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Data Management for the Bariatric Surgery Program

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Abbreviations

ABS	American Board of Surgery
ASMBS	American Society for Metabolic and Bariatric Surgery
BMI	Body mass index
BOLD	Bariatric Outcome Longitudinal Database
BSCN	Bariatric Surgery Center Network
CABG	Coronary artery bypass graft
COE	Center of excellence
COPD	Chronic obstructive pulmonary disease
CPAP	Continuous positive airway pressure
CTP	Child-Turcotte-Pugh
DVT	Deep Venous Thrombosis
EEA	End to end anastomosis
GERD	Gastroesophageal reflux disease
IRB	Institutional Review Board
IVC	Inferior vena cava
MBSAQIP	Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program
MBSC	Michigan Bariatric Surgery Collaborative
MI	Myocardial infarction
PCTI	Percutaneous coronary transluminal intervention
PE	Pulmonary embolus
POD	Postoperative day
PPI	Proton Pump Inhibitor
PSVT	Paroxysmal supraventricular tachycardia
SRC	Surgical Review Corporation
VTE	Venous thromboembolism

History of Database Management

As the field of bariatric surgery continues to expand and grow, the surgical treatment of morbid obesity has become more common and accepted by both medical and surgical colleagues. However, as with any emerging surgical specialty, it was subject to a barrage of criticism regarding the lack of published data to support surgical efficacy and safety. Prior to the mid-2000s, there was very little centralized data collection from surgeons regarding their results and morbidity/mortality. The drive for quality improvement, improved surgical safety, and evaluation of specific surgical procedures has pushed the field toward collection of more data for evaluation. Prior to this time, all results from bariatric surgery were limited to a few meta-analyses and published case series. Bariatric surgeons felt a great need for randomized clinical trials but more importantly centralized data collection. This data would further be utilized for certifying and accrediting surgeons and centers that perform high-volume surgery with good outcomes, which lead to the derivation of what is now known as "centers of excellence" (COEs) [1]. Data collection is also important for individual surgeons as the American Board of Surgery (ABS) now requires reporting outcomes for the maintenance of certification [2].

Many bariatric surgery programs have been recording their outcomes in private institutional databases for years; however, this data was not commonly shared outside the surgeons practice unless it was used for publications or conference presentations. Surgeons maintained these databases as it allowed them to quickly access their outcomes so they can provide patients with institution-specific rates of complications and weight loss expectations. It also allowed a system for tracking patient follow-up and reestablishing care for those with long intervals between visits. The need for these local databases will continue to exist as each institution may elect to track patient outcome variables that they deem to be important and may not be tracked nationally.

ACS-BSCN

The first national database used for center accreditation was started by the ACS in 2005 and was known as the Bariatric Surgery Center Network (BSCN) bariatric surgery database [3]. The database was a requirement to establish and maintain accreditation and 100 % capture of all data points and cases

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was required. It was easily accessed through the internet or could be managed on a local workstation platform with electronic data transmission. All data was encrypted and de-identified to protect the confidentiality of the surgeons and patients. Programs did not incur any additional cost for the database as it was included in their credentialing fees. Post surgical guidelines were established and standardized for a minimum follow-up of 30 days, 6 months, and annually thereafter. If an institution already participated in the National Surgical Quality Improvement Project (NSQIP), this data would auto-populate into the bariatric surgery database. However, more fields were required in the bariatric database specific to these types of patients requiring more data entry than what is required into NSQIP. It was mandated that data entry be done by a trained data collector, a position ideally filled by a medically trained person or dedicated bariatric staff member. The data entry person could not be a surgeon or mid-level provider with direct patient care responsibilities in an attempt to avoid reporting bias in the data. While outcomes were monitored for the safety of the program, accreditation was closely tied to institution and surgeon volume.

