First report of the pilot

Bariatric Surgery Registry

April 2013

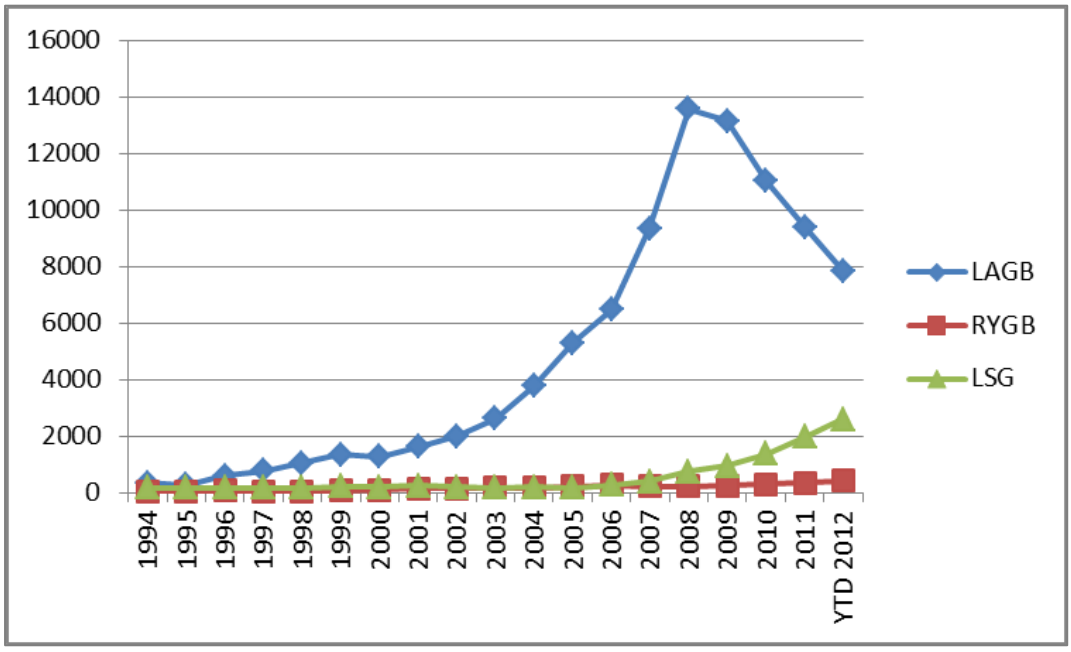
Funders:

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 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.

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

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 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 (attachment 1).

Funding for the pilot registry was obtained from a consortium of funders: Applied Medical, Allergan Health, Johnson and Johnson and GORE Health as well as OSSANZ (attachment 2).

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.

An interim steering committee was formed and met for the first time in February 2012. 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

An interim project officer (Leah MacDonald) was appointed, with a 0.6EFT appointment formally made in January 2013 (Margaret Anderson).

The pilot registry commenced on February 1, 2012. We are pleased to present the first year results.

Dataset and data dictionary

The current data elements being collected by the registry include:

