



Australian Government

Department of Health and Ageing



Protocol for reviewing existing MBS items

Quality Framework Review #2

Review name: Items for the surgical
treatment of obesity

Final - December 2010

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Glossary

ABS	Australian Bureau of Statistics
AIHW	Australian Institute of Health and Welfare
BPD-DS	biliopancreatic diversion with duodenal switch
BEACH	Bettering the Evaluation and Care of Health
BMI	body mass index
CWG	Clinical Working Group
DALY	disability adjusted life year
DOHA	Department of Health and Ageing
ICER	incremental cost effectiveness ratio
GDP	gross domestic product
LAGB	laparoscopic adjustable gastric banding
MBS	Medicare Benefits Schedule
MQFEAC	MBS Quality Framework Expert Advisory Committee
NHMRC	National Health and Medical Research Council
QALY	quality-adjusted life years
RCT	randomised controlled trial
RR	relative risk
RYGB	roux-en-Y gastric bypass
SAND	Supplementary Analysis of Nominated Data
SG	sleeve gastrectomy
SPANS	Schools Physical Activity and Nutrition Survey
UK	United Kingdom
US	United States
VBG	vertical banded gastroplasty
WHO	World Health Organization

1 Introduction to Quality Framework Reviews

In the 2009-10 Budget, the Australian Government agreed to put in place a new evidence-based framework for managing the Medicare Benefits Schedule (MBS) into the future through the measure: *'Medicare Benefits Schedule – A quality framework for reviewing services'* (MBS Quality Framework). A key component of the Framework is implementing a systematic approach to reviewing existing MBS items to ensure they reflect contemporary evidence, offer improved health outcomes for patients and represent value for money. A primary objective is identifying and evaluating current MBS services that present potential safety and quality issues, and identifying opportunities to encourage more appropriate clinical practice.

Access Economics, as part of its contract with the Department of Health and Ageing (DoHA), will undertake a review of the evidence relating to surgical intervention for the treatment of obesity, with the aim of aligning the existing MBS obesity items with current evidence and clinical best practice.

1.1 Principles to guide MBS reviews

MBS Quality Framework reviews are underpinned by the following key principles:

- reviews have a primary focus on improving health outcomes and the financial sustainability of the MBS, through consideration of areas potentially representing:
 - patient safety risk;
 - limited health benefit; and/or
 - inappropriate use (under or over use).
- reviews are evidence-based, fit-for-purpose and consider all relevant data sources;
- reviews are conducted in consultation with key stakeholders including, but not limited to, the medical profession and consumers;
- review topics are made public, with identified opportunities for public submission and outcomes of reviews published;
- reviews are independent of Government financing decisions and may result in recommendations representing costs or savings to the MBS, as appropriate, based on the evidence;
- secondary investment strategies to facilitate evidence-based changes in clinical practice are considered; and
- review activity represents efficient use of Government resources.

1.2 Purpose of this document

This document is intended to outline the methodology in providing evidence based analysis to support the review of MBS surgical obesity items 14215, 30511, 30512, 30514 and 30518. To this original list, Item 31441 has subsequently been added.

The objectives of the protocol are to:

- define the relevant clinical questions that the review will focus on;

-
- clarify the role of existing MBS service/items in current clinical practice;
 - clarify the mechanisms for identifying evidence and provide an opportunity for discussion of clinical and methodological issues;
 - clarify timelines associated with this project; and
 - clarify roles and responsibilities of key stakeholders.

1.3 Objectives of the review

To carry out an evidence-based assessment of MBS surgical obesity items to inform ongoing Government decisions in relation to MBS funding for these services¹.

¹ This review focuses on surgical interventions for the treatment of obesity only. Evidence-based assessment of non-surgical treatment of obesity including diet and exercise, behavioural treatments and pharmacotherapy are beyond the scope of this review. However, non- surgical interventions for the management of obesity are commonly considered conventional therapy and thus are included as a comparator in the economic evaluation.

2 Background on surgical items for obesity

2.1 Description of the current services

This section provides an outline of:

- the MBS services being reviewed, including item numbers and a description of the service;
- the conditions/diseases the services are used to monitor/treat/diagnose;
- service delivery setting;
- type of service provider or providers; and
- year of adoption into the Australian health system where available (e.g. approval by relevant bodies, year of introduction to Medicare, any major amendments to items).

2.1.1 Service item descriptors

The MBS services being reviewed are summarised in Table 2.1.

Table 2.1: MBS services being reviewed

MBS item	Item description
14215	LONG-TERM IMPLANTED RESERVOIR associated with the adjustable gastric band, accessing of to add or remove fluid (<i>for adding or removing fluid via the implanted reservoir to adjust the tightness of the gastric band</i>)
30511	MORBID OBESITY, gastric reduction or gastroplasty for, by any method (Anaes.) (Assist.)
30512	MORBID OBESITY, gastric bypass for, by any method including anastomosis (Anaes.) (Assist.)
30514	MORBID OBESITY, surgical reversal, by any method, of procedure to which item 30511 or 30512 applies (Anaes.) (Assist.) Revision of gastric procedure, for example to correct misplacement of the gastric band or other adverse effects of the initial surgery, involves complete reversal of the initial surgery immediately followed by another reduction, gastroplasty or bypass procedure. For revision item 30514 can be claimed with either item 30511 or 30512, whichever is relevant. For cases where division of adhesions exceeds 45 minutes either item 30378 (laparotomy) or item 30393 (laparoscopy) can also be claimed.
30518	PARTIAL GASTRECTOMY (Anaes.) (Assist.)
31441	LONG-TERM IMPLANTED RESERVOIR associated with the adjustable gastric band, repair, revision or replacement of (Anaes.)

Source: MBS.

2.1.2 The indication – clinically severe obesity

Obesity is a disease in which fat has accumulated to the point where health is impaired.

Obesity is the accumulation of excess fat in the body, defined here in terms of Body Mass Index (BMI) over 30 for adults and, for children and adolescents aged 2 to 18 years, a set of age-gender specific BMI thresholds.

BMI is the most commonly used measure of obesity and is calculated as the ratio of weight in kilograms to the square of height in metres.

$$BMI = weight (kg) / [height (m)]^2$$

For adults, weight classifications based on BMI are as follows, used in the Australian Bureau of Statistics (ABS) National Health Survey.

- Underweight <18.5
- Normal range 18.5 to < 20.0 and 20.0 to < 25.0
- Overweight 25.0 to < 30.0
- Obese ≥ 30.0
- The World Health Organization (WHO) categorizes obesity into three categories: Class I obesity 30.0 to <35.0;
- Class II obesity 35.0<40.0; and
- Class III obesity ≥ 40.0.

Class III obesity is further disaggregated into further categories.

- Clinically severe obesity (or morbid obesity²) ≥ 40, or between 35 and 40 where there are other major medical conditions such as high blood pressure and diabetes (DoHA, 2003).
- Super obese ≥ 45 or 50 (Sturm R, 2007)

These weight classifications are not necessarily suitable for all ethnic groups. For example, at the existing BMI cut-off point for overweight, there is a higher proportion of Asian people who are at high risk of type 2 diabetes and cardiovascular disease (WHO, 2010). Cut-off points vary between different Asian populations: overweight is between BMI of 22.0 and 25.0 while obese varies from BMI 26.0 to 31.0 (WHO, 2010). In addition, the Australian Institute of Health and Welfare (AIHW, 2006) notes that Polynesians would not be considered obese until they reached a higher BMI cut-off.

For children and adolescents (2-18 years), a set of age and gender specific BMI-thresholds have been developed for epidemiological purposes. These thresholds were developed by Cole et al

² The National Institutes of Health in the United States (US) suggests that the term 'clinically severe obesity' be used rather than 'morbid obesity'. The current guidelines in Australia and the MBS still use 'morbid obesity'. In this protocol, the term 'clinically severe obesity' is used from here on, in line with the NIH and CWG recommendation.

