



12 June 2008

Submission No. 75

(Inq into Obesity)

*18106108*

Committee Secretary  
Standing Committee on Health and Ageing  
House of Representatives  
PO Box 6021  
Parliament House  
CANBERRA ACT 2601

Dear Committee Secretary,

**Re: Review of Obesity in Australia submission by Allergan Australia**

Allergan would like to provide the attached submission to the Committee as a part of the review of Obesity in Australia.

Allergan, Inc. is a multi-specialty health care company focused on discovering, developing and commercialising innovative pharmaceuticals, biologics and medical devices that enable people to live life to its greatest potential.

Allergan Australia was established in 1968 and since then has provided products to the Australian community in the areas of Ophthalmology, Neurology, Paediatrics, Medical Aesthetics, Rehabilitation Medicine and since mid 2006 Obesity Management through the availability of the LAP-BAND® gastric adjustment system and Bioentrics Intra-gastric Balloon (BIB™).

Allergan is committed to quality Clinical Research and through our Clinical Research Team based in Australia servicing the Asia Pacific Region contributes significantly to the Global R&D program.

Specifically in the area of Obesity Management, Allergan provides significant support to the Centre of Obesity Research and Education (CORE) at Monash University. It also is currently conducting a clinical trial of the BIB™ at the Metabolism & Obesity Research Centre at the University of Sydney. It is our intention to expand our clinical research within Australia to support a greater understanding of obesity and its management.

If I can be any further assistance with our response please do not hesitate to contact me.

Yours sincerely

Mark Glover  
**VP and Managing Director**  
**Allergan Australia and New Zealand**



**REVIEW OF OBESITY IN AUSTRALIA**

**SUBMISSION**

**BY**

**ALLERGAN AUSTRALIA**

**June 2008**



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## **Executive summary**

### **The prevalence of obesity in the Australian population**

Australia has witnessed a steady increase in the average weight of its population and over the last 20 years and now one in two Australians are considered overweight or obese. The proportion of obese men has increased from 8.6% in 1989-90 to 22% in 2004-05 and the proportion of obese women has increased from 9.9% in 1989-90 to 18% in the same period. An alarming trend is that the obese category is growing faster than the overweight category.

Analysis shows reasonably similar levels of overweight and obesity across all states and territories in Australia - approaching 20% of the adult population over 18 years of age.

The presence of obesity can have serious consequences for diseases like asthma; cancer; diabetes; heart, stroke and vascular disease; and osteoarthritis, rheumatoid arthritis and osteoporosis. A common thread amongst all these diseases is that the risk of each one increases with rising BMI.

### **Clinical approaches to managing overweight and obesity in adults**

The National Health and Medical Research Committee (NHMRC) has suggested a stepped approach to the clinical management of overweight and obesity in Australia. This includes a range of measures from education, diet, physical activity, behavioural modification, pharmacotherapy (medicines) and surgery.

While education, diet and physical activity as prevention tools are accessible practices and are now being increasingly encouraged by the Federal Government, other interventions such as pharmacotherapy and surgery for obese and morbidly obese people are not as readily available. The NHMRC has found that non-surgical interventions for obesity generally result in weight loss of less than 10 kg for a variable duration. Surgery, however, is documented as the only consistently effective therapeutic intervention for the morbidly obese.

### **Bariatric surgery**

Bariatric surgery to reduce morbid obesity has been assessed by the Federal Government's Medical Services Advisory Committee (MSAC) and a range of other expert committees as being clinically and cost effective and is currently listed on the Medicare Benefits Schedule (MBS). Bariatric surgery refers to the various surgical procedures performed to treat obesity by modification of the gastrointestinal tract to reduce nutrient intake and/or absorption. The AMA considers that bariatric surgery is an effective measure for long-term reductions in weight and improved health outcomes for obese adults with significant co-morbidities for whom other measures have not been successful. Bariatric surgery has also been found to improve or completely resolve obesity-related co-morbidities. The post-operative period in bariatric surgery is particularly important because complications can arise. Regular



follow-ups during the immediate postoperative period are critical and an average ten adjustments is required for the rest of a patient's life.

In Australia, bariatric surgical procedures increased from 500 in 1994 to 4000 in 2004 and there has been further growth since then. In 2007, 96% of Allergan's gastric band procedures were undertaken in private hospitals but only 4% in public hospitals. Some publicly funded bands were supplied in Victoria NSW, Queensland and WA but no publicly funded bands were supplied in SA, TAS or NT. The AMA assesses that only 10% of bariatric surgery is carried out in public hospitals and that as obesity is more prevalent in lower socio-economic groups, the very limited access to public bariatric surgery by the population who most needs it raises significant equity issues.

### **Public policy approaches in managing overweight and obesity in adults**

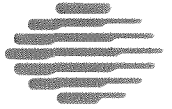
A range of policy measures over the last few years culminating in several recent Rudd Government announcements have been aimed at preventing obesity and tackling chronic disease, including those caused by obesity. Many of the Rudd Government announcements involve measures to prevent obesity. What is needed is for equal weighting to be given in policy, programs and funding for the treatment of obesity and morbid obesity. A focus solely on prevention would discount that surgery is the only consistently effective therapeutic intervention for the morbidly obese, and the connection between morbid obesity and chronic disease. In addition, at the present time treatment options for chronic disease seem to focus on treating just the disease without also treating obesity as the cause.

A key way in which morbid obesity treatment could be made more cost effective would be for procedural nurse practitioners to be able to obtain Medicare rebates to undertake some of the mandatory ongoing post-operative monitoring and adjustment functions of bariatric patients, currently undertaken by GPs. In addition to recognising the importance of treatment strategies to tackle obesity, introducing this practice would also complement a range of the Government's other stated objectives.

Bariatric surgery is a proven cost and clinically effective treatment in permanently reducing BMI in morbidly obese people and can greatly assist obese people to achieve substantial health benefits from reducing BMI which are costly to the health care system. The improved availability of bariatric surgery to an increased number of public patients nation-wide is rational both clinically and economically.

