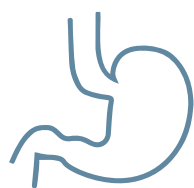


**JUNE
2017**



BSR

BARIATRIC SURGERY REGISTRY

Fifth Annual Report of the Bariatric Surgery Registry

Funding Partners

The Bariatric Surgery Registry received funding in the last 12 months from the Commonwealth Government of Australia and the following supporters



Medtronic

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Foreword from Chair of Steering Committee

Professor Ian Caterson

The BSR is getting bigger and bigger and we now have 28,308 patients in the BSR and over the last year have added 12,665 patients. As well we now have 92 hospitals and 146 surgeons contributing. All this is a credit to those who contribute, giving their and their staff's time – we really appreciate this.

We are reaching the stage with the BSR where we are able to get large scale, meaningful data on quality and safety, and outcomes from the registry. This will guide the provision of bariatric surgery for the future and will help by ensuring that the procedure(s) becomes even safer than it is now. My personal hope is that in time we will be able to give data which will enable better individual outcomes for patients, by enabling better and appropriate patient selection and appropriate operations.

The field of bariatric surgery is evolving rapidly with new operations and procedures appearing on a regular basis. The BSR will allow us to ensure that these newer procedures are effective and safe.

What is also emerging is the difficulty of getting the longer term follow-up. We need to work with the contributors and the patients to make sure we have a system that gets this important data. We are aiming for greater than 95% continuing follow-up! Of course the BSR is only as good as the contributions it gets and we are really appreciative of the efforts of so many people – however, please help us to get follow-up.

Finally we must thank the staff of the BSR. They are doing a wonderful job, are always cheerful and helpful (so ring if you have issues, please) and they are making sure that this registry works, works well and will make important contributions to health care in obesity. Very many thanks are due to them for their efforts which go above and beyond their duties.



Professor Ian D Caterson



List of Abbreviations

ANZGOSA Australia and New Zealand Gastro-Oesophageal Surgery Association

ACSQHC Australian Commission on Safety and Quality in Health Care

AMA Australian Medical Association

BMI Body Mass Index

BPD/DS Bilio-Pancreatic Diversion with Duodenal Switch

BSR Bariatric Surgery Registry

DOS Day Of Surgery

FY Financial Year

ICU Intensive Care Unit

IT Information Technology

LAGB Laparoscopic Adjustable Gastric Banding

LSG Laparoscopic Sleeve Gastrectomy

LTFU Lost To Follow-Up

MBS Medical Benefits Schedule

NSW New South Wales

NZ New Zealand

OP Operation

OSSANZ The Obesity Surgery Society of Australia and New Zealand

QLD Queensland

RACS Royal Australasian College of Surgeons

RYGB Roux-Y Gastric Bypass

SA South Australia

SAGB Single Anastomosis Gastric Bypass

SPHPM School of Public Health and Preventive Medicine

ST DEV Standard Deviation

TAS Tasmania

VIC Victoria

WA Western Australia

Data Period

The data contained in this document were extracted from the Bariatric Surgery Registry (BSR) as at 28 July 2017 but pertains to procedures that have occurred up to **30 June 2017**. As the Registry does not capture data in real time, there can be a lag between the occurrence of an event and its capture in the BSR.

Common Terms and definitions

Primary patients

participants whose first entry into the Registry is with their first bariatric surgical procedure

Legacy patients

participants whose first entry into the Registry is with a subsequent (or revision) bariatric surgical procedure

Primary procedure

the first bariatric procedure performed upon a patient

Revision procedure

a subsequent bariatric procedure performed upon a patient who has had a primary procedure

Opt-out

patients who have been sent Explanatory Statements and who have elected to not have their data included in the Registry

Partial opt-out

patients who have been sent Explanatory Statements and will allow the BSR to keep their information but do not want to be contacted by the Registry

Obesity

defined as having a body mass index (BMI, kg/m²) of 30 or over (Class I Obesity)

Severe Obesity

defined as having a body mass index (BMI, kg/m²) of 35 or over (Class II Obesity)

Morbid Obesity

defined as having a body mass index (BMI, kg/m²) of 40 or over (Class III Obesity)

Initial Weight

taken as the higher of the weight at *Intention to Treat* or weight at *Operation* of a Primary Patient

Excess Weight Loss (EWL)

measure of the percentage of *excess weight* a patient has lost from one time point to another where excess weight is defined as the patient's initial weight minus their ideal weight at BMI 25

Total Weight Loss (TWL)

measure of the percentage of weight a patient has lost from one time point to another. In the BSR this is measured from the patient's initial weight

Peri-operative Follow-Up

patient observation from any visit between 20-90 days post-operative (previously called 30 day follow-up)

Annual Follow-Up

patient observation taken from any visit on an annual basis from the Primary operation

Defined Adverse Event

(previously called sentinel event) indicated by the presence of a particular event occurring in the peri-operative phase (up to 90 days) in the healthcare setting, these are described as:

1. Unplanned Return to Theatre
 2. Unplanned Admission to ICU
 3. Unplanned Re-admission to Hospital
-

Financial Year

defined as the Australian financial year from 1 July to 30 June the following calendar year

Executive Summary

The Bariatric Surgery Registry (BSR) is proud to present its Fifth Annual Report as at 30 June 2017. The BSR has enjoyed another year of growth nearly doubling the registry to just under 30,000 patients. During the period the BSR welcomed the finalisation of agreements with both the HealthScope and Ramsay Health hospital groups. On the back of this the BSR was able to add 24 sites and 33 surgeons to its contributors.

The cohort of new patients acquired during the financial year 2016/17 (FY16/17) remains predominantly female (80%), in their mid-forties (mean age of 43.9 years), have their procedure in a private hospital (90%) and if they are a primary patient, their mean BMI on day of surgery is 42.9 and 14% of them identify as having diabetes.

Over 22,000 of the participating patients are primary patients and their progress will be tracked annually throughout 10 years of their bariatric journey including collection of their weight, diabetes treatment and reoperation history. There are currently more than 10,000 primary patients who have been followed up one year after their initial surgery while 78 patients have reached their 5 year mark.

Sleeve Gastrectomies have risen to 65% of all procedures in FY16/17 from 59% in FY15/16 with Gastric Bands falling further from 14% to 9%. A number of the BSR's original banding patients have converted their bands to sleeves (1%) and the BSR will continue to follow these treatment pathways as they emerge.

The rate of death from bariatric surgery remains low with 5 cases likely to be related to the procedure and 11 yet to be determined. In the peri-operative period, 2.4% of primary procedures for which there is a peri-operative follow-up and 7.3% of revision procedures had a Defined Adverse Event (unplanned return to theatre, admission to ICU or re-admission to hospital). In the primary patient cohort, 641 of them required a revision procedure (866 revisions in total) which represents 2.9% of the cohort.

In this year's report the BSR is publishing Total Excess Weight Loss (TWL) and the Excess Weight Loss (EWL) findings. EWL remains similar to last year for the 887 patients who have reached their 3 year review with EWL of 49.7%. TWL in the same cohort is 19.7%. The 12 month EWL is significantly higher at 62.8% this year. This most likely reflects the fact that more patients have undergone a sleeve gastrectomy. Weight loss usually peaks at 12-18 months with some weight regain expected after this time. By comparison patients who have undergone Gastric Banding tend to lose weight more gradually. It is expected that the next report will contain sufficient patients at each time point to see if this trajectory is borne out in the population.

For the cohort of primary patients identifying as having diabetes at baseline, it has been pleasing to note that 38% no longer identify as having diabetes 12 months after surgery. This continues to be an encouraging outcome and one which the BSR will continue to monitor.

Roll out of the BSR across Australia nears its end with only 26 more sites (17% of all sites where bariatric surgery is known to occur) requiring ethics approval and 39 surgeons to bring on board. The coming year will see the BSR working hard to acquire these final sites and surgeons. As well, the BSR is launching in New Zealand through a partnership with the University of Auckland and the support of OSSANZ.

The BSR plans to improve its data capture systems through a number of IT projects including the extraction of data for annual follow-up through surgeon's software, a new Call Centre management system, data linkages with State Governments, direct bulk loading of data into the BSR and the development of an SMS/ Secure Portal Platform. It is hoped these improvements in data capture will decrease the workload on surgeons while improving both cost efficiency and data quality. This will serve as a springboard for the on-going sustainability of the BSR.

Background

Rationale for Registry & Registry Collaborators

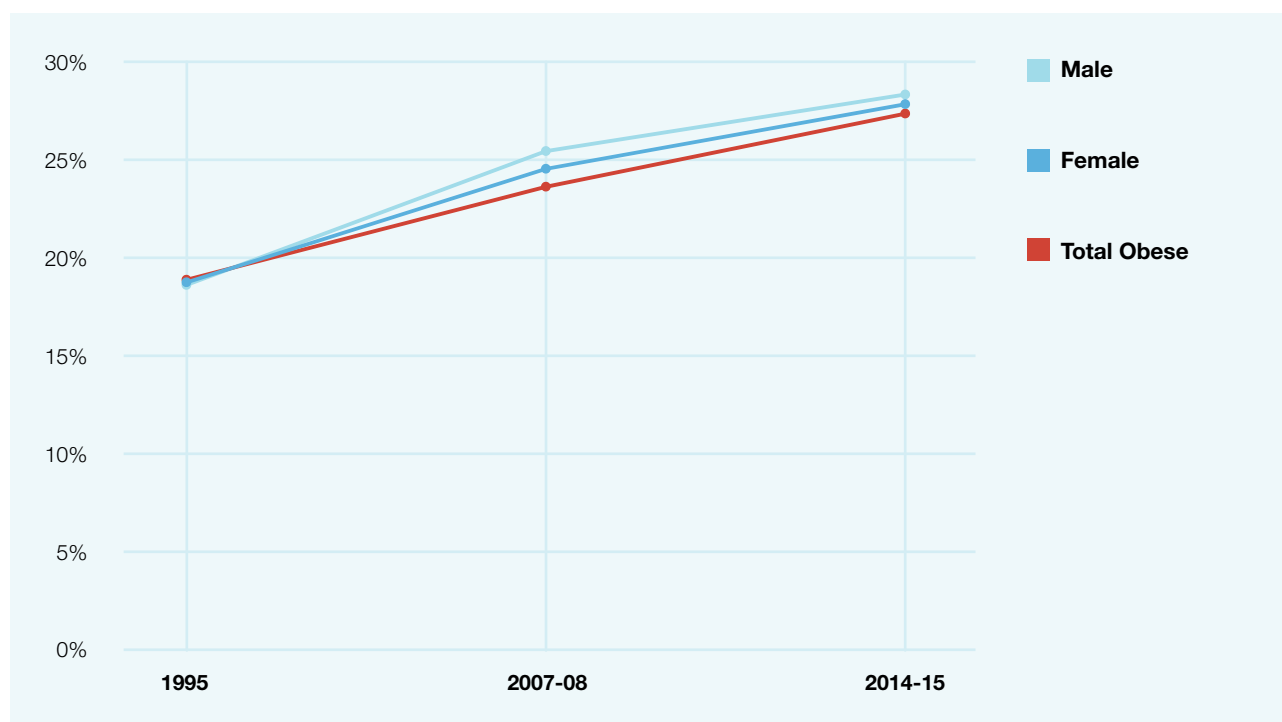
Obesity is one of the major challenges facing the Australian and New Zealand community. The incidence of obesity has continued to increase over the last two decades.

The Australian Federal Parliament recognised the need to address this issue in 2009 in the Georganas Report – **Weighing it Up**ⁱ, describing the increasing obese and overweight population as a “pressing health concern for Australia”. At that time it was estimated that 24.6% of the adult population of Australia were obese.

Seven years later, the AMA went further in their **Position Statement on Obesity**ⁱⁱ in 2016. With nearly 5 million Australian adults now estimated to be obese (27.9%), they described the situation as a “crisis” and called for the management of this disease to be a national and economic priority where “a whole of society response to obesity should be strategic, and coordinated”.

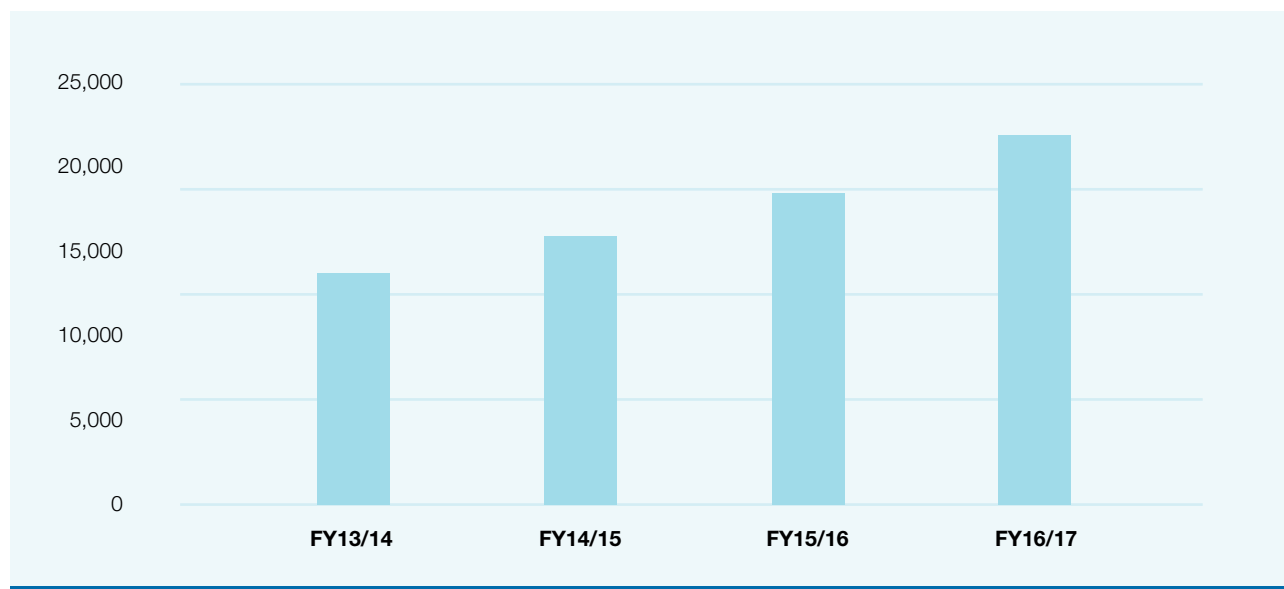
Research has shown that obesity is a difficult condition to prevent and treat. For the 6 million Australians who are overweight (BMI 25-30) and at risk of becoming obese, prevention strategies are critical. But for the 5 million Australians who are already obese (BMI>30), effective treatment options are required and to date, they appear to be limited. There is some evidence that the 1.5 million Australians with severe obesity (BMI>35) may benefit from bariatric surgery as it provides more predictable and durable weight loss than conservative regimes and is generally very safeⁱⁱⁱ. This has led to an increase in bariatric surgery of more than 63% in just the last four years. Largely funded privately (88% procedures in the BSR are private), Australians are choosing this treatment option.

