BSR
BARIATRIC SURGERY REGISTRY

Obesity Surgery Society of Australia & New Zealand

MONASH University

Semi-annual Report
Bariatric Surgery Registry

December 2015

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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

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 revisional) bariatric surgical procedure

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)

Data Period

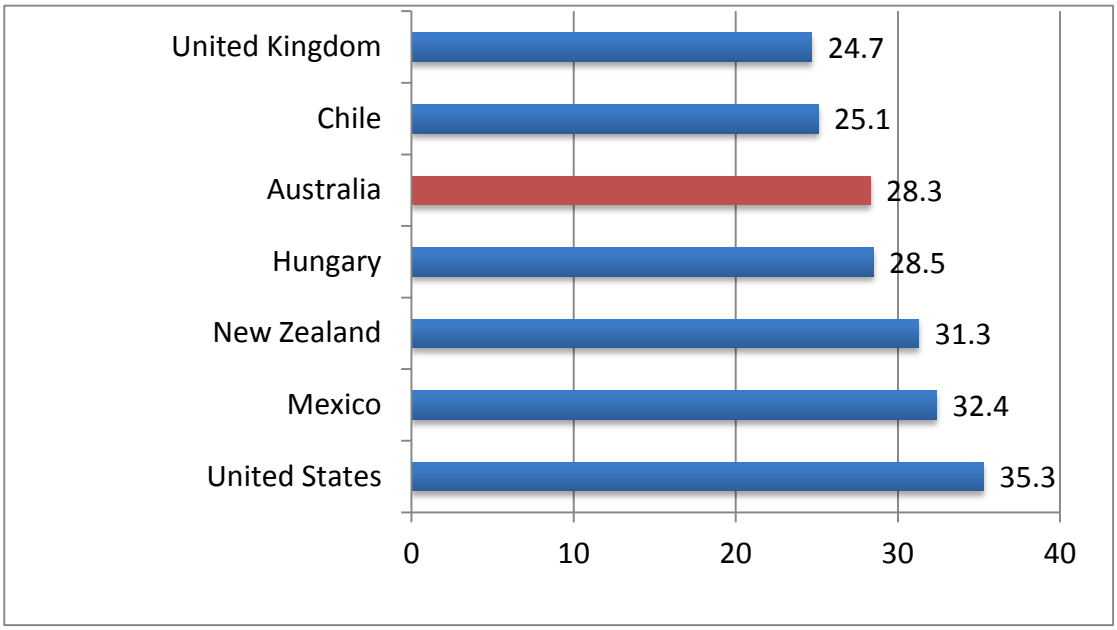
The data contained in this document was extracted from the Bariatric Surgery Registry (BSR) as at 8th and 11th February 2016, but pertains to procedures and follow-up that has occurred up to 31 December 2015. As the Registry does not capture data in real time, there can be a lag between occurrence of an event and capture in the BSR.

Background

The rising prevalence of overweight and obesity in several countries, including Australia, has been described as a global pandemic[1]. 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 cancers[2].

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 obese[3] 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.

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



Lifestyle interventions can be effective in the short term, however, are not usually sustainable in the long term[5,6]. For those with severe obesity there are several Randomised Controlled Trials (RCT)[7-10] and multiple case series[11] 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 this 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 outcomes[16].

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 relevant[17].

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.

A steering committee was also 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 – A/Prof Wendy Brown, Mr Andrew MacCormick, Emeritus Prof Paul O'Brien
- RACS – Ms Meron Pitcher
- Australia and NZ Gastro-Oesophageal Surgical Association (ANZGOSA) – Prof Mark Smithers
- Medical Technology Association of Australia (MTAA) – Mr David Ross
- Epidemiologist – Prof John McNeil
- Custodian – A/Prof Sue Evans
- Australian Commonwealth Department of Health – Ms Natasha Ryan

The pilot registry commenced on February 1, 2012, on the basis of the interim results, and with the support of seed funding from the Australian Commonwealth Department of Health. Later, in July 2014, the rollout of the Australian component of the Registry commenced. There have been three annual reports from the Registry. We are now pleased to present the semi-annual report of the Bariatric Surgery Registry, reporting until 31 December 2015.