### **Recommendations**

1. The Government – through the National Obesity Strategy being developed by the National Preventative Health Taskforce - should include a comprehensive pathway for the clinical management of morbidly obese patients in public sector Guidelines. The pathway should address the treatment of obesity and morbid obesity and recognise the role of obesity treatment in reducing and preventing certain chronic diseases.



2. The Government – through the National Obesity Strategy being developed by the National Preventative Health Taskforce – should recommend incentives through the new focus on prevention in Australian Health Care Agreements (AHCAs) for uniform clinical guidelines to be developed across the states and territories for the treatment of obesity.
3. The Government's policy approach to reducing obesity should address both preventative and treatment measures.
4. An effective public policy approach to treating chronic disease should recognise that chronic disease is often a by-product of obesity and that obesity needs to be treated in treating the chronic disease.
5. A Medicare item should be introduced for procedural nurse practitioners to undertake some of the mandatory ongoing post-operative monitoring and adjustment functions of bariatric patients currently undertaken by GPs.
6. Allergan supports the AMA's recommendation for the Federal Government to:
  - take a monitoring and evaluating role in relation to action to combat obesity and redirect action and resources to where they are needed;
  - encourage state and territory governments to develop clinical guidelines for bariatric surgery;
  - encourage state and territory governments to devote funding to trialling bariatric surgery in their hospitals for 3 year periods and then evaluate the economic effectiveness of this procedure prior to proceeding with ongoing funding.
7. In addition to encouraging state and territory governments to trial bariatric surgery in their hospitals and proceeding with ongoing funding if bariatric surgery proves cost effective – as the AMA has recommended - the Australian Government should inject funding through AHCAs dedicated to making increased bariatric surgery available to public patients.
8. The Government should support through all appropriate mechanisms improved access of public patients to bariatric surgery in recognition of its effectiveness in reducing BMI in morbidly obese people and the positive direct impact of bariatric surgery on co-morbidities which are costly to Australia's health system



## **1. Introduction**

### **1.1 Allergan Inc**

Allergan, Inc. is a multi-specialty health care company focused on discovering, developing and commercialising innovative pharmaceutical and biological products and medical devices which enable people to live life to its greatest potential.

Allergan Australia was established in 1968 and since then has provided products to the Australian community in the areas of Ophthalmology, Neurology, Paediatrics, Medical Aesthetics, Rehabilitation Medicine and, since mid 2006, Obesity Management through the availability of the LAP-BAND® gastric adjustment system and Bioentrics Intra-gastric Balloon (BIB™).

Allergan is committed to quality clinical research and through the work of our Australian clinical research team servicing the Asia Pacific Region contributes significantly to Allergan's global R&D program.

Specifically in the area of Obesity Management, Allergan provides significant support to the Centre of Obesity Research and Education (CORE) at Monash University, Victoria. It also is currently conducting a clinical trial of the BIB™ at the Metabolism & Obesity Research Centre at the University of Sydney. It is our intention to expand our clinical research within Australia to support a greater understanding of obesity and its management.

### **1.2 Responding to this Inquiry**

Our submission provides an overview of the incidence of obesity in the Australian population with a focus on future implications for Australia's health system – responding to the first of the Committee's terms of reference.

It then discusses bariatric surgery as a proven and cost effective treatment for managing morbid obesity in the adult population and its effectiveness in reducing chronic disease. It highlights the need to adopt both preventative and treatment strategies to tackle the obesity epidemic and highlights some of the current access problems to bariatric surgery across the states and territories. It then proposes a number of public policy approaches to increasing the accessibility of bariatric surgery to patients who most need it and to improving the cost effectiveness of some of the mandatory post-operative care functions of bariatric surgery.

## **1. The prevalence of obesity in the Australian population**

### **2.1 Increases over time**

Australia, like most other western countries, has witnessed a steady increase in the average weight of its population over the last 20 years and now one in two Australians are considered overweight or obese.



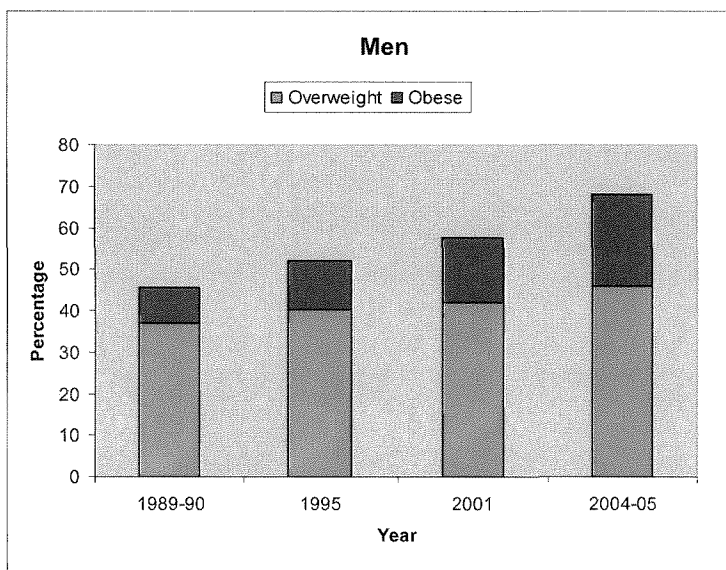
“Obesity” is defined as a condition in which the natural energy reserve, stored in fatty tissue, exceeds healthy limits. It is commonly defined as a body mass index (weight divided by height squared) of 30 kg/m<sup>2</sup> or higher. BMI, or body mass index, is a simple and widely used method for estimating body fat. BMI is calculated by dividing the subject’s weight by the square of his/her height. The most commonly used definitions of obesity, established by the World Health Organisation in 1997 and published in 2000, provide the following values:

- A BMI of 25.0–29.9 is *overweight*
- A BMI of 30.0–39.9 is *obese*
- A BMI of 40.0 or higher is *severely (or morbidly) obese*
- A BMI of 35.0 or higher *in the presence of at least one other significant comorbidity* is also classified by some bodies as *morbid obesity*.