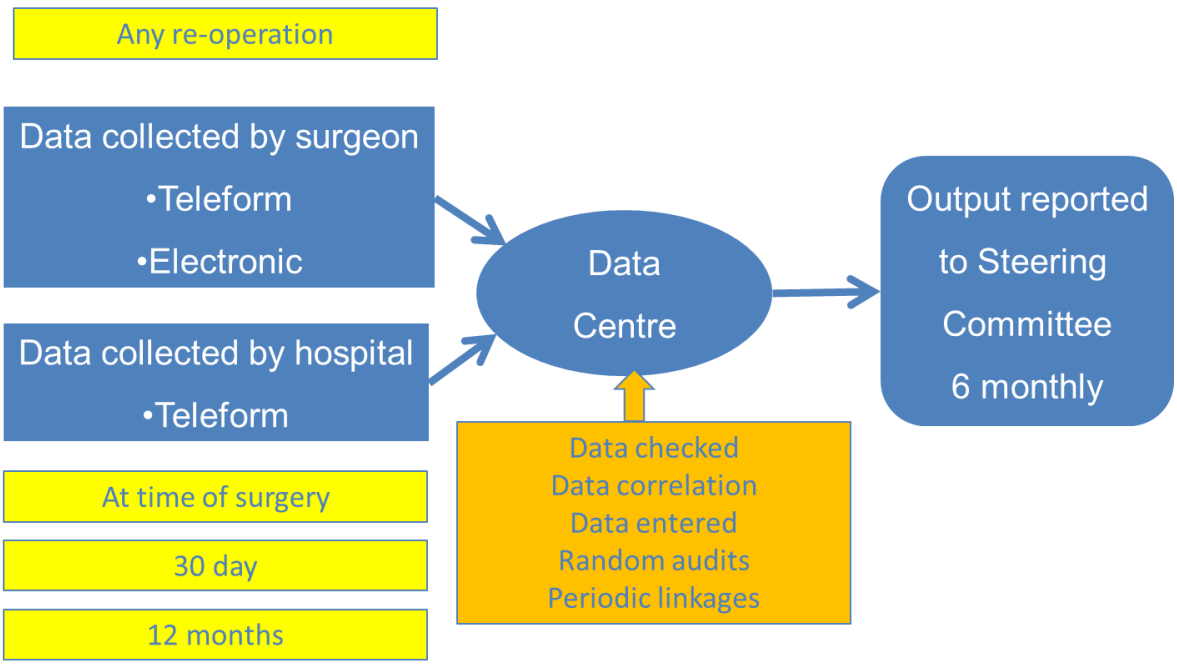
- Patient demographics
- Weight
    - Day of first appointment
    - Day of surgery
    - 30 day post-operative
    - Annual
- Height
- Diabetes status – yes/no
- Diabetes treatment: none/tablet/insulin/pump
- Complications 30 day
- Mortality 30 day
- Annual
    - Weight
    - Diabetes status
    - Diabetes treatment
    - Reoperation
    - Complications

A complete data dictionary is provided in attachment …

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. Datasheets are collated by a registry lead at participating hospitals and returned to the central registry office. Data sheets are appended in attachment 1.

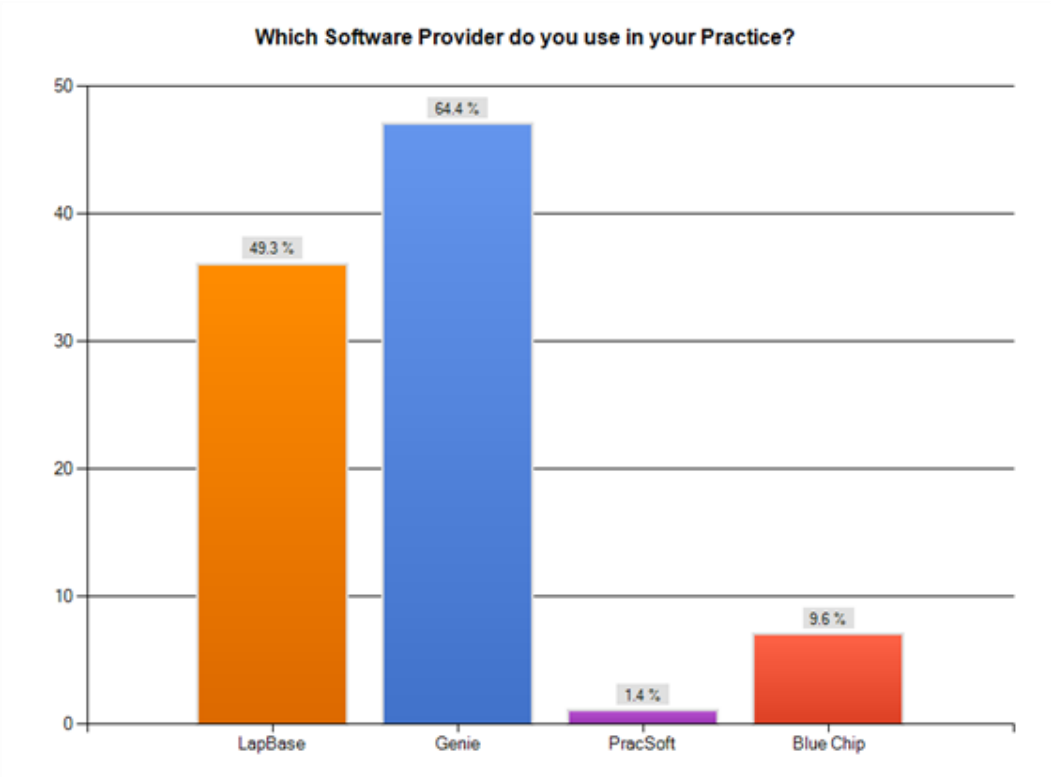
Two weeks following surgery, patient information forms along with opt-out consent forms are posted to the patient on hospital letterhead. The patient has a two week period to opt-out either by return free-post or by calling a 1800 number.