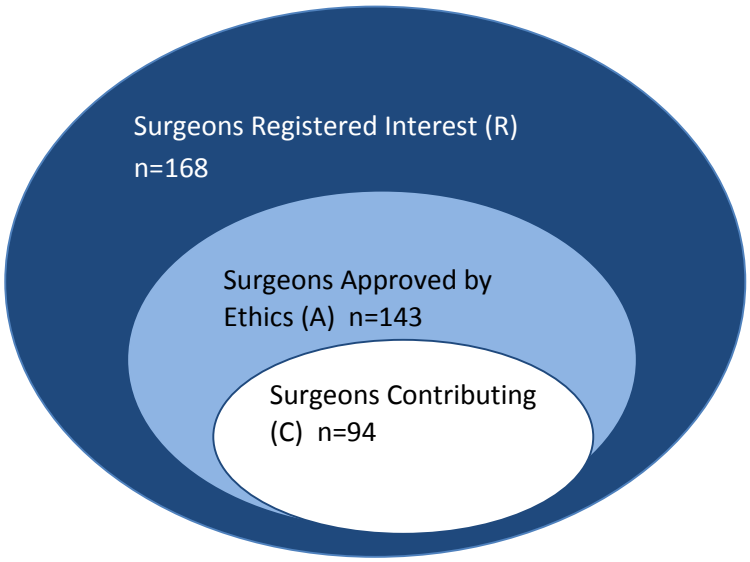
Site and Surgeon accrual

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 168 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 and both the contributing surgeon and the hospital site. These documents outline the responsibilities and expectations of each party.

In the six months from July 1 to 31 December 2015, an additional 17 sites have been approved by their ethics committees, bringing the total number of approved sites to 79 as at 31 December 2015. Along with this, the number of surgeons contributing data to the Registry has also increased from 65 to 94.

Figure 2 – Surgeons Performing Bariatric Surgery



Dataset

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), the patient's weight and BMI, the patient's health (diabetes status), the type of surgery undertaken, the device utilised and the need for revisional 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.

Data collection process

The data collection process is summarised in Figure 3. The surgeon or data collector at a public hospital returns the initial data-form to the Registry 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 not held by the Registry. Basic demographics are maintained on a "do not contact" list.

