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Introduction

In the United States, more than 11 million people suffer from severe obesity and an estimated 93 million people are obese. The comorbidities associated with obesity range from diabetes and heart disease to certain types of cancers. Metabolic and Bariatric surgical procedures have been shown to reduce obesity, improve mortality, and decrease the health risks from chronic diseases such as cardiomyopathy and diabetes. For these reasons, the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP®) will recognize those facilities that implement defined standards of care, document their outcomes, and participate in regular reviews to evaluate their metabolic and bariatric surgical programs.

Overview

A highly visible and important issue facing the medical profession and the healthcare industry today is the quality of care provided to patients. Numerous stakeholders including providers, payors, and private industries have invested a large amount of resources in order to be able to measure, report, and improve clinical care.

MBSAQIP works to advance safe, high-quality care for metabolic and bariatric surgical patients through the accreditation of metabolic and bariatric surgical centers. A metabolic and bariatric surgical center achieves accreditation following a rigorous review process during which it proves that it can maintain certain physical resources, human resources, and standards of practice. All accredited centers report their outcomes to the MBSAQIP registry.

History
The American College of Surgeons (ACS) was founded in 1913 with the goal of improving surgical care and setting standards, and the current Joint Commission (JCAHO) grew out of the ACS Hospital Standards Committee in 1951. The ACS has been accrediting trauma programs through the Trauma Verification Program since 1987 and cancer programs through the Commission on Cancer since 1930. In 2005, in response to a growing need in the metabolic bariatric surgery community, the ACS released the first Bariatric Surgery Center Network (ACS BSCN) accreditation standards manual.

The American society for Metabolic and Bariatric Surgery (ASMBS), founded in 1983, was formed to advance the art and science of metabolic and bariatric surgery by continually improving the quality and safety of care and treatment of people with obesity and related diseases through educational and support programs for surgeons and integrated health professionals. The leadership of the ASMBS found it within their mission to release their own set of accreditation standards for Bariatric Surgery Centers of Excellence (BSCOE) in 2004, creating two separate but similar accrediting bodies for bariatric surgery.

Both programs focused on three key principles: the leadership of surgeons, the necessity for a multidisciplinary team, and the reporting of outcomes to a national registry. Accreditation was based on procedure volume, as well as other structural and process measures that provided a framework for facilities performing these types of procedures. Even discounting the impact of the introduction of laparoscopy (a change from 2.1 percent in 1998 to more than 90 percent in 2008) and inclusion in the data of the adjustable gastric band (less 30 day mortality and morbidity), the adoption of accreditation standards led to a remarkable decrease in mortality from one in 200 patients to one in 1,750 patients. The majority of centers offering bariatric surgery programs in the United States participated in one of the former two accreditation programs. The data registries for both of the accreditation programs were under development in 2006 and in 2011 had more than 100,000 patients per year being entered into one of the two registries.

**Transition to the MBSAQIP**

The American College of Surgeons (ACS) and the American Society for Metabolic and Bariatric Surgery (ASMBS) combined their respective national bariatric surgery accreditation programs into a single unified program to achieve one national accreditation standard for bariatric surgery centers, the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP®).

On March 9, 2012, the ACS signed a memorandum of understanding with the ASMBS to unify their respective bariatric surgery center accreditation programs. As of April 1, 2012, all institutions that met the standards under the two separate programs—the ACS
BSCN program and the ASMBS BSCOE program—were extended accreditation in the joint MBSAQIP. The new, joint program is administered by the staff and committees of the ACS, and all centers now submit data to the existing ACS bariatric data registry.

MBSAQIP works to advance safe, high-quality care for bariatric surgical patients through the accreditation of bariatric surgical centers. A bariatric surgical center achieves accreditation following a rigorous review process during which it proves that it can maintain certain physical resources, human resources, and standards of practice. All accredited centers report their outcomes to the MBSAQIP registry.

How It Works

MBSAQIP collects data on preoperative risk factors, preoperative laboratory values, intraoperative variables, 30-day postoperative mortality and morbidity on all patients undergoing metabolic and bariatric procedures which meet program criteria. Long term data is collected for patients as well. Data are collected by highly trained and certified Metabolic and Bariatric Surgical Clinical Reviewers (MBSCRs), who enter the data into a secure internet website. After the data is entered, it is available to be viewed by a center continuously, and this data is risk-adjusted by MBSAQIP on a bi-annual basis. After thorough cleaning, the data is analyzed and odds ratios (ORs) are produced for each participating facility in bi-annual reports. An OR greater than 1 indicates that the center is experiencing more postoperative outcomes than expected. Conversely, an OR less than 1 indicates that the center is having better results than expected based on its patient characteristics and the complexity of the procedures performed. Bi-annually, detailed reports with ORs, statistical details, and hierarchical regression models are distributed to the participating centers. Centers with consistently low ORs are encouraged to share with the MBSAQIP the processes and structures that they consider to have contributed to their good performance.

Data Collection

At each participating center, a specially trained, dedicated MBSCR collects the preoperative, intraoperative, and postoperative outcome data on all cases that meet Program criteria. The MBSCR enters all collected data into the MBASQIP Data Registry. The data is then transmitted to MBSAQIP where (after performing data checks for valid data entry) the data is subjected to statistical analysis.

Risk-Adjustment
Risk-adjusted models for MBSAQIP participating centers are computed every 6 months, using data from the previous 12-month period (with a 6 month lag due to case locking and time required for the analysis) and are reported semi-annually in the Semi-annual Report (SAR). Risk-adjusted results are currently computed for Laparoscopic Sleeve Gastrectomy and Laparoscopic Roux-En-Y Gastric Bypass cases, including Morbidity, Reoperations, Interventions and Readmissions. Also included in the SAR are risk-adjusted results focusing on specific surgical occurrences. Risk adjustment is important because it takes into account differences in patient and procedure mix between centers, thus permitting fair comparisons of centers.

MBSAQIP modeling techniques have evolved and improved over time as new statistical techniques have become available. Our current risk-adjustment modeling process generally follows the below described process, though certain models might be approached somewhat differently.

- Forward stepwise logistic regression is then used to develop a predictive model for each outcome. At the first step, the predictor that is most strongly associated with the outcome is selected. After that, correlations between all remaining unselected variables and the outcome are adjusted for predictors already in the model, and the variable with the next strongest association is entered. This continues until no remaining variable is capable of significantly improving the model. This process chooses a useful predictive set from 30 or more potential predictive variables.

- The variables selected by the logistic regression are then used in a hierarchical model. One important advantage of hierarchical models, as we have implemented them, is that they are able to pool information about what is known about all centers with what is known about a specific center to achieve a best prediction about center quality. Particularly when the center sample size is small, thus pooling results in the center quality estimate being “shrunk” towards the mean of all centers. For technical reasons, the best center quality metric derived from a hierarchical model is the odds ratio.

- The odds ratio is the ratio of odds (number of patients exhibiting the event/number of patients not exhibiting the event) for a target group to the odds for a comparison group. An odds ratio of 1.0 implies that the event is equally likely in both groups. An odds ratio greater than 1.0 implies that the event is more likely in the first group and an odds ratio less than 1.0 implies that the event is less likely in the first group. For example, an odds ratio of 1.5 for preoperative hypertension versus no preoperative hypertension, means that there is a 50% increase in odds for the event for patients with preoperative hypertension. For MBSAQIP hierarchical modeling, an odds ratio is also constructed for the effect of center on the outcome. For these odds ratios, the numerator is the odds for the center (where the “observed” number of events and number of non-events are adjusted by the statistical model) and the denominator is the average odds for all centers. If the odds ratio is equal to 1.0, the center is doing as expected. If
the odds ratio is greater than 1.0, the center is doing worse than expected. If the odds ratio is less than 1.0, the center is doing better than expected.

**Use of MBSAQIP for Quality Improvement**

Bi-annually, the statistical results of the data are reported back to the participating centers for their review and utilization in quality improvement. This comprehensive report includes the ORs and the hierarchical regression models. These ORs provide an overview of the assessment of quality of care in the surgical service.

Additionally, a suite of continuously updated online reports are on the website for each center to use and review. These reports are currently utilized by the participating centers for early and on-going identification of areas for quality improvement.

**Reliable Data**

One of MBSAQIP’s strengths is its capture of clinically rich data pursuant to MBSAQIP Standard 7.0, Continuous Quality Improvement. MBSAQIP assures the reliability of the data through a variety of means, such as detailed initial training, continuing education, data integrity audits, testing, monthly educational questions and ongoing conference calls. Participants in MBSAQIP have come to trust the reliability of the data and use the online reports in conjunction with the bi-annual reports to identify opportunities to improve processes and outcomes of surgical care.

**MBSAQIP Surgeon Leadership**

The MBSAQIP surgeon committee structure consists of an overarching advisory committee and two subcommittees. The Committee for Metabolic and Bariatric Surgery (CMBS) serves to better the care and welfare of obese patients through outreach, standards development, outcomes assessment, measures development and endorsement, continuing education, and the creation of national quality initiatives. Two subcommittees of the CMBS support the program:

- Standards and Verification Subcommittee is responsible for the development and maintenance of accreditation standards by validation and certification that each individual center meets accreditation criteria.