ASMBS-SRC and BOLD

In 2007, the American Society for Metabolic and Bariatric Surgery (ASMBS) joined forces with the Surgical Review Corporation (SRC) to form a separate and distinct accrediting agency and bariatric database [4]. Their goals were similar to those of the ACS. The database they created was known as BOLD (Bariatric Outcomes Longitudinal Database). The guiding principles of database management and program organization were very similar to those of the ACS-BSCN. There were even features which interfaced with electronic medical records to expedite the entry of data and prevent duplication or errors in the transcription of data. One key difference in this database was the intention to use blinded data for research purposes accessed by third parties. It was thought that a large database such as this should be used to provide size and statistical power needed to study both high- and low-frequency occurrences. The database could also be easily accessed by each individual surgeon to query their own outcomes.

There were also many questions initially regarding how these databases could be used for research studies and whether they required institutional review board (IRB) approval to exist and/or be accessed. Eventually it was determined that according to 45 CFR Part 164.501, 506, these activities are implemented solely for the purpose of assessing the quality of care and do not require review by an IRB [5]. The BOLD database did undergo review through the Copernicus Group Independent Review Board prior to its inception. Nevertheless, it is still recommended that each institution wishing to review their own data via this database and publish related results may elect or may be required to obtain approval though their own hospital IRB.

MBSAQIP

In the years that followed the initiation of two separate data collection and accrediting agencies (ACS-BSCN and SRC-ASMBS BOLD), questions were raised why there was not one centralized database and credentialing agency. There were also criticisms of a lack of evolution of the BOLD database. There were also concerns about the exclusive nature of "centers of excellence" creating a two-tiered system implying superiority and inferiority. Common goals of quality, over a simple volume-based threshold, became the new focus. This eventually led to the creation of the new ASMBS-ACS quality program known as the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) [6, 7]. The fusion of these two programs began in April 2012. This transition was spearheaded by Robin Blackstone, MD, president of the ASMBS at that time. It was felt that the ACS database, which was a second-generation-type registry with many improvements over BOLD, would be maintained as the new centralized data collection registry. This second-generation database was considered progressive and changed over time as unnecessary data points were removed. Any data collected which did not impact quality and was not needed was no longer included. With fewer elements to report, primarily through yes and no questions, it became much easier for the program to comply. Data remains tied to NSQIP, which theoretically should strengthen it.

New requirements for data collection were also instituted under MBSAQIP with significantly important changes [8]. Data entry is required to be completed by a designated personnel who is not a patient care provider. This requirement for a single data collector at each site who was medically trained or an experienced chart abstractor became stricter with the addition of a web-based certification process. The program also created stricter definitions for adverse events so it was easier for the "Bariatric Surgery Clinical Reviewer" (BSCR) to enter this data. It was also recognized that the preferred method of data collection is by chart abstraction, not encounter forms, third-party data transmission, or real-time entry during patient visit. This does, however, create more work for the BSCR but will hopefully provide data with higher fidelity. The updated database also fixes problems such as how to correctly code comorbidity severity, complications, and revisional surgery, known to be common complaints of the BOLD database. One goal was to limit the amount of free text entries by standardizing definitions. The program also decreased the number of reportable complications and limited them to those which have an impact on risk adjustment. The comorbidity severity scale was changed to simplify the presence or absence of remission. Maintaining a patient on medications for preventative health, such as a

statin or metformin, is no longer considered treating a comorbidity as these types of medications are now commonly continued on patients even when their comorbidities have significantly improved. Likewise, treatment of atrial fibrillation with a beta blocker or calcium channel blocker in a patient with previous hypertension does not preclude them from being in remission. Outcome reporting is still required at 30 days, 6 months, 12 months, and annually thereafter. New time constraints have been enforced with data entry required within 120 days of each entry data point with a system lockout after that time. Follow-up windows are also lengthened after the initial 30 days to provide some flexibility in actual visit dates. For instance, the annual follow-up data can include 6 months on either side of the surgery anniversary.

