utilisation of hospital resources. Many of the ongoing support and care needs of bariatric surgery patients can be met in primary and community settings, and these options should be pursued wherever possible and appropriate. Both Victorian and Commonwealth governments are increasingly investing in preventative health, and it is likely that the next few years will see greater availability of community-based programs suitable for providing ongoing support of bariatric surgery patients. Programs currently in place in Victoria are noted on page 5.

Optimisation of nutrition and physical activity

Patients undergoing bariatric surgery should receive pre-operative and post-operative education and counselling aimed at optimising their weight management. This should include behaviour change strategies to increase physical activity levels, improve eating behaviour and the quality of the person's diet, and reduce energy intake.

Patients about to undergo bariatric surgery must be prepared for a complete upheaval in eating habits after surgery. The volume of food entering the stomach is severely restricted as a result of the procedure and therefore the diet must be of high nutritional quality. Patients are advised not to snack between meals but adopt an eating pattern of three meals per day. A lifetime of additional vitamin and mineral supplements is usually required.

In addition to these special dietary requirements, advice and support regarding food and eating are just as important for obese patients being treated with surgery as they are in any other protocol for weight reduction (see Appendix 1). Obesity surgery can offer rapid weight loss but, to be successful, it must be accompanied by healthy eating habits. Some patients receiving bariatric surgery regain lost weight by consuming numerous unhealthy meals throughout the day.

Exercise is also an important element of the patient's self-care, both before and after surgery. Any weight loss program that results in losing large amounts of weight may also cause loss of muscle mass. The most effective way to minimise muscle loss is through exercise. Where necessary, a physiotherapist or exercise physiologist may need to instruct patients on a graded exercise plan.

The components of the planned weight-management program should be tailored to the person's preferences, initial fitness, social circumstances and lifestyle, and the experience and outcome of previous treatments. The level of support should be responsive to changes in patient needs over time.

Discussions with the patient about weight management should be documented, and a copy of the agreed goals and actions retained by the patient and clinicians involved in their care.

Facility infrastructure, staffing and skill mix

Bariatric operations should be performed by surgeons who have substantial experience with the required procedures and who are working in a clinical setting with adequate support for all aspects of patient assessment, treatment and management.

Health services that provide or plan to provide a bariatric surgery program must have the specialised expertise and facilities required for patients undergoing bariatric surgery.

Staff and skills

Health services are responsible for ensuring that staff providing treatment and care to bariatric surgery patients have the necessary qualifications and skills, and for ensuring adequate staffing levels and skill mix.

All healthcare professionals involved in the delivery of interventions relating to bariatric surgery must have relevant competencies and have undergone specific training. Health services must identify the staff training and development needs in relation to the general management and care of obese patients during admission and as outpatients, and ensure that policies, procedures and resources are available to promote the safety of both patients and staff.

Bariatric surgery should be performed by an appropriately credentialled surgeon with access to specialised perioperative support. In credentialling and defining the scope of clinical practice for surgeons performing bariatric procedures, health services are expected to comply with relevant Department of Human Services' policy guidance.⁷⁰

As discussed on pages 13-14, a significant learning curve is associated with bariatric surgery techniques and the likelihood of post-operative complications has a negative correlation with the level of experience of the surgeons in performing the operation. Health services should take this into account in developing supervision, auditing and peer review processes for bariatric surgery. A useful resource in this regard is the International Federation for the Surgery of Obesity and Metabolic Disorders' recent report, *Guidelines for Safety, Quality and Excellence in Bariatric Surgery*.⁷¹

Bariatric surgery programs must have plans in place for the management of surgical complications, including failed bariatric surgeries requiring reversal or conversion to another bariatric surgical procedure.

Facilities and equipment

Health services that provide bariatric surgery must have appropriate facilities and equipment—operating room tables, instruments, furniture, and radiology equipment to provide safe and dignified treatment and care for morbidly obese patients.

