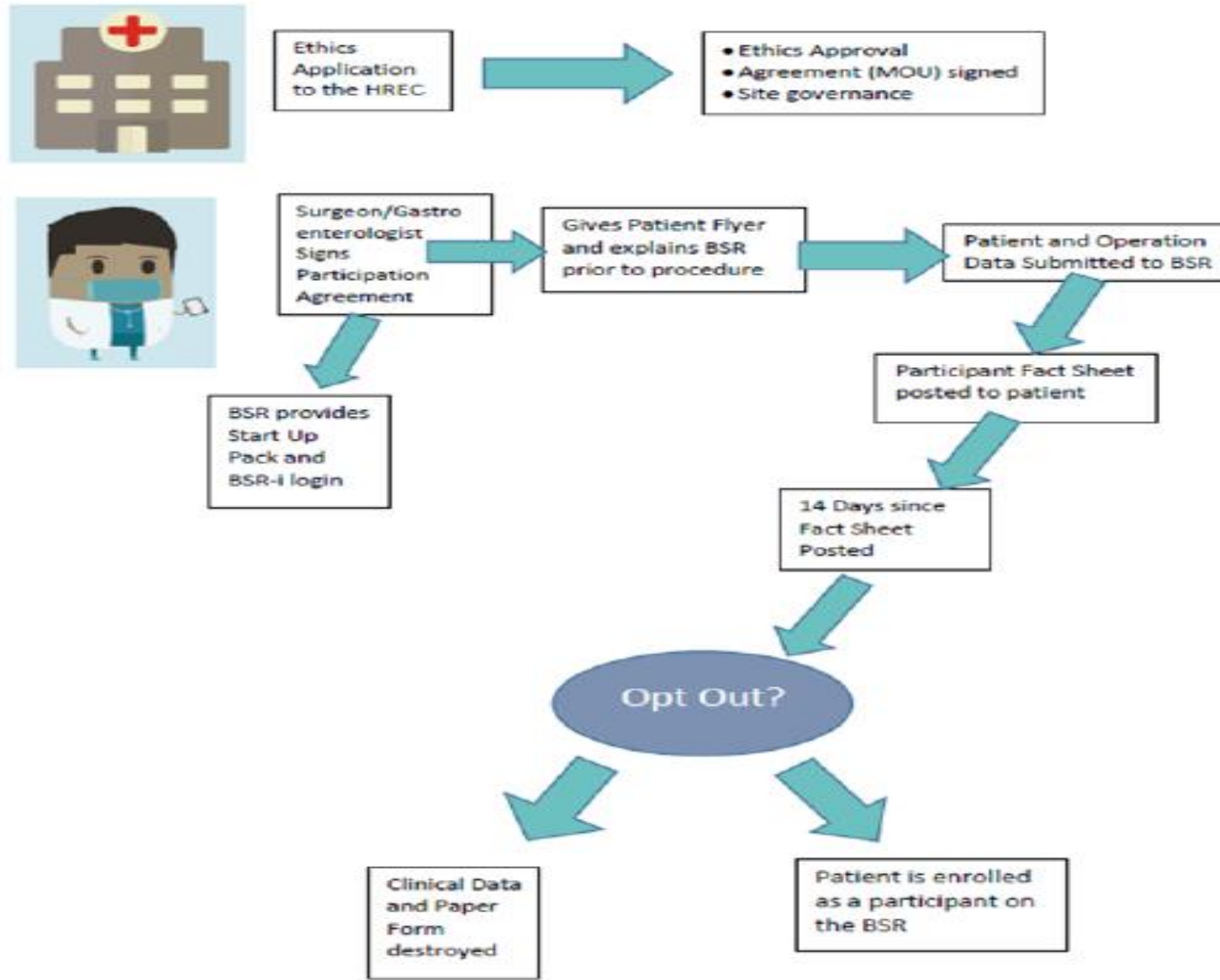