If the patient declines to participate, all information is destroyed prior to entry into the registry. If the opt-out consent form is not returned, patient data is entered into the registry database. 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.

It is anticipated that data collection will occur electronically now that the data dictionary is confirmed. 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 NZ



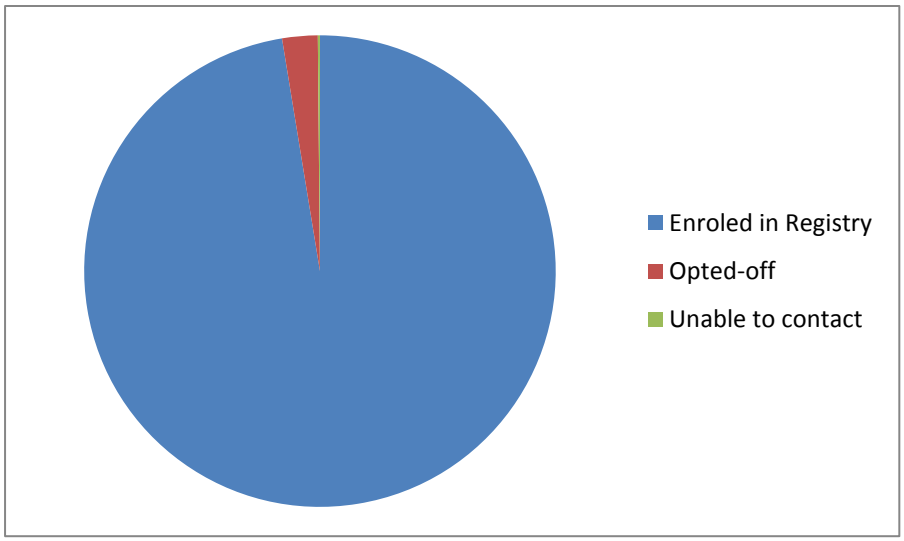
First results of the Bariatric Surgery Registry

Enrolment in Registry

Invitations to participate in the registry were sent to 699 patients who had undergone a bariatric surgery procedure at one of the pilot sites until April 1, 2013. A total of 714 procedures have been captured.

There have been 17 patients who have chosen to opt off, and one letter returned undeliverable (incorrect address).

Figure 4 – Patient enrolment in the registry



Of the 681 patients enrolled in the registry, 459 were primary procedures, 252 were revisional procedures and there were 3 abandoned procedures. It is important to note that some patients have had >1 operation, therefore there are 714 procedures captured. The majority of primary procedures were Laparoscopic Adjustable Gastric Bands (LAGB).