- Data and Quality Subcommittee is responsible for the data registry and provides input on analytical and reporting tools to support the needs of the program. This subcommittee also develops initiatives related to quality improvement.
collaborative work, and support of metabolic and bariatric surgical directors in leadership of their centers.

About this Operations Manual

This operations manual is intended to provide detailed guidelines for the MBSCR to assess cases and collect data for the MBSAQIP. While not all questions can be answered within a single source, this manual is a compendium of years of experience with MBSAQIP. Questions not answered in this source should be addressed with the Clinical Support Team. We hope that you find this manual a useful reference to guide your practice and we welcome feedback for future improvements.
Chapter 2 - The Data Collection Process

Overview – a snapshot of the data collection process

All metabolic and bariatric surgical procedures, including those performed by non-metabolic and bariatric surgery credentialed general surgeons, must be entered into the MBSAQIP Data Registry Platform. Documentation of each hospitalization and surgical procedure is required to obtain valid outcomes data. Data collection is ultimately the responsibility of the Metabolic and Bariatric Surgery (MBS) Director working collaboratively with the MBS Clinical Reviewer (MBSCR), the physician offices, and institution departments to ensure accurate short- and long-term results. Data is collected at 30 days, six months, one year, and annually thereafter.

The MBSAQIP Data Registry collects prospective, risk-adjusted, clinically rich data based on standardized definitions. Data variables are periodically updated, refined, added, or deleted to optimize information captured for quality improvement and assessment, while minimizing the data collection burden. The data registry was developed to minimize the ability to submit inaccurate data and to prevent missing data.

Following case identification, the MBSCR will collect the preoperative risk factors, preoperative laboratory values, and intraoperative information via a thorough review of the electronic and/or paper medical record.

After postoperative day 30 from the date of the metabolic or bariatric surgery, cases are reviewed for postoperative outcomes/occurrences, follow-up information, and entered into the data registry. Due to varying workflow processes, MBSCRs may choose to perform all aspects of data abstraction (preoperative, intraoperative, postoperative, and follow-up) after the 30th postoperative day in order to reduce the number of times the medical records are requested and/or entered. Long term follow-up data is reviewed for morbidity, mortality, readmission, reoperation, and intervention information. The data is then entered into the MBSAQIP data registry. Please keep in mind that surgical cases must be routinely reviewed to ensure entry into the data registry prior to the lock date.

Case Selection

The first step of the data collection process is case selection. It is the expectation for each site to collect 100% of the metabolic and bariatric procedures performed at their
facility. Please keep in mind that only 1 case per patient per 30 day timeframe can be entered into the data registry for a single site.

Consecutive metabolic/bariatric procedures performed within the 30 day postoperative timeframe should be captured as a reoperations or interventions as appropriate.

A list of surgical procedures performed will need to be obtained. This list is usually called an Operative Log. The MBS Director and/or MBS Coordinator, Surgical Administrator, or Operating Room (OR) Nurse Manager may guide you to the location of this log.

It is important to distinguish between an Operative Schedule and an Operative Log. The operative schedule is a list of the patients scheduled to have surgical procedures performed. It is a list prepared in advance of the day of operation. The operative schedule will not have emergency and other add-on procedures listed. The operative log documents the surgical procedures that were actually performed. This list will include elective, urgent, emergent, and add-on procedures. This list is usually produced, at minimum, the day after surgery and can provide you with the patient’s name, medical record number, procedure(s) performed, date and time of operation, OR room number, and perhaps, the type of anesthesia administered.

Once you obtain the operative log, you will need to determine which cases would be captured for MBSAQIP. To do so, you will need to find the following information:

- Procedure(s) performed with CPT code(s)
- Patient’s past surgical history

The procedure(s) performed is most often found on the operative log, with the exception of the CPT code. The CPT code is often found in the surgical department billing system or can be obtained from the Surgeon’s office. The availability of the CPT code may be several days after the performance of the surgical procedure. Please discuss the location of CPT codes with your MBS Director and/or MBS Coordinator, as well as how to obtain access to this information. It is crucial to data accuracy and reliability that you obtain access to this information.

In addition, if CPT coding is not timely, the MBSAQIP data registry provides a CPT code lookup. Simply enter the procedure name and search the database for the CPT code corresponding to the procedure performed.

### Case Inclusion

Once the MBSCR has obtained the operative log and CPT codes, the following criteria should be applied to determine case inclusion:
• Identify all primary metabolic and bariatric procedures, reoperations, revisions and interventions, as listed in Standard 6.1- Data Entry of All Metabolic and Bariatric Procedures and Interventions in MBSAQIP Standards Manual V2.0; Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient 2016. Also, refer to Appendix B of the MBSAQIP Operations Manual for a detailed list of procedures for case inclusion.
• Verify the procedure is being performed for metabolic or bariatric reasons.
• For revisional procedures, verify the patient has a history of a metabolic or bariatric procedure or surgery.
• When more than one metabolic or bariatric procedure is performed during that trip to the operating room, the most surgically complex metabolic or bariatric procedure is captured as the principal operative procedure in the MBSAQIP data registry.

Case Exclusion

Once the MBSCR has identified all of the metabolic and bariatric cases from the operative log, begin to exclude any of these cases that meet one or more of the following exclusion criteria:

• The procedure is not performed for metabolic or bariatric purposes including:
  o Cancer cases: Any patient who is admitted to the hospital and has an included procedure to address cancer.
  o Trauma cases: Any patient who is admitted to the hospital and has an included procedure to address a traumatic injury.
• Patient is under 10 years of age.
• Multiple MBSAQIP assessed cases within 30 days: Any patient who had an MBSAQIP assessed procedure entered within the previous 30 days at the site, the additional metabolic or bariatric procedure performed within 30 days is only entered as a reoperation or intervention. Only one MBSAQIP procedure can be entered into the date registry per patient, per 30 days, for a site.
• FDA preapproval trials

Where’s the Data?

Before you can begin collecting data for the MBSAQIP you need to determine where to find pertinent information. Although medical record systems can vary from hospital to hospital, certain patterns have emerged that can be utilized to guide you in your search for Program information. Consulting with people who know the hospital processes and systems best, such as MBS Director and/or the MBS Coordinator, for assistance in locating any Program information is always helpful and can save time and energy.
Patient Medical Record

Once you have determined the cases for inclusion, you are now ready to collect the preoperative, intraoperative, and postoperative information on each case. Access to the patient’s medical record is required.

The patient’s medical record at your hospital may be either paper, electronic, or some combination of the two.

- **Paper Medical Record**: It is vitally important to understand your hospital’s policy on requesting paper medical records and where they may be reviewed. There may be two types of paper record and their existence needs determination.
- **Hospital medical record**: Contains the patient’s inpatient or admission records. This record is usually located in the hospital medical record room.
- **Clinic medical record**: Contains the patient’s outpatient or clinic visit records. This record is located either in the surgical clinic or in an individual physician office.
- **Electronic Medical Record**: There may be one or more databases that contain the patient’s medical information. It may be very prudent to meet with a member of the IT Department to review the variables collected for the Program so that they may guide you to the location of the information as well as assist you in obtaining access to that information. Your MBS Director may need to approve your access to these databases as many hospital databases have high levels of security.

Data Collection Worksheet

Once case inclusion is determined, sites may choose to document the pertinent data from the operative log on the MBSAQIP data collection worksheet or directly into the MBSAQIP data registry. The MBSAQIP data collection worksheet will help guide the MBSCR as to the variables to be collected for each case. The worksheets are located in Appendix C and may be downloaded and/or printed as needed. Utilization of the MBSAQIP data collection worksheet is optional, as the MBSCR may wish to abstract information from their medical record directly into the MBSAQIP data registry. If you choose to abstract data onto the MBSAQIP paper data collection worksheet, the MBSAQIP program has no requirements to retain the data collection worksheet for future reference.

Data Collection Process
Establish the included patient/case in the MBSAQIP data registry:

Once the MBSCR have selected a case based on the inclusion/exclusion criteria, it is important that the patient be entered into the data registry in order to establish the case and obtain a case number.

The minimal information needed to set-up a patient and obtain a case number in the MBSAQIP data registry is:

- Patient’s IDN (Identification Number)
- Patient’s Date of Birth
- Date of Operation

Once the case is established in the data registry, it is recommended to file the case until postoperative day 31 or later. This will allow the MBSCR to enter all preoperative, intraoperative and 30 day postoperative information at one time, reducing the number of times in which the MBSCR enters the medical record and/or request patient charts.

**Collect the preoperative, intraoperative and postoperative variables**

After postoperative day 30, open the saved case form and begin to review the medical record for all applicable preoperative, intraoperative and postoperative information as described in Chapter 4.

Preoperative Risk Factors: Preoperative information can be obtained from, but not limited to, the history and physical, the pre-anesthesia assessment, progress notes, office visit notes, and reports from diagnostic studies. This information may also be obtained from the initial patient workup, upon transfer of the patient to the surgical service, or through a patient self-assessment that is part of the medical record.

