

COVIDIEN

Submission No. 133
(Inq into Obesity) JE 9/9/08

Mr Steve Georganas MP
Chairman
House of Representatives Committee on Health and Ageing
Parliament House
CANBERRA ACT 2600

Dear Mr Chairman

Inquiry into Obesity in Australia

Covidien is delighted to be able to make a submission to your Inquiry on this nationally-important subject.

We hope that your Inquiry can help identify new and effective approaches for both government policy and effective publicly-funded programmes and services that will not only benefit the prevention and management of obesity, but help better manage the wide range of its consequences.

In 2003 the National Health and Medical Research Council (NHMRC) undertook an extensive scientific review to identify current best practice for managing overweight and obesity. Its resulting evidence-based document; *Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults*, has since been the basis not only for good clinical practice but also for highly influential public policy development.

Five years on, this Inquiry is a timely opportunity to assess the changes since 2003 and where we, as a nation, can take useful next steps in the battle against obesity. Covidien is keen and willing to work with governments, health professionals and patients to ensure that obesity and its co-morbidities do not become a crippling personal and community burden in the years ahead.

Key Issues for Committee Consideration

- An effective policy development strategy for managing the epidemic of obesity and its major co-morbidity of type 2 diabetes, must include the complementary dimensions of (i) effective information for families on disease *prevention* (particularly diet and exercise) and (ii) appropriate *treatment* options for existing patients suffering from the disease.
- Appropriate treatment for obesity and type 2 diabetes includes a range of effective bariatric (weight management) surgery procedures.
- Patients and their health care professionals must work in partnership to ensure that individual surgical decisions are fully informed, that any chosen intervention is the most appropriate to their medical condition and that their particular surgery is capable of delivering effective and sustainable outcomes for them.
- Morbidly obese patients should have fair and reasonable access to the full range of treatment options, regardless of their means. In addition to services covered by private health insurance, there should be adequate public funding for that full range, including bariatric surgery.

About Covidien

Covidien (formerly Tyco Healthcare) is one of the largest manufacturers and distributors in the healthcare industry, especially in the areas of wound care and medical technology. The company's mission is to *create and deliver innovative healthcare solutions, developed in collaboration with medical professionals, which enhance the quality of life for patients and improve outcomes for our customers and our shareholders.*

This mission is something that Covidien takes very seriously. We believe in supporting the lifesaving work of medical professionals and researchers. While running a diverse international healthcare business, Covidien emphasises our vision of being an essential resource to the healthcare profession and therefore to doing our part to improve patient outcomes.

In Australia, Covidien has been closely involved in supporting the work of bariatric surgeons treating obesity and its co-morbidities since 1996. Our early commitment to this important field of surgery began by working with a small group of surgeons to help grow the Obesity Surgery Society of Australia and New Zealand (OSSANZ) to the point where it now has membership of approximately 150 bariatric surgeons. Throughout the last 12 years, Covidien has also been responsible for supporting the training of many General and Gastro Intestinal surgeons in the latest techniques used in the rapidly advancing field of metabolic surgery.

The Focus of the Submission

This submission will:

- Outline the prevalence of obesity¹, type 2 diabetes and their impact on Australian society;
- Outline the main prevention and management options for obesity and type 2 diabetes;
- Provide detail and background on bariatric surgery for obese patients, especially those with the co-morbidity of type 2 diabetes; and
- Identify key issues for consideration to allow bariatric surgery to be better integrated into the range of treatment options available to both public and private patients suffering from morbid obesity².

Prevalence & Effects of Obesity and Type 2 Diabetes

Prevalence

According to the latest edition of the Australian Institute of Health and Welfare's (AIHW) annual flagship report, *Australia's Health 2008*, over the last 20-30 years Australia's obesity problem has worsened³. Indeed, in a ranking of 25 OECD countries with data on obesity as a health risk factor, Australia languishes towards the bottom of the list⁴.

In 2003 the NHMRC concluded that overweight and obesity are in epidemic proportions throughout Australia. It estimated that 67 per cent of adult males and 52 per cent of adult females were overweight or obese in 1999, with even higher figures for some ethnic and age groups⁵. The

¹ This submission will use the World Health Organisation's Body Mass Index (BMI) definitions: Overweight is BMI 25-30 kg/m², Obese is BMI 30-35 kg/m² and Morbid Obesity is BMI ≥35 kg/m² where medical co-morbidities exist.

² The Australian Medicare Benefits Schedule cites Morbid Obesity as a criterion for surgery (see MBS item numbers 30511 and 30512).

³ Australian Institute of Health and Welfare. *Australia's Health 2008*. Cat. no. AUS 99. Canberra: AIHW, 2008 p160.

⁴ *Ibid*, p6.

⁵ National Health and Medical Research Council. *Clinical Guidelines for the Management of Overweight and Obesity in Adults*, 2003 p ix.

NHMRC also concluded that an estimated 20 to 25 per cent of children and adolescents were overweight or obese in 2003, a trend similar to that in other developed and developing countries⁶.

Amongst the aboriginal and Torres Strait Islander community, the age standardised rate of overweight and obesity is 62 per cent compared to 51 per cent in non-Indigenous people⁷. Relative to the general Australian community, the prevalence of diabetes and high blood sugar in the aboriginal and Torres Strait Islander community is 3.4 times worse⁸ and their ensuing death rate, where diabetes was the underlying cause, is 12 (twelve) times higher.⁹

Such results do not reflect well on a nation priding itself on its active outdoors lifestyle and love of sport. Indeed most, if not all, expert commentators believe that the prevalence of overweight and obesity is continuing to increase.

Effects

Just as alarmingly, there has been an upward trend in the prevalence of health complications arising from obesity, including hypertension and especially type 2 diabetes. A recent AIHW report noted national data showing that the proportion of people with diagnosed diabetes more than doubled between 1989-90 and 2004-05, a rise largely driven by type 2 diabetes¹⁰.

Further research by the AIHW in their very recent report *Diabetes: Australian Facts 2008* nominates the escalating prevalence of obesity as the most significant contributing factor to the rapid rise of type 2 diabetes in Australia. In addition, the report states that the risk of developing type 2 diabetes (and its serious complications) increases with increasing excess weight, to the extent that the prevalence of obesity amongst people with diabetes was three times that of those without diabetes¹¹.

