PROTOCOL

Establishment of a bariatric surgery clinical quality registry

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Data Custodian:
Monash University

Statement of Compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015), New Zealand's Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities (2012), Note for Guidance on Good Clinical Practice (CPMP/ICH- 135/95), ASCSQH Operating Principles and Technical Standards for Australian Clinical Quality Registries (2008), Monash University research policies and procedures and federal laws governing privacy and confidentiality.

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1 Glossary of Abbreviations & Terms

Abbreviation/ Term	Description (using lay language)
ACSQHC	Australian Commission on Safety and Quality in Health Care
BSR	Bariatric Surgery Registry
BSR-*i*	Bariatric Surgery Registry Interface
DC	Data Collector
DOS	Day of Surgery
HDEC	Health and Disability Ethics Committee
HIS	Health Information Service
HREC	Human Research Ethics Committee
ICD-10-AM	International Classification of Disease 10-Australia Modified
Legacy Participant	Participants whose first entry into the BSR is with a revision (or subsequent) bariatric surgical procedure
MBS	Medicare Benefits Schedule
NHI	National Health Index
NIHI	National Institute for Health Innovation
NHMRC	National Health and Medical Research Council
OSSANZ	Obesity Surgery Society of Australia and New Zealand
PFS	Participant Fact Sheet
PI	Principal Investigator
Primary Participant	Participants whose first entry into the BSR is with their first bariatric surgical procedure
PM	Project Manager

RA	Research Assistant
SMS	Short Message Service
SFTP	Secure File Transfer Platform

2 Study Sites and Ethics Committees

The Bariatric Surgery Registry is collecting information from surgeons at public and private hospitals where bariatric surgical procedures are known to have been performed in Australia and New Zealand. As it is made known that bariatric operations are being undertaken at additional healthcare facilities, those locations will be added as further study sites.

A list of study sites where the Registry is conducted is outlined in Table 1 for Australia and Table 2 for New Zealand. In addition, the ethics committees governing those sites are listed in Table 3.

Please note the potential involvement of additional sites as stated above.

Table 1. List of Study Sites in Australia

Site Name	Address	Local Investigator
Albury-Wodonga Private Hospital	West Albury, NSW 2640	Mr Adam Skidmore
Ashford Private Hospital	Ashford, SA 5035	Dr Benjamin Teague
Austin Hospital	Heidelberg, VIC 3084	Mr Ahmad Aly
Austin Repatriation Hospital	Heidelberg, VIC 3084	Mr Ahmad Aly
Baringa Private Hospital	Coffs Harbour, NSW 2540	Dr Andrew Ramsay
Belmont Hospital	Belmont, NSW 2280	Dr Timothy Wright
Bethesda Hospital	Claremont, WA 6010	Dr Susan Taylor
Box Hill Hospital	Box Hill, VIC 3128	Mr Patrick Moore
Brisbane Waters Private Hospital	Woy Woy, NSW 2256	Dr Kenneth Wong
Cabrini Hospital Brighton	Brighton, VIC 3186	Mr Paul Burton
Cabrini Hospital Malvern	Malvern, VIC 3144	Mr Paul Burton
Cairns Private Hospital	Cairns, QLD 4870	To be confirmed
Calvary Central Districts	Elizabeth Vale, SA 5112	Mr Paul Leong
Calvary North Adelaide	North Adelaide, SA 5006	Assoc Prof Lilian Kow
Calvary Riverina Hospital	Wagga Wagga, NSW 2650	Dr Richard Harrison Dr Nicholas Williams
Calvary St Vincent's	Launceston, TAS 7250	Mr Stephen Wilkinson
Calvary Wakefield Hospital	Adelaide, SA 5000	Dr Justin Bessell
Campbelltown Hospital	Campbelltown, NSW 2560	Dr Govind Krishna

Site Name	Address	Local Investigator
Concord Repatriation General Hospital	Concord, NSW 2139	Dr David Martin
Darwin Private Hospital	Tiwi, NT 0810	Mr P. John Treacy
Epworth Eastern	Box Hill, VIC 3128	Mr Patrick Moore
Epworth Freemasons	East Melbourne, VIC 3002	Mr Jason Winnett
Epworth Geelong	Waurn Ponds, VIC 3216	Mr Matthew Leong
Epworth Richmond	Richmond, VIC 3121	Mr Patrick Moore
Flinders Medical Centre	Bedford Park, SA 5042	Assoc Prof Lilian Kow
Flinders Private Hospital	Bedford Park, SA 5042	Assoc Prof Lilian Kow
Footscray Hospital	Footscray, VIC 3011	Miss Ingra Bringmann
Geelong Private Hospital	Geelong, VIC 3220	Mr Matthew Leong
Glen Iris Private Hospital	Glen Iris, VIC 3146	Mr Andrew Smith
Glengarry Private Hospital	Duncraig, WA 6023	Dr Kevin Dolan
Gold Coast Private Hospital	Southport, QLD 4215	Dr Jacobus Jordaan
Gosford Private Hospital	North Gosford, NSW 2250	Dr Kenneth Wong
Gosford Public Hospital	Gosford, NSW 2250	Dr Kenneth Wong
Greenslopes Private Hospital	Greenslopes, QLD 4120	Dr Michael Hatzifotis
Hamilton Hospital	Hamilton, VIC 3300	Dr Stephen Clifforth
Hobart Private Hospital	Hobart, TAS 7000	Mr Stephen Wilkinson
Hollywood Private Hospital	Nedlands, WA 6009	Prof Jeffrey Hamdorf
Holy Spirit Northside Hospital	Chermside, QLD 4032	Dr George Hopkins
Hospital for Specialist Surgery	Baulkham Hills, NSW 2153	Dr Roy Brancatisano
Hurstville Private Hospital	Hurstville, NSW 2220	Dr Govind Krishna
Ipswich General Hospital	Ipswich, QLD 4305	Dr Phillip Lockie
Jessie McPherson Private Hospital	Clayton, VIC 3168	Mr Zdenek Dubrava
John Fawkner Hospital	Coburg, VIC 3058	Mr Ian Michell
John Flynn Private Hospital	Tugun, QLD 4224	Miss Candice Silverman
John Hunter Hospital	Lambton Heights, NSW 2305	Dr Timothy Wright
Joondalup Health Campus	Joondalup, WA 6027	Mr David Yong
Kareena Private Hospital	Caringbah, NSW 2229	Dr Ken Loi
Kawana Private Hospital	Birtinya, QLD 4575	Dr Ian Baxter
Knox Private Hospital	Wantirna, VIC 3152	Mr Geoffrey Kohn

Site Name	Address	Local Investigator
Lake Macquarie Private Hospital	Gateshead, NSW 2290	Dr Timothy Wright
Latrobe Regional Hospital	Traralgon, VIC 3844	Mr David Chan
Launceston General Hospital	Launceston, TAS 7250	Mr Stephen Wilkinson
Linacre Private Hospital	Hampton, VIC 3188	Mr Adam Skidmore
Lingard Private Hospital	Merewether, NSW 2291	Dr Timothy Wright
Maryvale Private Hospital	Morwell, VIC 3840	Dr David Chan
Mater Private Hospital	South Brisbane, QLD 4101	Dr Samuel Baker
Mater Misericordiae Hospital Rockhampton	Rockhampton, QLD 4700	Dr Andrew Russell
Mater Private North Sydney Hospital	North Sydney, NSW 2060	Dr Craig Taylor
Mater Hospital Pimlico	Pimlico, QLD 4812	Dr Samuel Baker
Mildura Base Hospital	Mildura, VIC 3500	Mr Salim Chaloob
Mildura Private Hospital	Mildura, VIC 3500	Mr Salim Chaloob
Mitcham Private Hospital	Mitcham, VIC	Mr Ahmad Aly
Monash Medical Centre	Clayton, VIC 3168	Dr Stephen Blamey
Mount Hospital	Perth, WA 6000	Mr Leon Cohen
Nambour Selangor Private Hospital	Nambour, QLD	Mr Michael Donovan
National Capital Private Hospital	Garran, ACT 2605	Dr Charles Mosse
Nepean Private Hospital	Kingswood, NSW 2747	Dr Michael Devadas
Newcastle Private Hospital	Lambton, NSW 2305	Dr Timothy Wright
Noosa Private Hospital	Noosaville, QLD 4560	Dr Garth McLeod
North Shore Private Hospital	St Leonards, NSW 2065	Assoc Prof Garett Smith
North West Private Hospital (Brisbane)	Everton Park, QLD 4053	Dr Philip Lockie
North West Private Hospital (Burnie)	Burnie, TAS 7320	Mr Stephen Wilkinson
Northpark Private Hospital	Bundoora, VIC 3083	Miss Salena Ward
Norwest Private Hospital	Bella Vista, NSW 2153	Dr Michael Devadas
Nowra Private Hospital	Nowra, NSW 2541	Dr Mark Hehir
Peninsula Private Hospital	Langwarrin, VIC 3910	Mr Geoffrey Draper
Pindara Private Hospital	Benowa, QLD 4217	Dr Jason Free
Port Macquarie Private Hospital	Port Macquarie, NSW 2444	Dr Nigel Peck
Prince of Wales Private Hospital	Randwick, NSW 2031	Dr David Links