Figure 1 » Rate of Obesity in Australia (1995 to 2015)



Source: ABS- National Health Survey: First Results, 2014-15 & Overweight & Obesity in Adults in Australia: A Snapshot, 2007-08

Figure 2 » MBS Data on Number of Bariatric Procedures in Australia



Source: MBS Medicare Items Processed for Major Bariatric Procedures - Gastric Band, Sleeve Gastrectomy RYGB/SAGB

Georganas Report Recommendation 6:

“...the Minister for Health and Ageing develop a national register of bariatric surgery with the appropriate stakeholders. The register should capture data on the number of patients, the success of surgery and any possible complications. The data that is generated should be used to track the long-term success and cost-effectiveness of bariatric surgery.”

It was in this context that the Obesity Surgery Society of Australia and New Zealand (OSSANZ) auspiced the Bariatric Surgery Registry (BSR) in 2012. The Georganas Report had directly recommended such a registry and the profession responded piloting the BSR in Victoria. The Commonwealth Government provided 4 years of funding (May 2014-2018) to rollout the BSR across the 151 sites and 181 surgeons across Australia that undertake bariatric surgery.

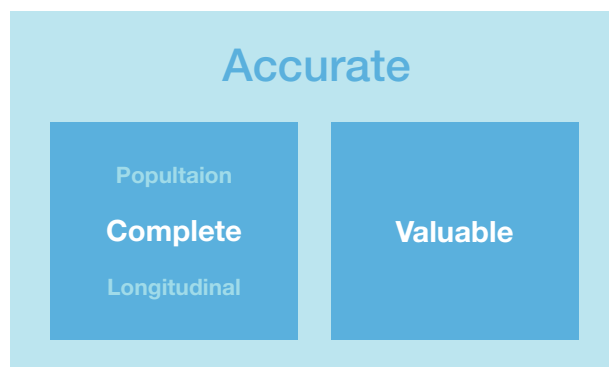
As a clinical quality and safety registry, the BSR seeks to answer:

1. Is this treatment **safe**?
2. Is this treatment **effective**?

The Australian Commission on Safety and Quality in Health Care (ACSQHC) promotes clinical quality registries as they are known to drive change and lead to **improved patient care** and outcomes^{iv}. In addition to benchmarking performance and determining variations in clinical outcomes, the data collected by the BSR can also track the longitudinal health outcomes of bariatric patients. This provides a unique opportunity to determine the **effectiveness** of this surgery upon the patients' obesity, diabetes management and the on-going need for further surgery over a ten year period.

To do this, the BSR has been designed with the underlying principle to provide data that is accurate, complete and valuable. To drive change and improve care, there must be confidence that the data is reflecting reality. The data governance framework of the BSR has been designed to control the definition, collection, verification, storage, analysis and reporting of data to ensure its **accuracy** and **completeness**.

In addition, stakeholders must find the data **valuable** – it has to answer the pressing questions they have about resource allocation, how to improve outcomes, effectiveness or risks. To this end, the BSR has collaborated with governments, surgeons, private hospital groups, individual hospitals, the medical technology industry, private insurers and medical defence organisations to determine their needs and develop reporting that delivers value. Most importantly, the BSR has also begun to speak directly with patients to understand their needs and how engagement with the Registry can help them in their decision making, assessment of risk and on-going journey of treatment.



Registry Governance

A **Steering Committee** was formed and met for the first time in February 2012. The Steering Committee has continued to meet quarterly since. The Chair is an independent obesity expert, Professor Ian Caterson. Current membership includes:

- » OSSANZ – Prof Wendy Brown (Clinical Lead),
Mr Andrew MacCormick, Emeritus Prof Paul O’Brien
- » RACS – Ms Meron Pitcher
- » Australia and NZ Gastro-Oesophageal Surgical Association (ANZGOSA) – Prof Neil Merrett
- » Medical Technology Association of Australia (MTAA) – Edwin Ho
- » Custodian/ Epidemiologist – Prof John McNeil
- » Australian Commonwealth Department of Health – Nathan Hyson
- » Community Representative – Corinna Musgrave

In the five years the Steering Committee has been operating its primary role has been to oversee the governance of the BSR,

provide strategic direction and ensure the agreed outcomes from the registry are achieved. To do this, it has worked with the BSR staff to develop a **Data Governance Framework** and the associated policies and processes that underpin the Registry including:

- » Ethics Protocol
- » Outlier Policy
- » Privacy Policy
- » Grievance & Complaint Policy
- » Call Centre Protocol & Scripts
- » Data Access & Reporting Policy
- » Data Dictionary (clinical & IT)
- » BSR-*i* Business Rules
- » Data Element Variation Processes
- » Data Capture Variation Processes
- » BSR-*i* System Change Request Processes
- » Reporting Templates

The **Registry Custodian** is the School of Public Health and Preventive Medicine (SPHPM) within the Faculty of Medicine, Nursing and Health Sciences at Monash University.

Registry Methodology

Participants – Site and Surgeon Accrual

A call was made to all surgeon members of OSSANZ in June 2013 asking them to register their interest in participating in the Registry. A further call was made in June 2014. As a result, 185 Australian surgeons registered their interest in the Registry (Figure 3). It is estimated there are another 24 surgeons who are currently performing bariatric surgery that have not registered interest with the Registry. In NZ, another 15 surgeons have been registered and are awaiting final locality approval to start contributing data.

Prior to commencing data collection at a given site, the Registry requires approval from the relevant ethics committee. A Memorandum Of Understanding (MOU), naming the Local Investigator (a contributing surgeon at the site), is signed between the Registry and the hospital site. These documents outline the responsibilities and expectations of each party.

In the year 1 July 2016 to 30 June 2017 an additional 41 sites have been approved by their nominated ethics committees, bringing the total number of sites with ethics approval to 125 as at 30 June 2017. It should be noted that this includes ten sites that have either closed or have no surgeons currently performing bariatric surgical procedures. The BSR estimates there are another 26 sites in Australia where bariatric procedures are performed, but probably in small numbers, that are yet to be approved by ethics.

The BSR now has 92 sites and 146 surgeons contributing data to the Registry.

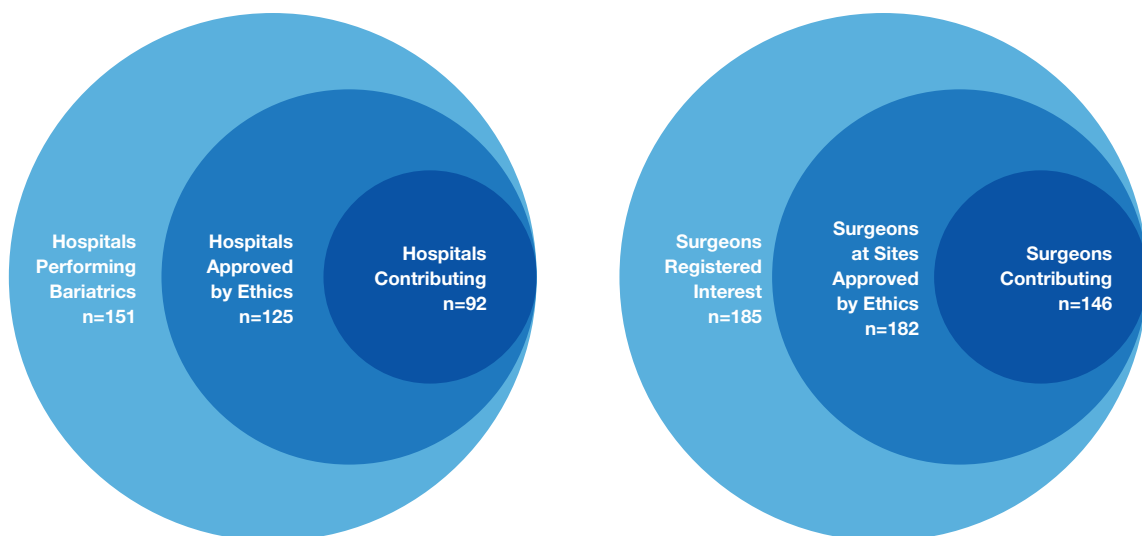
Data Elements

The need for near complete data capture is required to ensure the reliability of the Registry. Hence, the data elements that are currently collected by the Registry include only those elements that were most reliably completed during the pilot study (2012-2014).

The collected data provides information on the patient (to allow tracking and to identify risk factors), the patient's weight and BMI, the patient's health (diabetes status and treatment), the type of surgery undertaken, whether a concurrent liver or renal transplant took place, the device utilised, the need for revision or repeat surgery, unplanned admissions to ICU or readmissions to hospital as well as mortality.

Whilst it is possible to add further data elements in sub-studies of the Registry, the current intention is for this minimal dataset to formulate the main "spine" of the Registry dataset. For the data elements that are collected, please refer to the Appendix.

Figure 3 » Hospitals and Surgeons Performing Bariatric Surgery in Australia as at 30 June 2017



Data Collection Process

The data collection process is summarised in the Appendix. Surgeons or hospital data collectors provide data about the patients and their procedures using one of the following options:

- » Web browser with secure authorised entry using the Bariatric Surgery Registry Interface (BSR-*i*)
- » Paper based data forms (secure fax or posted)
- » Secure electronic record transfer from surgeons' or hospitals' electronic medical record

Upon receipt of this information the BSR sends the patient an Explanatory Statement about the Registry and their participation. The patient has a two week period to opt-out of the Registry by calling a "Free-call 1800-number". Patients have the option to completely opt-out, meaning that no data is held in the Registry other than that needed to identify them in the future should they have another procedure, or *partially opt-out*, meaning that they will allow their data to be held in the Registry but they do not wish to be called or contacted by the Registry. It is important to note that patients have the right to opt-out at any time during the follow-up period. If the patient declines to participate, information apart from name, date of birth, name of treating hospital and name of treating surgeon is deleted by the Registry. These basic demographics are maintained on a "do not contact" list.

Hospital Information Services (HIS) at each hospital site provide regular ICD-10 coding reports for bariatric procedures performed by surgeons who participate in the Registry. The coding reports include patient demographic and procedure information. These data are sent to the BSR using the secure file transfer platform (SFTP).

Data Reporting

The BSR follows a reporting cycle throughout the year to provide valuable data back to the key stakeholders. These reports include:

RELEASED TO	REPORT TYPE	REPORTING
Public	Annual Report	As at 30 June each year
Public	Semi-annual Update	As at 31 December each year
Surgeon	Individual Surgeon Reports	As at 30 September each year
Device Manufacturer (Funder)	Individual Industry Reports	As at 31 March each year
Hospital Group (Participant)	Hospital Group Reports	As at 31 March each year

As a clinical quality and safety registry, the BSR also reports on any identified outlier in accordance with the BSR's Outlier Policy.

ICD-10 coding reports provided by HIS are used to verify data submitted by surgeons/ hospital data collectors. If the surgeon or hospital has not previously provided information of a bariatric patient, the reports are used as the primary source of data. When ICD-10 coding is the primary source, surgeons are asked to complete the missing data elements not made available from the hospitals (e.g. device/stapling information, whether it is a primary or revision operation, height/ weight information and diabetes treatment).

Follow-up data are provided by surgeons or public hospital clinics, either by return of a paper form or through submission on the BSR-*i*. If surgeons or public data collectors indicate they have not seen the participant, BSR Call Centre staff will contact the participant for a brief 5 minute phone call (using set BSR Call Centre Protocols and Scripts) to collect the follow-up information related to the peri-operative period and/or 12 month intervals after surgery. Five attempts are made to contact the patient before they are allocated to "Lost to Follow-Up" (LTFU).

The BSR plans to develop an SMS, email or web-based secure portal platform to contact participants to obtain follow-up information. This platform will invite participants to link to a secure portal at various stages of their post-operative experience. If they do not respond to the request for follow-up, the Registry will call the participants. The SMS, email or website platform will be designed to engage with participants by providing useful information during their post-surgery experience and will allow them to give their own data back to the Registry.