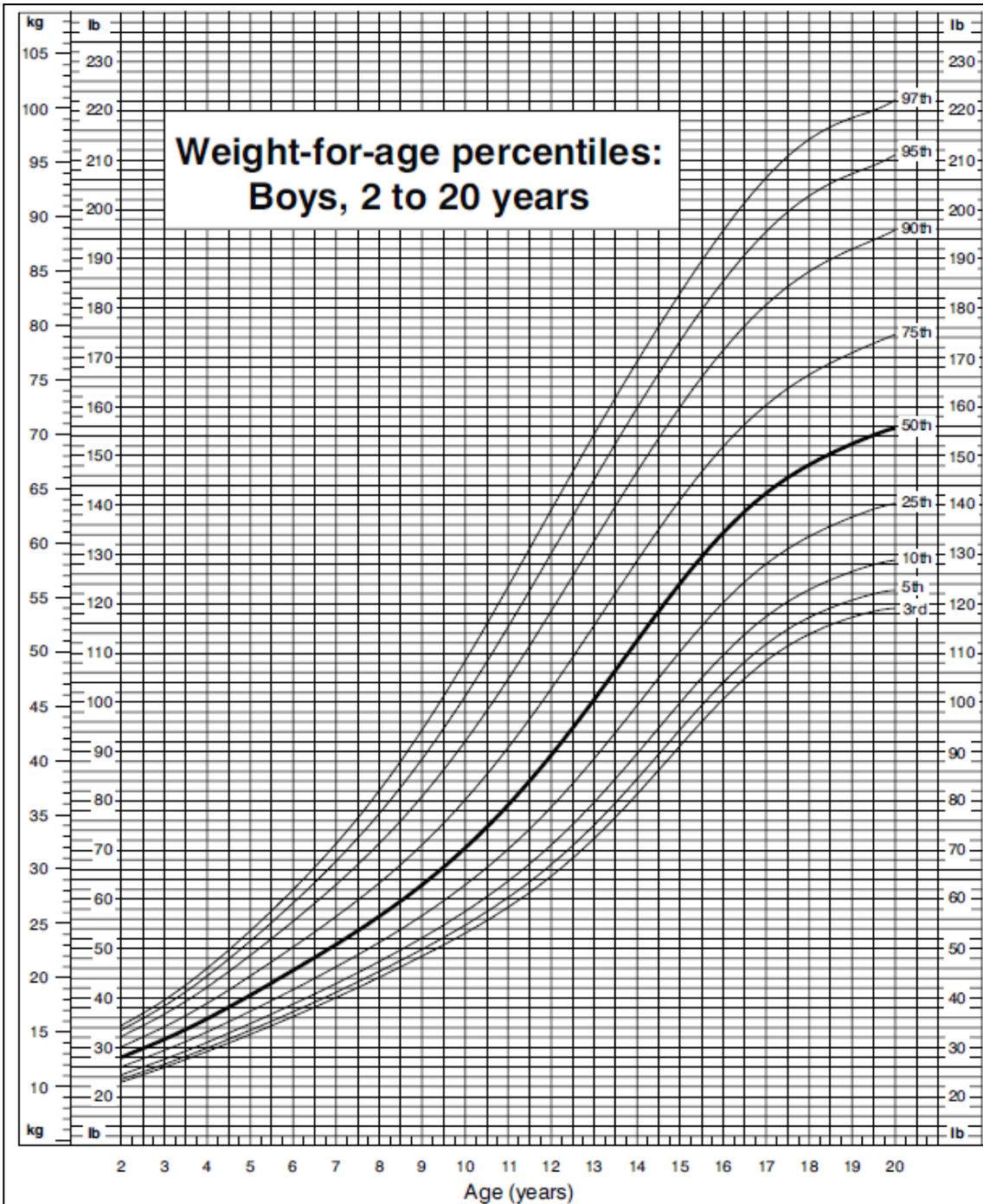
(2000) and are based on data from Brazil, Great Britain, Hong Kong, the Netherlands, Singapore and the United States, aligning with the adult obesity threshold of 30 kg/m² by age of 18 years. The thresholds have been accepted as the international reference standard for comparing obesity in children and adolescents for population and clinical research purposes (Table 2.2). In clinical practice, Australia adopts BMI-for-age charts from the US Centres for Disease Control and Prevention (CDC, 2000) to assess weight in relation to age for children and adolescents below the age of 18 years (Chart 2.1 and Chart 2.2). The percentile charts identify children with a BMI ranging between the 85th and 95th percentile as 'at risk of overweight' and those children with BMI values above or equal to the 95th percentile as obese (Denney-Wilson 2003, DoHA 2003a).

Table 2.2: Age and gender thresholds for overweight and obesity in children and adolescents

Age (years)	Body mass Index 25 kg/m ²		Body mass Index 30 kg/m ²	
	Males	Females	Males	Females
2	18.41	18.02	20.09	19.81
2.5	18.13	17.76	19.80	19.55
3	17.89	17.56	19.57	19.36
3.5	17.69	17.40	19.39	19.23
4	17.55	17.28	19.29	19.15
4.5	17.47	17.19	19.26	19.12
5	17.42	17.15	19.30	19.17
5.5	17.45	17.20	19.47	19.34
6	17.55	17.34	19.78	19.65
6.5	17.71	17.53	20.23	20.08
7	17.92	17.75	20.63	20.51
7.5	18.16	18.03	21.09	21.01
8	18.44	18.35	21.60	21.57
8.5	18.76	18.69	22.17	22.18
9	19.10	19.07	22.77	22.81
9.5	19.46	19.45	23.39	23.46
10	19.84	19.86	24.00	24.11
10.5	20.20	20.29	24.57	24.77
11	20.55	20.74	25.10	25.42
11.5	20.89	21.20	25.58	26.05
12	21.22	21.68	26.02	26.67
12.5	21.56	22.14	26.43	27.24
13	21.91	22.58	26.84	27.76
13.5	22.27	22.98	27.25	28.20
14	22.62	23.34	27.63	28.57
14.5	22.96	23.66	27.98	28.87
15	23.29	23.94	28.30	29.11
15.5	23.60	24.17	28.60	29.29
16	23.90	24.37	28.88	29.43
16.5	24.19	24.54	29.14	29.56
17	24.46	24.70	29.41	29.69
17.5	24.73	24.85	29.70	29.84
18	25	25	30	30

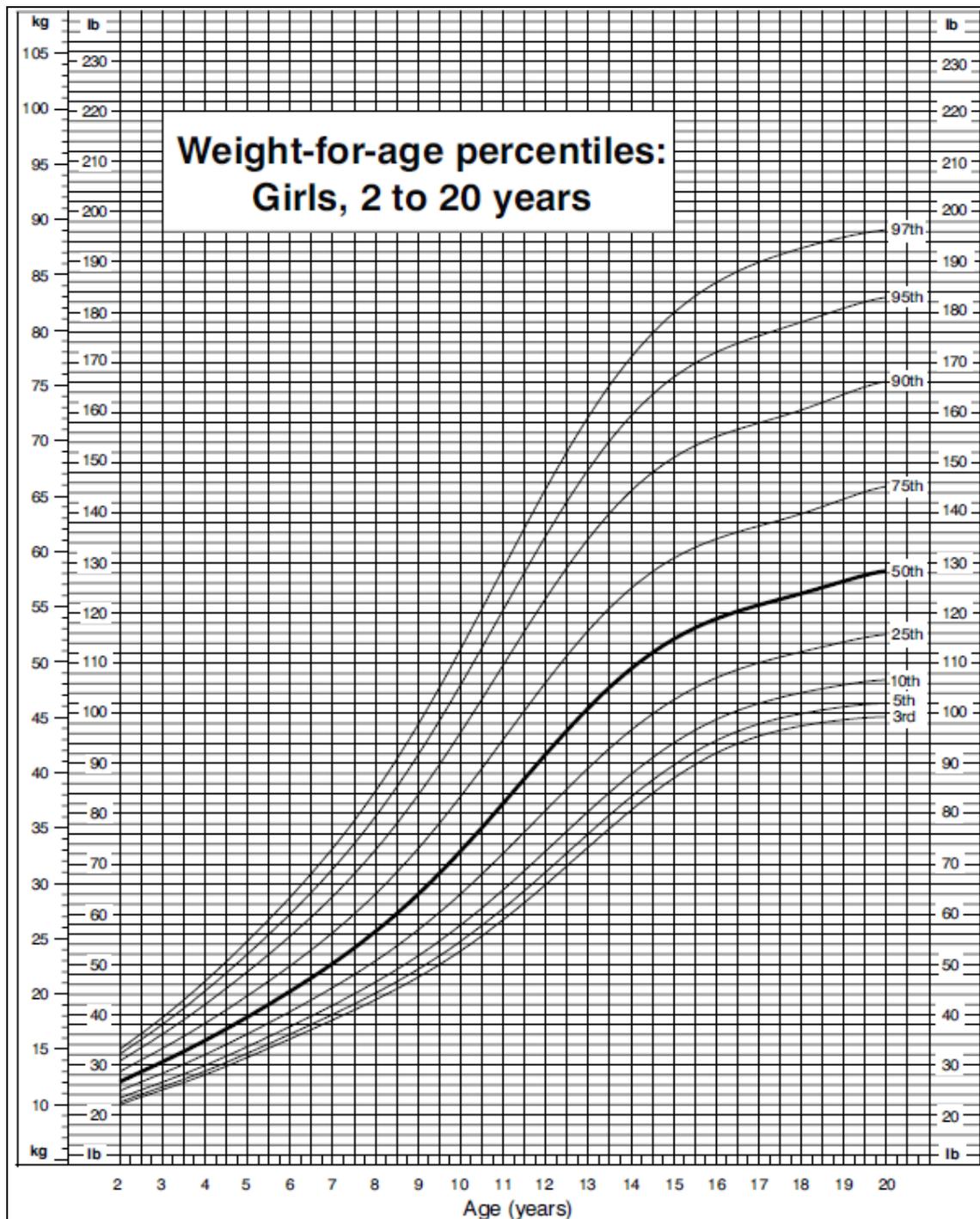
Source: Cole et al (2000)

Chart 2.1: Weight-for-age percentiles for boys



Source: CDC 2000.