In a *clinical* setting, physicians take into account race, ethnicity, lean mass (muscularity), age, sex, and other factors which can affect the interpretation of BMI.

A number of health surveys conducted over the last 15 years allow an examination of the changes over time in the proportion of the population that is overweight and obese.

**Figure 1** summarises the findings of these surveys and confirms that the proportion of men who are obese has steadily increased from 8.6% in 1989-90 to 22% in 2004-05. Similar increases are seen in the female population, with 9.9% obese women reported in 1989-90 increasing to 18% in 2004-05. One alarming trend highlighted by these changes is that the obese category is growing faster than the overweight category, suggesting that the average weight of the overall category is higher today than it was in 1989/90.





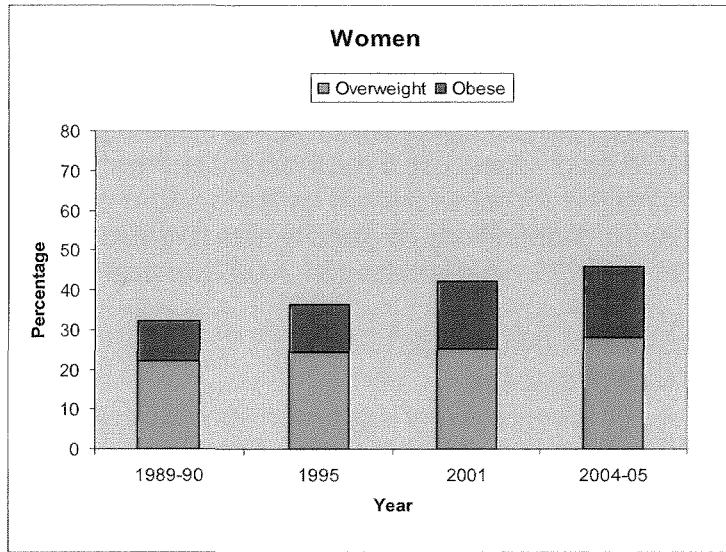


Figure 1: Changes over time in obesity and overweight in Australian

**2.2 Obesity rates by state and territory**

A summary of the rates of obesity by state and territory is provided in **Figure 2**. These estimates are derived from state health departments and although there are minor differences in the derivation of the data (self-reported versus clinic measured) and age group across the states, it essentially shows reasonably similar levels across all states and territories - approaching 20% of the adult population over 18 years of age. This confirms that obesity is a national problem and one where no particular state or territory has developed strategies to substantially impact on obesity levels.