Preoperative Laboratory Values: The MBSCR should select the preoperative lab values obtained closest to the date/time of surgery within 90 days prior to surgery or at the time the patient was being considered a candidate for surgery.

Intraoperative Information: Intraoperative information may be found in, but not limited to, the operative report, intraoperative nursing record, anesthesia intraoperative flow sheet/record, and/or brief operative note.

Postoperative Outcomes and 30 Day Follow-up: Each case entered into the MBSAQIP data registry must have the morbidity, reoperation, intervention, readmission, and mortality information followed out to 30 days postoperatively from the date of surgery. Outcome information can be obtained in a variety of ways in addition to a
thorough review of the patient’s electronic and/or paper medical record. The institution may utilize a separate clinic medical record to document outpatient follow-up visits. These records may be located either in the bariatric surgeon’s private office or the clinic. Additional methods would be either a phone call placed directly to the patient or a follow-up letter can be mailed or emailed for the patient to respond to in writing.

Enter the data into the MBSAQIP data registry

If you choose to abstract data onto a MBSAQIP data collection worksheet, once all of the pertinent information has been obtained, this information will need to be entered into the MBSAQIP data registry. If your site has chosen not to utilize the data collection worksheets, enter data directly into the MBSAQIP data registry.

Once the data entry is complete, be sure to mark the case as complete and save the case. If the case is not marked and saved as complete, the data for the case will not appear in the online reports or be included in the SAR.

30-day Follow-up

All assessed cases must be followed out to 30 days for postoperative mortality and morbidity. Refer to the 30-day follow-up guidelines in Chapter 4 and Appendix E for details to ensure complete follow-up. Each patient must be followed up to and including the 30th postoperative day, not just through discharge from the hospital.

If a patient remains in the acute hospital for 90 days after the surgical procedure, the MBSCR is responsible for following the case for 30 days for morbidity and 90 days for mortality. It is the expectation of the Program that all reasonable attempts be made to ensure complete follow-up via medical record review, and/or contact with the patient via follow-up letter or telephone call.

In order to be included in the Risk-Adjusted Semi-Annual Report (SAR) a site must have full 30 day follow-up for a minimum of 80% of cases for the SAR timeframe.

Long Term Follow-up

Centers must document each surgeon’s plan to follow the long-term progress of their metabolic and bariatric surgery patients. Documented processes should be in place to
achieve long-term follow-up of metabolic and bariatric surgery patients. Follow-up should be provided by a metabolic and bariatric specialist including:

- MBS Surgeon
- Bariatrician or physician which specializes in metabolic and bariatric practice
- Nurse practitioner
- Clinical nurse specialist
- Physician assistant

Patients lost to follow-up must have a minimum of two efforts to contact the patient (including one phone call and one letter) for each follow-up period (30-day, six-month, one-year, and annually thereafter). Patient contact attempts must be documented in all patient records. After two consecutive follow-up time periods (i.e., six-month and one-year follow-up) in which the patient remains lost to follow-up, the center may cease attempts to contact the patient.

Case Completion

Entry of Program data into the MBSAQIP data registry may be performed by the MBSCR or by a trained data entry person. However, the responsibility of case completion (thus the verification of data accuracy) lies with the MBSCR.

Data Completion Deadlines

Data must be entered into the Program data registry on a continuous basis. The goal for each site is to complete a case with full 30-day follow-up no later than 60 days after the date of surgery. Cases must be completed and saved within 90 days of the date of surgery. Cases that are greater than 90 days old are locked each night.

Once a case is locked, it cannot be accessed for editing. Incomplete and unsaved cases that are locked will not be included in the MBSAQIP online reports nor the Semiannual Risk-Adjusted Report (SAR).

Timely case accrual and completion is important in order for your data to be benchmarked against other participating site’s data. Old data is not actionable data. Additionally, if data is not collected and entered continuously it may be susceptible to last minute abstraction in anticipation of a deadline and case information may be incomplete.
Chapter 3 - Setting Up For Success

MBSCR Basics

Getting started as an MBSCR requires organization, planning, and resources. Here is a list that you may find useful to get started in your role as an MBSCR.

- Office/work space adequate for protecting patient health information
- Computer with internet and email access
- Access to programs which can read spreadsheets (such as Microsoft® Excel), word documents (such as Microsoft® Word) and a PDF reader (such as Adobe®)
- Phone with long distance capability and voicemail
  - Each MBSCR needs a dedicated phone and confidential voicemail for follow-up purposes.
- Postal Services and Email
  - MBSCR should have access to postal services at their facility in order to send and receive letters from patients to obtain 30-day follow-up.
- At times, sites have found it helpful to put a note (for example: “This is Not a Bill”) on the 30-day follow-up letter and/or envelope to obtain greater follow-up rates.
- Additional option for email follow-up: in lieu of a letter, sites may choose to send e-mails in an attempt to obtain follow-up information.
- Finalized Operative Log
  - MBSCRs will need to obtain the finalized Operative Logs for their site (not the operative schedule). This is discussed in greater depth in Chapter 2.
- Patient Chart(s)/Documents
  - You will need access to all areas of patient documentation and patient charts including:
    - Demographic information
    - Admission and discharge, dates, times, and diagnoses
    - Origin status and discharge destination
    - History & Physical, Consults, Progress Notes, Discharge Summary
    - Medication Administration Record
    - Nursing Notes
    - Ancillary Records (Physical Therapy, Respiratory Therapy, Occupation Therapy, etc.)
    - Laboratory, Microbiology, Pathology, Cytology
    - Radiology
    - Perioperative information (Preadmission testing, Preoperative record, Intraoperative record, Postoperative record or Post Anesthesia Recovery Unit record, etc.)
- Anesthesia record
- Operative report/Operative Note
- Any additional appropriate test results
- Surgeon Offices
- Hospital Follow-up
- Primary Care Provider Offices (as applicable)
- Physician Follow-up Clinic records (as applicable)

**How to obtain follow-up information**

If you are having issues obtaining records from a clinic, physician, or any other resource, please discuss this with your MBS Director, Medical Staff Office, Health Information Office, and/or other appropriate resources at your facility, for assistance in obtaining follow-up information.

**Organization System**

Due to the nature of the data collection for MBSAQIP, here are some suggestions which you may find useful to assist with data collection and long term follow-up:

- **Folder Organization System**
  - Some sites find it helpful to keep data collection sheets organized in binders
  - You may find it useful to keep cases in different folders for each follow-up period (60 days until lock date and need follow-up; 30 days until lock date and still need follow-up, etc.)

- **Color Coding**
  - You may find it useful to color-code which cases have complete follow-up versus cases that need follow-up

- **Spreadsheet for case tracking**
  - You can use this to assist you with determining attempted patient contact and methods
  - This can be used to track cases which are close to the lock date
  - It can be useful to track occurrences to assist with your site’s internal assessment to ensure data accuracy

**Develop a working relationship with your Metabolic and Bariatric Surgery (MBS) Director**
The MBS Director is the main advocate and mentor for MBSAQIP. His/her primary function is to ensure your success as the MBSCR along with the success of the program at your site. It is imperative to develop and maintain a professional and consistent working relationship with your MBS Director.

- Discuss the Program objectives.
- Describe your role as MBSCR (Metabolic and Bariatric Surgical Clinical Reviewer).
- Request his/her support in any problems encountered with collecting data elements from all members of the surgical team.
- Tell the MBS Director about the other individuals you'll be contacting to support your data collection efforts, such as the medical records staff, the ward administrator/surgical floor unit coordinators, the quality management coordinator, Infection Control, IT staff, etc.

**Additional Facility Resources and Important Hospital Contacts**

You must establish a good working relationship with the following people. However, as you work to establish yourself in the MBSCR position, be prepared to introduce yourself and the Program continuously when entering a new clinical or administrative area.

- **Chief of Anesthesia**
  - Discuss the Program objectives and your role as MBSCR.
  - Review the anesthesia variable collected for the Program. If needed, ask for his/her assistance in locating the information on the intraoperative anesthesia flowsheet.
- **Computer Support Staff (e.g. IRM, IT, IM, etc.)**
  - It is important to have the support of this service for trouble-shooting any access problems that may occur at the local site.
  - It may be of benefit to establish a computer support contact to assist you in locating data elements in the electronic medical record.
- **Supervisor/Director, Medical Records**
  - Discuss the Program with the MR Director, explaining the importance of accessing the medical records in a timely fashion.
- **Surgical Service Administrator**
  - Discuss with the administrator the importance of obtaining metered or stamped envelopes or postage for the 30-day follow-up letters. S/he should be able to assist you in obtaining these.
- **OR Nurse Manager**
  - Brief the OR Nurse Manager on the Program and explain your need to access the OR log for validation of operations performed and times in and out of the OR.
• Alert the OR staff to the importance of the accuracy and timeliness of obtaining the operative log and the intra-operative variables for MBSAQIP.

