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2016**



BSR

BARIATRIC SURGERY REGISTRY

Fourth Report of the Bariatric Surgery Registry



MONASH University
School of Public Health and Preventive Medicine



Obesity Surgery Society
of Australia & New Zealand

Funding Partners

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



Medtronic

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Foreword from Chair of Steering Committee

Professor Ian Caterson

The progress of the BSR amazes me. We now have accrued 15,643 patients and the follow-up is now out to 3 years. This magnificent result is due to the fantastic effort of those in the BSR office, the experience of the Monash team who work with the registries, and to the input from surgeons and hospital staff. A vote of thanks is due to you all!

Of course there are difficulties. Whilst essential, the ethics process can and does cause difficulties and delays (and frustrations), and it is costly in monetary terms and in time. However this scrutiny and ultimate approval does mean that we are doing the right thing by patients, doctors and hospitals. It has allowed us to get great data that will be of major importance in the delivery of medical and bariatric care.

As the BSR has developed so has the way we collect data, increasingly on-line. There is a constant scrutiny of our data dictionary to ensure that what we collect is clear and defined. It has also become evident that our next major hurdle will be the quality of the yearly follow-up data. We have to find ways of improving the ease of obtaining this so we can maintain a small “drop-out” rate so our data is meaningful. We look forward to the roll-out in New Zealand soon.

We need to thank our funding partners particularly.....as without their help we could not maintain and improve the BSR. I have been impressed by the dedication and enthusiasm of the BSR team (who, by the way, are extremely approachable if you need help and advice) who ensure the high quality and integrity of the BSR.



Professor Ian D Caterson



List of Abbreviations

ANZGOSA Australia and New Zealand Gastro-Oesophageal Surgery Association

BMI Body Mass Index

BOLD Bariatric Outcomes Longitudinal Database

BPD/DS Bilio-Pancreatic Device with Duodenal Switch

BSR Bariatric Surgery Registry

DOS Day Of Surgery

ICU Intensive Care Unit

LAGB Laparoscopic Adjustable Gastric Banding

LSG Laparoscopic Sleeve Gastrectomy

NSW New South Wales

OECD The Organisation for Economic Co-Operation and Development

OSSANZ The Obesity Surgery Society of Australia and New Zealand

QLD Queensland

RACS Royal Australasian College of Surgeons

RCT Randomised Controlled Trials

RYGB Roux-Y Gastric Bypass

SA South Australia

SAGB Single Anastomosis Gastric Bypass

SPHPM School of Public Health and Preventive Medicine

TAS Tasmania

VIC Victoria

WA Western Australia

WHO World Health Organisation

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-off

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

Partial opt-off

Patients who have been sent Explanatory Statements and who have indicated that they are happy to have information kept but don't 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 highest of the weight at *Intention to Treat* or weight at *Operation of a Primary Patient*.

Perioperative 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 perioperative 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

Data Period

The data contained in this document was extracted from the Bariatric Surgery Registry (BSR) as at 1 August 2016 but pertains to procedures that has occurred up to 30 June 2016. As the Registry does not capture data in real time, there can be a lag between occurrence of an event and capture in the BSR.

Executive Summary

The Bariatric Surgery Registry (BSR) is proud to present its Fourth Annual Report as at 30 June 2016. In the last 12 months we have grown the BSR three-fold to a total of 15,643 consented patients. We have achieved this through the growing support of the 113 surgeons that are contributing data at the 84 sites for which we now have ethics approval. Through their efforts we have data on over 16,000 procedures in both the public and private hospital systems right around Australia (although the vast majority of procedures occur in private hospitals – 86%).

Our cohort of patients is predominantly female (79%), in their mid-forties (mean age of 44.2 years) and if they are a primary patient, their mean BMI on day of surgery is 43 and 14.8% of them identify as diabetic. Nearly 12,000 of our consented patients are primary patients, meaning their first presentation to the BSR was with a primary procedure. This means we will be tracking three-quarters of our patients throughout their entire bariatric journey collecting their weight, diabetes treatment and reoperation history every year. Currently we have 5,366 patients who have reached at least one year of follow up while over 100 patients have reached their 4 year mark.

In the last 6 months nearly 60% of the procedures we have captured were Sleeve Gastrectomies while only 15% were Gastric Bands. Twelve months ago Gastric Bands represented 32% of our procedures captured. This reflects the changing pattern of procedures being used in the broader community including the rise of newer procedures such as the Single Anastomosis Gastric Bypass.

We have continued to see a low rate of deaths from bariatric surgery (0.04% of consented patients). In the perioperative period 2.1% of primary procedures for which we have perioperative follow up and 5.3% of revision procedures have had a Defined Adverse Event (unplanned return to theatre, admission to ICU or re-admission to hospital). In our primary patient cohort 280 of them have required a revision procedure (349) which is 2.4% of the cohort.

Our Excess Weight Loss (EWL) findings are similar to last year at the 2 year review with EWL of 51.2%. We have 3 year data in this report with EWL at 51.8% for those who have reached this point. The 12 month EWL is slightly higher at 55.7% this year, reflecting the change in the mix of our procedures captured.

For our cohort of primary patients who were being treated for diabetes at baseline, we have found that 38% of them no longer require diabetes treatment 12 months after surgery. This continues to be an encouraging outcome in our data and one we plan to monitor further.

We face a number of challenges as we continue to roll out – accrual of our remaining hospital sites, engagement of all surgeons at every site, maintaining a workable data capture system, linking with other data repositories to validate our data and securing a sustainable funding base. None of these are insurmountable and we continue to work hard to overcome them and ensure we are delivering a Registry with valuable data that is complete and trustworthy.

Background

Rationale for Registry & Registry Collaborators

The rising prevalence of populations being overweight and suffering obesity in several countries, including Australia, has been described as a global pandemic¹. The World Health Organisation (WHO) estimates that being overweight or obese contributes to 44% of diabetes, 23% of ischaemic heart disease and 7% - 41% of some cancers².

Obesity is one of the most important public health issues facing Australia in the 21st century. According to the latest Australian Health Survey, 28.3% of Australians are now obese³ which, according to OECD data, is the fifth highest prevalence of obesity in the developed world (Figure 1)⁴. Given that there has been a significant increase in obesity in Australia over the past 20 years, with a prevalence of 19% reported in 1995, it seems likely that the prevalence of obesity in our community will continue to increase.

Lifestyle interventions can be effective in the short term, however, weight loss is difficult to maintain in the long term^{5,6}. For those with severe obesity there are several Randomised Controlled Trials (RCT)⁷⁻¹⁰ and multiple case series¹¹ which suggest that Bariatric Surgery provides more predictable and sustainable weight loss than conservative regimes, and is generally very safe^{12,13}.

On the basis of these data, bariatric surgery is burgeoning in Australia. However there are no evidence based guidelines directing who should be offered this surgery, nor is there any long-term community data documenting the efficacy and safety of the procedures in our community.

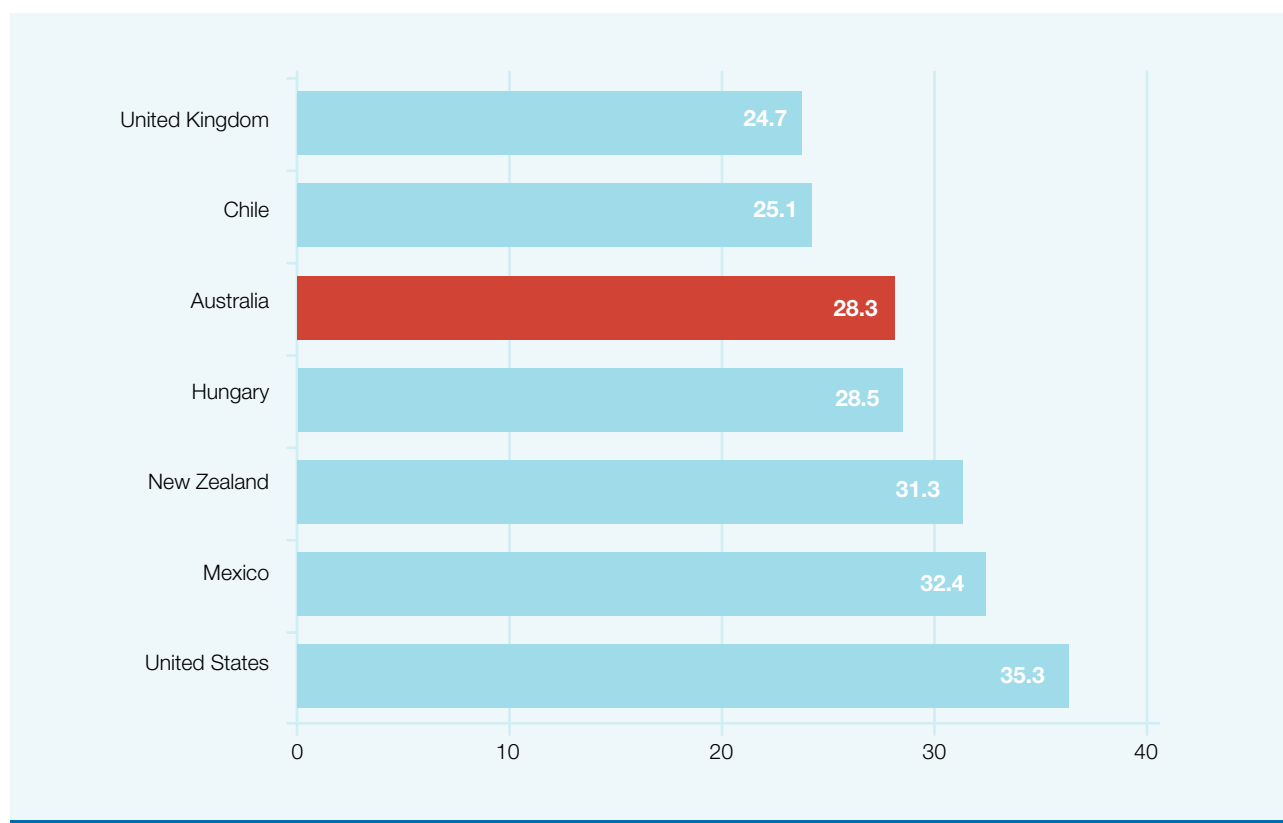
The need for a registry to track outcomes of bariatric surgery was identified by the Obesity Surgery Society of Australia and New Zealand (OSSANZ) in 2009. Clinical registries, as opposed to a research database, build on data collected from events in daily health care and use this information to assess care provision and implement quality improvements where required. They have an overlying governance structure which monitors data collection, data processing and the ethical conduct of the process^{14,15}. Participation in clinical registries has been documented to improve patient outcomes¹⁶.