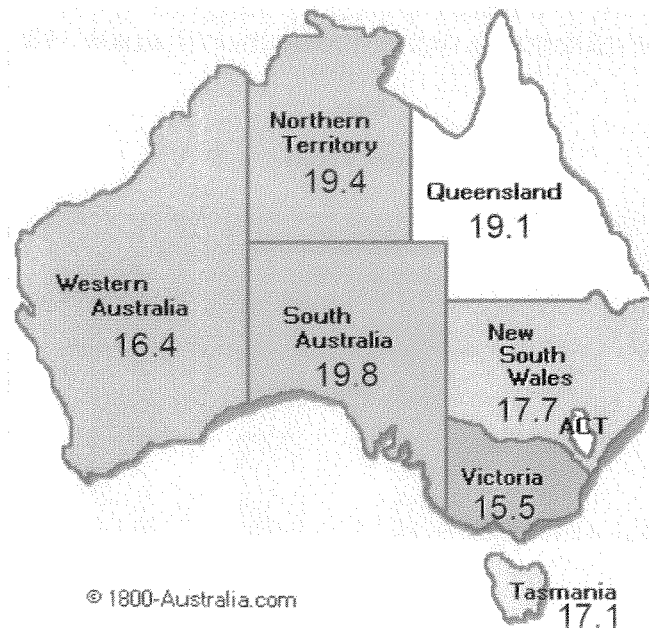


Figure 2: Obesity Rates by state and territory



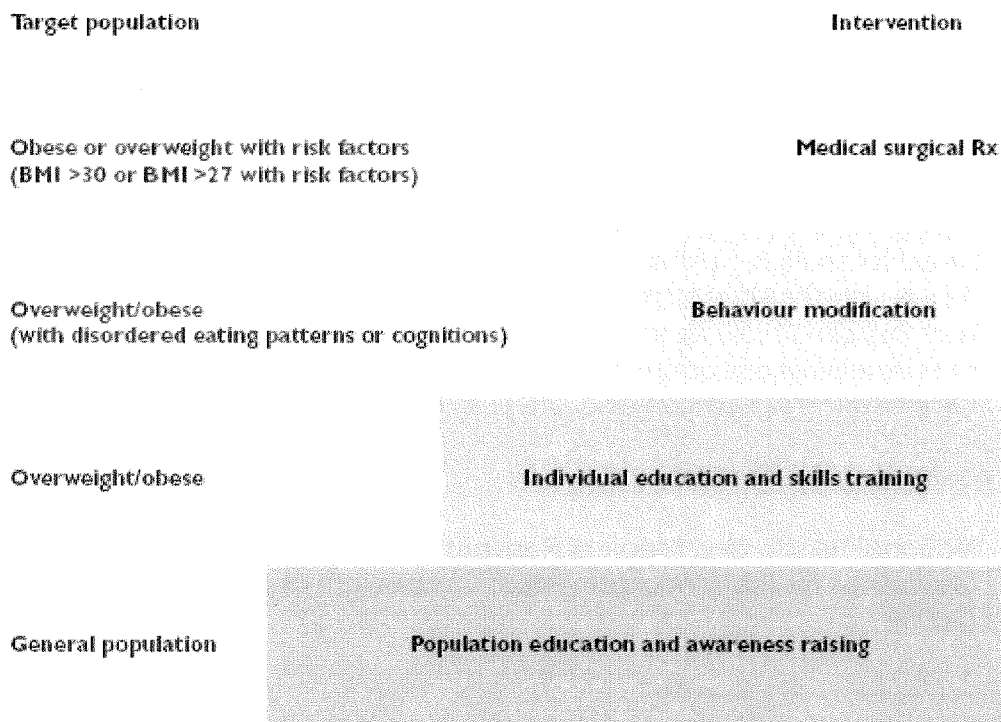
**Obesity-related co-morbidities**

The presence of obesity can have serious consequences for diseases like asthma; cancer; diabetes; heart, stroke and vascular disease; and osteoarthritis, rheumatoid arthritis and osteoporosis. A common thread amongst all these diseases is that the risk of each one increases with rising BMI. It is now recognised that increasing weight or BMI is one of the most serious challenges to maintaining and improving the health of Australians. Obesity, both directly and indirectly through obesity related co-morbidities, threatens to worsen these conditions and erode substantial health gains achieved which Australians have achieved over the last 100 years.

**3. Managing overweight and obesity in adults**

**3.1 Clinical approaches**

The National Health and Medical Research Committee (NHMRC) has suggested a stepped approach to the clinical management of overweight and obesity in Australia (see **Figure 3**). This includes a range of measures from education, diet, physical activity, behavioural modification, pharmacotherapy (medicines) and surgery.



**Figure 3: A stepped model for clinical management of overweight and obesity**



While education, diet and physical activity as prevention tools are accessible practices and are now being increasingly encouraged by the Federal Government, other interventions such as pharmacotherapy and surgery for obese and morbidly obese people are not as readily available.

Pharmacotherapy at this time is not subsidised by the Federal Government through the PBS and therefore access is limited to individuals able to afford such medication at prices charged by the manufacturer.

The NHMRC has found that non-surgical interventions for obesity generally result in weight loss of less than 10 kg for a variable duration<sup>1</sup>. Surgery, however, is documented as the only consistently effective therapeutic intervention for the morbidly obese<sup>2</sup>.

Bariatric surgery to reduce morbid obesity has been assessed by the Federal Government's Medical Services Advisory Committee (MSAC)<sup>3</sup> as being cost effective and, as mentioned earlier, is currently listed on the MBS. However while some bariatric surgery is performed in public hospitals, this is on a piecemeal basis and bariatric surgery is only readily accessible by privately insured Australians. (This is addressed further below).

### 3.1.1 Models of clinical care for overweight and obesity

There are numerous international and national guidelines for the best practice management of overweight/obesity. They largely refer to interventions such as:

- Appropriate patient selection;
- Preoperative assessment of cardiovascular, pulmonary, gastrointestinal, endocrine and other obesity-related diseases with increased risk for complication or mortality;
- Need for multidisciplinary treatment team;
- Adequate facility staffing, equipment, and administrative support;
- Appropriate follow-up and monitoring for early recognition and management of complications;
- Optimisation of nutrition and physical activity.

In Australia, guidelines include:

- National Health and Medical Research Council (NHMRC): Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults (2003);

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<sup>1</sup> National Health & Medical Research Council, Clinical practice guidelines for the management of overweight and obesity in adults. Canberra: NHMRC, September 2003.

<sup>2</sup> Buchwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta-analysis. JAMA 2004; 292; 1724-1737; NHMRC, 2003; Clegg A, Sidhu MK, Colquitt J, et al. clinical and cost effectiveness of surgery for people with morbid obesity. Southampton: National Institute for Clinical Excellence, 2001 – quoted in the AMA Victoria's submission to the Victorian State Budget 2008-09.

<sup>3</sup> Medical Services Advisory Committee, Australian Department of Health and Ageing, Laparoscopic Adjustable Gastric Banding for Morbid Obesity, MSAC reference 14. Assessment report, Canberra, 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);
- Dieticians Association Australia. Best Practice Guidelines for Treatment of Overweight and Obesity for Adults (2005).

We note that the Department of Health and Ageing's guidelines mentioned above currently only focus on prevention of obesity and not on the broader issues associated with effective obesity treatment or to prevent obesity-related co-morbidities such as diabetes and heart disease.

**Recommendation:** The Government – through the National Obesity Strategy being developed by the National Preventative Health Taskforce - should include a comprehensive pathway for the clinical management of morbidly obese patients in Department of Health & Ageing Guidelines. The pathway should address the treatment of obesity and morbid obesity and recognise the role of obesity treatment in reducing and preventing certain chronic diseases.

At the state/territory level in Australia, models care for the clinical management of obesity are gradually being developed but these efforts are piecemeal. These models are usually described to be multidisciplinary and aim to integrate conservative and surgical management across health sectors.

**Recommendation:** The Government – through the National Obesity Strategy being developed by the National Preventative Health Taskforce – should recommend incentives through the new focus on prevention in Australian Health Care Agreements (AHCAs) for standardised clinical guidelines to be developed across the states and territories for the treatment of obesity.

### 3.1.2 Bariatric surgery

Bariatric surgery, also known as weight loss surgery, to reduce morbid obesity refers to the various surgical procedures performed to treat obesity by modification of the gastrointestinal tract to reduce nutrient intake and/or absorption. The term does not include procedures for surgical removal of body fat such as liposuction or abdominoplasty ("tummy tuck").

On the basis of their physiological and mechanical action, current bariatric surgery can be broadly classified into:

- Restrictive procedures: vertical banded gastroplasty (VBG), laparoscopic adjustable gastric banding (LAGB);
- Malabsorptive procedures: jejunioileal bypass, biliopancreatic diversion (BPD), biliopancreatic diversion with duodenal switch (BPD/DS);



- A combination of Restrictive and Malabsorptive procedures: Roux-Y gastric bypass (RYGB);
- Other surgical procedures: lipsuction; sleeve gastrectomy; intragastric balloon; mini gastric bypass; abdominoplasty; gastric electrical stimulation.