Site Name	Address	Local Investigator
Princess Alexandra Hospital	Woolloongabba, QLD 4102	Assoc Prof Anthony Russell
Queen Elizabeth Hospital	Woodville, SA 5011	Mr Markus Trochsler
Queen Elizabeth II Jubilee Hospital	Coopers Plains, QLD 4108	Dr Chung Won
Repatriation General Hospital	Daw Park, SA 5041	Assoc Prof Lilian Kow
Royal Brisbane and Women's Hospital	Herston, QLD 4006	Dr George Hopkins
Royal Hobart Hospital	Hobart, TAS 7000	Mr Stephen Wilkinson
Royal North Shore Hospital	St Leonards, NSW 2065	Assoc Prof Garett Smith
Royal Prince Alfred Hospital	Camperdown, NSW 2025	Assoc Prof Tania Markovic
St Andrew's-Ipswich Private Hospital	Ipswich, QLD	Dr John Copp
St Andrew's War Memorial Hospital	Brisbane, QLD 4001	Dr Phillip Lockie
St George Private Hospital	Kogarah, NSW 2217	Assoc Prof Michael Talbot
St John of God Ballarat	Ballarat, VIC 3353	Mr Stuart Eaton
St John of God Berwick	Berwick, VIC 3806	Mr Raymond McHenry
St John of God Bunbury	Bunbury, WA 6230	Dr Senarath Werapitiya
St John of God Geelong	Geelong, VIC 3220	Mr Matthew Leong
St John of God Geraldton	Geraldton, VIC 6530	Dr Jacques Perry
St John of God Mt Lawley	Mount Lawley, WA 6050	Mr Leon Cohen
St John of God Murdoch	Murdoch, WA 6150	Dr Harsha Chandraratna
St John of God Subiaco	Subiaco, WA 6008	Mr Leon Cohen
St John of God Warrnambool	Warrnambool, VIC 3280	Mr Phillip Gan
St Vincent's Private Hospital	Fitzroy, VIC 3065	Mr Michael Hii
St Vincent's Public Hospital	Fitzroy, VIC 3065	Mr Michael Hii
Shepparton Private Hospital	Shepparton, VIC 3630	Mr David Dalton
Strathfield Private Hospital	Strathfield, NSW 2135	Dr David Martin
Sunnybank Private Hospital	Sunnybank, QLD 4109	Dr Mark Daoud
Sunshine Hospital	St Albans, VIC 3021	Miss Ingra Bringmann
Sunshine Coast Private Hospital	Birtinya, QLD 4556	Dr Ian Baxter
Sunshine Coast University Private Hospital	Birtinya, QLD 4556	Dr James Askew
Sydney Adventist Hospital	Wahroonga, NSW 2076	Dr Craig Taylor
Sydney Southwest Private Hospital	Liverpool, NSW 2170	Dr Govind Krishna

Site Name	Address	Local Investigator
The Alfred Hospital	Melbourne, VIC 3004	Professor Wendy Brown
The Avenue Private Hospital	Windsor, VIC 3181	Professor Wendy Brown
The Valley Private Hospital	Mulgrave, VIC 3170	Mr Chris Hensman
The Wesley Hospital	Auchenflower, QLD 4066	Dr Reza Adib
Wagga Wagga Rural Referral Hospital	Wagga Wagga, NSW 2650	Dr Richard Harrison
Waikiki Private Hospital	Waikiki, WA 6169	Dr Chris Couch
Wangaratta Private Hospital	Wangaratta, VIC 3677	Mr Adam Cichowitz
Warringal Private Hospital	Heidelberg, VIC 3084	Mr Ahmad Aly
Western Private Hospital	Footscray, VIC 3011	Mr Jason Winnett
Westmead Private Hospital	Westmead, NSW 2145	Dr Anthony Brancatisano
Williamstown Hospital 3016	Williamstown, VIC 3016	Miss Ingra Bringmann

Table 2. List of Study Sites in New Zealand

Site Name	Address
Auckland City Hospital	Grafton, Auckland 1023
Christchurch Hospital	Christchurch Central, Christchurch 4710
Mercy Ascot Greenlane Hospital	Remuera, Auckland 1050
Middlemore Hospital	Otahuhu, Auckland 2104
North Shore Hospital	Takapuna, Auckland 0620
Ormiston Hospital	Flat Bush, Auckland 2019
Southland Hospital	Kew, Invercargill 9812
Southern Cross Hospital	Hamilton, 3216
Tauranga Hospital	South Tauranga, 3112
Waikato Hospital	Hamilton, 3204
Wakefield Hospital	Newtown, Wellington, 6021
Wellington Hospital	Newtown, Wellington, 6021

Table 3. Ethics Committees

Name of HREC	Status of Review
Austin Health HREC	Approved
Bellberry HREC	Approved

Name of HREC	Status of Review
Calvary Health Care HREC (EC00302)	Approved
Cabrini Health HREC	Approved
Calvary Health ACT HREC	Approved
Calvary Healthcare Sydney HREC	Approved
Eastern Health HREC	Approved
Epworth HealthCare HREC	Approved
Gold Coast Hospital and Health Service HREC	Approved
Greenslopes Hospital HREC	Approved
Hollywood Private Hospital HREC	Approved
HREC of Northern Territory Department of Health and Menzies School of Health Research*	Yet to submit
HREC of the Queen Elizabeth Hospital/Lyell McEwin Hospital/Modbury Hospital (EC00190)	Approved
Joondalup Health Campus HREC	Approved
Latrobe Regional Hospital HREC	Approved
Mater Health Services HREC	Approved
Mater Health Services LTD North Queensland HREC	Approved
Mildura Base Hospital HREC	Approved
Monash Health HREC (EC00382)	Approved
Monash University Research Ethics Committee (EC00234)	Approved
North Shore Private Ethics Committee (EC00443)	Approved
Northern Sydney Local Health District (EC00112)	Approved
NZ Health and Disability Ethics Committee	Approved
Royal Brisbane and Women's Hospital HREC	Approved
South Australia Clinical Research Ethics Committee	Approved
St John of God Health Care Ethics Committee	Approved
South Metropolitan Health Service HREC (EC00265)	Approved
South West Healthcare Multidisciplinary Ethics Committee (EC00257)	Approved
St Vincent's Hospital (Melbourne) HREC EC00344	Approved
St Vincent's Health and Aged Care HREC (EC00324)	Approved
St Vincent's Hospital HREC (EC00140)	Approved
Sydney Local Health District Ethics Review Committee (EC 00113)	Approved
Tasmania Health and Medical HREC	Approved
The Alfred Hospital HREC	Approved
The Avenue Hospital HREC	Approved
The Adventist HealthCare LTD Ethics Committee	Approved
Uniting Care HREC	Approved
West Australia Country Health Service Board Research Ethics Committee	Approved
Western Health Low Risk Ethics Panel	Approved

The study also has been approved by the Monash University Research Ethics Committee and the Royal Australasian College of Surgeons Ethics Committee. The BSR has been granted Acceptance Status from the New Zealand Ministry of Health for New Zealand personal health information to be stored at Monash.

3 Introduction

3.1 Lay Summary

Obesity is a prevalent disease in Australia and New Zealand. This is a major concern for both countries as obesity is an important risk factor for ill health. Obese persons more likely to suffer from many other serious health conditions including diabetes, heart disease, liver disease, infertility, stroke and cancer. As a consequence, obese people are more likely to die young.

Lifestyle interventions have not been found to be an effective long-term solution for the treatment of obesity. When conservative weight loss measures tried by those with obesity are not successful, bariatric, or 'weight loss,' surgery may be considered.

Bariatric surgical procedures are operations performed with the intention of helping people with obesity achieve weight loss which is easier to maintain. Weight loss following bariatric surgery leads to significant improvement in health and wellbeing, and patients have been shown to live longer. However, it is invasive surgery and carries with it known surgical risks and potential side effects, which can be as severe as death. Given people are having this surgery to improve their health, it is critical that the surgery is performed with a minimum of side effects, otherwise it cannot be justified.

The purpose of the Bariatric Surgery Registry (BSR) is to monitor the safety of the surgery and to assess the long term changes in the health of people who undergo bariatric surgery in Australia and New Zealand.

The Registry collects data, or information, on the operation performed, who performed the operation, where the operation occurred, complications from the surgery, weight at various time points, and diabetes status and management. It is also necessary to keep patient details such as their name, date of birth, address and Medicare number (Australia) or National Health Index (NHI) number (New Zealand) to be able to identify patients on the registry and track their progress through data linkage to other datasets.

By systematically collecting information on every procedure performed in Australia and New Zealand, the Registry will help to identify when surgeons, hospitals or procedures are not performing to the expected standard. In time, this Registry should also be able to demonstrate how effectively bariatric surgery results in weight loss and improved health (using diabetes as a marker of health) across the two countries.

Participants in this study will have information related to their bariatric surgery provided to the Registry by their surgeon or hospital. They may also be contacted directly by the Registry staff to see if they suffered any complications and to check on the impact of surgery on their health (with regards to their diabetes status), weight, and well-being. The Registry will hold their identifying information as it aims to follow each bariatric patient for 10 years after their first bariatric operation.

The BSR is located at Monash University, School of Preventative Health and Public Medicine (Melbourne Australia) and expects to record data from 95% of the 20,000 (2016) bariatric surgeries performed in public and private health care facilities in Australia and New Zealand. In New Zealand, the BSR call centre functions are provided by Auckland UniServices Limited (UniServices), through its business unit, the National Institute for Health Innovation (NIHI).