A sub-committee was appointed by the OSSANZ executive. This sub-committee investigated all current bariatric surgical registries including the UK national registry, the BOLD database of the American Metabolic and Bariatric Surgery Society and the registry of the American College of Surgeons. It became apparent that a local registry was going to be required given our primary requirement for outcome and safety data which requires the storage of identifiable data which requires compliance with Australian Privacy Law. Another issue was that the data capture in these registries did not approach the 95% required for a clinical registry to minimise the risk of bias and be considered clinically relevant¹⁷.

OSSANZ therefore undertook a tender process and eventually partnered with the Monash University School of Public Health and Preventive Medicine (SPHPM) as Registry custodian. OSSANZ commissioned a report which was delivered in March 2010. Ethical approval for the first site of the pilot Registry was obtained from the Alfred Hospital in January 2012, with subsequent approval obtained from the Avenue Hospital, Box Hill Hospital, Royal Australasian College of Surgeons (RACS), St John of God Warrnambool and Monash University. Importantly, permission for an opt-out consent process was given. In July 2014, the national rollout of the Australian component of the Registry commenced with the support of the Australian Commonwealth Government.

We are now pleased to present the Fourth Annual Report of the Bariatric Surgery Registry, reporting until 30 June 2016.

Figure 1 » Obesity among adults, 2012 or nearest year (%population aged ≥15 years)³



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 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)** | Mark Smithers
- » **Medical Technology Association of Australia (MTAA)** | David Ross
- » **Custodian/ Epidemiologist** | Prof John McNeil
- » **Australian Commonwealth Department of Health** | Nathan Hyson

In the four years the steering committee has been operating their 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 they have worked with the BSR staff to develop a **Data Governance Framework** and the associated policies and processes that underpin the Registry including:

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

The **Registry Custodian** is The School of Public Health and Preventive Medicine 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, there have been 181 surgeons register interest in the Registry (Figure 2).

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

In the year 1st July 2015 to 30 June 2016 an additional 22 sites have been approved by their ethics committees, bringing the total number of approved sites to 84 as at 30 June 2016. In conjunction with this, the number of surgeons contributing data to the Registry has also increased from 65 to 113.

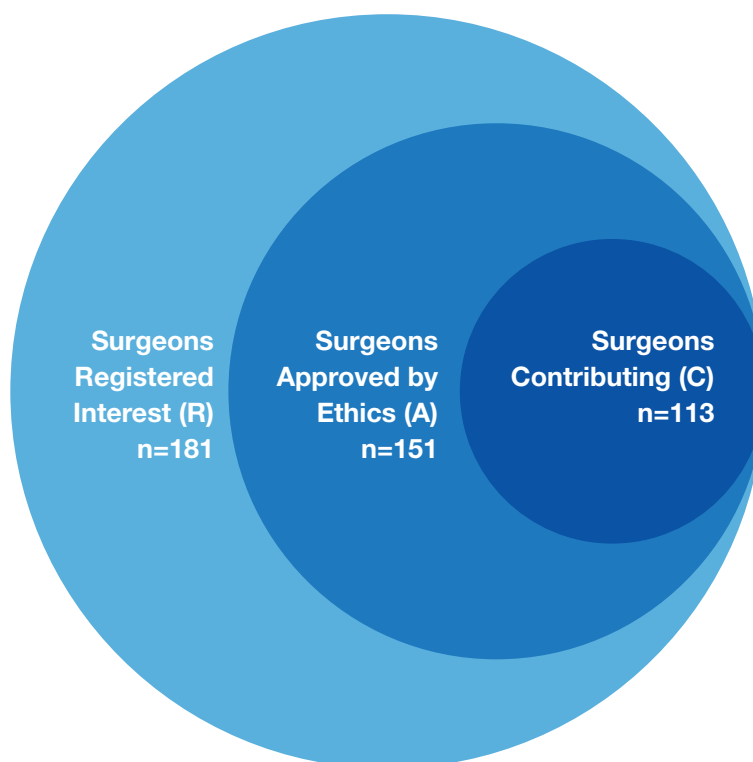
Data Elements

As a registry we understood and recognised the need for near complete data capture to ensure the reliability of the Registry. Hence, the data elements that are currently collected by the Registry now include only those elements that were most reliably completed during the pilot study.

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 and the need for revision or repeat surgery, unplanned admissions to ICU or readmissions to hospital as well as mortality. The data dictionary has been revised and reflects the changes to the collected dataset.

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 we collect, please refer to the Appendix.

Figure 2 » Surgeons Performing Bariatric Surgery



Data collection process

The data collection process is summarised in the Appendix. The surgeon or data collector at a public hospital returns the initial data-form to the Registry or inputs the data directly into the BSR-*i* (our online interface) as close as possible to the day of surgery. The Registry then posts a patient explanatory statement (with individual hospital logo) to the patient.

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-off*, 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-off*, meaning that they are happy to have data held in the Registry but they do not wish to be called or contacted by the Registry at any time. It is important to note that the patient has the right to opt-off 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.

Completeness of data capture is cross-checked with regular ICD code checks from participating hospitals. Should a procedure be identified as having occurred but not entered into the Registry, the surgeon is contacted and details of the missed procedure are sought. In the future similar external checks will be performed with State Offices of Births, Deaths and Marriages as well as other registries.

Follow up forms or email reminders are sent to the treating surgeon perioperatively for all procedures for both legacy and primary patients. The data collected is about whether any defined adverse events have occurred and, if they have occurred, the reason/ complication that was the cause. This data is accepted for visits occurring from 20 days post-surgery to 90 days post-surgery.

Annual forms or email reminders are also sent to the surgeon for primary patients of the Registry. The data collected includes the patient's weight, diabetes status and need for reoperation. This data is accepted for visits occurring from 90 days to 15 months post-operatively. If data is not forthcoming from the surgeon or the surgeon indicates that they have lost touch with a given patient, the Registry has the option to call patients to collect the same data elements using a scripted interaction as per our Call Centre Protocol.

Data can currently be provided by the surgeons via our web-based interface, the BSR-*i*, or via paper forms. We are also working with software providers of electronic medical records (EMR) to seek ways to streamline the process, particularly for follow-up.

Data Reporting

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

RELEASED TO	REPORT TYPE	REPORTING
Public	Annual Report	As at 30 June each year
Public	Semi-annual Report	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 Quality and Safety Registry, the Registry also reports on any identified outlier in accordance with our Outlier Policy.

Results of the Bariatric Surgery Registry as at 30 June 2016

1 Enrolment in the Registry

Since commencement in February 2012, Patient Explanatory Statements and Invitations to participate in the Registry have been sent to a total of 16,353 patients who had their operation before or on 30 June 2016. There have been 554 patients who have chosen to opt-off (3.4%) and 45 (0.3%) partial opt-offs (although partial opt-offs are still considered consented). A further 156 patients (1.0%) were still in the two week period and are pending consent when the data was drawn on 1st August 2016.

There have been nine patients in the Registry who are now deceased.

