



Second report of the pilot Bariatric Surgery Registry

April 2014

Funding partners:



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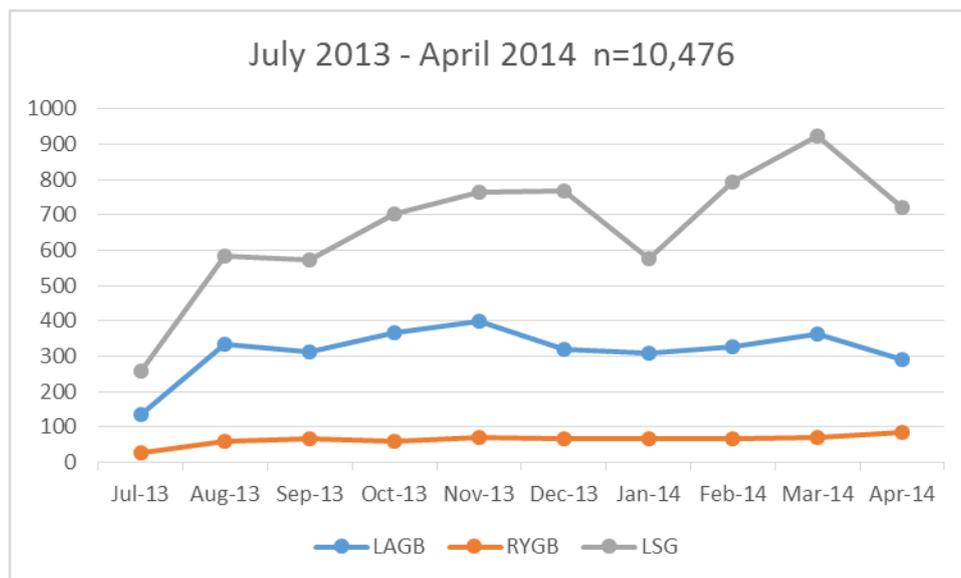
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Background

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/m²) there are several Randomised Controlled Trials (RCT)³⁻⁶ and multiple case series⁷ 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 2013 there are expected to be more than 12,000 such procedures performed at a direct cost of \$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), Biliopancreatic Diversion (BPD), as well as intraluminal devices including gastric balloon and duodenal liners (Endobarrier™).

Figure 1 – Estimated frequency of bariatric procedures in Australia. Medicare Data.



Recognising this need, a pilot bariatric surgery registry (BSR) was established. The BSR has the primary aim of measuring quality and safety. The registry tracks the performance of hospitals, surgeons and devices. The ability to track all persons undergoing bariatric procedures longitudinally offers an unprecedented opportunity to:

1. Confirm the outcomes from clinical trials on bariatric surgery at a community level;
2. Measure the change in diabetes status over time in this population;
3. Translate these efficacy and health outcomes into practice guidelines;
4. Utilise the Registry as a resource for future research projects

The aim of the pilot was to confirm our methodology prior to binational rollout.

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 relevant¹²

OSSANZ therefore undertook a tender process and eventually partnered with the Monash University School of Public Health and Preventative 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 Gastroesophageal 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

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, the role out of the Australian component of the registry commenced in July 2014.

We are pleased to present in this document the second annual report of our pilot registry.

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 status) 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

- Patient demographics
- Weight
 - Day decision made to undergo surgery.
 - Day of surgery
 - 30 day post-operative
 - Annual
- Height
- Name of surgeon
- State
- Hospital
- Diabetes status
 - Yes
 - No
- Diabetes treatment:
 - Diet/exercise;
 - Oral therapy
 - Monotherapy
 - Polytherapy
 - Insulin
- Procedure performed
 - Primary
 - Type of procedure
 - Secondary
 - First procedure
 - Current procedure

30 day follow-up

- Patient demographics
- Name of surgeon
- Operation date
- Date of follow up
- Patient weight
- Mortality
 - Yes
 - No
- Sentinel event
 - Unplanned return to theatre
 - Unplanned ICU admission
 - Unplanned re-admission to hospital
 - Prolonged LOS
- Reason
 - Free text box

