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BSR

BARIATRIC SURGERY REGISTRY

Third 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 from the Australian Government and the following supporters:

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Foreword from Chair of Steering Committee

Professor Ian Caterson

An amazing amount of progress has been made in a relatively short time and the results achieved are shown in this Third Report of the Bariatric Surgery Register (BSR). With over 6000 patients invited to participate and a 3.5% opt-off rate the BSR is on the way to achieving its aims to capture all the bariatric procedures in Australia.

There are issues that still slow the progress, and amongst these are the multiple ethics applications necessary for the BSR to be established. It will be good when a more centralised process becomes available. The staff at the BSR are working through all the issues and really are making sure the BSR is functioning properly and well.

The BSR itself is important for safety of bariatric procedures but also for assessing the proper management of obesity. It is good to be able to provide an increasing amount of interesting and very useful data.

Professor Ian D Caterson

Foreword from Custodian

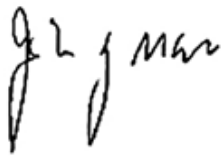
Professor John McNeil, Monash University School of Public Health and Preventive Medicine

I would like to congratulate the excellent team that has undertaken the work outlined in this report. The tasks involved in establishing a nationwide registry involves extraordinary dedication, persistence and patience. However there is no better way of providing credible data to surgeons to improve practice and benefit patients undergoing these procedures.

As custodian, the Monash Department of Epidemiology and Preventive Medicine is responsible for overseeing the operations of the registry and ensuring the highest levels of security and data quality. We must also operate within a strict ethical framework imposed by the many dozens of separate committees that the team has interacted with.

With over 15,000 bariatric procedures annually this registry meets all of the criteria for a high cost-high significance procedure where a compelling case exists for a clinical quality registry. Over the next year I am confident that we will see further rapid progress towards the ultimate goal of complete national coverage and near complete follow-up. As this eventuates the true value of the registry will increasingly be seen, both in encouraging best outcomes and in monitoring the medium and long-term safety of these types of surgery.

Finally I would like to acknowledge the outstanding work of Professor Wendy Brown and her team and the great leadership of Ian Caterson in chairing the Steering Committee of the BSR. Monash University is proud to be involved in such a worthwhile undertaking.



Professor John McNeil

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
GI	Gastric Imbrication
LAGB	Laparoscopic Adjustable Gastric Banding
LSG	Laparoscopic Sleeve Gastrectomy
NSW	New South Wales
NR	Not Reported
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
VIC	Victoria
WA	Western Australia
WHO	World Health Organisation

Common Terms and definitions

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)

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

Invitations Sent to Participate

number of participants who had a first procedure recorded in the BSR in the reporting period and to whom an Explanatory Statement has been sent.

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

number of 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

Consented to Participate (Previously called "Enrolments in the Registry")

number of patients who have been sent Explanatory Statements and who have not opted off and where it is more than 2 weeks since Explanatory Statement has been sent, therefore considered "consented"

Procedures Captured

number of procedures that are in the database. This can include multiple procedures for one patient and abandoned procedures. Excludes procedures of patients who have opted off but includes procedures of patients who have partially opted off.

Data Period

The data contained in this document was extracted from the Bariatric Surgery Registry (BSR) as at 23 August 2015, but pertains to procedures that had occurred up to 30 June 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. Therefore these annual figures may change in future reports.

Data Included in the Report

Only information from patients who have been consented - ie there has been at least 2 weeks since they were sent their Explanatory Statement and they have not fully opted off - are included in this report. This means that there will be procedures that occurred before 30 June 2015 but are not included in this report due to the lag time in receiving the datasheets and patients currently being in the window for consent.

Key Findings and Achievements in this Report

- First annual report of the registry since national roll-out commenced in July 2014.
- Completion of the electronic database interface BSR-*i*
- As of 30 June 2015, 62 of the 164 sites we have identified as performing bariatric surgery who have been approved by their ethics committee to participate in the BSR. This represents an approval at 37.8% of all hospitals performing bariatric surgery, and 51.7% of high volume centers.
- As of 30 June 2015, we identified 196 surgeons who were performing bariatric surgery in Australia
  - 113 of these surgeons have received ethical approval to contribute information to the BSR (57.7%)
  - 65 surgeons actively contributing to the BSR (33%)
- For the period 1 July 2014 – 30 June 2015:
  - Captured 4006 procedures of the 15,281 total bariatric procedures (26.2%) performed in Australia in the same time period.
    - 42.4% of all LAGB performed;
    - 16.8% of all LSG performed;
    - 28.3% of all RYGB performed.
- Since February 2012 – 30 June 2015:
  - Invitations to participate sent to 6139 patients with 5788 patients consenting to participate in the BSR (94.4%) with a further 133 (2.2%) patients still in the window for consent.
  - 3.5% opt-off rate
  - Captured information on 6112 procedures on consented patients in the registry.
  - Lost to follow up rate 3.1%
  - Re-operation rate in all primary patients 3.6%
  - Excess weight loss (all procedures) 47.1% at year 1; 51.6% at year 2
  - Diabetes being treated in 14.2% of all primary patients at baseline
    - At one year follow up 33% required no medication for diabetes
    - The proportion of patients requiring Insulin has dropped from 20.7% at baseline to 12.8% at 12 months
  - Death rate 0.08% across the Registry; Death rate related to bariatric surgery 0.05%
  - 30 day sentinel event rate of 1.9% for Primary Patients and 6.6% for Legacy patients

Background

Obesity is one of the most important public health issues facing Australia in the 21st century. It has proved difficult to prevent and according to the latest Australian Health Survey, 28.3% of Australians are now obese, up from 19% in 1995. Lifestyle interventions can be effective in the short term, however, are not really sustainable in the long term[1,2]. However, for those with severe obesity (BMI>35kg/m^2) there are several Randomised Controlled Trials (RCT)[3-6] and multiple case series[7] which suggest that Bariatric Surgery provides more predictable and sustainable weight loss than conservative regimes, and is generally very safe[8,9].