The department's bariatric surgery working group has offered the following recommendations about minimum equipment requirements:

- chairs that patients can sit in comfortably in wards and outpatient departments
- ward beds that are weighted appropriately
- scales that weigh above 150 kg
- appropriately weighted outpatient examination couches
- toilets that are not wall suspended
- operating tables with higher weightings and the ability to be extended to accommodate lateral spread
- long surgical instruments
- anaesthetic equipment specialised for bariatric surgery patients
- x-ray equipment that is able to cope with patients who weigh over 150 kilograms
- appropriate equipment for patient transfer.

Most bariatric surgery—in particular gastric banding—is very safe and there is only a minimal requirement for high dependency or intensive care associated with the procedures; however, access to these beds should be considered in planning for bariatric surgery.

Administrative support and data collection

Good administrative support is needed for the effective operation of bariatric surgery programs. Key administrative functions include: facilitating continuity of care within the multidisciplinary team, data collection and record keeping, appointment scheduling; and patient liaison and follow-up.

Quality and outcome monitoring

Health services providing bariatric surgery will need to undertake clinical data collection and monitoring of performance and patient outcomes. The bariatric surgery literature provides several useful resources to inform the development of bariatric surgery quality assurance programs.^{72,73}

As discussed below, bariatric surgery programs may also be required to participate in independent multi-centre registry, research and/or evaluation projects.

Part C: Further research and evaluation

Part C: Further research and evaluation

Although there is some robust research regarding the clinical and cost-effectiveness of bariatric surgery, many reviews—including the VPACT commissioned literature review, another recent Australian review⁷⁴ and the Australia and New Zealand Horizon Scanning Network (ANZHSN) report⁷⁵—have noted significant limitations in the overall evidence base. Key knowledge gaps are described below:

- Most of the published reports and research data are from studies in the United States and United Kingdom, and few Australian studies have been conducted.
- Many studies have been poorly designed in the sense that they do not include control or comparator groups. Specifically, there is a lack of controlled studies comparing surgical with comprehensive non-surgical interventions. Most bariatric procedures are performed in conjunction with other multidisciplinary treatments (such as counselling, support and behavioural interventions) which might have confounding effects on the results.
- Most of the published systematic reviews and meta-analyses included studies with short-term follow-up: there is little information about the long-term consequences of bariatric surgery, particularly past 10 years post-surgery.
- Data on the demographics of people receiving bariatric surgery are patchy and there has been little attention paid to equity issues in access to the surgery.

Given the growing pressure on the public health system to provide an adequate level of bariatric surgery, and the step-wise investment that may be necessary, it is essential that planning for bariatric programs is based on careful research and evaluation to ascertain the most effective models of care in the Victorian context.

To contribute to current evidence and the development of best practice approaches to bariatric surgery, the Department of Human Services will:

- support selected health services to strengthen their bariatric surgery programs in accordance with the bariatric surgery framework outlined in this document, and commission a formal evaluation of the implementation, appropriateness, usefulness and impact of the framework
- facilitate collaboration between selected Victorian bariatric surgery centres, including the development of data collection and patient outcome monitoring mechanisms
- monitor studies being conducted into bariatric surgery, particularly effectiveness studies and economic evaluations
- seek advice from clinical experts on areas where there is a need for further research or evaluation.

Summary of framework for bariatric surgery in public hospitals

Victorian public health services must ensure that patients receiving bariatric surgery are appropriately selected and prioritised according to clinical need and capacity to benefit from the surgery. While decision-making about the care of individual patients is a matter for clinical judgment, the guidelines advise that suitable candidates for bariatric surgery are those who:

- have a BMI of more than 40 or a BMI of more than 35 with medically important comorbid obesity-related conditions
- are aged between 18 and 65 years
- have tried but failed to achieve or maintain clinically beneficial weight loss using non-surgical measures
- have the motivation and capacity to make the dietary and lifestyle changes needed for a successful long-term outcome from the surgery
- have a realistic understanding of the risks and benefits of the surgery
- do not have significant medical contraindications to surgery
- do not have psychiatric, behavioural or cognitive conditions that impair their capacity to give informed consent or commit to post-operative care plans.

