



**SUBMISSION TO THE PREVENTATIVE HEALTH
TASKFORCE**

BY

ALLERGAN AUSTRALIA

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A. Overview

Tackling the burden of chronic disease caused by obesity and how best to address this through primary prevention is one of the aims of the Preventative Health Task Force. This submission presents a case that laparoscopic adjustable gastric banding (LAGB) should be considered in this preventative framework. The submission does not argue that LAGB should be used to prevent obesity but rather that it should be considered in a preventative framework once individuals become severely obese at a BMI level that is acceptable and value for money (i.e. cost-effective) from an Australian societal perspective. Risk of mortality and co-morbidity increase dramatically and exponentially above BMI 35, and LAGB could be considered as an option for these individuals where other preventative strategies have failed.

B. Introduction

The LAGB is a highly effective ¹ and cost-effective intervention ² for obese individuals. It has a vital role to play in the treatment of:

1. **Obese individuals with a BMI > 35 with co-morbidities such as diabetes.** In this treatment population the LAGB has been shown to mediate remission of diabetes in 73% of patients compared to 13% remission rates in patients treated by standard medical management³.
2. **Obese individuals with a BMI > 40 without co-morbidities.** In a large, long term study of 1,863 patients treated with LAGB patients BMI reduced from a mean pre-operative BMI of 43.7 kg/m² to 34.8 kg/m² at 2 years. These reductions were maintained over 5 years of follow-up⁴

C. Comparative associations with chronic health conditions for tobacco, alcohol and obesity.

A recent study by Sturm has compared the association of obesity, overweight, smoking, and problem drinking on co-morbidity risk, health care use and health status based on United States survey data. Obesity is significantly associated with an odds ratio larger than 1 for every condition in Figure 1; aging is significantly associated with every condition except asthma; and daily smoking is significantly associated with lung disease and cancer (all at $p < .05$, most at $p < .01$). Obesity and aging have significantly larger effects on heart disease, hypertension, and diabetes (common conditions treated with long-term drug regimens) than smoking or problem drinking has ($p < .05$). In contrast, smoking has the strongest effects on cancer and lung disease (in the case of lung

¹ [http://www.health.gov.au/internet/main/publishing.nsf/Content/obesityguidelines-guidelines-adults.htm/\\$FILE/adults.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/obesityguidelines-guidelines-adults.htm/$FILE/adults.pdf).

² [http://www.msac.gov.au/internet/msac/publishing.nsf/Content/92DBCCFBD8B30B2DCA25745C001DDB17/\\$File/Ref%2014%20-%20Laparoscopic%20Adjustable%20Gastric%20Banding.pdf](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/92DBCCFBD8B30B2DCA25745C001DDB17/$File/Ref%2014%20-%20Laparoscopic%20Adjustable%20Gastric%20Banding.pdf).

³ Dixon JB, O'Brien PE, Playfair J, et al. Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial. *Jama* 2008;299(3):316-23.

⁴ Angrisani, L. et al. Lap Band adjustable gastric banding system. *Surg Endosc* (2003) 17: 409–412.



disease, the effect is significantly larger than the effect of obesity at $p < .01$). Obesity has roughly the same association with chronic health conditions as does twenty years' aging; this greatly exceeds the associations of smoking or problem drinking.

