

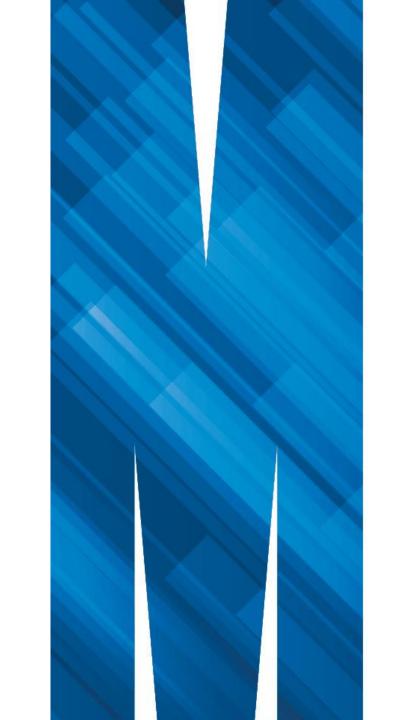


Bariatric Surgery Registry WORKSHOP

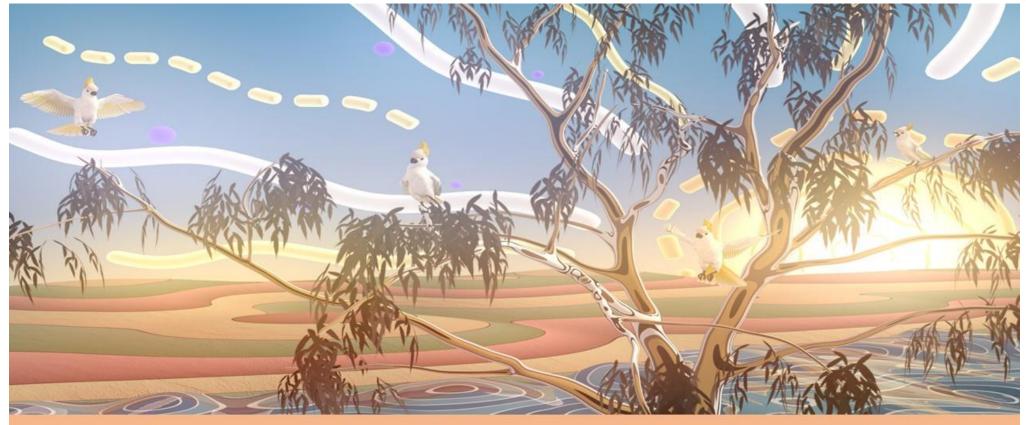
5th September 2024 IFSO 2024 Conference, Melbourne







Acknowledgement of Country



We acknowledge the **Boonwurrung** and the **Wurrundjeri clans** of the **Kulin Nation** who are the custodians of the land and waters, and pay our respects to Elders past and present.



WORKSHOP PROGRAM

Topic	Presenter
1. Welcome & Registry overview	Prof Wendy Brown
2. Latest outcome data from 2023 Annual Report	Prof Wendy Brown
3. Operational update	Rachana Pattali
4. IT projects update	James Wetter
5. Research and future directions	Wendy Brown





1. Registry Overview

Prof Wendy Brown







Registry Timeline





2007

BUNKER BAY OSSANZ MEETING 2009

Georganas
Senate
Review
recommends
establishment
of Bariatric
Surgery
Registry

2010

Monash University appointed custodian 2012

BSR pilot
begins Aus

2014

BSR Australian roll out begins 2018

BSR Aotearoa New Zealand roll out begins 2020

BSR enrols 100,000th patient 2023

BSR enrols 150,000th patient

2024

180,000+ procedures PROMs pilot tested







CLINICAL QUALITY (AND SAFETY) REGISTRY

- Clinical Quality (& Safety) Registry
- Bi-national Australia and Aotearoa New Zealand
- Governed by overarching Steering Committee

AIMS

- Monitor immediate safety of bariatric surgery
- Longitudinal safety and efficacy of bariatric surgery
 - Assessing procedures, devices, complications & adverse events
 - Track key health changes incl: Weight loss/BMI, diabetes management
- Report accurate population level data to inform health practices and policy
- Asset/platform for further research into bariatric surgery as a safe and effective treatment of obesity
- Allow better economic analysis of benefits of bariatric surgery





Annual

outcome

data

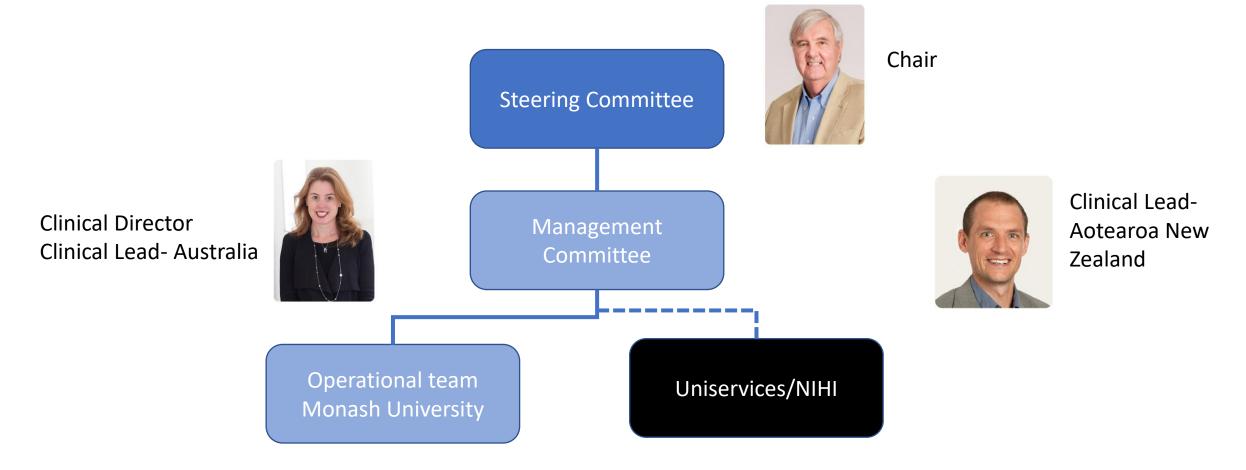
Mortality



 Diabetes status and treatment



GOVERNANCE







PARTICIPATION

Is voluntary

Hospitals Involved

Surgeons Participating



18 in Aotearoa New Zealand



193 in Australia

19 in Aotearoa New Zealand

DATA COLLECTED

- Day of surgery data- procedure, patient characteristics
- 90-day outcome data (Peri-operative data)
- Annual outcome data (Follow-up)
- Patient-reported outcome data future