3.2 Background

Obesity poses a major public heath challenge for Australia and New Zealand. According to the Australian Health Survey (2014-15) nearly 28% of the adult population are considered obese (defined as a BMI >30 kg/m^2) compared to 18% in 2004/05[ii]. New Zealand's 2015-2016 Health Survey indicated that the nation's rate of obesity has been increasing by 1% every year since 1989, with 32% of the adult population being obese according to the New Zealand Health Survey 2015-2016. The rate of adult obesity for Pacific and Māori peoples, according to the NZ survey, were 67% and 47%, respectively [iii].

Obesity is a major risk factor for many preventable diseases including type 2 diabetes, heart disease, hypertension, stroke, cancer, and musculoskeletal disorders. It can also significantly affect quality of life and shorten lifespan [iv-viii]. As those with obesity may suffer from other chronic medical conditions, the cost of their healthcare is much greater than for those of a healthy weight [ix]. In 2005, the direct cost of obesity on the Australian economy was estimated to be AUS$21 billion [x]. A New Zealand study approximated the healthcare cost of obesity to be NZ$722 million and the cost of lost productivity was estimated to be NZ$849 million [xi]. These figures demonstrate that the management of obesity demands to be a national priority for both countries.

Although lifestyle interventions can be effective in the short term, they are rarely durable in the long term [xii, xiii]. Maintenance of weight loss for the long term is a challenge for those on lifestyle intervention programmes. For those with severe obesity (BMI>35kg/m2), several Randomized Controlled Trials (RCT) [xiv , xv, xvi] and multiple case series suggest that bariatric surgery provides more predictable and durable weight loss than conservative regimes [xvii] and is generally very safe [xviii, xix].

Bariatric surgery is burgeoning in Australia. The Medicare Benefits Schedule (MBS) data for 2016 indicates the number of procedures has grown to nearly 19,000 procedures [xx] at a direct cost of $222 million [xxi]. Still, this reflects only 1.4% of the Australian morbidly obese having bariatric surgery as an intervention. NZ figures show that 889 bariatric procedures were performed for the year ending 2014, representing 0.4% of those with a BMI >40[xxii].

3.3 Rationale

A clinical quality registry is a specific type of registry which uses the data it collects to benchmark performance and determine variations in clinical outcomes. These data are used to develop guidelines and standards for clinical practice. The Australian Commission on Safety and Quality in Health Care (ACSQHC) promotes clinical quality registries as they are known to drive change and lead to improved patient care and outcomes[xxiii].

A clinical quality registry focusing on bariatric surgery could be used to determine if bariatric surgical procedures are a safe and effective treatment for obesity at a population level. Data from a *clinical quality* bariatric surgery registry have the potential to give confidence to patients, surgeons, governments, health funds, hospitals and the wider community that bariatric surgery is safe and is achieving improvement in health outcomes for all patients.

With the support of the Obesity Surgery Society of Australia and New Zealand, the Bariatric Surgery Registry (BSR) was established in 2012 following specific recommendations from: the Georganas Senate Inquiry into Obesity (published as "Weighing it up" May 2009 Recommendation 6 [xxiv]), the

Australian Commission on Safety and Quality in Healthcare (2008) [xxv], and the Health Technology Review Report (Review of Health Technology Assessment in Australia, 2009) [xxvi].

Following a successful two year (2012-2014) pilot study, the Australian rollout began in 2014. Roll-out across New Zealand is planned to commence in mid to late 2017 upon attainment of locality approvals for each participating New Zealand site.

The BSR is underpinned by a comprehensive governance structure and is funded to ensure that independent assessment of data quality occurs on an ongoing basis. As the BSR holds identifiable patient information, the project adheres to the Guidelines provided under Section 95 of *Privacy Act 1988* (Commonwealth of Australia), the *Privacy Act* 1993 (New Zealand), the *Health Information Privacy Code* 1994, the *National Statement on Ethical Conduct in Human Research 2007* (Updated May 2015) and New Zealand's *Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities* (2012).

4 Aims and Purpose

The purpose of the Bariatric Surgery Registry (BSR), as a clinical quality registry, is to gather and analyse information that is used to monitor and enhance the quality of care received by obese persons undergoing bariatric surgery.

The stated aims of the BSR are to:

- Record the immediate safety of bariatric surgery in Australia and New Zealand.
- Study longitudinally the safety and efficacy of bariatric surgery in Australia and New Zealand assessing procedures, devices, complications and adverse events.
- Track key health changes including weight loss/ BMI and diabetes management following bariatric surgery in Australia and New Zealand.
- Report accurate population level data which will be used to shape health practices and policy.
- Be a basis for further research into bariatric surgery as a safe and effective treatment for obesity.
- Allow better analysis of the economic benefits of bariatric surgery as a treatment for obesity related illness.

4.1 Outcome Measures

The ability to longitudinally track patients who have undergone bariatric surgery is unprecedented in Australia and New Zealand. The incidence of adverse events and deaths related to bariatric surgery will be monitored.

Clinical outcomes (for Primary Participants) will be assessed to determine long term health effects of having bariatric surgery by following weight/BMI changes, differences in managing diabetes in patients identified as diabetic, the need for revision surgery, and the effect on lifespan.

The establishment of a bariatric surgery clinical quality registry has the opportunity to achieve the following important outcomes:

- Measure and confirm the outcomes from clinical trials of bariatric surgical procedures at a population level.
- Support measurement and understanding of determinants of obesity and disparities in health outcomes for Māori and Pacific patients.
- Identify variations in care and the reasons for those differences.
- Provide an ability to track the long term effects of bariatric surgery as an intervention for obesity.
- Promote evidence-based practice by assessing compliance with best practice.
- Provide important information to inform public health policy and practice.
- Provide confidence to clinicians and institutions that they are delivering a high quality service.
- Assure the public that bariatric surgical procedures are performed under the oversight of a robust quality assurance programme.
- Provide patients with important information about treatment risks and benefits. This will empower patients to make informed decisions about care and treatment options. Benefits

will be realised in the short term by producing risk adjusted comparative outcome data based on currently available treatment and in the longer term by assessing the impact of new technologies and discoveries on outcome.

- Enable further studies and research, including studies evaluating patient reported outcomes (PROMS) recognizing that the patients' sense of wellbeing is one of the most important outcomes from this type of surgery. It is important to measure, monitor and understand the impact on bariatric patients when losing excess weight.

5 Study Design

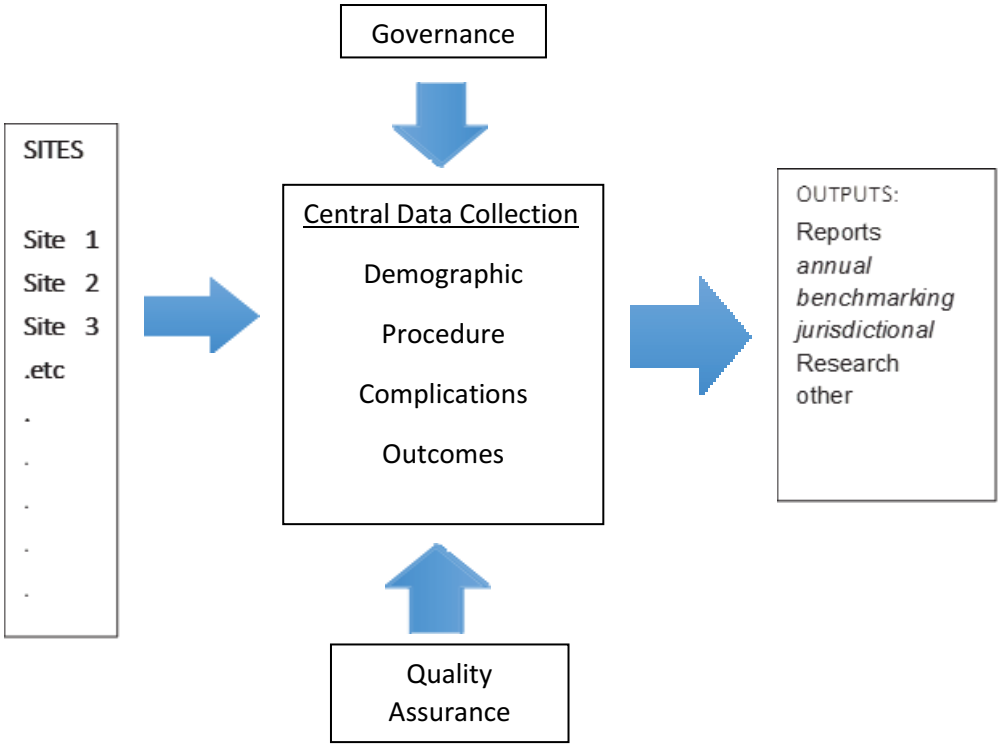
The BSR is a population based observational quality improvement study of patients with obesity undergoing bariatric surgery and collects identifiable data obtained from participants' medical records, the participants themselves and from surgeons or hospitals. When mature, the BSR will collect data from all public and private hospitals in Australia and New Zealand that perform bariatric surgery (estimated to be around 152 sites in Australia and 12 in NZ).

Data is captured for participants:

- following their bariatric procedure;
- peri-operatively (20-90 days following procedure); and
- annually for 10 years (for primary participants only).

The BSR will conform to the national operating principles for clinical quality registries as set out by the ACSQHC. The BSR is expected to be ongoing and data will be retained indefinitely.

Figure 1. Operational overview of the Bariatric Surgery Registry



5.1 Participant Recruitment

Eligible participants will be identified through:

- Surgeon or public hospital data collector submitting patient details into the BSR-*i* or completion of a BSR Operation form, and
- Receipt of hospital-generated ICD-10-AM coding reports received periodically from each contributing site.