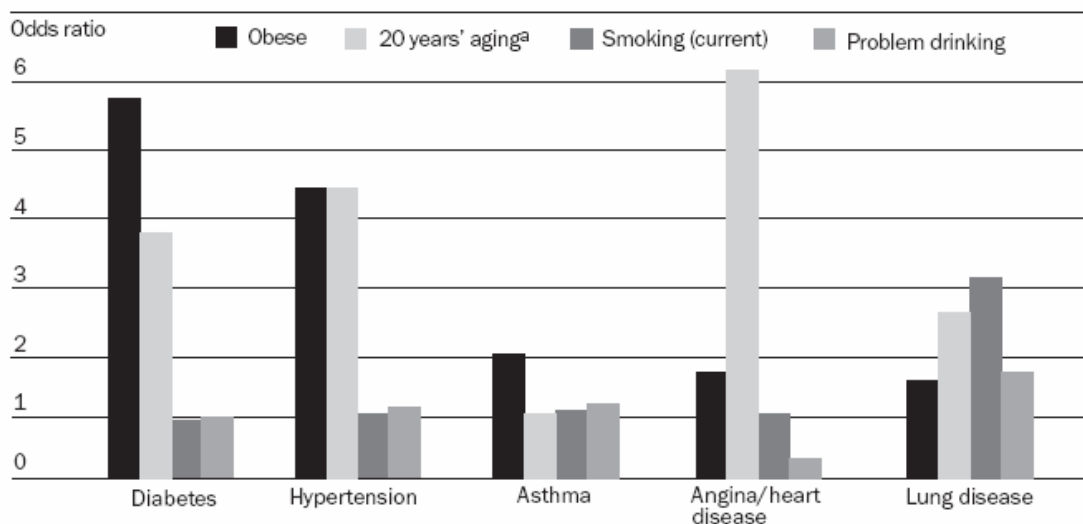


Figure 1 Odds Ratios For Selected Physical Conditions Related To Obesity, Aging, Smoking, And Drinking, 1998⁵.

The association between obesity and other co-morbidities does not end there however. Dixon has summarised current knowledge on obesity-related co-morbidities and the strength of the association of these co-morbidities and BMI⁶. **Table 1** summarises the long list of co-morbidities and the increases in relative risk of these co-morbidities in obese individuals.

Table 1 The relative risk of some of the co-morbidities, conditions and risks associated with obesity⁷

Relative Risk >5	Relative Risk 2 to 5	Relative Risk 1 to 2
Type 2 diabetes	All-cause mortality	Cancer mortality
Dyslipidemia	Hypertension	Breast cancer
Obstructive sleep apnea	Myocardial infarction and stroke	Prostate and colon cancer in men
Breathlessness	Endometrial carcinoma in women and hepatoma in men	Impaired fertility
Excessive daytime sleepiness	Gallstones and complications, incl. cancer	Obstetric complications, incl. fetal abnormalities
Obesity hypoventilation syndrome	Polycystic ovary syndrome	Asthma
Idiopathic intracranial hypertension	Osteoarthritis (knees)	Gastroesophageal reflux
Nonalcoholic steatohepatitis	Gout	Anesthetic risk

⁵ From Sturm R. The effects of obesity, smoking, and drinking on medical problems and costs (Author's calculation based on data from the Healthcare for Communities (HCC) survey, wave 1. a Twenty years' aging is from age thirty to age fifty.)

⁶ Dixon JB (2008) Referral for a Bariatric Surgical Consultation: It is Time to Set a Standard of Care. OBES SURG DOI 10.1007/s11695-008-9765-7.

⁷ From Dixon 2008 see previous footnote.



D. Is there a role for laparoscopic gastric banding in primary prevention?

Consistent with the terms of reference of the taskforce, this submission argues that LAGB could be considered as a part of a primary prevention framework for severely obese individuals with, for example, a BMI > 35 or a BMI > 40. This could be achieved by not considering obese individuals as a single homogenous population with a BMI above 30 kg/m², but rather discrete patient cohorts with differing levels of severity, defined by the risk of developing co-morbid conditions such as type 2 diabetes, as classified by the World Health Organisation (see **Table 2**). In this framework prevention of progression from Class 1 to 2 and 3 could be seen as important primary prevention, with a role for LAGB in prevention of both Class 2 and Class 3 obesity.

Table 2 Classification of BMI for Obese people 18 years and over

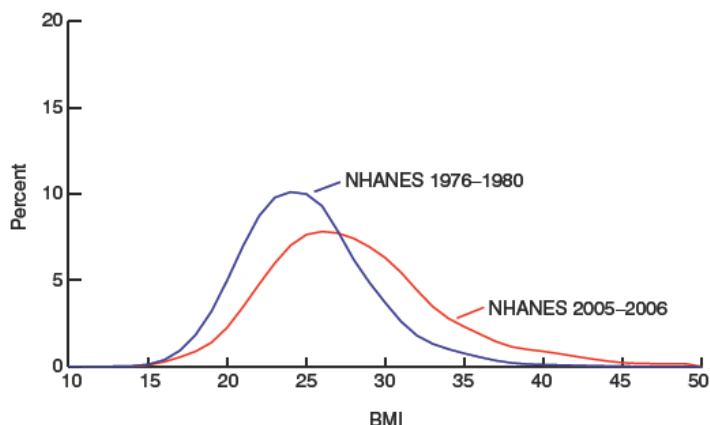
BMI (kg/m ²)	Classification	Risk of co-morbidities
30 or more	Obese	
30 to less than 35	Obese Class 1	Moderate
35 to less than 40	Obese Class 2	Severe
40 or more	Obese Class 3	Very Severe

Source: WHO 2000

D1. Primary prevention of Class 2 obesity (BMI> 35) or Class 3 obesity (BMI>40)?