In Australia, LAGB is the preferred procedure amounting to 90% of all bariatric procedures performed in 2000-2004, with RYGB making up the rest<sup>4</sup>.

Worldwide, there are four operative procedures commonly undertaken. These are Roux-en-Y Gastric Bypass, Vertical Banded Gastroplasty, Laparoscopic Adjustable Gastric Banding and Bilio-pancreatic Diversion. The preferred use of, and in some geographical areas dominance of, a specific bariatric procedure has been reported to reflect local regulatory and insurance factors as well as surgical experience and skills<sup>5</sup>.

### 3.1.3 Clinical effectiveness of bariatric surgery

Bariatric surgery has been evaluated by the NHMRC<sup>6</sup>, the UK National Institute for Clinical Excellence (NICE)<sup>7</sup> and the US National Institute of Health (NIH)<sup>8</sup> as clinically effective and all three agencies have explicitly recommended that surgery be made available to selected morbidly obese patients. A surgical approach to obesity treatment is also supported by the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASEERNIP-S)<sup>9</sup> and, as already mentioned, Australia's MSAC<sup>10</sup>.

The AMA also considers that bariatric surgery is an effective measure for long-term reductions in weight and improved health outcomes for obese adults with significant co-morbidities for whom other measures have not been successful<sup>11</sup>.

A summary of the clinical effectiveness of bariatric surgery from NHMRC's Clinical Practice Guidelines for the Management of Overweight and Obesity

<sup>4</sup> Quoted in AMA Victoria's response to Victorian State Budget, 6 May 2008.

<sup>5</sup> Reported in Brand Dr C Amatya Dr B, Literature Review of Bariatric Surgery for the Treatment of Morbid Obesity, Clinical Epidemiology & Health Service Evaluation Unit, Royal Melbourne Hospital, September 2006.

<sup>6</sup> NHMRC, Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults, Canberra, September 2003, quoted in AMA Victoria response to Victorian State Budget, 6 May 2008.

<sup>7</sup> Clegg A, Sidhu MK, Colquitt J, et al, Clinical and Cost Effectiveness of Surgery for People with Morbid Obesity, National Institute for Clinical Excellence, Southampton, 2001, and NHS National Institute for Clinical Excellence, Guidance on the Use of Surgery to Aid Weight Reduction for People with Morbid Obesity, Technology Appraisal Guidance No 46, London: NCE, July 2002, quoted in AMA Victoria response to Victorian State Budget, 6 May 2008.

<sup>8</sup> US National Heart, Lung and Blood Institute. Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults, Bethesda, MD: NHLBI, 1998, quoted in AMA Victoria response to Victorian State Budget, 6 May 2008.

<sup>9</sup> Chapman A, Gam P, O'Brien P, et al, 'Systematic review of laparoscopic adjustable gastric banding in the treatment of obesity: Update and re0-appraisal', Australian Safety and Efficacy Register of New Interventional Procedures – Surgical, Royal Australasian College of Surgeons, Adelaide, June 2002, quoted in AMA Victoria response to Victorian State Budget, 6 May 2008.

<sup>10</sup> MSAC Report, 2003, quoted in AMA Victoria response to Victorian State Budget, 6 May 2008.

<sup>11</sup> AMA Position Statement on Obesity, 2008.



in Adults is set out in **Table 1** below. In morbidly obese patients, bariatric surgery provides substantial weight loss (between 31kg and 53 kg over two years) and, importantly, this weight loss is maintained over the longer term.

**Table 1: The effects of weight loss treatments in obese adults**

Treatment	Weight loss/gain (kg) over 1-2 years <sup>1</sup>	Weight loss/gain (kg) over >2 years <sup>2</sup>	Ability to prevent regain?
Surgery			
Gastric bypass	-46 (-53 to -35) -36%	-42 (-62 to -29) over 3-14 years	Yes
Biliopancreatic bypass	-53 (-62 to -42) -38%	-54 (-84 to -37) over 3-8 years	Yes
Non-adjustable gastroplasty	-41 (-63 to -25) -32%	-25 (-39 to -17) over 3-8 years	Some weight regain
Adjustable gastric banding	-31 (-46 to -22) -24%	-34 (-43 to -28) over 3-4 years	Yes

Bariatric surgery has also been found to improve or completely resolve obesity-related co-morbidities such as diabetes, hypertension, obstructive sleep apnoea and dyslipidaemia.

Its benefit in relation to diabetes is highlighted in a recent study (Dixon et al, 2008). The study was conducted in Australia and enrolled Type 2 diabetic patients. One group of study participants received standard medical management, whilst the other group received standard medical management *and* a gastric band. After two years, 73% of patients in the gastric band group had remission of diabetes (normal glucose control and no diabetes medication) compared with 13% in the medical management group. Two findings in the study are particularly relevant:

1. *The degree of weight loss, not the method, appeared to be the major driver of glycemic improvement and diabetes remission in obese patients.*
2. Only a few patients with less than 10% weight loss achieved diabetes remission whilst virtually all patients with a 10% or larger weight loss achieved diabetes remission, regardless of whether or not they received the band.

These findings have important implications for the management of morbidly obese people with diabetes. Diabetes now affects a substantial number of Australians and even if only a small number (ie, those who are morbidly obese) were suitable for bariatric surgery to enable remission, the clinical and cost-effectiveness benefits of providing increased access to bariatric surgery are substantial and long term. The study for instance referred to bariatric surgery being able to cure obese diabetics for the "bargain" price of \$17,000 where a diabetic person can cost the nation between \$5,000 and \$10,000 per year to treat, and referred to gastric banding for mildly to severely obese people recently diagnosed with diabetes as being "extremely cost effective". Professor Paul O'Brien, head of the Centre for Bariatric Surgery at Monash



University, is quoted as saying that surgeons hope these findings will make the procedure more widely available.