On the basis of these data, bariatric surgery is burgeoning in Australia (figure 1). In 2015 there are expected to be more than 15,000 such procedures performed at a direct cost of over $200 million. 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 Australia. Procedures performed in Australia include Laparoscopic Adjustable Gastric Banding (LAGB), Roux en-Y Gastric Bypass (RYGB), Laparoscopic Sleeve Gastrectomy (LSG) and Biliopancreatic Diversion (BPD).

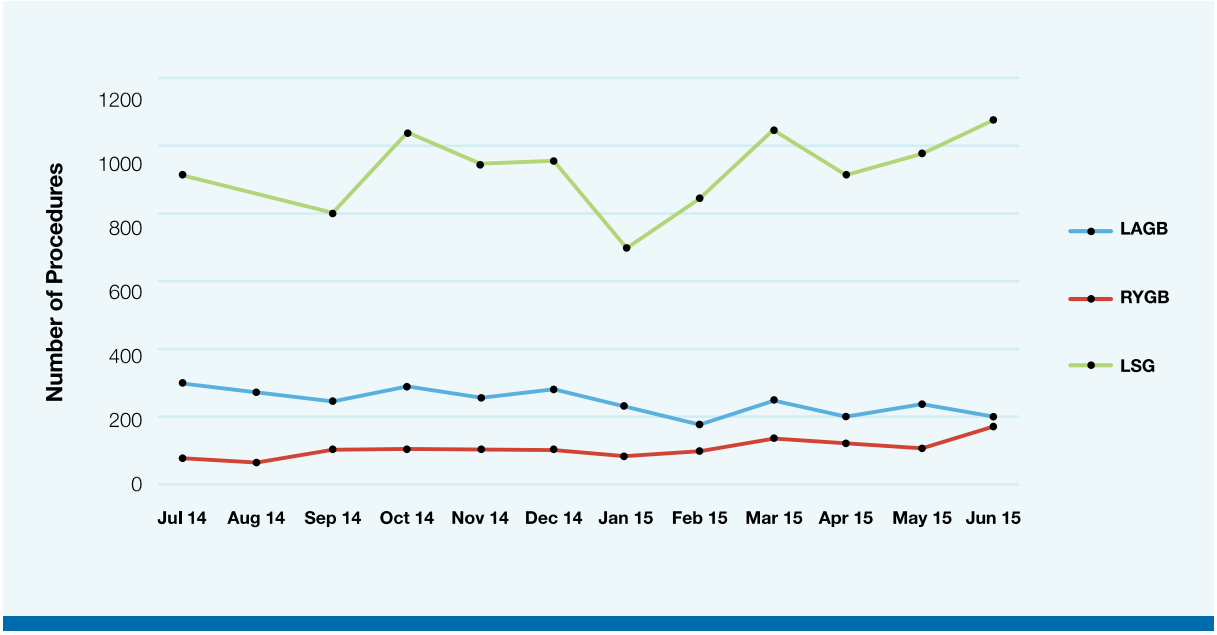
Recognising this need, a pilot bariatric surgery registry (BSR) was established. Mid 2014 the methodology in the pilot was confirmed and the national roll out of the BSR commenced.

The BSR has the primary aim of **measuring** and **improving** the quality and safety of Bariatric surgery in Australia. The Registry tracks the performance of hospitals, surgeons and devices. Such a population level, longitudinal, complete data set offers an unprecedented opportunity to:

1. Improve **safety** and manage the risk of bariatric surgery;
2. Improve the **quality** of bariatric surgery through improved techniques; and
3. Improve resource allocation decisions through evidence-based data that will improve the **efficiency** of health expenditure.

Figure 1 » Estimated Frequency of Bariatric Procedures in Australia 2014-2015

Medicare Data



Registry Development

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[10,11]. Participation in clinical registries has been documented to improve outcomes.

A sub-committee was appointed by the executive (Patrick Moore, Wendy Brown and Paul O'Brien). This sub-committee investigated all current bariatric surgical registries including the UK national registry (hosted by Dendrite), 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 outcomes and safety data. This means that any registry would need to store identifiable data meaning data could not be held in one of the overseas servers with current Australian privacy regulations. Similarly, one of the overseas registries had capacity to link complications to the patient, meaning if a patient had a complication managed by a surgeon other than the primary surgeon it would not link back to the patient but appear as a separate event. Data capture in these registries did not approach the 97% required for a clinical registry to be relevant.[12]

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 from this group which was delivered in March 2010. This report outlined a suggested process for registry development, data dictionary and governance. Funding for the pilot registry was obtained from a consortium of funders: Applied Medical, Allergan Health, Johnson and Johnson, GORE Health and Covidien as well as OSSANZ.

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), Warrnambool and Monash University. Importantly, permission for an opt-out consent process was given.

A steering committee was formed and met for the first time in February 2012. They have met quarterly since. The chair is independent obesity expert Professor Ian Caterson. Current membership includes representation from:

- **OSSANZ** | Wendy Brown, Patrick Moore, Paul O'Brien
- **RACS** | Meron Pitcher
- **Australia and NZ Gastroesophaeal Association (ANZGOSA)** | Mark Smithers
- **Medical Technology Association of Australia (MTAA)** | David Ross
- **Custodian** | John McNeil, Sue Evans
- **Monash University Clinical Informatics & Data Management Unit** | David Morrison and Christopher Reid
- **Australian Commonwealth Department of Health** | Megan Keaney

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 141 surgeons register interest in the Registry (Figure 2).