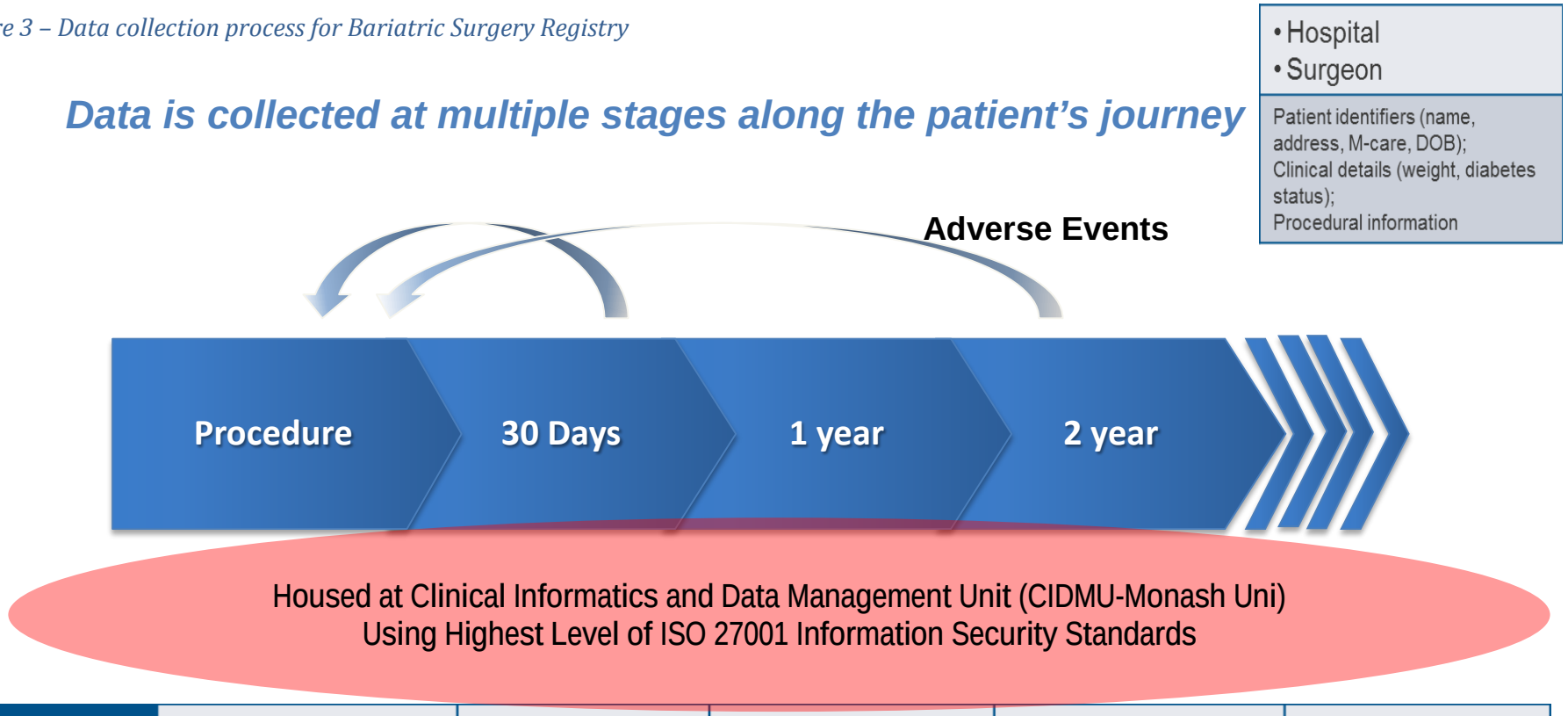
Completeness of data capture is cross-checked with regular ICD code checks from participating hospitals. Should a procedure be identified as having occurred but not entered into the Registry, the surgeon is contacted and details of the missed procedure are sought. In the future similar external checks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

Follow up forms are sent to the treating surgeon at 30 days post any procedure for both legacy and primary patients. These collect information on the clinical indicators as listed above. These forms are accepted for visits occurring from 20 days post-surgery to 90 days post-surgery.

Annual forms are also sent to the surgeon for primary patients of the Registry. These collect information on weight, diabetes status and need for reoperation. These forms are accepted for visits occurring from 90 days to 15 months post-operatively. If these forms are not returned, 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 (Call Centre Protocols A & B)).

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.

Figure 3 – Data collection process for Bariatric Surgery Registry



Data Collection Point	• Hospital	• Surgeon's Practice	• Surgeon's Practice; or • State BDM • Patient call	• Surgeon's Practice; or • State BDM • Patient call	• Surgeon's Practice; or • State BDM • Patient call
Via	• Teleforms • X-ref to ICD-10 data	• Web-based capture; or • Paper based	• Web-based capture; or • Paper based; or • Call Centre direct entry		
Data to be Collected	Patient identifiers (name, address, M-care, DOB); Clinical details (weight, height, diabetes status); Procedural information	Patient identifiers (name, address, M-care, DOB); Clinical details (weight, diabetes status); Adverse events (complications, revisions, reversals, procedures related to death)			

Results of the Bariatric Surgery Registry as at 31 December 2015

1) Enrolment in the Registry

Patient Explanatory Statements and Invitations to participate in the Registry have been sent to a total of 11,093 patients who had their operation before or on 31 December 2015. There have been 403 patients who have chosen to opt-off (3.6%) and 25 (0.2%) partial opt-offs (although partial opt-offs are still considered consented). A further 114 patients (1.0%) were still in the two week period and are pending consent when the data was drawn on 8th February 2016.

There have been six patients in the Registry who are now deceased and their enrolment is considered ceased.

This means we currently have 10,570 patients (95.3%) 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 nearly doubled the size of the BSR in the last 6 months and tripled our numbers in the last year. This increased capture rate has had minimal effect on our opt-off rate.