Chart 2.2: Weight-for-age percentiles for girls



Source: CDC 2000.

While BMI is by far the most commonly reported measure of obesity, a number of measures which reflect the distribution of fat stored in the body are also popular. Centrally distributed fat has been found to be a better indicator of metabolic risks for a range of diseases (such as cardiovascular disease, type 2 diabetes, and cancer) than total body mass when BMI is below 35 (DoHA, 2003b). Measures of weight distribution are technically measures of a subset of obesity known as abdominal obesity or central adiposity. These measures include the waist-

to-hip ratio, and waist circumference (Ebbeling et al, 2002). Cut-offs for waist circumference values associated with an increased risk of metabolic complications are provided in Table 2.3.

Table 2.3: Waist circumference cut-offs correlated to disease risk

Risk of metabolic complications	Males	Females
Increased	94.0-101.9 cm	80.0-87.9 cm
Substantially increased	≥102.0 cm	≥88.0 cm

Source: DoHA 2003b.

People who are obese have higher rates of mortality and morbidity than those who have a healthy body weight, with a high body mass index (BMI) responsible for 7.5% of the total burden of disease in 2003 (Begg et al, 2007). Being overweight increases the relative risk of a variety of conditions which affect health and quality of life (see Table 2.4). Obesity causes almost one-quarter of type 2 diabetes (23.8%) and osteoarthritis (24.5%), and around one-fifth of cardiovascular disease (21.3%) and colorectal, breast, uterine and kidney cancer (20.5%) (Preventative Health Taskforce, 2009).

Table 2.4: Diseases and conditions associated with obesity

Relative risk (RR)	Associated with metabolic consequences	Associated with excess weight
Greatly increased (RR>3)	Type 2 diabetes	Sleep apnoea
	Gall bladder disease	Breathlessness
	Hypertension	Asthma
	Dyslipidaemia	Social isolation and depression
	Insulin resistance	Daytime sleepiness and fatigue
	Non-alcoholic fatty liver disease	
Moderately increased (RR 2-3)	Coronary hear disease	Osteoarthritis
	Stroke	Respiratory disease
	Gout/hyperuricaemia	Hernia
		Psychological problems
Slightly increased (RR 1-2)	Cancer (breast, endometrial, colon and others)	Varicose veins
	Reproductive abnormalities/impaired fertility	Musculoskeletal problems
	Polycystic ovaries	Bad back
	Skin complications	Stress incontinence
	Cataract	Oedema/cellulitis

Source: DoHA (2003).

Weight loss can reduce the severity of some of these conditions, as well as improving cholesterol levels, blood pressure and glycaemic control and decreasing the symptoms of osteoarthritis.

2.1.3 The service delivery setting, providers and health system adoption

While weight management through diet and exercise is first line therapy, with a role also for pharmacological management, there is evidence that bariatric surgery plays a part in treating

people who are clinically severely obese and have not been able to achieve long-term weight loss through more conservative means (Access Economics, 2008).

The current clinical practice guidelines recommend bariatric surgery as a management strategy in clinically severe obese children and adolescents, and recommend that it should only be pursued in tertiary institutions with specialist obesity services, where appropriate assessment, therapy planning and multi-disciplinary support are available (DoHA, 2003).

Increased prevalence of clinically severe obesity (DoHA, 2003) and community awareness of the effectiveness of surgery in producing weight loss have led to growing demand for bariatric surgery in the public hospital system.

In the community setting, gastric reduction or gastroplasty (Item 30511), gastric bypass (30512), surgical reversal (30514) and partial gastrectomy (30518) have been subsidised under the MBS since 1992, while the reservoir items (14215 and 31441) were added in 1999.

2.2 Context

This section provides an outline of;

- incidence and prevalence of the diseases or conditions for which the services are provided;
- MBS usage and expenditure;
- alternate MBS funded services/comparator services;
- other potentially impacted services; and
- any other relevant information.

2.2.1 Prevalence of obesity

Obesity is considered one of the greatest public health challenges confronting Australia and many other industrialised countries. Even among developed nations, Australia is one of the most overweight, with over 60% of adults and one in four children overweight or obese, according to the Preventative Health Taskforce (2009).

Access Economics (2008) estimated the prevalence of obesity in Australia based on Australian measured anthropomorphic data from the 2000 AusDiab dataset (International Diabetes Institute, 2001) and from the NSW Schools Physical Activity and Nutrition Survey (SPANS, 2004) study for children (Booth et al, 2006, 2003), together with and self-reported data from the 2006-07 Supplementary Analysis of Nominated Data (SAND) from the general practice study, *Bettering the Evaluation and Care of Health* (BEACH).³ Due to a lack of definitive data, obesity rates were conservatively assumed to be 0% for children under the age of four years, increasing with age thereafter to peak in the 55-64 year age group, thereafter falling (Table 2.5).

³ Other data sources were investigated but rejected for various reasons (e.g. age), including the National Nutrition Study (1995) and the Child and Adolescent Physical Activity and Nutrition Survey in Western Australia.

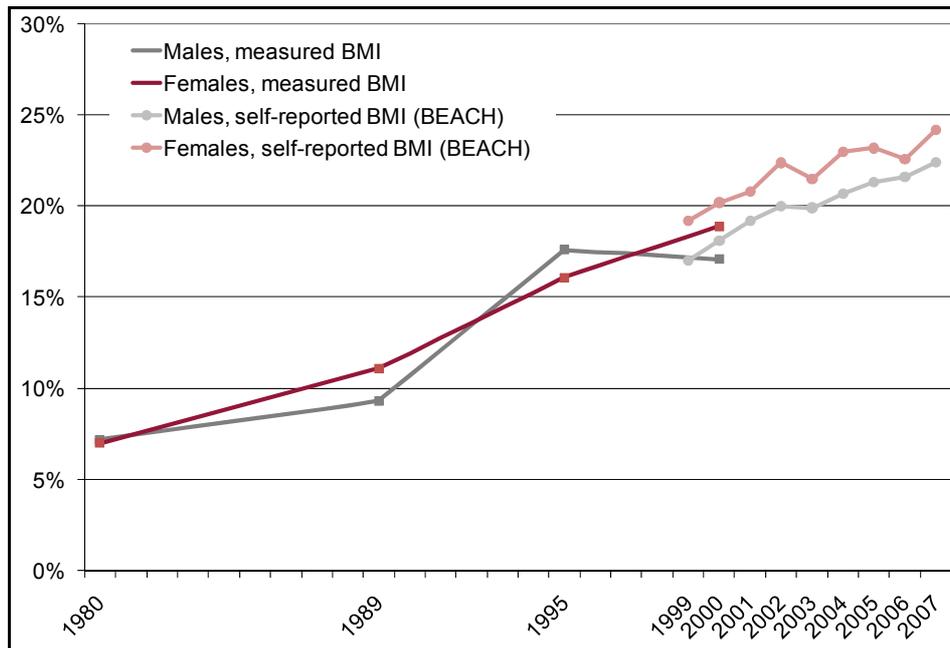
Table 2.5: Prevalence rates for obesity by age and gender

Age Group	Males (%)	Females (%)	Males ('000)	Females ('000)	Total ('000)
0-4	0%	0%	0	0	0
5-19	7.8%	6.2%	165.4	124.9	290.3
20-24	11.1%	9.3%	84.7	68.2	152.9
25-34	19.4%	13.5%	281.8	193.0	474.8
35-44	19.9%	21.2%	301.5	324.6	626.1
45-54	23.2%	29.2%	338.6	430.8	769.4
55-64	28.5%	35.6%	344.9	431.7	776.6
65-74	22.2%	31.9%	164.4	244.2	408.6
75+	14.2%	16.9%	79.6	134.3	213.9
Total	16.5%	18.5%	1,760.8	1,951.8	3,712.5

Source: Access Economics (2008).