Figure 5 – Procedure status

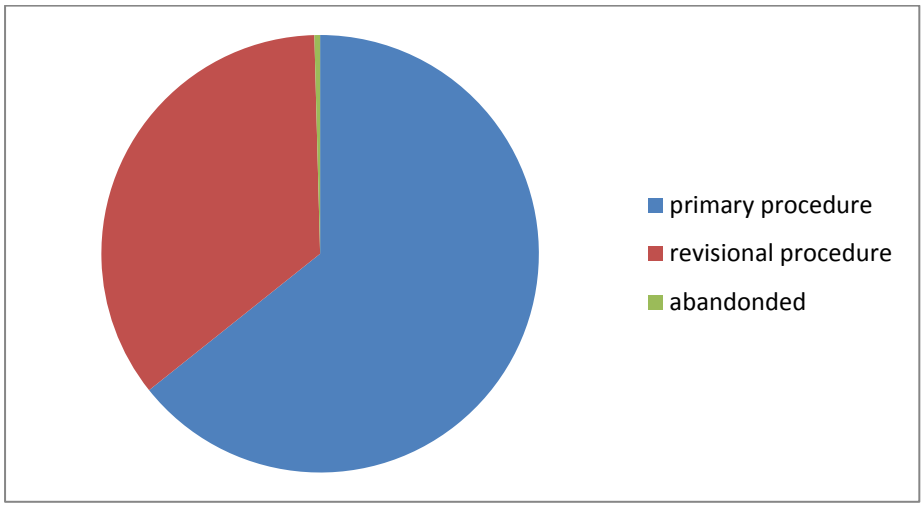
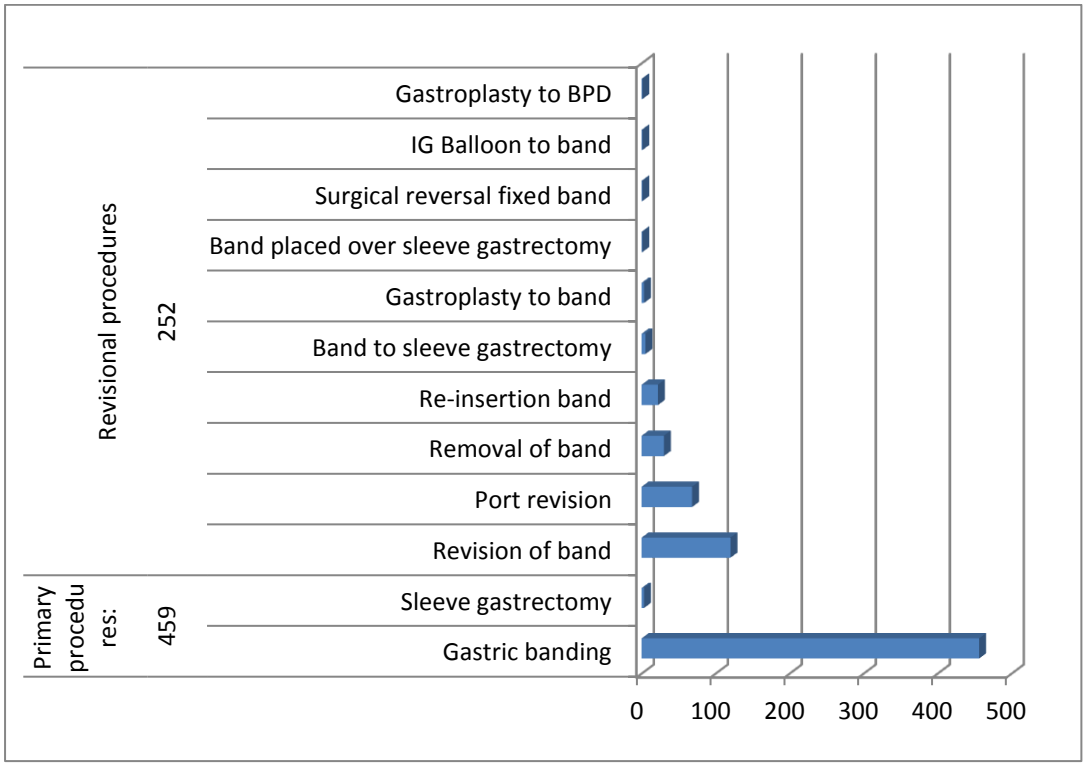


Figure 6 – Breakdown of bariatric procedures performed



Demographics of population

Primary procedures:

Male: 133; Female: 352
Mean age: 42.7 years
Mean start BMI: 43.7
Mean DOS BMI: 42.8
Mean 30 d BMI: 41.03

Secondary procedures:

Male:29; Female:215
Mean age: 44.3
Mean DOS BMI: 37.6
Mean 30 d BMI: 37.7

Diabetes status and treatment

Of the 459 primary patients, there were 40 patients with diabetes identified (8.7%).