Table 1 – Patient Participation in the BSR Over Time

	As at 31 Dec 2015	As at 30 June 2015	As at 31 Dec 2014
Consented	10,570	5,788	3,180
Opted Off	403	213	102
Opt Off Rate	3.6%	3.5%	3.07%

2) Procedures Captured by the Registry

There have been 11,133 procedures performed on the 10,570 consented patients. The number of procedures is higher than the total number of consented patients due to multiple procedures occurring in some patients. This is an 82% increase from 6,112 procedures in our Annual Report as at 30 June 2015.

We have captured a total of 4,401 procedures that were performed in the six months from 1 July 2015 to 31 December 2015 (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 36% of LSG, 62% of LAGB and 47% of RYGB. This compares to the capture rate as at 30 June 2015 of 17% of LSG, 43% of LAGB and 28% of RYGB.

Table 2 – Procedures Performed by Type (1 July 2015-31 December 2015)

	Total BSR	BSR Last 6 months	MBS Data Last 6 Months
Gastric Banding (LAGB)	3,835	747	1,208
R-Y gastric bypass (RYGB)	936	445	947
Sleeve gastrectomy (LSG)	4,918	2,521	6,933
Other Procedures	1,444	688	NA
Total Procedures	**11,133**	**4,401**	**9,088**

Primary Patients

There have been 7,999 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 at 30 days as well as annual tracking of diabetes status, need for reoperation (and complication) and weight.

The number of each different primary procedures by type as at 30 June 2015 and 31 December 2015 is shown in Table 3. There has been a 145% increase in the number of LSGs recorded in the last 6 months with only a 27% in the number of LAGBs recorded. This most likely reflects the broadening of the BSR's clinician and hospital base.

Table 3 – Primary procedures in BSR by type as at 30 June & 31 December 2015

Description	30 June 2015	31 December 2015
LAGB	2,364	2,996
LSG	1,777	4,350
R-Y gastric bypass	200	461
Single anastomosis gastric bypass	26	161
Gastric imbrication, plus LAGB (iBand)	5	9
Gatroplasty	0	2
Bilio pancreatic bypass/duodenal switch	2	4
Not stated/inadequately described as abandoned	13	16
Total	**4,387**	**7,999**

There have been 214 patients (2.7 %) who had their primary procedure captured by the Registry who have gone on to have a subsequent procedure with a total of 265 revision procedures in this group. Some of these patients requiring multiple revisions (Table 4).

Table 4 – Revision procedures performed on Primary Patients (2012 to 31 December 2015)

Primary Patients having a total of:	2012 to 31 December 2015
One Revision Procedure	173
Two Revision Procedures	35
Three Revision Procedures	2
Four Revision Procedures	4

Legacy Patients

There were 2,571 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 at 30 days.

There have been 270 legacy patients (10.5% 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 299 procedures in this group as some of these patients have undergone multiple operations (Table 5).

Table 5 – Revision procedures performed on Legacy Patients (2012 to 31 December 2015)

Legacy Patients having a total of:	2012 to 31 December 2015
One Revision Procedure (original presentation to BSR)	2294
Two Revision Procedures	249
Three Revision Procedures	13
Four Revision Procedures	8

4) Demographics

There have been 2,228 males (21%), 8,339 females (79%) and 3 intersex or indeterminate persons who were consented to be included in the Registry as at 31 December 2015. There have been 1,873 (23%) males who were primary patients, 6,124 (77%) females and 2 intersex or indeterminate persons. The mean age of all patients at their first procedure was 44.3 years. Primary patients have a lower mean age (43.3 years) than legacy patients (47.4 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.

Table 6 – Demographics of Patients at Time of Their First Procedure (2012 to 31 December 2015)

	All Patients	Primary Patients	Legacy Patients
Male: Female Ratio	1:3.7	1:3.3	1:6.2
Mean age	44.3	43.3	47.4
Mean age Female	43.8	42.6	47.1
Mean age Male	46.0	45.3	49.8
Minimum Age	14.2		
Maximum Age	84.4		

The distribution of captured bariatric procedures by state is outlined in Table 7. 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 7 – States where Procedures Occurred (number of procedures)

State	As at 31 December 2015	% Total Procedures	% Increase over Annual Report 30 June 2015
NSW	1505	14%	89%
QLD	1180	11%	541%
SA	772	7%	88%
TAS	237	2%	85%
VIC	5666	51%	37%
WA	1773	16%	290%
AUS TOTAL	**11,133**	**100%**	**82%**