Australia's Health 2008 notes that diabetes is one of the top ten leading causes of death among Australians, directly or indirectly claiming 9.1 per cent of Australian deaths in 2005¹². In 2005 some 42 per cent of diabetes-related deaths were specifically attributed to type 2 diabetes, against just 10 per cent for Type 1¹³.

Disability, Burden of Disease & Health Service Use

As a specific cause of burden from disease or injury to the Australian community, type 2 diabetes ranks third, behind heart disease and depression. In disability adjusted life year (DALY) terms, it accounts for more than the *combined* total of all lung cancers and road traffic accidents¹⁴. Within 15 years, type 2 diabetes is projected to be the leading specific cause of disease burden for males and the second leading specific cause for females¹⁵.

Obesity and type 2 diabetes make daily functioning harder for patients, especially those who are morbidly obese. Based on the 2003 Survey of Disability, Ageing and Carers, in 2005 it was estimated that 56 per cent of people with diabetes also had some form of disability. Of these, almost

⁶ National Health and Medical Research Council. *Clinical Guidelines for the Management of Overweight and Obesity in Children and Adolescents*. 2003 p vii.

⁷ Australian Institute of Health and Welfare. *Diabetes: Australian Facts 2008*. Diabetes series no. 8. Cat. no. CVD 40. Canberra: AIHW. 2008 p51.

⁸ *Australia's Health 2008, op. cit.* p70.

⁹ *Diabetes: Australian Facts 2008, op. cit.* p52.

¹⁰ *Ibid*, p viii-ix.

¹¹ *Ibid*, p26.

¹² *Australia's Health 2008, op. cit.* p196.

¹³ *Diabetes: Australian Facts 2008, op. cit.* p88.

¹⁴ *Australia's Health 2008, op. cit.* p57.

¹⁵ *Ibid* p197.

half again had a profound or severe activity limitation which at least sometimes required other people's help to manage¹⁶.

Similarly, diabetes was responsible for nearly six per cent of Australia's total burden of disease in 2003, making it the eighth leading cause of burden and disease and injury. But when co-morbidities such as coronary heart disease and stroke were added, the attributable burden became 8.3 per cent, with an overall ranking of fourth¹⁷.

Obesity and consequent type 2 diabetes are major consumers of health services. The Bettering the Evaluation and Care of Health (BEACH) report on general practice activity in 2006-07 reported that, after hypertension, diabetes was the most frequently seen chronic condition managed by GPs.¹⁸ Underscoring this position is the fact that since 1998-99, the GP consultations attributable to diabetes have increased by 1,110,000¹⁹ or 42 percent. Apart from pregnancy, this increase for diabetes was the largest percentage increase of all problems managed by GPs.²⁰

Perhaps unsurprisingly, type 2 diabetes is the problem most frequently referred by GPs to specialists and other health professionals²¹. These patients accounted for 80,380 or 8 per cent of all hospitalisations in 2005-06 (a 33 per cent increase in just 5 years) who stayed there for 2.4 days longer than the average stay for all hospitalisations. Diabetes was a diagnosis for an additional 506,355 patients²².

Translated into episodic cost terms, and based on an average casemix-adjusted public hospital episodic cost of \$3,700 in 2006-07²³; 650,000 diabetes-related separations would have an indicative cost of about \$2.4 billion. Assuming obesity plays a large part in the majority of these hospitalisations, either directly or as an underlying cause, this high cost exemplifies the severe physical and financial demands that morbid obesity places upon the chronically hard-pressed hospital system.

Costs of Obesity and Type 2 Diabetes

In 2002-03 dollar terms, the twin epidemics of obesity and diabetes have been estimated by the AIHW to result in Australian health expenditure on diabetes growing 401 per cent to \$7 billion by 2032-33, putting health expenditure on diabetes nearly \$2 billion above the projected expenditure for all cancers *combined*.²⁴

The respected firm Access Economics has estimated, in their October 2006 authoritative report on *The economic costs of obesity*, the total cost of obesity in 2005 to be \$21 billion, comprised of \$17.2 billion as a result of lost wellbeing (burden of disease) and \$3.8 billion in financial costs²⁵. The individual's burden of disease is equivalent to 82 per cent of the entire cost of obesity in Australia. Given Access's estimate of 3.24 million obese Australians, the total average cost of obesity for a single person was calculated at that time to be \$6,485 *per year*. Of the total financial costs of obesity, 45 per cent or \$1.7 billion are borne by the suffering individual and their family or friends, whilst the Federal Government carries a smaller 37 per cent or \$1.4 billion of these costs.²⁶

¹⁶ *Ibid* p197.

¹⁷ Begg S et al. *The burden of disease and injury in Australia 2003*. Cat No PHE 82. AIHW 2007 Canberra.

¹⁸ Britt H et al. *General practice activity in Australia 2006-07*. AIHW 2008, p77.

¹⁹ *Ibid* p93.

²⁰ *Ibid* p80-81.

²¹ *Australia's Health 2008*, *op. cit.* p197.

²² *Ibid* p198.

²³ Productivity Commission 2008, *Report on Government Services 2008*, p10.56

²⁴ *Australia's Health 2008*, *op. cit.* p430.

²⁵ Access Economics 2006, *The Economic Costs of Obesity, a Report for Diabetes Australia*, p99.

²⁶ *Ibid* p99

In respect of type 2 diabetes, Access Economics also calculated that 66 per cent or \$6.9 billion of the total financial costs are borne by the affected individual and their family or friends whilst the Federal Government carries only 23 per cent or \$2.373 billion of these financial costs²⁷.

Given these high and ongoing costs of supporting and treating people with such chronic disease, obesity and consequent type 2 diabetes are a curse on individuals, their families and the entire Australian community. Not only does morbid obesity make people far less happy and productive, but it diverts scarce public funding dollars from other needs. Tackling it must, therefore, be a particular priority for Australian policy makers.