Annual Follow-Up (every 12 months following surgery)

- 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 (free text explanation)
 - No

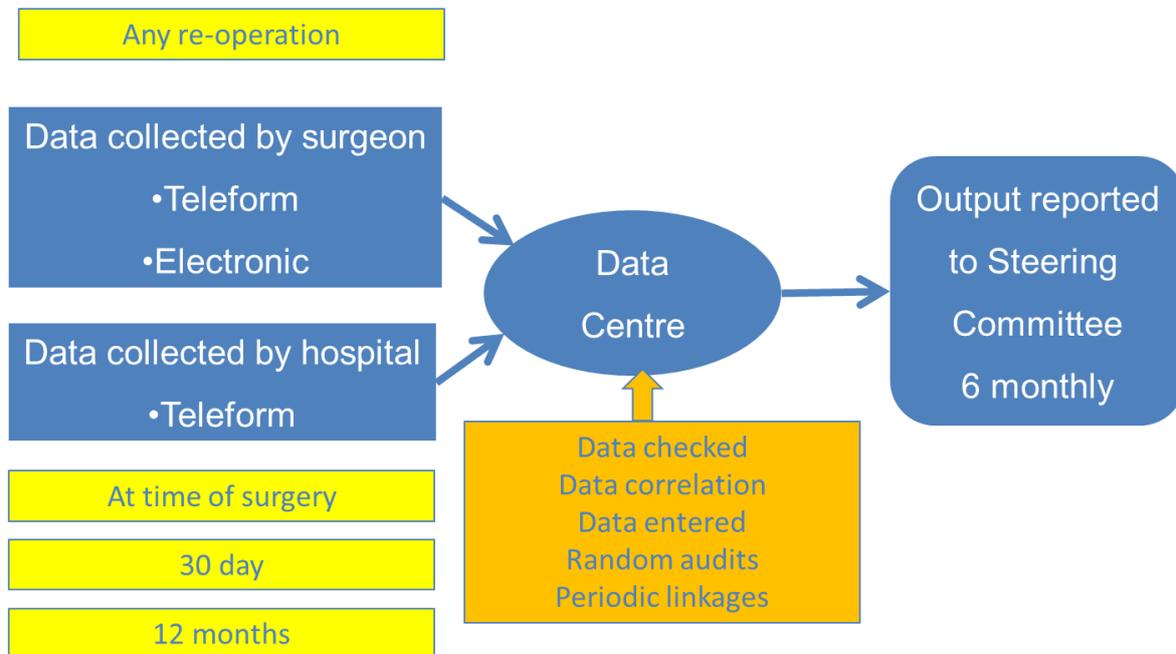
Mortality information

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

Data collection process

The data collection process is summarised in figure 2.

Figure 2 – Data collection process for Bariatric Surgery Registry



Data elements are collected initially in theatre. Data sheets (appendix 1) are collated by a registry lead at participating hospitals and returned to the central registry office.