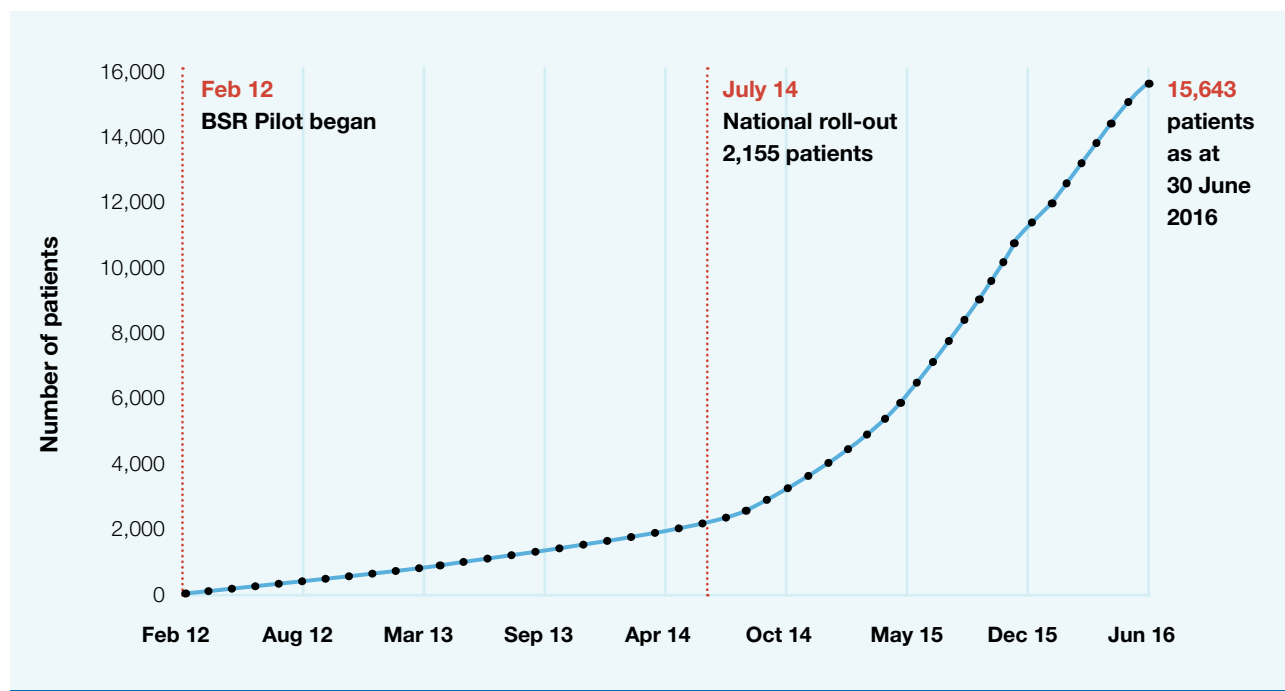
This means we currently have 15,643 patients (95.7%) who have consented to have their information included in the Registry. This is the cohort on which this report is based.

You will note in Table 1 that we have tripled the size of the BSR in the last 12 months. This increased capture rate has had minimal effect on our opt-off rate.

Table 1 » Patient Participation in the BSR Over Time

	AS AT 30 JUNE 2016	AS AT 31 DEC 2015	AS AT 30 JUNE 2015	AS AT 31 DEC 2014
Consented	15,643	10,570	5,788	3,180
Opted Off	554	403	213	102
Opt Off Rate	3.4%	3.6%	3.5%	3.07%

Figure 3 » Accumulation Rate of Patients Participating in the BSR (February 2012 to 30th June 2016)



2 Procedures Captured by the Registry

There have been 16,577 procedures performed on the 15,643 consented patients with the type of procedures undertaken described in (Table 2). The number of procedures is higher than the total number of consented patients due to multiple procedures occurring in some patients. This is a 171% increase from 6,112 procedures in our Annual Report as at 30 June 2015. The vast majority of these primary (87%) and revision procedures (85%) occur in the private hospital system (Table 3).

We have captured a total of 4,598 procedures that were performed in the six months from 1 January to 30 June 2016 (Table 2) which we estimate to be nearly half of the procedures that occurred in Australia over the same period (MBS figures). Of the three most popular procedures, we captured 40% of LSG, 68% of LAGB and 68% of RYGB/SAGB*. This compares to the capture rate as at 31 December 2015 of 36% of LSG, 62% of LAGB and 47% of RYGB*.

Table 2 » Procedures Performed by Type

	TOTAL BSR (Feb 2012 to 30 June 2016)		BSR LAST 6 MONTHS (1 Jan to 30 June 2016)		MBS DATA LAST 6 MONTHS (Est of % collected in brackets)
	Primary	Revision	Primary	Revision	
Sleeve gastrectomy (LSG)	7,270	838	2,483	222	6,748 (40%)
Gastric Banding (LAGB)	3,600	1,013	541	133	991 (68%)
R-Y gastric bypass (RYGB)	691	775	198	256	1,043 (68%)*
Single anastomosis gastric bypass (SAGB)	309	239	132	122	
Surgical Reversals	NA	1,469	NA	436	NA
Other Procedures	40	333	12	63	NA
Total Procedures (incl Abandon)	11,910	4,667	3,366	1,232	NA
Abandoned Procedures	20	15	6	4	NA

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

Figure 4 » Change in Procedure Type Captured by BSR

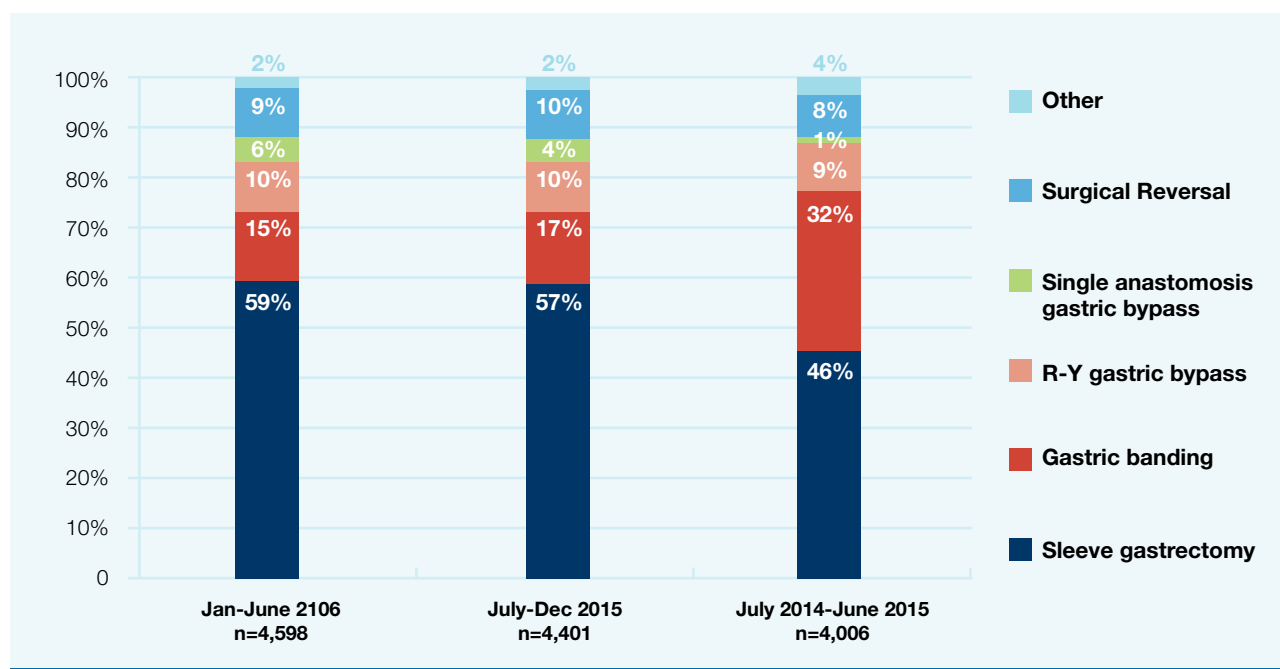


Table 3 » Procedures Performed in Public Hospitals

	TOTAL BSR (Feb 2012 to 30 June 2016)				BSR LAST 6 MONTHS (1 Jan to 30 June 2016)			
	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)	923	13%	99	12%	244	10%	21	9%
Gastric Banding (LAGB)	572	16%	215	21%	64	12%	17	13%
R-Y gastric bypass (RYGB)	78	11%	78	10%	11	6%	9	4%
Single anastomosis gastric bypass (SAGB)	28	9%	8	3%	15	11%	1	1%
Bilio pancreatic bypass/ duodenal switch (BPD)	3	27%	14	56%	0	0%	0	0%
Port Revision	NA	NA	47	21%	NA	NA	6	14%
Surgical Reversal	NA	NA	235	16%	NA	NA	49	11%
Other Procedures	1	3%	11	13%	0	0%	2	12%
Total Procedures	1,605	13%	707	15%	334	10%	105	9%

Of the 16,577 procedures captured by the Registry there has only been one Revision procedure where a concurrent Renal Transplant took place. There have been no concurrent Liver Transplants reported as yet.

Primary Patients

There have been 11,904 consented patients whose first presentation to the Registry was with a primary procedure. These patients are termed "Primary Patients". Primary patients have quality and safety measures recorded perioperatively as well as annual tracking of diabetes status, need for reoperation (and complication) and weight.

The number of primary procedures by type as at 30 June 2015 and 2016 is shown in Table 4. There has been nearly a 310% increase in the number of Sleeve Gastrectomies captured the last 12 months as compared to only a 52% increase in the number of Gastric Banding procedures recorded. This most likely 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 broader community.

Table 4 » Primary procedures in BSR by type as at 30 June 2015 and 2016

DESCRIPTION	30 JUNE 2016	30 JUNE 2015
Sleeve gastrectomy	7,270	1,777
Gastric banding	3,600	2,364
R-Y gastric bypass	691	200
Single anastomosis gastric bypass	309	26
Gastric imbrication, plus gastric band (iBand)	9	5
Gastroplasty	3	0
Bilio pancreatic bypass/duodenal switch	11	2
Other (specify)	4	-
Not stated/inadequately described	13	13
TOTAL	11,910	4,387

There have been 280 patients (2.4 %) who had their primary procedure captured by the Registry who have gone on to have a subsequent procedure with a total of 349 revision procedures in this group. Some of these patients requiring multiple revisions (Table 5). There are 78 primary patients that have had a surgical reversal and of these, 59 patients have not gone on to have another bariatric procedure at this stage. We do not continue to follow these patients as their treatment has ceased. If they return to have another bariatric procedure in the future, we will recommence their annual follow up.