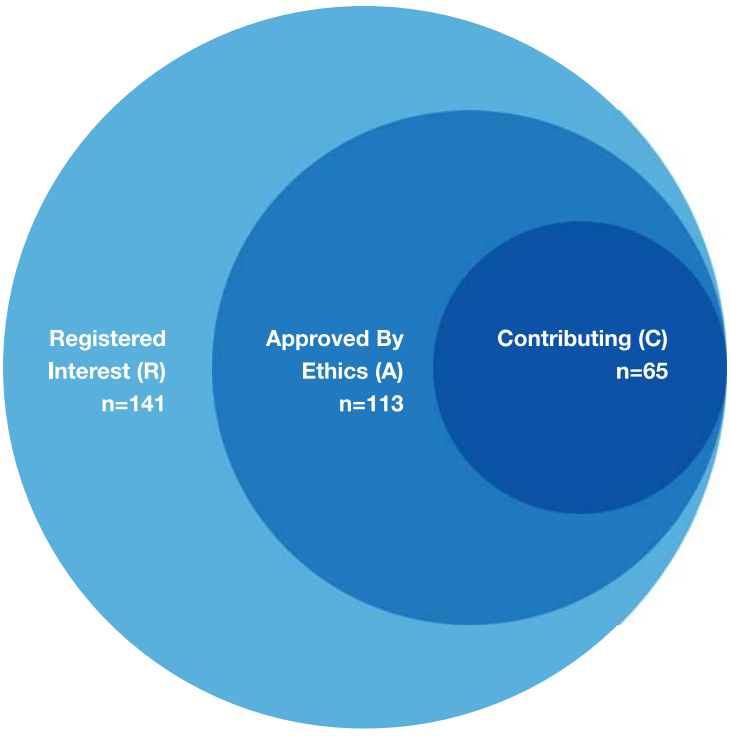
Prior to commencing data collection from a given site, the Registry requires approval from the relevant ethics committee. A Memorandum Of Understanding (MOU) is signed between the Registry and both the contributing surgeon and the hospital site. These documents outline the responsibilities and expectations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

There are now 62 sites who have been approved by their ethics committee to participate in the BSR, with an additional 57 sites included in the twelve months from July 1 2014 -30 June 2015. These hospitals are listed in Appendix 2.

From a combination of OSSANZ and Commonwealth MBS data, we estimate that there are 164 hospitals performing bariatric surgery in Australia. Of these hospitals, 120 sites are considered to be performing bariatric surgery regularly. Therefore the BSR has been approved at 37.8% of all hospitals performing bariatric surgery, and 51.7% of high volume centres.

Along with this, the number of surgeons contributing to the registry has also increased (Figure 2). We believe that there are 196 surgeons who are or who have recently performed bariatric surgery in Australia. There is no definitive registration process for bariatric surgery, so this number is constantly in flux. This means as of 30 June 2015, 33% of surgeons were actively contributing, with 57.7% approved to contribute. There is a lag time from receiving ethical approval and commencement of contribution which may explain this difference.

Figure 2 » Surgeons Performing Bariatric Surgery



Dataset

Recognising the need for near complete data capture to ensure the reliability of the Registry, 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 treatment) and the need for revisional or repeat surgery 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.

The data elements being collected by the Registry include:

DAY OF SURGERY

- Operation Date
- 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
    - Polytherapy
  - Insulin
- Procedure performed
  - Primary
    - Type of procedure
  - Revision
    - Last procedure
    - Current procedure
- Device
  - Type
  - Brand
  - Model
  - Serial Number
- Concurrent Renal or Liver Transplant

30 DAY FOLLOW-UP

- Patient demographics
- Name of surgeon
- Operation date
- Date of follow up
- Patient weight
- Mortality
  - Yes
  - No
  - If yes, related to procedure?
- Sentinel event
  - Unplanned return to theatre
  - Unplanned ICU admission
  - Unplanned re-admission to hospital
- Reason
  - Complication List

ANNUAL FOLLOW-UP (every 12 months following surgery for primary patients)

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

MORTALITY INFORMATION

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

Data Collection Process

The data collection process is summarised in Figure 3.

The surgeon or hospital returns the initial data-form (appendix 1) to the Registry or enters the details directly into the on-line interface (called the BSR-*i*) as close as possible to the day of surgery. The launch of the BSR-*i* has been a major achievement of 2015.

The Registry then posts patient explanatory statements (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 and date of birth is not entered into the Registry. Basic demographics are maintained on a "do not contact" list.

Completeness of data capture is cross-checked with regular ICD code checks. These codes are provided regularly from the participating hospital information services and allow the Registry to ensure no procedures have been overlooked by treating surgeons. 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 such as the ICU registry.

Follow up is sent to the treating surgeon at 30 days either electronically via the BSR-*i* or in paper format to collect information on the clinical indicators as listed above. This data is accepted for visits occurring from 20 days post-surgery to 90 days post-surgery.

Annual follow up is similarly sent to surgeons on the annual anniversary of the patient's surgery each year. This follow up collects 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*). The acceptable window for data collection and the times at which data is considered missing or uncollectable is shown in Figure 4.

It is anticipated that the majority of data collection will eventually occur electronically through the BSR-*i*. We are also working with software providers of electronic medical records (EMR) to seek ways to streamline the process, particularly for follow-up.

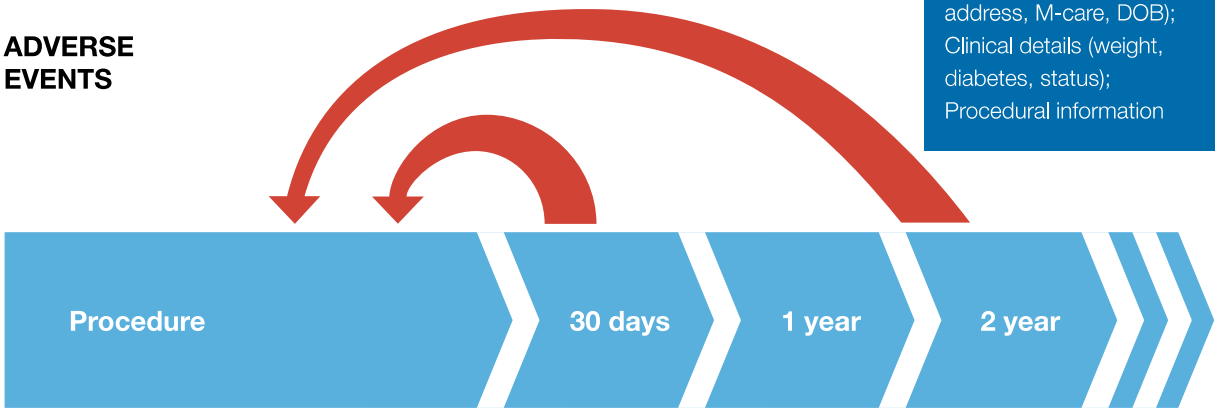
Figure 3 » Data Collection Process for Bariatric Surgery Registry