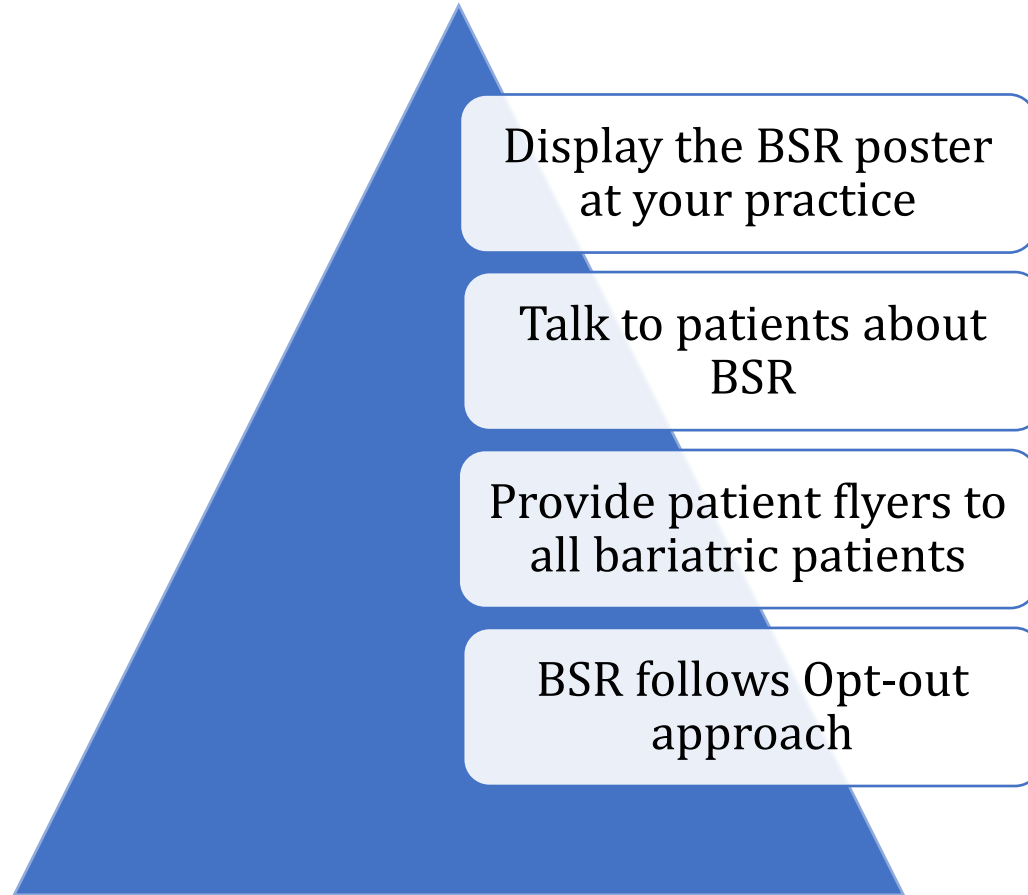


