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SHORT REPORT

Bariatric surgery to treat severely obese patients with type 2 diabetes: A consensus statement

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1. Why is this statement needed?

This statement provides a consensus view from a group of Australian and New Zealand endocrinologists on the role of bariatric surgery in severely (morbidly) obese patients with type 2 diabetes. A number of expert evidence-based consensus statements have been released internationally on the indications for, and implementation of, bariatric surgery. However, there are none in Australia or New Zealand which have addressed bariatric surgery as a treatment option for type 2 diabetes from the endocrinologists' perspective.

The prevalence of obesity in Australia and elsewhere in the world has increased dramatically, and is forecast to increase further. Although obese individuals may appear to be responsible for their weight, this view fails to reflect the very strong genetic basis to severe obesity and the pervasive obesity-promoting effects of modern societies (the 'obesogenic environment'), in which an abundant food supply, changes in food preparation, low levels of obligatory physical activity and other factors make weight control a difficult task. Furthermore, it ignores the emerging evidence that body weight may be defended by powerful physiological mechanisms [1—4] making long term maintenance of weight loss difficult.

In Australia 1 in 12 adults has diabetes, and an additional 1 in 6 has impaired glucose metabolism (prediabetes) that places them at high risk of developing diabetes [5]. The overall rates in New Zealand are similar but reach 1 in 8 for Maori and 1 in 6 or 7 for Pacific Islanders [6]. Economic modelling

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Table 1 Classification of weight by body mass index (BMI).

BMI 18.5—25	Healthy weight
25—30	Overweight
>30	Obese
>40 (or >35 with obesity related comorbidity)	Morbidly obese

has estimated that obesity-related type 2 diabetes costs the Australian government and community about $8.3 billion annually [7].

There is increasing evidence that the health of severely obese people with type 2 diabetes, including their control of diabetes, can benefit substantially from bariatric surgery — that is, surgical procedures to produce substantial weight loss [8,9]. Existing Australian guidelines recognise that surgery is the most effective treatment for this group [10].

2. How is obesity defined?

Obesity is usually classified by body mass index (BMI), calculated as body weight in kilograms divided by the height in metres squared (kg/m^2). Classifications of BMI, based on associations with adverse health consequences, are listed in Table 1.

BMI categories have been developed primarily in populations mainly of European ethnicity, and may underestimate health risks in other populations. In addition, BMI does not necessarily reflect the proportion of body weight that consists of fat, or the distribution of fat: both these aspects of body composition can affect the health risks of excess weight. Nevertheless, at present, in the absence of a better alternative, BMI is the internationally accepted standard used by researchers and policy makers to allocate individuals to different size categories.

(Where the term severe or morbid obesity is used in this consensus statement it refers to people with type 2 diabetes and a BMI over 35.)

3. What is the link between obesity and type 2 diabetes?

Although the causes of type 2 diabetes have yet to be fully explained, obesity is considered the primary risk factor [11]. It has been estimated that the risk of developing type 2 diabetes is increased 93-fold in women and 42-fold in men who are obese rather than of healthy weight [12,13]. A small proportion of people with type 2 diabetes are not overweight, and about three-quarters of obese people do not have diabetes, indicating that other factors also influence the risk. The tendency to substantial weight gain and the associated risk of type 2 diabetes are known to be strongly genetically-determined [14].

In the short term, even modest weight loss in people with type 2 diabetes who are overweight or obese is associated with improvements in blood glucose levels and also associated conditions such as hypertension and lipid disorders. However, there is strong evidence that significant weight loss by obese people is rarely sustained [15]. Significant and sustained weight loss amongst severely obese individuals through diet and exercise alone is even less likely [9].

4. Is behavioural modification and medication sufficient to treat type 2 diabetes?

Guidelines on the treatment of type 2 diabetes note that weight loss, with its many benefits, safety profile and low cost, should be the most cost-effective means of controlling type 2 diabetes [11]. Lifestyle interventions to promote weight loss and increase physical activity should, with rare exceptions, be included as part of a diabetes treatment program. Unfortunately, such strategies have very limited success in controlling blood glucose levels amongst the severely obese, with the large majority of these patients also requiring glucose-lowering medication. A number of these medications, including insulin, may themselves cause weight gain.