5) Follow-up

The follow-up rates achieved at each data collection point are shown in Table 8. Data is defined as "due" on the appropriate anniversary from the date of operation, ie 30 day data is due 30 days after the surgery date, 1 year data is due one year after the surgery data. 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 30 day follow up) is 3%. 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 8 – Follow Up Completion by Type

	30 day	Year 1	Year 2	Year 3	Total
Total Complete	8,217	2,320	1,010	273	11,820
Due	10,970	2,966	1,117	341	15,394
% Complete	75%	78%	90%	80%	77%
Incompletes:					
Due	921	552	107	68	1,648
Overdue	1,384	70	-	-	1,454
Out of Window	NA	23	-	-	23
Uncollectible	448	1	-	-	449
% Uncollectible	4.1%	0.0%	0.0%	0.0%	2.9%

6) Safety Reporting

Deaths

Deaths are extremely rare in the BSR but there has been one reported death since our last report as at 30 June 2015.

There are now 6 patients of the BSR who have died (0.06% of consented patients), however two of these deaths are not attributable to surgery, making the rate of death reported to the Registry due to the procedure 0.04% of consented patients. The deaths reported are listed in Table 9 below:

Table 9 – Deaths reported to the BSR until 31 December 2015

Date of Death	Group	Procedure	Cause of Death
05-Mar-14	Legacy	LAGB to LSG	Staple line leak
07-Oct-14	Primary	RYGB	Anastomotic leak, multi-organ failure
15-Oct-14	Legacy	Sleeve	Pancreatic Cancer
09-Jan-15	Primary	LAGB	Trauma Death – not related to surgery
08-Feb-15	Primary	RYGB	Anastomotic leak, multi-organ failure
06-Nov-15	Primary	Sleeve	Undetermined – Coroners report is still pending

Sentinel Events and Complications

There have been 274 sentinel events reported. These sentinel events relate to 305 complications that occurred in 198 patients (116 primary and 82 legacy) within the data window of the 30 day follow up (ie 90 days post-operative). The sentinel events and complications are noted in Table 10 and Table 11 respectively.

Table 10 –Sentinel Events in all Patients up to 31 December 2015

	Total
Unplanned Return to Theatre	171
Unplanned Admission to ICU	13
Unplanned Re-admission to Hospital	90

There is not a one-to-one match between the number of complications and number of sentinel events as one complication can lead to more than one sentinel event and a patient may experience multiple complications causing a single sentinel event. Note that the numbers in the primary and legacy groups in Table 10 includes primary procedures as well as subsequent revisional operations. Considering just the patients in each group, sentinel events were noted in 1.5 % of primary patients and 3.2% of legacy patients.

Table 11 – Reasons Listed for Sentinel Events in all Patients up to 31 December 2015

	Grand Total
Prolapse/Slip	1
Symmetrical pouch dilatation	2
Gastric Perforation	5
Infected Gastric Band	4
Leak from Gastric Band	1
Malposition of Band	1
Port	43
Band unbuckled	1
Wound dehiscence	6
Wound infection	7
DVT/PE	2
Haemorrhage	3
Staple line haemorrhage	4
Leak	26
Dysphagia NOS	2
Haemorrhage NOS	3
Internal hernia	4
Malnutrition	1
Other	189
TOTAL	**305**

Need for Reoperation

As mentioned previously there were 265 revision procedures performed on 214 primary patients. Currently, in our Annual Follow Up, we collect the reasons for these re-operations. The data collected is below in Table 12. You'll note that only 173 complications are listed for these re-operations – this is so that we can identify in the BSR when a re-operation occurs. The reason, however, is collected at the annual follow up so the complication numbers will always lag the re-operation numbers.

Table 12 – Reasons Listed for Reoperations on Primary Patients up to 31 December 2015

	Grand Total
Prolapse/Slip	10
Symmetrical pouch dilatation	9
Erosion of Band	1
Gastric Perforation	1
Infected Gastric Band	1
Leak from Gastric Band	1
Malposition of Band	2
Port	85
Wound dehiscence	2
Wound infection	2
DVT/PE	1
Leak	2
Dysphagia NOS	1
Internal hernia	1
Other	54
TOTAL	**173**

7) Weight Outcomes

The mean start BMI for patients undergoing primary procedures was 44.1 (st dev 8.2) with a mean BMI of 43.1 (st dev 7.8) on the day of surgery (DOS). Table 13 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.