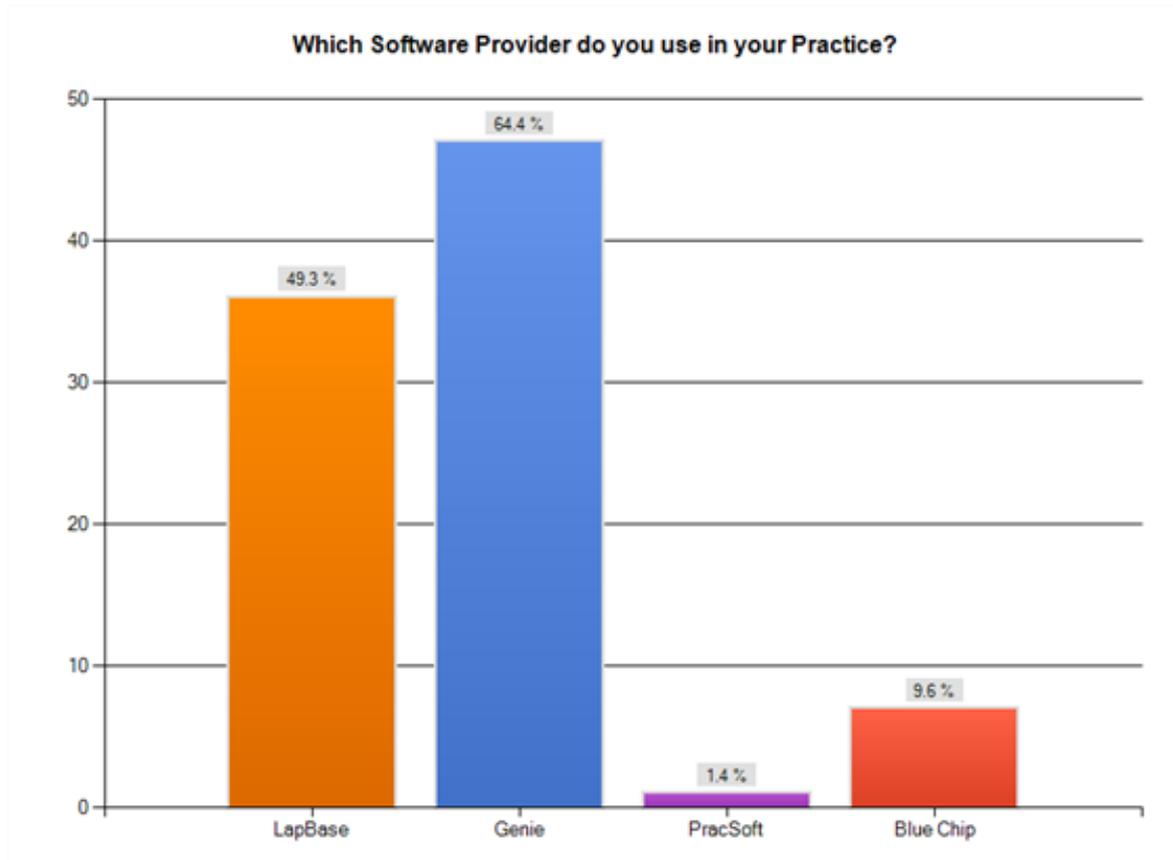
Two weeks following surgery, patient explanatory statements (with individual hospital logo) are posted to the patient. The patient has a two week period to opt out of the registry by calling a Freecall 1800 number. The patient may still opt out at any point of contact during the follow-up period.

If the patient declines to participate, information is removed from the registry. Data capture is cross checked with regular ICD code checks with the participating hospital information service.

Follow up forms are sent to the treating surgeon at 30 days. Annual forms are also posted to the surgeon with the option to call patients to collect missing data elements using a scripted interaction (*Aide Memoire*).

It is anticipated that data collection will eventually occur electronically through a web-based interface. We will work with software providers of electronic medical records (EMR) to streamline the process. A survey was recently sent to OSSANZ surgeon members, 140 in total, to ascertain the different EMR utilised in practice. There were 100 replies; the results are shown in Figure 3.

Figure 3 – Software providers of EMR used by bariatric surgeons in Australia and New Zealand