Clinical Quality (& Safety) Indicators

	Clinical Quality Indicator	Interval of interest
	MortalityFact and date of deathCause of death	90-day outcome and long-term Surgery – 10 yrs post-op
QUALITY/SAFETY	 Defined adverse events Unplanned readmission Unplanned ICU admission Unplanned return to theatre Prolonged length of stay 	90-day outcome
	Re-operation rate	Long-term: 1-10 yrs post-op
EFFICACY	Weight loss% Total weight loss% Excess weight loss	Long-term: 1-10 yrs post-op
	Change presence of diabetes	Long-term: 1-10 yrs post-op
	Change in diabetes management	Long-term: 1-10 yrs post-op





REPORTING

- Annual Report
 - Full Report
 - Summary Report
 - Summary Report Poster
- Individual Surgeon Reports
- Hospital Reports
- Ad Hoc Reports



Bariatric Surgery Registry 2023 Annual Report

> BARIATRIC SURGERY REGISTRY

RISK-ADJUSTED BENCHMARKED ANALYSIS

- Updated risk-model for primary surgeries
- 6-monthly analysis and outlier review
- Future state: risk-adjusted funnel plots for safety indicators in deidentified public reports grouped by hospital





2. Latest outcome data from 2023 Annual Report

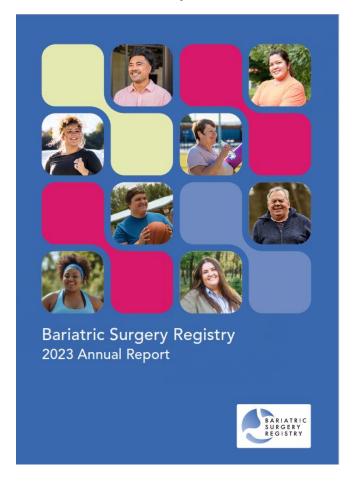
Prof Wendy Brown



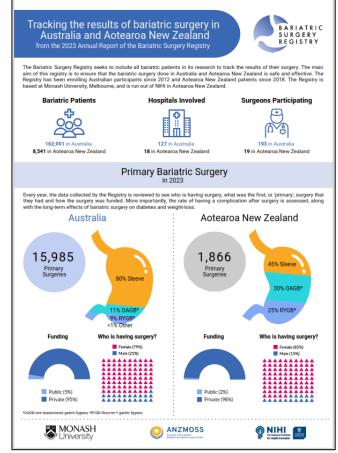


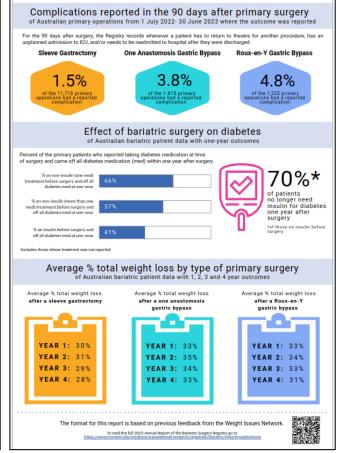
2023 Annual Report

2023 Annual Report



2023 Summary Report



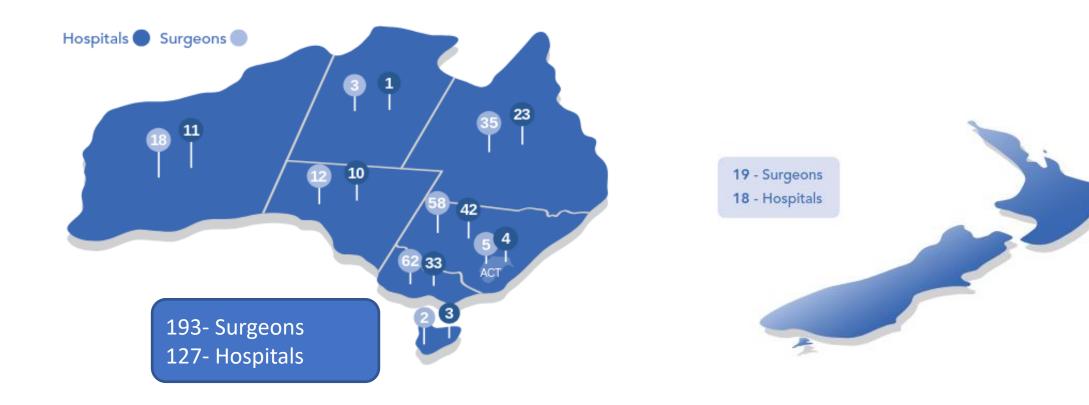






2023 Annual Report

Contributing hospitals and surgeons for 2023 procedures







Australia

Participation over time

- 127 Hospitals
- 193 Surgeons

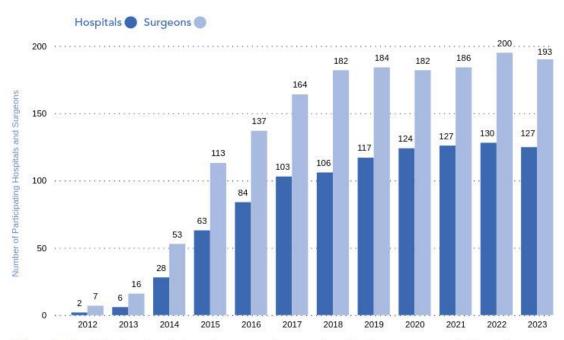


Figure 2 - Participating hospitals and surgeons by year since Registry commenced, Australia