The often cited community levels of overweight and obese individuals are concerning enough however they do not provide a complete picture of a more disturbing trend; a shift in the underlying BMI distribution, with a larger tail, at the very high BMI levels (see **Figure 2** for details⁸). **Figure 2** provides a summary of weight changes over time by comparing the distribution of BMI in 1976–1980 with the distribution in 2005–2006 for adults 20–74 years of age in the US. Between 1976–1980 and 2005–2006 the distribution of BMI shifted to the right but the shift was greatest at the upper percentiles of the distribution. This indicates that the entire adult population is heavier, and the heaviest have become much heavier since 1980. For the obese cohort, the average BMI was approximately 33 in 1980; this had increased to approximately 39 by 2006. Although it is US data, an identical trend is no doubt being replicated in Australia.

⁸ Ogden CL, Carroll MD, McDowell MA, Flegal KM. Obesity among adults in the United States— no change since 2003–2004. NCHS data brief no 1. Hyattsville, MD: National Center for Health Statistics. 2007.



SOURCE: CDC/NCHS, National Health and Nutrition Examination Survey (NHANES).

Figure 2 Changes in the distribution of body mass index (BMI) between 1976–1980 and 2005–2006, adults aged 20–74 years: United States⁹.

The implication of this shift in BMI is significant when mortality risk and BMI are examined. In 1999, Calle et al published results from a prospective study that followed more than 1 million US adults for 14 years (1982–1996)¹⁰. The findings of this study confirmed that even after adjusting for smoking and disease history (stroke, cancer, heart disease, respiratory disease, or current illness of any type), the relative risk of all-cause mortality increased dramatically with increasing BMI (see **Figure 3**). Outside of the normal BMI range of 18.5 to 24.9 kg/m², the RR of death increases with BMI. When one overlays the changes in BMI in the obese population over time, obese individuals in 1980 would have been, on average, at medium risk of increased mortality with a BMI of 33, whereas by 2006 they were at high risk of increased mortality by virtue of the increase in average BMI to 39. Clearly both the size and the risk within the obese cohort are rising dramatically over time.

⁹ See footnote 8.

¹⁰ Calle EE, Thun MJ, Petrelli JM, Rodriguez C, Heath CW, Jr. Body-mass index and mortality in a prospective cohort of U.S. adults. *N Engl J Med* 1999;341(15):1097-105.