• Quality Management Coordinator and the Chief, Nursing Service
  • It will be beneficial to brief him/her on the MBSAQIP and your role.
  • Maintain contact with your professional colleagues through in-services, clinical activities and any other communications that may assist you in improving patient care through various nursing channels.

• Infection Control Practitioner
  • It will be beneficial to brief him/her on the MBSAQIP.
  • Use this contact to assist in the collection and reporting of postoperative surgical site infections, postoperative pneumonia, and other postoperative infections. You may also be helpful to the infection control practitioner to aid them in the accurate and complete collection of postoperative infections.

• Manager/Supervisor
  • Discuss the Program objectives
  • Request his/her support in any problems encountered with collecting data elements
  • Request an introduction to the billing and coding department, IT staff, Director of Medical Records and medical records personnel, Infectious Disease department, Quality Management Coordinator, Chief of Nursing Service, and/or Surgical Services Administrator

CPT® and ICD Codes

You will need access to the CPT® codes for the operative procedures. The way in which CPT® codes are obtained will vary from site to site, so it is up to each site to determine the process. The exact CPT® code you assign to each case is a site-level decision.

When determining CPT® codes for the cases listed on your operative log, it is important to note that the actual procedure performed in the operating room may differ from the procedure listed on the operative log. You should always verify the actual procedure that was performed with the surgeon’s operative note.

We recommend that your site communicates with each surgeon’s office, explaining your need for the codes for NSQIP data-reporting, and advising that you may be contacting them for CPT® codes.

Other resources for obtaining CPT® and ICD Codes:

• ICD-9, ICD-10 and CPT Code Look Up in the Data Registry
• American Medical Association (AMA) resources (online, books)
• Coding websites
• Coding Department within your hospital
• Surgeon’s offices

Discrepancies

If there is a coding discrepancy, work with your MBS Director and/or other appropriate resources at your facility to determine how to decide what the appropriate CPT® and ICD code(s) are for that case

Once a process for determining CPT® and ICD codes at your facility is completed, the MBSCR should document the agreed-upon method determined for queries regarding coding

Important Surgical Meetings

MBS Committee is considered the primary forum for Continuous Quality Improvement, as outlined in Standard 6. It provides a confidential setting for sharing best practices, for responding to adverse events, and for fostering a culture to improve patient care. All surgical practices performing bariatric surgery at the center must participate in these initiatives in a collaborative manner focusing on improved quality care for the metabolic and bariatric patient.

Internal Assessment to Ensure Data Accuracy

The MBSCR(s) at the site should determine an appropriate system to perform internal assessments of data to ensure accuracy. Some of the variables that can be checked include:

• Checking heights/weights/BMI to make sure that this information is correct
• Checking individual variables, such as a single postoperative occurrence, for multiple cases
• Review deaths have been captured at your facility for mortality data

Please keep in mind, once a case is “locked,” if you find an error, you should document this information keep it as needed for your site visit or data integrity audit. Once an error has been identified, you should attempt to put a process in place to prevent inaccurate data from being entered and saved.
Attendance & participation on conference calls

MBSCR conference calls are generally held quarterly. Topics discussed may include definition updates, definition reviews, answers to clinical questions, data collection issues, and clinical presentations. These conference calls are also important venues for the dissemination of news and information as well as sharing of ideas. Participation in these conference calls is crucial for ensuring the most up-to-date information and education.

Online Resources

- **FAQ Database**
  - The Clinical FAQ Database is an online collection of frequently asked questions submitted by MBSCRs with correspondence provided by the Clinical Team.
  - The FAQ Database is available 24/7 on the MBSAQIP Resource Portal of the data registry, and is searchable.
  - When submitting questions via the FAQ Database, MBSCRs will receive a tracking number and confirmation that the email was received by Clinical Support.
  - Please remember to review the date that the FAQ was posted to ensure that you are utilizing the most current data available. Always defer to program documents for the most current information.

- **Toolkits**
  - A toolkit for MBSCRs is available on the Resource Portal. The toolkit contains information which may be useful for sites implementing MBSAQIP.

- **MBSAQIP.org**
  - Contains MBSQIP Standards - Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient.
  - Schedule for Ask MBSAQIP - An informal, monthly webinar series where we invite you to ask Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) staff and surgeon experts anything you want to know about participation in the MBSAQIP
Chapter 4

Chapter 4 - MBSAQIP® Variables & Definitions

Demographics

- Identification Number (IDN)
- Local Medical Record Number (LMRN)
- Date of Birth
- Gender
- Race
- Hispanic Ethnicity
- Preferred Language

Surgical Profile

- Initial Primary Procedure
- History of Surgery
- Related to a Previous Surgery
- CPT Code
- Principal Operative Procedure

Case Profile

- Revision/Conversion
- Initial Procedure Performed at Your Center
- Mini-Loop Gastric Bypass (MGB)
- Gastric Plication
- Endoscopic Therapy
- Intragastric Balloon
- Vagal Blocking Therapy (VBLOC Therapy)
- Other
- CPT Code for Case Profile
- Balloon Brand
- Band Brand
- Hospital Admission Date
- Operation Date
- Anesthesia Type
- Medical Specialist
- Attending/Staff Surgeon NPI
• Attending Surgeon ID Number (IDN)
• Local Case Number (LCN)
• Encounter Number
• MBSAQIP Case Number

Preoperative Risk Assessment

There are differing timeframes for preoperative risk factors. Please be aware of the specific times frames when assigning these variables.

Only preoperative information can be utilized to assign preoperative variables; unless otherwise specified by the definition.

Exception: In the scenario where an urgent or emergent surgery is performed and the situation does not allow for complete preoperative documentation of a history and physical (H&P), information from the H&P, which was dictated postoperatively but within 48 hours of the Principal Operative Procedure, may be utilized to assign preoperative variables. Such documentation must describe the patient’s previous medical history. Information derived solely as a result of the Principal Operative Procedure or established during the postoperative timeframe may not be utilized, unless a particular variable specifically allows it. This guidance resembles current Centers for Medicare and Medicaid (CMS) rules.

General

• Height [Preop]
• Highest Recorded Weight within 1 year at the Program
• Weight Closest to Surgery
• Diabetes Mellitus Requiring Therapy with Non-Insulin Agents or Insulin [Preop]
• Current Smoker Within One Year
• Functional Health Status

Pulmonary

• History of Severe COPD
• Oxygen Dependant
• History of Pulmonary Embolism
• Obstructive Sleep Apnea Requiring CPAP/BiPAP (or similar technology)

Gastrointestinal

• Gastroesophageal Reflux Disease (GERD) Requiring Medication [Preop]

Musculoskeletal
• Is the Patient's Ambulation Limited Most or All of the Time?

Cardiac

• History of Myocardial Infarction
• Previous PCI/PTCA
• Previous Cardiac Surgery
• Hypertension Requiring Medication [Preop]
• Number of Anti-Hypertensive Medications
• Hyperlipidemia Requiring Medication [Preop]

Vascular

• Vein Thrombosis Requiring Therapy [Preop]
• Venous Stasis
• Does the patient have an IVC filter?

Renal

• Currently Requiring or On Dialysis
• Renal Insufficiency

Nutritional/Immune/Oncology/Other

• Steroid/Immunosuppressant Use for a Chronic Condition
• Therapeutic Anticoagulation
• Previous Obesity Surgery/Foregut Surgery
• Previous Organ Transplant

Preoperative Labs

• Preoperative Lab Value Information

Operative Information

Much of the operative information is obtained from the anesthesia record, operative report, operative log, and/or the surgical software entries before and during the operative procedure.

• First Assistant
• Emergency Case
• ASA Classification
• Surgical Approach
• Was the procedure converted to another approach?
• Was the Case Aborted?
• Drain Placed at Time of the Initial Operation?
• Was a swallow study performed the day of or the day after the procedure?
• Was the anastomosis checked with a provocative test to assess for leak?
• Procedure/Surgery Start Time (PST)
• Procedure/Surgery Finish (PF)

Gastric Sleeve

• Bougie (or sizing device) size
• Distance from the Pylorus (in cm)
• Staple Line Reinforcement
• Oversew

Other Procedures

• Other Procedure
• Concurrent Procedure
• Is this a Stapling Procedure? (Bariatric Stapling Procedures)

Postoperative Occurrences

Guidance: A postoperative occurrence must be reported if it presents within 30 days following the principal operative procedure AND meets any of the corresponding variable criteria. Each day comprising this 30 day postoperative period is commonly referred to as a postoperative day or POD. The 30-day postoperative period begins the date the patient's surgery ends. This date is considered postop day (POD) "0," the next day POD1, etc.