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

» **HOSPITAL**
» **SURGEON**

Patient identifiers (name, address, M-care, DOB); Clinical details (weight, diabetes, status); Procedural information

ADVERSE EVENTS

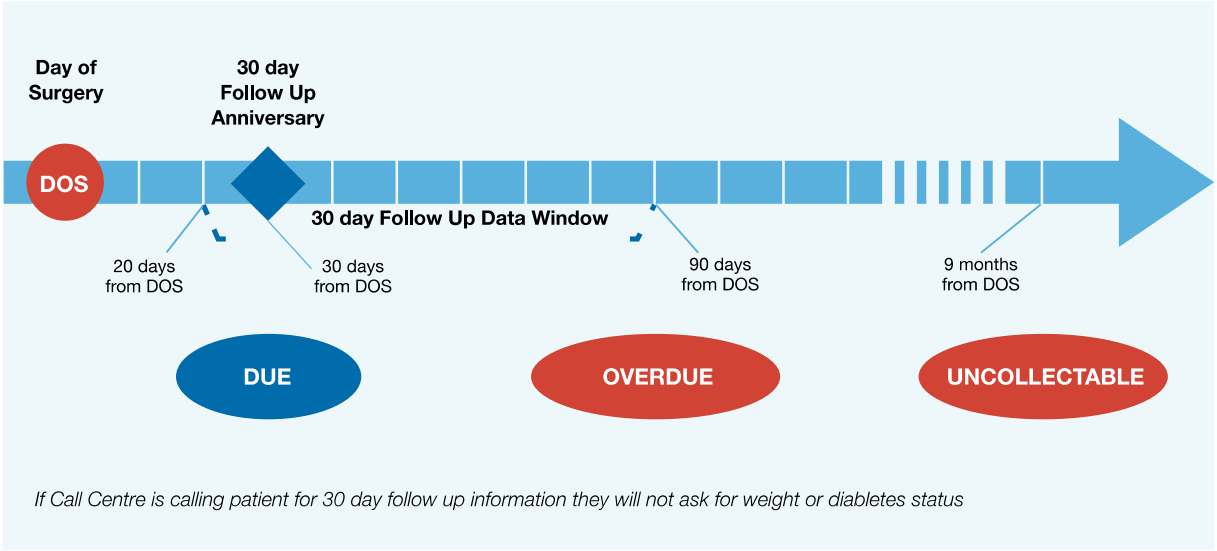


HOUSED AT CLINCIAL INFORMATICS AND DATA MANAGEMENT UNIT (CIDMU-MONASH UNI) USING HIGHEST LEVEL OF ISO 27001 INFORMATION SECURITY STANDARDS

DATA COLLECTION POINT	Hospital Surgeon's Room	Surgeon's Practice	Surgeon's Practice; or State BDM Patient call
VIA	BSR-*i* X-ref to ICD-10 data	BSR-*i*; or Paper based	BSR-*i*; or Paper based; or Call Centre direct entry
DATA TO BE COLLECTED	Patient identifiers (name, address, M-care, DOB); Clinical details (weight, 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)	

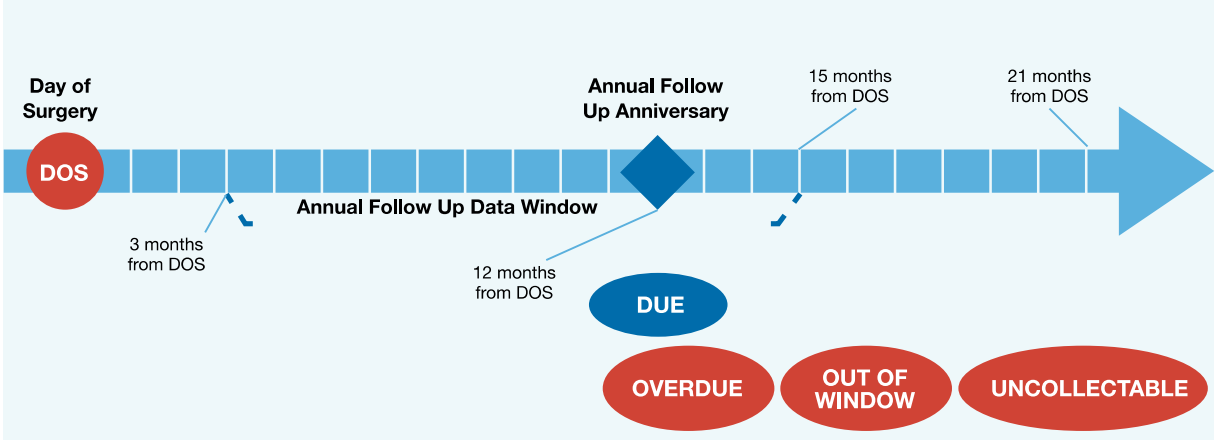
Figure 4 » Acceptable Windows for Data Capture

4a Follow-up at 30 days



If Call Centre is calling patient for 30 day follow up information they will not ask for weight or diabletes status

4b Annual Follow-up



If Call Centre is calling patient for annual follow up information they will not ask for weight or diabletes status if out of window

Results of the Bariatric Surgery Registry to June 30, 2015

Enrolment in the Registry

Patient explanatory statements and invitations to participate in the Registry have been sent to a total of 6139 patients who had their operation as of 30 June 2015. There have been 213 patients who have chosen to opt-off (3.5%) and 20 (0.3%) partial opt-offs (although partial opt-offs are still considered consented). A further 133 patients (2.2%) are still in the opt-off period. There have been 5 deaths in the Registry and their enrolment is considered ceased. This means we currently have 5788 patients (94.4%) who have currently consented to have their information included in the Registry. This is the cohort on which this report is based.