The table shows that, combining these prevalence rates with demographic data from the ABS, in 2008, 3.71 million Australians (17.5%) were estimated to be obese. Historically, rates of obesity have been increasing (Chart 2.3).

Chart 2.3: Trends in obesity prevalence for adults, 1980 to 2007



Source: Access Economics (2008).

By 2025, a total of 4.6 million Australians (18.3% of the population) are projected to be obese on current trends (Access Economics, 2008).

2.2.2 MBS expenditure on the review items

MBS expenditure by item is shown in Table 2.6 with growth rates in the five items averaging well over 30% per annum, more than three times the growth rates in total MBS expenditures. In current dollar terms, expenditure has increased from \$6.3 million in 2005 on the six items to \$19.3 million in 2009. Data for the review itself will include data up to the 2009-10 year.

Table 2.6: MBS expenditure by item

	2005	2006	2007	2008	2009
14215 (\$'000)	2,754	3,872	5,251	7,808	9,785
30511 (\$'000)	2,686	3,324	4,806	6,990	6,732
30512 (\$'000)	127	170	143	136	156
30514 (\$'000)	538	747	1,093	1,403	1,861
30518 (\$'000)	90	141	213	449	579
31441 (\$'000)	75	90	106	133	170
Total items (\$ million)	6.3	8.3	11.6	16.9	19.3
Growth (%)	41.4	33.1	39.2	45.7	14.0
MBS Total (\$ billion)	10.6	11.3	12.4	13.7	15.1
Growth in MBS (%)	14.5	6.4	9.9	10.7	10.1

Source: MBS online data. Note: Item number 30518 may be claimed for other purpose not related to bariatric surgery.

2.2.3 Alternate and other impacted MBS services

The downstream impacts of obesity (diabetes, cardiovascular disease, cancers and osteoarthritis), affect other MBS items and health system expenditures. The total financial costs of obesity in Australia in 2008 were estimated as \$8.3 billion (Access Economics, 2008). Of these costs, the Australian Government bears over one-third (34.3% or \$2.8 billion per annum), and state governments 5.1%.

In addition, while performing bariatric surgery it is important for surgeons to find and repair hiatus hernia as this greatly reduces the rate of complications (e.g. reflux) post surgery. Clinical experts suggested that hernia is located in around one quarter to one half of patients undergoing surgery. As such, this review will also examine items claimed on the same day as the bariatric surgery with a patient and surgeon match. This may reveal other linked items such as:

- 31468 - repair of PARA-OESOPHAGEAL HIATUS HERNIA, with complete reduction of hernia, resection of sac and repair of hiatus, with or without fundoplication.

2.3 Justification for review

This section provides an outline of:

- the review identification mechanism; and
- key issues raised to date.

2.3.1 The review identification mechanism

The demonstration reviews were identified, having regard to current literature, as presenting potential quality and safety concerns or the opportunity to encourage more appropriate clinical use. The review of the surgical items for the treatment of obesity will inform recommendations aimed at strengthening the evidence-base of the items and their use.

The systematic approach to reviewing existing MBS items, in the context of the MBS Quality Framework, will commence with several demonstration reviews to test the proposed review process. This review will serve as one of these demonstration reviews. The report will be completed by mid-February 2011 and review outcomes will feed into the 2011-12 budget process.

2.3.2 Key issues to date

Currently the existing MBS descriptors for surgical treatment of obesity do not:

- define morbid obesity; or
- place any restrictions on the use of procedures, potentially hindering compliance with clinical best practice by not distinguishing procedures which are:
 - more safe or efficacious;
 - more cost effective; or
 - only so in a particular target population.

Given that bariatric surgery is a significant procedure with potential complications, the provision of bariatric surgery should be targeted to patients for whom the benefits of surgery clearly outweigh the risks. By strengthening the evidence base for the safety, effectiveness and cost-effectiveness of each of the surgical procedures for the treatment of bariatric surgery, rational, consistent and equitable access to bariatric surgery can be promoted. It is expected that by offering only high quality bariatric surgery programs to carefully selected patients, health outcomes can be improved and the financial sustainability of the MBS can be maintained.

3 Clinical/research questions

This section outlines the process for defining the clinical questions for the review.

The PICO criteria are used to develop the clinical questions. The four elements of the PICO criteria are:

- the target **population** for the intervention;
- the **intervention** being considered;
- the **comparator** for the existing MBS service (where relevant); and
- the clinical **outcomes** that are most relevant to assess safety and effectiveness.

A key aim of the stakeholder consultations and literature review, described in chapters 4 and 5 respectively, will be to better define these clinical questions in terms of the specific populations, interventions, comparators, and outcomes relevant for Australian practice. This chapter therefore presents the clinical research questions in more general terms. This review includes several interventions (MBS items) and comparators for surgical interventions for obesity.

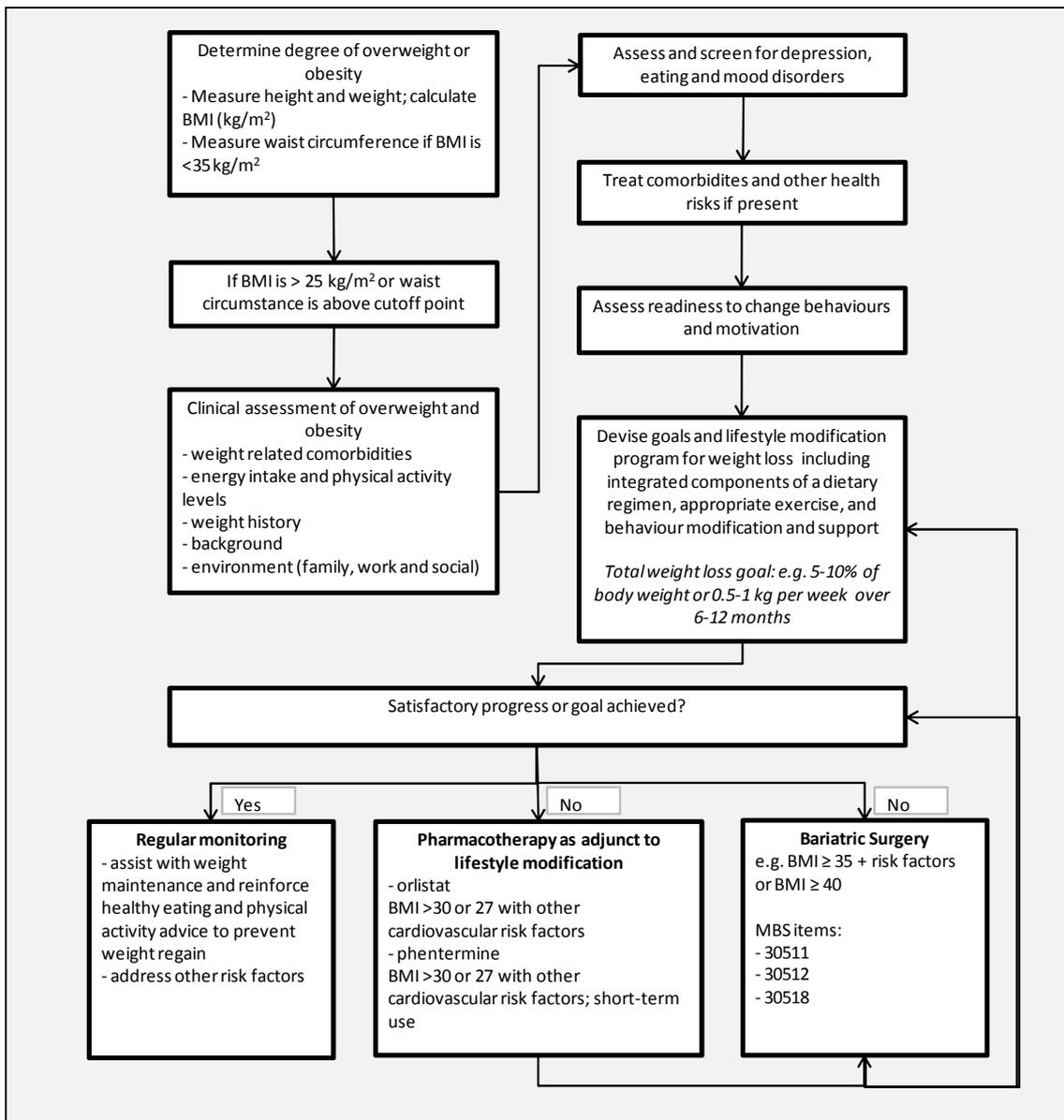
3.1 Population

The target population is identified by breaking down larger populations into those relevant for each intervention.