Table 5 » Number of Primary Patients by the Number of Procedures they have Undergone in Total (Feb 2012 to 30 June 2016)

# PRIMARY PATIENTS WHO HAVE HAD	NUMBER	%
Only an Abandoned Procedure	13	0.11%
Only a Primary Procedure	11,611	97.54%
A Primary Procedure & 1 Revision	224	1.88%
A Primary Procedure & 2 Revisions	49	0.41%
A Primary Procedure & 3 Revisions	2	0.02%
A Primary Procedure & 4 Revisions	4	0.03%
A Primary Procedure & 5 Revisions	1	0.01%
TOTAL PRIMARY PATIENTS	11,904	100%

Table 6 » Average Number of Days between Initial Primary Procedure and First Revision Procedure by Type of Primary (Feb 2012 to 30 June 2016)

	# PRIMARY PROCEDURES WITH AT LEAST ONE REVISION	AVERAGE # DAYS BETWEEN PRIMARY & FIRST REVISION (Std Dev)
Sleeve gastrectomy (n=7,270)	15	130 (119)
Gastric banding (n=3,600)	251	419 (348)
R-Y gastric bypass (n=691)	11	137 (196)
Single anastomosis gastric bypass (n=309)	2	83.5 (103)

Legacy Patients

There were 3,739 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 perioperatively.

There have been 533 legacy patients (14.3% patients) who first presented to the Registry with a revision procedure who have required a subsequent revision procedure. This is a higher rate than for the Primary Patient cohort, reflecting the complexity of revision surgery. There are 1,104 procedures in this group as some of these patients have undergone multiple operations (Table 7).

Table 7 » Revision procedures performed on Legacy Patients (2012 to 30 June 2016)

# LEGACY PATIENTS WHO HAVE HAD	FEB 2012 TO 30 JUNE 2016
Only an Abandoned Procedure	8
Only 1 Revision recorded on BSR	3,198
2 Revisions recorded on BSR	505
3 Revisions recorded on BSR	18
4 Revisions recorded on BSR	10
TOTAL LEGACY PATIENTS	3,739

3 Demographics

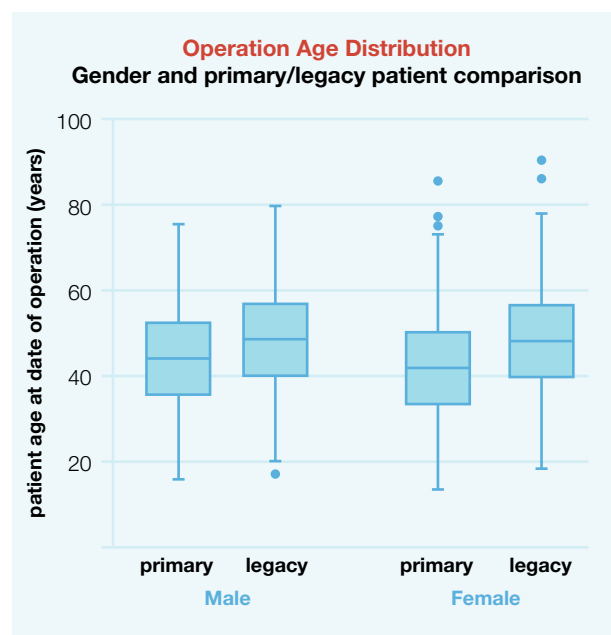
There have been 3,260 males (21%), 12,378 females (79%) and 5 intersex or indeterminate persons who were consented to be included in the Registry as at 30 June 2016. Within the Primary Patient cohort there have been 2,719 (23%) males and 9,181 (77%) females and 4 intersex or indeterminate persons. Males make up a lower proportion of our legacy patient cohort at 14%. Of those primary patients that have had a revision, males are also a lower proportion of the cohort at 17% indicating that males may have a lower propensity to have revisional surgery.

The mean age of all patients at their first procedure was 44.2 years. Primary patients have a lower mean age (43.2 years) than legacy patients (47.6 years) who are further along their bariatric journey. Women tend to be younger than men, on average by 3 years, when they have their primary procedures which we found to be a statistically significant difference.¹

Table 8 » Demographics of Patients at Time of Their First Procedure in the BSR (2012 to 30 June 2016)

	ALL PATIENTS	PRIMARY PATIENTS	LEGACY PATIENTS
% Female	79%	77%	86%
Mean age	44.2	43.2	47.6
Median age	44.2	43.3	47.7
Mean age – Female	43.7	42.5	47.2
Mean age – Male	46.2	45.4	50.1
Minimum Age	14.2	14.2	17.5
Maximum Age	87.9	84.2	87.9

Figure 5 » Operation Age Distribution at Time of Their First Procedure in the BSR Feb 2012 to 30 June 2016)



Note: Five patients with indeterminate gender are not included in this box plot analysis

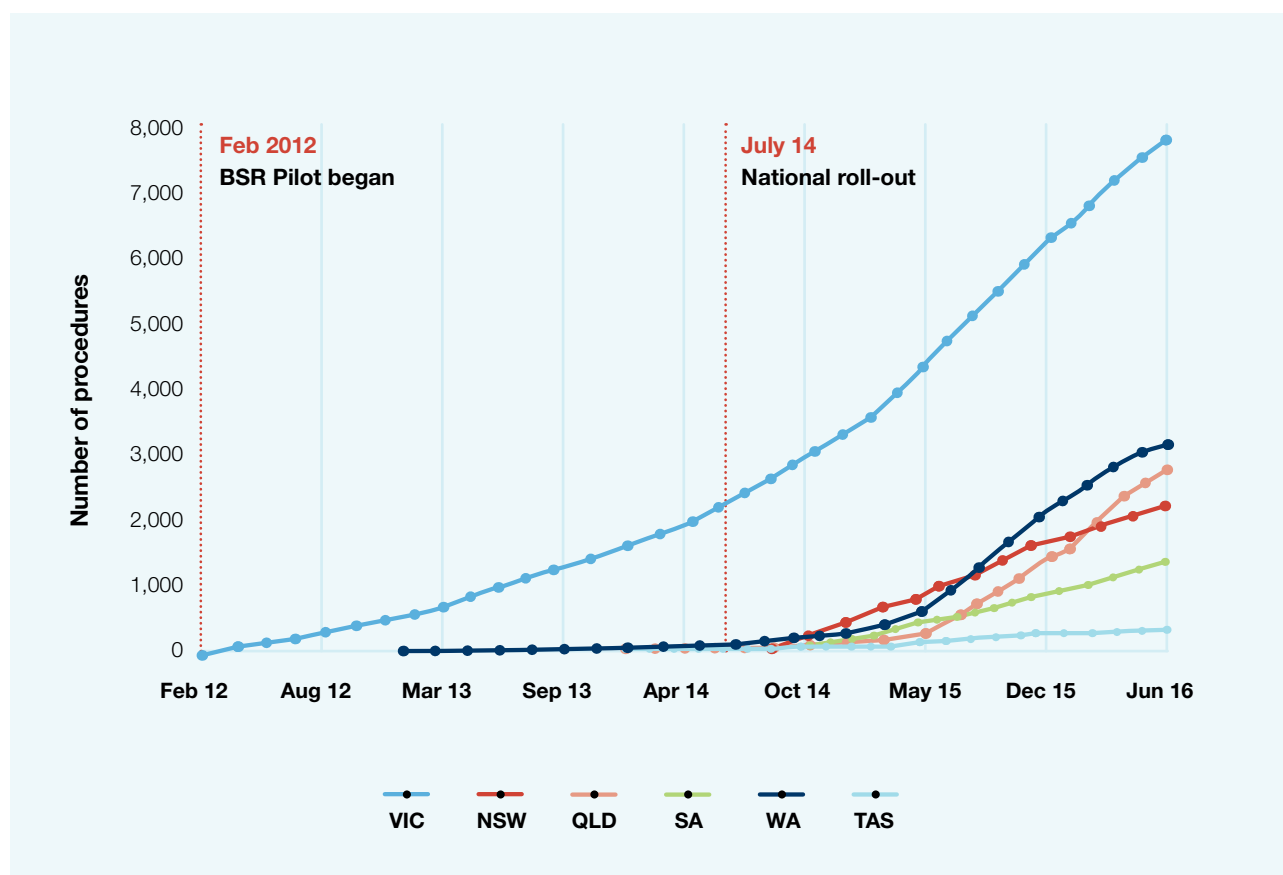
¹ Two sample t-test between unpaired groups with unequal variances was performed where P-value<0.0001

The distribution of captured bariatric procedures by state is outlined in Table 9. Hospitals are listed in the Appendix. There has been improvement in the penetration across States in the last six months, particularly in Queensland and Western Australia.

Table 9 » States where Procedures Occurred Feb 2012 to 30 June 2016

STATE	PRIMARY PROCEDURES		REVISION PROCEDURES		TOTAL PROCEDURES
NSW	1,671	14%	426	9%	2,097
VIC	5,025	42%	2,343	50%	7,368
QLD	2,174	18%	436	9%	2,610
SA	775	7%	466	10%	1,241
WA	1,997	17%	963	21%	2,960
TAS	268	2%	33	1%	301
AUS TOTAL	11,910	100%	4,667	100%	16,577

Figure 6 » Accumulation Rate of BSR Procedures by State (February 2012 to 30th June 2016)



4 Follow-up

The follow-up rates achieved at each data collection point are shown in Table 10. Data is defined as “due” on the appropriate anniversary from the date of operation, ie perioperative follow up is due 30 days after the surgery date, 1 year data is due one year after the surgery date. Data is defined as “Overdue”, “Out of Window” and “Uncollectible” according to the definitions for data windows described in the Appendix.