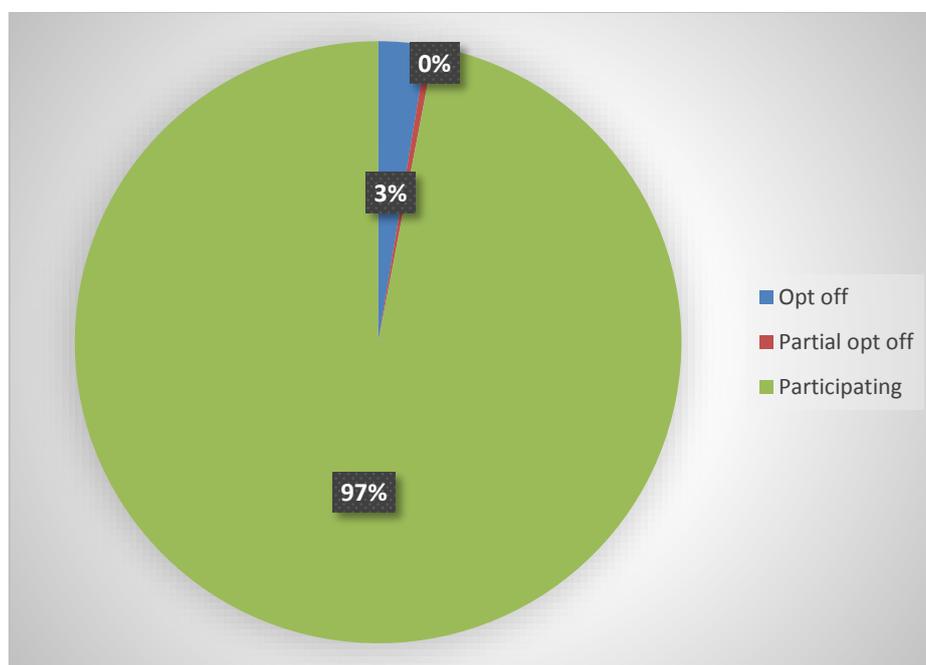
Results of the Pilot Bariatric Surgery Registry

Enrolment in Registry

Invitations to participate in the registry were sent to 1740 patients who had undergone a bariatric surgery procedure at one of the pilot sites. A total of 1782 procedures have been captured until April 1, 2014.

There have been 45 patients who have chosen to opt off (2.6%) and 7 partial opt-offs with patients requesting that they not be contacted, although they were happy for their surgeon to provide information.

Figure 4 – Patient enrolment in the registry



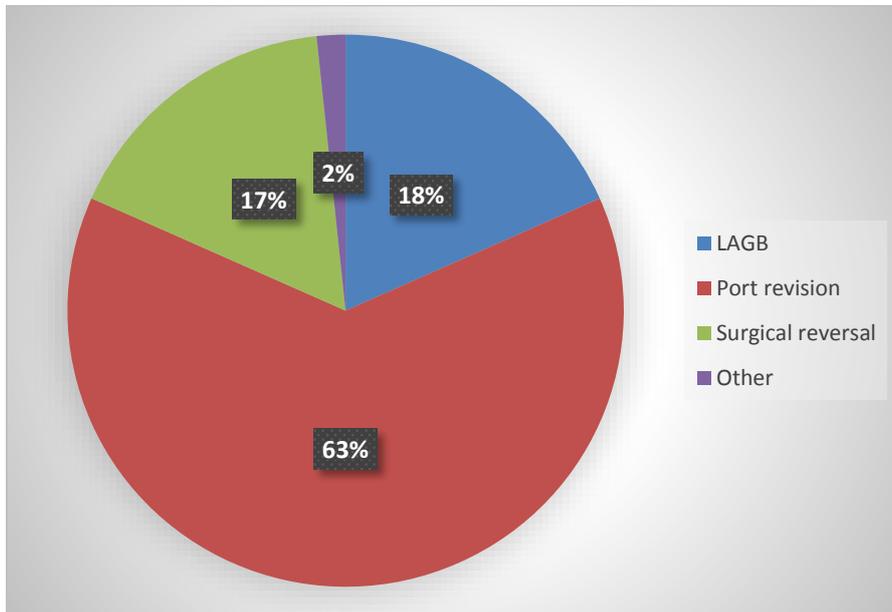
Procedures captured by the registry

There have been 1685 enrolments in the registry:

- There have been 1325 *primary procedures* presented to the registry. The majority of these were LAGB, reflecting the work load of our pilot sites. There were 1225 LAGB, 83 LSG, 7 RYGB, 9 Endobarrier, 1 BPD.
- There were 360 *revisional procedures* enrolled in the registry (legacy cases). The original procedure was performed prior to commencement of the registry, and the only information we have on these initial procedures is from the datasheet submitted at the time of enrolment with the revisional procedure (appendix 1). The initial procedure performed and the subsequent revisional operation chosen are summarised in Table 1.