Results of the Bariatric Surgery Registry as at 30 June 2017

1 Enrolment in the Registry

Since commencement in February 2012, Explanatory Statements that invite patients to participate in the Registry have been sent to a total of 30,120 patients who had their operation before or on 30 June 2017. There have been 1,146 patients who have chosen to opt-out (3.8%) and 107 (0.4%) partial opt-out (although those who choose partial opt-out are still considered participants). When the data was drawn on 28 July 2017, a further 666 patients (2.2%) were still in the two week period where their participation was pending.

This means there are currently 28,308 patients who are participating and have their information included in the Registry. This is the cohort on which this report is based.

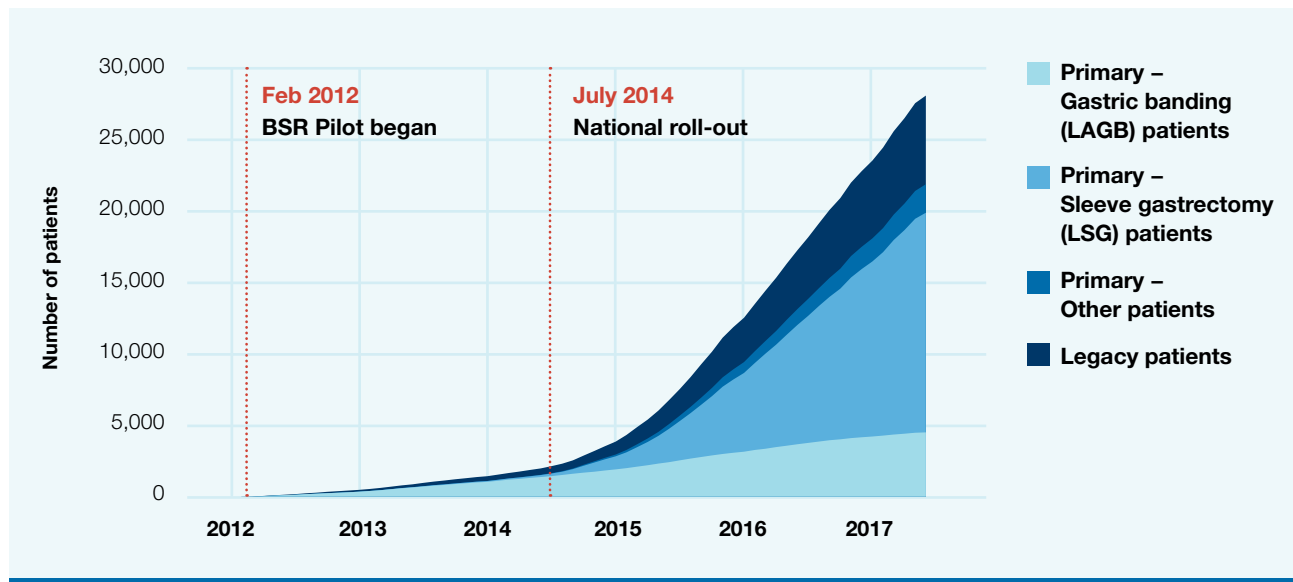
Table 1 illustrates that the BSR has grown nearly six-fold over the last 24 months while maintaining an opt-out rate below 4%.

Table 1 » Patient Participation in the BSR Over Time

	AS AT 30 JUNE 2015	AS AT 30 JUNE 2016	AS AT 30 JUNE 2017
Participating	5,788	15,643	28,308*
Opted Out	213	554	1,146
Opt Out Rate	3.5%	3.4%	3.8%

* Includes 44 patients who only had an abandoned procedure

Figure 4 » Accumulation Rate of Patients Participating in the BSR by Patient Type (February 2012 to 30th June 2017)



2 Procedures Captured by the Registry

The BSR has captured 30,473 completed procedures performed on 28,264 participants. The BSR has also captured another 68 abandoned procedures. 44 of these abandoned procedures involved participants who did not go on to have a completed procedure.

In the last financial year 11,872 completed procedures have been captured by the BSR (Table 2). It is estimated that this is nearly half of the 21,216 procedures that occurred in Australia over the same period (MBS figures). Of the three most popular procedures, we captured 46% of LSG, 66% of LAGB and 65% of RYGB/SAGB*. This compares to the capture rate as at 30 June 2016 of 40% of LSG, 68% of LAGB and 68% of RYGB/SAGB.

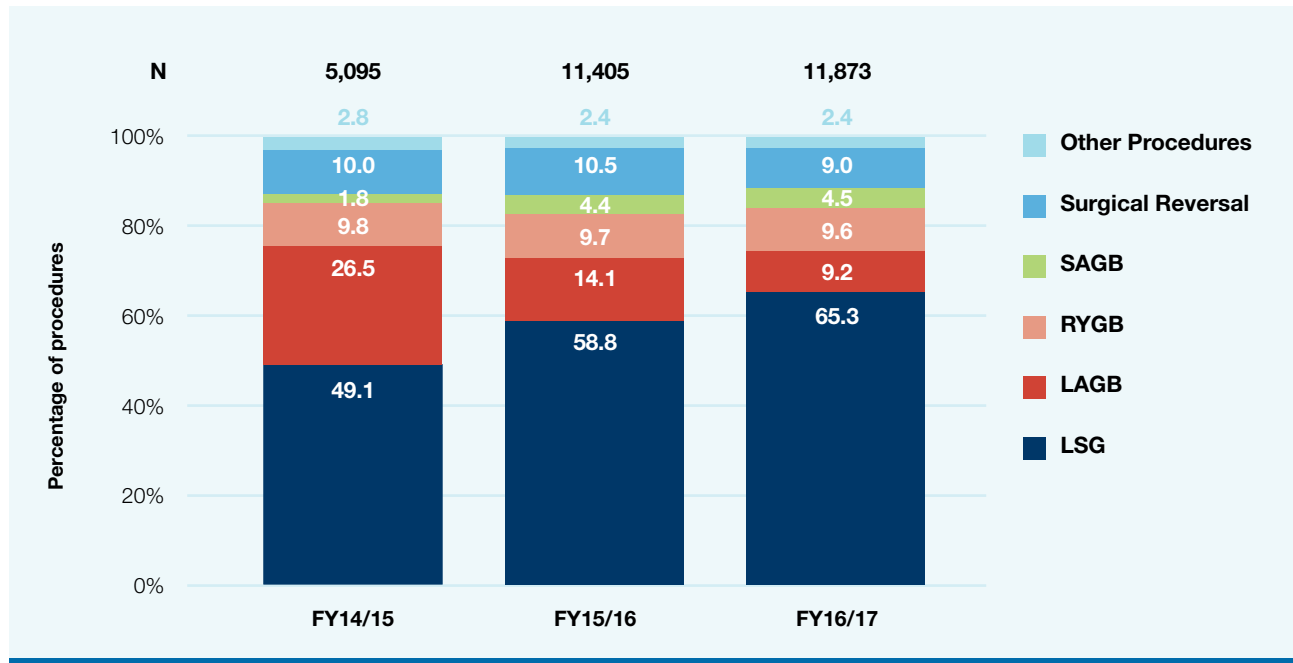
The types of procedures undertaken are also described in Table 2. The mix of procedures captured by the BSR has changed dramatically over the last three years as shown in Figure 5. Sleeve gastrectomy (LSG) represents nearly two-thirds of all procedures captured in FY16/17.

Table 2 » Procedures Performed by Type

	TOTAL BSR (Feb 2012 to 30 June 2017)			BSR FY16/17 (1 July to 30 June 2017)			MBS DATA FY16/17 (Est of % collected in brackets)
	Primary	Revision	Total	Primary	Revision	Total	
Sleeve gastrectomy (LSG)	15,478	1,670	17,148	7,068	689	7,757	16,990 (46%)
Gastric Banding (LAGB)	4,528	1,300	5,828	835	260	1,095	1,650 (66%)
R-Y gastric bypass (RYGB)	1,276	1,517	2,793	521	616	1,137	2,576 (65%)
Single anastomosis gastric bypass (SAGB)	678	458	1,136	338	201	539	
Surgical Reversals	NA	2,794	2,794	NA	1,066	1,066	NA
Other Procedures	54	720	774	29	249	278	NA
Total Procedures (excl Abandon)	22,014	8,459	30,473	8,791	3,081	11,872	NA
Abandoned Procedures	38	30	68	16	9	25	NA

* There is no separate MBS code for SAGB so it is assumed most surgeons put it under RYGB

Figure 5 » Change in Procedure Type Captured by BSR



Notes: N = number of procedures. Abandoned procedures are excluded

Figure 6 » Procedures Captured by the BSR by State and Procedure Type (FY16/17)

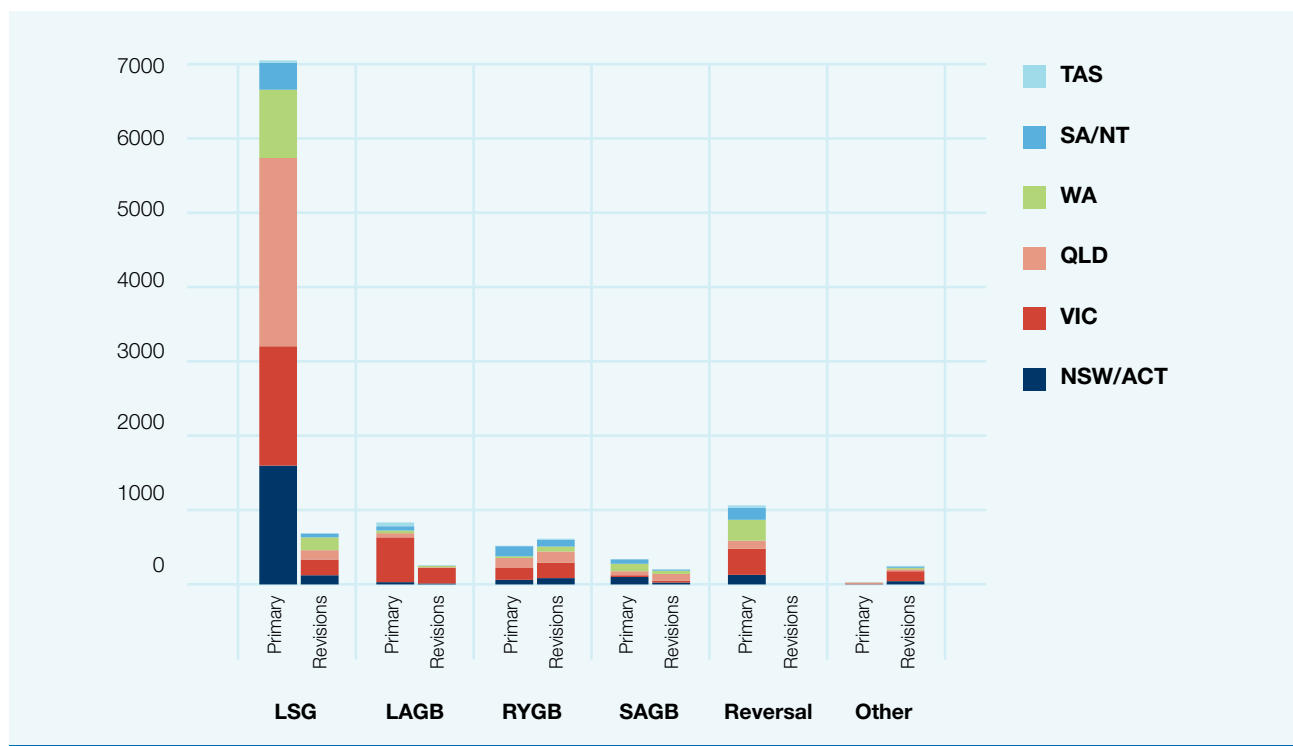


Figure 7 indicates the procedures captured by state in the public and private hospital systems during last financial year. The BSR's capture rate varies significantly in each state with Victoria remaining the BSR's strongest contributor. NSW has the lowest capture rate but has improved markedly during the period.