Despite substantial recent advances in medication and other aspects of diabetes management, ideal control of blood glucose levels and associated metabolic changes is uncommon [16]. The challenges of controlling blood glucose and associated risk factors such as lipid levels have been identified in Australian patients managed in general practice [17—19], and even in a specialised tertiary clinic [20].

A review paper from the American Diabetes Association and the European Association for the Study of Diabetes notes the difficulties in achieving sufficient blood glucose control through diet and exercise alone. The authors recommend that medication be introduced at the time of diagnosis, together with interventions to decrease weight and increase activity, rather than employing lifestyle modification alone as the first measure [11].

5. Is bariatric surgery for severe obesity an effective treatment for type 2 diabetes?

Bariatric procedures aim to reduce weight and maintain weight loss through restricting food intake. There also appear to be independent metabolic benefits, resulting from (as yet) undefined hormonal changes after some surgical procedures, in addition to weight loss. For example, rapid and sustained improvements in control of blood glucose levels can be achieved within days of gastric bypass surgery, before any significant weight loss is evident.

A Cochrane review including patients with and without diabetes concluded that bariatric surgery resulted in greater weight loss than conventional treatment in moderate (BMI > 30) as well as morbid obesity, accompanied by improvements in comorbidities such as type 2 diabetes, hypertension and improvements in health-related quality of life [21].

A systematic review and meta-analysis of 621 studies including about 135,000 patients identified 103 studies reporting on the resolution of the clinical and/or laboratory manifestations of diabetes [8]. Overall, 78.1% of patients had complete remission of diabetes following surgery, defined as a normal fasting blood glucose level (<5.5 mmol/L) or HbA_{1c}<6.0% while not taking diabetes medication. Amongst patients with diabetes at baseline, 62% remained in remission more than two years after surgery. The extent of remission of type 2 diabetes is influenced by the choice of bariatric procedure, as well as each patient's commitment to modifying their diet and levels of exercise within a framework of ongoing multidisciplinary care.

A randomised study at Monash University is one of the few to investigate bariatric surgery specifically as a treatment for type 2 diabetes [22]. Laparoscopic adjustable gastric banding as part of a comprehensive management program was compared to conventional diabetes therapy with a focus on weight loss by diet and exercise. After two years, remission of diabetes was significantly more common in those having surgery (73% vs. 13%).

6. Is bariatric surgery cost-effective?

The costs of type 2 diabetes are substantial. In the United States, the lifetime cost has been estimated at US$172,000 for a person diagnosed at the age of 50, and US$305,000 if diagnosed at the age of 30 [23]. The estimate included both the direct medical costs of diabetes and its complications, and indirect costs caused by work absence, reduced productivity at work, disability and premature death. Over 60% of the medical cost was incurred within 10 years of diagnosis.

Bariatric surgery for severe obesity, regardless of diabetes status, has been assessed as cost-effective. For example, in an analysis structured for the United Kingdom healthcare system, the cost per quality-adjusted life year gained by surgery was within the range regarded as cost-effective by the National Health Service [24].

An analysis of the costs and benefits for third-party payers in the United States found the cost of bariatric surgery, averaging US$17,000—26,000 depending on the procedure, was recouped within two years after surgery [25]. The return on the 'investment' in bariatric surgery was consistent with the well-demonstrated immediate and long-lasting benefits over many years on conditions including type 2 diabetes, coronary artery disease, hypertension and sleep apnoea.

The relative cost-effectiveness of bariatric surgery for morbidly obese people with type 2 diabetes needs to be assessed in relation to:

- The public and private costs of other weight loss programs, including commercial programs.
- Costs of treating the diabetes and other associated diseases (see Table 2).
- Costs of diabetes complications.

7. Are there other benefits of bariatric surgery for patients with type 2 diabetes?

Severe obesity is associated with a large number of health problems in addition to type 2 diabetes (Table 2).

A review of more than 900,000 participants in prospective studies, mainly in Western Europe and North America, concluded that each 5 unit increase in BMI was associated with a 30% increase in mortality [26]. The effect on cause-specific mortality was greatest for diabetes: the risk of diabetes-related death was quadrupled for morbidly obese individuals.