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 perioperative follow up) is 3.6%. If these patients have a subsequent procedure, they will re-enter the follow up system and we will begin capturing their follow up details again then.

Table 10 » Follow Up Completion by Type (excluding LTFU)

	PERIOP	YEAR 1	YEAR 2	YEAR 3	YEAR 4	TOTAL
Total Complete	12,316	3,291	1,298	517	49	17,471
Total Follow Ups	16,396	5,366	1,585	675	106	24,138
% Complete	75%	61%	82%	77%	46%	72%
Incompletes:						
Due	1,125	906	122	77	32	2,262
Overdue	1,305	269	31	18	4	1,627
Out of Window	NA	819	133	63	21	1,036
Uncollectible	1,650	81	1	0	0	1,732
% Uncollectible	10%	2%	0%	0%	0%	7%

5 Safety Reporting

Deaths

Deaths are extremely rare in the BSR but there have been four reported deaths since our last Annual Report as at 30 June 2015.

There are now 9 patients of the BSR who have died (0.06% of consented patients), however two of these deaths we are certain are not attributable to surgery which takes it to 0.04% of consented patients. We are also still investigating 4 of these deaths to ascertain if they were related to the bariatric surgery or not. The deaths reported are listed in Table 11 below:

Table 11 » Deaths Related to Bariatric Procedure reported to the BSR until 30 June 2016

DATE OF DEATH	PATIENT GROUP	PROCEDURE	CAUSE OF DEATH	NOTES
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	Sleeve	Undetermined	Awaiting Coroners Report
Q4 2015	Primary	LAGB	Undetermined	Investigating through Coroner
Unknown (Q4 2015?)	Primary	LAGB	Undetermined	Investigating through Coroner
Unknown (Q1 2016?)	Legacy	RYGB	Undetermined	Investigating through Coroner

Perioperative Defined Adverse Events and Complications

There have been 434 Defined Adverse Events reported in the perioperative period. These events relate to 375 complications in 369 procedures that occurred in 347 patients (203 primary and 144 legacy) within the perioperative follow up data window (ie 90 days post-operative).

Table 12 » Defined Adverse Events in all Patients up to 30 June 2016

RESULTING IN	PRIMARY PROCEDURES	REVISION PROCEDURES	ALL PROCEDURES
Unplanned Return to Theatre	110	132	242
Unplanned Admission to ICU	13	11	24
Unplanned Re-admission to Hospital	97	71	168
Any Defined Adverse Event	189	180	369

If we look at the procedures where we have perioperative follow up completed we can identify those procedures that have had one or more defined adverse events. Tables 13 & 14 shows the rate of incidence of defined adverse events by primary procedure and revision procedure type. As you would expect, the data indicates that revision procedures are more likely to result in a defined adverse event than a primary procedure.

Table 13 » Primary Procedures by Type with a Defined Adverse Events up to 30 June 2016

PRIMARY PROCEDURES	# PROCEDURES WITH ANY DEFINED ADVERSE EVENT	TOTAL # PROCEDURES WITH PERIOP FOLLOW UP	% WITH A DEFINED ADVERSE EVENT
Sleeve gastrectomy	94	4,953	1.9%
Gastric banding	56	3,194	1.8%
R-Y gastric bypass	33	479	6.9%
Single anastomosis gastric bypass	5	238	2.1%
Gastric imbrication, plus gastric band (iBand)	1	8	12.5%
Other Primary Procedures	0	16	0.0%
TOTAL	189	8,888	2.1%

Table 14 » Revision Procedures by Type with a Defined Adverse Events up to 30 June 2016

REVISION PROCEDURES	# PROCEDURES WITH ANY DEFINED ADVERSE EVENT	TOTAL # PROCEDURES WITH PERIOP FOLLOW UP	% WITH A DEFINED ADVERSE EVENT
Sleeve gastrectomy	23	602	3.8%
Gastric banding	48	897	5.4%
R-Y gastric bypass	45	515	8.7%
Single anastomosis gastric bypass	13	182	7.1%
Gastroplasty	2	9	22.2%
Port revision	23	198	11.6%
Surgical reversal	15	955	1.6%
Other Revision Procedures	11	70	15.7%
TOTAL	180	3,428	5.3%

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 event and a patient may experience multiple complications causing a single defined adverse event.

Table 15 » Reasons Listed for Defined Adverse Events in all Patients up to 30 June 2016

	GRAND TOTAL		GRAND TOTAL
Prolapse/Slip	1	Haemorrhage	3
Symmetrical pouch dilatation	3	Staple line haemorrhage	5
Gastric Perforation	3	Leak	41
Infected Gastric Band	5	Refractory Reflux	1
Leak from Gastric Band	1	Dysphagia NOS	2
Malposition of Band	1	Haemorrhage NOS	12
Port	52	Internal hernia	5
Band unbuckled	1	Malnutrition	2
Wound dehiscence	7	Other	167
Wound infection	14	Not Stated	42
DVT/PE	7	TOTAL	375

Need for Reoperation for Primary Patients

As mentioned previously there were 349 revision procedures performed on 280 primary patients. Prior to May 2016 we collected the reasons for these re-operations in our Annual Follow Up so there was always a lag between the number of revision procedures on our primary patients and the total number of complications. We now collect the reason for the reoperation at the time of the operation so these numbers will become more closely aligned. The data collected is below in Table 16.

Table 16 » Reasons Listed for Reoperations on Primary Patients up to 30 June 2016

	GRAND TOTAL		GRAND TOTAL
Prolapse/Slip	18	Port	111
Symmetrical pouch dilatation	15	Wound dehiscence	3
Erosion of Band	2	Wound infection	3
Gastric Perforation	1	DVT/PE	1
Infected Gastric Band	2	Leak	2
Leak from Gastric Band	2	Refractory Reflux	1
Malposition of Band	1	Dysphagia NOS	2
		Other	103

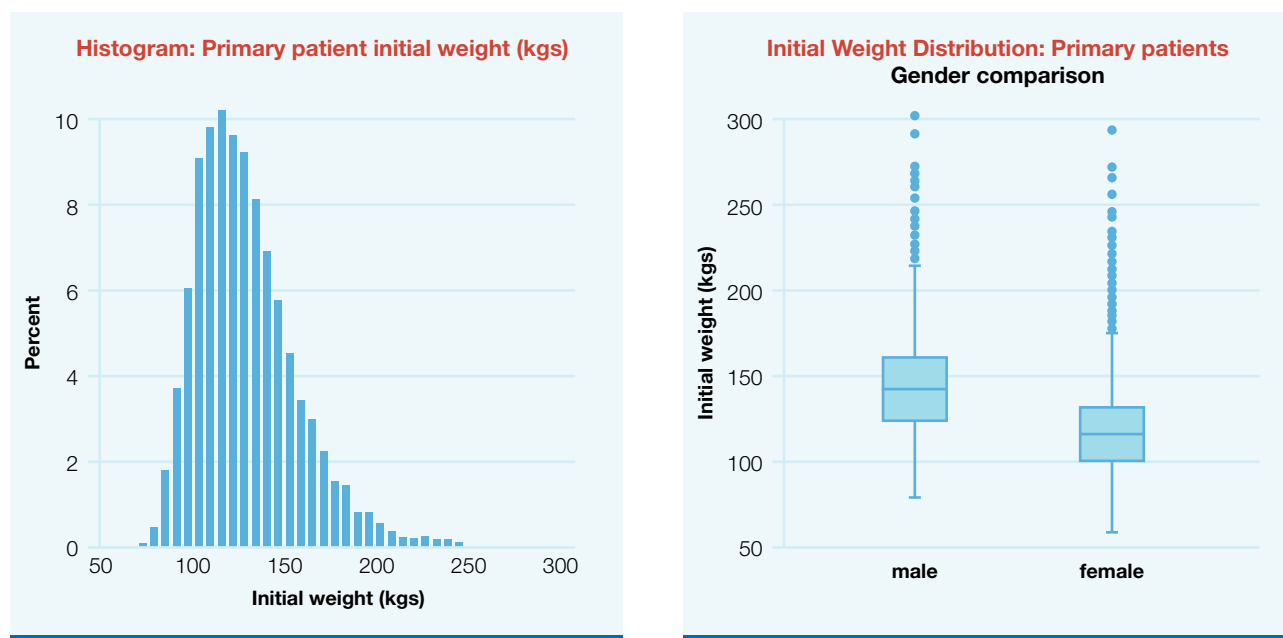
6 Weight Outcomes

The mean start BMI for patients undergoing primary procedures was 44.1 (st dev 8.1) with a mean BMI of 43.0 (st dev 7.7) 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 2016

WEIGHT MEASURE	FEMALE	MALE	ALL
Mean Start BMI (Standard Deviation)	43.8 (8.1)	45.1 (8.3)	44.1 (8.1)
Mean DOS BMI (Standard Deviation)	42.8 (7.6)	43.9 (7.8)	43.0 (7.7)
Mean Start BMI – Private (Standard Deviation)	43.0 (7.6)	44.3 (7.8)	43.3 (7.7)
Mean DOS BMI – Private (Standard Deviation)	42.0 (7.1)	43.2 (7.3)	42.3 (7.2)
Mean Start BMI – Public (Standard Deviation)	48.9 (9.2)	50.0 (9.5)	49.1 (9.3)
Mean DOS BMI – Public (Standard Deviation)	47.2 (8.5)	47.7 (9.3)	47.3 (8.7)