• Present at the Time of Surgery (PATOS)
• Wound Occurrences
• Superficial Incisional SSI
• Superficial Incisional SSI - PATOS
• Deep Incisional SSI
• Deep Incisional SSI - PATOS
• Organ/Space SSI
• Organ/Space SSI - PATOS
• Wound Disruption

Respiratory Occurrences

• Pneumonia
• Pneumonia - PATOS
• Intraoperative or Postoperative Unplanned Intubation
• Intraoperative/Postoperative Pulmonary Embolism
• On Ventilator > 48 Hours
• **On Ventilator > 48 Hours - PATOS**

**Urinary Tract Occurrences**

• **Progressive Renal Insufficiency/Acute Renal Failure Requiring Dialysis**
• **Urinary Tract Infection**
• **UTI - PATOS**

**Central Nervous System Occurrences**

• **Intraoperative/Postoperative Stroke/Cerebral Vascular Accident (CVA)**

**Cardiac Occurrences**

• **Intraoperative or Postoperative Cardiac Arrest Requiring CPR**
• **Intraoperative or Postoperative Myocardial Infarction**

**Other Surgical Occurrences**

• **Transfusion Intra/Postop (RBC within the First 72 Hours of Surgery Start Time)**
• **Vein Thrombosis Requiring Therapy [Postop]**
• **Postoperative Clostridium difficile (C.diff) Colitis**
• **Sepsis**
• **Sepsis - PATOS**
• **Septic Shock**
• **Septic Shock - PATOS**
• **Other Postoperative Occurrence (ICD Code)**

**Metabolic/Bariatric Postoperative Occurrences**

• **Coma > 24 Hours**
• **Peripheral Nerve Injury**
• **Unplanned Admission to ICU within 30 Days**
• **Other Postoperative Occurrence (ICD Code)**

**Discharge Information**

• **Acute Hospital Discharge Date**
• **Hospital Discharge Destination**
• **Still in Hospital > 30 Days**
• **Death During Operation (Intraoperative Death) or Postoperative Death within 30 Days of Procedure**
• **Date of Death [30 Day]**
• **Was the Death Likely Related to the Operation?**
• **Most Likely Cause of Death**
• **Was the Death Reviewed by the Bariatric Committee within 60 Days of Death?**
• Did the Patient Receive Treatment for Dehydration (Nausea and Vomiting, Fluid, Electrolyte, or Nutritional Depletion) as an Outpatient?
• Was the Patient Seen in any Emergency Department (ED) Which Did Not Result in an Inpatient Admission?

Hospital Readmissions

• Did the Patient have a Hospital Readmission within 30 Days of the Principal Procedure?

Reoperations/Interventions Performed After the Principal Metabolic or Bariatric Procedure

Reoperations

• Did the Patient have a Reoperation within the 30 Day Postoperative Period?
• Was this Reoperation Unplanned at the Time of the Principal Procedure?
• Most Likely Reason for Reoperation
• Date Performed
• Information Source

Interventions

• Did the Patient have an Intervention within the 30 Day Postoperative Period?
• Was this Intervention Unplanned at the Time of the Principal Procedure?
• Intervention
• Most Likely Reason for Intervention
• Anesthesia Type
• Date Performed
• Information Source

Visit Period

• Were You Able to Follow the Patient for the Full 30 Days?
• What is the Assessment Date? [30 Day]
• Was an Exam Performed by a Bariatric Physician, Nurse Practitioner, or Physician's Assistant?
• Was the Patient Seen By Any Clinician?

General

• Weight
• Was Anticoagulation Initiated for Presumed/Confirmed Venous Thrombosis/PE? [30 Day]
• Was an Incisional Hernia Noted on Exam? [30 Day]
• Was an Operative Drain Still Present at 30 Days?

Attempts By the Bariatric Center to Contact Patient

• Long Term Follow-up Guidance
• Was a Follow-Up Appointment Made but Patient Did Not Show for Appointment?
• Was a Phone Call Placed to the Patient?
• Was a Letter Sent to the Patient?
• Was the Patient's Care Transferred to Another Bariatric Specialist?
• Is the Patient Refusing Follow-Up?

Contact Management

• Patient Contact Management [30 Day]

Long Term Follow Up

• What is the Assessment Date? [Long Term]
• Is the Patient Alive?
• Was an Exam Performed by a Bariatric Physician, Nurse Practitioner, or Physician's Assistant?
• Was the Patient Seen By Any Clinician?

General

• Height [Long Term]
• Weight
• Was Anticoagulation Initiated for Presumed/Confirmed Venous Thrombosis/PE? [Long Term]
• Was an Incisional Hernia Noted on Exam? [Long Term]

Comorbidity List

• Sleep Apnea
• Gastroesophageal Reflux Disease (GERD) Requiring Medication [Long Term]
• Hyperlipidemia Requiring Medication [Long Term]
• Hypertension Requiring Medication [Long Term]
• Number of Anti-Hypertensive Medications
• Diabetes Mellitus Requiring Therapy with Non-Insulin Agents or Insulin [Long Term]

Attempts By the Bariatric Center to Contact Patient

• Was a Follow-Up Appointment Made but Patient Did Not Show for Appointment?
• Was a Phone Call Placed to the Patient?
• Was a Letter Sent to the Patient?
• Was the Patient's Care Transferred to Another Bariatric Specialist?
• Is the Patient Refusing Follow-Up?
• Is the Patient Lost to Follow-Up?

Mortality Information

If mortality occurs, please enter the date of the patient's death and the suspected cause of death.

• Date of Death [Long Term]
• Was the Death Likely Related to the Operation?
• Most Likely Cause of Death

Hospital Readmissions

It is not necessary to capture unrelated readmissions after the one year follow-up period.

• Did the Patient have a Hospital Readmission?

Reoperations/Interventions

It is not necessary to capture unrelated reoperations and interventions after the one year follow-up period.

• Did the Patient have a Reoperation/Intervention?
• Reoperations
• CPT code for Reoperation
• Interventions
• Most Likely Reason for Reoperations/Intervention
• Date Performed
• Information Source
• Was this Reoperation/Intervention Likely Related to a Bariatric or Metabolic Procedure?

Contact Management

• Patient Contact Management [Long Term]
Demographics

Identification Number (IDN)

Variable Name: Identification Number (IDN)

Intent of Variable: This number can be used to look up the patient in the MBSAQIP registry.

Definition: The identification number (IDN) is a unique number, which permanently identifies the patient in the MBSAQIP database.

Criteria: The IDN is a permanent number which is distinct to that particular patient and is assigned at the discretion of the participating hospital.

Options:
- Enter Value

Notes:
- The IDN and Birth Date are the two required fields used to establish the patient in the MBSAQIP database.
- If a patient appears in subsequent samplings (operative logs) and meets criteria, a new case form should be added to that existing patient IDN, instead of creating a new IDN.
- The IDN is transmitted securely to the MBSAQIP database.
Local Medical Record Number (LMRN)

Variable Name: Local Medical Record Number (LMRN)

Intent of Variable: To allow institutions to capture a record number relevant to local purposes.

Definition: The LMRN is a distinct number representing the patient and is assigned by the hospital.

Criteria: A site may choose to create a LMRN or use an existing site number.

Options:
- Enter Value

Notes:
- For hospitals with a web based version of the workstation, both the IDN and LMRN are transmitted securely to the MBSAQIP database.
Date of Birth

Variable Name: Date of Birth

Intent of Variable: To be able to calculate patient’s age at the time of the principal operative procedure.

Definition: Date the patient was born.

Criteria: Enter patient’s date of birth in the format of mm/dd/yyyy.

Options:
- Enter date (mm/dd/yyyy)

Notes:
- The IDN and Birth Date are the two required fields used to establish the patient in the MBSAQIP database.
- The database will not accept patients under age 10.
Gender

Variable Name: Gender

Intent of Variable: To capture gender for purpose of analysis. Gender can confer differential risk.

Definition: Distinguish between males and females.

Criteria: Report the patient’s gender as per the medical record.

Options:

- Male
- Female

Notes:

- If your hospital assigns a gender not listed as male or female, please follow up with your Metabolic and Bariatric Surgery Director or the surgeon who performed the case for guidance.
Race

Variable Name: Race

Intent of Variable: To capture the race assigned to the patient at the institution. This may be self-assigned by the patient or assigned by institutional personnel per internal practices. Race can be utilized to investigate disparities in care or other relevant issues.

Definition:

- **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
- **Black or African American:** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" can be used in addition to "Black" or "African American."
- **American Indian or Alaska Native:** A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.
- **Native Hawaiian or Other Pacific Islander:** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- **Asian:** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
- **Unknown:** if documentation does not state patient’s race, report as Unknown.

Criteria: Report the patient’s race as per the medical record or as self-assigned by the patient.

Options:

- White
- Black or African American
- American Indian or Alaska Native
- Native Hawaiian or Other Pacific Islander
- Asian
- Unknown/Not Reported

Notes:

- Categories are consistent with the US Census Bureau.
- If documentation indicates the patient has more than one race (e.g. Black-White or Indian-White), select the first race listed.
- Although the terms Hispanic and Latino are actually descriptions of the patient’s ethnicity, it is not uncommon to find them referenced as race. If the patient’s race is documented only as Hispanic/Latino, select “White.”
• If the patient is documented as bi-racial such as Black and Hispanic or multi-racial, then use whatever race is listed first (e.g. Black-Hispanic – select Black).
• Hispanic/Latino Ethnicity is a separate variable (listed below) where you can report the patient’s ethnicity.
Hispanic Ethnicity

Variable Name: Hispanic Ethnicity

Intent of Variable: To capture the ethnicity assigned to the patient at the institution. This may be self-assigned by the patient or assigned by institutional personnel per internal practices. Ethnicity can be utilized to investigate disparities in care or other relevant issues.