The overall population is Australians obtaining care under the MBS. The most recent Australian clinical practice guidelines (currently under review) indicate bariatric surgery for adults with a BMI greater than 40 or with a BMI greater than 35 and serious medical comorbidities who have instituted but failed adequate non-operative measures for weight loss with integrated components of a dietary regimen, appropriate exercise, and behaviour modification and support (see Figure 3.1) (DoHA 2003b).

In overweight and obese children and adolescents, bariatric surgery is considered as a non-conventional weight-management strategy. Currently, there are no published guidelines for bariatric surgery in children and adolescents (DoHA 2003a). However, the more recent published position paper (ANZAPS/OSSANZ/RACP 2010) recommends that surgical treatment should only be considered, along with other criteria, in adolescents with severe obesity (BMI greater than 40 or a BMI greater than 35 with severe obesity associated complications) who are over the minimum age of 15 years. All candidates for surgery need to be carefully assessed by a multi-disciplinary team. The stakeholder consultations and literature review detailed in chapters 4 and 5 would confirm the target population for each of the interventions, which may be subsets of the above population.

Figure 3.1: Clinical decision pathway for the management of the overweight or obese person

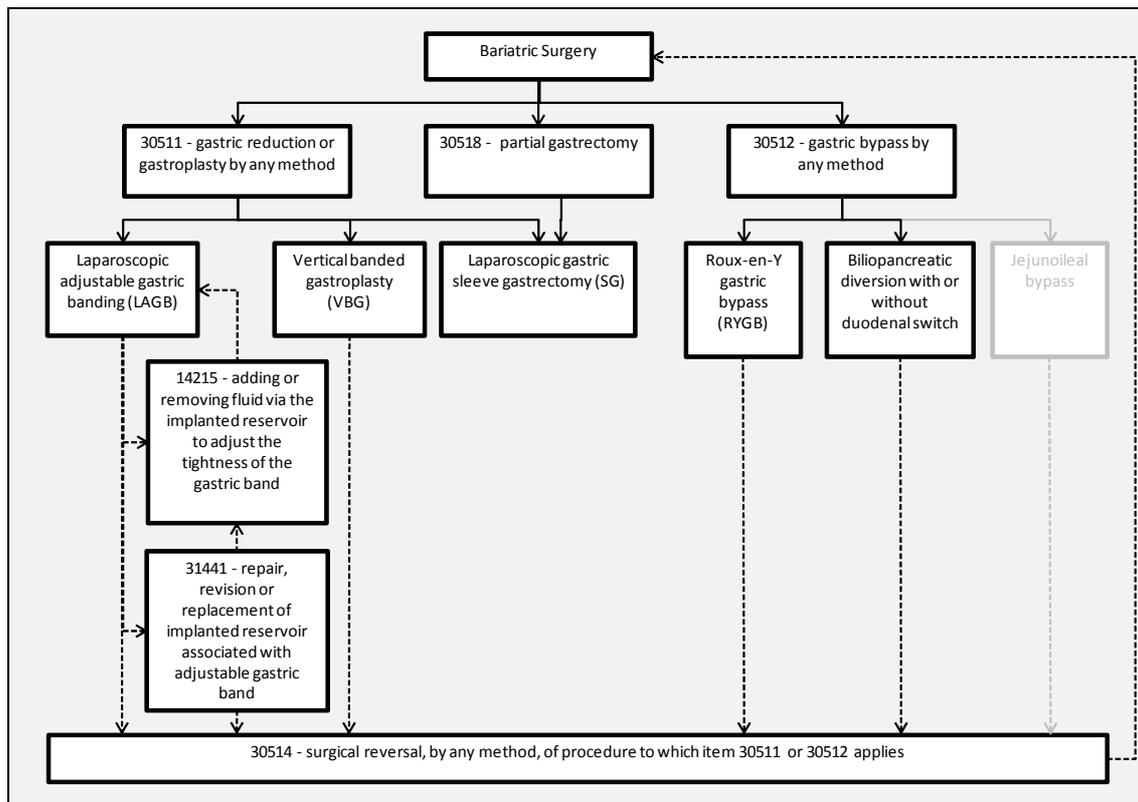


Source: DoHA 2003b. Note: The validity of this preliminary flowchart would be confirmed as part of the review of clinical guidelines.

3.2 Intervention

The interventions being considered are surgical procedures for obesity that are currently practised in Australia and with the MBS item numbers under review (listed in Table 2.1). Figure 3.2 illustrates the possible patient pathways through the current MBS item numbers.

Figure 3.2: Flowchart of patient pathway through MBS items under review



Source: CWG. Note: The validity of this preliminary flowchart would be confirmed as part of the review of clinical guidelines. Dotted line indicates 'if required'. Note: Roux-en-Y gastric bypass (RYGB) includes open and laparoscopic RYGB with or without duodenal switch.

Some of these MBS items include a range of different procedures, for example:

- item 30511 includes laparoscopic adjustable gastric banding (LAGB), vertical banded gastroplasty (VBG) and sleeve gastrectomy (SG); and
- item 30512 includes roux-en-Y gastric bypass (RYGB), biliopancreatic diversion with duodenal switch (BPD-DS) and jejunioileal bypass.

On the other hand, for some procedures, various item numbers may be used. For example sleeve gastrectomy (SG) may be claimed under item 30511 (as above) or item 30518.

The complexity of the MBS data do not permit breakdown of service numbers into specific types of surgical procedure, nor enable a reclassification of item numbers. However, research conducted during the review, including discussions with the CWG members and stakeholders, may enable an approximation of the relative proportions of different procedures performed under each of these item numbers.

A key aim of the stakeholder consultations and literature review will be to determine which of these procedures are performed in Australia. This will assist in defining precisely the interventions included in the clinical research questions presented in section 3.5.

3.3 Comparator

The safety and efficacy of bariatric procedures currently used in Australia will be evaluated against one another using the following comparators:

1. non-surgical intervention;
2. LAGB; and
3. other relevant comparators as identified in the literature review and data analysis.

Non-surgical treatment comprises various combinations of behaviour modification (including exercise), pharmacotherapy and/or low-energy or very low-energy diets and in some instances, no treatment. The comparator will enable the interventions to be compared with each other (including LAGB) in terms of their absolute safety and efficacy.

Surgical procedures in current use would also be compared with LAGB (an intervention as well as a comparator) as this is by far the most widely used technique in Australian, making up the large majority of all procedures (DoHA, 2003). This comparator will enable other interventions to be compared with the most common current practice regarding the target population for whom bariatric surgery is indicated.

Other comparators in the literature and analysis will also be reviewed for relevance for the economic evaluation (see section 5.4).

3.4 Outcomes

Safety of the various bariatric procedures would be assessed in terms of procedure-related complications and adverse events. Procedural specific risks associated with bariatric surgery would be evaluated based on:

- rate of converting laparoscopic to open procedure;
- rate of reoperation;
- post-operative length of hospital stay;
- short-and long-term procedural specific and non-specific morbidity associated with surgery to be identified in the literature review;
- mortality (short term e.g. 90 days mortality, and long term e.g. 10 years mortality); and
- any other adverse events identified during the literature review and stakeholder consultation process.

Procedural specific benefits associated with bariatric surgery would be evaluated based on:

- weight loss, measured as percentage of starting weight, an absolute weight loss, or 'excess weight' (relative to a normal BMI);
- maintenance of weight loss (durations used to define clinically relevant outcomes will be established during the review);
- quality of life;
- improvement in and resolution of obesity-related comorbidities (e.g. diabetes mellitus, hypertension and hyperlipidaemia); and

- any other relevant efficacy outcomes identified during the literature review and stakeholder consultation process.

3.5 Research questions

The research questions for this review are determined using the PICO criteria (section 3.1 to section 3.4). Listed below are the generalised research questions for this review. These will be refined during the review as information on each of the PICO criteria is evaluated in more detail. For example, safety and effectiveness would be measured based on the risks and benefits mentioned in section 3.4, and the populations, interventions, and comparators included under these questions would be defined based on Australian best practice.

- What is the safety of LAGB, VBG, SG and RYGB compared to non-surgical treatment of obesity?
- What is the safety of VBG, SG and RYGB compared to LAGB in the treatment of obesity?
- What is the effectiveness of LAGB, VBG, SG and RYGB compared to non-surgical treatment of obesity?
- What is the effectiveness of VBG, SG and RYGB compared to LAGB in the treatment of obesity?

4 Key stakeholders

This chapter identifies all key stakeholders involved in the review, including their roles and responsibilities. For each stakeholder in each section of the chapter, an engagement strategy is summarised.