AUSTRALIA

Enrolment over time

- 162,991 participants
- 2.0% opt-out rate

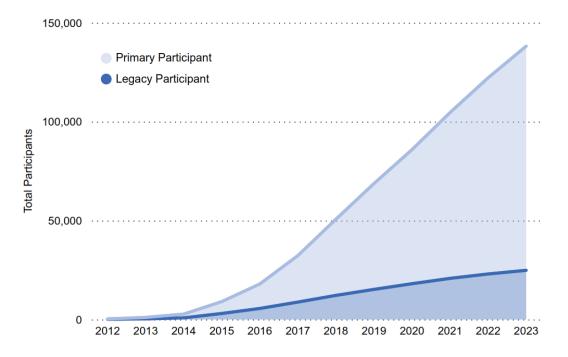


Figure 3 - Cumulative enrolment by participant type, Australia





Aotearoa New Zealand

Participation

- 18 Hospitals
- 19 Surgeons

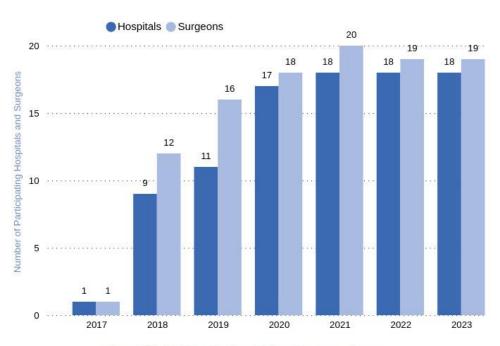
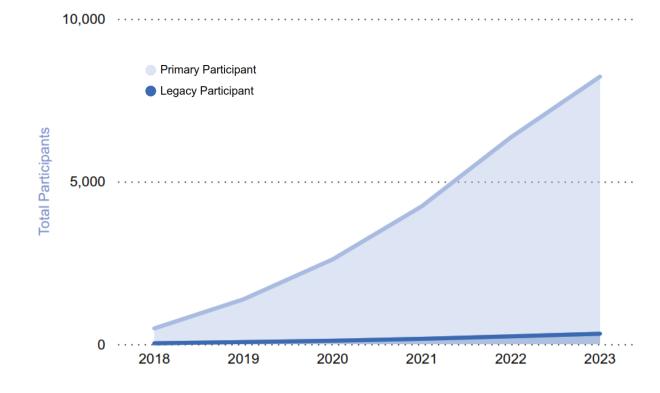


Figure 27 - Participating hospitals and surgeons by year since Registry commenced, Aotearoa New Zealand