Definition: Hispanic or Latino is defined as a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, “Spanish origin,” can be used in addition to “Hispanic” or “Latino.”

Criteria: Report if the patient is of Hispanic or Latino ethnicity as per the medical record or as self-assigned by the patient.

Options:

- Yes
- No
- Unknown

Notes:

- Race is required in addition to this data element.
Preferred Language

Variable Name: Preferred Language

Intent of Variable: This field is linked to the 30 day follow-up letter function. The follow-up letter will be generated in the language selected.

Definition: Patient’s preferred spoken language.

Criteria: Report the patient’s language as either English or Spanish.

Options:

- English
- Spanish
Surgical Profile

Does the Patient Have a History of Metabolic or Bariatric Surgery?

Variable Name: Does the Patient Have a History of Metabolic or Bariatric Surgery?

Intent of Variable: To assist in determining if the patient has a prior metabolic or bariatric surgery.

Definition: See "Criteria" section below.

Criteria: Please indicate if the patient has a history of surgery for metabolic or bariatric purpose.

Options:

- Yes
- No

Scenarios to Clarify (Assign Variable):

- The patient has any history of metabolic or bariatric surgery.

Scenarios to Clarify (Do Not Assign Variable):

- Do not capture cases which are not being completed for bariatric or metabolic purposes.
  - Patient undergoes a Roux-en-Y gastric Bypass due to cancer. As this case was not completed for metabolic or bariatric purposes, this case would not be captured in the database.
  - Patient is status post gastric sleeve. Patient undergoes a Roux-en-Y gastric Bypass due to cancer. As this case was not completed for metabolic or bariatric purposes, this case would not be captured in the database.

Notes:
If "No" is chosen for all of the following questions, this indicates that this procedure was not completed for metabolic or bariatric purposes and should not be captured in the workstation.

- Is the principal operative procedure an initial primary metabolic or bariatric procedure?
- Does the patient have a history of metabolic or bariatric surgery?
- Is the principal operative procedure related to a previous metabolic or bariatric surgery?
Is the Principal Operative Procedure Related to a Previous Metabolic or Bariatric Surgery?

**Variable Name:** Is the Principal Operative Procedure Related to a Previous Metabolic or Bariatric Surgery?

**Intent of Variable:** To assist in determining if the principal operative procedure is a revision or reoperation of a prior metabolic or bariatric surgery.

**Definition:** See "Criteria" section below.

**Criteria:** Please indicate if the principal operative procedure is related to a prior metabolic or bariatric procedure.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- The patient has any history of metabolic or bariatric surgery.

**Scenarios to Clarify (Do Not Assign Variable):**
- Do not capture cases which are not being completed for bariatric or metabolic purposes.
  - Patient undergoes a Roux-en-Y gastric Bypass due to cancer. As this case was not completed for metabolic or bariatric purposes, this case would not be captured in the database.
  - Patient is status post gastric sleeve. Patient undergoes a Roux-en-Y gastric Bypass due to cancer. As this case was not completed for metabolic or bariatric purposes, this case would not be captured in the database.

**Notes:**
- If “No” is chosen for all of the following questions, this indicates that this procedure was not completed for metabolic or bariatric purposes and should not be captured in the workstation.
  - Is the principal operative procedure an initial primary metabolic or bariatric procedure?
  - Does the patient have a history of metabolic or bariatric surgery?
- Is the principal operative procedure related to a previous metabolic or bariatric surgery?


Intent of Variable: To capture the CPT® code of which corresponds to the principal operative procedure being reviewed in MBSAQIP.

Definition: Per the American Medical Association (AMA) CPT codes are “…medical nomenclature used to report medical procedures and services…” (AMA, 1995-2012) *. The CPT® code system is copyrighted by the American Medical Association (AMA).

Criteria: Provide the CPT® code of the principal operative procedure as reported in the Operative report, operative note, operating room log, or surgical billing.

Options:
- Enter value
- Entering the Procedure Description is optional

Scenarios to Clarify (Assign Variable):
- Assign most complex metabolic or bariatric surgical procedure
- Example: Patient has a removal of a lap band and a Roux-en-Y Gastric Bypass performed. The most surgically complex case would be the Roux-en-Y Gastric Bypass and the lap band removal would be entered as an “Other” or “Concurrent” procedure.

Notes:
- CPT Code (Guidance): When assigning the CPT Code of the principal operative procedure, use the CPT code of the principal bariatric or metabolic operative procedure as reported in the Operative Report, Operative Note, Operating Room log, or surgical billing. This code must be on the MBSAQIP list of CPT codes for this procedure to be entered into the database.

In those instances where a bariatric or metabolic procedure has an assigned CPT code which is not on the MBSAQIP CPT code list (e.g. laparoscopic anastomotic revision, endoscopic overstitch, open removal of lap band) but is required to be captured by the program (e.g. reversals, take downs, laparoscopic internal hernia repairs), please assign the unlisted CPT code of 43659 or 43999 in order to capture the case in the database.

If you assign an unlisted CPT code (43659 or 43999) as the principal operative procedure, this will trigger the secondary CPT code field under the Case Profile
section. Here you will enter the CPT code assigned by your site for the principal operative procedure. If your site has assigned one of the unlisted codes for the principal operative procedure, please re-enter the unlisted code in the Case Profile CPT code field.

- **Unlisted CPT Codes:**
  - 43659 for laparoscopic approach
  - 43999 for open approach

- **Guidance** - If the intended surgical procedure was not performed or was aborted, capture the intended procedure if the CPT code meets inclusion criteria. If the intended procedure was not completed due to an intraoperative complication, the case (based upon intended procedure) should still be captured. See example listed below.
  - **Example:** Patient enters the Operating Room for an open Roux-en-Y and the patient codes during surgery; the procedure is stopped (aborted) to administer CPR. The patient expires in the Operating Room. This case would be reviewed as the open Roux-en-Y and the intraoperative occurrence of death would be assigned to the intended open Roux-en-Y procedure.
  - **Example:** Patient enters the Operating Room for a laparoscopic sleeve gastrectomy. Upon starting the procedure, the surgeon encounters numerous adhesions which take several hours to remove. The surgeon ends up only performing the lysis of adhesions and elects not to perform the sleeve gastrectomy. This case would be reviewed as a sleeve gastrectomy as this was the intended procedure.
  - **Example:** If the principal operative procedure was underway via the laparoscopic approach and then a determination was made to convert to an open approach, code the open approach as the Principal Operative Procedure.

- **ACS advises each MBSCR to discuss and develop an internal process for determining the correct CPT® code with their Bariatric Director and/or administration. MBSAQIP is reluctant to mandate particular internal processes for each institution on this issue, but will attempt to assist institutions once internal resources have been involved.**
Principal Operative Procedure

Variable Name: Principal Operative Procedure

Intent of Variable: To assist in determining which surgical procedure and corresponding CPT® code will be the primary MBSAQIP abstracted procedure. This procedure is considered the primary focus of assessment.

Definition: See Criteria section below

Criteria: The principal operative procedure is the bariatric or metabolic procedure performed during this encounter in the operating room. If more than one bariatric or metabolic procedure is performed, report the most surgically complex procedure as the principal operative procedure. Additional procedures requiring separate CPT codes and/or concurrent procedures will be entered separately in the “Other Procedures” or “Concurrent Procedures” categories in the “Other Procedures” tab of the MBSAQIP database.

Notes:

- ACS advises each MBSCR to discuss and develop an internal process for determining the correct Principal Operative Procedure with their Bariatric Director and/or administration. MBSAQIP is reluctant to mandate particular internal processes for each institution on this issue, but will attempt to assist institutions once internal resources have been involved.
Case Profile

Revision/Conversion

Variable Name: Revision/Conversion

Intent of Variable: To identify operative procedures which are metabolic or bariatric revisions or conversions.

Definition: A revision is a procedure in which the patient has a history of having a metabolic or bariatric procedure for weight loss or metabolic purposes and the bariatric or metabolic procedure is revised. A conversion is a procedure in which the patient has a history of having a metabolic or bariatric procedure for weight loss or metabolic purposes and the metabolic or bariatric procedure is revised or converted to another type of bariatric or metabolic procedure.

Criteria: Indicate if the principal operative procedure CPT code is for a revisional procedure or conversional procedure.

Options:

- Yes
- No

Scenarios to Clarify (Assign Variable):

- Patient has any history of metabolic or bariatric surgery.
- The patient has a history of an intragastric balloon placement and the principal operative procedure is a revision or removal of the intragastric balloon.

Scenarios to Clarify (Do Not Assign Variable):

- The patient has a history of intragastric balloon placement and removal.