Bariatric surgery programs in Victorian public health services should offer:

- a comprehensive pre-surgical assessment of the patient's medical and psychosocial suitability for bariatric surgery
- pre-surgical counselling and patient information about the possible risks of surgery
- pre and post-surgical assistance in making and maintaining dietary changes and optimising physical activity
- surgery performed by appropriately experienced surgeons
- active post-surgical follow-up appropriate to the surgical procedure and the condition of the patient.

Health services are responsible for ensuring that staff involved in the treatment and care of bariatric surgery patients have appropriate skills and credentials, and for maintaining an appropriate level and mix of staff. It is expected that bariatric surgery programs will provide a multidisciplinary approach to patient assessment, treatment and post-operative care, including: input from an experienced bariatric surgeon; a nurse or nurse practitioner; an anaesthetist with experience and expertise in bariatric surgical patients; a psychologist or other licenced mental health care provider; and a dietician. Furthermore, the program must provide access to specialists and diagnostic services required for the management of patient comorbidities.

Health services providing bariatric surgery are also responsible for providing:

- appropriate facilities and equipment for the management of bariatric patients
- administrative support for coordination of patient care and fulfilling quality assurance and accountability requirements.

Useful websites

Australia

- Medical Services Advisory Committee, www.msac.gov.au
- Australian Safety and Efficiency Register of New Interventional Procedures – Surgical (Royal Australasian College of Surgeons), www.surgeons.org/Content/NavigationMenu/Research/ASERNIPS/default.htm
- National Health and Medical Research Council, www.nhmrc.gov.au
- Australia and New Zealand Horizon Scanning Network, www.horizonscanning.gov.au
- Obesity Surgery Society of Australia and New Zealand (OSSANZ), www.ossanz.com.au/
- Centre for Obesity Research and Education (CORE), www.core.monash.org/

Europe

- National Institute for Health and Clinical Excellence (UK), www.nice.org.uk
- National Coordinating Centre for Health Technology Assessment (UK), www.ncchta.org
- EuroScan (European Consortium), www.euroscan.bham.ac.uk/
- Swedish Council on Technology Assessment in Healthcare (Sweden), www.sbu.se
- Emergency Care Research Institute (ECRI), www.ecri.org/

North America

- Canadian Agency for Drugs and Technologies in Health (Canada), www.cadth.ca/index.php/en/home
- Evidence-based Practice Centres (US/Canada), www.ahrq.gov/clinic/epcix.htm
- Agency for Healthcare Research and Quality (US), www.ahrq.gov/clinic/techix.htm
- Agency for Healthcare Research (Canada), www.ahrq.gov/clinic/techix.htm
- Medical Advisory Secretariat/Ontario Health Technology Advisory Committee, www.health.gov.on.ca/english/providers/program/mas/mas_mn.html
- Blue Cross-Blue Shield Technology Evaluation Centre (USA), www.bcbs.com/tec/
- Alberta Heritage Foundation for Medical Research (Canada), www.ahfmr.ca/
- American Society for Bariatric Surgery, www.asbs.org/
- Aetna Inc, USA, www.aetna.com/
- International Federation Of Bariatric Surgeons, www.obesity-online.com/ifso/
- American Society of Bariatric Physician, www.asbp.org/

Appendices

Appendix 1: Clinical guidelines for managing overweight and obese patients

There are numerous international and national guidelines for the management of overweight/obesity. The organisations that have developed guidelines to assist practitioners and patients' decision making in regards to appropriate management of obesity, include:

Australian

- National Health and Medical Research Council (NHMRC): Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults (2003)
- NHMRC: Overweight and Obesity in Adults: A Guide for General Practitioners (2003)
- NHMRC: Dietary Guidelines for Australian Adults (2003)
- Department of Health and Ageing, Australian Government: National Physical Activity Guideline for Adults (2005)
- Dietitians Association Australia. Best Practice Guidelines for Treatment of Overweight and Obesity for Adults (2005)
- Austin Health: Management of Severe Obesity (2005, unpublished).