This is an increase from the 3180 people who were consented to participate in the Registry as of 31 December 2014, and a major increase since our last reports on the pilot project on 30 April 2014 (Table 1).

Table 1 » Patient Participation in the BSR Over Time

	2013 REPORT	2014 REPORT	2015 REPORT
Invitation to participate	699	1740	6139
Patients consenting to participate	681	1685	5788 (94.4%)
Opt-off	2.4%	2.6%	213 (3.5%)
Partial opt-off	NR	0.4%	20 (0.3%)
Still in window for consent	NR	NR	133 (2.2%)

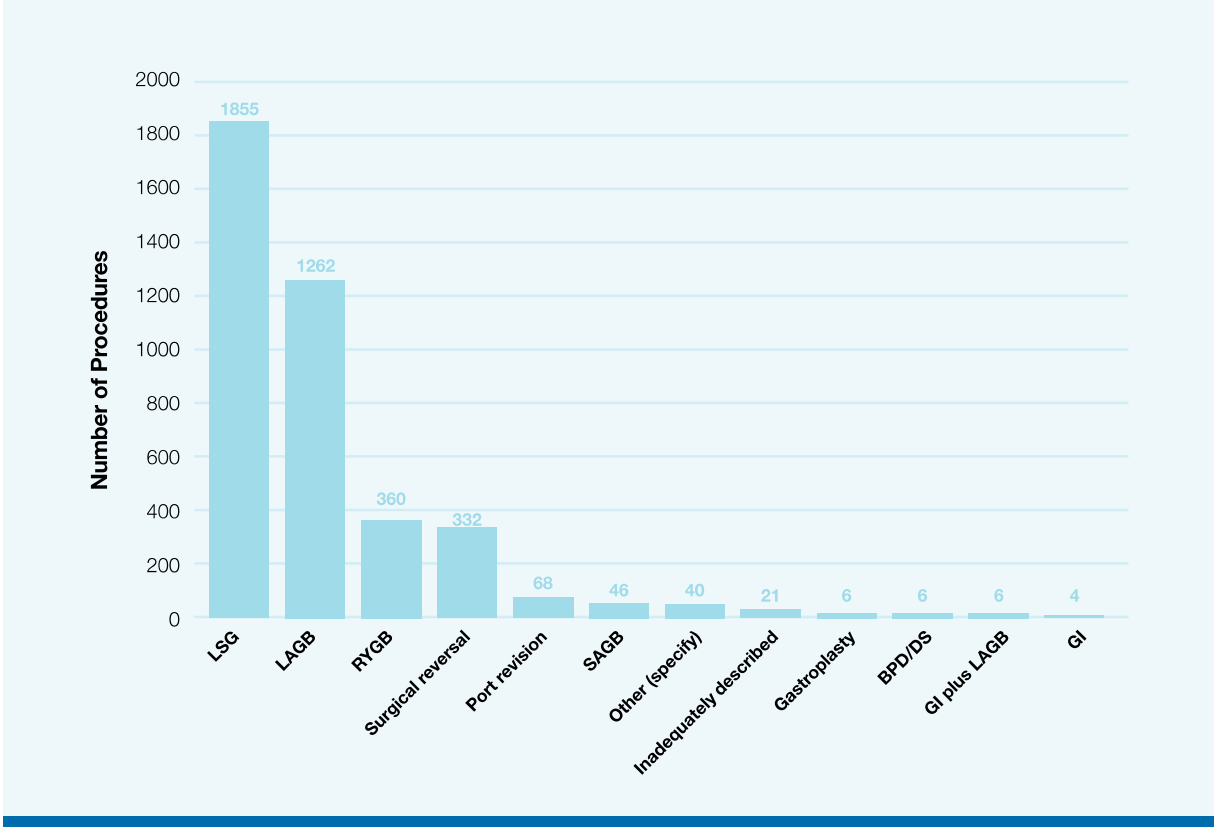
Procedures Captured by the Registry

As of 30 June 2015, there have been 5788 patients consented to participate in the Registry.

There have been 6112 procedures performed on these 5788 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 increase from 1745 procedures reported in our 2014 report (April 2014) meaning we have captured an additional 4367 bariatric procedures since the national roll-out began.

From 1 July 2014 until 30 June 2015 we captured 4006 procedures (figure 5) which is 26.2% of the procedures that occurred in Australia over the same period (MBS figures). Of the three most popular procedures, we captured 16.8% of LSG, 42.7% of LAGB and 28.3% of RYGB.

Figure 5 » Procedures Performed by Type 1 July 2014 – 30 June 2015



Primary Patients

There were 4387 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 weight.

The number of each different primary procedures type is shown in Table 2. Note that these are cumulative numbers not numbers for each year of reporting.

Table 2 » Primary Procedures in BSR by Type as at 30 June 2013, 2014 & 2015

DESCRIPTION	2013	2014	2015
Bilio pancreatic bypass/duodenal switch	0	1	2
LAGB	456	1225	2364
Gastric imbrication, plus LAGB (iBand)	0	0	5
Not stated/inadequately described	0	0	9
Other (specify)	0	9	4
R-Y gastric bypass	0	7	200
Single anastomosis gastric bypass	0	0	26
LSG	3	83	1777
Total	**459**	**1325**	**4387**

As seen in Table 2 there has been a substantial increase in the number of primary procedures captured in the Registry in this reporting period. There has also been a shift in the types of procedures captured, with the biggest increase seen in LSG. This is the most popular procedure in Australia and as the roll out continues we anticipate that this trend will continue.

There have been 159 patients (3.6%) who had their primary procedure captured by the registry who have gone on to have a subsequent procedure with a total of 190 revisional procedures in this group. Some of these patients have required multiple revisions (Table 3).

Table 3 » Revision Procedures Performed on Primary Patients (2012 to 30 June 2015)

PRIMARY PATIENTS HAVING	2012 TO 30 JUNE 2015
One Revision Procedure	133
Two Revision Procedures	23
Three Revision Procedures	1
Four Revision Procedures	2

Legacy Patients

There were 1401 patients whose first presentation to the registry was with a revisional procedure. These patients are classified as “Legacy Patients”. Legacy patients only have their quality and safety measures recorded at 30 days.