Follow-up of participants in the Swedish Obese Subjects Study after an average of 11 years found that bariatric surgery was associated with a 29% reduction in all-cause mortality after accounting for sex, age and risk factors [9]. Bariatric surgery also led to a specific reduction in cancer incidence in women [27].

It would be expected that morbidly obese patients who have bariatric surgery as a treatment

Table 2 Key health problems associated with severe obesity.

Type 2 diabetes	Infertility associated with polycystic ovary syndrome
Metabolic syndrome (central adiposity, hyperglycaemia, dyslipidaemia and hypertension)	Non-alcoholic liver disease (steatohepatitis)
Psychological consequences of social stigma and discrimination	Gallbladder disease
Increased all-cause mortality	Gastro-oesophageal reflux disease
Cardiovascular disease (in addition to that caused as a complication of diabetes)	Osteoarthritis
Increase in specific cancers, including cancer of the breast, liver, prostate and colon	Low testosterone and erectile dysfunction in men
Respiratory difficulties including obstructive sleep apnoea, asthma and breathlessness	Lower urinary tract symptoms or problems in men and women
	Gout
	Obstetric complications
	Higher risks associated with anaesthesia

primarily for type 2 diabetes would also experience the benefits of weight loss on other aspects of their health, for example debilitating osteoarthritis or obstructive sleep apnoea.

8. What guidelines exist on bariatric surgery for type 2 diabetes?

A number of guidelines exist on the use of bariatric surgery for the treatment of severe obesity in general, and for the treatment of type 2 diabetes in particular. For example, Australia's National Health and Medical Research Council [10] concluded that:

- Surgery is the most effective treatment for severe obesity. Surgical procedures in motivated, severely obese patients can result in weight losses of 16—43% that are reasonably well maintained over three to eight years.
- Surgically-induced weight loss results in a marked reduction in the incidence and severity of some of the comorbidities associated with morbid obesity (particularly diabetes) and improved quality of life.
- Bariatric surgery may prove cost-effective in severely obese patients.

The United Kingdom National Institute for Health and Clinical Excellence [28] recommends bariatric surgery as a treatment option if all of the following criteria are fulfilled:

- The person is severely obese.
- 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 follow-up.

NICE also recommends bariatric surgery as a possible first-line option for adults with a BMI of more than 50.

The National Service and Technology Review Committee of the New Zealand Ministry of Health [29] recommended that funding be made available for bariatric surgery for the management of those who are morbidly obese. The Committee recommended that bariatric surgery be funded for at least 0.5% of morbidly obese patients every year.

American Diabetes Association recommendations for people with type 2 diabetes [30] include the following:

- Bariatric surgery should be considered for adults with a BMI > 35 especially if the diabetes or associated comorbidities are difficult to control with lifestyle and pharmacologic therapy.
- Lifelong lifestyle support and medical monitoring should be provided after surgery.
- There is currently insufficient evidence to generally recommend surgery in patients with BMI < 35 outside a research protocol.
- Research should continue on the long-term benefits, cost-effectiveness, and risks of bariatric surgery in people with type 2 diabetes.

An international diabetes surgery expert consensus [16] recommended that bariatric surgery for morbid obesity should be considered for the

treatment of type 2 diabetes in acceptable surgical candidates with a BMI of 35 or more who are inadequately controlled by lifestyle and medical therapy.

9. Do bariatric procedures vary in their effectiveness?

A number of bariatric surgical procedures are effective in achieving weight loss. Those that involve more extensive surgery, such as Roux-en-Y gastric bypass, generally lead to greater weight loss and more profound metabolic changes than less invasive, restrictive procedures such as laparoscopic adjustable gastric banding. Bypass procedures are thought to influence the gut hormonal milieu and potentially alter the mechanisms of type 2 diabetes. There is no evidence to support subcutaneous lipectomy (liposuction) as a treatment for type 2 diabetes in obese patients [10].

The choice of bariatric procedure is complex, and must be made by severely obese patients in consultation with their surgeons and physicians. Factors to consider in patients with type 2 diabetes include:

- The expected metabolic effects associated with the procedure itself and with weight loss.
- The degree of morbid obesity.
- The patient's comorbidities.
- The potential to either reverse the procedure or progress to a more complex procedure.
- The morbidity and mortality associated with the specific procedure.
- The follow-up regimen for the procedure (e.g. the requirement to regularly adjust a gastric band) and the commitment of the patient to adhere to it.
- The experience of the surgeon who performs the operation.