Figure 7 » Procedures Captured by the BSR by State and Public/ Private (FY16/17)

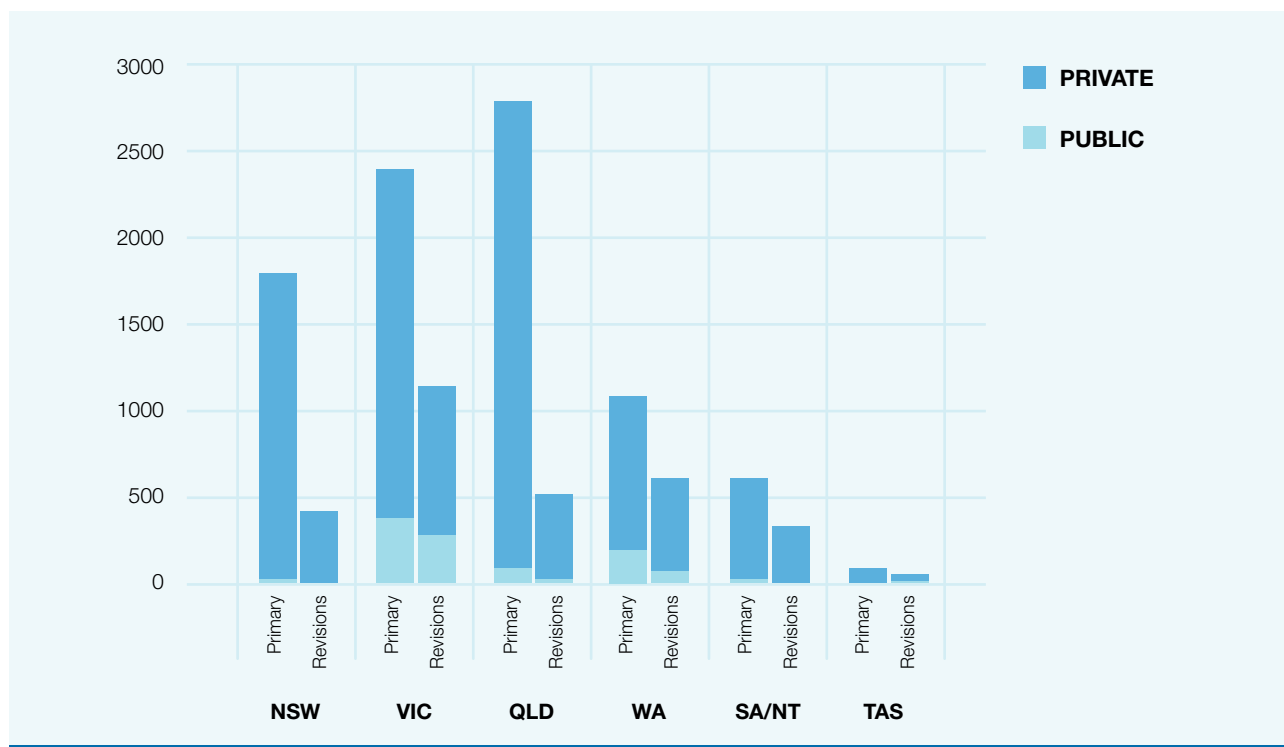


Table 3 » Procedures Captured by BSR by State (FY16/17)

	NSW & ACT	VIC	QLD	SA & NT	WA	TAS
MBS Data*	6,662	3,291	6,373	1,088	3,515	287
% MBS Data captured by BSR	31%	93%	50%	71%	40%	37%

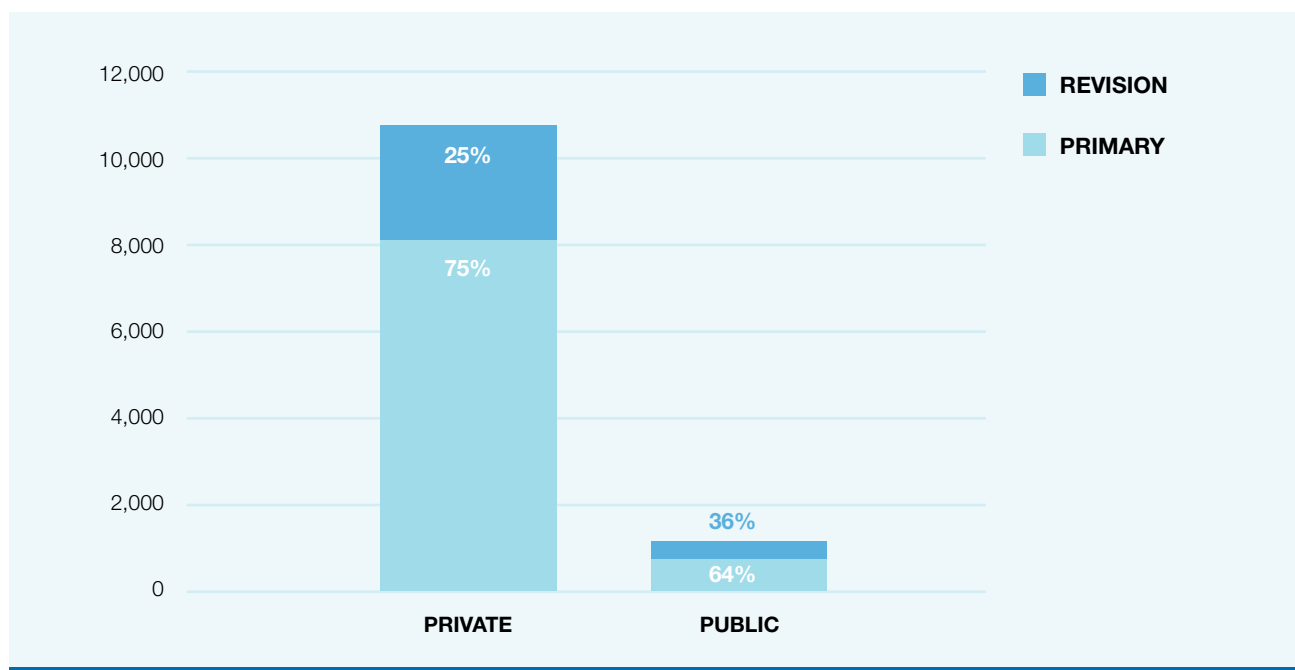
* MBS data for LSG, LAGB, RYGB/ SAGB only

The vast majority of procedures are still performed in private hospitals. The BSR has captured over 92% of its primary procedures and 87% of its revision procedures in private hospitals over the last 12 months (Table 4). It is unclear as yet, how representative this figure is overall, as we do not have a high enough capture rate in states outside Victoria.

Table 4 » Procedures Performed in Public Hospitals

	TOTAL BSR (Feb 2012 to 30 June 2017)				BSR LAST 12 MONTHS (1 July 2016 to 30 June 2017)			
	Primary in Public		Revision in Public		Primary in Public		Revision in Public	
	#	% of That Procedure Type	#	% of That Procedure Type	#	% of That Procedure Type	#	% of That Procedure Type
Sleeve gastrectomy (LSG)	1,471	10%	176	11%	558	8%	77	11%
Gastric Banding (LAGB)	747	16%	258	20%	114	14%	38	15%
R-Y gastric bypass (RYGB)	119	9%	147	10%	40	8%	51	8%
Single anastomosis gastric bypass (SAGB)	25	4%	19	4%	13	4%	9	4%
Surgical Reversal	NA	NA	447	16%	NA	NA	164	15%
Other Procedures	9	17%	185	26%	5	17%	64	26%
TOTAL PROCEDURES	2,371	11%	1,232	15%	730	8%	403	13%

Figure 8 » Primary and Revision Procedures Captured by the BSR Public/ Private (FY16/17)



Of the 30,474 procedures captured by the Registry only three procedures had a concurrent Renal Transplant, two of which took place in the last 12 months. There have been no concurrent Liver Transplants reported as yet.

Table 5 » Concurrent Renal Transplants

CONCURRENT RENAL TRANSPLANT WITH:	PRIMARY BARIATRIC PROCEDURE	REVISION BARIATRIC PROCEDURE
Financial Year 2016/17	1	1
February 2012 to 30 June 2017	1	2

Primary Patients

There have been 22,014 participants whose first presentation to the Registry was with a completed primary procedure. These patients are termed "Primary Patients". Primary patients have quality and safety measures recorded peri-operatively as well as annual tracking of diabetes status/ treatment, need for reoperation (and complication) and weight.

The number of primary procedures by type is shown in Table 6 for each financial year. The change in the procedure mix reflects the broadening of the BSR's clinician and hospital base as well as a shift in the type of procedures being undertaken in the community as a whole.

Table 6 » Primary procedures in BSR by type

DESCRIPTION	FY12/13		FY13/14		FY14/15		FY15/16		FY16/17	
	#	%	#	%	#	%	#	%	#	%
Sleeve gastrectomy (LSG)	18	3%	123	14%	2,216	62%	6,053	75%	7,068	80%
Gastric banding (LAGB)	645	97%	734	84%	1,050	29%	1,264	16%	835	9%
R-Y gastric bypass (RYGB)	0	0%	17	2%	255	7%	483	6%	521	6%
Single anastomosis gastric bypass (SAGB)	0	0%	0	0%	52	1%	288	4%	338	4%
Gastric imbrication	0	0%	0	0%	0	0%	0	0%	1	0%
Gastric imbrication, plus gastric band (iBand)	0	0%	0	0%	5	0%	4	0%	2	0%
Gastroplasty	0	0%	0	0%	1	0%	3	0%	0	0%
Bilio pancreatic bypass/ duodenal switch	0	0%	1	0%	1	0%	10	0%	23	0%
Other (specify)	0	0%	0	0%	0	0%	0	0%	1	0%
Not stated/inadequately described	0	0%	0	0%	0	0%	0	0%	2	0%
TOTAL	663	100%	875	100%	3,580	100%	8,105	100%	8,791	100%

Amongst the Primary Patient cohort, 641 patients (2.9 %) have gone on to have a revision procedure. A total of 866 revision procedures have been recorded in this group as some of these patients have required multiple revisions (Table 7).

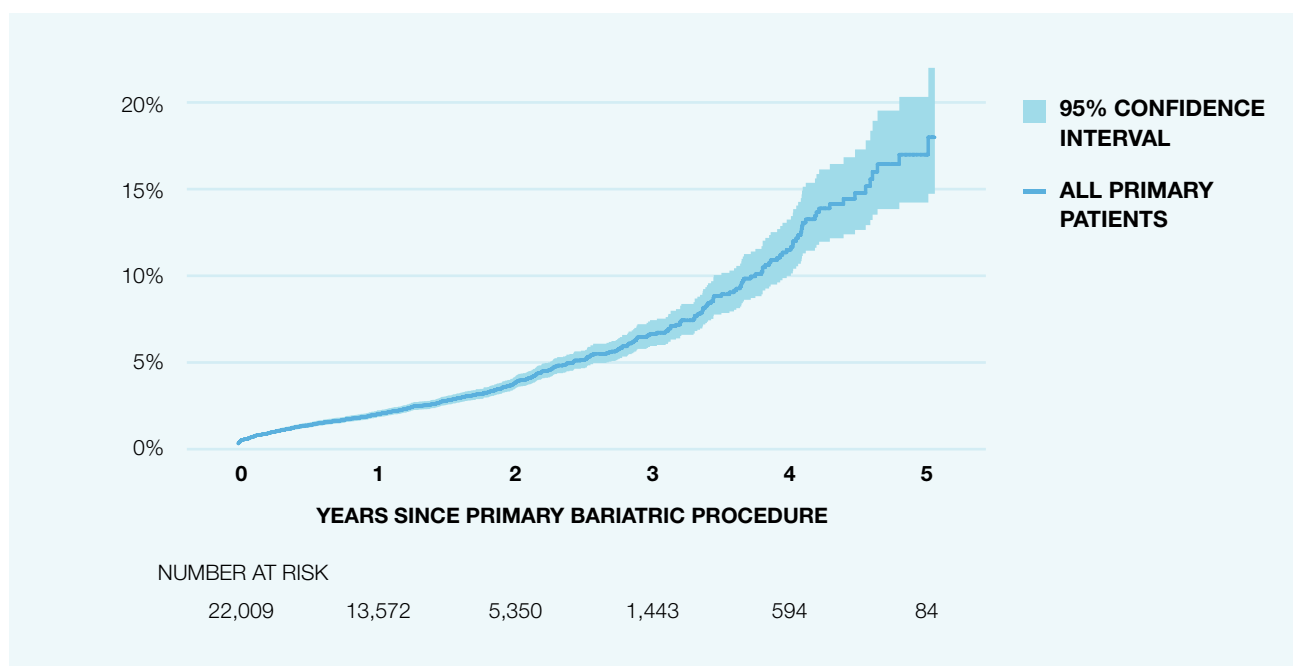
Table 7 » Number of Procedures Undergone by Primary Patients (Feb 2012 to 30 June 2017)

# PRIMARY PATIENTS WHO HAVE HAD:	NUMBER	%
Only an Abandoned Procedure	26	NA
Only a Primary Procedure	21,373	97.1%
A Primary Procedure & 1 Revision	514	2.3%
A Primary Procedure & 2 Revisions	96	0.4%
A Primary Procedure & 3 Revisions	17	0.1%
A Primary Procedure & 4 Revisions	9	0.0%
A Primary Procedure & 5 Revisions	3	0.0%
A Primary Procedure & more than 5 revisions	2	0.0%
TOTAL PRIMARY PATIENTS*	22,014	100%

*Excludes those with only an abandoned procedure

Revision incidence rates have been analysed by calculating the time between the primary bariatric procedure and the first revision procedure (see Figure 9). Survival analysis techniques have been used to analyse these data^v. The Nelson-Aalen cumulative probability estimates in Figure 9 show a low revision incidence rate of bariatric procedures. At one year post primary procedure, 1.8% (95% CI 1.6% to 2.0%) of patients are estimated to have had their first revision procedure. At two years post primary procedure, 3.6% (95% CI 3.2% to 3.9%) are estimated to have had their first revision procedure.

Figure 9 » Revision Incidence Rates for Primary Bariatric Procedures as at 30 June 2017



There are 163 primary patients with a gastric band that had a surgical reversal recorded. 53 of these patients have had another bariatric procedure recorded. 110 patients have not. There is also one RYGB patient who has had their bypass reversed and not gone on to have another bariatric procedure. The Registry does not continue to follow up these patients annually as their treatment has ceased. If they return to have another bariatric procedure in the future, their annual follow-up will recommence.