For primary patients, the mean BMI at 12 months on the 2,180 patients for whom we have collected follow up weight data was 35.1% (st dev 7.7). This represents an Excess Weight Loss (EWL) of 51.2% from initial weight. There are 906 primary patients who have reached their 2 year review and their excess weight loss was 50.6%. There are 230 primary patients for whom we have collected their 3 year data and their excess weight loss at Year 3 was 50.5%. The EWL plot for primary patients who have reached 2 years and 3 years can be seen at Figure 4 and Figure 5 respectively.

Table 13 – Mean BMI for All Primary Procedures

Weight Measure	Female	Male	All
Mean Start BMI (Standard Deviation)	43.8 (8.2)	45.0 (8.3)	44.1 (8.2)
Mean DOS BMI (Standard Deviation)	42.8 (7.7)	43.9 (8.0)	43.1 (7.8)
Mean Start BMI – Private (Standard Deviation)	42.9 (7.6)	44.1 (7.8)	43.2 (7.7)
Mean DOS BMI – Private (Standard Deviation)	41.9 (7.2)	43.1 (7.4)	42.2 (7.2)
Mean Start BMI – Public (Standard Deviation)	49.0 (9.1)	50.0 (9.4)	49.3 (9.2)
Mean DOS BMI – Public (Standard Deviation)	47.3 (8.4)	48.1 (9.5)	47.5 (8.7)
Mean BMI at 12 Mo (Standard Deviation)	34.8 (7.6)	36.2 (7.7)	35.1 (7.7)

There is currently insufficient annual weight loss data for each different bariatric procedure to meaningfully compare weight loss, however we anticipate in the next annual report to be able to report these figures.

Figure 4: Excess Weight Loss for those Primary Patients who have reached their 2 Year Annual Follow Up (n=906)[1]