Anyone who undergoes bariatric surgery in Australia or New Zealand will be eligible for inclusion in the study.

Participants of all ages are eligible for inclusion (see Section 5.2.1 for explanation of consent for those under 18).

Participants who cannot speak English will be included in the study. In Australia, the Participant Fact Sheet (PFS) is available in commonly spoken Languages Other Than English (LOTE). In New Zealand the PFS will be available in English. If the BSR must directly contact a participant who cannot speak English and a translation is unavailable, then no further direct attempts to obtain follow up information will be made. The participant will be considered "Lost to Follow-Up."

5.1.1 Recruitment Procedure

Contributing surgeons or public hospital clinics are required to make patients undergoing bariatric procedures aware that information related to their procedure will be provided to the BSR. Surgeons and public hospital clinics are required to display a poster that identifies their practice/clinic as one which contributes to the Bariatric Surgery Registry ('This Practice is proud to be associated with the Bariatric Surgery Registry'). They must also give all bariatric patients an information flyer ('Our Practice is proud to contribute to the Bariatric Surgery Registry'). These steps ensure that patients are aware that their sensitive health data is being transmitted to a third party, provides preliminary information about the BSR that is reinforced by the PFS, and offers an opportunity for more information to be provided if required.

Surgeons, public hospital data collectors, nurses, and hospital information services will capture data related to prospective participants' details and their bariatric procedures and provide that data to the Registry. Upon the BSR's receipt of this data, the BSR posts potential participants a Participant Fact Sheet and flyer. The PFS explains the BSR, why the registry project is being undertaken, and the processes involved. It invites them to participate voluntarily and explains how to opt out. All data received from surgeons or hospitals is held until the opt out period has passed. If the patient does decide to opt out, then all information about the patient is destroyed apart from information in effort to ensure that the BSR will not contact them again (see **sections 5.2.1 and 5.2.2**).

Participants are identified as "primary" if they are entered the Registry with their first bariatric procedure or as "legacy" if they are entered with a revision bariatric procedure.

5.2 Consent

5.2.1 Opt Out Approach to Participation

The BSR collects identifiable, personal information about bariatric patients. This information allows hospitals, surgeons, and their staff to link back to participants' medical records and provide information on participants' health status following their procedures.

In Australia, the BSR must comply with the *Privacy Act of 1988*. Principle 6 of this Act states that stored personal information must not be used or disclosed for a secondary purpose unless patient consent is obtained or there is a permitted health situation. Section 16B of the Act defines the permitted health situations. This definition includes research relevant to public health or public safety and specifically provides for a waiver of consent where it is not practical to obtain consent or public interest outweighs individual privacy concerns. The use or disclosure of personal information must be conducted under guidelines approved under Section 95A of the Act, and compliance with this Section is assessed by a nominated HREC. In NZ, the BSR must comply with the *Privacy Act 1993* and the *Health Information Privacy* Code 1994.

In accordance with the *Operating Principles for Clinical Quality Registries* [xxviii], approval for using the opt out approach will be sought from each Ethics Committee nominated by every hospital whose patients' details are being to be added to the Registry.

The scale and significance of the BSR is such that an opt out approach to participation is necessary. All quality and safety registries require near total capture of potentially eligible participants to ensure reliable reporting of outcomes. If participation in a quality and safety registry is less than 90% there is significant risk of bias and underreporting of adverse outcomes [xxviii]. Based on current MBS data, it is estimated that from 2017 at least 20, 000 bariatric patients per year will be eligible for recruitment. It would not be practical to obtain direct consent from this number of patients annually, and international experience suggests that participation rates would drop to around 60% making data unreliable.

As prospective participants, bariatric patients are first made aware of the Registry pre-operatively in their surgeons' rooms or public hospital clinic, by way of a prominently displayed poster, and are individually provided with an information flyer. In plain language, both the poster and flyer advise prospective participants that they will be contacted by the Registry following their surgery. The flyer explains what information the BSR collects and that it aims to follow the progress of everyone who has a bariatric procedure in Australia and New Zealand to establish the safety and efficacy of bariatric surgery. The flyer explains the voluntary nature of their participation and advises of how to opt out if they decide not to take part. It also advises patients that they can inform their surgeon of their intention for non-participation.

Following their surgery and upon the Registry receiving patient demographic and procedure information from the surgeon or the hospital, bariatric patients are posted a Participant Fact Sheet further advising that participation in the BSR is voluntary and their decision not to participate in the BSR, or to participate and later opt out, will not affect their relationship with their treating surgeon or the hospital, and their surgeon will be unaware of their participation status. The PFS lists a free call number to call and inform the Registry of their decision to opt out. In New Zealand, this free call number shall be supported by UniServices.

For bariatric patients under 18 years old, separate copies of the PFS will be posted to the patient and the patient's parents (or legal guardian). If the patient's parents (or legal guardian) choose to opt out the bariatric patient from the BSR, they can do this on the patient's behalf by calling the free call number. All participants retain the right to opt out from the BSR at any time.

Once the PFS have been posted, bariatric patients have two weeks to contact the Registry staff via the free call telephone number to opt out. Their participation will be presumed if no contact is made within that period. Participants will always retain the right to opt out for the duration of the study.

There are three options for participation:

1. **Full participation** - Data is included on the BSR, and BSR staff may contact the participant during follow-up care. The participant is required to do nothing upon receiving the Participant Fact Sheet.
2. **Partial opt out** - Data is included on the BSR but BSR staff will not contact the participant during the follow-up period by either phone call or SMS. The participant is required to phone the free call 1 800 number to state their decision to partially opt out.
3. **Complete opt out** - No clinical data is included on the BSR. Patients are required to phone the free call 1 800 number listed on the PFS and state their decision not to participate. The Registry will keep the patients' name, date of birth, treating hospital & UR Number/NHI and treating surgeon on a "Do Not Contact" file to ensure the patients will not be contacted in the future should they have a revision bariatric procedure. All information related to their bariatric procedure will be removed from the database and destroyed if in paper form. The patients who withdraw can be sent a letter confirming their withdrawal from the registry if requested or if they have left a voice message.

[Note: BSR-*i* users, outside of Registry staff, are denied access to the "Do Not Contact" file and may inadvertently add a patient who previously chose to opt out. There may be the occasional instance when someone who has opted out is sent a PFS inviting them to participate in the Registry following a subsequent surgery.]

The BSR recognises that patients' data may be held without providing them the opportunity to opt out twice during the data acquisition process:

1. This occurs from the time the surgeons and hospitals provide patients' information before the PFS is posted and two weeks has passed.

2. This may also occur from the time when the BSR receives the Health Information Services discharge coding (ICD-10-AM reports) and patients are identified whose data was not provided by surgeons or hospitals until the PFS is posted and two weeks has passed.

These are two specific points in the process of acquiring data for the BSR that have been carefully considered by Monash University Office of General Counsel and 40 ethics committees (see Table 3 at Section 2). Their opinions were that this is an acceptable process under the *Privacy Act of 1988*, and it was also their opinion that this process is preferable to the surgeon obtaining direct consent at the time of consultation which holds a risk of power imbalance, coercion and would be difficult to document that the process had occurred. Ethical considerations are discussed more completely in **Section 6**.

The BSR adheres to the *National Statement for Ethical Conduct in Human Research 2007* (2015) Section 3.2.4 which states that "…approval may be given to the use of identifiable data to ensure that the linkage is accurate, even if consent has not been given…Once linkage has been completed, identifiers should be removed from the data…unless consent has been given for its identifiable use [xxix]." The BSR also complies with New Zealand's *Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities* (2012). Section 6.47 of the NZ guidelines states, "In the case of audits and related activities it may be ethical to use health information without additional or specific consent, as these activities are sometimes an essential part of high-quality health care delivery, so the activity may be one of the reasons why the data were collected [xxx]."

The BSR disposes of such information in accordance with the *National Statement for Ethical Conduct in Human Research 2007* (2015) for those who choose to opt out.

5.2.2 Waiver of Consent

Apart from the waiver of consent provided to allow for the opt out approach as described above, a waiver of consent will be required in the event that the patient dies following bariatric surgery so as not to burden next of kin. Information related to a mortality is essential to determine if the death is likely to have been caused by the bariatric surgery. The Alfred HREC (Australia) considered this waiver and approved its use. Having a waiver of consent for this instance implies that the deceased did not need to give previous consent to request or hold their information, nor is consent required from their next of kin to hold the data of the deceased.

5.3 Data

5.3.1 Data Collection

Surgeons, nurses or hospital data collectors in Australia are to provide data using one of the following options:

- Web browser with secure authorised entry using the Bariatric Surgery Registry Interface (BSR-*i)*
- Paper based data forms securely faxed or posted
- Secure electronic record transfer from surgeons' or hospitals' electronic medical record

In New Zealand, data will only be collected through direct entry through the BSR-*i*.

Hospital Information Services (HIS) at each hospital site or of a private hospital group provide regular ICD-10-AM coding reports for bariatric procedures performed by surgeons who participate in the Registry. The coding reports include patient demographic and procedure information. In Australia, these reports are sent to the BSR using a secure file transfer platform (SFTP). In New Zealand, these reports are sent to UniServices in accordance with the agreed MoU for each site.