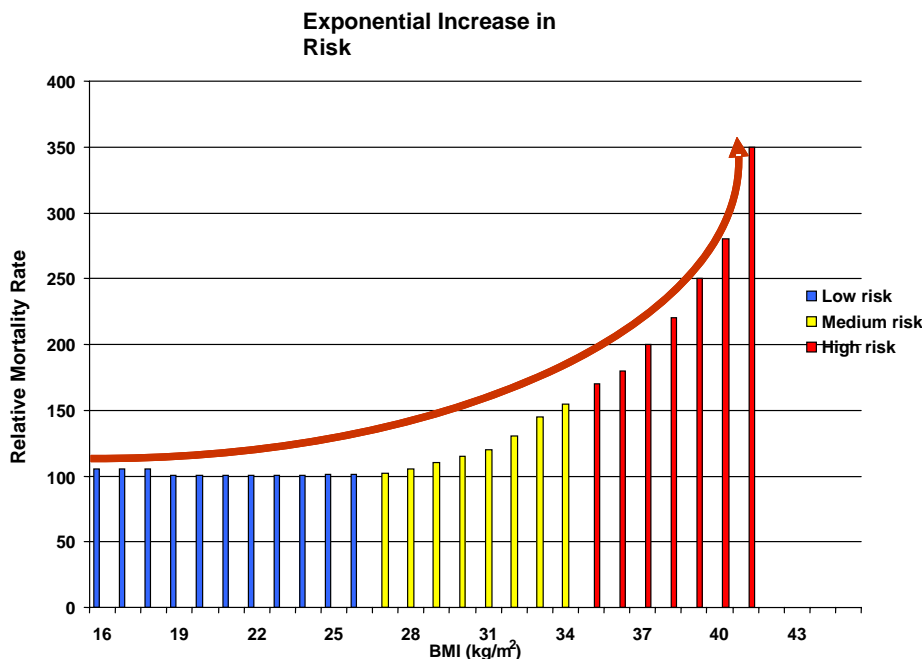


Figure 3 Relationship between mortality risk and BMI in the United States (from Calle et al., 1999).

In a comprehensive preventative framework even individuals that have become obese (i.e. Class 1) should be provided with some strategies to prevent further progression to severe obesity (Classes 2 and 3). There is strong evidence that treating patients with LAGB should they progress to Class 2 obesity will prevent further weight gain and also significantly reduce the risk and the presence of co-morbidities, such as diabetes. For example, a recent randomised, controlled study¹¹ provides a very valuable insight into the health impact of LAGB. The study was conducted in Australia and enrolled obese Type 2 diabetic patients with BMI's between 30 and 40 kg/m². One arm of the study received standard medical management (diet, exercise and pharmacotherapy) whilst the other arm received standard medical management and a gastric band. After two years, 73% of patients in the gastric band arm had remission of diabetes (normal glucose control and no diabetes medication) versus 13% in the medical management arm. This was associated with a mean reduction of baseline body weight of 20.0% (SD, 9.4%) in the surgical group and 1.4% (SD, 4.9%) in the control group (P<0.001). This represents a reduction in BMI from 36.9 to 29.5 in the surgical group compared with a reduction from 37.1 to 36.6 in the control group.

This study demonstrates that LAGB provides two important benefits in obese individuals, these are:

1. Reductions in the relative risk of all obesity related co-morbidities through significant reductions in BMI.

¹¹ Dixon JB, O'Brien PE, Playfair J, et al. Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial. *Jama* 2008;299(3):316-23.



2. Specific evidence that LAGB results in remission of diabetes in the treated population with a 60% absolute risk difference between LAGB (73% remission) and conventional management (13% remission).

Summary

There is a general consensus that the obesity epidemic in Australia must be addressed aggressively and expeditiously. Australia needs to adopt both a short and long term strategy to tackle the obesity epidemic. A long term preventive strategy achieved through education focused on a healthy diet and lifestyle, particularly in Australian children is clearly important. However, the current obesity pandemic must also be considered in the equation. It is critical that health administrators move beyond the view that obesity is a “life style” problem and that treatment based primarily on diet and exercise (+/- pharmacotherapy) is sufficient for this chronic, relapsing disorder. Rather, a more pragmatic position must be adopted to provide some real options that could assist patients in reducing their BMI and the risk of associated co-morbidities.

The LAGB has been demonstrated to be cost-effective in individuals with a BMI above 35 with a co-morbidity or with a BMI>40 without a co-morbidity. If it were a pharmacotherapy, this would have been sufficient to obtain a general listing on the PBS. However, as a device, virtually no public patients in Australia have access due to the current state-based decisions on health delivery and funding that has created a disconnect between identifying cost-effective hospital based interventions at a federal government level and effective delivery of such services in Australia. In 2007, for example, 96% of LAGB procedures occurred in private hospitals, in privately insured individuals, with the remaining procedures (300-400) conducted in public hospitals.

This submission argues that obesity and obese individuals should not be viewed as a single homogenous population. In a similar manner, prevention of obesity and prevention of increasing severity of obesity requires a comprehensive and pragmatic solution. Clearly, prevention of obesity per se is a priority but it must also be considered that prevention of movement of obese individuals from Obese Class 1 to Class 2 and Class 3 has significant implications to both health care costs in Australia but also for the health and quality of life of obese individuals. In this more comprehensive framework, LAGB could be viewed as primary prevention to reduce the levels of severe obesity. The sponsor believes there is a strong rationale for including the LAGB as an important element of a preventative framework for individuals with severe obesity where other preventative approaches have not been successful.