International

- American College of Physicians: Pharmacological and Surgical Management of Obesity in Primary care: A clinical practice guideline (2005)
- US Preventive Task Force: Screening and intervention for obesity in adults (2004)
- National Heart, Lung and Blood Institute: Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults (1998)
- European Association for Endoscopic Surgery (EAES): Obesity Surgery - Evidence-based guidelines of the European Association for Endoscopic Surgery (2005)
- Association of Operating Nurses (AORN): AORN Bariatric Surgery Guideline (2004)
- National Institute for Health and Clinical Excellence, UK: Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children (2006)
- *Management of Obesity in Adults: European Clinical Practice Guidelines*, published online at www.karger.com/ofa

According to these guidelines, non-surgical strategies for weight loss include calorie reduction, increased physical activity, and behaviour therapy designed to improve eating and physical activity habits. Specific recommendations include:

- Moderate regular physical activity
- Reducing dietary fat and calories
- Reduction of 10 per cent of baseline weight as an initial goal, an amount that reduces obesity-related risk factors
- A reasonable time line (six months) for a 10 per cent reduction in body weight

- Weight-maintenance
- Lifestyle therapy for at least six months before embarking on physician-prescribed drug therapy
- Pharmacological interventions for long-term use may be tried as part of a comprehensive weight loss program that includes dietary therapy and physical activity in carefully selected patients (BMI >30 without additional risk factors, BMI >27 with two or more risk factors) who have been unable to lose weight or maintain weight loss with conventional non-drug therapies
- Pharmacological therapy may also be used during the weight maintenance phase of treatment. However, drug safety and effectiveness beyond one year of total treatment have not been established
- Counselling on strategies to avoid further weight gain for obese patients refusing other treatments.

Appendix 2: Types of bariatric surgery

There are five main types of bariatric surgery operations: laparoscopic adjustable gastric band (LAGB), Roux-en-Y gastric bypass (RYGB), biliopancreatic bypass with a duodenal switch (BPD), vertical banded gastroplasty (VBG) and sleeve gastrectomy (SG). Information on the possible complications of the first four of these surgical methods is sourced from a 2005 conference consensus statement of American bariatric surgeons.⁷⁶

Laparoscopic adjustable gastric band

LAGB works primarily by decreasing food intake. Food intake is limited by placing a small bracelet-like band around the top of the stomach to produce a small pouch about the size of a thumb. The outlet size is controlled by a circular balloon inside the band that can be inflated or deflated with saline solution to meet the needs of the patient.

Gastric banding is the least invasive of the purely restrictive bariatric surgery procedures. It consists of a small pouch and a small stoma created by a band high on the stomach. The stomach is not cut or crushed by staples, and no anastomoses are made.

Adjustment of the band through the access port is an essential part of laparoscopic adjustable gastric banding therapy. Appropriate adjustments are critical for successful outcomes.

Possible complications associated with laparoscopic adjustable gastric banding include gastric prolapse, stomal obstruction, esophageal and gastric pouch dilation, gastric erosion, and access port problems.

Roux-en-Y Gastric Bypass

RYGB works by restricting food intake *and* by decreasing the absorption of food. Food intake is limited by a small pouch that is similar in size to the adjustable gastric band. In addition, absorption of food in the digestive tract is reduced by excluding most of the stomach, duodenum, and upper intestine from contact with food by routing food directly from the pouch into the small intestine.

Possible complications of gastric bypass procedures include dumping syndrome, stomal stenosis, marginal ulcers, staple line disruption, internal hernias, and nutrient deficiencies (if an appropriate supplementation routine is not followed).

Biliopancreatic diversion with a duodenal switch

Biliopancreatic diversion with duodenal switch is a complex bariatric operation that includes removing the lower portion of the stomach and creating a gastric sleeve with the small pouch that remains. That pouch is connected directly to the small intestine, completely bypassing the duodenum and upper small intestine from contact with food. BPD produces significant weight loss. However, the mortality rate is higher than with other bariatric operations and there are more long-term complications because of decreased absorption of food, vitamins, and minerals.