Another common problem with BOLD was data auditing [8]. BOLD data auditing used to only check the 1 year prior to recertification and only those surgeons who were COE surgeons at a facility were required to report. In the new system, facility certification takes greater precedence. In the past, BSCOE program individual surgeons were credentialed separately from the institution. Program certification could exclude particular surgeons at a facility and their data was not included. Now all surgeons' data must be included and reported at each facility. Program data audit previously only occurred every 3 years with site inspection, but programs may now also be subject to closer interval or random auditing to keep programs honest.

Tracking patient follow-up is another improvement of MBSAQIP database over BOLD. BOLD has incomplete follow-up data, as the definition of lost to follow-up only includes patients that died while all others were still considered "eligible" for follow-up years after their last data entry [8]. The new system also has an easier way to track patient follow-up with specific tracking reports. These reports show which patients are due for follow-up and when. It will also allow programs to track when patients are contacted to attempt to reestablish care and document discharge or transfer from the practice or inability to contact. Both data systems still suffer from the lack of being able to track patients as they may switch practices or have a complication treated by another provider.

The new program will also report a program's risk-adjusted outcomes compared to national risk-adjusted benchmarks, a feature not available in BOLD [8]. Comorbidity remission data is also now provided in a useful table that providers can use for quality improvement, application for hospital certifications, or insurance coverage.

Many questions have been raised regarding the fate of BOLD data [8]. While demographics were rather easy to transfer from BOLD to the new MBSAQIP database, adverse event data was too unreliable to transfer over. Data from BOLD will be returned to programs for their internal use. A public-use file will also be maintained for research purposes, both for ongoing studies and for those wishing to access it in the future. BOLD data is also being used for state by state comparisons to evaluate access to care issues.

MBSC (Michigan Bariatric Surgery Collaborative)

There has been interest by some groups in the country to obtain a more detailed bariatric database that can be used for quality improvement and optimal outcome-based cost containment. The best example of this type of program is the MBSC, which is a clinical outcome registry formed from a regional, voluntary consortium of hospitals and surgeons that perform bariatric surgery in Michigan [9]. The project is funded by Blue Cross and Blue Shield of the Michigan/Blue Care Network and coordinated at the University of Michigan under the lead direction of Nancy Birkmeyer, PhD. Over 40 hospitals participate and data is not excluded from low-volume centers which differentiate it from the other larger national databases. Given that the guiding principle for the program is quality improvement, the group meets multiple times per year to examine their data and to design and implement changes in care that result in better outcomes for their bariatric patients. Quality improvement projects resulting from this database have led to reduction in the use of preoperative inferior vena cava (IVC) filter placement, as well as risk stratification for VTE prophylaxis [10, 11]. Their data has also contested the notion that high-volume COEs have improved outcomes compared to low-volume non-COEs [12]. This has pushed credentialing agencies to move toward outcome-based certification rather than strictly volume based.

Creating the Ideal Internal Database

It is likely that bariatric surgeons may wish to track their outcomes locally on an institutional database for easier access and customizability. This section is dedicated to how to design the ideal internal database. While listing every customizable database program is beyond the scope of this chapter, certain factors should go into the decision of which program to choose. The software should be easy to use for both input and data extraction. A modifiable entry form with user designed prompts for each different patient encounter makes data entry easier. Search functions should allow the user to identify and sort data with multiple tiers of data points and create a spreadsheet from these desired data points. The program would ideally be made by a manufacturer that is well established and will continue to be in business for some time so the product can be serviced and grow as platforms and operating systems change over time, as opposed to one