Figure 7 » Histogram and Distribution of Initial Weight of all Primary Patients Feb 2012 to 30 June 2016²



² Note: n=11,810, 90 primary patients have missing weight data, and four patients with indeterminate gender are not included

Figure 8 » Initial BMI Classification for Primary Patients Feb 2012 to 30 June 2016³

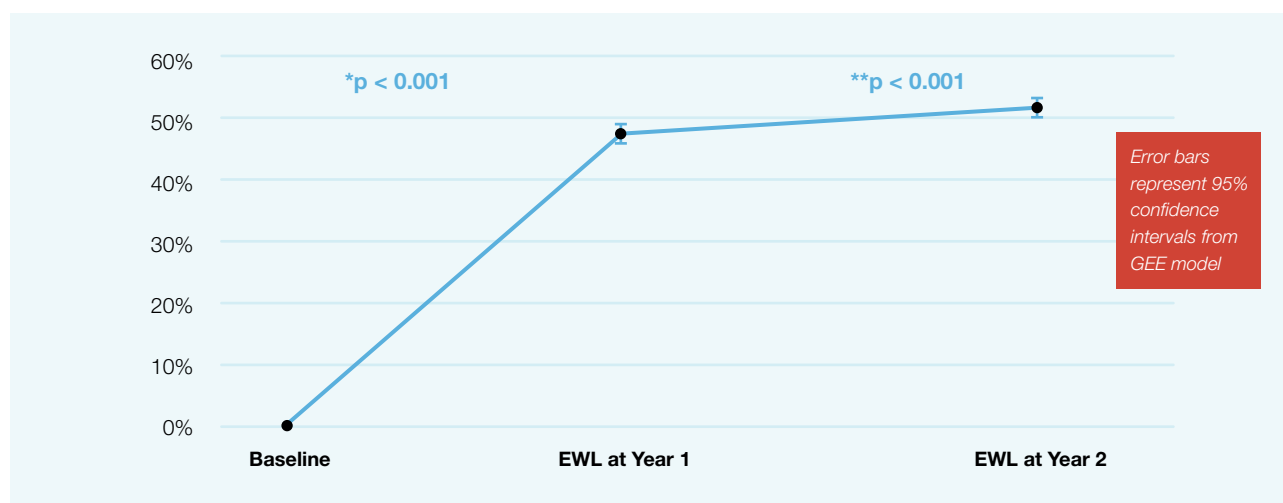


For primary patients, the mean BMI at 12 months on the 3,046 patients for whom we have collected follow up weight data was 34.3 (st dev 7.7). This represents an Excess Weight Loss (EWL) of 55.7% from initial weight. There are 1,173 primary patients who have reached their 2 year review and their excess weight loss was 51.2%. There are 450 primary patients for whom we have collected 3 years of data and their excess weight loss at Year 3 was 51.8%. The EWL plot for primary patients who have reached 2 years and 3 years can be seen at Figure 9 and Figure 10 respectively.

Table 18 » Mean BMI at 12 months for All Primary Procedures Feb 2012 to 30 June 2016

WEIGHT MEASURE	FEMALE	MALE	ALL
Mean BMI at 12 Mo (Standard Deviation)	34.0 (7.6)	35.3 (7.8)	34.3 (7.7)

Figure 9 » Excess Weight Loss for those Primary Patients who have reached their 2 Year Annual Follow Up (n=1,173)⁴

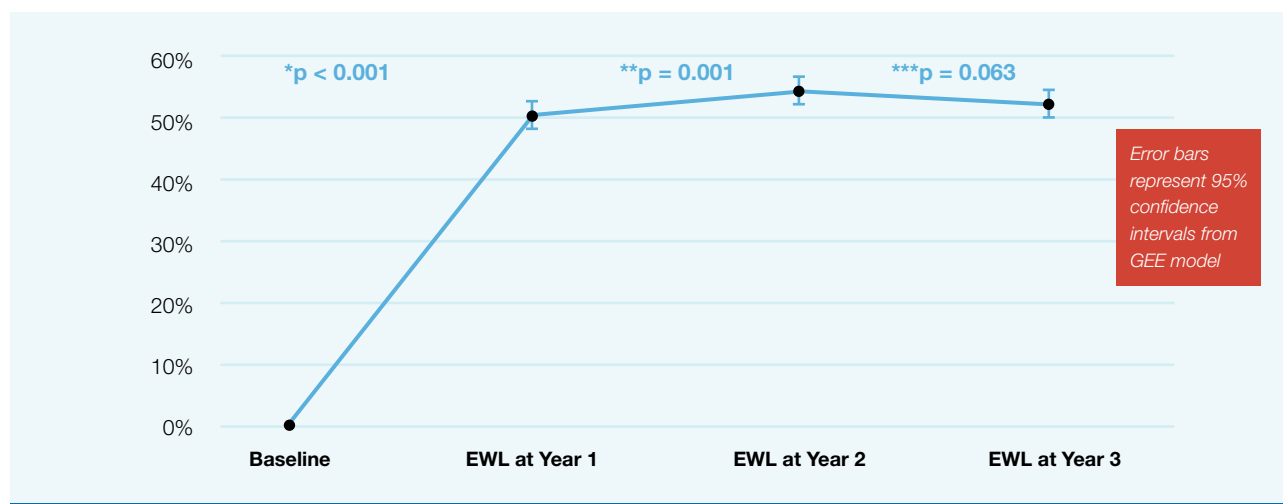


³ Note: used international bmi classification for adults reported by WHO: 2% of Primary Patients had initial BMI missing

⁴ All p-values from generalized estimating equation (GEE) model with gaussian distribution & exchangeable correlation structure specified

* p-values comparing EWL at Yr 1 with Baseline; ** p-values comparing EWL at Yr 2 with Yr 1; ***p-values comparing EWL at Yr 3 with Yr 2

Figure 10 » Excess Weight Loss for those Primary Patients who have reached their 3 Year Annual Follow Up (n=450)⁴



For revision procedures the mean BMI at day of surgery was 39.6 (st dev 8.5).

Table 19 » Mean BMI for All Revision Procedures Feb 2012-30 June 2016

WEIGHT MEASURE	FEMALE	MALE	ALL
Mean DOS BMI – Private (Standard Deviation)	39.1 (8.1)	41.4 (8.5)	39.5 (8.2)
Mean DOS BMI – Public (Standard Deviation)	39.7 (9.8)	42.3 (10.0)	40.1 (9.8)
Mean DOS BMI (Standard Deviation)	39.2 (8.4)	41.5 (8.7)	39.6 (8.5)

7 Diabetes Outcomes

Of our 11,904 primary patient, there were 1,754 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 (21.7%) who identify as being diabetic than females (12.7%) and the rates are substantially higher in the public system than in the private (see Table 20).

Table 20 » % Primary Patients identifying as having Diabetes at Presentation Feb 2012 to 30 June 2016

	FEMALE	MALE	ALL
Public*	25.6%	36.3%	28.1%
Private	10.7%	19.3%	12.6%
All	12.7%	21.7%	14.7%

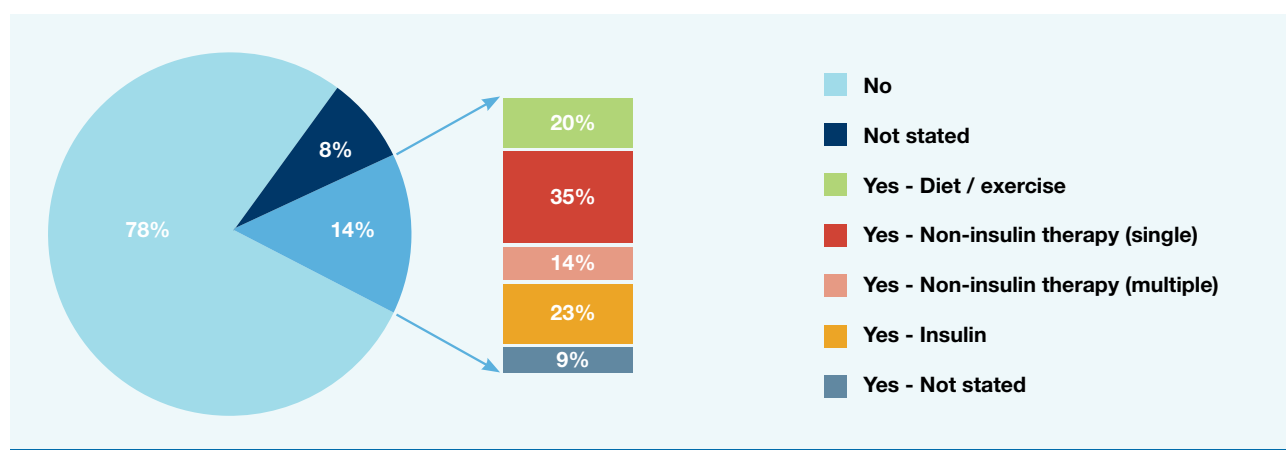
* NB: unknown diabetes status is much lower in public (2%) as compared to private (9%)

Their treatment of these patients at baseline (day of surgery) is outlined in Table 21 where you can see the rate of insulin treatment is higher in Males than Females.