Enrolment over time

- 8,538 participants
- 1.1% opt-out rate



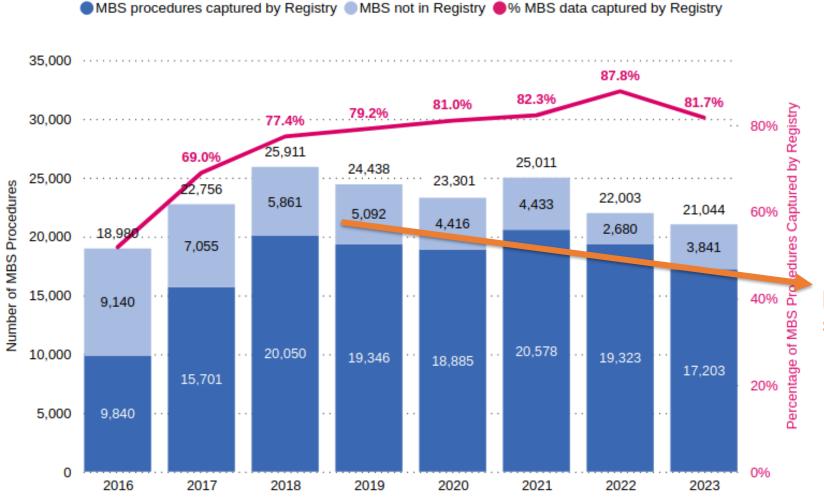




Procedure capture - Australia



81.7% for 2023



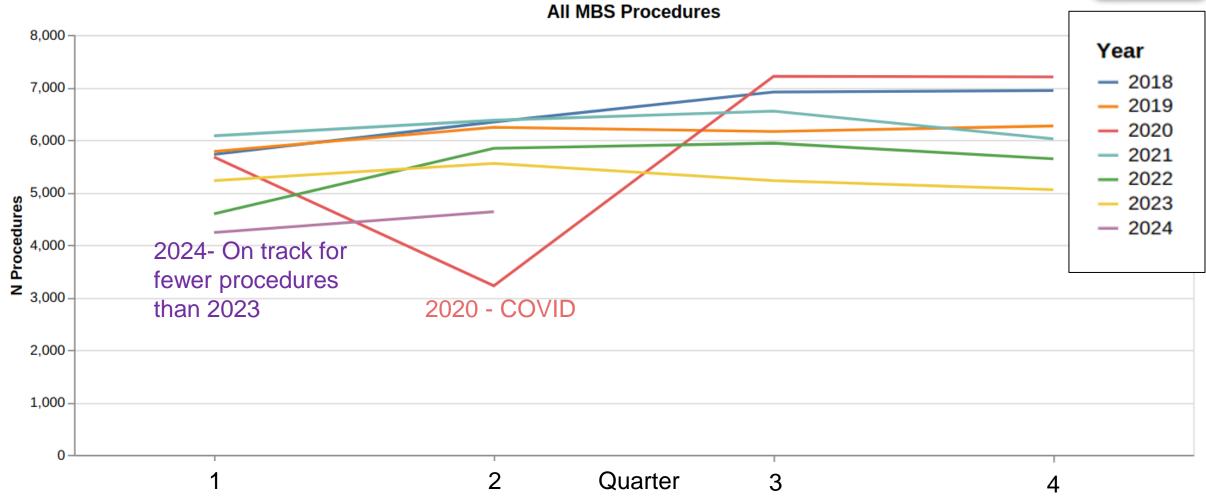
Reduction in procedures since 2018





Declining Procedures

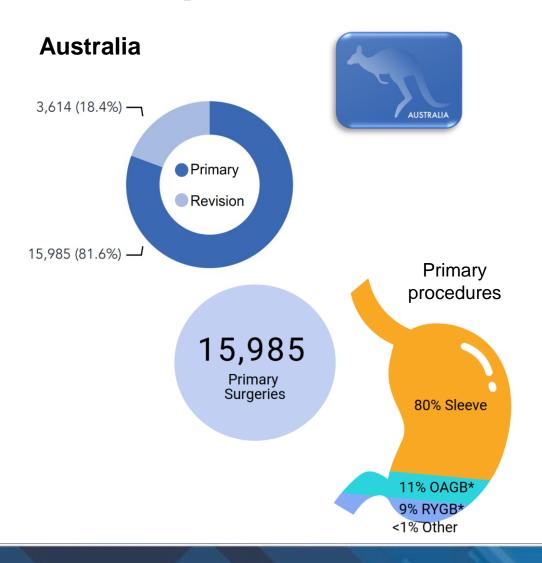


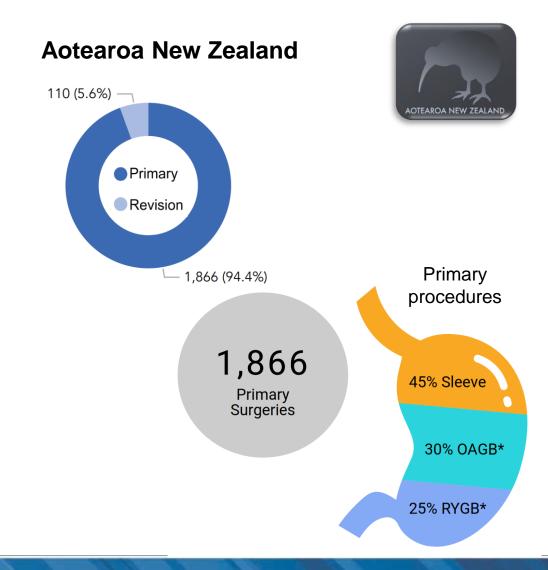






2023 procedures



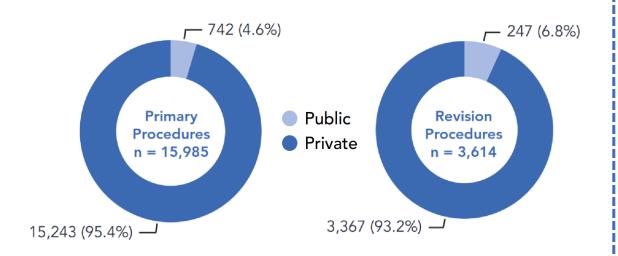




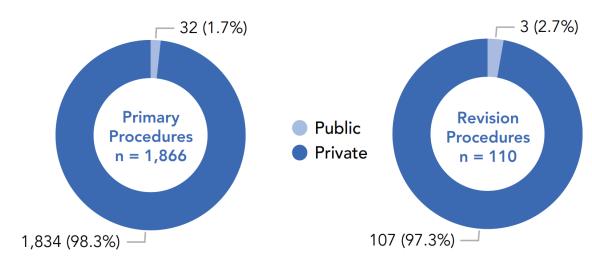


2023 procedure funding













2023 Participant Characteristics

Who had primary bariatric surgery in 2023

	Australia	Aotearoa New Zealand
Female – n (%)	12,643 (79.1%)	1,851 (84.7%)
Age -mean (SD)	41.8 (11.2)	44.2 (11.1)
 BMI Classification* – n (%) Overweight Obese class I Obese class II Obese class II 	57 (0.4) 1,516 (9.5) 4,532 (28.4) 9,616 (60.2)	2 (1.0) 154 (8.3) 399 (21.5) 1304 (70.1)
 Unknown 	257 (1.6)	2 (<0.1)
Diabetes at surgery – n (%)YesNoNot stated	1,633 (10.2%) 13,934 (87.2) 418 (2.6)	243 (13.0) 1,611 (86.3) 12 (0.6)