There have been 112 patients (8.0%) who presented to the registry with a revisional procedure who have required a subsequent revisional procedure. There are 134 procedures in this group as some of these patients have undergone multiple operations (Table 4).

Table 4 » Revision Procedures Performed on Legacy Patients (2012 to 30 June 2015)

LEGACY PATIENTS HAVING SUBSEQUENT REVISIONS	2012 TO 30 JUNE 2015
One Subsequent Revision Procedure	97
Two Subsequent Revision Procedures	8
Three Subsequent Revision Procedures	7

Demographics

There have been 1247 (22%) men and 4541 (78%) women consented to be included in the Registry to date. There have been 1052 (24%) males undergoing primary procedures and 3335 (76%) women with a mean age of 43.6 years. There have been 195 (13.9%) men and 1206 (86.1%) women who entered as a legacy patient with a mean age of 46.4 years.

The States where patients had surgery are outlined in Table 5. Hospitals are listed in Appendix 2. There has been good penetration across States this year, with only the NT and ACT not represented in the BSR.

Table 5 » States where Procedures Occurred (number of consented patients)

STATE	2015
NSW	797
QLD	184
SA	410
TAS	128
VIC	4138
WA	455

Follow-up

The follow-up rates achieved at each data collection point are shown in Table 6. Data is defined as “Due” on the appropriate anniversary from the date of operation, i.e. 30 day data is due 30 days after the surgery date, 1 year data is due one year after the surgery date. Data is defined as “Overdue” according to the definitions for data windows described in the introduction and depicted in Figure 4. Data becomes “Out of Data Window” once the time is beyond the defined data window. Patients are considered “lost to follow-up” (LTFU) when we are not able to collect the data from either the surgeon or by directly contacting the patient.

Table 6 » Follow-up Rates Achieved at Each Data Collection Point in the BSR

	30 DAY	YR1	YR2	YR3
Due	5668	1544	656	95
Overdue	580	0	0	0
Out of Data Window	0	1	0	0
In process of contacting patient	14	0	0	0
LTFU	178	47	8	3
Collected	4516	1674	793	156

Our current LTFU at 30 days is 3.1%, a rate of LTFU that is stable over time. There is 10.2% of data that is overdue at the 30 day time point, however, there is still sufficient time for these data to be included in the registry. The increase in overdue rate from previous reports at 30 days reflects the migration of the BSR to the electronic interface (BSR-*i*). At this time no new data could be entered into the registry and there was a flow on disruption to our follow-up functions in May whilst the primary data was entered.

Safety Reporting

Deaths

There have been 5 deaths reported to the BSR (0.08% of all procedures; 0.09% of consented patients), however two of these deaths are not attributable to surgery making the true rate of death reported to the registry 0.04% of procedures or 0.05% of consented patients. The deaths reported are listed in table 7.

Table 7 » Deaths reported to the BSR until 30 June 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	Other medical reason
08-Feb-2015	Primary	RYGB	Anastomotic leak, multi-organ failure

The Outlier Policy was ratified at the Steering Committee meeting on 12 June 2015. Under this policy all deaths related to bariatric surgery will trigger a Level 2 response which mandates a checking of data as well as ensuring that the RACS audit of surgical mortality is aware of the event.

Sentinel Events and Complications (within 30 Days post-operative)

There have been 179 sentinel events reported. These sentinel events relate to 177 complications that occurred in 161 patients (81 primary and 80 legacy) within 30 days of surgery (Table 8). The complications are noted in Table 9.

There are more sentinel events than complications as one complication can lead to more than one sentinel event. Note that the numbers in the primary and legacy groups in Table 8 includes index procedures as well as subsequent revisional operations. Considering just the patients in each group, sentinel events were noted in 1.8% of primary patients and 5.7% of legacy patients.

Table 8 » Sentinel Events Occurring Within 30 days until 30 June 2015

SENTINEL EVENT	PRIMARY (N=4577)	LEGACY GROUP (PROCEDURE N=1535)	TOTAL GROUP (N=6112)
Unplanned return to theatre	56 (1.2%)	75 (4.9%)	131 (2.1%)
Unplanned readmission to hospital	31 (0.68%)	15 (1.0%)	46 (0.8%)
Unplanned ICU admission	5 (0.1%)	2 (0.1%)	7 (0.1%)

Table 9 » Complications Reported until 30 June 2015.

COMPLICATION	LAGB	PORT REVISION	RYGB	SAGB	LSG	SURGICAL REVERSAL
Band unbuckled	1					
Gastric Perforation	5					
Haemorrhage	2					1
Haemorrhage NOS					1	
Infected Gastric Band	4					
Internal hernia			2			
Leak			1		2	
Leak from Gastric Band	1					
Malposition of Band	1					
Other	19	3	3	1	8	2
Port revision	33	7				
Symmetrical pouch dilatation	2					
Wound dehiscence	2	1			1	
Wound infection			1			
Total number of complications	**70**	**11**	**7**	**1**	**12**	**3**
Complication rate	**2.2%**	**8.3%**	**1.7%**	**2.0%**	**0.6%**	**0.8%**

Need for Reoperation

There have been 159 primary patients (3.6%) who underwent a total of 190 revisional procedures (Table 10) and 112 legacy patients (8%) that underwent 134 subsequent revisional operation. The numbers of subsequent operations are described in Tables 3 and 4.

Table 10 » Subsequent Operations for Primary Patients

REVISION PROCEDURE(S)	PRIMARY PROCEDURE		
	LAGB	RYGB	LSG
Bilio pancreatic bypass/duodenal switch	1		
Gastric Banding	36		
Other	5	4	3
Port Revision	100		
SAGB	1		
Sleeve Gastrectomy	5		
Surgical Reversal	35		

There were 56 legacy patients whose first revision procedure captured by the registry was LAGB. The majority of the subsequent procedures were port replacements (n=31; 55.3%). There were 9 patients whose first revision procedure captured by the registry was LSG who went on to have a subsequent procedure. The majority of subsequent procedures were re-sleeves (44.4%). Three patients whose first revision procedure was a RYGB went on to have a subsequent procedure. Two of these were another RYGB and one was a stent for a leak. There was one patient who had a gastroplasty as their first revision operation that went on to have a reversal.