4.1 Clinical Working Group

A Clinical Working Group (CWG) has been established for the duration of the review which comprises:

- Professor Joe Proietto, CWG (nominated by Royal Australasian College of Physicians);
- Associate Professor John Dixon, CWG, NHMRC Senior Research Fellow, Obesity Research (nominated by Obesity Surgery Society of Australia and New Zealand);
- Dr Ken Loi (nominated by Obesity Surgery Society of Australia and New Zealand);
- Dr Anthony Moore, Clinical Advisor, DoHA; and
- Craig Rayner Director, Medical Benefits Reviews Task Group, DOHA (chair).

In addition, Professor Louise Baur is a clinical expert on the Access Economics team. The CWG held its first meeting on 26 August.

The CWG will ensure that the review reflects an understanding of current Australian clinical practice and draws valid conclusions from the available evidence. The CWG will be given the opportunity to comment on this review protocol and on the final report, but will not make recommendations on future financing arrangements.

4.2 Clinical craft groups and others

Clinical craft groups representing those that provide the MBS services under review are a key stakeholder. This draft protocol and the draft review report will be uploaded to the DoHA website and as such there are no exclusions from the consultation process. DoHA has identified a number of organisations, including clinical craft groups, who will be notified in writing of the review and asked to comment on this draft protocol and again on the draft review report. Stakeholder details are withheld from this protocol due to confidentiality.

Access Economics will incorporate comments on this draft protocol and the draft report in the final versions of each document. Any one-on-one consultations requested and approved by DoHA would be undertaken using teleconference facilities on an as-needed basis. Any subsequent follow-up from such stakeholder meetings would be undertaken through individual telephone meetings and email.

4.3 Consumers and the general public

Consumers and the general public (which may include individual service providers, include device manufactures, sponsors of medical technologies, and the MTAA) will be given two

opportunities to comment on elements of the review – this draft protocol and the draft review report.

As outlined in the previous section, this draft protocol and the draft review report will be uploaded to the DoHA website and as such there are no exclusions from the consultation process. In addition, key consumer and public stakeholders have been identified by DoHA and will be notified in writing of the upload of this draft protocol and the draft review report, to facilitate an inclusive public comments process.

In addition, the Consumers’ Health Forum of Australia will be contacted once the protocol is uploaded to the DoHA website, to arrange a meeting to discuss this draft protocol, during September 2010. The Consumer’s Health Forum of Australia will be similarly notified of the upload of the draft review report with another meeting to discuss that milestone. DoHA staff will be present at these meetings.

4.4 Consultants

Access Economics is responsible for drafting the review protocol and identifying, analysing and synthesising the evidence related to surgical obesity items through the methodology identified in chapter 5. Access Economics will provide a review report at the completion of the project that will help inform the Government’s consideration of MBS subsidy of these services into the future.

Access Economics has the required technical ability to provide the services. The company is one of Australia’s leading and best known economic consultancies, highly regarded for its professional and high quality modelling and assessments and for commitment to sound policy analysis and advice. Access Economics is a valued panel provider of health economics services to numerous Government departments, with many high profile projects (e.g. the national cancer screening program economic evaluations and aged care modelling for DoHA).

Access Economics has demonstrated experience providing services similar to this review, in the area of obesity, analysis of surgical services, health service delivery reviews, MBS item and structure reviews, literature review and stakeholder consultation. Access Economics has no conflict of interest in undertaking the review.

Details of the operational personnel conducting the review are in the table below.

Name	Lynne Pezzullo
Title/Office Held	Director
Qualifications	B.Ec (First Class Honours), University of Adelaide (1986)
Previous Experience	Lynne has broad specialist experience in health economics, and authored the major reports on obesity that Access Economics produced in 2006 and 2008. Lynne has a long history of project management and leadership in Government review processes. She has exceptional skills in health research, modelling, consultative engagement, analysis and strategic policy development for public, private, academic and peak consumer bodies across the health and social services sectors. Lynne has been instrumental in developing the Access Economics competency and public profile in health economics and is one of Australia’s experts in health evaluation services. Lynne led the Access Economics team that conducted the 2007 National Bowel Cancer Screening Program economic evaluation and the

	<p>National Dementia Priority Initiative (2006-09) evaluation for DoHA. Other relevant qualifications include:</p> <ul style="list-style-type: none"> ■ Reviewer for <i>Medical Journal of Australia</i> ■ Prime Minister’s 2020 Summit participant 2008, Health stream ■ ABC ACT radio spokesperson on health economics issues ■ Telstra Business Woman of the Year ACT 2008 ■ <i>Who’s Who Australian Women</i> 2009; <i>Global Heritage Who’s Who</i> 2010
Role	Lynne will lead the team including high level consultation with DoHA, the CWG, and MQFEAC, provide methodological oversight and project planning, ensuring timeliness and provide quality assurance for the project as a whole.
Name	Adam Gordois
Title/Office Held	Principal Health Economist
Qualifications	MSc Health Economics (Distinction) University York UK, BA (Hons) Business Economics (First) University of Leicester, UK
Previous Experience	Adam is a specialist health economist and modeller and has undertaken a wide range of health economics and outcomes research projects for government health departments, the pharmaceutical/medical device industry, and non-government organisations in both the UK and Australia. He has a long list of peer reviewed publications and is a reviewer for journals including <i>Value in Health</i> , <i>Expert Review of Pharmacoeconomics and Outcomes Research</i> , and <i>American Journal of Cardiovascular Drugs</i> . Adam is experienced in a range of analytical, spreadsheet, presentation and word processing packages used for data analysis, modelling and review in health economics. Adam has been involved in a number of past projects for DoHA and a cost-effectiveness and financial impact analysis of the NBCSP in NSW.
Role	Adam will manage the project on a day-to-day basis, participate in methodological development, lead the stakeholder consultation process, provide oversight of literature review and data collection, conduct TreeAge modelling and contribute to report writing for all phases of the project.

Name	Daphni Chao
Title/Office Held	Health Economist
Qualifications	MHEcon (Adv), The University of Queensland, BPharm, The University of Queensland
Previous Experience	Daphni is a specialist in the field of health economic evaluation. Her past work includes a review of the literature on the cost-effectiveness of renal replacement therapy (RRT) and modelling to assess the cost-effectiveness of RRT for people with end-stage renal disease. During her studies she worked at the Centre of Burden of Disease and Cost Effectiveness where she gained experience in modelling using Microsoft Excel and Ersatz, contributed to parts of the ACE-Prevention Project and was involved in the dissemination of ACE-Prevention results. At Access Economics Daphni has been involved in literature review, epidemiological modelling, consultation processes and economic evaluation in areas such as dementia, PBS access, and pharmacoeconomics.
Role	Daphni will participate in literature analysis, summarise the public comments and submissions, and provide research support for the project.
Name	Louise Baur
Title/Office Held	Obesity specialist
Qualifications	BSc (Med), MBBS, University of Sydney, FRACP, PhD, University of Sydney
Previous Experience	Louise is an obesity specialist and paediatrician at The Children’s Hospital at Westmead Clinical School. Louise complements the health economics, literature review and data analysis skills of the team with her specialty and deep knowledge of obesity issues in Australia, and her clinical expertise. Louise is under sub-contract to Access Economics in this project.
Role	Louise will contribute to the CWG meetings, review protocol development, and literature and data analysis.

4.5 The Department of Health and Ageing

DoHA has contracted Access Economics to undertake this review and is responsible for the ongoing management of this contract. DoHA is also responsible for ensuring that the draft protocol and draft review report are made available online for public comment.

Following the finalisation of the review report, DoHA will be responsible for providing advice to the Minister for Health and Ageing on future subsidy arrangements for the surgical obesity items. This advice will be informed by the review report but will also draw on other information such as budgetary considerations.

5 Review methodology

This chapter outlines the proposed methodology for reviewing the MBS services against the clinical questions developed above. It includes a literature analysis, MBS data analysis, summary of stakeholder consultation, and economic evaluation.

5.1 Literature review

This section outlines databases to be searched, search terms used, supplementary search strategies and how evidence will be classified.

The aims of the literature review are:

- to identify contemporary clinical guidance on the use of bariatric surgery for obesity in Australia and overseas;
- to obtain efficacy and safety data for bariatric surgeries for obesity commonly performed in Australia; and
- to address the research questions in chapter 3 of this protocol using this information.

The databases to be searched for this review include Medline, EMBASE, and the Cochrane library. The search strategy, including search terms and limits, is presented in Appendix A of this protocol.

Only studies meeting the NHMRC's highest levels of evidence will be included in the review, including meta-analyses and systematic reviews of randomised controlled trials (RCTs) (Grade I evidence) and any RCTs published since these reviews (Grade II evidence). Any recent RCTs will be identified through the literature search and discussions with the CWG members and professional bodies. This strategy will ensure all RCTs are included either within the Grade I studies or more recent Grade II studies.