^{*}Less than 18 years at surgery excluded n=7





90-day (perioperative) outcomes

Primary procedures with any defined adverse event



Sleeve Gastrectomy



One Anastomosis Gastric Bypass

3.8%

of the 1.615 primary operations had a reported complication

Roux-en-Y Gastric Bypass

4.8%
of the 1,223 primary operations had a reported complication



Sleeve Gastrectomy

2.8%
of the 888 primary operations had a reported complication

One Anastomosis Gastric Bypass

3.6%
of the 590 primary
operations had a reported
complication

Roux-en-Y Gastric Bypass

2.9%
of the 452 primary
operations had a reported
complication





Outcomes-Australia

Diabetes and weight



Diabetes treatment at one year



70%*

of patients no longer need insulin for diabetes one year after surgery

*of those on insulin before surgery

Average % total weight loss after a sleeve gastrectomy



Weight outcomes

Average % total weight loss after a one anastomosis gastric bypass



Average % total weight loss after a Roux-en-Y gastric bypass

```
YEAR 1: 33%
YEAR 2: 34%
YEAR 3: 33%
YEAR 4: 31%
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Outcomes- Aotearoa New Zealand

Diabetes and weight



Diabetes treatment at one year



70%*

of patients no longer need insulin for diabetes one year after surgery

*of those on insulin before surgery

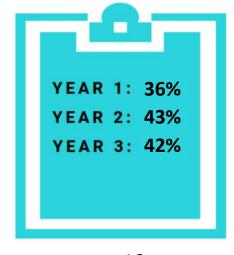
Average % total weight loss after a sleeve gastrectomy



n=295

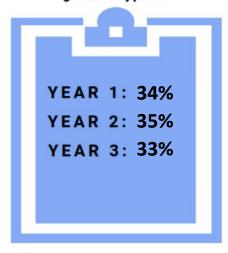
Weight outcomes

Average % total weight loss after a one anastomosis gastric bypass



n=12

Average % total weight loss after a Roux-en-Y gastric bypass



n=73

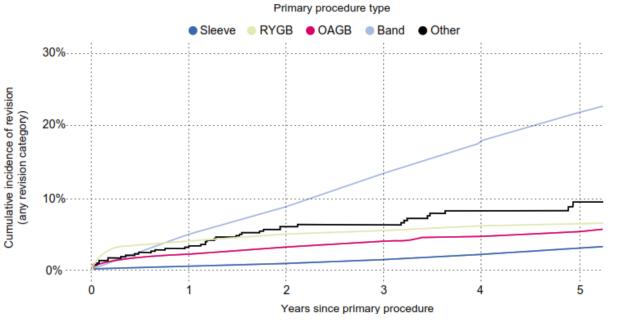


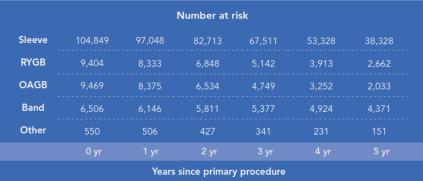


Subsequent procedures- Australia

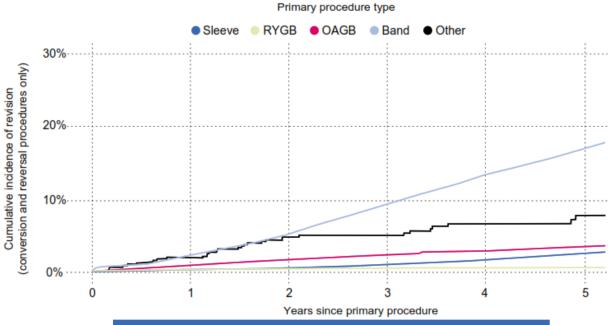
Cumulative incidence of revision

(all subsequent procs)





Cumulative incidence of revision (conversion and reversal procs only)



		1	Number at r	isk			
Sleeve	104849	97,612	83,260	68,019	53,783	38,705	
RYGB	9404	8,688	7,218	5,481	4,202	2,901	
OAGB	9496	8,507	6,656	4,841	3,332	2,081	
Band	6506	6,331	6,057	5,649	5,204	4,652	
Other	550	515	433	346	237	155	
	0 yr	1 yr	2 yr	3 yr	4 yr	5 yr	
		Years	since primary	procedure			



ASIrsity

3. Operational update

Rachana Pattali





Little bit about myself

Joined BSR as Operations Manager in April this year

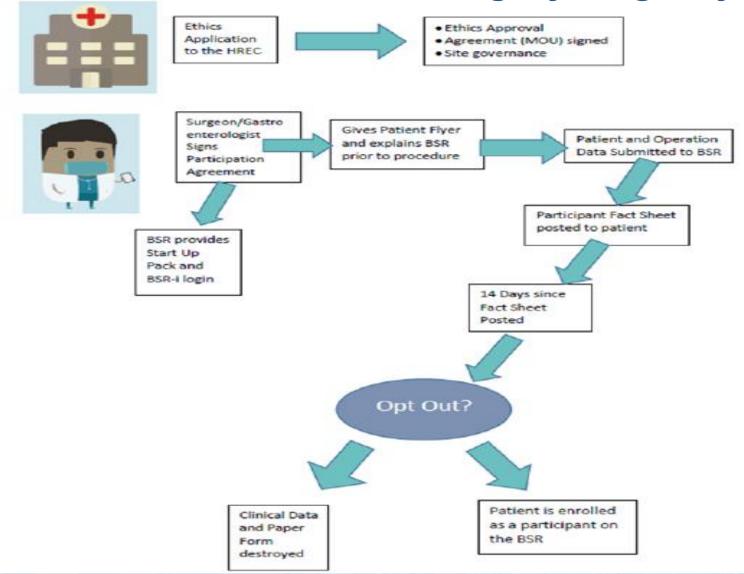
Previous roles were:

Pharmacist by background Managed Women's Mental Health Clinic at Alfred Health Team Leader at Epworth Richmond





Recruitment for the Bariatric Surgery Registry







Operational policies and protocols to follow while recruiting participants

Display the BSR poster at your practice

Talk to patients about BSR

Provide patient flyers to all bariatric patients

BSR follows Opt-out approach





Display the A4 poster 'This practice is proud to be associated with the Bariatric Surgery Registry'

Medicine, Nursing and Health Sciences

This practice is proud to be associated with the Bariatric Surgery Registry.

This Registry tracks the outcomes and quality of all weight loss, or 'bariatric,' surgery performed across Australia and New Zealand. This allows us to ensure that we are providing the highest quality of care to you, our patients.

A Participant Fact Sheet will be sent to you from Monash University explaining the Registry in detail after your surgery. This will outline what you are required to do if you do NOT wish to participate.

Participation is entirely voluntary and your care at this practice will not be affected by your decision.

Please speak to your surgeon or staff at reception if you have any questions.







CRICOS seculdos Mosesh Universitati





Discuss the registry and data sharing with your patient during the consultation prior to their surgical procedure







Please provide BSR flyer 'Our practice is proud to contribute to the Bariatric Surgery Registry' to all bariatric patients



OUR PRACTICE IS PROUD TO CONTRIBUTE TO THE BARIATRIC SURGERY REGISTRY

The Bariatric Surgery Registry is a study that aims to show the safety of weight loss, or 'bariatric,' surgery in Australia and New Zealand. It also studies the effects of weight loss surgery on people's long-term health. Monash University and the University of Auckland are conducting this study.

After your operation, your surgeon, gastroenterologist, or hospital will send your personal information directly to the Registry database at Monash University. This includes your name, date of birth, information about your weight, height, diabetes status and the operation you had. Monash University will send you a letter with more details about the study. The letter is called a Participant Fact Sheet. It also explains what to do if you do not want to be in the study.