### 3.1.4 The importance of post operative care

The post-operative period in bariatric surgery is particularly important because complications can arise and the ongoing effectiveness of the surgery in effecting weight loss needs to be ensured. Bariatric patients should be regularly evaluated and a long-term commitment from both the patient and the bariatric surgical team is needed. Shen et al (2004)<sup>12</sup> evaluated the impact of patient follow up on weight loss and the Laparoscopic Adjustable Gastric Band (LAGB) and Roux-en-Y Gastric Bypass (RYGB). They reported that of those patients who underwent LAGB, a significantly higher excess weight loss was reported in the group who were followed up more than 6 times a year (50% excess weight loss), compared to the group who attended 6 or fewer follow-up visits a year (42% excess weight loss,  $p=0.05$ ). In patients who underwent RYGB, the excess weight loss was less in those who had three or fewer follow-up visits in the first year compared to those who has 3 or more follow-up visits (66.1% versus 67.6%). Inadequate follow up was associated with serious complications and mortality.

Best practice post operative care has been cited as:

- Regular follow-ups during the first postoperative year - the first two years is the most critical for follow-up;
- 1 to 4 follow ups during the second year; and
- 1 or 2 follow ups per year thereafter, depending upon the condition of the patient - an average ten adjustments is required for the rest of a patient's life.

The American Society of Bariatric Surgery in a conference statement on surgical treatment of morbid obesity<sup>13</sup> states, "Patients require appropriate lifelong follow-up with nutritional counselling and biochemical surveillance. Surgeons need to be aware of the needs of severely obese patients in terms of facilities, supplemental equipment, staff and procedures and should plan the personal time, specialised staff and/or multidisciplinary referral as required. This multidisciplinary approach includes medical management of co-morbidities, dietary instruction, exercise training, specialised nursing care and psychological assistance as needed. Post-operative management of co-morbidities should be directed by the practitioner familiar with the operation performed and the changes created."

<sup>12</sup> Quoted in Brand Dr C & Amatya Dr B, "Literature Review of Bariatric Surgery for the Treatment of Morbid Obesity", Clinical Epidemiology & Health Service Evaluation Unit, Royal Melbourne Hospital, September 2006

<sup>13</sup> Quoted in Brand Dr C & Amatya Dr B, *ibid*, P 52.



### **3.1.5 Access to bariatric surgery in Australia**

In Australia, bariatric surgical procedures increased from 500 in 1994 to 4000 in 2004 and there has been further growth since then. Research is focusing on extending the scope of surgery to patient populations that are obese but do not have morbid obesity and to newer techniques of bypass and banding surgery and newer procedures<sup>14</sup>.

Allergan has examined the public and private provision of its gastric band (LAP-BAND®, Allergan Pty Ltd) in the Australian system and it serves as an example of the fragmented delivery of health services across Australia. Usage by sector is summarised as follows.

### **3.1.6 Bariatric surgery in public hospitals**

- Of the 6,253 bands provided in 2007, 96% were in private hospitals, with the remaining 4% (223 bands) in public hospitals.
- When examined by state, usage varies widely. No publicly funded bands were supplied in SA, TAS or NT. Victoria provided the greatest number, 157; whilst NSW, Queensland and WA provided 10, 55 and 1 respectively.
- If one assumes that morbidly obese patients account for about half of the obese population in each state then Victoria provides gastric banding for 0.030% of eligible public patients, NSW 0.0015% and Queensland 0.013%.

The Australian Medical Association (AMA)<sup>15</sup> points out that obesity is more prevalent in lower socio-economic groups, but that only 10% of bariatric surgery is carried out in public hospitals. The AMA points out that while Medicare currently pays for privately insured patients to undergo bariatric surgery and for some post-surgical care, uninsured patients are largely denied access to bariatric surgery in public hospitals. This means that a significant proportion of the population who would most benefit from bariatric treatment therefore miss out, and this raises significant equity issues. The AMA says that funding bariatric surgery is an economically efficient decision for the community and will help to promote equity of access to effective care.

At the current time, ensuring adequate nation-wide delivery of public bariatric surgery is made complex because of the fragmented state based health system. This can cause barriers to the adoption of certain clinical procedures because separate assessments are required in each state and territory. Allergan realises that the recently established National Health and Hospitals Reform Commission has been tasked with developing a long term reform plan to improve the performance of Australia's health care system, and that this and future expansion of the AHCA's focus to include preventative and primary care agendas, may address some of these difficulties.

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<sup>14</sup> Quoted in Brand Dr C et al, op cit.

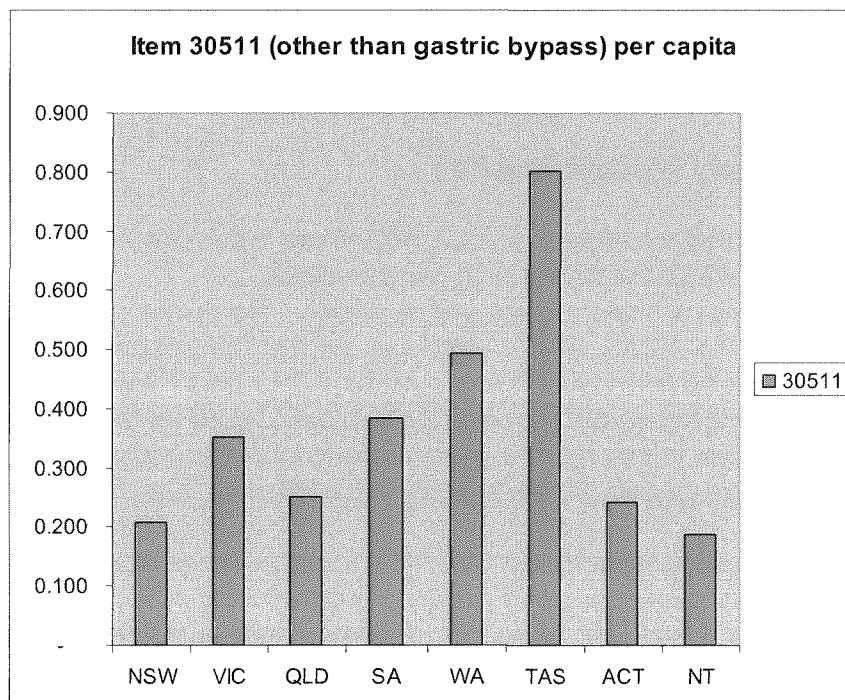
<sup>15</sup> AMA Position Statement on Obesity, 2008.