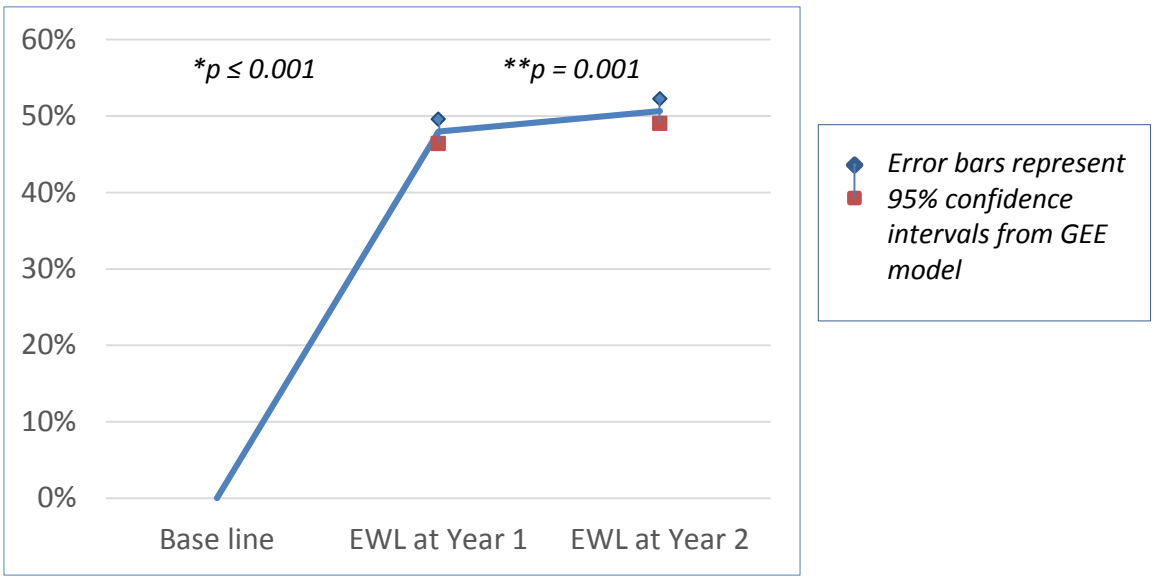
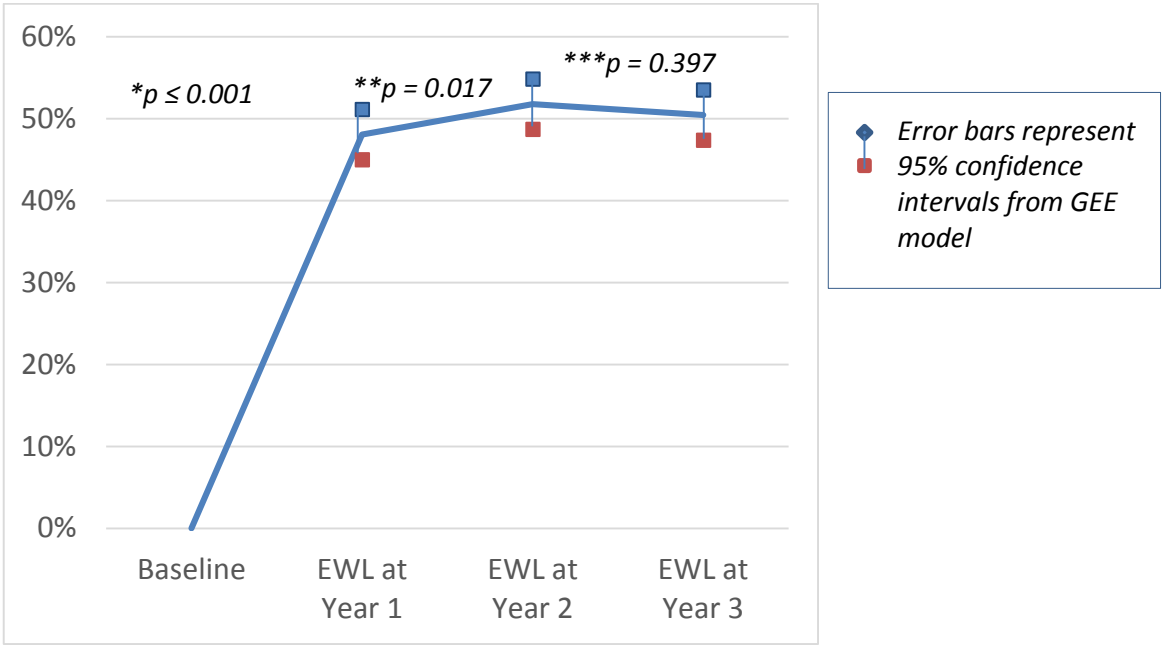


Figure 5: Excess Weight Loss for those Primary Patients who have reached their 3 Year Annual Follow Up (n=230)[1]



[11] All p-values from generalized estimating equation (GEE) model with a gaussian distribution and an exchangeable correlation structure specified
* p-values comparing EWL at Year 1 with Baseline
** p-values comparing EWL at Year 2 with Year 1
***p-values comparing EWL at Year 3 with Year 2

For revision procedures the mean BMI at day of surgery was 39.2 (st dev 8.5).

Table 14 – Mean BMI for All Revision Procedures

Weight Measure	Female	Male	All
Mean DOS BMI – Private (Standard Deviation)	38.9 (8.1)	40.8 (8.3)	39.1 (8.2)
Mean DOS BMI – Public (Standard Deviation)	39.4 (9.6)	43.0 (10.6)	39.9 (9.8)
Mean DOS BMI (Standard Deviation)	38.9 (8.4)	41.1 (8.7)	39.2 (8.5)

8) Diabetes Outcomes

Of our 7,999 primary patient, there were 1,196 patients who were identified as having diabetes and receiving treatment (15%) at their time of surgery. Their treatment at baseline (day of surgery) is outlined in Table 15.