Table 21 » Treatment for Diabetes at Presentation Feb 2012 to 30 June 2016

TREATMENT FOR DIABETES	FEMALES		MALES		ALL	
Diet/exercise	249	21%	100	17%	349	20%
Non-Insulin (mono) therapy	433	37%	181	31%	614	35%
Non-Insulin (poly) therapy	150	13%	88	15%	238	14%
Insulin	232	20%	170	29%	402	23%
Not stated	100	9%	51	9%	151	9%
TOTAL	1,164		590		1,754	

Figure 11 » Primary Patients' Diabetes Status and Treatment at Primary Procedure Feb 2012 to 30 June 2016



There have been 436 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 22.

Table 22 » Treatment of patients with diabetes reported at baseline followed up at 12 month (n=436)

DIABETES TREATMENT	BASELINE		12 MONTHS	
Diet/exercise	78	18%	28	6%
Non-Insulin (mono) therapy	156	36%	62	14%
Non-Insulin (poly) therapy	51	12%	14	3%
Insulin	99	23%	42	10%
Treatment not stated	52	12%	124	28%
Surgery Alone	NA		166	38%

A substantial proportion of this cohort require no diabetic medications at 12 months (indicated as "Surgery Alone" or "Diet/Exercise" – 44%). The proportion of patients requiring Insulin has dropped from 23% at baseline to 10% at 12 months.

We still have concerns that this data element is difficult to collect, noting that in 28% of cases we were unable to establish the treatment the patients had received one year after surgery. However, we are pleased that this has fallen from 35% in the last annual report.

Conclusions

There has been significant growth in the numbers of patients accrued in the BSR in the last 6 months. The BSR now has good penetrance across most states and territories with good 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.

We hope in the next 6 months to achieve near total enrolment of clinicians and sites. 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 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.

Many thanks to the staff of the BSR who have made this report possible. Dianne Brown for her expert project management, Aileen Heal for managing the day-to-day running of the BSR, Brittany Smith and Jenifer Cottrell our Customer Relationship team and Anna Palmer who has coordinated our ethics applications. This report would not have been possible without their hard work and enthusiasm.

We could not function without our data entry and other administrative staff Melissa Boglis, Lucy Davenport, Berihun Zeleke, Matthew McMillan, Jazmin Padarath, Sue Laisch, Edomgenet Woldemareyam, Maddie Goodman, Sonya Palmer, Adrian Heal and Dylan Lester. Thank you for your careful work ensuring our data is of the highest quality. To this end the efforts of Monash University's Breanna Pellegrini and A/Prof Arul Earnest in their biostatistical and data analysis are also greatly appreciated.

I would also like to acknowledge the contributions of Margaret Anderson and Charity Bowen. Both were involved in our Registry from the beginning and have unfortunately moved on to different fields. Their input was invaluable, and they are missed.

We would particularly like to acknowledge and thank the surgeons, their staff and the participating hospital sites for their engagement and support. Without their input none of these data could be collected.

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



Professor Wendy Brown
Clinical Lead

References

1. Ng M, Fleming T, Robinson M, et al. Global, regional, and national prevalence of overweight and obesity in children and adults during 1980-2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 2014; **384**(9945): 766-81.
2. Weiner R, Gutberlet H, Bockhorn H. Preparation of extremely obese patients for laparoscopic gastric banding by gastric-balloon therapy. *Obes Surg* 1999; **9**(3): 261-4.
3. Buchmueller TC, Johar M. Obesity and health expenditures: Evidence from Australia. *Econ Hum Biol* 2015; **17c**: 42-58.
4. OECD (2014), OECD Health Statistics 2014.
5. Wadden TA, Neiberg RH, Wing RR, et al. Four-year weight losses in the Look AHEAD study: factors associated with long-term success. *Obesity* 2011; **19**(10): 1987-98.
6. Wing RR, Phelan S. Long-term weight loss maintenance. *Am J Clin Nutr* 2005; **82**(1 Suppl): 222S-5S.
7. Dixon J, O'Brien P, Playfair J, et al. Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial. *Jama* 2008; **299**(3): 316-23.
8. Dixon JB, Schachter LM, O'Brien PE, et al. Surgical vs conventional therapy for weight loss treatment of obstructive sleep apnea: a randomized controlled trial. *JAMA* 2012; **308**(11): 1142-9.
9. O'Brien PE, Dixon JB, Laurie C, et al. Treatment of mild to moderate obesity with laparoscopic adjustable gastric banding or an intensive medical program: a randomized trial. *Ann Intern Med* 2006; **144**(9): 625-33.
10. O'Brien PE, Sawyer SM, Laurie C, et al. Laparoscopic adjustable gastric banding in severely obese adolescents: a randomized trial. *JAMA* 2010; **303**(6): 519-26.
11. Colquitt JL, Picot J, Loveman E, Clegg AJ. Surgery for obesity (Review). *Cochrane Review* 2009.
12. Flum D, Belle S, King W, et al. Perioperative safety in the longitudinal assessment of bariatric surgery. *New England Journal of Medicine, The* 2009; **361**(5): 445-54.
13. Hutter MM, Schirmer BD, Jones DB, et al. First report from the American College of Surgeons Bariatric Surgery Center Network: laparoscopic sleeve gastrectomy has morbidity and effectiveness positioned between the band and the bypass. *Ann Surg* 2011; **254**(3): 410-20.
14. Dreyer NA, Garner S. Registries for robust evidence. *JAMA* 2009; **302**(7): 790-1.
15. Evans SM, Bohensky M, Cameron PA, McNeil J. A survey of Australian clinical registries: can quality of care be measured? *Intern Med J* 2011; **41**(1a): 42-8.
16. van der Veer SN, de Keizer NF, Ravelli AC, Tenkink S, Jager KJ. Improving quality of care. A systematic review on how medical registries provide information feedback to health care providers. *International journal of medical informatics* 2010; **79**(5): 305-23.
17. Tu JV, Willison DJ, Silver FL, et al. Impracticability of informed consent in the Registry of the Canadian Stroke Network. *N Engl J Med* 2004; **350**(14): 1414-21.

Appendix – Data Elements Captured

DAY OF SURGERY

- Name
- Date of Birth
- Gender
- Address
- Phone Numbers
- Medicare & DVA Information
- Hospital UR number
- Name of Hospital & State
- Indigenous status
- Date of Surgery
- Weight – Day decision made to undergo surgery
- Weight – Day of Surgery
- Height
- Diabetes Status
- Diabetes Treatment
 - » Diet/exercise;
 - » Non-Insulin Therapy (Mono)
 - » Non-Insulin Therapy (Poly)
 - » Insulin
- Status of Procedure (Primary vs Revision)
 - If Revision* – Last Bariatric Procedure
 - If Revision* – Planned or Unplanned
 - If Unplanned* – Reason
- Procedure Abandoned vs Completed
- Type of Procedure
- Device Type
- Device Brand
- Device Model
 - If stapling* – Buttress?
- Concurrent Liver Transplant
- Concurrent Renal Transplant

PERIOPERATIVE FOLLOW UP

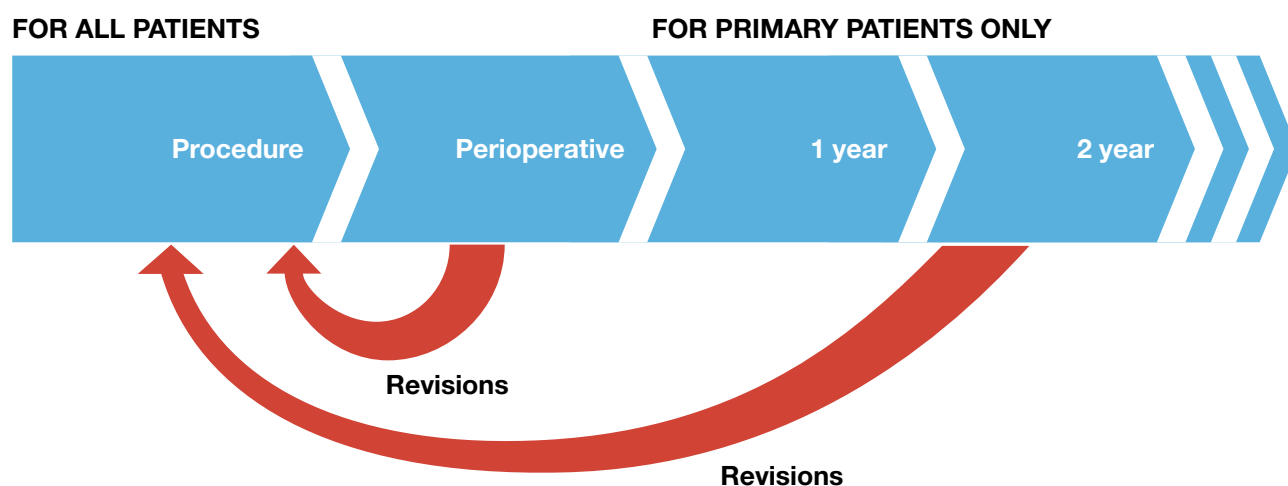
- Date of follow up
- Mortality
 - If yes* –
 - » Date of death
 - » Cause of death
 - » Death related to procedure?
- Defined Adverse Event
 - » Unplanned return to theatre
 - » Unplanned ICU admission
 - » Unplanned re-admission to hospital
- If yes* – Reason
- BSR to follow up