Table 1. Initial visit

Initial visit date
Seminar date
Patient demographics
Name
Date of birth
Medical record number
Gender
Race
Primary language
Height (cm, inches)
Weight at first patient contact (kg, lb) + date
BMI at first patient contact + date
Excess body weight (calculate from ideal body weight)
Smoking (current pack per day, pack/year history, or how long ago had the patient quit smoking)
Mobility status (if not fully mobile, document immobile, or mobility aids needed)
Previous abdominal surgery history
Obesity history
Overweight since what age
Highest weight
Most weight ever lost
Attempting to lose weight for how many years
Unsuccessful commercial diets/pills
Current exercise regimen
Previous weight loss operations (which one)
Obesity-related medical conditions
Diabetes mellitus
Type I/II
Controlled/uncontrolled
Controlled with diet, oral meds, or insulin
Diabetic complications (nerve, eye, kidney, skin)
Hemoglobin A1c and fasting blood sugar + date
Hypertension
Controlled/uncontrolled
Number of and class of medications
Hyperlipidemia
Gastroesophageal reflux disease
Medication treatment (PPI or H2 blocker)
Previous surgical or endoluminal therapy
Nonalcoholic steatohepatitis or cirrhosis
Obstructive sleep apnea (sleep study, STOPBang score, CPAP)
Other non-obesity-related medical conditions
Asthma
COPD (home oxygen requirement)
Coronary artery disease (h/o MI, PCTI, or CABG)
CHF (recent EF %)
Atrial fibrillation or PSVT
Pacemaker
Peripheral vascular disease
Peptic ulcer disease (*Helicobacter pylori* status)
Gallstones (present or history of cholecystectomy)

(continued)

Table 1. (continued)

Stress incontinence
Renal failure (creatinine, dialysis, transplant patient/candidate)
Cirrhosis (cause, CTP class, MELD score, transplant patient/candidate)
DVT/PE (history, previous/current treatment)
Psychological (anxiety, depression, substance abuse, suicidal, bipolar, eating disorder)
Connective tissue disorder (which one?)
Bleeding disorder (which one?)

Table 2. Preoperative H and P visit

Preoperative visit date
Weight + BMI
Planned procedure + date
Labs/tests
Anemia (hemoglobin)
Arterial blood gas
C-reactive protein
Creatinine
Coagulation panel (if necessary)
Chest X-ray
EKG
Vitamin/micronutrient deficiency
H. pylori (histology, serology, stool antigen, urea breath test, CLO test)
Upper endoscopy
Upper gastrointestinal series

which may be obsolete in a decade or less. While each individual surgeon may wish to track uncommon data points important to them, the following tables list items every surgeon may want to include in their database. These tables are arranged according to when the data should be recorded based on patient visits in a chronological order. They include the initial visit (Table 1), the preoperative history and physical visit (Table 2), the operative encounter (Table 3), postoperative visits in the perioperative period within 30 days of surgery (Table 4), and long-term visits defined as after 30 days from the date of surgery (Table 5).

Conclusion

As the field of bariatric surgery moves forward, accurate data collection and reporting will become a critical part of any practice. Risk-adjustment models are being developed that will help surgeons, patients, and payors understand outcomes in a way that more accurately reflects the patients a specific program cares for. Whether the data is used for internal process improvement, payor reimbursement, or as part of a national accreditation program, a thoughtful and detailed approach to data collection and reporting will be necessary.

TABLE 3. Operation

- Procedure performed + date
- Approach (open, laparoscopic, converted to open)
- Procedure changed or aborted (+reason)
- OR procedure time (incision to closure) Additional OR procedures (cholecystectomy, hiatal hernia, liver biopsy, abdominal wall hernia)
- Intraoperative complications
- Procedure specifics
  - Adjustable gastric band
    - Band type
      - Allergan LAP-BAND AP standard or large
      - Ethicon REALIZE Band or REALIZE Band-C
    - Gastro-gastric sutures placed?
  - Gastric bypass
    - Roux limb length (cm)
    - Estimated pouch size (cc)
    - Banded pouch
    - GJ anastomosis
    - Linear staple (Length in cm)
    - Circular staple (21 vs. 25 mm EEA)
    - Ante-ante or retro-retro Roux limb position
    - Close Peterson's defect?
    - Intraoperative leak test (method and result)
    - Drain placed?
  - Duodenal Switch
    - Alimentary limb length (cm)
    - Common channel limb length (cm)
    - Sleeve bougie size (Fr)
    - Duodenoileostomy anastomosis
      - Linear staple (length in cm)
      - Circular staple (21 vs. 25 mm EEA)
    - Intraoperative leak test (method and result)
    - Drain placed
  - Sleeve gastrectomy
    - Initial staple fire length from the pylorus (cm)
    - Sleeve bougie size (Fr)
    - Staple line reinforcement (none vs. SEAMGUARD vs. suture imbrication)
    - Intraoperative leak test (method and result)
    - Drain placed