ICD-10-AM coding reports provided by HIS are to be used to verify data submitted by surgeons/ hospital data collectors. In the case where the surgeon or hospital have not previously provided information of a bariatric patient, the reports will be the primary source of data. When ICD-10-AM coding is the primary source, surgeons are asked to complete the missing data elements not made available from the hospitals (e.g. device/stapling information, whether it is a primary or revision operation, height/ weight information and diabetes treatment). Patients whose details are obtained from ICD-10-AM reports will be sent a PFS and the opt-out approach is followed according to the process described in **section 5.2.1**. If the surgeons do not supply the missing data elements, registry staff will contact the patient to confirm whether procedure was a primary or revision and to ascertain the participant's height, weight, diabetes status and treatment prior to surgery.

The steps to initially identify participants and allow for the decision whether to participate or opt out, data capture and data verification are shown in Figure 2.

Follow-up data are provided by surgeons or public hospital clinics, either by return of a paper form or electronic completion of a secure data request. If surgeons or public data collectors indicate they have not seen the participant, registry staff will contact the participant for a brief phone call (using the Call Centre Protocol) to collect the follow-up information related to the perioperative period and/or 12 month intervals after surgery. This call may also include the missing data elements about their procedure if the surgeon or data collector has not provided them.

As explained in the PFS, participants do not have to agree to this contact and can fully opt out of the Registry or choose to have their information kept on the Registry but not be contacted directly at any point (partial opt out). Five attempts will be made to contact the patient before they are allocated to "Lost to Follow-Up".

The BSR plans to develop an SMS, email or web-based secure portal platform to contact participants to obtain follow-up data. This platform will invite participants to link to a secure portal at various

stages of their post-operative experience. If they do not respond to the request for follow-up, the Registry will call the participants. The SMS, email or website platform will be designed to engage with participants by providing useful information during their post-surgery experience and will allow them to give their own data back to the Registry.

Figure 3 outlines the steps involved in collecting follow up data.

If the surgeons are providing the missing operation data with the ICD-10-AM report verification process, they will also be asked to provide their perioperative follow-up data at the same time to enable efficiency. More comprehensive data can potentially be collected by interested sub-groups, with the approval of the Steering Committee and HREC/HDEC.

Figure 2. Participant Recruitment and Data Collection Scheme

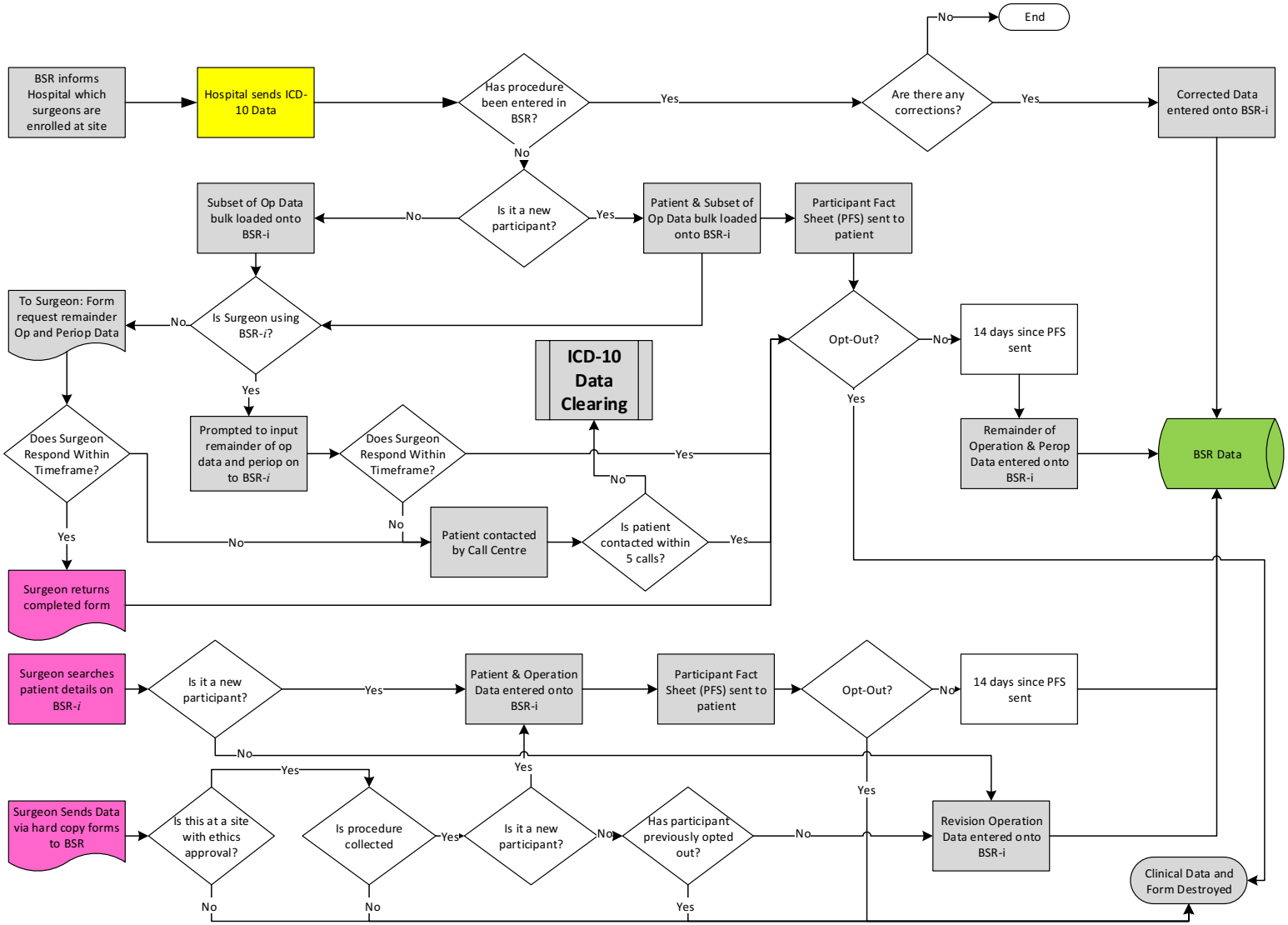
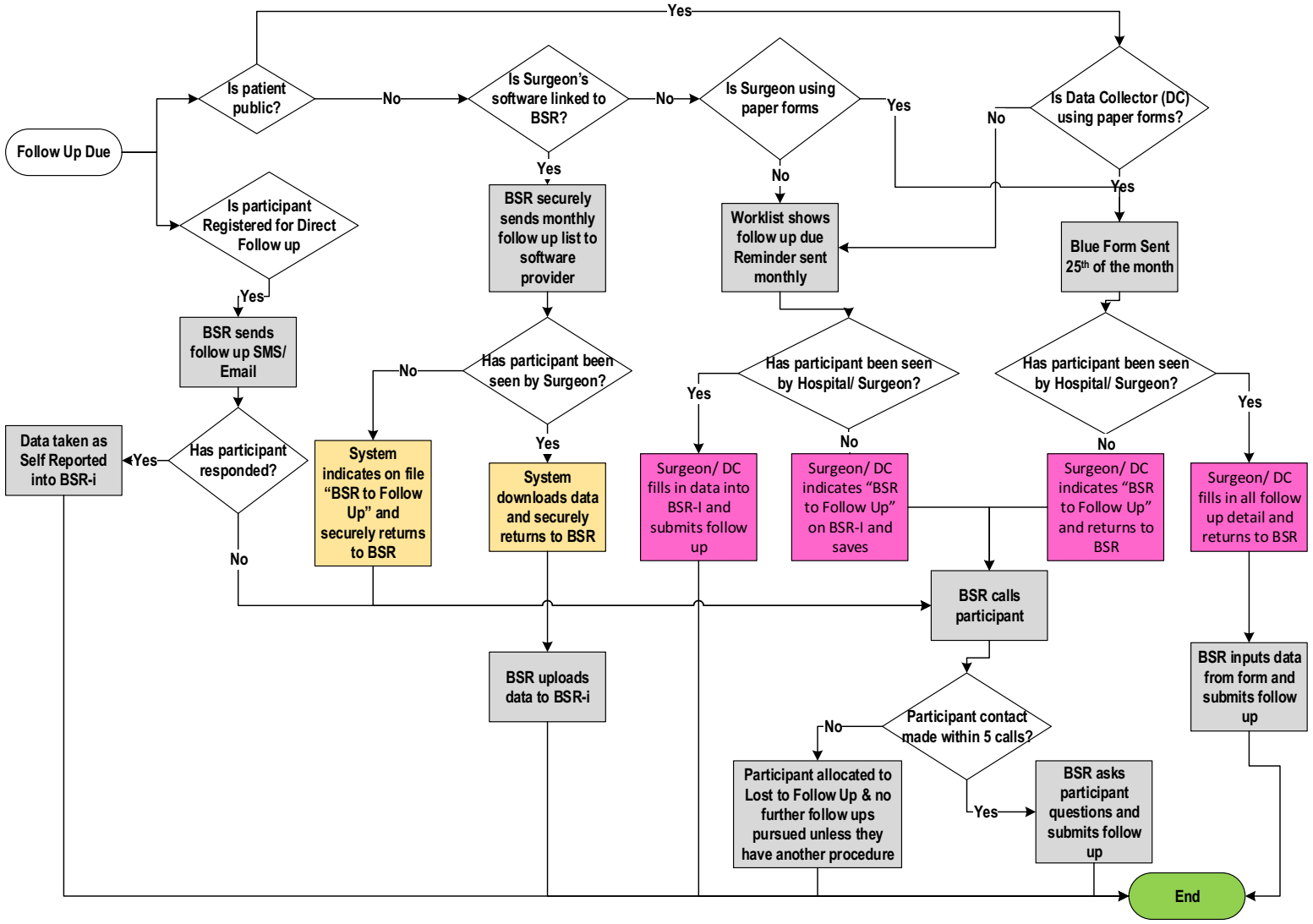


Figure 3. Follow-Up Data Collection Scheme.