Notes:

- If the principal operative procedure CPT code is for a revisional procedure, conversion procedure, mini-loop gastric bypass, gastric plication, endoscopic primary or revisional procedure, investigational or clinical trial procedure, or “unlisted” code (either 43659 or 43999), indicate the performed procedure(s) by checking “Yes” to all the options that apply.
- If you enter either “Unlisted” CPT code 43659 or 43999, please choose one of the previous options as well as complete the CPT® (Current Procedural Terminology) Code for Case Profile field.
• If "yes" is marked for "Revision/Conversion," the case will **not** be eligible for inclusion in the SAR.
Was the Initial Primary Metabolic or Bariatric Procedure Performed at your Center?

Variable Name: Was the Initial Primary Metabolic or Bariatric Procedure Performed at your Center?

Intent of Variable: To identify whether the patient’s initial metabolic or bariatric surgical procedure was completed at the same site as that is performing the revision/conversion.

Definition: See criteria below.

Criteria: The patient’s initial metabolic or bariatric surgical procedure was completed at the site which is now performing a revision/conversion of the initial metabolic or bariatric surgical procedure.

Options:

- Yes
- No

Scenarios to Clarify (Assign Variable):

- The patient’s initial metabolic or bariatric surgical procedure is not captured in your site’s MBSAQIP database but completed at your site.
- The patient’s initial metabolic or bariatric surgical procedure was completed by a different surgeon or a surgeon at a different practice, both of whom operate at your site.

Scenarios to Clarify (Do Not Assign Variable):

- The patient’s initial metabolic or bariatric surgical procedure was not completed at your site.
Mini-Loop Gastric Bypass (MGB)

Variable Name: Mini-Loop Gastric Bypass (MGB)

Intent of Variable: To identify patients for which a mini-loop gastric bypass was the principal operative procedure.

Definition: A surgical technique used during the bariatric or metabolic procedure where the surgeon creates a surgical configuration at the top of the small intestine in an area called the jejunum. Part of the small intestine is connected directly to the stomach pouch.

Criteria: A mini-gastric bypass (MGB) procedure which includes a loop gastrojejunostomy.

Options:

- Yes
- No

Notes:

- If the principal operative procedure CPT code is for a revisional procedure, conversion procedure, mini-loop gastric bypass, gastric plication, endoscopic primary or revisional procedure, investigational or clinical trial procedure, or “unlisted” code (either 43659 or 43999), indicate the performed procedure(s) by checking “Yes” to all the options that apply.
- If you enter either “Unlisted” CPT code 43659 or 43999, please choose one of the previous options as well as complete the CPT® (Current Procedural Terminology) Code for Case Profile field.
- If "Yes" is marked for "Mini-Loop Gastric Bypass (MGB)," the case will not be eligible for inclusion in the SAR.
Gastric Plication

Variable Name: Gastric Plication

Intent of Variable: To capture patients who underwent a bariatric or metabolic procedure that utilized restrictive surgical methods.

Definition: A restrictive surgical procedure that reduces the size of the stomach and limits food intake by plicating (folding) the stomach along the outer curvature.

Criteria: A restrictive surgical procedure that does not involve the removal of any part of the stomach or bypass of the intestine, but rather by plication (folding) of the stomach.

Options:
- Yes
- No

Scenarios to Clarify (Assign Variable):
- Laparoscopic Greater Curvature Plication (LGCP)
- Laparoscopic Gastric Plication (LGP)
- One row plication
- Two row plication
- Combination procedures

Scenarios to Clarify (Do Not Assign Variable):
- Sleeve Gastrectomy
- Vertical Sleeve Gastrectomy (VSG)
- Vertical Banded Gastroplasty (VGB)
- Gastric Imbrication
- Adjustable Gastric Band (Lap-Band® or AGB)
- Plication performed at same time as resection
- Oversewing of the Staple Line

Notes:
- Gastric Plication may potentially be reversed or converted to another procedure, if needed.
- Gastric Plication can be performed with or without banding.
- As gastric plication is still considered an investigational procedure, the site must have IRB approval.
• If the principal operative procedure CPT code is for a revisional procedure, conversion procedure, mini-loop gastric bypass, gastric plication, endoscopic primary or revisional procedure, investigational or clinical trial procedure, or “unlisted” code (either 43659 or 43999), indicate the performed procedure(s) by checking “Yes” to all the options that apply.

• If you enter either “Unlisted” CPT code 43659 or 43999, please choose one of the previous options as well as complete the CPT® (Current Procedural Terminology) Code for Case Profile field.

• If "Yes" is marked for "Gastric Plication," the case will not be eligible for inclusion in the SAR.
Endoscopic Therapy

**Variable Name:** Endoscopic Therapy

**Intent of Variable:** To capture patients who have undergone a primary bariatric or metabolic or revisional bariatric or metabolic procedure utilizing the endoscopic approach.

**Definition:** Bariatric or metabolic surgical procedures performed using only an endoscopic approach.

**Criteria:** A primary bariatric or metabolic or revisional bariatric or metabolic procedure performed for weight loss or metabolic purposes utilizing only an endoscopic approach.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- Assign if N.O.T.E.S. was the only surgical approach for the principal operative procedure.

**Scenarios to Clarify (Do Not Assign Variable):**
- Do not assign for intragastric balloon cases.
- Do not assign if the principal operative procedure approach was single incision, robotic-assisted, laparoscopic, laparoscopic assisted, or open.

**Notes:**
- If the principal operative procedure CPT code is for a revisional procedure, conversion procedure, mini-loop gastric bypass, gastric plication, endoscopic primary or revisional procedure, investigational or clinical trial procedure, or "unlisted" code (either 43659 or 43999), indicate the performed procedure(s) by checking “Yes” to all the options that apply.
- If you enter either “Unlisted” CPT code 43659 or 43999, please choose one of the previous options as well as complete the CPT® (Current Procedural Terminology) Code for Case Profile field.
- If "Yes" is marked for "Endoscopic Therapy," the case will **not** be eligible for inclusion in the SAR.
Intragastric Balloon

Variable Name: Intragastric Balloon

Intent of Variable: To capture the insertion of an intragastric balloon related to a metabolic or bariatric diagnosis for the purposes of weight loss.

Definition: See criteria below.

Criteria: The endoscopic insertion of an intragastric balloon (ORBERA®, ReShape) for weight loss or metabolic purposes.

Options:

- Yes
- No

Scenarios to Clarify (Assign Variable):

- Assign for intragastric balloon insertion revision, or removal.

Notes:

- If "Yes" is marked for "Intragastric Balloon," the case will not be eligible for inclusion in the SAR.
Vagal Blocking Therapy (VBLOC™ Therapy)

**Variable Name:** Vagal Blocking Therapy (VBLOC™ Therapy)

**Intent of Variable:** To capture the insertion of a Vagal Blocking Therapy (VBLOC™ Therapy) device related to a metabolic or bariatric diagnosis for the purposes of weight loss.

**Definition:** See criteria

**Criteria:** The insertion of Vagal Blocking Therapy (VBLOC™ Therapy) device for weight loss or metabolic purposes.

**Options:**

- Yes
- No

**Notes:**

- If "Yes" is marked for "Vagal Blocking Therapy (VBLOC™ Therapy)," the case will **not** be eligible for inclusion in the SAR.
Other

Variable Name: Other

Intent of Variable: To capture patients undergoing bariatric or metabolic procedures which are non-standard procedures that require IRB approval.

Definition: Non-standard procedures that require IRB approval.

Criteria: Gastric or metabolic surgical procedures that are performed using non-standard techniques and have granted IRB approval from the site.

Options:

- Yes
- No

Scenarios to Clarify (Assign Variable):

- For endoscopic gastric bubble procedures select both the “Endoscopic Therapy” and “Other” options.

Notes:

- If "Yes" is marked for "Other," the case will not be eligible for inclusion in the SAR.

**Variable Name:** CPT® (Current Procedural Terminology) Code for Case Profile

**Intent of Variable:** To capture the CPT® code of which corresponds to the principal operative procedure being reviewed in MBSAQIP.

**Definition:** Per the American Medical Association (AMA) CPT codes are “…medical nomenclature used to report medical procedures and services…” (AMA, 1995-2012) *. The CPT® code system is copyrighted by the American Medical Association (AMA).

**Criteria:** If you assigned either “Unlisted” CPT code 43659 or 43999, provide the CPT® code of the principal operative procedure as reported in the OR report, operative note, operating room log, or surgical billing.

**Options:**
- Enter value
- Entering the Procedure Description is optional

**Scenarios to Clarify (Assign Variable):**
- Assign most complex metabolic or bariatric surgical procedure.

**Notes:**
- If you assign either unlisted CPT code (43659 or 43999) as the principal operative procedure, please complete the secondary CPT code field under the Case Profile Section. Here you will enter the CPT code assigned by your site for the principal operative procedure. If your site has assigned one of the unlisted codes, please re-enter the unlisted code.
- ACS advises each MBSCR to discuss and develop an internal process for determining the correct CPT® code with their Bariatric Director and/or administration. MBSAQIP is reluctant to mandate particular internal processes for each institution on this issue, but will attempt to assist institutions once internal resources have been involved.
**Balloon Brand**

**Variable Name:** Balloon Brand

**Intent of Variable:** To capture patients whose bariatric or metabolic surgical procedure utilized the placement of an intragastric balloon.