Table 8a » Current Status of Sleeve Gastrectomy Primary Patients as at 30 June 2017

# SLEEVE GASTRECTOMY PRIMARY PATIENTS WHO CURRENTLY HAVE:	
Only a Primary LSG	15,380
Any Revision of LSG	98
→ Conversion to RYGB	18
→ Conversion to SAGB	4
→ Other Revision	76
TOTAL	15,478

Table 8b » Current Status of Gastric Banding Primary Patients as at 30 June 2017

# GASTRIC BAND PATIENTS WHO CURRENTLY HAVE:	
Only a Primary Gastric Band	4,055
Any Revision of Band	473
→ Port Revision	174
→ Band Revision	123
→ Band Reversal	110
→ Conversion to LSG	42
→ Conversion to RYGB	7
→ Conversion to SAGB	11
→ Other Revision	6
TOTAL	4,528

Table 8c » Current Status of RY Gastric Bypass Primary Patients as at 30 June 2017

# RY GASTRIC BYPASS PRIMARY PATIENTS WHO CURRENTLY HAVE:	
Only a Primary RYGB	1,219
Any Revision of RYGB	57
→ Conversion to SAGB	1
→ Conversion to LSG	2
→ Other Revision	54
TOTAL	1,276

Table 8d » Current Status of Single Anastomosis Gastric Bypass Primary Patients as at 30 June 2017

# SINGLE ANASTOMOSIS GASTRIC BYPASS PRIMARY PATIENTS WHO CURRENTLY HAVE:	
Only a Primary SAGB	666
Any Revision of SAGB	12
→ Conversion to RYGB	9
→ Conversion to LSG	0
→ Other Revision	3
TOTAL	678

Legacy Patients

There were 6,250 patients whose first presentation to the Registry was with a revision procedure. These patients are classified as “Legacy Patients”. Legacy patients only have their quality and safety measures recorded peri-operatively.

Amongst this cohort of Legacy Patients, there have been 1,234 patients (19.7%) who have gone on to have a further revision procedure. This is a higher rate than for the Primary Patient cohort, reflecting the complexity of revision surgery. There are 1,343 procedures in this group as some of these patients have undergone multiple operations (Table 9).

Table 9 » Number of Procedures Undergone by Legacy Patients (Feb 2012 to 30 June 2017)

# LEGACY PATIENTS WHO HAVE HAD:	NUMBER	%
Only an Abandoned Revision Procedure	18	NA
Only One Revision Procedure	5,016	80.3%
2 Revision Procedures on BSR	1,154	18.5%
3 Revision Procedures on BSR	59	0.9%
4 Revision Procedures on BSR	14	0.2%
5 Revision Procedures on BSR	6	0.1%
More than 5 Revision Procedures on BSR	1	0.0%
TOTAL LEGACY PATIENTS*	6,250	100%

*Excludes those with only an abandoned procedure

3 Demographics

Bariatric surgery is still predominantly performed on females. There have been 22,369 females (79%), 5,886 males (21%) and 9 intersex or indeterminate persons who are included in the Registry as at 30 June 2017. Within the Primary Patient cohort there have been 17,039 (77%) females and 4,969 (23%) males and 6 intersex or indeterminate persons. Males make up a lower proportion of our legacy patient cohort at 15%.

Table 10 describes the key demographic indicators of patients in the BSR who had their procedure in the last financial year (FY16/17). The mean age of all patients at their procedure was 43.9 years. As would be expected, primary patients have a lower mean age (43.1 years) than patients having a revision (47.6 years) who are further along their bariatric journey. Males tend to be older than females, between 3-4 years, when they have their primary procedures and also tend to have a higher BMI, both of which are a statistically significant difference¹. Males also tend to have a higher incidence of diabetes than females.

Table 10 » Demographics of Patients at Their Procedure (FY16/17)

MEASURE	PRIMARY PROCEDURES			REVISION PROCEDURES			ALL PROCEDURES		
	Public	Private	All	Public	Private	All	Public	Private	All
Procedure Number	730	8,061	8,791	403	2,678	3,081	1,133	10,739	11,872
Females undergoing procedure	558	6,333	6,891	351	2,256	2,607	909	8,589	9,498
	76%	79%	78%	87%	84%	85%	80%	80%	80%
Males undergoing procedure	172	1,726	1,898	52	420	472	224	2,146	2,370
	24%	21%	22%	13%	16%	15%	20%	20%	20%
Mean Age at Op	43.1	42.6	42.6	47.6	47.6	47.6	44.7	43.8	43.9
Mean Age at Op – Female	42.2	41.9	41.9	47.4	47.1	47.1	44.2	43.3	43.3*
Mean Age at Op – Male	45.8	45.1	45.1	48.9	50.5	50.4	46.5	46.1	46.2*
Minimum Age at Op	16.1	13.0	13.0	20.0	15.1	15.1	16.1	13.0	13.0
Minimum Age at Op – Female	16.1	13.2	13.2	20.0	15.1	15.1	16.1	13.2	13.2
Minimum Age at Op – Male	18.8	13.0	13.0	22.4	23.0	22.4	18.8	13.0	13.0
Max Age at Op	79.0	80.9	80.9	77.6	77.8	77.8	79.0	80.9	80.9
Max Age at Op – Female	79.0	78.1	79.0	77.6	77.8	77.8	79.0	78.1	79.0
Max Age at Op – Male	70.9	80.9	80.9	71.8	75.4	75.4	71.8	80.9	80.9
Mean BMI at Op	45.7	42.6	42.9	41.0	39.7	39.9	44.1	41.7	42.0
Mean BMI at Op – Female	45.5	42.4	42.7	41.0	39.4	39.6	43.8	41.5	41.8**
Mean BMI at Op – Male	46.5	43.2	43.6	41.5	41.1	41.2	45.4	42.7	43.0**
Max Weight at Op	234	250	250	259	218	259	259	250	259
Max Weight at Op – Female	234	250	250	259	215	259	259	250	259
Max Weight at Op – Male	218	220	220	200	218	218	218	220	220
% Patient identifying as having Diabetes at Baseline	23%	14%	14%	NA					
% Patient identifying as having Diabetes at Baseline – Female	19%	12%	12%	NA					
% Patient identifying as having Diabetes at Baseline – Male	36%	21%	22%	NA					

¹ *p-value < 0.001 (Two sample t-test) statistically significant difference in mean age at operation between males and females

** p-value < 0.001 (Two sample t-test) statistically significant difference in mean BMI at operation between males and females

Figure 10 » Patients' Age Distribution at Time of Procedure in the BSR (FY16/17)

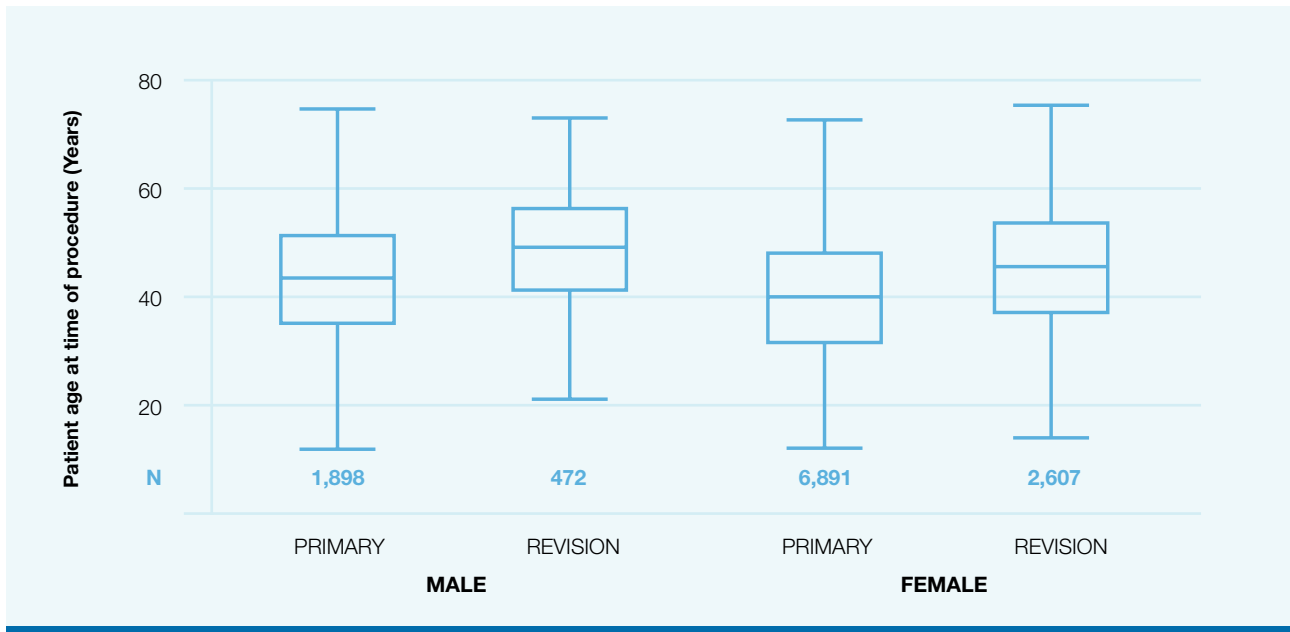
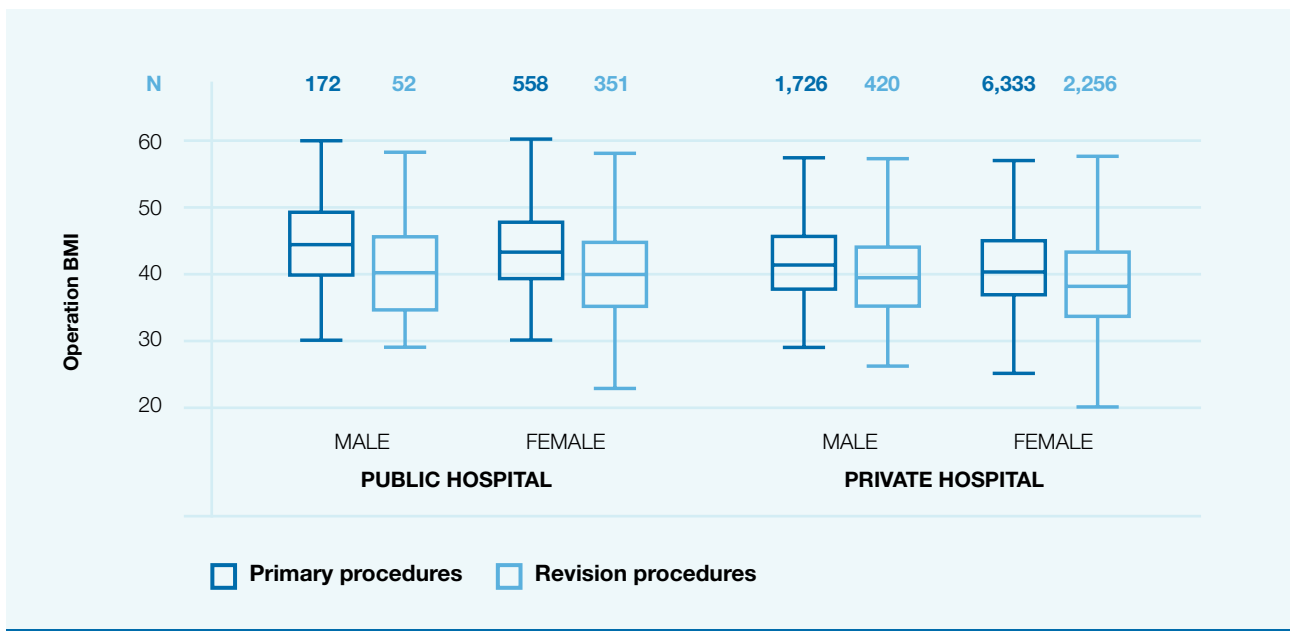
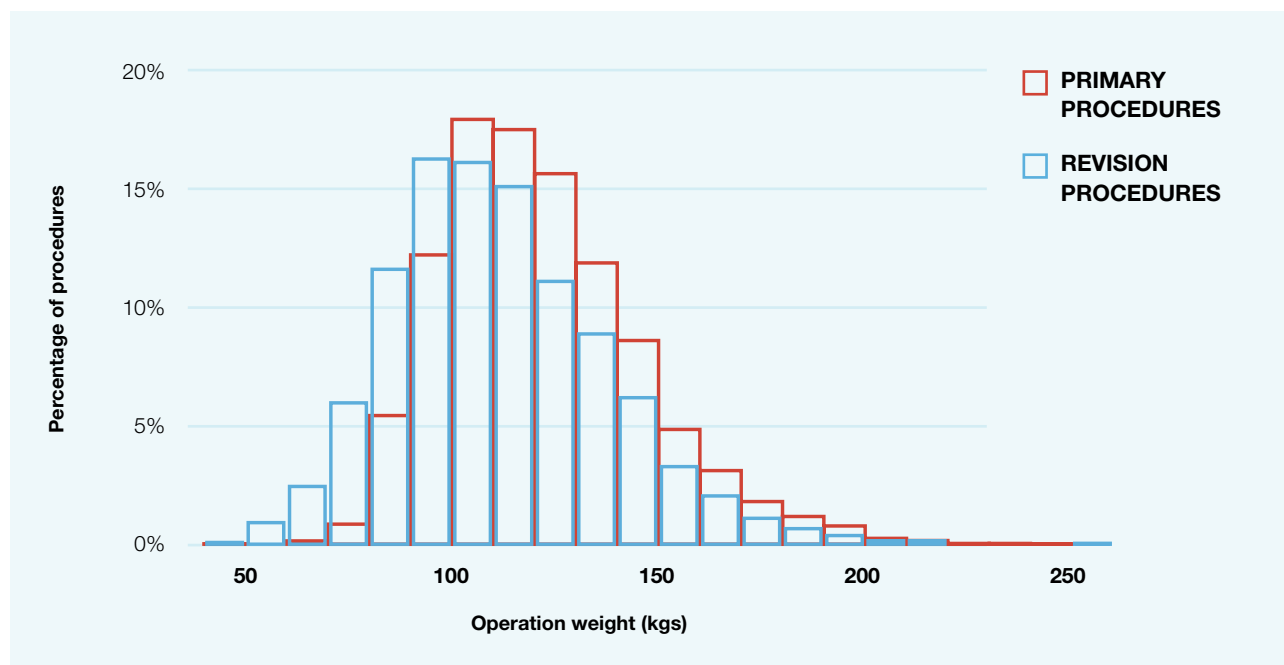


Figure 11 » Patients' BMI Distribution at Time of Procedure in the BSR (FY16/17)



Note: Six patients with indeterminate gender are not included in the box plot analyses above
 N= Number of primary or revision procedures by gender
 Extreme values outside of the whiskers are not shown[†]

Figure 12 » Patients' Weight at Time of Procedure in the BSR (FY16/17)



4 Follow-up

The follow-up rates achieved at each data collection point are shown in Table 11. Data is defined as “due” on the appropriate anniversary from the date of operation, ie peri-operative follow-up is due 30 days after the surgery date, 1 year data is due one year after the surgery data.