5.3.2 Data Elements

Data collected are defined in the BSR's data dictionary and governed by the Steering Committee with any changes managed through a data element variation process.

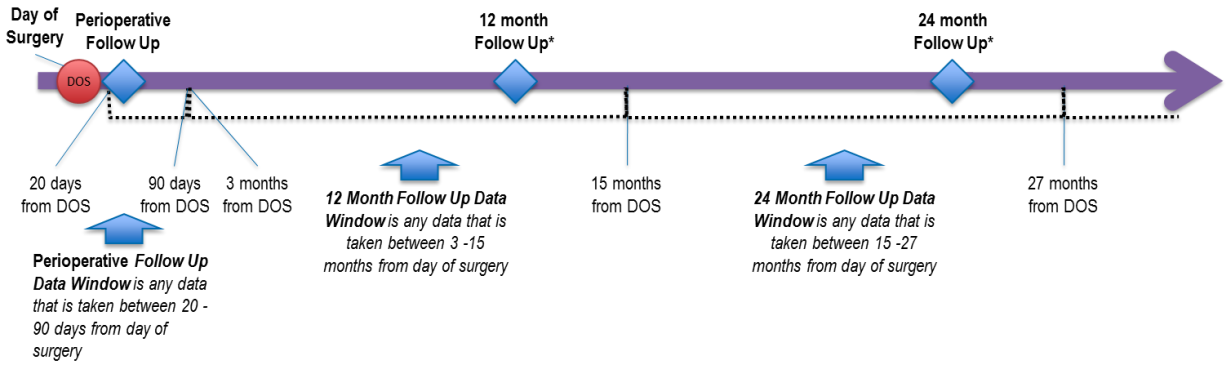
The data elements collected include:

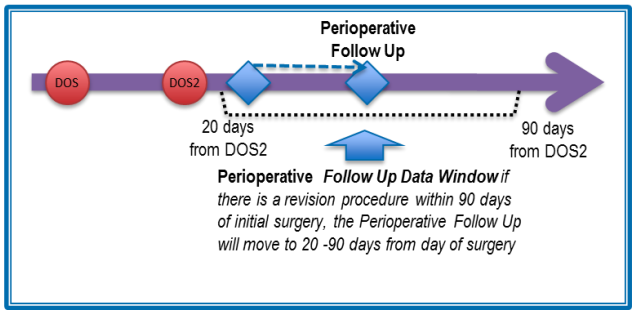
- Patient Information:
  - Patient Identifiers: full name, address, date of birth, UR number/hospital (and IHI numbers when available), email address (if supplied by patient)
  - Patient Demographic Information: Medicare, or DVA number, NHI in NZ, phone numbers, gender & indigenous status/ethnicity (NZ)
- Procedure Information:
  - Procedural information: surgeon name, procedure date, procedure type, primary/ planned revision or unplanned revision status, reason for revision, bariatric procedure prior to revision, procedure abandoned or not, length of hospital stay, mortality status and if death likely related to bariatric procedure
  - Clinical details: start weight (for primary patients only), day-of-surgery (DOS) weight, height, diabetes status and treatment, concurrent renal and liver transplant
  - Device or Staple details: type, brand, model, port fixation method, buttressing
- Follow-up Information:
  - Outcome data:
    - Peri-operative (up to 90 days post-surgery): date patient examined for follow-up; defined adverse events (unplanned return to theatre, unplanned admission to ICU, unplanned re-admission to hospital, prolonged hospital stay and reason/ complication that caused the adverse event); mortality status and if death likely related to bariatric procedure
    - Annually (only primary participants) for 10 years after surgery: weight, diabetes status and treatment, re-operation and reason; mortality status and if death likely related to bariatric procedure
  - Subsequent Clinical data:
    - Annually (primary patients only, for ten years): weight, diabetes status and treatment, re-operation and reason; mortality status and if death likely related to bariatric procedure
  - Participant Feedback
    - For quality assurance purposes, and as a basis for the potential development of the SMS/Secure Portal platform as described above, participants will be given the opportunity to provide feedback on their experience with the Registry and to advise how the BSR could better support their journey as bariatric patients. This feedback may take place during follow-up phone calls made by the BSR Call Centre staff or via a SMS and web-based portal described above.

Follow-up data is to be collected for certain periods (Figure 4):

- Perioperative follow-up data refers to the period between 20 and 90 days post-surgery
- Annual follow-up refers to the period between 9 months prior to anniversary or 3 months following.

Figure 4. Data Periods for Follow-Up





Annual follow up only occurs from Primary patients who have not had a subsequent reversal, have not opted off

5.33 Data Quality

Data completeness and accuracy are optimized through in-built validation and completion checks in the Registry database to minimize data entry error. These include:

- Data entry controlled by form logic and limited to feasible data.
- The use of built in edit checks to ensure data meet required formats and ranges.
- Accuracy enhanced by the use of exhaustive drop down lists providing all possible answers to minimize free text entry where applicable.
- The use of hide and show mechanisms to guide data entry to required fields.
- Use of explanatory texts to assist data entry.
- Validation rules applied at the time of submission with alerts to assist with errors and missing data.
- The use of a participant management system to list incomplete data and other actions required.

Additional quality checks post data entry includes checks for:

- Duplicate data
- Missing data
- Data consistency

Data quality and completeness are checked at a number of stages of the data management process. Errors in data quality, when identified, may be referred back to contributing surgeons or sites for review.

Case ascertainment as well as both brief and comprehensive audit processes will be performed on site by Monash University registry staff (Australia only). Registry staff will perform regular remote audit checks to verify the accuracy of data received from surgeons. This will be done during the course of a follow-up phone call from the call centre or by registry staff directly contacting surgeons' rooms.

Completeness and accuracy of the eligible population captured by the Registry will be assessed using hospital International Classification of Disease 10-Australia Modified (ICD-10-AM) codes. This is to ensure that all eligible patients are included in the Registry, minimizing the risk of data "cherry picking" by contributing surgeons. Cross-checking with ICD-10-AM codes allows for complete data capture at each hospital site and provides data validation for each procedure submitted by the surgeon. These data are provided at regular intervals by the administering organising and will only contain data of contributing surgeons.

In Australia, it is intended that the BSR will periodically link to other repositories, or datasets, of health information which can validate registry data. This is to verify critical quality data such as patient mortality, defined adverse events and other outcome measures are completely captured, minimising the risk of surgeons selectively choosing whom they enter on the BSR. Requests to link New Zealand BSR data to national data sets will be considered by the Steering Committee on a case by case basis. For data linkages in Australia and New Zealand, the necessary approvals from an HREC/HDEC will be sought when required. Examples of repositories, their role in data validation, and what information will be collected and disclosed by the Registry are described in Table 4.

Table 4: Examples of Repositories of Health Information and the Information to be Collected and Disclosed

Repository	Owner	Data Validation Description	Data Collected by BSR	Data Disclosed by BSR
ICD-10-AM Extract	Each Hospital	Ascertain cases that are coded to the set of bariatric codes to determine if reported to BSR or omitted	Patient name, address, DOB, Medicare number, treating surgeon, length of hospital stay, procedure codes	Patient name and date of birth
Births Deaths & Marriages (Australia)	Each State Jurisdiction	Ascertain death of bariatric patient/registry participant to ensure it is recorded and that no further attempts to collect follow up are made *subject to application*	Name, address and Date of Birth, Date of death, Cause of death	Patient name and date of birth
Private Health Insurers' Datasets Current: Latrobe Health Sevice Future: TBA via amendment	Private Insurers	Ascertain if registry participants have returned to hospital (defined adverse event), been admitted to ICU and/ or if they have had a procedure (includes procedures not in the bariatric code set but revision procedures for stapling procedures e.g. stents, lavage, etc.	Patient name, address, DOB, Medicare number, treating surgeon, length of hospital stay, procedure codes, hospital re-admissions	None
Coronial Court Findings (Australia)	Each State Jurisdiction	Ascertain the likelihood that death was related to bariatric procedure *subject to application and ethics committee approval*	Name, address and Date of Birth, Date of death, Cause of death	Patient name and date of birth
National Coronial Information System (NCIS)	Commonwealth of Australia	Ascertain the likelihood that death was related to bariatric procedure *subject to application and ethics committee approval*	Name, address and Date of Birth, Date of death, Cause of death	Participant name, dates of birth and death
National Death Index	Commonwealth of Australia	Ascertain the likelihood that death was related to bariatric procedure *subject to application and ethics committee approval*	Name, address and Date of Birth, Date of death, Cause of death	Participant name, dates of birth and death
New Zealand Collections	New Zealand Ministry of Health	National collections including Mortality Collection that can be linked using NHI, *subject to application*	Patient name, address, DOB, Medicare number, treating surgeon, length of hospital stay, procedure codes, hospital re-admissions, cause of death	Participant name, date of birth and death

Admission and episodic datasets for each State or Territory: ACT: Admitted Patient Care Collection, NT: In-Patient Activity, NSW: Admitted Patient Data Collection, QLD: Hospital Admitted Patient Data Collection, SA: Integrated South Australia Activity Data Collection, TAS: Public Hospital Admitted Patient Collection, VIC: Victoria Admitted Episodes Dataset WA: Hospital Morbidity Data Collection	Each Jurisdiction	Ascertain if registry participants have returned to hospital (defined adverse event) and/ or if they have had a procedure (includes procedures not in the bariatric code set but revision procedures for stapling procedures e.g. stents, lavage, etc.) *subject to application and ethics committee approval*	Patient name, address, DOB, Medicare number, treating surgeon, length of hospital stay, procedure codes, hospital re-admissions	None

5.3.4 Data Confidentiality

Registry data will be stored according to values and principles of the NHMRC National Statement Guidelines and Australian Privacy Principles, the Privacy Act 1993 (New Zealand), the Health Information Privacy Code 1994 and New Zealand's Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities (2012). Only the researchers and those employed by Monash and UniServices for the purpose of the project, such as registry epidemiologists, data custodian, clinicians involved with the research, research assistants and data managers will have access to the data and such access shall be limited to the extent required to perform their employment duties.