There have been 60 patients who had their primary procedure captured by the registry who have gone on to have a subsequent procedure (4.5%) (figure 5). A more detailed summary of the patient journey as captured by the registry is provided in table 1. Please note, port revisions are not included in this table.

Figure 5 – Subsequent operations captured on patients who had their primary operation enrolled on the registry (n=60)



There have been 28 patients who presented to the registry with a revisional procedure who have required a subsequent revisional procedure (7.8%). Table 1 provides a more detailed breakdown of this population.

Figure 6 – Subsequent operations captured on patients who had their secondary operation enrolled on the registry

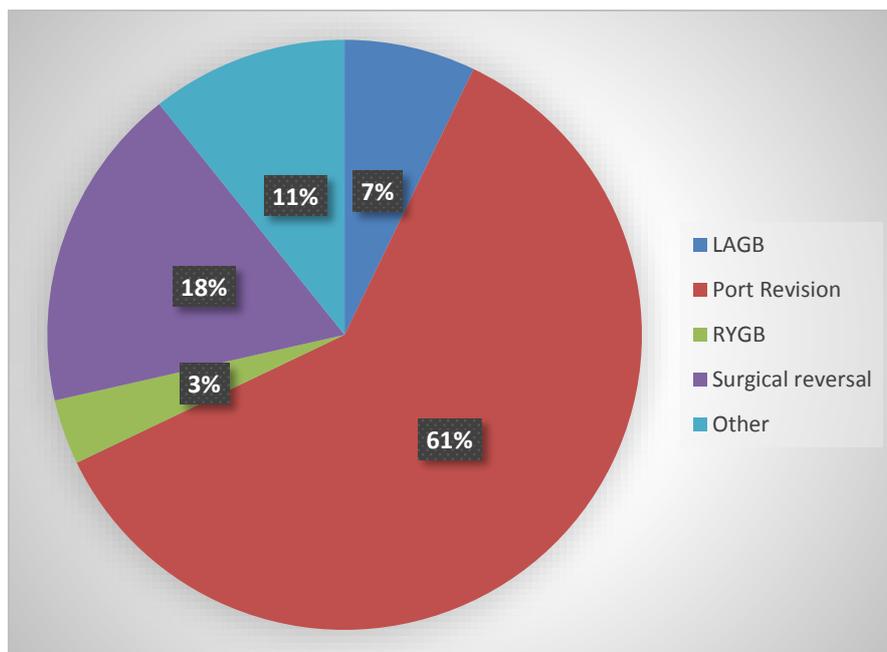


Table 1 – Bariatric “migration”: revisional procedures in all patients

Original procedure (Either captured by registry or reported on data sheet when enrolled)	1st bariatric procedure in registry	n	2 nd bariatric procedure in registry	n	3 rd bariatric procedure in registry	n
LAGB n = 1573	LAGB	1530	LAGB	12		
			Surgical reversal	14	LAGB	2
	LSG	29	RYGB	1		
	RYGB	13				
	BPD	1				
LSG n=75	LSG	74				
	RYGB	1				
BPD n=11	BPD	11				
Gastroplasty n=16	LAGB	10	Surgical reversal	1		
	BPD	4				
	RYGB	2				
Other n=11	Other	9				
	LAGB	2				
RYGB n=6	RYGB	4				
	LAGB	2				
Unknown n=6	LAGB	4				
	RYGB	1				
	BPD	1				

Legend

Primary cases enrolled on registry

Legacy cases enrolled on registry

Demographics

There have been 383 men and 1312 women enrolled in the registry to date. There have been 342 males undergoing primary procedures and 983 women with a mean age of 43.4 years. There have been 47 males and 378 females who have had secondary procedures with a mean age of 45.5 years.