Relevance of the literature identified in the search will be assessed according to the following criteria:

- **study type:** meta-analysis, systematic review, or evidence-based clinical guidelines;
- **interventions:** comparative analyses of bariatric surgeries that are commonly performed in Australia; and
- **outcomes:** identifiable and comparative efficacy/safety data, and/or evidence-based clinical practice recommendations.

The review team will identify and exclude any studies that have been superseded by others identified in the search. For example, only the most recent versions of clinical guidelines and meta-analyses will be included for review.

The clinical guidelines review will be restricted to Canada, New Zealand, the UK and the US (in so far as relevant guidelines are available). In addition, English language versions of guidelines from other European countries will be reviewed. Guidelines will be considered relevant where specifically providing recommendations for bariatric surgery for obesity. Greater priority will be given to guidelines based on evidence standards equivalent to NHMRC Grades I and II. The

clinical guidelines review will inform whether the MBS items under review require amendment or removal. Particular focus will be on the recommended indications/restrictions for the use of surgery, views on surgery in adolescents, and minimum recommended thresholds for BMI, age and other patient characteristics when considering surgery.

The review of meta-analyses and systematic reviews will inform the comparative safety and efficacy outcomes for different bariatric surgery procedures performed in Australia. These data will enable an assessment of which procedures provide the best outcomes for the Australian population with obesity.

The classification of evidence will be relatively narrow, since the review will only include the highest levels of clinical evidence. Grey literature will not be included in the literature review unless the CWG suggests specific papers for inclusion. Meta-analyses will be given a higher classification than systematic reviews because they increase the precision of overall results. The classification of clinical guidelines will depend on: (a) the levels of evidence used to support their recommendations; and (b) the relevance of the guidelines to the Australian population. Guidelines for Australia and countries with similar populations and health care systems will be classified more highly.

The advice resulting from this review will primarily concern indications for the MBS procedures. The outcomes of the literature review will assist in possible splitting of item numbers.

5.2 MBS data

This section includes information on the MBS data that will be analysed including item numbers, level of disaggregation, timeframes and the purpose of the analysis. The Department will facilitate access to necessary data as appropriate.

The relative usage and costs of MBS items for bariatric surgery will be evaluated using data on the following MBS item numbers:

- 14215 – long-term implanted reservoir associated with adjustable gastric band, accessing of to add or remove fluid;
- 30511 – morbid obesity, gastric reduction or gastroplasty for, by any method (Anaes.) (Assist.);
- 30512 – morbid obesity, gastric bypass for, by any method including anastomosis (Anaes.) (Assist.);
- 30514 – morbid obesity, surgical reversal, by any method, of procedure to which item 30511 or 30512 applies (Anaes.) (Assist.);
- 30518 – partial gastrectomy; and
- 31441 – long term implanted reservoir associated with the adjustable gastric band, repair, revision or replacement of (Anaes.).

Data will be obtained for each item by subgroup, defined by gender and five-year age group (e.g. males aged 30-34 years, females aged 20-24 years) and aggregations of these groups (e.g. males and females aged 30-34 years, males of all ages). Data will also be aggregated for subgroups where service numbers are too low to be reported due to confidentiality issues.

This approach is more accurate than inputting service numbers where data are reported as 'fewer than n services'. Data will be obtained for the last five years in order to evaluate trends in relative usage of different surgical procedures (i.e. five 12-month periods ranging from July 2005 – June 2006 to July 2009 – June 2010).

The CWG has indicated a number of procedures that may be performed alongside these surgeries including reduction of hiatus hernia and anti-reflux operation by fundoplasty. Therefore, data will also be obtained for the ten most frequent MBS items recorded under the same claim as the item numbers above to evaluate additional usage/costs of MBS items associated with surgery for obesity.

The types of analyses that are performed using these MBS data will include subgroup analyses and trend analyses.

For the **subgroup analyses**, historical usage and expenditure for each MBS item will be established for each gender/age subgroup and aggregates of these subgroups. These data will be used to inform the trend analyses described below. The subgroup analyses will also be used to observe any increasing or decreasing trends in the use of MBS items that are comparators for each other (e.g. 30511 and 30512).

For the **trend analyses**, projections of future use/expenditure for these MBS items will be performed using the historical data trends, ABS projections of demographic changes, and current obesity prevalence rates by age and gender. The time horizon for these projections will be five years. Projections would incorporate reasonable assumptions about how any modifications to MBS item numbers might alter utilisation patterns (e.g. by restricting utilisation to particular age or risk groups).

Several issues are anticipated in identifying specific procedure numbers from the MBS data.

- Some MBS items will include procedures for different reasons. For example, partial gastrectomy (item 30518) may be performed for stomach cancer rather than obesity. This issue will be addressed using any available MBS-linked data that identify primary diagnoses/indications for surgery, which can be accessed within the timeframe of this review. These data sets could include the DVA, Western Australia Department of Health, and BEACH, as well as additional MBS data reporting co-claimed items that are likely to be independent of obesity management.
- Some MBS items do not distinguish between types of surgery. For example, item 30512 does not distinguish between laparoscopic or open bypass, and item 30511 does not distinguish between adjustable banding, gastroplasty or sleeve gastrectomy. To address this issue, supplementary data and expert opinion will be used to disaggregate these usage figures based on current trends in surgery for obesity.
- Some types of surgery may be recorded under different item numbers; for example, MBS item coding for gastric sleeve resection is unclear. The supplementary data described above can also be used to determine the usage in Australia of newer procedures where the MBS item allocation is unclear.

5.3 Stakeholder consultation

This section summarises the stakeholder consultation process detailed in chapter 4 of this protocol.

In summary, this review protocol and the draft report will be available for comment through a public consultation process and placement on the DoHA website. In addition, critical stakeholders on the DoHA consultation list (stakeholder details are withheld from this protocol due to confidentiality) will be notified of the protocol and draft review and provided an opportunity to comment. Given the limited timeframe for this review and the geographical dispersion of the stakeholders, any one-on-one consultations requested and approved by DoHA will be undertaken using teleconference facilities on an as-needed basis. Any subsequent follow-up from such meetings will be undertaken through individual telephone meetings and email.

Ongoing stakeholder consultation during the project will include:

- ongoing discussion with clinical experts (CWG members);
- regular updates and meetings with the DoHA;
- face-to-face discussion with the Consumers' Health Forum of Australia; and
- two face-to-face discussions with the MQFEAC at the draft and final report stages.

5.4 Economic evaluation

This section includes an outline of how the economic evaluation of the MBS services will be undertaken, should this be appropriate (i.e. if the services reviewed are found to be safe and effective).

The recommendations of this review will be independent of funding decisions, although the findings may help inform such decisions in the future. However, one key aim of this review is to determine whether the MBS items should be better defined in terms of patients and/or procedures. These decisions may be driven by consideration of cost effectiveness.

Within the timeframe and scope of this review, evidence of cost effectiveness will be restricted to previous studies where available, and to those procedures found to be safe and effective, and which are commonly used in Australia. A literature search will be performed using Medline, EMBASE and the Cochrane library to identify any published economic evaluations conducted in Australia or similar countries (i.e. countries for which clinical guidelines have been examined – see section 5.1). As this search will be dependent on establishing the safety and efficacy of interventions, the precise search strategy has not yet been finalised, but will be a variant of the strategy at Appendix A identifying only economic studies published from the year 2000 onwards.

Economic evaluations included in the review will be those comparing each surgical procedure with the most common procedure (expected to be laparoscopic adjustable gastric banding) and/or no surgical intervention. The latter comparator will ensure all procedures can be evaluated on their own merits and be ranked by cost effectiveness.

A literature review of Australian and international economic evaluations will be conducted. The literature search will use a similar search strategy to the review of clinical evidence, with the study inclusion criteria being full economic evaluations (rather than systematic reviews, meta-analyses, and clinical guidelines). A full economic evaluation is defined as a study that assessed both the incremental costs and incremental benefits of one or more types of bariatric

surgery compared with either LAGB or no surgery, and synthesises these to estimate an incremental cost effectiveness ratio (e.g. cost per life year gained).

Although there is a preference for evaluating final health outcomes using quality-adjusted life years (QALYs), the outcome metric(s) will reflect the available literature, and may include QALYs, disability-adjusted life years (DALYs), or natural health units such as BMI, deaths, or obesity cases.

Other preferences for the types of economic evaluations used to draw conclusions about cost effectiveness would include both international and national identifying evaluations that are consistent with MSAC's guidelines, such as:

- Australian studies (i.e. relevance of costs and outcomes to the national context);
- costs from the societal perspective, as defined by MSAC (this perspective is essentially the health care payer; deadweight losses and in most cases productivity changes will be excluded when interpreting the published evidence);
- a lifetime horizon (to evaluate long term cost effectiveness); and
- accounting of cost offsets due to a reduction in other diseases and conditions associated with obesity (e.g. diabetes, osteoarthritis, bowel cancer, breast cancer, coronary heart disease and stroke), where data are available.