If you do not want your information provided to the Registry at this time, please let your surgeon and hospital know your decision. No letter will be sent to you if you opt out at this time. Also, you must also call the Registry's number below and say

If you opt out from this study, your health information is deleted from the database. Paper records are securely destroyed. Your name will be kept on a separate opt out list. Otherwise, you may be asked again about your operation for this study.

The Registry also collects information about any complications during the first three months after your surgery. The Registry may call you to get this information. Keeping track of your progress shows the long-term effects of weight loss surgery. The Registry will collect information after your first weight loss surgery for up to 10 years. The Registry may call you to get this information. Information about further weight loss surgery is only collected about problems in the first three months.

You can be sure that you will never be identified in any study report or presentation. Monash University securely stores all information collected for the purpose of this research. Study information will be stored indefinitely by Monash University.

Participation is voluntary. Your care will not be affected by your decision to participate or not to participate.

Call the Bariatric Surgery Registry for more information, or if you do not want to be in the study:

T: 03 9903 0725 or

Free call: 1800 998 722

W: monash.edu/medicine/ccs/research/registries/bariatric

A partnership between:









BSR Flyer V2.1 3 May 2023





Opt-Out approach



BSR follows an opt-out approach for adults

Minors will only be recruited with signed consent from a parent or guardian

Patients who receive a participant fact sheet from BSR are provided with the choice to opt out of the registry. If they decide to opt out, they should reach out to us directly either by calling 99030725 or emailing med-bsr@monash.edu





Age variations for minors in Aus vs NZ

In New Zealand, the age at which an individual can provide independent informed consent is 16 years. However, the Registry will use the age of 18 years in Australia, as the age when an individual can provide independent consent varies amongst its states and territories. This will ensure consistency amongst Australian participants. Written informed consent will be used for those considered to be 'minors' (those under the age of 16 in New Zealand and under the age of 18 in Australia).





Data Contribution to BSR

Paper- based data forms

Entering directly to BSR user interface(BSR-i)





BARIATRIC SURGERY REGISTRY Patient & Operation Form v14.2 06/2022

ID: _____ BSR use only

Complete Patient Details or Affix Sticker
Name Female Male Intersex/Indeterminate
Date of Birth
Address
Postcode
Mobile Ph
Home Ph.:
Email
Hospital UR (MRN) Number
Medicare NumberRef
Indigenous Status Tick box Neither Aboriginal or Torres Strait Islander Aboriginal Torres Strait Islander Both Aboriginal and Torres Strait Islander Unknown/Not stated
Hospital
Surgeon
Operation Date
Heightkg
Operation Weight kg
Diabetes ☐ Yes (select treatment below) or ☐ No ☐ Diet/exercise ☐ Non-insulin therapy (single) ☐ Insulin ☐ Non-insulin therapy (multiple) ☐ Insulin and Non-Insulin Therapy
Operation Details Tick box ☐ Procedure Completed ☐ Procedure Abandoned <u>State reason below</u> and <u>enter the</u> <u>details of the intended procedure</u> in next column.

Procedure Details Primary bariatric operation Revision bariatric operation or subsequent intervention What was the previous bariatric operation? What is the reason for this revision or intervention?
Indicate Procedure(s) Performed:
` ,
Sleeve gastrectomy Revision of previous sleeve
Roux-en-Y gastric bypass
One anastomosis gastric bypass
Revision of previous bypass
☐ Surgical reversal of bypass
☐ SIPS/SADI-s
☐ Bilig-pancreatic bypass/duodenal switch
☐ Addition of ring over bypass or sleeve
☐ Endoscopic sleeve gastroplasty (ESG)
☐ Gastroplasty
☐ Reversal of gastroplasty
☐ Gastric imbrication ☐ Plus band (j-band)
☐ Laparoscopic gastric band
☐ Surgical reversal of gastric band
□ Port revision □ Removal OR □ Insertion
☐ <u>Removal</u> of ring over bypass or sleeve
☐ Sub-total gastrectomy
☐ Small bowel resection
☐ Control of bleeding
☐ Dilatation of stricture
☐ Division of adhesions
☐ Lavage/washout <u>+</u> drainage
☐ Stent ☐ Removal OR ☐ Insertion
☐ Wound debridement
☐ Incisional or ventral hernia repair
☐ Concurrent transplant ☐Liver ☐Kidney

☐ Other (specify)_

Sı	urgical Approach	Tick one
	Laparoscopic	☐ Robotic
	Open (Laparotomy)	☐ Robotic converted to Open
	Lap converted to Open	☐ Robotic converted to Lap
	Endoscopic	

Device/Staple Tracking Complete, or affix
stickers below.
Gastric Band Brand/size
☐ Access Port Alone ☐Tubing Repair Kit
☐ Fixed Gastric Ring Brand