Prevention and Management of Obesity and Type 2 Diabetes

Obesity and diabetes are similar manifestations of dysfunctional human energy management, or metabolism. For obesity, it is too much energy in (from food) and not enough energy out (from metabolism and exercise). In diabetes, the problem is the body's inability to effectively manage the energy from food that is consumed. Diabetes is identified by high blood glucose levels due to a lack of insulin production, an inability to use insulin or both. Insulin is a hormone produced in the pancreas that is normally used in muscles to help convert glucose into energy. Patients with type 2 diabetes develop glucose imbalance later in life, with a strong correlation to the development of obesity.

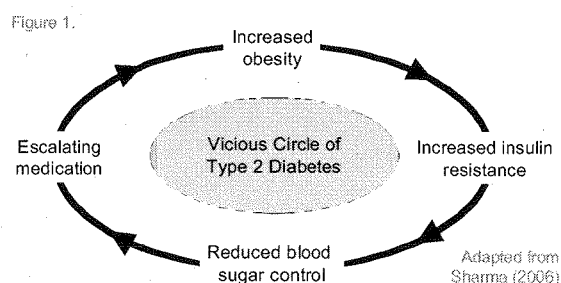


Figure 1²⁸ illustrates the vicious circle of type 2 diabetes; firstly an increase in weight leads to the body finding it progressively more difficult to use the insulin the pancreas produces. This problem is called insulin resistance which then results in a rise in blood glucose levels. The pancreas senses the raised glucose levels and makes even more insulin to try and lower them. If this cycle runs out of control, the patient can experience both raised insulin and glucose levels.

Eventually, the cells in the pancreas which have been making high levels of insulin become overworked and begin to fail in their effort to counteract the body's insulin resistance. Beyond this point, the patient's glucose levels can only be lowered to normal with the addition of insulin from injections.

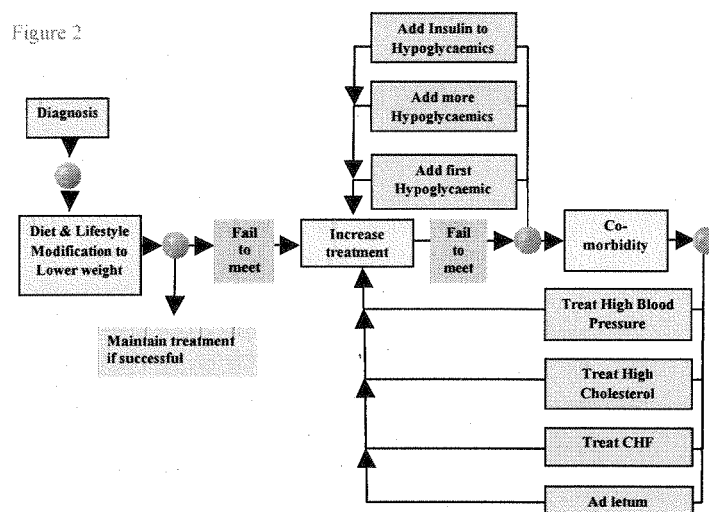
Medical treatment

Both diabetes and obesity have traditionally been treated by overlaying successively more intense medical therapies, starting with making changes to diet and lifestyle. If these measures are inadequate or the patient cannot adhere to the required changes, a medication for type 2 diabetes is prescribed. If the patient still does not meet their blood glucose goals, several additional glucose lowering medications (known as hypoglycaemics) may be successively prescribed. Finally, insulin injections are prescribed for patients when their pancreas cannot produce sufficient insulin to control their blood glucose.

²⁷ *Ibid* p101.

²⁸ Sharma AM. *The obese patient with diabetes mellitus: From research targets to treatment options*. The American Journal of Medicine 2006;119 (5A):17S-23S.

Figure 2 illustrates how complex the treating decision-making framework can become for people suffering from type 2 diabetes:



The majority of healthcare costs associated with type 2 diabetes are associated with treating the severe complications that force a patient to seek hospital services and intensive chronic care support. As complications associated with diabetes (such as hypertension, congestive heart failure, neuropathy, and nephropathy) accumulate and worsen, the need for more intensive management becomes necessary. At this point, patient compliance in medical control of blood glucose is often very poor. Most Australians with diabetes do not meet their treatment goals in controlling their blood sugar, mainly due to not taking their medication as prescribed^{29,30}.

Characteristics of the morbidly obese patient

A person with type 2 diabetes of average height (180cm) who weights 114kg has a BMI of 35.2, putting them only just into the morbidly obese category. In other words, this person will need to lose 33kg (all their excess weight) in order to lower their BMI to 25, which is at the upper limit of the normal BMI range. It is generally agreed that a loss of 50% of excess weight is deemed to be a successful outcome of treatment.³¹

When considering the relative efficacy of all the different treatments for a patient's morbid obesity (which is beyond the scope of this submission), it is important understand the relative power of the treatment being considered against the scale of the task at hand. This will help ensure that the BMI reduction achieved by a patient after their treatment is in line with reasonable expectation.

There are several intervention options to help suitable patients break the nexus between excessive energy intake and their morbid obesity. One option is pharmacotherapy, using prescription medicines to help rein in and control a patient's weight. Another option, growing in stature, is surgical intervention, called bariatric surgery.

²⁹ Bryant W et al. *Diabetes guidelines: easier to preach than practice?* Medical J Australia 2006;185(6):305-309.

³⁰ Davis TM et al. *Glycaemic levels triggering intensification of therapy in type 2 diabetes in the community: the Fremantle Diabetes Study.* Medical J Australia 2006;184(7):325-8.

³¹ Hall et al. *Gastric surgery for morbid obesity: the Adelaide study.* Annals of Surgery 1990;211(4):419-27

Bariatric Surgery for Morbid Obesity and Type 2 Diabetes

NHMRC Guidelines & Bariatric Surgery

In 2003 the National Health & Medical Research Council, in collaboration the Department of Health and Ageing, conducted a comprehensive assessment of the scientific literature in order to identify evidence of proven practices for managing overweight and obesity from which recommendations could be derived. Their publication, *Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults* contains the following statements³²:

- “Surgery – mainly of the types that restrict the intake or absorption of food – is the most effective weight loss treatment in severely obese patients [BMI \geq 35].”
- “Surgically induced weight loss results in a marked reduction in some of the co-morbidities associated with obesity (particularly diabetes) and an improvement in quality of life.”
- “Although it may appear expensive relative to other treatments, obesity surgery is one of the most cost-effective treatments available.”