Our Lost to Follow-Up (LTFU) rate of patients (meaning those patients we have stopped pursuing and for whom we will not send out annual follow-up or reminders for their outstanding peri-operative follow-up) is 7.5%. If these patients have a subsequent procedure, they will re-enter the follow-up system and we will begin capturing their follow-up again.

The BSR Call Centre has been used to complete 6,261 follow-ups (15%).

Table 11 » Follow-Up Completion by Type (excluding LTFU)

	PERIOP	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5	TOTAL
Total Follow-Ups	29,872	13,019	4,644	1,371	543	78	49,527
Total Complete	25,408	10,077	3,477	1,195	461	57	40,675
% Complete	85%	77%	75%	87%	85%	73%	82%

5 Safety Reporting

Deaths

Deaths are rare in the BSR but as a longitudinal registry there is an expectation that some participants will die. Since our last Annual Report as at 30 June 2016 there has been thirteen reported deaths.

There are now 22 patients of the BSR who have died (0.08% of participants). It has been confirmed that in 6 of these cases the death was not attributable to surgery. In another 11 cases it has yet to be determined if the death was related to the bariatric surgery or not. The deaths reported are listed in Table 12 and Table 13 below:

Table 12 » Deaths reported to the BSR up to 30 June 2017

AS AT 30 JUNE 2017	
Unrelated to procedure	6
Likely related to procedure	5
Not determined as yet	11
TOTAL	22

Table 13 » Cause of Death that was Likely Related to Bariatric Procedure up to 30 June 2017

DATE OF DEATH	PATIENT GROUP	PROCEDURE	CAUSE OF DEATH
Q1 2014	Legacy	LAGB to LSG	Staple line leak
Q4 2014	Primary	SAGB	Anastomotic leak, multi-organ failure
Q1 2015	Primary	RYGB	Anastomotic leak, multi-organ failure
Q4 2015	Primary	LSG	Fistula track
Q4 2015	Primary	LAGB	Sepsis

Peri-operative Defined Adverse Events and Complications

There have been 1,019 Defined Adverse Events reported. These events occurred as a result of 863 procedures performed on 733 patients (438 primary and 295 legacy) within the peri-operative follow-up data window (i.e. up to 90 days post-operative). For procedures with completed peri-operative follow-up it is possible to identify those procedures that have had one or more Defined Adverse Events.

Table 14 » Defined Adverse Events in all Patients up to 30 June 2017

RESULTING IN:	PRIMARY PROCEDURES	REVISION PROCEDURES	ALL PROCEDURES
Unplanned Return to Theatre	225	332	557
Unplanned Admission to ICU	29	23	52
Unplanned Re-admission to Hospital	232	178	410
Any Defined Adverse Event	413	450	863

Tables 15 & 16 shows the rate of incidence of Defined Adverse Events by primary procedure and revision procedure type. As would be expected, the data indicates that revision procedures are more likely to result in a Defined Adverse Events than a primary procedure.

Table 15 » Primary Procedures by Type with a Defined Adverse Events (FY16/17)

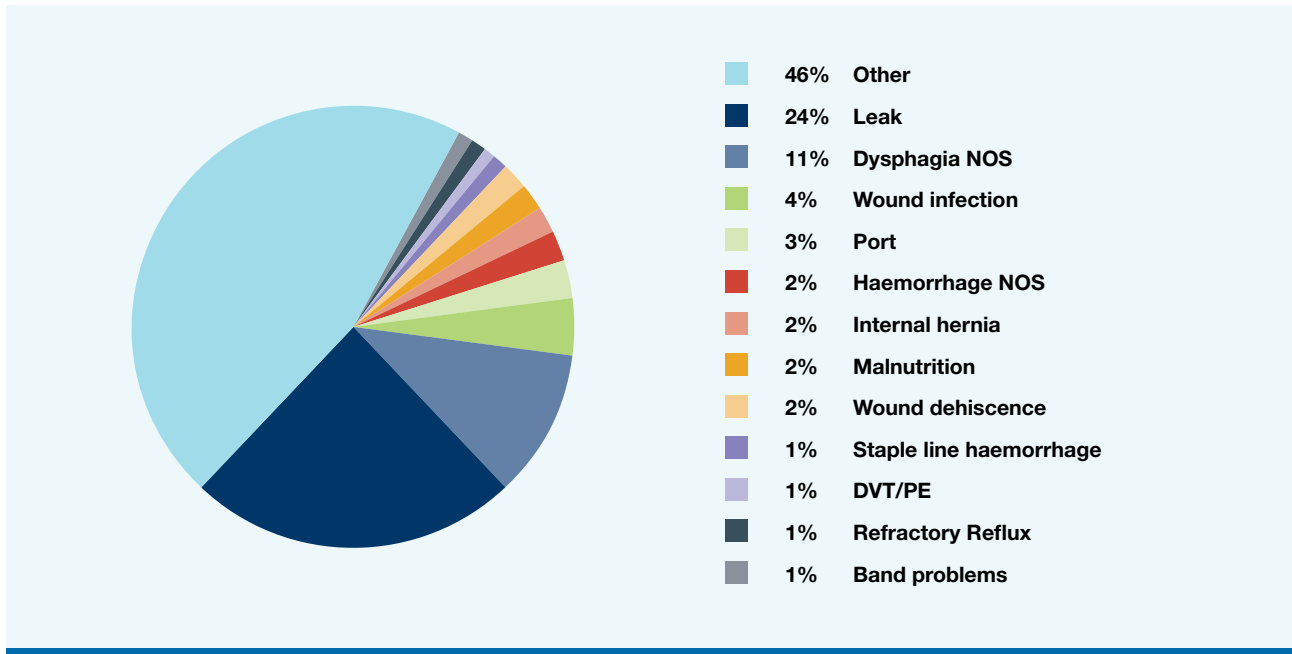
PRIMARY PROCEDURES	# PROCEDURES WITH ANY DEFINED ADVERSE EVENT	# PROCEDURES WITH PERIOP FOLLOW-UP	TOTAL	% WITH A DEFINED ADVERSE EVENT
Sleeve gastrectomy (LSG)	98		4,766	2.1%
Gastric banding (LAGB)	10		652	1.5%
R-Y gastric bypass (RYGB)	33		377	8.8%
Single anastomosis gastric bypass (SAGB)	5		288	1.7%
Other Primary Procedures	0		24	0.0%
TOTAL	146		6,107	2.4%

Table 16 » Revision Procedures by Type with a Defined Adverse Events (FY16/17)

REVISION PROCEDURES	# PROCEDURES WITH ANY DEFINED ADVERSE EVENT	# PROCEDURES WITH PERIOP FOLLOW-UP	TOTAL	% WITH A DEFINED ADVERSE EVENT
Sleeve gastrectomy (LSG)	16		437	3.7%
Gastric banding (LAGB)	7		185	3.8%
R-Y gastric bypass (RYGB)	62		494	12.6%
Single anastomosis gastric bypass (SAGB)	9		163	5.5%
Port revision	6		63	9.5%
Surgical reversal	13		735	1.8%
Other Revision Procedures	46		96	47.9%
TOTAL	159		2,173	7.3%

There is not a one-to-one match between the number of complications and number of Defined Adverse Events as one complication can lead to more than one Defined Adverse Events and a patient may experience multiple complications causing a single Defined Adverse Event. The complications causing Defined Adverse Events in FY16/17 are shown in Figure 13. A large number of “other” complications have been collected and as a result 18 new categories have been developed and will be implemented next financial year.

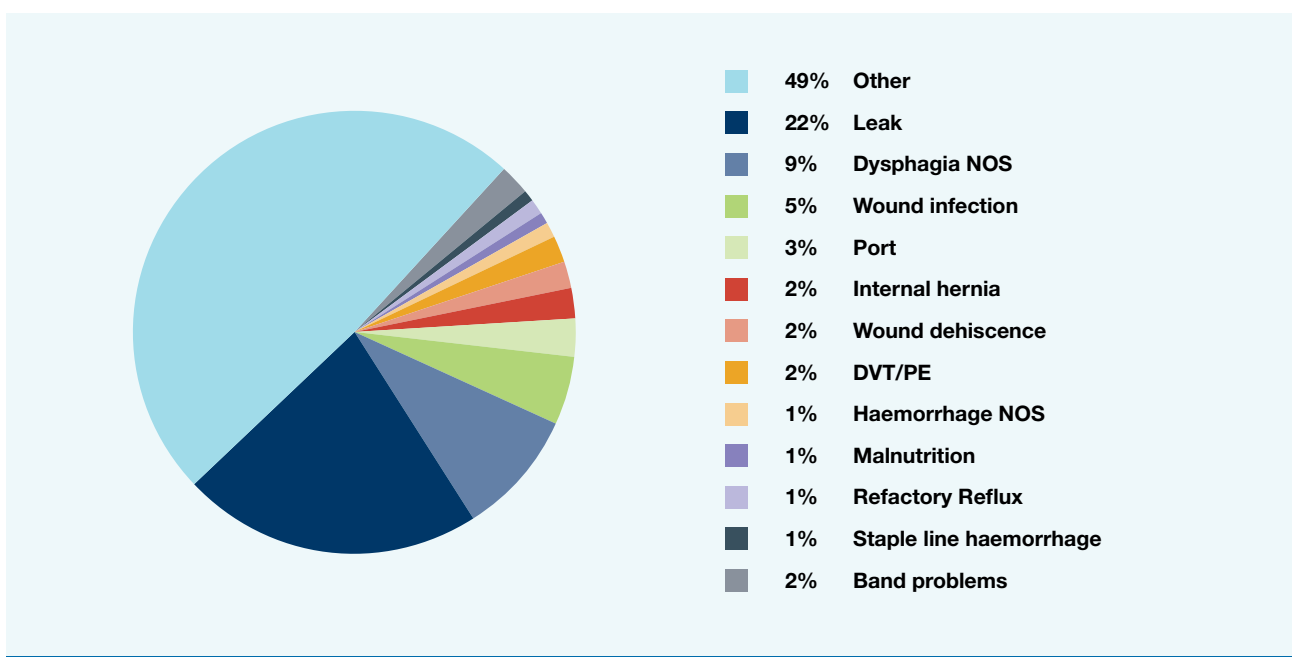
Figure 13 » Reasons Listed for Defined Adverse Events in all Patients (FY16/17)



Need for Reoperation for Primary Patients

As mentioned previously in the BSR as a whole there were 866 revision procedures performed on 641 primary patients. In the FY16/17, 358 of these revision procedures were performed and the complications that caused these procedures are presented in Figure 14.

Figure 14 » Reasons Listed for Reoperations on Primary Patients (FY16/17)



6 Weight Outcomes

The mean start BMI for patients undergoing primary procedures was 44.1 (st dev 8.0) with a mean BMI of 42.9 (st dev 7.5) on the day of surgery (DOS). Table 17 shows the mean BMI for all primary patients by type – there are some interesting differences between the means of males and females as well as between private and public patients which warrant further investigation.

Table 17 » Mean BMI for All Primary Procedures Feb 2012 to 30 June 2017

WEIGHT MEASURE	FEMALE	MALE	ALL
Mean Start BMI	43.8	45.0	44.1
(Standard Deviation)	8.0	8.1	8.0
Mean DOS BMI	42.7	43.7	42.9
(Standard Deviation)	7.5	7.5	7.5
Mean Start BMI – Public	47.9	49.4	48.2
(Standard Deviation)	9.0	9.3	9.1
Mean DOS BMI – Public	46.4	47.3	46.6
(Standard Deviation)	8.1	8.6	8.3
Mean Start BMI – Private	43.3	44.5	43.6
(Standard Deviation)	7.7	7.8	7.7
Mean DOS BMI – Private	42.2	43.2	42.4
(Standard Deviation)	7.3	7.2	7.3

For primary patients who were over 18² at the time of their primary procedure, the mean BMI at 12 months on the 7,648 patients for whom we have collected follow-up weight data was 32.9 (st dev 7.3). This represents an Excess Weight Loss (EWL) of 62.8% from initial weight and a Total Weight Loss (TWL) of 25% (Table 18). There are 887 primary patients for whom we have collected 3 years of data and their EWL at Year 3 was 49.8% and TWL at Year 3 was 19.7%. The EWL and TWL plot for primary patients who have reached 3 years can be seen at Figure 15 and Figure 16 respectively.

Table 18 » Weight Outcomes at 12 months for All Primary Procedures Feb 2012 to 30 June 2017

WEIGHT MEASURE	ALL*
Mean BMI at 12 Mo	32.9
(Standard Deviation)	7.3
Mean EWL at 12 Mo	62.8%
(Standard Deviation)	30%
Mean TWL at 12 Mo	25.0%
(Standard Deviation)	11%

* Excludes patients who were 18 years old or under at their primary procedure

² All Weight Outcome analysis excludes participants that are 18 years and under at the time of their primary procedure as the BSR is unable to collect the participant's height if/as they grow during the 10 years of annual follow up, making their BMI calculation invalid.