The states and hospitals accruing the patients are outlined in tables 2 and 3.

Table 2 – States where patients enrolled in the BSR are living

VIC	1673
NSW	16
ACT	1
Q'LAND	2
WA	1
TAS	1
SA	1
NT	1

Table 3 – Hospitals contributing to the BSR pilot

Box Hill Hospital	58
St John of God Warrnambool	21
The Alfred	268
The Avenue	1297
Epworth Eastern	7
Epworth Richmond	44

Follow-up

We have received 30 day follow up data on 93.4% of patients at 30 days with 6.1% currently due or about to be due. We have received annual data from 570 (92.5%) patients from 616 patients who are currently at this time point. Of these there are 27 self-reported weights (4.3%). We are awaiting data on 38 patients (6.2%) and have lost 8 patients (1.3%) to follow up.

Weight outcomes

The mean start BMI for primary procedures was 44.1, with a mean BMI DOS 43.5 and a mean BMI at 30 days of 41.1. The mean BMI at 12 months was 35.7. This represents an EWL of 44% from day of first presentation. There is insufficient data to separate meaningfully by procedure at this stage.

The secondary procedures had mean BMI DOS of 36.9 and a mean BMI at 30 days of 36.2. The mean BMI at 12 months was 34.2. This represents an EWL overall of 22.7%. This reflects the fact that patients had typically lost weight prior to a revisional procedure, and demonstrates that weight loss appears to be maintained following a revisional procedure.

In the final registry these data will be able to be separated by procedure with greater statistical power, as this cohort is dominated by LAGB which is no longer the dominant procedure in Australia (Figure 1).

Diabetes outcomes

Of the 1325 primary patients, there were 169 patients with diabetes identified (12.8%). At 12 months the prevalence of diabetes was 2.1% (table 4 & 5). More data is needed to confirm this trend.

Table 4 – Prevalence of diabetes and treatment at presentation

Diabetes at presentation	(of denominator 1325 primary pats)	169
On treatment:	Diet/exercise	25
	Oral therapy (mono)	75
	Oral therapy (poly)	9
	Insulin	31
	No treatment recorded on form	29

Table 5 – Prevalence of diabetes and treatment at 12 months

Diabetes at 12mo f-up	(of 520 primary pats who have reached 12mo f-up with follow-up information available)	11
On treatment:	Oral therapy (mono)	6
	Oral therapy (poly)	1
	No treatment recorded on form	4

There have been 52 primary patients who were captured as diabetic at baseline who have now reached 12 month follow-up, and 9 patients who have reached 24 month follow-up. Of the 12 month cohort, 8 patients were noted to still be diabetic (85% remission rate). Change in treatment is noted in table 6.

Table 6 – Treatment of patients with diabetes reported at baseline and 12 month (n=52)

Treatment	Baseline	12 months
Diet/exercise	9	0
Oral therapy (mono)	17	3
Oral therapy (poly)	0	1
Insulin	5	0
No treatment recorded on form	21	4

None of the 24 month cohort were recorded as diabetic. Again, these numbers are too small to draw any conclusions, but confirm our ability to collect these data within the registry.

Sentinel Events (within 30 Days post-operative)

There have been 30 sentinel events within 30 days of admission – 1.7% of all procedures. Table 7 outlines the events captured.

Table 7 – Sentinel events at 30 days (n=1782 procedures)

Unplanned return to theatre	3
Unplanned readmission to hospital	26
Prolonged LOS	1

Complications reported to the registry

There have been a total of 30 complications (1.7%) reported at 30 days – correlating to sentinel events as reported above - and 14 complications reported after 30 days (0.7%). The specific complications are listed in table 8.

Table 8 – Complications reported at 30 days and beyond 30 days.