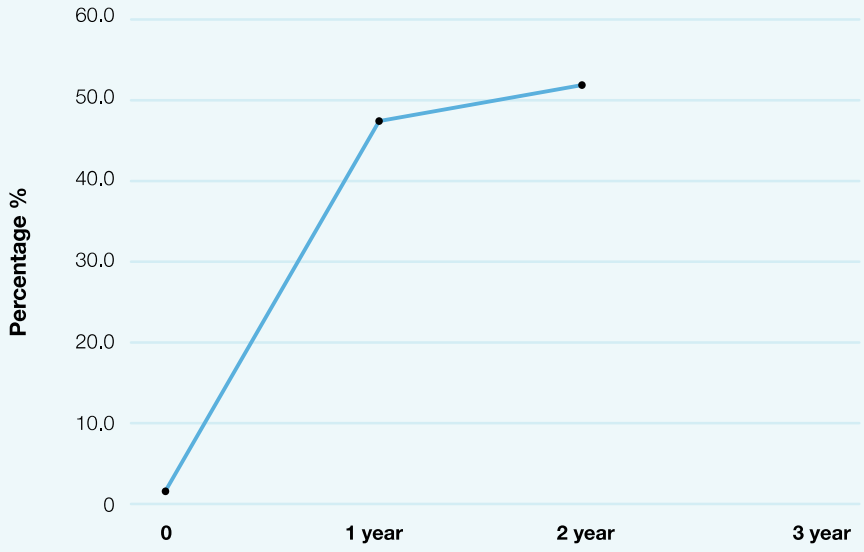
There were 43 legacy patients whose first presentation to the Registry was with a surgical reversal who then had a subsequent procedure. The majority of these subsequent procedures were LSG (n=27; 62.8%) followed by RYGB (n=11; 25.6%) SAGB (n=4; 9.3%) and 1 inadequately described (n=1; 2.3%). This means that 38.4% of reoperations in the legacy group were most likely planned reoperations rather than a surgical response to a complication.

Weight Outcomes

The mean start BMI for patients undergoing primary procedures was 44.2, with a mean BMI of 43.3 on the day of surgery (DOS). The mean BMI at 12 months on the 1644 patients for whom we have collected follow up weight data was 35.7. This represents an EWL of 47% from initial weight with weight loss continuing at year 2 (EWL 51.6%; n=738) (Figure 6).

There is currently insufficient annual weight loss data for each different bariatric procedure to meaningfully compare weight loss between procedures, however, we anticipate being able to present this metric in our next report given the large number of patients accrued in the last 12 months.

Figure 6 » Percent Excess Weight Loss (all procedures)



Diabetes Outcomes

Of the 4387 primary patients, there were 622 patients who were identified as having diabetes (14.2%). Their treatment at baseline is outlined in table 11.

Table 11 » Treatment for Diabetes at Presentation

TREATMENT FOR DIABETES	NUMBER	%
Diet/exercise	111	17.8%
Insulin	140	22.5%
Not stated	65	10.5%
Oral (mono) therapy	229	36.8%
Oral (poly) therapy	77	12.4%

There have been 227 primary patients who were identified as having diabetes at baseline who have now reached 12 month follow-up. The treatment these patients received for diabetes at baseline and 12 months of this cohort is listed in table 12.

Table 12 » Treatment of Patients with Diabetes Reported at Baseline Followed Up at 12 month (n=227)

DIABETES TREATMENT	BASELINE N (%)	12 MONTHS N (%)
Diet/exercise	38 (16.7%)	10 (4.4%)
Oral (mono) therapy	82 (36.1%)	33 (14.5%)
Oral (poly) therapy	22 (9.7%)	9 (4.0%)
Insulin	47 (20.7%)	29 (12.8%)
Treatment not stated	38 (16.7%)	81 (35.6%)
Surgery Alone	0	65 (28.6%)

A substantial proportion of this cohort require no diabetic medications at 12 months (Indicated as surgery alone or diet/exercise - 33%). The proportion of patients requiring Insulin has dropped from 20.7% at baseline to 12.8% at 12 months.

It is concerning that we did not collect the diabetes treatment in 81 patients post procedure (35.6%). This means that the interpretation of these data must be undertaken with caution due to the risk of bias. This is an area we have flagged for improvement in the next year, and we hope that the implementation of the BSR-*i* will help us to better record this parameter in the future.

Summary

The national roll-out of the BSR started in July 2014. Over that time we have made substantial progress with the numbers consented to participate, the sites obtaining ethical approval as well as engaging surgeons.

This report confirms the efficacy of bariatric surgery in terms of weight loss and diabetes management in the short term as well as the safety at a population level.

There is currently insufficient data to make meaningful comparisons between procedures or to perform benchmarking, however, if we continue at our current rate of growth we anticipate being able to make these assessments in the next year.

Acknowledgements and thanks

We would like to thank the Commonwealth Government of Australia (Department of Heath) for their support of the BSR pilot and roll-out. We would also like to thank our other funders: Apollo Endosurgery, Applied Medical, Covidien and Gore Medical.

Many thanks to the staff of the BSR who collated these data for the report– Dianne Brown, Monira Hussain, Brittany Smith and Margaret Anderson; as well as those involved in the day to day running of the registry and data entry – Charity Bowen, Melissa Boglis, Lucy Davenport, Berihun Zeleke, Matthew McMillan, Jazmin Padarath, Sue Laisch and Edomgenet Woldemareyam.

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.

Professor Wendy Brown
Clinical Lead BSR

References

1. 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;19:1987-98.

2. Wing RR, Phelan S. Long-term weight loss maintenance. Am J Clin Nutr 2005;82:222S-5S.

3. 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;299:316-23.