Figure 15 » Excess Weight Loss for those Primary Patients who have reached their 3 Year Annual Follow-Up (n=887)³

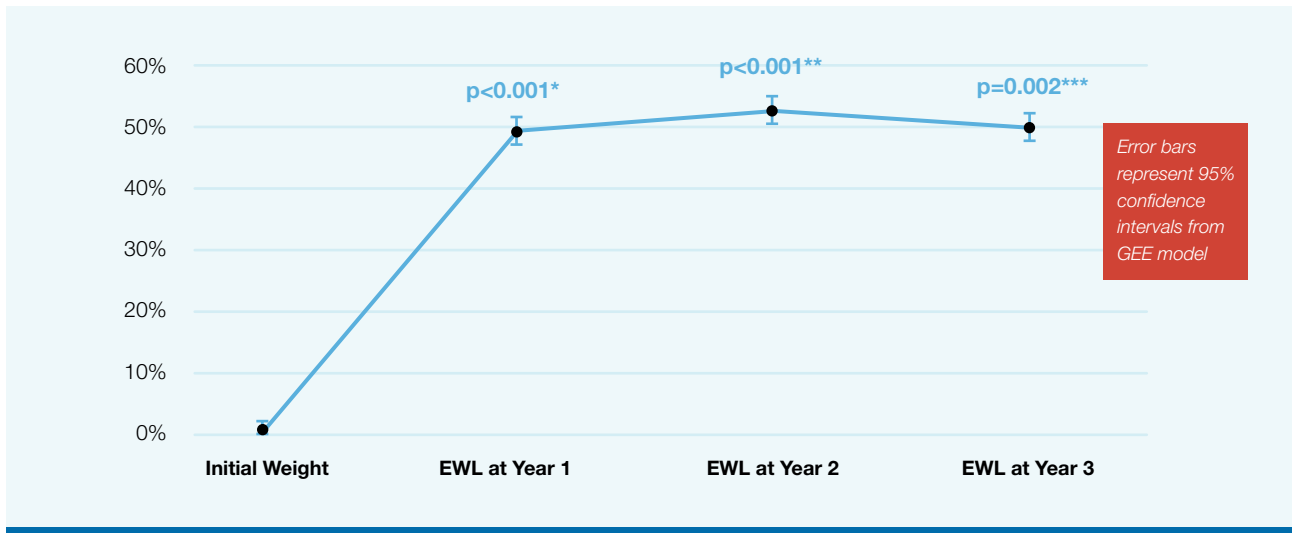
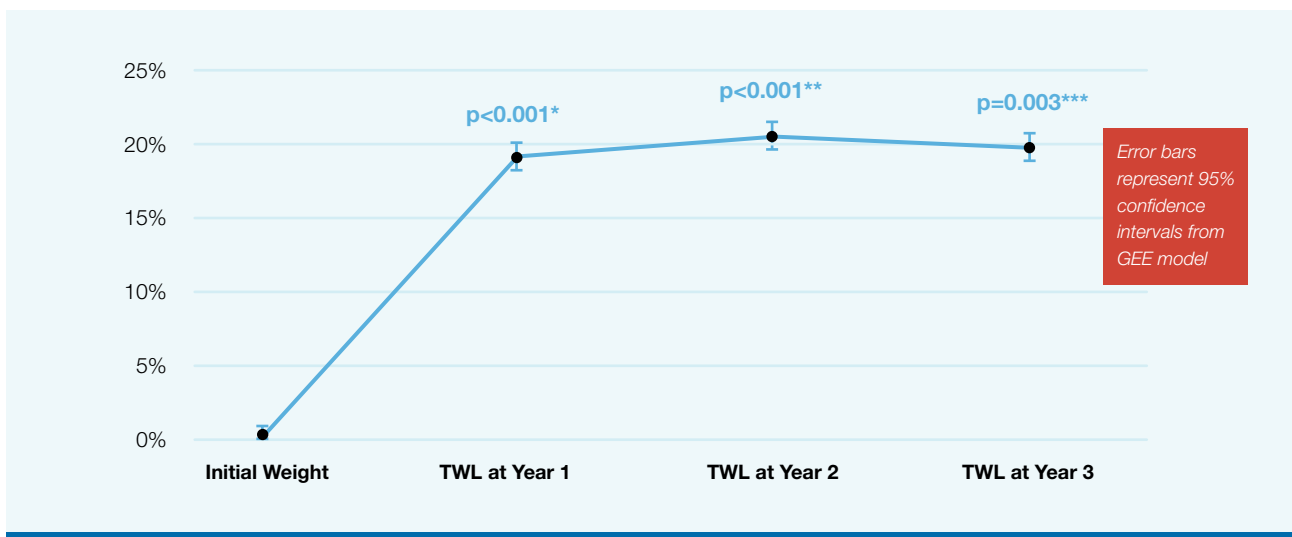


Figure 16 » Total Weight Loss for those Primary Patients who have reached their 3 Year Annual Follow-Up (n=887)²



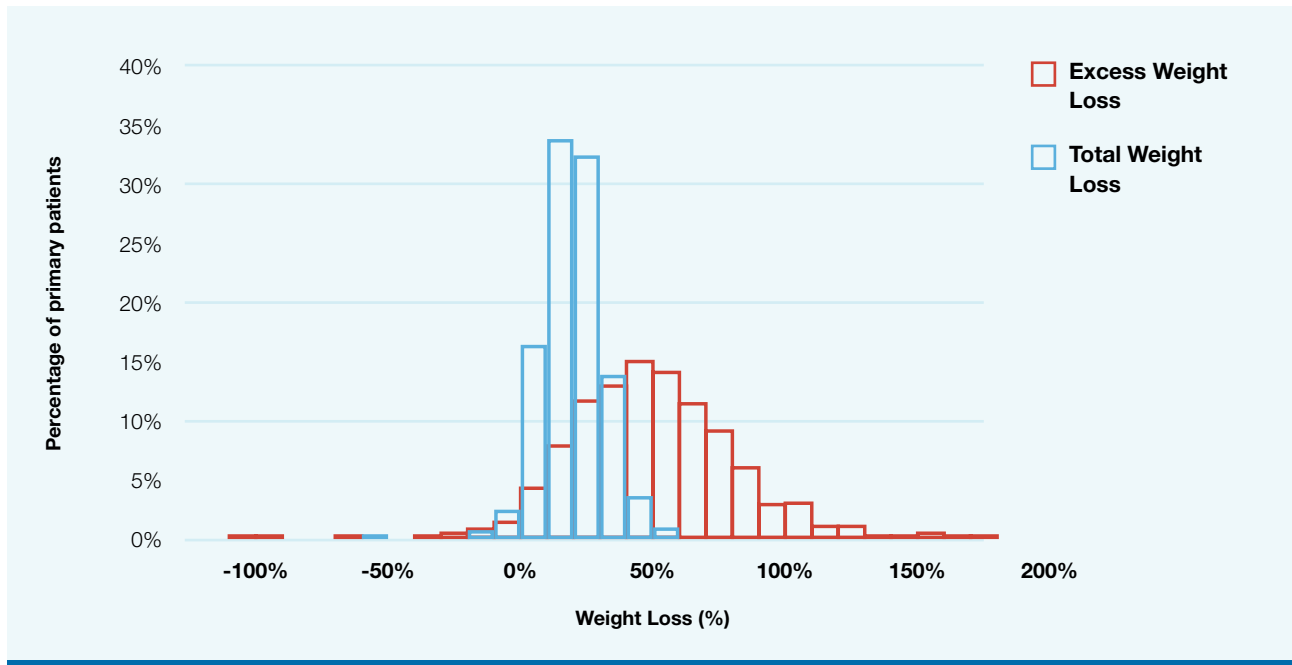
³ All p-values from generalized estimating equation (GEE) model with gaussian distribution & exchangeable correlation structure specified

* p-value comparing EWL/TWL at Yr 1 with Initial Weight;

** p-value comparing EWL/TWL at Yr 2 with Yr 1;

*** p-value comparing EWL/TWL at Yr 3 with Yr 2

Figure 17 » Weight loss at Three Years Post-Primary Procedure as at 30 June 2017



Note: N = 887 primary patients aged over 18 years who have completed three years of annual follow

7 Diabetes Outcomes

Of our 22,014 primary patients, there were 3,229 patients who were identified as having diabetes and receiving treatment (14.7%) at their time of surgery. Interestingly, there are a higher proportion of males (22.1%) who identify as being diabetic than females (12.5%) and the rates are substantially higher in the public system than in the private (see Table 19).

Table 19 » Primary Patients identifying as having Diabetes at Baseline Feb 2012 to 30 June 2017

	FEMALE	MALE	ALL
Public*	22.6%	35.3%	25.5%
Private	11.3%	20.5%	13.4%
All	12.5%	22.1%	14.7%

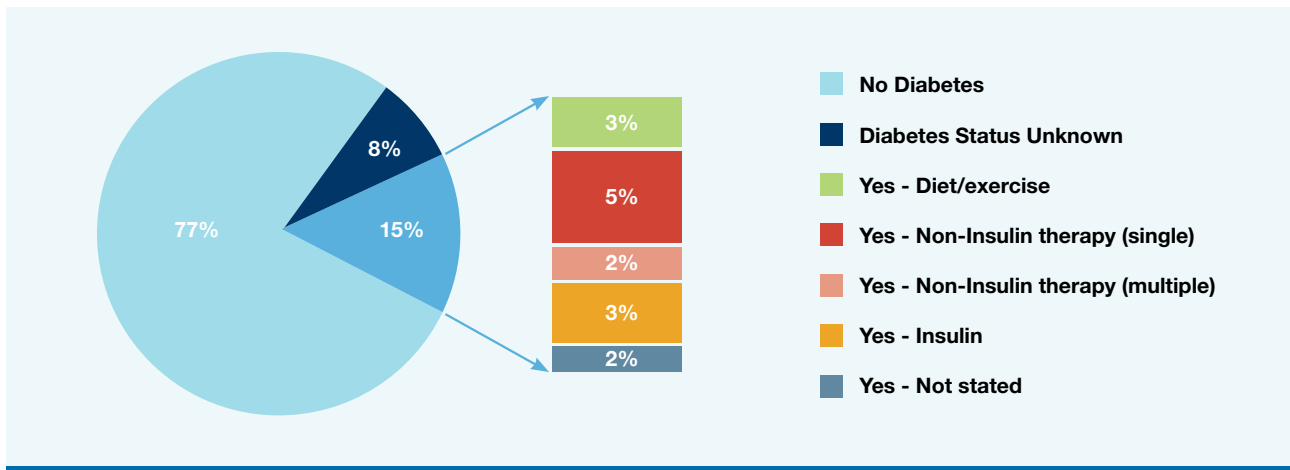
* NB: unknown diabetes status is much lower in public (4%) as compared to private (9%)

The treatment of these patients at baseline (day of surgery) is outlined in Table 20 where you can see the rate of insulin treatment is higher in Males than Females.

Table 20 » Treatment for Diabetes at Baseline Feb 2012 to 30 June 2017

TREATMENT FOR DIABETES	FEMALES		MALES		ALL	
Diet/exercise	472	22%	169	15%	641	20%
Non-Insulin (mono) therapy	773	36%	338	31%	1111	34%
Non-Insulin (poly) therapy	276	13%	195	18%	471	15%
Insulin	417	20%	298	27%	715	22%
Not stated	191	9%	100	9%	291	9%
TOTAL	2,129		1,100		3,229	

Figure 18 » Primary Patients' Identifying as having Diabetes and Treatment at Primary Procedure Feb 2012 to 30 June 2017



There have been 1,547 primary patients who were identified as having diabetes at baseline who have now reached their 12 month annual follow-up and we have collected their diabetes data. The treatment these patients received for diabetes at baseline and 12 months is shown in Table 21.

Table 21 » Treatment of Patients with diabetes reported at baseline followed up at 12 months

DIABETES TREATMENT	BASELINE		12 MONTHS	
Diet/exercise	300	19%	133	46%
Surgery Alone	NA	NA	584	
Non-Insulin (mono) therapy	550	36%	178	12%
Non-Insulin (poly) therapy	208	13%	36	2%
Insulin	354	23%	102	7%
Treatment not stated	135	9%	514	33%
TOTAL	1,547	100%	1,547	100%

A substantial proportion of this cohort require no diabetic medications at 12 months (indicated as "Surgery Alone" or "Diet/Exercise" – 46%). The proportion of patients requiring Insulin has dropped from 23% at baseline to 7% at 12 months although we still do not know the treatment of 33% of patients in this cohort.

Conclusions

There has been significant growth in the numbers of patients accrued in the BSR in the last 12 months. The BSR now has good penetration across most states and territories with a pleasing uptake from hospitals and clinicians alike.

The data to date confirms the safety and efficacy of bariatric surgery although data must be interpreted with caution until the entire population is captured. The numbers of procedures performed around Australia continues to grow at a rapid pace. In this setting, it is more critical than ever that we monitor our outcomes and constantly seek to improve the care we provide our patients.

We hope in the next 6 months to achieve near total enrolment of clinicians and sites. We also look forward to welcoming surgeons from New Zealand on to the Registry. We thank surgeons, hospitals, industry and government for their ongoing support and look forward to presenting a more complete reflection of bariatric surgery activity in Australia and New Zealand next year.