### 3.1.7 Bariatric surgery by privately insured Australians

In 2007 approximately 9,350 gastric band procedures were performed in privately insured patients across Australia (the number of other bariatric surgery procedures (eg, gastric bypass) was small in comparison (less than 300)). When one examines usage across all states and territories, clear differences emerge as the following chart shows.

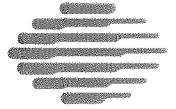


Private health insurance may provide more consistent delivery at the current time than publicly funded procedures, however many of the private insurers are state based and inconsistencies are also evident in the provision of privately insured bariatric procedures. The major limiting factor to private health insurance is its expense, making it increasingly unavailable to many Australians.

### 3.2 Public policy approaches in managing overweight and obesity in adults

Australia has made substantial gains in the health of its population over the last hundred years, evidenced by increases in life expectancy. The Australian Institute of Health and Welfare has found for instance that between 1901-2000, life expectancy at birth increased in Australia by 21.4 years for males and 23.3 years for females. To maintain and continue to improve national health levels is no doubt the aim of all Australian governments.

In 2003, then Australian Health Ministers acknowledged that Australia was facing an epidemic of obesity and agreed that joint national action be taken to increase healthy eating and physical activity amongst children, young



people and their families. Agreeing to take what is essentially a preventative approach, the Ministers agreed that reducing obesity levels would take some time but action needed to start immediately to build on work already commenced in several states.

In November 2005, the then Australian Health Ministers' Conference (AHMC) endorsed a policy to manage and improve chronic disease prevention and care. This led to the development of a national framework across Australia. Five disease areas were identified for particular focus: asthma; cancer; diabetes; heart, stroke and vascular disease; and osteoarthritis, rheumatoid arthritis and osteoporosis. A common thread amongst these priority areas is that the risk of each disease increases with rising body mass index (BMI). It is now recognised that increasing weight or BMI is one of the biggest challenges to maintaining and improving the health of Australians. Obesity, both directly and indirectly through obesity related co-morbidities, threatens to erode the historical health gains achieved.

Since November 2007 the Rudd Government has announced a number of encouraging initiatives aimed at preventing obesity and tackling chronic disease (including those) caused by obesity. These initiatives include:

- Establishment of the National Preventative Health Taskforce to **deliver a long term strategy for tackling chronic disease** (particularly caused by excessive alcohol, tobacco and **obesity**).
- The Australian Health Ministers' Conference agreement on 18 April 2008 to make obesity a National Health Priority Area where one of the first tasks of the National Preventative Health Taskforce will be to **develop a National Obesity Strategy** which should involve driving collaborative efforts to tackle obesity at national, local, state and territory levels and ensuring that obesity receives the attention it deserves "as a matter of urgency".
- Establishment of the National Health and Hospitals Reform Commission to provide advice to the Government on the design of Australia's future health system and the Commission's draft report<sup>16</sup> - which has been described as one of the most comprehensive reviews of Medicare in decades - calling on the Federal Government to assume a more active role in **ensuring adequacy of a full range of primary health services** - which would involve moving beyond general practice to allied health services, district nursing, mental health services and community health services.
- Recognition by the Government<sup>17</sup> that the fastest escalation in costs in health expenditure will be for **diabetes** (@ 400%) and that Access Economics estimates the total financial costs to the economy are in the range of: \$38 billion per annum for obesity and \$10.3 billion per annum for diabetes and that this had implications for **care models** and also for **the way in which the health workforce is utilised**.

<sup>16</sup>Beyond the Blame Game: Accountability and performance benchmarks for the next Australian Health Care Agreements, April 2008, pp14-17.

<sup>17</sup>In a speech by the Health Minister on 30 April 2008 to the Committee for Economic Development of Australia.



- Announcing the delivery of 10,000 **extra nurses** into Australia's health system.
- The 2008-09 Federal Budget announcement of:
  - an increased focus on the health needs of people at risk of acquiring **type 2 diabetes** through establishing a **Type 2 Diabetes Risk Evaluation Medicare item** to be introduced in July 2008 to assist to reduce the growth rate of type 2 diabetes. The new item would encourage GPs to review people with high risk factors of developing type 2 diabetes and instigate early interventions to reduce their risk levels.
  - The Budget's announcement of the establishment of other targeted Medicare items relating to a renewed focus on preventative care and team-based multidisciplinary approaches to care.
  - A broadening of the focus of the Australian Health Care Agreements beyond hospital funding to include **prevention, primary care and aged care**, and to this end developing a **National Preventative Health Care Partnership**.

In addition to committing to reduce obesity, these announcements suggest the potential for a supportive policy environment with regard to morbid obesity. What is required is for equal weighting to be given in policy, programs and funding to treatment measures as well as preventative measures to address obesity and morbid obesity. Allergan supports the AMA's contention that "combating obesity demands a whole-of-society approach, requiring the participation of governments, non-government organisations, the health and food industries, the media, employers, schools and community organisations". "A whole of society response should incorporate both preventative measures and treatment measures for individuals who are obese"<sup>18</sup>.