Over the last five years, there has been considerable growth in the body of scientific evidence relating to obesity and morbid obesity. Of particular interest is the relationship between obesity and its significant co-morbidities; particularly diseases such as type 2 diabetes. Whilst the exact nature of the relationship between diabetes and obesity has yet to be fully understood, we do know that despite considerable attention and investment in public healthcare and education campaigns over many years that both diseases are gathering momentum in Australia.

People who are severely obese (BMI of ≥ 35) and have a serious co-morbidity such as type 2 diabetes are classified as ‘morbidly obese’. At this point it is likely that other less invasive options, such as diet and exercise, have already been tried without lasting success. When a patient gets to this situation, they are suffering from a serious medical condition and tend to find it progressively more difficult to extricate themselves.

Given that patients in the earlier stages of type 2 diabetes have been shown to respond to surgery more effectively than those with longer-standing disease, it is in the earlier stages of disease that a more serious intervention to treat the patient’s worsening medical condition, such as bariatric surgery, warrants serious consideration³³.

Types of bariatric surgery

Internationally, there are many different bariatric surgical procedures in use for the treatment of morbid obesity and more recently, type 2 diabetes.

Some bariatric procedures work by simply restricting the quantity and/or type of food which can be eaten. Others work by altering the arrangement of the intestines to reduce the body’s ability to absorb energy from food. Those bariatric procedures with the greatest effect on weight loss and co-morbidity resolution, rely on a combination of these two mechanisms.

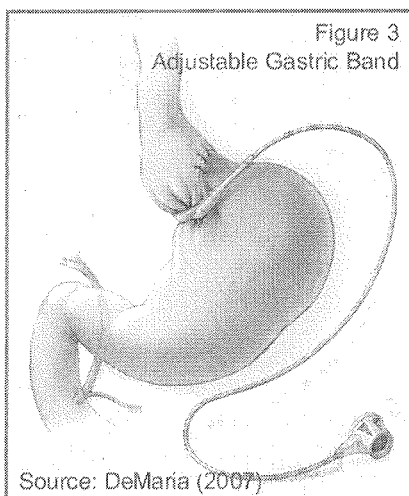
This submission will only focus on the three most widely used bariatric procedures in Australia and New Zealand. All these procedures are routinely carried out laparoscopically, through several small incisions in the abdomen, and usually result in patients returning home 1-3 days after surgery.

³² *Clinical practice guidelines for the management of overweight and obesity in adults, op. cit. pxii.*

³³ Vidal et al. *Type 2 diabetes mellitus and the metabolic syndrome following sleeve gastrectomy in severely obese subjects.* *Obesity Surgery* 2008;18:1077–1082

Adjustable Gastric band

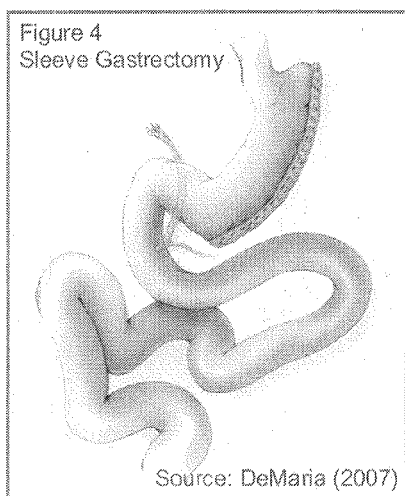
The most common restrictive procedure performed in Australia is the adjustable gastric band, depicted in Figure 3³⁴. In this procedure, a silicone band is placed around the top of the stomach, creating a small pouch. The band is prevented from slipping out of position by sewing a fold of the stomach over the top of it. The internal circumference of the band acts like a belt which can be tightened or loosened by changing the volume of water in it via the reservoir attached to the tubing. The reservoir is placed under the skin by the surgeon and accessed by a needle and syringe.



The patient can only take in a small quantity of food before they feel full, but generally obtains sufficient nutrition to ensure that their state of general health is not compromised.

Sleeve Gastrectomy

Figure 4 shows a sleeve gastrectomy. Rather than implant a silicone band, tubing and access port to restrict the quantity of food being eaten, this procedure actually reduces the size of the stomach by approximately 75 per cent to achieve its restrictive effect.



Given the sleeve gastrectomy's increasing popularity in Australia and New Zealand, it was the focus of an October 2007 Horizon Scanning Report by the Dept of Health and Ageing. In addition to reiterating the NHMRC's view that bariatric surgery delivers unsurpassed long-term efficacy relative

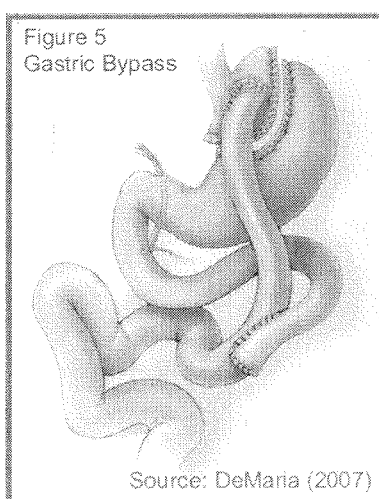
³⁴ DeMaria EJ. *Bariatric surgery for morbid obesity*. New England Journal of Medicine 2007;356:2176-83.

to any dietary, behavioural or pharmaceutical treatment, the report makes the following summary statements:

- "Randomised trials and comparative studies are generally supportive of the effectiveness of SG [Sleeve Gastrectomy] in inducing superior weight loss compared to lap-band."
- "The weight loss induced by SG should translate to decreased co-morbidities, as confirmed by Vidal et al. (2007³⁵) where 50% patients with type 2 diabetes experienced complete resolution while 28.6% required less medication at 4-months post-surgery."³⁶

Gastric Bypass

There are a number of variations of the gastric bypass procedure being used around the world. In Australia and New Zealand, the most commonly performed of these procedures is the Laparoscopic Roux-en-Y Gastric Bypass, illustrated in Figure 5. This procedure is generally considered in the medical literature to be one of the most effective at promoting weight loss and type 2 diabetes remission, because it combines both the restrictive and malabsorptive modes of action, as described above.