Possible complications of biliopancreatic diversion with duodenal switch procedures include diarrhoea, malodorous stools and flatus, nutrient deficiencies, and post-operative dumping.

Vertical banded gastroplasty

The vertical banded gastroplasty, introduced in the early 1970s, is a relatively fast and simple operation to perform. It consists of the creation of a small upper gastric pouch with a restricted orifice to the rest of the stomach. It has the advantage of not bypassing, resecting, or rearranging any part of the gastrointestinal tract. Since 1990, the percentage of patients undergoing vertical banded gastroplasty has decreased, but the operation is still performed at centers in the United States and worldwide.

For the most part, vertical banded gastroplasty is performed by open procedure, but is also feasible laparoscopically.

Possible complications of vertical banded gastroplasty include vomiting, lodging of a food particle within the band or ring (necessitating endoscopic removal if not relieved spontaneously in 24 hours), outlet obstruction resulting from adhesion formation and twisting of the ring or band.

Gastric sleeve

Gastric sleeve or sleeve gastrectomy is usually performed as the first stage of biliopancreatic bypass with duodenal switch in patients who may be at high risk for complications from more extensive types of surgery. These patients' high risk levels are due to body weight or medical conditions. A gastric sleeve operation restricts food intake and does not lead to decreased absorption of food. However, most of the stomach is removed, which may decrease production of a hormone called ghrelin.

A decreased amount of ghrelin may reduce hunger more than other purely restrictive operations, such as gastric band.

There is little information on the possible complications of sleeve gastrectomy as it is a relatively new procedure. However, a recent randomised controlled trial⁷⁷ comparing laparoscopic sleeve gastrectomy to LAGB reported that although the overall complication rate was higher in LAGB patients (35 per cent) compared to sleeve gastrectomy patients (10 per cent), the complications experienced by the sleeve gastrectomy patients (intraoperative bleeding and gastric ischaemia) were more severe.

Appendix 3: Pre-operative medical assessment^v

The pre-operative medical work-up for bariatric surgery patients should include assessments for secondary causes of obesity (such as Cushing syndrome, hypothyroidism and side effects of medication).

The following pre-operative testing may be undertaken:

Test	Indication
Complete blood count	All bariatric surgery candidates
Blood pressure	All bariatric surgery candidates
Glucose, glycated haemoglobin (Hb A1c)	All bariatric surgery candidates
Comprehensive metabolic panel, liver function tests	Renal failure, congestive heart failure, diuretic use, nonalcoholic steatohepatitis
Creatinine	Age >50 yr, diuretic use
Prothrombin time (PT)/partial thromboplastin time (PTT)	Malnutrition (e.g. in cases of revisional bariatric surgery)
Electrocardiogram	Men >40 yr, women >50 yr, known coronary artery disease, hypertension, diabetes
Chest radiograph	Age >50 yr, known or suspected cardiac or pulmonary disease

The following medical risk factors may require specific interventions prior to surgery:

Risk factor	Intervention
Endocrine disorder	HbA1c <7 is essential to reduce adverse events
Cardiac risk/coronary disease	Consider beta-blockers one week pre-operatively to reduce blood pressure
Obstructive sleep apnoea (present in 39-71 per cent of bariatric surgical patients)/ other respiratory risk factors	Consider pre-operative initiation of continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BiPAP) for at least 4 weeks pre-operatively to reduce hypercarbia, hypoxaemia and pulmonary artery vasoconstriction
Hypercoagulability (obesity is an independent risk factor for venothromboembolic events (VTE))	VTE prophylaxis
Nonalcoholic fatty liver disease (this is a risk factor for liver tearing during surgery)	Patients should undergo the Optifast regime (very low calorie diet) for two weeks prior to surgery to reduce liver size.
Smoking	Encourage patients to quit prior to surgery

v. Based on recommendations of the Department of Human Services Bariatric Surgery Working Group, May–November 2008

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