MONASH University

Obesity Surgery Society of Australia & New Zealand

BSR

BARIATRIC SURGERY REGISTRY

Frequently Asked Questions

- Does the BSR only collect **online** data or can you still use **hard copy** forms?
  The BSR-*i* is a web-based interface that allows people to submit their data directly into the BSR database. Training can be provided in the use of the BSR-*i* for surgeons and their room's staff. If surgeons decide that they prefer to use a paper based system, this can be arranged. Please contact the BSR at med.bsr@monash.edu to make these arrangements.

- Who can log into the BSR-*i*?
  It's up to each surgeon to decide whether they delegate it to their staff or they fill in the data themselves. Each surgeon will be provided one log-in and it is up to the surgeon to decide to whom they delegate this responsibility.

- Are you collecting data on **intragastric balloons** or any other **intraluminal devices?**
  No

- Do you collect data on **bariatric reversals** / (band) **removals**?
  Yes but not removal of intraluminal devices.

- Do you collect data when a band is removed and there has been **no replacement band fitted**?
  Yes, please select "Surgical Reversal".

- Do you collect **retrospective cases**?
  No, we only collect patient data from the date of ethics approval of each hospital.

- Should I provide detail about my patients that have had a Bariatric Procedure in my **private rooms**?
  No, we can only accept patient data procedures at ethics approved hospital sites not private rooms.

- Why must I search for patients using their **UR number** and not their name?
  The BSR's protocol is very strict in relation to privacy. In order to gain ethics approval at all sites, we must ensure identifiable patient data is only viewable by those who have a legal right to view it. Thus we are unable to allow surgeons to search for patients by name and must rely on the UR number of the hospital.

- Why is it compulsory to provide **device details**?
  As a quality and safety registry, it is essential that the BSR consistently captures data about devices and their safety and efficacy. To do this, we must systematically collect the information provided by the device manufacturer on the labels that accompany the device.
  *Please note, the 'Serial/Lot number' field for devices is not mandatory. You can ignore this field and submit without the serial/Lot number.

- What information about devices does the BSR collect?

  The BSR collects individual device information on gastric bands, including ports as well as the type of stapling devices/ staples used for R-Y bypass and sleeve gastrectomy's. We do not collect information about the type of buttress used nor adhesive material, rather we ask if a buttress is used with a particular type of staple or not.
  To view a complete list of all devices that the BSR collects, please email med-bsr@monash.edu to request a device checklist.

- The **timing of our appointments** are not at 30 days after surgery, is that ok?

  Surgeons have different regimes for post-operative follow up so we allow any visit between 20 days and 90 days from the date of the procedure to be used as the 30 day follow up. The BSR-*i* will prompt you if the date of your follow up is out of this data window.

  If the patient has been seen **after** 90 days, it is still possible to complete the 30 day follow up. You need to answer the sentinel event questions (was there an unplanned return to theatre, ICU admission or hospital readmission) or was there a death **in the 90 days post surgery**. You would then date the follow up as at 90 days from the operation date and submit the follow up. If you have any queries about this, please email med-bsr@monash.edu to discuss.

- What about timing of **annual follow up**?

  For primary patients, the first annual follow up will be from 3 months after the date of surgery to 15 months. If the follow up occurs after 15 months from surgery, it will be considered their 2 year visit. The BSR-*i* will prompt you if the date of your follow up is out of these data window.

- How will follow up be handled in the situation of a patient having **multiple operations**?

  There is a 30-day follow up for all procedures unless the patient has had a subsequent surgery within that 30 day time frame (ie up to 90 days). In that situation the 30-day follow up will occur 30 days following the subsequent procedure. Annual follow up will always occur 12 months from the primary procedure if the BSR has captured this event.

- If a patient has their first surgery by surgeon X and after several months the patient has subsequent surgery by surgeon Y. **Who is responsible** for the patient's annual follow up?

  Annual follow up will remain with surgeon X (primary surgeon) unless surgeon Y (subsequent surgeon) indicates they will be providing continuing care when they submit their information about the subsequent procedure. 30-day follow up of the subsequent procedure will always be with the surgeon who has performed the procedure.

- How are **unexpected hospital admissions** and/ or **returns to surgery** treated within the BSR?

  Our aim is to capture all information about patient's unexpected hospital admissions either through surgeons providing the procedure data or through the follow up process.

- I have a patient who wants to **opt off**, what do they need to do?

  Patients may opt-off at any time via the free call 1800 998 722 number. Their choice to opt-off will not affect their relationship with their treating surgeon or the care they receive. The opt-off option reflects the voluntary nature of the BSR.

- What happens to **patient data** after they **opt off**?

  Once patients have followed the opt-off procedure, clinical data will be destroyed. We will retain identifying data such as the patient's name and their date of birth to ensure the patient is not contacted again in the future. The BSR will not send follow up requests for these patients and will inform surgeons if they attempt to input subsequent procedures for these patients.

- Who owns the **data**?

The Registry owns the data and it is currently housed with our Custodian, Monash University.

- How is the **data protected**?
  Data is housed with the highest level of security which will be compliant with ISO27001 standards.

- Will the **online database be hackable**?
  Our online platform will have ISO27001 security standards – the same level of security as banks.

- Will the Government or anybody else have **access to the data**?
  Data access is strictly controlled by the Steering Committee and includes protocols that are constantly reviewed ensuring the highest levels of privacy.
  General reports will only contain de-identified data.
  In the future surgeons will receive reports specific to their data, however this data may not be used for commercial and marketing purposes.
  Researchers can apply to the Steering Committee for access to the database.
  BSR staff and Steering Committee members who have access to identifiable data will all sign confidentiality agreements to ensure privacy is maintained.
  For a full explanation of the policy please go to:
  (http://www.med.monash.edu.au/sphpm/depts-centres-units/bariatric/policies-procedures.html)

- How will registry data be **cited in publications**?
  Researchers who gain approval from the Steering Committee to use the data will acknowledge the BSR as the source of data, but they won't list all contributing surgeons.

- How do I **inform patients** that I will be submitting their data to the BSR?
  Ideally, this will be mentioned to patients pre-operatively. We provide flyers and a poster to facilitate this.
  However, patients will receive an explanatory statement from the BSR in the weeks following their surgery informing them about the registry and their options to opt-off.

- How will I know when **another site** I work at is approved for ethics?
  In the BSR-*i* only those sites that are approved for ethics can be selected. The BSR will inform all surgeons that a new site has gained ethics approval regardless of whether the surgeon is already contributing to the BSR or not. It will then appear as an option in the BSR-*i*.