Restriction is made possible by separating the top of the stomach into a small pouch. This is then attached to a section of the small intestine which would normally be positioned approximately a metre below the stomach. Re-routing the intestine in this way means that the stomach and first section of the intestine below it are bypassed and play no role in the digestion of food. Whilst this malabsorption causes very effective weight loss, it may also lead to deficiencies in vitamin and mineral absorption – leading to the lifelong need for patients to use dietary supplements.

Incidence of bariatric surgical procedures

The incidence of bariatric surgery has risen steadily as surgical techniques have become increasingly safer and reliable. A study just published in the *Medical Journal of Australia*, investigating patients in Western Australia, shows that the incidence of bariatric surgery increased from 1.2 procedures per 100,000 people in 1988 to 21.2 procedures per 100,000 in 2004³⁷. It concluded that whilst bariatric surgery is a safe procedure that gives patients excellent prospects of survival, prospective candidates for bariatric surgery should continue to be carefully selected and counselled on the potential and

³⁵ Vidal J et al. *Short-term effects of sleeve gastrectomy on type 2 diabetes mellitus in severely obese subjects*. *Obesity Surgery* 2007;(8):1069-74.

³⁶ Department of Health and Ageing 2007, *Sleeve gastrectomy as a single-stage bariatric procedure*, p30-31.

³⁷ Smith FJ et al. *Incidence of bariatric surgery and postoperative outcomes: a population-based analysis in Western Australia*. *Medical J of Australia* 2008; 189(4): 198-202

inherent risks posed by surgery³⁸. This prudent and eminently sensible advice regarding informed consent would apply to all surgical candidates.

Efficacy of Different Bariatric Procedures

Bariatric surgery has been shown to support significant weight loss in morbidly obese patients and has demonstrated effectiveness in generating remission of type 2 diabetes and other co-morbidities.

One of the key results that has emerged from the practice of bariatric surgery is that not only can it result in long term weight loss, it can also send type 2 diabetes into remission. As the body re-establishes itself in a more normal and manageable weight pattern, the crippling metabolic and other side-effects of type 2 diabetes can recede or even disappear. The Roux-en-y gastric bypass has long been recognised as having a very positive effect on diabetes^{39,40}.

Perhaps even more importantly, the death rate falls in patients following gastric bypass compared to similar patients not undergoing surgery. A Canadian study compared outcomes over 6 years in 1,035 severely obese patients receiving bypass surgery with a matched group of patients who did not undergo bariatric surgery. They reported an 89 per cent reduction in mortality ($p < 0.001$) and an 80 per cent reduction in co-morbid illness following gastric bypass⁴¹. The Swedish Obesity Study (SOS) showed a 29 per cent reduction in 10-year mortality compared to a non-surgically treated control group⁴². Adams et al (2007)⁴³ showed that patients undergoing gastric bypass resulted in a 92 per cent reduction in diabetes related deaths compared to a matched control group.

Whilst most studies have involved morbidly obese patients, recent work has shown similar outcomes in obese patients as well. Cohen et al (2006)⁴⁴ and Lee et al (2008)⁴⁵ have reported on the effect of gastric bypass surgery on obese patients (BMI 30- 35) with type 2 diabetes. Both groups show significant weight loss after gastric bypass surgery. Cohen performed gastric bypass surgery in 37 obese patients with type 2 diabetes, hypertension, and lipid disorder. After surgery, 36 patients had remission of all their co-morbidities. Lee's group of patients with an initial BMI < 35 showed fasting plasma glucose returning to normal in 76.5 per cent of patients. Furthermore, glycosylated haemoglobin (another key measurement of glucose levels in blood) was normalized in 92 per cent of patients.

For gastric banding, Dixon et al (2008)⁴⁶ from Melbourne, have shown in a randomised trial that adjustable gastric banding is more effective than medical therapy in achieving glycaemic control in obese patients with type 2 diabetes (BMI > 30). In this study, it was shown that 73 per cent of the surgically treated patients normalized their glucose levels compared to 13 per cent in the conventionally treated patients. Each patient was required to visit the practice's multidisciplinary team every 4-6 weeks for the full 2 year duration of the study, to ensure that the gastric band was at optimal tightness and also to repeatedly reinforce the benefits of the diet and exercise programme.

³⁸ Ibid.

³⁹ Pories WJ et al. *Surgical treatment of obesity and its effect on diabetes: 10-year follow-up*. American Journal of Clinical Nutrition 1992;55:582S-5.

⁴⁰ Schauer PR et al. *Effect of laparoscopic Roux-en-Y gastric bypass on type 2 diabetes mellitus*. Annals of Surgery 2003;238:467-84.

⁴¹ Christou NV et al. *Surgery decreases long-term mortality, morbidity, and health care use in morbidly obese patients*. Annals of surgery 2004;240(3):416-23

⁴² Sjöström L et al. *Effects of bariatric surgery on mortality in Swedish obese subjects*. New England J Medicine 2007;357(8):741-752

⁴³ Adams TD et al. *Long-term mortality after gastric bypass surgery*. New England J Medicine 2007;357(8):753-761.

⁴⁴ Cohen R et al. *Laparoscopic Roux-en-Y gastric bypass for BMI < 35 kg/m²: a tailored approach*. Surgery for Obesity and Related Diseases 2006;2(3):401-4

⁴⁵ Lee WJ et al. *Effect of laparoscopic mini-gastric bypass for type 2 diabetes mellitus: comparison of BMI > 35 and < 35 kg/m²*. J Gastrointestinal Surgery 2008;12(5):945-52.

⁴⁶ Dixon JB et al. *Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial*. J American Medical Association 2008;299(3):316-23.