□ Stapling □ Powered or □ Manual
☐ Echelon Endopath with GST
☐ Endo GIA Tri Staple
☐ Reinforced Endo GIA Tri Staple
☐ Aeon (Lexington Medical)
□ Sureform
☐ OTHER
Reloads Used (colour and length):
☐ Staple Line Reinforcement
Type:
☐ Overstitch Endoscopic Suturing System
Notes

Notes
☐ Translated Participant Fact Sheet required
Language:



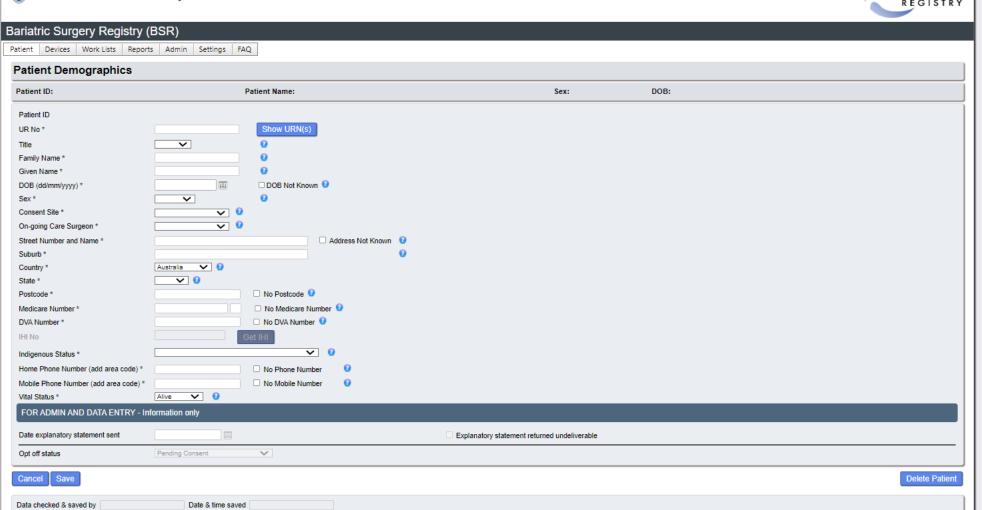
Return form in envelopes provided. If faxing, a cover sheet must be provided indicating number of forms included. Do not email forms unless encrypted. Fax: 03 9492 7253















Take away points







Talk to patients about Bariatric Surgery Registry



Provide flyers to patients



Opt out approach

Do you all think it would be a good idea to keep a record of handing out the flyers to your patients?





Questions?



Please feel free to contact me directly on 99030721 or email me rachana.pattali@monash.edu for any operational issues/needs/ training





3. IT projects update

James Wetter





Data Breaches in the News

Canva criticised after data breach exposed 139m user details

Latitude Financial cyber-attack worse than first thought with 14m customer records stolen

Optus says it will defend allegations it failed to protect confidential details of 9 million customers in cyber attack





Often Medical Data is Targeted

MediSecure reveals 12.9 million Australians had personal data stolen in cyber attack earlier this year

Why health data hacks keep happening

A cancer centre is Australia's latest cyber attack victim, with a criminal gang hoping to extort more than \$100,000.

How Medibank allegedly ignored the warning signs in one of Australia's worst cybersecurity breaches





Improving Cybersecurity for BSR-i

- The BSR houses sensitive patient data
- We care about privacy of our participants
- We are working to improve data security of the BSR-i
- The BSR-i will introduce two factor authentication in the coming months





Two Factor Authentication (2FA)

A Familiar Example

- To use an ATM two things are needed
 - o A bank card
 - o A PIN
- If a bank card is lost, it cannot be used by a thief without the PIN







Two Factor Authentication (2FA)

- Authentication (sign in) that requires two 'factors'
 - A bank card & a PIN
 - A normal password & a one time password delivered via SMS
- Why is the BSR-i adding 2FA?
 - Passwords are not invulnerable
 - A second authentication factor ensure even after a password is cracked or leaked, participant data remains safe

Number of Characters	Numbers Only	Lowercase Letters	Upper and Lowercase Letters	Numbers, Upper and Lowercase Letters	Numbers, Upper and Lowercase Letters, Symbols
4	Instantly	Instantly	3 secs	6 secs	9 secs
5	Instantly	4 secs	2 mins	6 mins	10 mins
6	Instantly	2 mins	2 hours	6 hours	12 hours
7	4 secs	50 mins	4 days	2 weeks	1 month
8	37 secs	22 hours	8 months	3 years	7 years
9	6 mins	3 weeks	33 years	161 years	479 years
10	1 hour	2 years	1k years	9k years	33k years
11	10 hours	44 years	89k years	618k years	2m years
12	4 days	1k years	4m years	38m years	164m years
13	1 month	29k years	241m years	2bn years	11bn years
14	1 year	766k years	12bn years	147bn years	805bn years
15	12 years	19m years	652bn years	9tn years	56tn years
16	119 years	517m years	33tn years	566tn years	3qd years
17	1k years	13bn years	1qd years	35qd years	276qd years
18	11k years	350bn years	91qd years	2qn years	19qn years

Source: Hive systems





Two Factor Authentication (2FA)

What is Changing in BSR-i?

- First, each BSR-i user will need to register a mobile phone number
 - You only need to do this once
- Then, for every log in:
 - Enter your username and password
 - Receive a one time password (OTP) on your mobile phone
 - o Enter the OTP to access the BSR-i



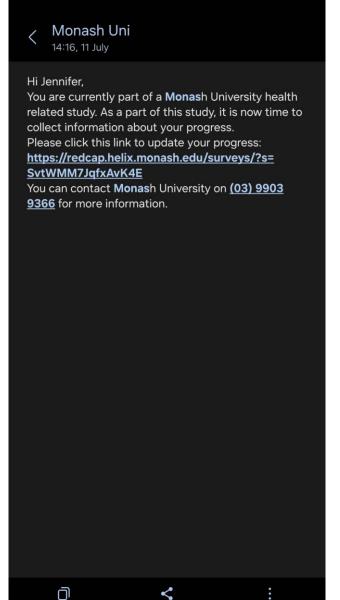


Electronic capture of patient-reported data

- The registry has been trialing a new system to collect annual follow up
- An SMS is automatically sent to a participant
- The participant is directed to an online survey
- The participant's response inserted into BSR-i







Share

More



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AAA

⊕ ⊡

Monash University Research

Dear Robin,

You are receiving this survey as you are a participant in a Monash University study. We invite you to complete a survey on your annual progress. Your participation is voluntary and no report or publication using this information will ever identify any participant.

You may remember hearing about this initiative. If you have any questions please contact Monash on (03) 9903 9366 for more information.

Thank you for considering completing this survey. We will be asking a series of questions that will help us understand your progress. This information is securely stored on Monash University servers.

To begin, please click continue and log in to the system using your date of birth.