The key point is that Australia needs to adopt both preventative and treatment strategies to tackle the obesity epidemic. It is critical that public policymakers and administrators move beyond the view that obesity is more a "life style" than a growing public health problem, and can only be resolved through prevention. A focus solely on prevention would discount that surgery is the only consistently effective therapeutic intervention for the morbidly obese, and the connection between morbid obesity and chronic disease

**Recommendation:** The Government's policy approach to reducing obesity should address both preventative and treatment measures.

In addition, policies, programs and funding need to recognise that obesity is a primary cause of (some) chronic diseases. At the moment, treatment options for chronic disease focus on treating the disease itself without also necessarily addressing its cause. It is incongruous for instance that there is still no PBS listed medicine for obesity whereas the use of lipid lowering medication,

<sup>18</sup> AMA Position Statement on Obesity, 2008, P52.



hypertensive agents and diabetes treatments - which for obese people treat only co-morbidities associated with obesity and not obesity itself - now account for approximately 2.4 billion dollars in PBS expenditure. The Government's policy approach to treating chronic disease should recognise that chronic disease is often a by-product of obesity and that obesity needs to be treated in treating the chronic disease.

**Recommendation:** The Government's policy approach to treating chronic disease should recognise that chronic disease is often a by-product of obesity and that obesity needs to be treated in treating the chronic disease.

A key way in which morbid obesity treatment could be made more cost effective would be for procedural nurse practitioners to be able to obtain Medicare rebates to undertake some of the mandatory ongoing post-operative monitoring and adjustment functions of bariatric patients which are currently undertaken by GPs.

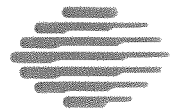
At the moment Medicare pays for the bariatric surgery procedure in privately insured patients and for GPs to undertake adjustments post surgery. What we are proposing is for these monitoring and adjustment functions to also be able to be rebated if they are performed by procedural nurse practitioners. In Allergan's view, in addition to adopting treatment (as well as prevention) strategies to tackle obesity, introducing this practice would also complement the Government's stated objectives to:

- address GP workforce shortages;
- provide greater emphasis on a multi-disciplinary team approach to care by moving beyond general practice to district nursing (and allied health services, mental health services and community health services etc);
- utilise the health workforce more efficiently with "different models of care" to address obesity and chronic disease.

It would also provide incentives for nurses to develop skills in a growing area of health care management.

**Recommendation:** A Medicare item should be introduced for procedural nurse practitioners to undertake some of the mandatory ongoing post-operative monitoring and adjustment of bariatric patients currently undertaken by GPs.

Allergan also supports the AMA's recommendations regarding public policy approaches to obesity management, ie, that they should be strategic and coordinated at a national level by the federal government, which must develop specific national goals for reducing obesity in Australia and play a special role in coordinating and supporting the efforts of other governments and stakeholders in this regard.



**Recommendation:** Allergan supports the AMA's recommendation for the Federal Government to:

- take a monitoring and evaluating role in relation to action to combat obesity and redirect action and resources to where they are needed;
- encourage state and territory governments to develop clinical guidelines for bariatric surgery;
- encourage state and territory governments to devote funding to trialling bariatric surgery in their hospitals for 3 year periods and then evaluate the economic effectiveness of this procedure prior to proceeding with ongoing funding.

Bariatric surgery is a proven cost and clinically effective treatment in permanently reducing BMI in morbidly obese people and can greatly assist obese people to achieve substantial health benefits from reducing BMI which are costly to the health care system. The improved availability of bariatric surgery to an increased number of public patients nation-wide is rational both clinically and economically.

**Recommendation.** In addition to encouraging state and territory governments to trial bariatric surgery in their hospitals and proceeding with ongoing funding if bariatric surgery proves cost effective – as the AMA has recommended - the Australian Government should inject funding through AHCAs dedicated to making increased bariatric surgery available to public patients.

**Recommendation:** The Government should support through all appropriate mechanisms improved access of public patients to bariatric surgery in recognition of its effectiveness in reducing BMI in morbidly obese people and the positive direct impact of bariatric surgery on co-morbidities which are costly to Australia's health system.

#### 4. Recommendations

1. The Government – through the National Obesity Strategy being developed by the National Preventative Health Taskforce - should include a comprehensive pathway for the clinical management of morbidly obese patients in public sector Guidelines. The pathway should address the treatment of obesity and morbid obesity and recognise the role of obesity treatment in reducing and preventing certain chronic diseases.
2. The Government – through the National Obesity Strategy being developed by the National Preventative Health Taskforce – should recommend incentives through the new focus on prevention in Australian Health Care Agreements (AHCAs) for uniform clinical guidelines to be developed across the states and territories for the treatment of obesity.
3. The Government's policy approach to reducing obesity should address both preventative and treatment measures.



4. An effective public policy approach to treating chronic disease should recognise that chronic disease is often a by-product of obesity and that obesity needs to be treated in treating the chronic disease.
5. A Medicare item should be introduced for procedural nurse practitioners to undertake some of the mandatory ongoing post-operative monitoring and adjustment functions of bariatric patients currently undertaken by GPs.
6. Allergan supports the AMA's recommendation for the Federal Government to:
  - take a monitoring and evaluating role in relation to action to combat obesity and redirect action and resources to where they are needed;
  - encourage state and territory governments to develop clinical guidelines for bariatric surgery;
  - encourage state and territory governments to devote funding to trialling bariatric surgery in their hospitals for 3 year periods and then evaluate the economic effectiveness of this procedure prior to proceeding with ongoing funding.
7. In addition to encouraging state and territory governments to trial bariatric surgery in their hospitals and proceeding with ongoing funding if bariatric surgery proves cost effective – as the AMA has recommended - the Australian Government should inject funding through AHCA's dedicated to making increased bariatric surgery available to public patients.
8. The Government should support through all appropriate mechanisms improved access of public patients to bariatric surgery in recognition of its effectiveness in reducing BMI in morbidly obese people and the positive direct impact of bariatric surgery on co-morbidities which are costly to Australia's health system.



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