Sleeve gastrectomy may be as effective as gastric bypass in treating type 2 diabetes. Vidal et al (2008)⁴⁷ in a 12 month study showed that 84.6 per cent of patients undergoing either sleeve gastrectomy or gastric bypass both experienced remission of their diabetes. Recent results from Sydney report that the sleeve gastrectomy is more effective than banding in treating diabetes⁴⁸; agreeing with the results shown in the 2007 Horizon Scanning report on sleeve gastrectomy⁴⁹.

Not all procedures are equally effective at treating obesity and its associated comorbidities. It appears that in terms of weight loss and diabetes resolution, gastric bypass and sleeve gastrectomy are more effective than banding^{50,51}. In case matched⁵² and randomized studies⁵³, patients undergoing bypass lost more weight; had better resolution of their comorbidities and better quality of life compared to patients undergoing banding⁵⁴.

Several authors report on the early improvement in diabetic patients, within days of undergoing gastric bypass surgery and prior to any substantial weight loss^{55,56}. It seems that those procedures that physically change the digestive tract may have an additional effect on diabetes due to altering the hormonal balance associated with eating and energy usage^{57,58}.

Bariatric surgery has shown to be very clinically effective. In addition, economic analyses also show that surgery is equally cost effective, especially considering the extent of co-morbidity remission and disease prevention discussed⁵⁹. Not only did the Canadian study (above) show an decrease in mortality, it showed that the cost of surgery was offset by healthcare cost saving in about three and half years⁶⁰. Other studies have shown the cost of surgery to be recouped from as little as 13 months⁶¹ to over 5 years⁶². Bariatric surgery is also cost effective when comparing surgery to non-operative treatment using quality adjusted life year analyses⁶³. Economic modelling has shown that patients treated by gastric bypass costs A\$19,000 per quality adjusted life year (QALY) compared to

⁴⁷ Vidal J et al. *Type 2 diabetes mellitus and the metabolic syndrome following sleeve gastrectomy in severely obese subjects*. Obesity Surgery 2008;18(9):1077-82. Epub 2008 Jun 3.

⁴⁸ Gan SS et al. *Efficacy of surgery in the management of obesity-related type 2 diabetes mellitus*. ANZ J Surgery 2007;77(11):958-62.

⁴⁹ Department of Health and Ageing 2007 op. cit.

⁵⁰ *Ibid*

⁵¹ Buchwald H et al. *Bariatric surgery: a systematic review and meta-analysis*. J American Medical Association 2004;292(14):1724-37.

⁵² Weber M, et al. *Laparoscopic gastric bypass is superior to laparoscopic gastric banding for treatment of morbid obesity*. Ann Surg. 2004;240(6):975-82;

⁵³ Angrisani L et al. *Laparoscopic adjustable gastric banding versus Roux-en-Y gastric bypass: 5-year results of a prospective randomized trial*. Surgery for Obesity & Related Disorders 2007;3(2):127-32

⁵⁴ Müller MK et al. *Quality of life after bariatric surgery-a comparative study of laparoscopic banding vs. bypass*. Obesity Surgery. 2008[Epub ahead of print]

⁵⁵ Ballantyne GH et al. *Changes in insulin resistance following bariatric surgery and the adipoinular axis: role of the adipocytokines, leptin, adiponectin and resistin*. Obesity Surgery 2005;15(5):692-9.

⁵⁶ Mottin CC et al. *Behaviour of type 2 diabetes mellitus in morbid obese patients submitted to gastric bypass*. Obesity Surgery 2008;18:179-181

⁵⁷ le Roux CW et al. *Gut hormone profiles following bariatric surgery favor an anorectic state, facilitate weight loss, and improve metabolic parameters*. Annals of Surgery 2006;243(1):108-14.

⁵⁸ Rubino F et al. *The early effect of the Roux-en-Y gastric bypass on hormones involved in body weight regulation and glucose metabolism*. Annals of Surgery 2004;240(2):236-42.

⁵⁹ Sjöström L et al. *Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery*. New England J Medicine 2004;351(26):2683-93

⁶⁰ Sampalis, JS et al. *The impact of weight reduction surgery on health-care costs in morbidly obese patients* Obesity Surgery 2004 14:939-947

⁶¹ Gallagher SF et al. *The impact of bariatric surgery on the Veterans Administration healthcare system: a cost analysis*. Obesity Surgery. 2003;13(2):245-8.

⁶² Finkelstein EA, Brown DS. *A cost-benefit simulation model of coverage for bariatric surgery among full-time employees*. American J Managed Care. 2005;10:641-6.

⁶³ Salem L et al. *Cost-effectiveness analysis of laparoscopic gastric bypass, adjustable gastric banding, and nonoperative weight loss interventions*. Surgery for Obesity and Related Diseases. 2008;4(1):26-32. Epub 2007 Dec 19.

medical management⁶⁴. In comparison, high cholesterol treatment costs A\$13,510 per QALY compared to placebo in patients with heart disease⁶⁵.

Ensuring the Best Treatment Choices for Morbid Obesity

Confronting obesity is one of the greatest challenges of our time. Without significant changes, as our lives and culture continue to become more sedentary and as a nation we continue to take in more calories than we burn up, the rates of morbid obesity and type 2 diabetes in Australia will continue to increase ever more sharply. This is not an alarmist statement; it simply reflects the trend of the last two decades.

Public policy should be ensuring that the causes of obesity be tackled up front, and that encouraging better diet and exercise is a community interest as well as a personal responsibility. Covidien supports the overwhelming consensus that poor diet and inadequate exercise are the key causal factors that any policy strategy must address. While many people have a genetic disposition to putting on weight (and also find it harder to lose excess weight), the fact remains that the fundamental obesity equation comes down to correcting the balance between energy intake and output. That should always be the main, but not the only, policy focus.

It is good that the obesity issue has caught the attention of Coalition and Labor Commonwealth and State governments, not least under the banner of the Council of Australian Governments' (COAG) Better Health Initiative and related anti-obesity and anti-diabetes strategies. The decision by COAG to implement the ALP's federal campaign promise of making obesity a National Health Priority (joining diabetes on the national list) is also very welcome in that it focuses policy-makers' attention on obesity issues generally. We do note, however, that the May Federal Budget did not provide funding for new obesity initiatives outside the Rudd government's election commitments; such as the Stephanie Alexander school kitchen garden programme.