Table 1 – Diabetic treatment of primary diabetic patients enrolled in the registry

Treatment	**Number**
Oral hypoglycaemics	18
Insulin	10
No current treatment	8
Treatment not indicated	3
Diet only	1

Complications

There have been four unplanned returns to theatre (0.5%). One was for a gastric perforation, one for band malposition and two for mobile port requiring resuturing.

There have been 13 non-surgical unplanned readmissions to hospital within 30 days of surgery (2.1%). Reasons for readmission are outlined in table 2.

Table 2 – Reasons for unplanned readmissions within 30 days

Reason for readmission	**Number**
Infected port	4
Infected wound site	3
Band infection	2
Wound dehiscence - for IV antibiotics	1
Anxiety	1
Chronic Paroxysmal Atrial Fibrillation	1
Band leak (tubing rubbed through, for replacement)	1

There have been 9 complications outside 30 days or not requiring readmission (1.3%). These complications are outlined in table 3.

Table 3 – Complications outside of 30 days or not requiring re-admission

Complication	**Number**
Haematoma/seroma NOS	4
Port infection (for removal)	1
Port haematoma (aspirated under x-ray)	1
Extruding port (for revision)	1
Post-op bleed: Dx with von Willibrand's disease	1
Needed band closure (as Daycase)	1

Summary

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

- Funding model established
- Project officer appointed
- Ethics approval from multiple centres
- Regular meeting of steering committee
- Data dictionary finalized
- Data collection and collation processes finalized

This first report confirms that our pilot process has been effective. We are now confident proceding to national roll out 1 July 2013, and look forward to continued improvement in our processes and procedures.

References

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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.
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PATIENT INFORMATION OPERATION FORM

BARIATRIC SURGERY REGISTRY

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 _____

_____ **Post Code** _____

Hospital Patient # _____ **Home Ph** _____

Medicare # _____ **Mobile Ph** _____

Name of Hospital _____ **State** _____

Name of Surgeon _____

PLEASE COMPLETE THIS SECTION IN FULL

Operation date ___/___/_____

Patient height _____

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

Patient op weight _____

Diabetes ☐ Yes ☐ No

Treatment:
- ☐ Insulin
- ☐ Tablets
- ☐ Pump
- ☐ No treatment

Procedure status
- ☐ Primary procedure

Procedure
- ☐ Gastric Banding
- ☐ Gastroplasty
- ☐ R-Y gastric bypass
- ☐ Sleeve gastrectomy
- ☐ Biliopancreatic bypass /Duodenal switch
- ☐ Gastric Imbrication

OR

Procedure status
- ☐ Revision
- ☐ Reversal

Original Procedure
- ☐ Gastric Banding
- ☐ Gastroplasty
- ☐ R-Y gastric bypass
- ☐ Sleeve gastrectomy
- ☐ Biliopancreatic bypass /Duodenal switch
- ☐ Gastric Imbrication

Current Procedure
- ☐ Gastric Banding
- ☐ Gastroplasty
- ☐ R-Y gastric bypass
- ☐ Sleeve gastrectomy
- ☐ Biliopancreatic bypass /Duodenal switch
- ☐ Gastric Imbrication
- ☐ Port revision
- ☐ Surgical reversal

Device tracking (attach sticker or fill in)

Type: _____

Model: _____

S/N: _____

Other information:

Thank you for completing this form

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

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

BARIATRIC SURGERY REGISTRY

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 _____

Mortality ☐ Yes ☐ No

Complications

Yes	No	
☐	☐	Wound dehiscence
☐	☐	Deep wound infection requiring return to theatre
☐	☐	Leak
☐	☐	Mal-positioned band

Sentinel events

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

ANNUAL FOLLOW-UP (EVERY 12 MONTHS AFTER SURGERY)

Date of follow-up ___/___/_____

Patient weight _____

Diabetes ☐ Yes ☐ No

Treatment: ☐ Insulin ☐ Tablets

Complications ☐ Yes ☐ No

If yes, please describe:

PLEASE FILL IN IF MORTALITY HAS OCCURED

☐ Yes ☐ No

If yes, date: ___/___/_____

Describe details/attached relevant reports:

Primary procedure date: ___/___/_____

Death related to primary procedure:

☐ Yes ☐ No

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

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