The final results of each economic evaluation included in the review – the incremental cost effectiveness ratios (ICERs) – will be reported as the cost per QALY gained (or other common and suitable health outcome metric reflected in the literature search). The ICER for each surgical procedure relevant to its comparator would be assessed as either:

- 'dominant' (saving costs and improving health outcomes);
- highly cost effective (based on benchmarks such as the World Health Organization (WHO) benchmark of costing less than gross domestic product per capita per DALY averted);
- cost effective (e.g. one to three times GDP per capita per DALY averted under the WHO benchmarks);
- not cost effective (e.g. more than one to three times gross domestic product (GDP) per DALY averted under the WHO benchmarks); or
- dominated (higher costs and worse health outcomes).

The economic analysis would provide a strong evidential basis for any changes recommended from the review.

6 Review timeframe

This chapter outlines the expected timeframes for the review protocol.

Timelines for the protocol are summarised in Table 6.1.

Table 6.1: Proposed timing of tasks and milestones

Deliverables	Date
Protocol on web, Consumers' Health Forum of Australia meeting	2/11-16/11/10
Public comment on protocol closes	16/11/10

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Appendix A: Draft literature review protocol

Search Strategy

Embase.com (Embase+MEDLINE) was searched for published articles using the search terms for the disease under evaluation – the search was not limited by date, but was limited to articles published in the English language. A summary of the search of Embase.com is presented in Table A.1.

Table A.1 – Embase.com search, <1966 to 1 September 2010 (*)

Embase Session Results

No.	Query	Results
#58	#57 AND [english]/lim	469
#57	#16 OR #44 OR #56	516
#56	#12 AND #55	358
#55	#45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54	670409
#54	(clinical NEXT/2 (protocols OR protocol)):ab,ti	3228
#53	'clinical pathway':ab,ti OR 'clinical pathways':ab,ti	1686
#52	'best practice':ab,ti OR 'best practices':ab,ti	7101
#51	guideline*:ab,ti OR consensus:ab,ti	238555
#50	'evidence based practice'/de	10815
#49	'consensus'/de	9832
#48	'gold standard'/de	6019
#47	'professional standard'/de	17550
#46	'standard'/de	279111
#45	'practice guideline'/exp	226445
#44	#22 OR #39 OR #43	153
#43	#12 AND #42	10
#42	#40 OR #41	29459
#41	(pooled NEXT/4 analys?s):ab,ti	29459
#40	'pooled analysis':de	10
#39	#12 AND #38	101
#38	#32 OR #37	127513
#37	#33 AND #36	97084
#36	#34 OR #35	405017
#35	qualitative:ti OR literature:ti OR evidence:ti OR 'evidence based':ti	247628
#34	systematic:ti OR critical:ti OR methodologic:ti OR quantitative:ti	167131
#33	synthesis:ti OR overview:ti OR review:ti OR survey:ti	599158
#32	#28 AND #31	42908
#31	#29 OR #30	1825619
#30	consensus:ti OR literature:ti OR overview:ti	122324
#29	review:it,ti OR guideline:it,ti OR guidelines:it,ti	1788094
#28	#23 OR #27	75469
#27	#25 AND #26	65150
#26	handsearch*:ab,ti OR search*:ab,ti	186312
#25	#23 OR #24	542640
#24	hand:ab,ti OR manual:ab,ti OR electronic:ab,ti OR bibliograph*:ab,ti OR	517044

No.	Query	Results
	database:ab,ti OR databases:ab,ti	
#23	cochrane:ab,ti OR medline:ab,ti OR embase:ab,ti	48097
#22	#12 AND #21	87
#21	#17 OR #18 OR #19 OR #20	96178
#20	cochrane:jt	10090
#19	quantitative*:ab OR systematic*:ab OR methodologic*:ab AND (review*:ab OR overview*:ab)	64056
#18	quantitative*:ti OR systematic*:ti OR methodologic*:ti AND (review*:ti OR overview*:ti)	18152
#17	'systematic review'/de	35818
#16	#12 AND #15	51
#15	#13 OR #14	65613
#14	'meta analysis':ab,ti OR 'meta analyses':ab,ti OR 'meta analytical':ab,ti OR metanaly*:ab,ti	36748
#13	'meta analysis'/de	49989
#12	#3 AND #11	7192
#11	#4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10	11888
#10	'stomach bypass':ab,ti OR 'gastric bypasses':ab,ti OR 'gastroileal bypass':ab,ti OR 'gastric reduction':ab,ti OR gastroplasty:ab,ti OR gastroplasties:ab,ti OR 'partial gastrectomy':ab,ti OR 'partial stomach resection':ab,ti OR 'stomach partial resection':ab,ti OR 'gastric bandings':ab,ti OR 'stomach banding':ab,ti OR 'gastric bands':ab,ti OR 'sleeve gastrectomies':ab,ti	3900
#9	'gastric bypass':de,ab,ti OR 'gastric band':de,ab,ti OR 'gastric banding':de,ab,ti OR 'sleeve gastrectomy':de,ab,ti	6741
#8	'banded gastroplasty':de OR 'band gastroplasty':de OR 'vertical gastroplasty':de	73
#7	'gastric banding'/de	2363
#6	'partial gastrectomy'/de	950
#5	'gastroplasty'/de	2423
#4	'stomach bypass'/de	4903
#3	#1 OR #2	209320
#2	obesity:ab,ti OR obese:ab,ti OR obesitas:ab,ti OR adipositas:ab,ti OR adiposity:ab,ti OR corpulency:ab,ti OR overweight:ab,ti OR 'adipose tissue hyperplasia':ab,ti OR 'fat overload syndrome':ab,ti	154078
#1	'obesity'/exp	175168

* The search was conducted using Elsevier's Embase Biomedical Answers Web site on 2 September 2010.

The **Cochrane Library** was searched for systematic reviews, controlled trials, economic evaluations and studies using the search terms for the disease under evaluation – the search was not limited by date and there were no database restrictions. A summary of the search of The Cochrane Library is presented in Table A.2 and Table A.3.

Table A.2 – The Cochrane Library search, 2010 Issue 8 (*)

Current Search History

ID	Search	Hits
#1	MeSH descriptor Obesity explode all trees	5192
#2	obesity OR obese OR obesitas OR adipositas OR adiposity OR corpulency OR overweight OR "adipose tissue hyperplasia" OR "fat overload syndrome"	9530
#3	(#1 OR #2)	9554
#4	MeSH descriptor Gastric Bypass, this term only	216
#5	MeSH descriptor Gastroplasty, this term only	175
#6	"banded gastroplasty" OR "band gastroplasty" OR "vertical gastroplasty"	64
#7	"gastric bypass" OR "gastric band" OR "gastric banding" OR "sleeve gastrectomy"	407
#8	"stomach bypass" OR "gastric bypasses" OR "Gastroileal Bypass" OR "gastric reduction" OR gastroplasty OR gastroplasties OR "partial gastrectomy" OR "partial stomach resection" OR "stomach partial resection" OR "gastric bandings" OR "stomach banding" OR "gastric bands" OR "sleeve gastrectomies"	321
#9	(#4 OR #5 OR #6 OR #7 OR #8)	560
#10	(#3 AND #9)	431
#11	Meta-Analysis:pt	423
#12	"meta analysis" OR "meta analyses" OR "meta analytical" or metanaly*	16469
#13	(#11 OR #12)	16469
#14	(#10 AND #13)	20
#15	Guideline:pt	28
#16	Practice Guideline:pt	20
#17	MeSH descriptor Consensus, this term only	32
#18	MeSH descriptor Evidence-Based Practice explode all trees	1489
#19	guideline* OR consensus	22899
#20	"best practice" or "best practices"	401
#21	"clinical pathway" OR "clinical pathways"	256
#22	clinical NEAR/2 (protocols OR protocol)	2413
#23	(#15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22)	26280
#24	(#10 AND #23)	49
#25	(#14 OR #24)	56

* The search was conducted using Wiley Interscience on 2 September 2009.

Table A.3 – Breakdown of database retrieval from The Cochrane Library, 2010 Issue 8

Database	Results
Cochrane Database of Systematic Reviews	13 [^]
Database of Abstracts of Reviews of Effects (DARE)	8
Cochrane Central Register of Controlled Trials (CENTRAL)	5
Cochrane Methodology Register (CMR)	0
Health Technology Assessment Database (HTA)	9
NHS Economic Evaluation Database (NHSEED)	21
Cochrane Groups	0
Total	43