Recognising the value of direct interventions to break the personal obesity spiral

Whilst these are all welcome developments, there are two important dimensions to tackling obesity which must be the focus of policy development. The first dimension is the long-term strategy of identifying and managing the known risks in our 'obesogenic' society – especially those affecting our children. The implementation of bold, effective and sustainable *prevention strategies* is the best long-term solution to bringing the current obesity epidemic under control. Such strategies may include general marketing campaigns and messages relating to diet and exercise at one end of the scale, through to tax and legislation at the other. As experts such as Professors Paul Zimmet and Garry Jennings have written:

*The contemporary environment promotes obesity...Policies aimed solely at individuals are inadequate, and simply increasing the number or type of small-scale interventions is not enough to reverse the trend. Significant effective action to prevent obesity at population level is required...we need efforts from the promotion of healthy diets to a redesign of urban environments that promotes walking and other forms of exercise.*⁶⁶

Zimmet and Jennings are entirely correct. But this is a long-term vision that will involve willing and coordinated action by governments, urban planners, health professionals, service providers, the pharmaceutical and medical devices industries and, above all, individuals and families at risk of obesity and its consequences. While such visionary action may prevent a worsening of the obesity epidemic over time, large-scale policy action of this type is not going to address the immediate medical needs of patients suffering the serious consequences of morbid obesity in the short term.

⁶⁴ Minshall M Unpublished data, Center for Outcomes Research, IMS Health, Indianapolis IN USA private communication August 2008

⁶⁵ Dalziel K et al. *Review of Australian health economic evaluation – 245 interventions: what can we say about cost effectiveness?* Cost Effectiveness and Resource Allocation. 2008; 6: 9.

⁶⁶ Zimmet and Jennings, "Curbing the obesity epidemic". *The Age*, 22 February 2008

The second dimension, therefore, is one of interventional *treatment strategies* for patients with existing obesity and its co-morbidities such as type 2 diabetes. With varying degrees of sustained effectiveness, these range from medications promoting weight loss and blood sugar control through to the different bariatric surgery options described previously. As highlighted in this and other evidence to the Committee, a large cohort of morbidly obese patients with intractable, debilitating and expensive co-morbidities currently exists. Managing these patients' often complex conditions currently comes at a big personal and community cost. The sooner the problems of people currently suffering from morbid obesity are tackled appropriately and effectively, the better it will be for our entire community.

Together, these twin strategies of prevention and treatment represent our community's armoury of measures to tackle the contemporary problem of morbid obesity, as well as setting us up to manage the longer term. Like any armoury, the key to winning battles is to select the most appropriate weapon (from a range of proven options) for each different situation you find yourself in.

The appropriate role of surgical intervention

In the same article quoted earlier, Paul Zimmet and Garry Jennings made a passionate plea to avoid "*public policy that accepts such drastic action (as surgery) as the solution*"⁶⁷. In this regard, interventional treatment including bariatric surgery and pharmacotherapy should not be discounted. They have proven and reliable efficacy and are carefully used now when other options have been exhausted or are deemed to be inappropriate for a particular morbidly obese patient.

As already noted in this submission, bariatric surgery has been practised around the world with increasingly lower risk of complication for decades now. As the study of Western Australian bariatric procedures over almost two decades concluded:

*"Our results indicate that bariatric surgery is a safe procedure, with excellent prospects of survival. Given that obesity is associated with increased mortality, it is encouraging that postoperative survival rates in our cohort were in line with survival rates in the general population. It seems that Australia has adopted a treatment modality that poses low short-term risk in an otherwise high-risk population".*⁶⁸

We agree with Zimmet and Jennings' general conclusion, if not with their overall reservations about bariatric surgery as a treatment for morbid obesity. Bariatric surgery is not the magic bullet for obesity treatment, but is a serious tool to be used in serious circumstances, such as where a patient's morbidity and mortality risks would be significantly greater if they chose *not* to have surgery. Indeed, like most laparoscopic procedures, bariatric surgery is invasive, uncomfortable and carries the risk of serious complications. It is not an easy way out. Not all patients are suitable candidates for bariatric surgery. It should only be considered when non-surgical options in the treatment armoury are inappropriate and/or proven to be ineffective for a particular patient's situation. The patient must always undergo counselling as to their options and be committed to life long changes in diet, exercise and lifestyle in order to achieve expected results.

While the chances are very good, we accept that there is no guarantee that all patients will lose all the weight they want or necessarily find their type 2 diabetes goes into complete remission. Each different bariatric surgery option is only a tool. Like any set of tools, they work best and deliver on their potential only when the patient is properly trained and conscientious in their use. With the chances of type 2 diabetes remission as high as 85 per cent⁶⁹, and in a clinically-controlled environment where clinicians are closely involved, the possibility of full or partial freedom from the crippling burden of obesity and its equally-diabolical co-morbidities is a legitimate expectation for patients – if the conditions are right.

⁶⁷ *Ibid.*

⁶⁸ Smith et al, (2008), *op cit.*

⁶⁹ Buckwald et al (2004), Vidal et al (2008), Dixon et al (2008) *op. cit.*

The NHMRC's 2003 guidelines on obesity, including the use of bariatric surgery, are generally accepting of this option (see page 7). It may simply be that they need to be updated to reflect the most recent research and clinical evidence. They should not however be diminished insofar as they countenance options that lead to appropriate discussion.

More Accessible *Appropriate* Bariatric Surgery to Those in Greatest Need

In Australia most bariatric surgery is performed in the private health system, either funded by private health insurance or self-funded. This accounts for 9 out of 10 bariatric surgical episodes⁷⁰.

The Commonwealth's support of private health insurance has kept the private choice affordable for many Australians on lower to middle incomes. This means that thousands of patients have access to bariatric surgery through their private cover. But with the total insured population including less than 45 per cent of Australians, and this proportion being likely to fall significantly due to impending changes to the Medicare Levy Surcharge thresholds, well over half the population are still completely dependent on the public healthcare system.