4. 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;308:1142-9.

5. 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;144:625-33.

6. O'Brien PE, Sawyer SM, Laurie C, et al. Laparoscopic adjustable gastric banding in severely obese adolescents: a randomized trial. JAMA 2010;303:519-26.

7. Colquitt JL, Picot J, Loveman E, Clegg AJ. Surgery for obesity (Review). Cochrane Review 2009.

8. Flum D, Belle S, King W, et al. Perioperative safety in the longitudinal assessment of bariatric surgery. New England Journal of Medicine, The 2009;361:445-54.

9. 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;254:410-20.

10. Dreyer NA, Garner S. Registries for robust evidence. JAMA 2009;302:790-1.

11. Evans SM, Bohensky M, Cameron PA, McNeil J. A survey of Australian clinical registries: can quality of care be measured? Internal medicine journal 2011;41:42-8.

12. Tu JV, Willison DJ, Silver FL, et al. Impracticability of Informed Consent in the Registry of the Canadian Stroke Network. New England Journal of Medicine 2004;350:1414-21.

PATIENT INFORMATION OPERATION FORM

BARIATRIC SURGERY REGISTRY

v 8.5 5/2014

Place **PATIENT DETAILS** label here

and/or

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

Surname _____ ☐ **Female** ☐ **Male**

Given name _____ **DOB** ___/___/_____

Address _____

_____ **Postcode** _____

Hospital MR No # _____ **Home Ph** _____

Medicare # _____ **Mobile Ph** _____

Name of Hospital _____ **State** _____

Name of Surgeon _____

PLEASE COMPLETE THIS SECTION IN FULL

Operation date ___/___/_____

Patient height _____ cms

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

Patient op weight _____ kgs

Diabetes ☐ Yes ☐ No

Treatment: (tick one)

☐ **Diet/exercise**

☐ **Oral therapy**

☐ Monotherapy

☐ Polytherapy

☐ **Insulin**

Procedure status:

☐ Primary bariatric procedure

☐ Procedure abandoned

OR

☐ Revision

☐ Procedure abandoned

OPERATION:

Primary procedure:

☐ Gastric Banding
☐ Gastroplasty
☐ R-Y gastric bypass
☐ Single anastomosis gastric bypass
☐ Sleeve gastrectomy
☐ Biliopancreatic bypass /Duodenal switch
☐ Gastric imbrication
☐ Gastric imbrication, plus band (iBand)
☐ Other (Specify)

_____

Original procedure:

☐ Gastric Banding
☐ Gastroplasty
☐ 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:

☐ Gastric Banding
☐ Gastroplasty
☐ 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

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

30 DAY FOLLOW-UP/ANNUAL FOLLOW-UP/ADVERSE EVENT FORM

BARIATRIC SURGERY REGISTRY

v 8.6 7/2014

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 _____

Operation date ___/___/_____

PLEASE COMPLETE THE RELEVANT SECTION

30 DAY FOLLOW-UP (30 DAYS AFTER SURGERY)

Date of follow-up ___/___/_____

Patient weight _____ kgs

Mortality ☐ Yes ☐ No

Sentinel event

- ☐ Unplanned return to theatre
- ☐ Unplanned ICU admission
- ☐ Unplanned re-admission to hospital

Reason

ANNUAL FOLLOW-UP (EVERY 12 MONTHS AFTER SURGERY)

Date of follow-up ___/___/_____

Patient weight _____ kgs

Diabetes ☐ Yes ☐ No

Treatment: (tick one)

- ☐ **Diet/exercise**
- **Oral therapy**
  - ☐ Monotherapy
  - ☐ Polytherapy
- ☐ **Insulin**

Re-operation (in past 12 mos)**:** ☐ Yes ☐ No

Specify:

PLEASE FILL IN IF MORTALITY HAS OCCURRED

Yes ☐ ☐ No

If yes, date of death: ___/___/_____

Describe details/attached relevant reports:

Primary procedure date: ___/___/_____

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

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

Appendix 2
List of Participating Hospitals

SITE NAME	STATE
Ashford Private	SA
Austin Hospital	VIC
Austin Repatriation	VIC
Box Hill Hospital*	VIC
Brisbane Waters Private	NSW
Cabrini Brighton	VIC
Cabrini Malvern	VIC
Calvary Central Districts	SA
Calvary North Adelaide	SA
Calvary Riverina	NSW
Calvary St Vincent's Launceston	TAS
Calvary Wakefield	SA
Castle Hill Day Surgery	NSW
Concord RGH	NSW
Epworth Eastern	VIC
Epworth Freemasons	VIC
Epworth Richmond	VIC
Flinders MC	SA
Flinders Private	SA
Hamilton	VIC
Hobart Private	TAS
Hollywood Private	WA
Ipswich General	QLD
John Flynn Private	QLD
Joondalup Health Campus	WA
Latrobe Regional	VIC
Maryvale Private	VIC
Mater Pimlico	QLD
Mater Rockhampton	QLD
Mater Sydney	NSW
Mildura Base Hospital	VIC

SITE NAME	STATE
Monash Medical Centre	VIC
North Shore Private	NSW
North West Private (Brisbane)	QLD
North West Private (Burnie)	TAS
Peninsula Private	VIC
Pindara Private	QLD
Queen Elizabeth Hospital	SA
Repatriation General Hospital	SA
Royal Brisbane	QLD
Royal Hobart	TAS
Royal Prince Alfred	NSW
SJOG Ballarat	VIC
SJOG Berwick	VIC
SJOG Bunbury	WA
SJOG Geelong	VIC
SJOG Mt Lawley	WA
SJOG Murdoch	WA
SJOG Subiaco	WA
SJOG Warrnambool*	VIC
St Andrew's War Memorial	QLD
St George Private	NSW
St Vincent's Private	VIC
The Alfred*	VIC
The Avenue*	VIC
The Valley	VIC
The Wesley	QLD
Waikiki Private	WA
Wangaratta Private	VIC
Warringal Private	VIC
Waverley Private	VIC
Western Private	VIC

Denotes a pilot site for the BSR