ANNUAL FOLLOW UP

- Date of follow up
- Weight
- Diabetes Status
- Diabetes Treatment
 - » Diet/exercise;
 - » Non-Insulin Therapy (Mono)
 - » Non-Insulin Therapy (Poly)
 - » Insulin
- Reoperation in last 12 months?
 - If yes* – Reason
- Mortality
 - If yes* –
 - » Date of death
 - » Cause of death
 - » Death related to procedure?
- BSR to follow up

Appendix – Data Collection Process

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



PRIMARY DATA COLLECTION POINT	<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
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

Appendix – Paper Forms

1 Patient and Operation Form

PATIENT AND OPERATION FORM
BARIATRIC SURGERY REGISTRY

ID: _____

v8.6 4/2016

Place **PATIENT DETAILS** label here
and/or
if any patient details are not available on the hospital label please complete below

Surname _____ Gender _____

Given Name _____ DOB _____

Address _____ Postcode _____

Hospital MR # _____ Home Ph _____

Medicare # _____ / _____ Mobile Ph _____

Name of Hospital _____ State _____

Name of Surgeon _____

Operation Date _____

Patient height _____ cms

Pre-op weight _____ kgs (if different from op weight)

Patient op weight _____ kgs

Diabetes ☐ Yes (answer below) ☐ No

If Yes, Diabetes Treatment (tick one)

☐ Diet/ Exercise
☐ Non-insulin therapy (single)
☐ Non-insulin therapy (multiple)
☐ Insulin
☐ Not stated

OR

Procedure status:

☐ Primary bariatric procedure

☐ Procedure abandoned

Current procedure:

☐ Gastric Banding

☐ Gastric bypass

☐ R-Y gastric bypass

☐ Single anastomosis gastric bypass

☐ Sleeve gastrectomy

☐ Biliopancreatic bypass/ Duodenal switch

☐ Gastric imbrication

☐ Gastric imbrication, plus band (iBand)

☐ Other (specify) _____

Revision bariatric procedure

☐ Procedure abandoned

Last Bariatric procedure:

☐ Gastric Banding

☐ Gastric bypass

☐ R-Y gastric bypass

☐ Single anastomosis gastric bypass

☐ Sleeve gastrectomy

☐ Biliopancreatic bypass/ Duodenal switch

☐ Gastric imbrication

☐ Gastric imbrication, plus band (iBand)

☐ Other (specify) _____

Current Procedure ☐ Unplanned **OR** ☐ Planned

Current Procedure Type

☐ Gastric Banding

☐ Gastric bypass

☐ R-Y gastric bypass

☐ Single anastomosis gastric bypass

☐ Sleeve gastrectomy

☐ Biliopancreatic bypass/ Duodenal switch

☐ Gastric imbrication

☐ Gastric imbrication, plus band (iBand)

☐ Port revision

☐ Surgical reversal

☐ Other (specify) _____

Device tracking (attach sticker or fill in):

Type: _____

Model: _____

S/N: _____

Concurrent:

☐ Renal transplant

☐ Liver transplant

If Unplanned Revision, reason for revision

2 Perioperative Follow Up Form

ID: _____

v8.7 4/2016

PERIOPERATIVE FOLLOW UP BARIATRIC SURGERY REGISTRY

<p>Place PATIENT DETAILS label here</p> <p>and/or</p> <p>If any patient details are not available on the hospital label please complete below</p> <p>Surname _____ <input type="checkbox"/> Female</p> <p>Given Name _____ <input type="checkbox"/> Male</p> <p>DOB _____</p>	<p>PLEASE FILL IN IF MORTALITY HAS OCCURRED</p> <p>Date of death: _____</p> <p>Describe details/attach relevant reports: _____</p> <p>Date of Bariatric Procedure: _____</p> <p>Please tick one:</p> <p><input type="checkbox"/> Death related to bariatric procedure</p> <p><input type="checkbox"/> Death unrelated to bariatric procedure</p>
<p>Name of Surgeon _____ Hospital _____</p> <p>Operation Date _____</p>	<p><input type="checkbox"/> Patient Not Seen so BSR to Follow Up</p>

<p>PERIOPERATIVE FOLLOW-UP (20-90 DAYS AFTER SURGERY)</p> <p>Date of follow-up _____</p> <p>Mortality <input type="checkbox"/> Yes (see next column) <input type="checkbox"/> No</p> <p>Has a Defined Adverse Event Occurred? (<i>multiple options can be ticked</i>)</p> <p><input type="checkbox"/> Unplanned return to theatre</p> <p><input type="checkbox"/> Unplanned ICU admission</p> <p><input type="checkbox"/> Unplanned re-admission to hospital</p> <p>Reason _____</p>	
---	--

Please return form to BSR Data Officer, 6th Floor, The Alfred Centre, 99 Commercial Road, Melbourne 3004, or FAX to: 03 9903 0717

3 Annual Follow Up Form

ANNUAL FOLLOW UP BARIATRIC SURGERY REGISTRY

ID: _____
v8.7 4/2016

Place **PATIENT DETAILS** label here
and/or

If any patient details are not available on the hospital label please complete below

Surname _____ ☐ Female
Given Name _____ ☐ Male
DOB _____

Name of Surgeon _____ Hospital: _____
Operation Date _____

ANNUAL FOLLOW-UP*

Year 1 2 3 4 5 6 7 8 9 10 *(please circle year)*

Date of follow-up _____

Patient weight _____ kgs

Diabetes ☐ Yes (answer below) ☐ No

If Yes, Diabetes Treatment

(tick one) ☐ Diet/ Exercise ☐ Non-insulin therapy (single)
 ☐ Non-insulin therapy (multiple)
 ☐ Insulin
 ☐ Not stated

Re-operation (in past 12 months)? ☐ Yes ☐ No

Specify Reason for Re-operation:

PLEASE FILL IN IF MORTALITY HAS OCCURRED

Date of death: _____

Describe details/attach relevant reports:

Date of Bariatric Procedure: _____

Please tick one:

☐ Death related to bariatric procedure
☐ Death unrelated to bariatric procedure

☐ Patient Not Seen so BSR to Follow Up

Please return form to **BSR Data Officer, 6th Floor, The Alfred Centre, 99 Commercial Road, Melbourne 3004**, or FAX to: **03 9903 0717**

Appendix – Hospitals With Ethics Approval in BSR*

NAME	STATE	NAME	STATE
Ashford Private Hospital	SA	Mildura Base Hospital	VIC
Austin Hospital	VIC	Mildura Private Hospital	VIC
Austin Repatriation Hospital	VIC	Monash Medical Centre	VIC
Bethesda Hospital	WA	North Shore Private Hospital	NSW
Box Hill Hospital	VIC	North West Brisbane	QLD
Brisbane Waters Private Hospital	NSW	North West Private (Burnie)	TAS
Cabrini Hospital Brighton	VIC	Peninsula Private Hospital	VIC
Cabrini Hospital Malvern	VIC	Pindara Private Hospital	QLD
Calvary Central District Hospital	SA	Princess Alexandra Hospital	QLD
Calvary North Adelaide Hospital	SA	Queen Elizabeth Hospital	SA
Calvary Riverina Hospital	NSW	Queen Elizabeth II Jubilee Hospital	QLD
Calvary St Vincents	TAS	Repatriation General Hospital	SA
Calvary Wakefield Hospital	SA	Royal Brisbane and Women's Hospital	QLD
Castle Hill Day Surgery	NSW	Royal Hobart Hospital	TAS
Concord Repatriation General Hospital	NSW	Royal North Shore Hospital	NSW
Epworth Eastern Hospital	VIC	Royal Prince Alfred Hospital	NSW
Epworth Freemasons Hospital	VIC	St Andrew's War Memorial Hospital	QLD
Epworth Richmond Hospital	VIC	St George Private Hospital	NSW
Flinders Medical Centre	SA	St John of God Ballarat	VIC
Glen Iris Private	VIC	St John of God Berwick	VIC
Gosford Private Hospital	NSW	St John of God Bunbury	WA
Gosford Public Hospital	NSW	St John of God Geelong	VIC
Greenslopes Private Hospital	QLD	St John of God Geraldton	WA
Hamilton Hospital	VIC	St John of God Mt Lawley	WA
Hollywood Private Hospital	WA	St John of God Murdoch	WA
Holy Spirit Northside Hospital	QLD	St John of God Subiaco	WA
Hospital for Specialist Surgery	NSW	St John of God Warrnambool	VIC
Hurstville Private Hospital	NSW	St Vincent's Private Hospital - Fitzroy	VIC
Ipswich General Hospital	QLD	St Vincent's Public Hospital	VIC
John Flynn Private Hospital	QLD	Sunshine Coast Private Hospital	QLD
John Hunter Hospital	NSW	Sydney Adventist Hospital	NSW
Joondalup Health Campus	WA	The Alfred Hospital	VIC
Kareena Private Hospital	NSW	The Avenue Private Hospital	VIC
Kawana Private Hospital	QLD	The Valley Private Hospital	VIC
Latrobe Regional Hospital	VIC	The Wesley Hospital	QLD
Launceston General Hospital	TAS	Wagga Wagga Rural Referral Hospital	NSW
Lingard Private Hospital	NSW	Waikiki Private Hospital	WA
Maryvale Private Hospital	VIC	Wangaratta Private Hospital	VIC
Mater Private North Sydney	NSW	Warringal Private Hospital	VIC
Mater Private Rockhampton	QLD	Waverley Private Hospital	VIC
Mater Private Townsville - Pimlico	QLD	Western Private Hospital	VIC

* There are an additional 2 hospitals who have requested that their participation in the BSR not be publicly acknowledged