Within 30 days	Band perforation – ret to theatre	1
	Band malposition – ret to theatre	1
	Bile leak from liver edge	1
	OG junction perforation (and infection), Explant	1
	Colon perforation, Explant	1
	Band infection, Explant	1
	Obstruction, Explant	1
	Fluid in abdo, Explant	1
	Abdominal collection – for drainage	1
	Band revision complicated by ?pneumoniae/aspiration, Explant	1
	?Band erosion, Explant	1
	Expant, NOS	1
	Obstruction, revise band	1
	Collapse, pain NOS	2
	Wound dehiscence	1
	Infected port, removal	5
	Mobile port, refixation	2
	Flipped port, refixation	1
	Medical issues - Prolonged LOS	1
	Evacuate haematoma	1
	Paroxysmal AF	1
	Anxious NOS	2
	Unrelated viral pneumonia	1

Outside 30 days	Late Cx: Ischaemic stomach – gastrectomy (at 9/12)	1
	Oesophageal Cancer, Explant	1
	Infected port, removed	1
	Port haematoma/seroma	3
	Wound infection	1
	Wound dehiscence	1
	Abdo pain, NOS	1
	Needs band closed as day case	1
	Dx with VWD: Post-op bleed	1
	DVT	1
	Multiple medical post-op Cx, Explant	1
	Leaking serous fluid from wound (no infection)	1

Summary

The second year of the pilot bariatric surgery registry has seen significant milestones:

- Seed funding for Australia wide role out obtained from the Australian Commonwealth Government Department of Health
- Australian nationwide role out commenced
- Data manager, data entry officer and research officer appointed
- Ethics approval from further centres
- Regular meeting of steering committee with established governance structure
- Data dictionary finalised
- Data collection and collation processes finalized
- Achieved 2.6% opt off rate
- Achieving 98.7% 12 month follow-up rate

This second report confirms that our pilot process has been effective. We now have a robust dataset and data collection process that means that the data is of the highest integrity and ensures accurate reporting.

We have also determined that the registry will record and report all outcomes on those enrolling with a primary procedure. Legacy cases will still be recorded, however, only sentinel events and reoperations will be reported. This is due to the heterogeneous nature of the data and the lack of prospectively collected data on the primary procedure.

The pilot process has now effectively closed and the registry proper has commenced. We look forward to being able to provide the public, the profession and government with data that provides surety that Bariatric Surgery across Australia and New Zealand is being delivered with the highest standards.

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Glossary of Abbreviations

Abdo	Abdomen
ANZGOSA	Australia and New Zealand Gastroesophageal Surgery Association
BMI	Body mass index
BPD	Bilopancreatic Diversion
BSR	Bariatric Surgery Registry
Cx	Complications
DOS	Day of surgery
DOH	Department of Health
Dx	Diagnosis
LAGB	Laparoscopic Adjustable Gastric Banding
LSR	Laparoscopic Sleeve Gastrectomy
MTAA	Medical Technology Association of Australia
NOS	Not otherwise specified
OSSANZ	Obesity Surgery Society of Australia and New Zealand
RACS	Royal Australasian College of Surgeons
RCT	Randomised controlled trial
RYGB	Roux en-Y Gastric Bypass

Appendix 1 – Data sheets

PATIENT INFORMATION OPERATION FORM

BARIATRIC SURGERY REGISTRY

v 8.4.3/2014

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

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

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: Diet/exercise
 Oral therapy Monotherapy
 Polytherapy
 Insulin

Procedure status:
 Primary bariatric procedure
 Procedure abandoned

OR

OPERATION:
Primary procedure:
 Gastric Banding
 Gastroplasty
 R-Y gastric bypass
 Mini-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
 Mini-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
 Mini-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: _____

Thank you for completing this form

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 8.4 3/2014

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
 Prolonged LOS

Reason

ANNUAL FOLLOW-UP (EVERY 12 MONTHS AFTER SURGERY)

Date of follow-up ____/____/____
Patient weight _____ kgs
Diabetes Yes No
Treatment: 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 primary procedure
 Death unrelated to primary procedure

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