Table 15 – Treatment for Diabetes at Presentation

Treatment for diabetes	Number	%
Diet/exercise	224	18%
Oral (mono) therapy	425	36%
Oral (poly) therapy	157	13%
Insulin	272	23%
Not stated	118	10%

There have been 325 primary patients who were identified as having diabetes at baseline who have now reached their 12 month annual follow up. The treatment these patients received for diabetes at baseline and 12 months is listed in Table 16.

Table 16 – Treatment of patients with diabetes reported at baseline followed up at 12 month (n=325)

Diabetes treatment	Baseline	12 months
Diet/exercise	61 (19%)	16 (5%)
Oral (mono) therapy	113 (35%)	43 (13%)
Oral (poly) therapy	34 (10%)	12 (4%)

Insulin	73 (22%)	33 (10%)
Treatment not stated	44(14%)	113 (35%)
Surgery Alone	NA	108 (33%)

A substantial proportion of this cohort require no diabetic medications at 12 months (indicated as "Surgery Alone" or "Diet/Exercise" – 38%). The proportion of patients requiring Insulin has dropped from 22% at baseline to 10% at 12 months.

We continue to be concerned that we did not collect the diabetes treatment in 113 patients post procedure (35%) This means that the interpretation of these data must be undertaken with caution due to the risk of bias. This is an area we are continuing to flag for improvement in the coming year.

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.

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

- Patient demographics
- Weight
    - Day decision made to undergo surgery
    - Day of surgery
- Height
- Name of surgeon
- State of hospital
- Hospital
- Indigenous status
- Diabetes status
    - Yes
    - No
- Diabetes treatment:
    - Diet/exercise;
    - Oral therapy
        - Monotherapy
        - Poly therapy
    - Insulin
- Procedure performed
    - Primary
        - Type of procedure
    - Revision
        - First procedure
        - Current procedure
- Device
    - Type
    - Brand
    - Model
    - Serial number

30 day follow-up

- Patient demographics
- Name of surgeon
- Operation date
- Date of follow up
- Mortality
    - Yes/ No
    - If yes – date of death
        - Free text description
        - Death related to procedure
            - Yes/ No
- Sentinel event
    - Unplanned return to theatre
    - Unplanned ICU admission
    - Unplanned re-admission to hospital
- Reason

Annual Follow-Up (every 12 months following surgery for primary patients only)

- Patient demographics
- Name of surgeon
- Operation date
- Date of follow up
- Patient weight
- Diabetes status
    - Yes
    - No
- Diabetes treatment
    - Diet/exercise;
    - Oral therapy
        - Monotherapy
        - Poly therapy
    - Insulin
- Re-operation (in past 12 months)
    - Yes/ No
        - If Yes, Reason

Mortality information

- Mortality
    - Yes/ No
    - If yes – date of death
        - Free text description
        - Death related to procedure
            - Yes/ No

Appendix – Hospitals Participating in BSR*

Name	
Austin Hospital	Peninsula Private
Austin Repatriation	Pindara Private
BHH	Queen Elizabeth Hospital
Cabrini Malvern	Royal Brisbane
Calvary Central Districts	Royal Hobart
Calvary North Adelaide	Royal Prince Alfred
Calvary Riverina	SJOG Ballarat
Calvary St Vincent's Launceston	SJOG Berwick
Calvary Wakefield	SJOG Bunbury
Concord RGH	SJOG Geelong
Epworth Eastern	SJOG Mt Lawley
Epworth Freemasons	SJOG Murdoch
Epworth Richmond	SJOG Subiaco
Essendon Private	SJOG Warrnambool
Hamilton	St Andrew's War Memorial Hospital
Flinders Medical Centre	St George Private
Hollywood Private	St Vincent's Private
Holy Spirit Northside	St Vincent's Public
Ipswich General	Sydney Adventist Hospital
John Flynn Private	The Alfred
Joondalup Health Campus	The Avenue
Latrobe Regional	The Valley
Maryvale Private	The Wesley
Mater North Queensland	Waikiki Private
Mater Rockhampton	Wangaratta Private
Mater Sydney	Warringal Private
Mildura Private	Western Private
North West Private (Brisbane)	
North West Private (Burnie)	

** There are an additional 3 hospitals who have requested that their participation in the BSR not be publicly acknowledged*

Appendix – Acceptable windows for data capture

Follow-up at 30 days

Annual Follow-up