10. What are the risks of bariatric surgery?

The 30-day mortality associated with bariatric surgery is estimated at 0.28%, a rate similar to that for laparoscopic cholecystectomy and described as 'low' [10]. Longer-term concerns include vitamin and mineral deficiencies, osteoporosis and, rarely, Wernicke's encephalopathy and severe hypoglycaemia from insulin hypersecretion [30].

The risks of each procedure need to be considered in the light of potential reductions in mortality. Australian guidelines stress the need to assess the risk-benefit ratio individually for each patient, accounting for both peri-operative risk and possible long-term complications [10].Continuing efforts are required to monitor the prevalence of any adverse effects of the bariatric surgery procedure [8]. The House of Representatives committee on obesity in Australia [31] recommended a national register of bariatric surgery to capture data on the number of patients, the success of surgery and incidence of complications.

11. What are the components of successful bariatric surgery?

Comprehensive guidelines from the UK National Institute for Health and Clinical Excellence [28] list some of the essential components in providing successful bariatric surgery. They include the following:

- A comprehensive preoperative assessment of any psychological or clinical factors that may affect adherence to postoperative care requirements, such as changes to diet and exercise, is essential.
- Immediately prior to bariatric surgery, short term (otherwise unsustainable) weight loss from a medically supervised Very Low Energy Diet (VLED) and exercise programme is sometimes required to help make the surgery safer.
- The surgical team must have undertaken relevant supervised training, have specialist experience in bariatric surgery and be willing to submit ongoing patient outcome data for clinical audit.
- If the original operation requires revisional surgery, it should be undertaken only in specialist centres by surgeons with extensive experience because of the increased rates of complications and mortality.
- Surgery must be performed within a multidisciplinary team that can provide preoperative assessment (including a risk-benefit analysis and specialist assessment for eating disorders), information on the different procedures including potential weight loss and associated risks, regular postoperative assessment including specialist dietetic and surgical follow-up, management of comorbidities, psychological support before and after surgery and access to suitable equipment for the medical and surgical care of obese patients.
- Regular, specialist postoperative dietetic monitoring is required, with attention to appropriate diet after the procedure, monitoring of micronutrient status, and individualised nutritional sup-

plementation, support and guidance to achieve long-term weight loss and weight maintenance.
- In order to help sustain ongoing weight loss from bariatric surgery, patients must be committed to increased levels of ongoing daily physical activity.

12. Which patients with type 2 diabetes should be considered for bariatric surgery?

Some issues favouring bariatric surgery for a person with type 2 diabetes and a BMI of greater than 35 include:

- The absence of irreversible diabetes complications.
- Poor control of blood glucose levels and the presence of associated metabolic abnormalities despite conscientious efforts at treatment.
- Demonstrated failure of diet and exercise to achieve adequate sustained weight loss.
- Access to a comprehensive, multidisciplinary bariatric surgery service.
- Becoming generally fit for anaesthesia and surgery.
- Commitment to participate in ongoing follow-up care.

Discussion at a societal level would, ideally, assist in prioritising treatment for those patients with type 2 diabetes who are likely to gain the most benefit from bariatric surgery.

13. How should bariatric surgery be integrated into diabetes treatment algorithms?

Existing Australian and New Zealand treatment guidelines for type 2 diabetes provide little information on the role of bariatric surgery in treatment algorithms to normalise blood glucose levels [15]. In contrast, the American Diabetes Society recommends that bariatric surgery be considered as a treatment option for type 2 diabetes when the patient's BMI exceeds 35 [30].

Almost all severely obese patients are unsuccessful in their efforts to achieve sustained and significant weight loss and there is evidence that weight loss induced by bariatric surgery can lead to remission of hyperglycaemia in the majority of patients with diabetes [8]. In the remaining patients, residual hyperglycaemia is easier to manage following bariatric surgery.

It can, therefore, be argued that bariatric surgery for the severely obese with type 2 diabetes should be considered early as an option for eligible patients, rather than being held back as a last resort.