Acknowledgement

We would like to thank the Commonwealth Government of Australia (Department of Health) for their support of the BSR pilot and roll-out. We would also like to thank our other funders for their on-going support: Applied Medical, Medtronic and Gore Medical. Their commitment to best quality care is much appreciated.

Many thanks to the staff of the BSR who make not only this report but the BSR possible. Our project manager Dianne Brown, data manager Aileen Heal, customer relationship manager Jenifer Cottrell, our administrative officer Marlene Jacobs, research assistant Ashleigh Kumar and database support officer Adrian Heal. You all do an incredible job and we are so lucky to have such a strong team. I would like to welcome Dana Briggs to the team. I am sure she will be a very welcome addition.

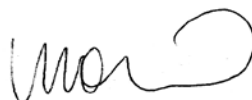
We could not function without our data entry and call centre staff. These are currently Alli Holt, Bekk Ashman, Eddy Woldemareyam, Jazz Padarath, Matt McMillan, Nilab Hamidi, Sonya Plamer, Seba Joseoph, TJ Muhlen-Schulte, Pari D'Cruz and Henry Truong. Thank you for your careful work ensuring our data is of the highest quality.

The Monash University Registry Sciences Unit provide us with the expertise necessary to ensure that these data are collected, stored and analysed according to rigorous standards. Many thanks to John McNeil, Breanna Pellegrini, Arul Earnest and Susannah Ahern for all of your support.

I would like to particularly thank Dianne Brown for her expert project management over the past few years. Without her, the BSR would not exist. We have been so fortunate to be able draw on her considerable skills and knowledge as we have gone through our establishment phase. We will miss you Dianne – but we are also glad to have you on board in a consultant role.

It would be remiss of me not to acknowledge the considerable effort that every bariatric surgeon in Australia, their teams and the participating hospital sites have put into the establishment of this registry. It is extra work, it is time consuming, yet the universal enthusiasm and will to make the BSR work has been overwhelming. Thank you so much for making the BSR possible. It is so heartening to see how committed we all are as a bariatric surgical community to improving the quality of the care we provide our patients.

And finally thank you to our patients who generously share their information with us to improve the quality of Bariatric Surgery in Australia and NZ. We are indebted to each and every one of you!



Professor Wendy Brown
MBBS (hons) PhD FACS FRACS
Clinical Lead

Appendix – Data Elements Captured

FOR ALL PATIENTS AND OPERATIONS

Field Name

- UR Number
- Title
- Family Name
- First Name
- DOB
- Street Number and Name
- Suburb
- State
- Postcode
- Gender
- Medicare Number
- Medicare Ref #
- Indigenous Status
- Home Phone
- Mobile Phone
- Hospital
- Surgeon
- Operation Date
- Primary or Revision
- Procedure Type
- Abandoned
- *If Revision*, Planned or Unplanned
- *If Unplanned*, Reason/Complication
- *If Primary*, Start Weight
- DOS Weight
- Height
- Diabetes Status
- *If Yes*, Diabetes Treatment
- Device Type
- Brand Name
- Device Description
- Device Model
- Device Manufacturer
- Serial No/Lot No
- *If Stapling Device*, Buttress
- *If Access Port Alone or Gastric Band*, Port Fixation Method
- *If Access Port Alone or Gastric Band*, Primary Port Retained
- Concurrent Renal Transplant
- Concurrent Liver Transplant

PERIOPERATIVE DATA FIELDS

Field Name

- Date of Follow up
- Unplanned return to theatre
- Unplanned Admission to ICU
- Unplanned Admission to Hospital
- *If Yes to any*, Reason/Complication
- Death?
- Have not seen patient, so BSR to follow up

ANNUAL DATA FIELDS (PRIMARY PT ONLY)

Field Name

- Date of Follow up
- Follow up Weight
- Diabetes?
- *If Yes*, Diabetes Treatment
- Reoperation in last 12 months?
- *If Yes*, Reason/Complication
- Death?
- Have not seen patient, so BSR to follow up

Appendix – Hospitals with Ethics Approval in BSR

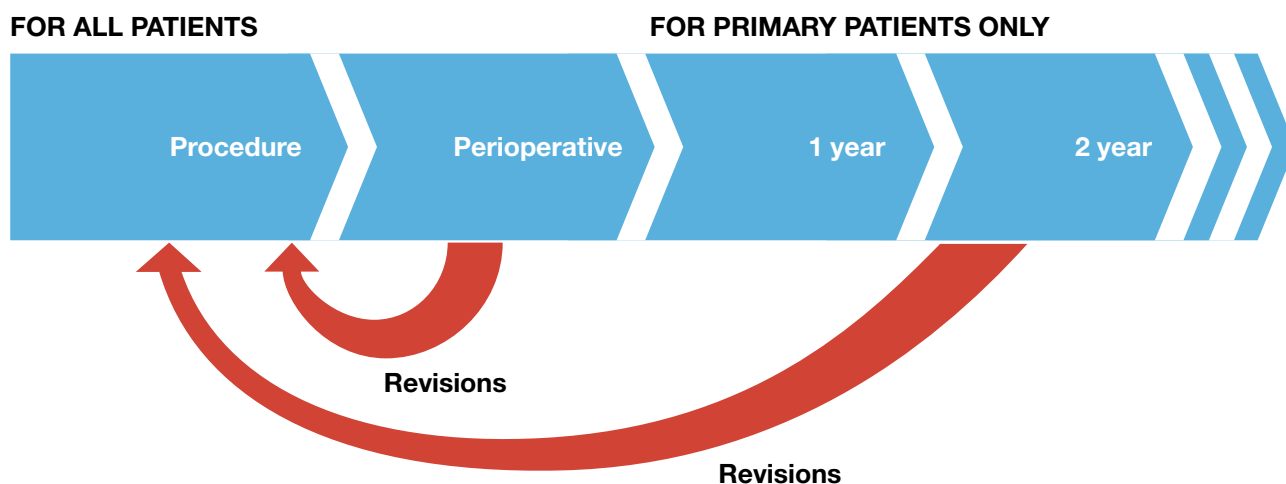
HOSPITAL	STATE
Albury-Wodonga Private Hospital	NSW
Ashford Private Hospital	SA
Austin Hospital	VIC
Austin Repatriation Hospital	VIC
Baringa Private Hospital	NSW
Belmont District Hospital	NSW
Bethesda Hospital	WA
Box Hill Hospital	VIC
Brisbane Waters Private Hospital	NSW
Cabrini Hospital Brighton	VIC
Cabrini Hospital Malvern	VIC
Cairns Private Hospital	QLD
Calvary Central District Hospital	SA
Calvary North Adelaide Hospital	SA
Calvary Riverina Hospital	NSW
Calvary St Vincents	TAS
Calvary Wakefield Hospital	SA
Campbelltown Private Hospital	NSW
Castle Hill Day Surgery	NSW
Concord Repatriation General Hospital	NSW
Darwin Private Hospital	NT
Epworth Eastern Hospital	VIC
Epworth Freemasons Hospital	VIC
Epworth Geelong Hospital	VIC
Epworth Richmond Hospital	VIC
Essendon Private Hospital	VIC
Fiona Stanley Hospital	WA
Flinders Medical Centre	SA
Flinders Private Hospital	SA
Footscray Hospital	VIC
Geelong Private Hospital	VIC
Glen Iris Private	VIC
Glengarry Private Hospital	WA
Gold Coast Private Hospital	Qld
Gosford Private Hospital	NSW
Gosford Public Hospital	NSW
Greenslopes Private Hospital	QLD
Hamilton Hospital	VIC
Hobart Private Hospital	TAS
Hollywood Private Hospital	WA
Holy Spirit Northside Hospital	QLD
Hospital for Specialist Surgery	NSW
Hurstville Private Hospital	NSW

HOSPITAL	STATE
Ipswich General Hospital	QLD
Jessie McPherson Private Hospital	VIC
John Fawkner Hospital	VIC
John Flynn Private Hospital	QLD
John Hunter Hospital	NSW
Joondalup Health Campus	WA
Kareena Private Hospital	NSW
Kawana Private Hospital	QLD
Knox Private Hospital	VIC
Lake Macquarie Private Hospital	NSW
Latrobe Regional Hospital	VIC
Launceston General Hospital	TAS
Linacre Private Hospital	VIC
Lingard Private Hospital	NSW
Maryvale Private Hospital	VIC
Mater Private (North Sydney)	NSW
Mater Private Hospital Pimlico	QLD
Mater Private Rockhampton	QLD
Mildura Base Hospital	VIC
Mildura Private Hospital	VIC
Mitcham Private Hospital	VIC
Monash Medical Centre	VIC
Mount Hospital	WA
Nambour Selangor Private Hospital	QLD
National Capital Private Hospital	ACT
Nepean Private Hospital	NSW
Newcastle Private Hospital	NSW
Noosa Private	QLD
North Shore Private Hospital	NSW
North West Private (Brisbane)	QLD
North West Private (Burnie)	TAS
Northpark Private Hospital	VIC
Norwest Private	NSW
Nowra Private Hospital	NSW
Peninsula Private Hospital	VIC
Pindara Private Hospital	QLD
Port Macquarie Private Hospital	NSW
Prince of Wales Private Hospital	NSW
Princess Alexandra Hospital	QLD
Queen Elizabeth Hospital	SA
Queen Elizabeth II Jubilee Hospital	QLD
Repatriation General Hospital	SA
Royal Adelaide Hospital	SA

HOSPITAL	STATE
Royal Brisbane and Women's Hospital	QLD
Royal Hobart Hospital	TAS
Royal North Shore Hospital	NSW
Royal Prince Alfred Hospital	NSW
Shepparton Private Hospital	VIC
Southern Highlands Private Hospital	NSW
St Andrew's War Memorial Hospital	QLD
St Andrew's-Ipswich Private Hospital	QLD
St George Private Hospital	NSW
St John of God Ballarat	VIC
St John of God Berwick	VIC
St John of God Bunbury	WA
St John of God Geelong	VIC
St John of God Geraldton	WA
St John of God Mt Lawley	WA
St John of God Murdoch	WA
St John of God Subiaco	WA
St John of God Warrnambool	VIC
St Vincent's Hospital Melbourne (Public)	VIC
St Vincent's Private Hospital - Fitzroy	VIC
Strathfield Private Hospital	NSW
Sunnybank Private Hospital	QLD
Sunshine Coast Private Hospital	QLD
Sunshine Coast University Private Hospital	QLD
Sunshine Hospital	VIC
Sydney Adventist Hospital	NSW
Sydney Southwest Private Hospital	NSW
The Alfred Hospital	VIC
The Avenue Private Hospital	VIC
The Valley Private Hospital	VIC
The Wesley Hospital	QLD
Wagga Wagga Rural Referral Hospital	NSW
Waikiki Private Hospital	WA
Wangaratta Private Hospital	VIC
Warringal Private Hospital	VIC
Waverley Private Hospital	VIC
Western Private Hospital	VIC
Westmead Private Hospital	NSW
Williamstown Hospital	VIC

Appendix – Data Collection Process

Data is collected at multiple stages along the patient's journey



PRIMARY DATA COLLECTION POINT	FOR ALL PATIENTS	FOR PRIMARY PATIENTS ONLY
	<ul style="list-style-type: none"> Public Hospital Data Collector Surgeon 	<ul style="list-style-type: none"> Public Hospital Data Collector Surgeon
VIA	<ul style="list-style-type: none"> Teleforms BSR-<i>i</i> 	<ul style="list-style-type: none"> State BDM Patient Teleforms BSR-<i>i</i> Call Centre System Generated
DATA TO BE COLLECTED	<ul style="list-style-type: none"> Patient Identification Patient Demographics Operation Data Clinical Data Device Data 	<ul style="list-style-type: none"> Outcome Data Outcome Data Subsequent Clinical Data

References

- i. Australian Parliament House of Representatives Standing Committee on Health and Ageing. **Weighing it up : obesity in Australia**, http://www.aph.gov.au/Parliamentary_Business/Committees/House_of_Representatives_Committees?url=haa/./obesity/report/fullreport.pdf

- ii. Australian Medical Association, **AMA Position Statement – Obesity 2016**, <https://ama.com.au/position-statement/obesity-2016>

- iii. Dixon J, O'Brien P, Playfair J, Chapman L, Schachter LM, Skinner S, Proietto J, Bailey M, Anderson M., **Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial**. *Jama* 2008;299:316-23.

- iv. Australian Commission on Safety and Quality in Health Care. **Information Strategy**. Sydney: ACSHQ, 2007.25.2007.

- v. Revision incidence rates can be analysed by calculating the time between primary bariatric procedure to the first subsequent revision procedure. Those patients with a primary procedure soon after February 2012 are observed for longer time periods than those with a primary procedure later in the observation period. Survival analysis techniques (ie. Nelson-Aalen method) estimate the probability of revision at each follow-up time point based on the number at risk of revision and the number of revisions at that time point. This method censors patients that are revision free at the end of the observation period and truncates patients who have already experienced a revision prior to the observation period. The Nelson-Aalen cumulative probability estimates in Figure 9 show a low revision incidence rate of bariatric procedures. At one year post primary procedure, 1.8% (95% CI 1.6% to 2.0%) of patients are estimated to have had their first revision procedure. At two years post primary procedure, 3.6% (95% CI 3.2% to 3.9%) are estimated to have had their first revision procedure.

- vi. For interpretation of the box plots in Figures 10 and 11, the box region indicates the interquartile range (IQR), and the horizontal line inside the box region indicates the median operation age or BMI. The ends of the whiskers indicate the most extreme values within (75th percentile + 1.5*IQR) and (25th percentile - 1.5*IQR). Extreme values outside of the whiskers are not shown