Recruitment for the Bariatric Surgery Registry



Operational policies and protocols to follow while recruiting participants



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.



v1.1.11 October 2018

CRICOS provider Monash University 00008C MMS370513

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 that you want to 'opt out'.

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

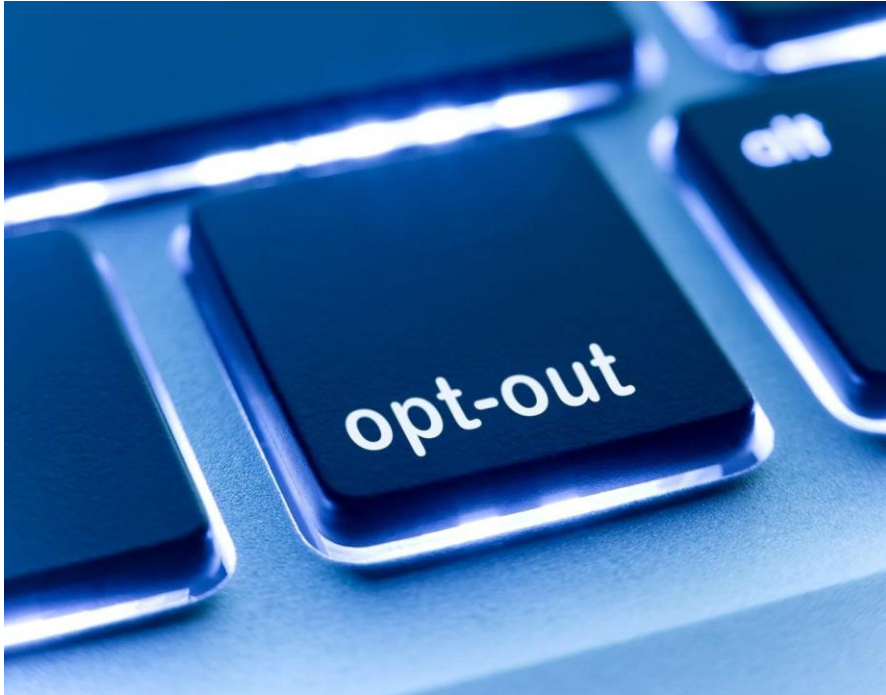
A partnership between:



BSR Flyer V2.1 3 May 2023

MONASH UNIVERSITY | 2023 02/25/2023 02:14:46 PM | 10/101111/0001

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)

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 Number _____ Ref _____
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 _____
 Height _____ Pre-Op Weight _____ kg
 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 *State reason below and enter the details of the intended procedure in next column.*

Procedure Details

- Primary** bariatric operation
 Revision bariatric operation or subsequent intervention
 1. **What was the previous bariatric operation?** _____
 2. **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
 Bilio-pancreatic bypass/duodenal switch
 Addition of ring over bypass or sleeve
 Endoscopic sleeve gastroplasty (ESG)
 Gastroplasty
 Reversal of gastroplasty
 Gastric imbrication Plus band (i-band)
 Laparoscopic gastric band
 Surgical reversal of gastric band
 Port revision Removal OR Insertion
 Removal of ring over bypass or sleeve
 Sub-total gastrectomy
 Small bowel resection
 Control of bleeding
 Dilatation of stricture
 Division of adhesions
 Lavage/washout ± drainage
 Stent Removal OR Insertion
 Wound debridement
 Incisional or ventral hernia repair
 Concurrent transplant Liver Kidney
 Other (specify) _____

Surgical 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

- 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

Bariatric Surgery Registry (BSR)

Patient | Devices | Work Lists | Reports | Admin | Settings | FAQ

Patient Demographics

Patient ID: Patient Name: Sex: DOB:

Patient ID

UR No * [Show URN\(s\)](#)

Title [?](#)

Family Name * [?](#)

Given Name * [?](#)

DOB (dd/mm/yyyy) * DOB Not Known [?](#)

Sex * [?](#)

Consent Site * [?](#)

On-going Care Surgeon * [?](#)

Street Number and Name * Address Not Known [?](#)

Suburb * [?](#)

Country * Australia [?](#)

State * [?](#)

Postcode * No Postcode [?](#)

Medicare Number * No Medicare Number [?](#)

DVA Number * No DVA Number [?](#)

IHI No [Get IHI](#)

Indigenous Status * [?](#)

Home Phone Number (add area code) * No Phone Number [?](#)

Mobile Phone Number (add area code) * No Mobile Number [?](#)

Vital Status * Alive [?](#)

FOR ADMIN AND DATA ENTRY - Information only

Date explanatory statement sent Explanatory statement returned undeliverable

Opt off status Pending Consent

[Cancel](#) [Save](#)

[Delete Patient](#)

Data checked & saved by Date & time saved

Take away points



**Display poster at
your practice**



**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

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
 - A bank card
 - 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
 - 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



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](tel:0399039366) 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](tel:0399039366).