14. Would improved access to bariatric surgery for severe obesity in type 2 diabetes undermine efforts at prevention?

Weight gain is a threat to health worldwide. Increases in the prevalence of overweight and obesity will require concerted, multi-sectoral action that addresses the modern obesogenic environment and ultimately reduces the incidence of type 2 diabetes [32].

However, it is essential to clearly distinguish clearly between (i) initiatives to prevent the onset of new cases of concomitant severe obesity and type 2 diabetes and (ii) the need to effectively treat individual patients when preventative measures have failed.

In morbidly obese people, preventive lifestyle programs mostly fail to achieve significant and sustained weight loss. Nevertheless such programs are likely to deliver significant benefit following bariatric surgery by helping maximise and then sustain weight loss.

15. Is there equitable access to bariatric surgery?

Obesity is more common in socioeconomically disadvantaged people but the vast majority of bariatric surgery procedures in Australia (88%) and New Zealand are performed in the private sector. Current access to surgical treatment for people with severe obesity and type 2 diabetes is not equitable and discriminates against individuals who are most likely to benefit. The House of Representatives Standing Committee on Health and Ageing in Australia [31] recommended that government fund bariatric surgery and ongoing multidisciplinary support to ensure equitable access for appropriate morbidly obese patients.

There will be resource implications from increasing access to bariatric surgery but it is essential to consider not just the financial costs of the procedures and necessary follow-up, but also the potential savings from achieving improved control of type 2 diabetes, its related metabolic and other complications and comorbidities.

16. How do societal attitudes affect approaches to treating severe obesity and type 2 diabetes?

Negative societal attitudes to obesity have been a barrier to the provision of clinically effective, and cost-effective, health care for people with severe obesity and type 2 diabetes [33,34]. The advocacy group Obesity Action Coalition (www.obesityaction.com) has noted that obesity is a complex, multifactorial and chronic disease with serious adverse consequences for health which requires a comprehensive approach to both prevention and treatment.

However, severe obesity is too often misconstrued as a 'cosmetic' problem and a result of personal failure or a lack of motivation. In fact, severe obesity is not a condition of personal choice, but a consequence of genetic predisposition compounded by physical, emotional and social issues and the modern obesogenic environment. People affected by severe obesity often struggle not only with the health and physical consequences of their chronic condition, but discrimination at work, socially and within the healthcare system.

New Zealand health experts have argued that, for too long, society has attributed obesity to ''sloth and gluttony'', while ignoring more important but poorly-understood influences on body weight. They concluded that: ''Prejudice aside, it is a moral, practical and fiscal duty of the health system to make bariatric surgery accessible for the morbidly obese'' [34].

Consensus statement

1. Severe (morbid) obesity is a complex and chronic medical condition. Societal prejudices about severe obesity, which also exist within the health care system, must not act as a barrier to the provision of clinically effective and cost-effective treatment options.
2. Continuing population-based efforts are essential to prevent the onset of obesity and type 2 diabetes. At the same time, effective treatment must also be available for people who have developed type 2 diabetes associated with severe obesity.
3. Bariatric surgery should be a treatment option in people who have type 2 diabetes and a BMI of 35 or more. The likely metabolic benefits of the procedure are an important factor in selecting the best surgical option for each patient.
4. Government funding is required to ensure equitable access to bariatric surgery as a clinically effective and cost-effective treatment option for patients with severe obesity and type 2 diabetes. Strategies to prioritise access to surgery may be required to ensure that the procedures are available to those most likely to benefit.
5. Evidence indicates that bariatric surgery for obese patients with type 2 diabetes is cost-effective.
6. Bariatric surgery for type 2 diabetes must be performed within accepted guidelines, such as those of NICE, requiring comprehensive and ongoing multidisciplinary care, patient education, follow-up and clinical audit, as well as safe and effective surgical procedures.
7. The morbidity and mortality associated with bariatric surgery is generally low, and similar to that of well-accepted procedures such as gall bladder or gall stone surgery.
8. Bariatric surgery in morbidly obese patients with type 2 diabetes has a range of health benefits, including a reduction in all-cause mortality.
9. A national registry of patients having bariatric surgery is essential in order to ensure quality patient care and to monitor both short- and long-term patient outcomes.
10. National guidelines for bariatric surgery in obese people with type 2 diabetes and a BMI of 35 or more need to be developed and promulgated.

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