We use your date of birth to validate your identity before confirming your contact details and collecting your information. This helps us ensure we do not share or release any data to the wrong person.

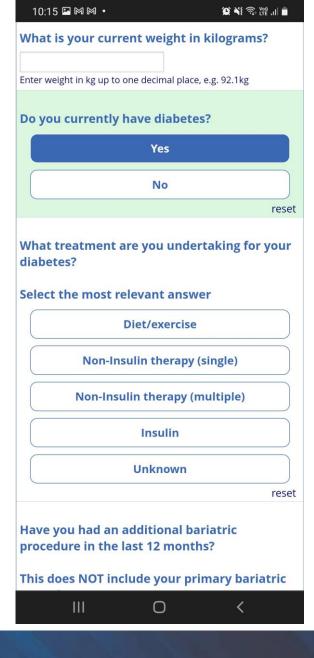
You may opt out of SMS communications after confirming your date of birth.

If you are happy to proceed, please select continue below.

If you have any concerns or suggestions about any aspect of the project, the way it is being conducted, or any questions about being a research participant in general, then you may contact us on (03) 9903 9366.

Continue

Save & Return Later



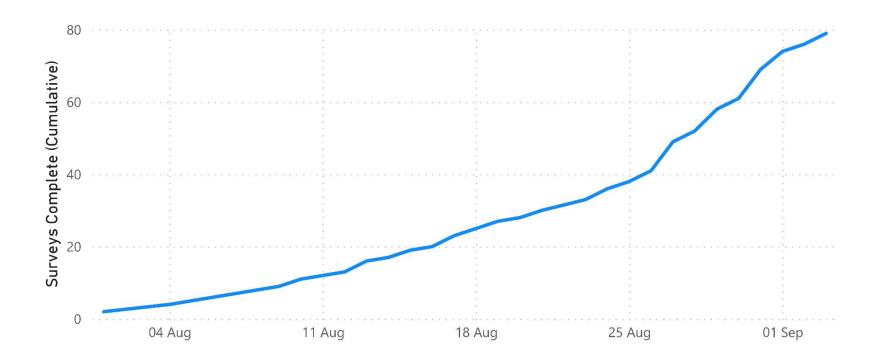


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Roll out

- This system is currently in a trial phase
- It will be rolled out to all participants in the coming months







Letting participants know

- To notify patients of the new system
- We would appreciate it if you could display a poster



UPDATE:

Introducing Text Messages for Annual Outcome Collection



WHAT TO EXPECT

The Bariatric Surgery Registry currently collects information from you every year up to 10 years after your first bariatric surgery.

You may receive an SMS with a link to report your annual outcome data. This will require your date of birth for you to complete your survey.

You may also be contacted via phone call or email.

If you receive an SMS and are unsure if its from the Registry, please get in touch with us.

Participation is entirely voluntary and your care at this practice will not be affected by your decision to complete the survey.

Monash Uni

Hi Jane,

You are currently part of a Monash University health-related study. As a part of this study, it is now time to collect information about your progress.

Please click this link to update your progress: https://redcap.helix.monash .edu/surveys/?s=PdXRqInc A6xEZhl

You can contact Monash on (03) 9903 9366 for more information

NEED MORE INFORMATION



Contact the Bariatric Surgery Reserach team if you require further information

Email: med-bsr@monash.edu Phone: 1800 998 722





5. Research and future directions

Prof Wendy Brown





Research

Projects

Project		
PROMs project (PhD)	Ms Alyssa Budin, PhD candidate Thesis under review	
Development of PROMs for the BSRMood Change after Bariatric Surgery		
Robotic Bariatric Surgery Outcomes	Dr Yit Leang, PhD candidate	

Future projects

- Analysis of revisions and outcomes
- In-registry trial/s?
- Data linkage studies?





Data sharing

 Release of data is governed by the Registry's Steering Committee, Data Access Policy and Data Custodian (Monash University),

AND needs to comply with:

- Registry ethics approvals
- Relevant legislation and guidelines
- Confidentiality and privacy are of utmost importance in considering release of data.
- Data Access Policy recently updated
- How to access data for research?
 - Contact the Registry
 - Read Data Access Policy and consult Data Dictionary (both on BSR website)
 - Submit formal data request for review by Steering Committee (where required)





Data sharing

Some key considerations in assessing requests for data

- Data Access Policy and ethics approvals
- Requestors data management plan
- Potential for (re-)identification of participants, individual surgeons and individual health services and their outcomes
- Whether a participant or surgeon would reasonably expect data to be released
- Proposed use of data research, industry request, surgeon requesting "own" data
- Quality of data requested for release
- Justification for each data item requested





Future directions

- Annual outcomes follow-up:
 - Representative sample of participants
 - o Focus on 1, 5 and 10 years post-primary procedure
- Implementation of Patient-Reported Outcomes Measures (PROMs) data collection
- Establishment of a Consumer and Community Advisory Group
- Establishment of Data and Research Sub-Committee through EOI process
- Consider grant/funding opportunities for further research and collaborative studies
- Improve digital capability of the Registry
- Update of patient-facing Registry information
- Tracking impact of Registry on clinical practice





Questions, comments, feedback



Coming Soon

Feedback survey for clinicians, clinics and their staff





Contact details

Visit us at our conference booth

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FOLLOW US ON THE PLATFORM FORMERLY KNOWN AS TWITTER

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Acknowledgements

- Registry Participants (Patients)
- Contributing Surgeons and Hospitals



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Australian Government Department of Health and Aged





Shaping the future of surgery





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Thank You...