Any researchers or registry staff involved with data monitoring, analysis or reporting will undertake training by Monash University to ensure that they understand their obligations in regard to data confidentiality and privacy relating to research activities. The researchers and staff will be required to complete a Confidentiality Agreement. Each registry database user has their own username and password to access the database.

For the purpose of monitoring and/or audit to determine case ascertainment, accuracy, and completion of data, authorised registry staff will liaise with surgeons and sites to organise access to patient records.

5.35 Data Security

Prior to conversion to electronic files by Registry staff, forms completed in hard copy will be stored securely in a locked filing cabinet, behind locked and swipe card-only accessible doors. Other electronic files will be stored on the Monash University secure shared drive which is password protected.

The BSR-*i* database is held electronically and stored securely within the Clinical Data Management Unit, Monash University at Melbourne Australia, where other confidential registries are stored and maintained.

All communication between the users' browsers and the server (BSR-*i*) occurs on a secure channel, commonly referred to as Secure Sockets Layer (SSL). SSL ensures that all data is encrypted by a private key on the server before being sent to the user where it is decrypted by a public key. This ensures the data are not compromised in transit.

All users of the BSR-*i* access the system through a login screen with a pre-figured username and password controlled by administrators of the system.

The Registry database is routinely backed up and encrypted (according to ISO27001 level of accredited standards) in the event of unauthorised data access.

Disposal of any information will be in accordance with the *National Statement on Ethical Conduct in Research Involving Humans 2007* (2015) and New Zealand's *Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities* (2012). Archived information will be stored indefinitely in a secure location.

6 Ethical Considerations

The BSR adheres to the NHMRC *National Statement on Ethical Conduct in Human Research 2007* (2015), the *Privacy Act of 1988* (2014), the Australian Privacy Principles as set out in the Act, the NHMRC *Guidelines Approved under Section 95A of the Privacy Act 1988* (2014), the *Privacy Act 1993* (New Zealand), the *Health Information Privacy Code* 1994 and New Zealand's *Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities (2012)*.

Registry participants will be followed longitudinally, therefore, identifying information is required. As previously discussed, the Australian Privacy Act 1988 and the Health Information Privacy Code 1994 require any this activity be approved by a constituted ethics committee. Ethical review submissions are therefore prepared for all new sites.

The initial HREC for the Registry's pilot, The Alfred Hospital Human Research Ethics Committee (Australia), did not approve of surgeons seeking prior consent for their patients' participation in the Registry as it could be seen to put undue pressure on patients to participate due to the power imbalance. To avoid the perception that the patients' decision to participate may influence the care they receive or adversely affect the surgeon-patient relationship, it was advised that the BSR take responsibility for the opt out approach. With the approach described in **Section 5.2.1**, the BSR can systematically record and control the mailing of PFS as well as maintain the log of those who decline to participate.

As noted in **Section 5.2.1**, this process carries a risk as the BSR holds data without consent for a period of time whilst the opt out approach is being undertaken, and also in the event of discharge coding revealing a patient that a surgeon has omitted to enter into the BSR. This risk is somewhat mitigated by the provision of information about the BSR to the patient by the participating surgeon, display of BSR posters in the surgical rooms and a patient information flyer provided by the surgeon to the patient. Monash Office of General Council, 40 ethics committees in Australia, and New Zealand's Health and Disabilities Ethics Committee have considered this to be an adequate process and a waiver of consent is provided to allow for the opt out approach to occur.

Data from New Zealand will be held at Monash University in Melbourne Australia. The BSR has been granted Acceptance Status from the New Zealand Ministry of Health for New Zealand personal health information to be stored at Monash**.**

As many bariatric patients have revision bariatric surgical procedures which may be subsequently reported to the Registry through hospital ICD-10-AM reports or by a second surgeon, some identifiable information of patients who opt out will be retained by the Registry in a "Do Not Contact" file so as not to contact them again. [See Note **section 5.2.1**]. No data from patients who have declined to participate will be included in any data analysis or reporting as their clinical information will be securely destroyed.

No identifiable information will be shared nor will personal information about participants be disclosed in any publication or report.

7 Participant Risk Management and Safety

The BSR is an observational study collecting data at the time of procedure or from medical records and is unlikely to result in any harm to participants. Participants who are contacted by telephone for follow-up information may experience minimal discomfort answering personal questions related to their weight, health and medical procedures. BSR Call Centre staff are trained to follow Call Centre Protocol for managing such patients to minimise potential harm.

8 Reporting

The BSR uses regular reports to deliver data that is valuable to key stakeholders. There are a range of reports as described below.

All data related to participant information are presented in aggregate and are non-identifiable to protect patient privacy. Data related to individual surgeons are also presented in reports in aggregate and non-identifiable. Contributing hospitals are listed, but data related to the procedures and outcomes at those sites are not reported publicly or to other parties without their consent. The only exception to this rule is in the situation of an outlying surgeon, device, hospital or procedure being identified. In this situation some identifiable information may need to be provided to investigative bodies. These investigative bodies will be required to sign confidentiality agreements unless covered by relevant legislation.

8.1 Publicly Available Reports

As required by the 2008 ACSQHC Operating Principles, the BSR produces regular publicly available reports. **Annual reports** comprehensively review the data held on the BSR database, analysing the safety and quality of bariatric surgical procedures and the effect of on participants' clinical outcomes (diabetes management, total and excess weight loss maintained following surgery). These aggregate reports are available on the BSR website and are sent directly to contributing surgeons, hospital executives, hospital group executives, HRECs/HDEC, state and federal health departments, medical device manufacturers, third party private insurers and other professional organisations with a vested interest in the outcomes of bariatric surgery. **A semi-annual brief update** is also made available by the same channels.

Annual reports are published as at June 30 each year and are released in the September of each year. The semi-annual update is published as at 31 December each year and is released in the following March.

8.2 Individual Reports

Contributing surgeons receive benchmarked reports once they have submitted sufficient data to the Registry to allow for comparison. These reports compare the non-identifiable data for that surgeon against the Registry as a whole and includes information on their case mix, demographics of their participating patients, follow-up rates and the safety and clinical outcomes. These are published as at 30 September each year and are individually released to each of the surgeons in the following December.

Other key BSR stakeholders including hospital groups and device manufacturers receive benchmarked annual reports. All information presented in their reports is based on aggregate data and no identifying patient or surgeon information is disclosed.

Progress reports for the BSR are also prepared and delivered annually for each contributing hospital and the HREC/HDEC which gave approval for the hospital to partake in the project. These reports generally detail participant recruitment and withdrawal figures and disclose serious adverse events and mortality figures.

According to the Registry's Outlier Policy, identifiable information is only released to the concerned parties upon the identification of an outlier by the Steering Committee of the Bariatric Surgery Registry. The Outlier Policy is in line with the recommendations of the Australian Commission for Quality and Safety in Healthcare in their Framework for Australian Clinical Quality Registries. If identifiable information is provided, involved parties will need to sign confidentiality agreements unless covered by relevant legislation.

8.3 Monitoring of Outcomes

Non-identifiable data for both Australia and New Zealand will be provided to an independent biostatistician employed by the Monash University, Department of Epidemiology and Preventive Medicine by secure file transfer for review on at least a six monthly basis. Participants, hospitals and surgeons will not be identified in this dataset.

The results will be provided to the Monash Project Manager. Only non-clinical registry staff will have access to identifiable data. All data to be used in reports or publications are to be cleaned and verified prior to analysis. Routine, re-analysis of data will be undertaken by the Project Manager of the BSR to ensure findings are reproducible.

The Steering Committee has an "early warning model" that provides the opportunity to review the factors contributing to an outlier designation, according to the Outlier Policy, with all stakeholders including surgeons, device manufacturers and hospitals. The BSR will provide information that should minimise patient harm should a device, procedure, surgeon or hospital prove to be deficient. The BSR could also be a useful tool in contacting participants should a device recall ever be necessary.

When potential outliers are found, the Steering Committee will follow a detailed process to review data entry, continue to monitor outcomes and communicate with the parties involved (see Table 5. *Summary of Potential Outlier Process*).