This uninsured population includes millions in the lower socio-economic groups in our society, not least pensioners, Indigenous and migrant groups especially susceptible to obesity and type 2 diabetes, as we have seen. If their obesity becomes intractable, and all else has failed, they have nowhere to go for bariatric surgery other than the public hospital system. In oral evidence to this Committee, Dr Wendy Peters, Head of Clinical Research at Monash University's Centre for Obesity Prevention and Education, summed up the problem:

"Patients with the economic ability to access the private system are able to have the surgery readily. Around 9,000 surgeries were performed in Australia in the last financial year in the private sector. Patients reliant on the public sector, however, are not so fortunate. We do not have exact figures on the number done in the public sector; however, based on our local experience, we would estimate that only around 400 or 500 are done in Australian public hospitals each year. This inequity of access needs to be addressed urgently."

"Whilst my private patients can expect to wait one month for a consultation and four to six weeks for a surgery, my publicly treated patients can expect to wait two to three years for an appointment just to see me and then three to five years to have their surgery. It is heartbreaking for me as a surgeon to see these people and tell them that they are going to have to wait such a long time for an intervention that we know will improve not only their health but their quality of life and their ability to contribute to our society. While they wait, their health deteriorates and more health dollars are spent."⁷¹

Access to the full range of treatment alternatives should be fair and equitable, regardless of means. Simply being unable to afford private health insurance should not preclude those who might benefit from bariatric surgery from gaining such access. Given that successful treatment might reduce the cost of their care and support to the wider community suggests that there are both public and private benefits to such outcomes.

There are signs that this is starting to register on public policymakers. On 4 August 2008 the NSW Minister for Health, the Honourable Reba Meagher MP, announced a \$36 million NSW Health Obesity Strategy to tackle the rising incidence of overweight and obesity across that State.⁷² Among a suite of measures, including social marketing, advice lines and parenting support, the strategy provides for the establishment of multidisciplinary medical and surgical clinics targeting obesity. Through them bariatric surgery will be considered and provided for considerably more than the 53 public patients whose bariatric surgery was funded by NSW Health in 2007.⁷³

Most importantly, the NSW strategy announcement makes it clear that bariatric surgery will only be approved if a patient satisfies strict clinical criteria. This is perfectly right and appropriate.

⁷⁰ Smith et al (2008) *op. cit.*

⁷¹ Health and Ageing Committee, *Hansard*, 21 June 2008, page HA33.

⁷² The Hon Reba Meagher MP, *New \$36 million state-wide strategy to tackle rising obesity*, media release, 4 August 2008

⁷³ State to pay for obesity surgery, *The Sydney Morning Herald*, 3 August 2008

The recent NSW announcement about more bariatric surgery for public patients is both welcome and overdue. It is making these procedures accessible to the disadvantaged social groups that arguably need them most, and itself offers a precedent for other States and Territories to consider and follow.

Where Next?

Since the Rudd government came to office the emphasis in health policy has been on review and reform. Broad strategic directions are being considered by the National Health and Hospitals Reform Commission chaired by Dr Christine Bennett. There is a National Preventive Health Task Force chaired by Professor Rob Moodie. There are bureaucratic policy processes supporting the COAG Better Health Initiative.

Work is currently being done by the Diabetes Australia Guideline Development Consortium to update the NHMRC's evidence based guidelines for type 2 diabetes. It is encouraging to note that the draft of these guidelines, currently available for public comment, includes a recommendation that bariatric surgery be considered as an option for preventing type 2 diabetes in selected morbidly obese individuals at high risk of disease.⁷⁴

Potentially most importantly, however, there will soon be hard negotiations between the Commonwealth, State and Territories on the next Australian Health Care Agreements. In government, money talks. These agreements, which hitherto have concentrated on public hospital funding, are to contain funding incentives to the States to meet certain performance benchmarks and targets. In a very recent speech the Minister for Health and Ageing, the Honourable Nicola Roxon MP, indicated that these may well include obesity-related targets.⁷⁵

Covidien believes that the provision of bariatric surgery for public patients suffering from obesity and type 2 diabetes should be factored into the funding equation. This should naturally only be on the basis of prevailing evidence based clinical guidelines and when other treatment options are less appropriate or have previously failed for that patient. The numbers of patients likely to be treated, as an overall share of all public patients, are still likely to be relatively small. We therefore hope that as governments finalise the next Australian Health Care Agreements, they look closely at the NSW obesity strategy and consider what options to fund and how best to fund them.

The NSW strategy is notable not only for its willingness to fund appropriate bariatric surgery, but for its willingness to look at the challenge carefully and holistically. It is sensible and measured.

Conclusion

Obesity and its consequences are an invidious pressure not only on individuals and their families, but on our entire society and economy. If we do nothing, or even not enough, it could well overwhelm our nation's capacity not only to deal with them, but also our ability to resource health care in Australia as a whole.

Australia's approach to obesity needs to be coordinated and holistic. It is the sum of its parts, and tackling its underlying causes and mitigating its terrible consequences are separate, although complementary and equally important issues. In this context, it is important to recognise and make available the full range of prevention, care and treatment options. The development of successful policy to deal with Australia's obesity problem, which has effective and durable outcomes, will rely on a balanced approach and not simply focus on any particular strategy, such as improving diet and exercise.

⁷⁴ <http://www.diabetesaustralia.com.au/PageFiles/763/Draftupdatedguidelinesoverview.pdf>. Accessed Aug 2008.

⁷⁵ The Hon Nicola Roxon MP, *The case for change*, speech to the National Press Club, 13 August 2008.

Interventions including a range of bariatric surgery procedures are effective components of our society's armamentarium to treat morbid obesity, with each one having proven usefulness in differing circumstances. Bariatric surgery is definitely not for everybody, but for those in whom it can genuinely help, it is an important treatment option to be considered sooner rather than later.

Covidien would be very happy to discuss these issues with the Committee at a hearing before it finalises its report.

Yours sincerely

A handwritten signature in black ink, appearing to read 'M Hill', with a horizontal line underneath.

Michael C Hill
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