TABLE 4. First postoperative visit (<30 days)

Visit date + POD#
Weight
Procedure performed + date
POD#1 upper GI series result
Drain removed on POD# (if placed)
VTE prophylaxis
Foot pumps or SCDs
IVC filter (if yes: temporary or permanent)
Chemical
Type: UFH or LMWH or other
Pre-op, intra-op, post-op, post-discharge (include dosages)
Complications
Death (suspected cause)
Abscess/wound infection (superficial, deep, organ space + treatment)
Bleeding (intra-/extraluminal, reoperation, transfusion, lowest Hgb, splenectomy)
Port-site hernia or wound dehiscence
Respiratory (hypoxia, prolonged oxygen requirement, reintubation)
Hospital infection (pneumonia, urinary tract, *Clostridium difficile*)
Venous thromboembolism (DVT or PE + treatment)
Cardiac event (MI, cardiac arrest)
Renal failure
Gastric bypass or duodenal switch specific complications
Leak (site, day diagnosed, treatment)
Bowel obstruction (location, cause, treatment)
Stricture (location, cause, treatment)
Anastomotic ulcer
Sleeve gastrectomy specific complications
Leak (site, day diagnosed, treatment)
Stricture (location, cause, treatment)
Adjustable gastric band specific complications
Gastric perforation
Band outlet obstruction
Port-site infection
Band slippage

TABLE 5. Follow-up visit (>30 days)

Visit date + month/years out from surgery
Procedure
Weight (include also current BMI, BMI lost, lb lost, kg lost, % EWL, % WL, % EBMIL)
Exercise program
Food choices
Supplementation intake
Late complications
Gastric bypass or duodenal switch
Bowel obstruction (location, cause, treatment)
Stricture (location, cause, treatment)
Anastomotic ulcer
Nonhealing leak
Dumping syndrome
Vitamin/micronutrient deficiencies
Sleeve gastrectomy specific complications
Nonhealing leak
Stricture (location, cause, treatment)
Severe GERD
Adjustable gastric band specific complications
Band slippage
Gastric erosion
Port-site infection
Band malfunction/defect (does not fill properly or leaks)
Band intolerance/removal
Modifiable bariatric comorbidity (improved/remission—# of medications off, still on)
Diabetes mellitus
Document HbA1c levels
Preventative metformin does not imply non-resolution
Hypertension
Document current blood pressure
Preventative beta blockers does not imply non-resolution
Hyperlipidemia
Document lab improvement
Preventative statin does not imply non-resolution
Gastroesophageal reflux disease
Symptom resolution, still on medication, reflux worse (sleeve/band)
Obstructive sleep apnea
Off CPAP, improved symptoms
Emergency department visits (reason and number of visits)
Adjustable gastric band
Adjustment #
Current band volume
Adjustment volume
New band volume
Hungry
Making good food choices?
Exercise

Table 5. (continued)

Yearly Labs (in order of importance depending on the type of procedure performed)
Complete blood count
Basic metabolic panel
Iron
Vitamin D
PTH
Vitamin B12
Vitamin B1
Vitamin A
Copper, selenium, zinc (for malabsorptive procedures or clinically indicated)

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