The BSR will compare a surgeon's/ hospital's/ device's performance against all other surgeons, hospitals or devices in the same class after risk adjustment has occurred. Safety Performance Measures include:

- Perioperative unplanned readmission to hospital;
- Perioperative unplanned ICU admission;
- Perioperative unplanned return to theatre;
- Prolonged hospital stay;
- Need for reoperation amongst primary participants; and
- Mortality if likely to be related to bariatric surgery

If the value of a performance indicator is more than a specified number of standard deviations (SD) from the expected performance level, over a specified period of time, it will be considered an outlier. For instance, those surgeons or hospital who fall 2 SDs from the expected level of performance will be considered as a level 1 ‘alert’. If in two subsequent reporting periods the surgeon or hospital continues at 2 SD from the expected level of performance, they will progress to a level 2 ‘alert’.

Table 5 indicates the three stages that are to be followed in managing a potential outlier, the actions that need to be taken, the people involved and the maximum time scales. It aims to be feasible and fair to providers identified as potential outliers and sufficiently rapid so as not to unduly delay the publication of comparative information.

Table 5. Summary of Potential Outlier Process

	Definition	Action by BSR	Expected Outcome	Reporting
Level 1 Alert	Two standard deviations below the mean; OR Statistically significant deterioration in outcomes between reporting period (annual reports)	Surgeon, device or hospital flagged as level 1 alert will not be subject to the review process. This is because this size of difference from the national average may occur simply from random variation alone.		To support regular local review of data submissions and clinical practice, the BSR will notify surgeons of their "alert" status.
Level 2 Alert	Three standard deviations below the mean; OR Two reporting period at two standard deviations below the mean, OR If a patient dies during or as a consequence of the bariatric surgical procedure.	Data will be checked for major errors e.g. validate against hospital records and devices, ensure data entry are correct. Data checked for accuracy, major shift (case-mix) and other potential confounders. Assess whether there are case-mix factors peculiar to this situation that may explain the observed variations. Check with the surgeon or hospital whether the submitted data is correct. If not, request correct data.	<u>No case to answer:</u> Submitted data in BSR revised, updated results show provider is not an outlier <u>Case to answer:</u> data in BSR records revisited, reanalysis shows potential outlier status persists	The surgeon and the hospital where he/she is practicing should be notified of the finding. Support will be offered to surgeons. If a device is raises a level 2 alert, the device manufacturer should be notified of the finding.

	Definition	Action by BSR	Expected Outcome	Reporting
Level 3 Alert	Two reporting periods at three standard deviations below the mean OR continued performance at two standard deviations below the mean despite corrective measures	Chair of steering committee convenes investigation committee. New data checked and old data re-checked for accuracy, major shift (case-mix) and other potential confounders.	No case to answer: Submitted data in BSR revised, updated results show provider is not an outlier Case to answer: Appropriate pathway decided by Investigation Committee including reporting to appropriate body	If performance is persistently at the level 3 stage and the Investigation Committee is satisfied with the validity of the data, reporting to the appropriate regulatory body by the Chair of the Steering Committee will be mandated. For example – • A device will be notified to the Therapeutic Goods Authority (TGA) (Australia) or Medsafe (New Zealand) • A surgeon will be reported to the Royal Australasian College of Surgeons (RACS) (Australia). • A surgeon will be reported to the relevant Head of Department for investigation then, if deemed necessary will be reported to the General Medical Council (New Zealand). • A hospital will be reported to The Department of Health or the regulator in each state.

8.4 Data Access for Research and Non-Research Purposes

Ad-hoc reports may be prepared following data requests approved in accordance with the Bariatric Surgery Registry Data Access Policy. Where a request for data for research purposes utilizes only non-identifiable existing registry data, ethics approval for the project may be sought from a single HREC/HDEC.

9 Registry Organisation

The Bariatric Surgery Registry is a multi-centred, investigator driven endeavour. Each site will have a local Principal Investigator (PI) who will be responsible for ensuring that research activities undertaken at their site are conducted in accordance with the Registry protocol, site registry agreements and related policy documentation. Site registry activities include recruitment of participants and data submission and will be conducted at contributing hospitals by site staff and overseen by the PI at each site. To contribute the BSR, all surgeons will must enlist their willingness to participate and sign an agreement with Monash outlining the responsibilities of the surgeon.

Each Australian hospital site will obtain ethics approval from their nominated HREC and grant governance for the Registry project. A Memoranda of Understanding (MOUs) will be executed between the site or private hospital group outlining the roles and responsibilities of the respective site or hospital group, and Monash. The MoU will also document the agreement of the relevant site to make the necessary resources and reports available for the BSR. Data will only be collected from hospital sites once these necessary steps are taken.

In New Zealand, Memoranda of Understanding (MOUs) will be executed between each approved site and UniServices outlining the roles and responsibilities of the respective site, surgeon(s), Monash and UniServices. The MoU will also document the agreement of the relevant site to make the necessary resources and reports available for the BSR. Ethical and governance approval, including locality, will be obtained prior to the collection of data at any hospital site where bariatric surgical procedures are performed.

Monash University (School of Public Health and Preventive Medicine) is the data custodian. Custodianship responsibilities of Monash University entails accountability for the information held within the Registry. Day to day project management will also be undertaken by Monash University. While Monash Registry staff will oversee all project related activities, contributing surgeons and hospitals will ultimately be responsible for ensuring timely and accurate data collection (where central data collection is not used). This will be supervised by the Data Manager and Project Manager at Monash who will report and provide feedback on data completion and quality to sites and the Bariatric Surgery Registry Steering Committee, the governing body of the BSR.

Support for the free call number for New Zealand will be provided by trained staff located at the National Institute for Health Innovation, UniServices in conjunction with Monash University. UniServices will also provide support with implementations of MoUs with new sites and the on boarding and training of surgeons. Monash retains overall responsibility for project

management of the BSR in New Zealand and for ensuring that the Protocol is updated and ethical approvals are maintained for the duration of the study.

9.1 Registry Governance

The governance structure will be in keeping with the operating principles established by the ACSQHC and the Terms of Reference for the Steering Committee are written with this in mind. The BSR Steering Committee will oversee the governance of the BSR, provide strategic direction and ensure the agreed outcomes of the Registry are achieved. The committee will meet at least 4 times a year.

The BSR has engaged key stakeholders as members of a broad based Steering Committee. Membership currently representation from the bariatric surgical profession (through OSSANZ), the broader surgical profession (through RACS and ANZGOSA), Monash University (as custodians), the Commonwealth (as major funders and key users of bariatric surgery services), the medical technology industry (as providers of devices used in bariatric procedures) and a community advocate. The Chair is an independent obesity expert who is not a surgeon to maintain impartiality across the Registry's processes. A Clinical Lead is nominated by the Steering Committee.

The Steering Committee is to:

- Provide oversight of the Registry including the Executive Management Committee (EMC).
- Provide ongoing review of the objectives of the Registry and its effectiveness in meeting them.
- Establish policies to address issues of clinical interest or significance that may arise.
- Facilitate policy support for issues identified by the Executive Management Committee.
- Provide advice on the Registry's management, organisation, scope, development and funding.
- Monitor the Registry's data quality management processes and timeliness of reporting.
- Develop and monitor policies for access to data and responses to quality of care issues identified.
- Review and advise on outputs from the Registry.
- Review all research and data requests for identifiable data.
- Review publications arising from the Registry.
- Review and advise on communication strategies, including communication with the media and consumers.

9.2 Funding

Sufficient Commonwealth funding up to $1,000,000 per year for the period May 2013-May 2018 has been secured to support Australian implementation, quality control, data collection and reporting.

A broad-based funding model engaging other stakeholders (including the profession, insurers, medical technology industry, federal, state and territory governments and medical defense organisations) is being developed to secure at least 20 stakeholders as funders, each contributing initially $20,000 per annum then increasing to $50,000 per annum towards the Registry when the Commonwealth funding ceases.

Funding for the New Zealand launch of the Registry has been provided by the medical technology industry and further funding will be sought from additional sources to support the on-going maintenance.

9.3 Quality Assurance

As part of the funding agreement with the Commonwealth Government, BSR management will undertake quality assurance activities with its stakeholders including patients, surgeons, hospitals, medical technology industry, health services and the Jurisdictions. These activities may be undertaken as on-line surveys, focus groups, forums, or other related self-audit endeavours designed to gain understanding of the service the Registry provides.

10 Significance

Establishing a bariatric surgery clinical quality registry will allow for community wide comparisons of the safety of care provided by procedures, devices, surgeons and hospitals. This provides surety for patients, surgeons and payers that the delivered services are of the highest quality. Importantly, they also provide the opportunity for early recognition of a problem device, procedure, surgeon or hospital, allowing for rapid intervention to prevent patient harm. In New Zealand, the BSR has the potential to identify ethnic disparities for Pacific and Māori and can support improving quality outcomes for these groups. In the future, it is hoped that these data will enable the development of guidelines for bariatric surgical procedures leading to improved outcomes for all patients.

The BSR will provide the only longitudinal, long term community data on the outcomes of bariatric surgery including weight loss, change in diabetes and need for reoperation. At an individual level, these data will give patients a more accurate view of what to expect from a bariatric procedure, and will enable more valid informed consent for surgery. At a community level, these data will allow for the assessment of the economic and societal benefits that bariatric surgery potentially holds when offered as a treatment for obesity.

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The latest approved versions of the following documents will be provided to each site

- BSR Poster
- BSR Flyer
- Participant Fact Sheets
- Data Forms (Australian sites only)
- Call Centre Protocol
- Outlier Policy
- Data Access Policy
- Data Dictionary
- Steering Committee Terms of Reference