Continue

Save & Return Later

Monash Uni
14:16, 11 July

Hi Jennifer,
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=SvtWMM7JqfxAvK4E>
You can contact **Monash** University on **(03) 9903 9366** for more information.

Copy text Share More

10:15 [icons]

What is your current weight in kilograms?

Enter weight in kg up to one decimal place, e.g. 92.1kg

Do you currently have diabetes?

Yes

No

reset

What treatment are you undertaking for your diabetes?

Select the most relevant answer

Diet/exercise

Non-Insulin therapy (single)

Non-Insulin therapy (multiple)

Insulin

Unknown

reset

Have you had an additional bariatric procedure in the last 12 months?

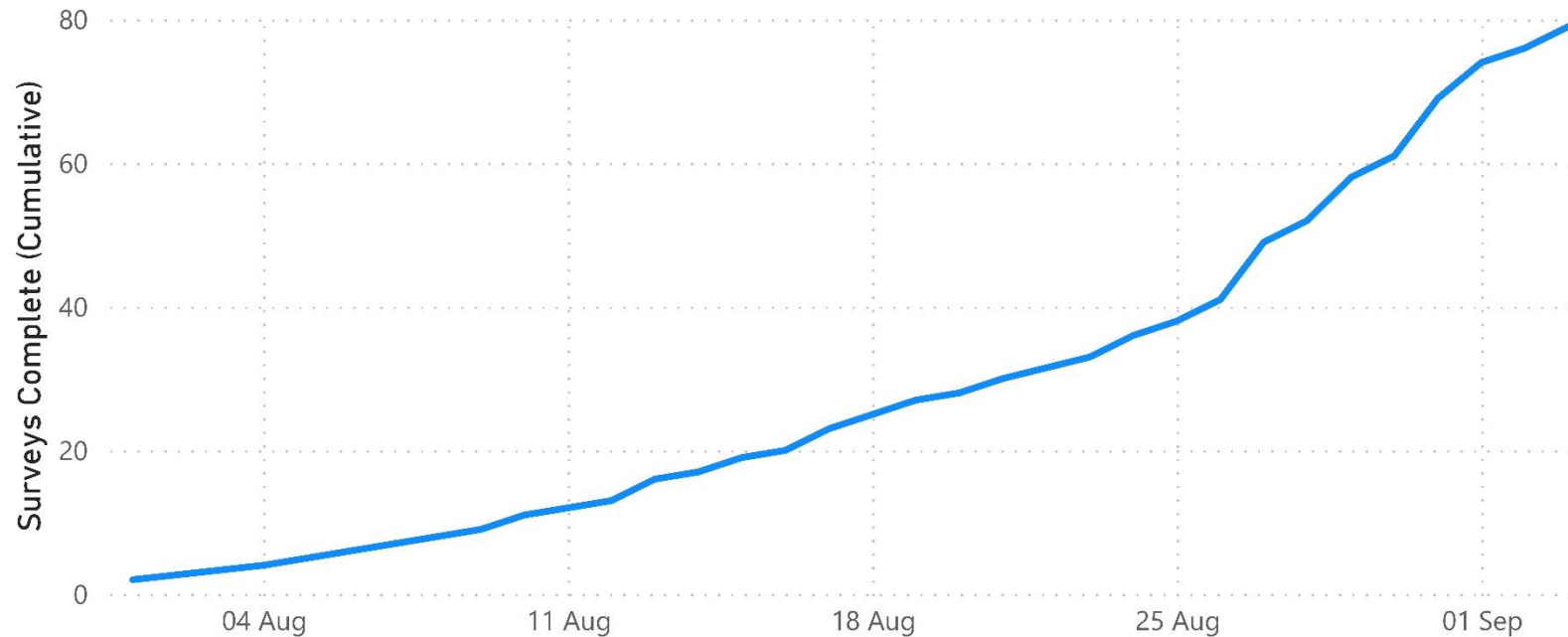
This does NOT include your primary bariatric

[navigation icons]



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=PdXRqlncA6xEZhl>

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