**Definition:** A bariatric or metabolic surgical procedure in which an intragastric balloon is placed in the patient’s stomach to restrict the amount of oral intake.

**Criteria:** If the principal procedure is the placement of an intragastric balloon, please select the brand of balloon used.

**Options:**

- Elipse™ (Allurion Technologies)
- Obalon™ (Obalon Therapeutics)
- Orbera™ (Apollo Endosurgery)
- ReShape™ (ReShape Medical)
- Spatz™ (Spatz)
- Other
- Unknown
**Band Brand**

**Variable Name:** Band Brand

**Intent of Variable:** To capture patients whose bariatric or metabolic surgical procedure utilized the placement of a gastric band.

**Definition:** A bariatric or metabolic surgical procedure in which an adjustable gastric band is placed around the patient’s stomach to restrict the amount of oral intake.

**Criteria:** If the principal procedure CPT code is related to bands (43770, 43772, 43773, 43774), please select the brand of band used.

**Options:**
- Realize™ Band (Ethicon)
- Lap-Band™(Allergan/Inamed)
- Other
- Unknown
Hospital Admission Date

Variable Name: Hospital Admission Date

Intent of Variable: This is to capture the date that the patient was considered officially admitted to the acute hospital setting.

Definition: The date the patient was admitted to your hospital/institution’s acute care setting.

Criteria: The date the institution has assigned to the start of the acute care for the hospital admission for the principal operative procedure.

Options:

- Enter date (mm/dd/yyyy)
- Enter time (hh:mm)

Notes:

- If the patient came through the Emergency Department or a same-day elective surgery program, went directly to the operating room, and was admitted to the hospital, then use either the date the patient enters the operating room or the date that anesthesia care begins; (whichever comes first) as the date of admission. Do not use the date the patient came into the Emergency Department.
- Admission time is an optional variable that is not required to complete the case.
**Operation Date**

**Variable Name:** Operation Date

**Intent of Variable:** To capture the date when the patient enters the surgical suite for the principal operative procedure.

**Definition:** The date the patient enters the surgical suite for the principal operative procedure.

**Criteria:** Enter the date the patient enters the surgical suite for the principal operative procedure being captured in MBSAQIP.

**Options:**

- Enter date (mm/dd/yyyy)

**Notes:**

- If the date of operation runs over into the next day enter either the date that anesthesia care begins or the date the patient enters the operating room, whichever comes first.
- The IDN and Birth Date are the two required fields used to establish a patient in the MBSAQIP database. Once established in the MBSAQIP database, the Operation Date is required to generate a Case Number.
- Subsequently the operative date fields are prepopulated from this date, but finish date can be modified if needed.
Anesthesia Type

Variable Name: Anesthesia Type

Intent of Variable: To capture the type of anesthesia administered during intragastric balloon cases.

Definition: The type of anesthesia administered during the intragastric balloon case, as reported by the anesthesia provider.

Criteria: Select from the list below the principal anesthesia technique used during the intragastric balloon intervention case as documented by the anesthesia provider or nurse providing IV sedation.

Options: Select the appropriate anesthesia technique from the dropdown menu.

- General- including IV anesthesia with intubation or laryngeal mask airway (LMA).
- Monitored anesthesia care (MAC)/IV sedation. Also, categorize cases where IV sedation is administered in the Operating Room by a registered nurse.
- Topical
- None
- Other
- Unknown

Notes:

- Anesthesia providers would include: anesthesiologists, anesthesia fellows, anesthesia residents, Certified Registered Nurse Anesthetists, and Certified Registered Nurse Anesthetist students.
- If IV sedation is provided by a registered nurse, you may use the medical record.
- This variable will only be answered if “Yes” is checked for “Intragastric Balloon.”
Medical Specialist

Variable Name: Medical Specialist

Intent of Variable: To capture the medical specialty of the physician performing the principal operative procedure.

Definition: See criteria below.

Criteria: Select the medical specialty of the physician performing the principal operative procedure.

Options: Select the most appropriate specialty from the drop down menu.

- Metabolic and bariatric surgeon
- General surgeon
- Gastroenterologist
- Interventional radiologist
- Other healthcare professional
Attending/Staff Surgeon NPI

Variable Name: Attending/Staff Surgeon NPI

Intent of Variable: For sites to have the ability to track each surgeon’s surgical cases.

Definition: “The NPI is a unique identification number for health care providers that will be used by all health plans. Health care providers and all health plans and health care clearinghouses will use the NPIs in the administrative and financial transactions specified by HIPAA. The NPI was proposed as an 8-position alphanumeric identifier. However, many commenters preferred a 10-position numeric identifier with a check digit in the last position to help detect keying errors. The NPI contains no embedded intelligence; that is, it contains no information about the health care provider such as the type of health care provider or State where the health care provider is located.”

Criteria: Assign the Attending Surgeon’s NPI.

Options:

• Select the appropriate Surgeon (NPI).

+Cen...
Attending Surgeon ID Number (IDN)

Variable Name: Attending Surgeon ID Number (IDN)

Intent of Variable: For sites to have the ability to track each surgeon’s surgical cases.

Definition: A number assigned to each surgeon by their hospital.

Criteria: Each surgeon must be given a unique identifying number assigned by the hospital.

Options:
- Select the appropriate Surgeon (NPI) from the dropdown menu.

Notes:
- This variable will not be transmitted. It is for the hospital's internal use only.
- To create a surgeon list in the database:
  A. Select the “My Account” tab
  B. Select “Manage Custom Lists”
  C. Select “Surgeon”
  D. Select “New Code”
  E. Enter the surgeon information and select “Save”

- If you have entered a duplicate surgeon or need to deactivate a surgeon, go to the “My Account” Tab and select “Manage Custom Lists” link: Select the “Surgeon” link, and then select “Edit” for the duplicate surgeon or surgeon which needs to be deactivated from the list. Enter the past date 01/01/1999 for “Starting Date” and 01/02/1999, for “Ending Date,” and select “Save.” This surgeon entry will now be removed from the list on the forms.
LCN

Variable Name: LCN

Intent of Variable: To allow hospitals the option to assign a separate unique tracking number.

Definition: The local case number (LCN) is an optional number the hospital can assign.

Criteria: Per sites discretion.

Options:
- Enter value (optional)

Notes:
- This field may be utilized for internal tracking purposes.
- This is an optional variable that is not required to complete the case.
Encounter Number

Variable Name: Encounter Number

Intent of Variable: To allow hospitals the option to assign a separate unique tracking number.

Definition: The encounter number is an additional optional number the hospital can assign.

Criteria: Per site’s discretion.

Options:

- Enter value (optional)

Notes:

- This field may be utilized for internal tracking purposes.
- This is an optional variable that is not required to complete the case.
**MBSAQIP Case Number**

**Variable Name:** MBSAQIP Case Number

**Intent of Variable:** The case number is the identifier for a patient's particular surgical procedure.

**Definition:** A workstation generated case ID number to show that a case has been entered into the MBSAQIP.

**Criteria:** The minimal information needed to set up a case in the database is:

- IDN
- Date of Birth
- Date of Operation

**Options:** Case number is automatically generated by the database after entering the above criteria.

**Notes:**

- Record the case number on your data collection form. The case number is utilized by QuintilesIMS to identify and resolve any data entry issues you may encounter.
- This number is not a patient identifier, but rather an identifier for the surgical procedure being abstracted.
Preoperative Risk Assessment
General

Height [Preop]

Variable Name: Height

Intent of Variable: To capture the height of the patient to calculate body mass index (BMI).

Definition: The height of a patient.

Criteria: Report the patient’s most recent height documented in the medical record in either inches (in) or centimeters (cm) within the 30 days prior to the principal operative procedure or at the time the patient is being considered a candidate for surgery.

Options:

- Enter value
  - Select centimeters/inches
- Unknown
**Highest Recorded Weight within 1 Year at the Program**

**Variable Name:** Highest Recorded Weight within 1 year at the Program

**Intent of Variable:** To capture the highest recorded weight of the patient taken by the bariatric center or bariatric specialist’s office within one year prior to the principal operative procedure.

**Definition:** The amount a patient weighs.

**Criteria:** Report the patient’s highest weight documented in the medical record in either pounds (lbs.) or kilograms (kg), within one year prior to the principal operative procedure.

**Options:**
- Enter value
  - Select pounds/kilograms
- Enter date for Highest Recorded Weight, if known.
  - Select “Unknown” if the date of Highest Recorded Weight is not known.
- Select “Unknown” if the highest weight is not known.

**Scenarios to Clarify (Do Not Assign Variable):**
- Do not enter any weights that are self-reported by the patient.

**Notes:**
- If the same (highest) weight is noted on 2 dates, please enter the date of the first highest recorded weight within 1 year.
**Weight Closest to Surgery**

**Variable Name:** Weight Closest to Surgery

**Intent of Variable:** To capture the weight of the patient to calculate body mass index (BMI).

**Definition:** The amount a patient weighs.

**Criteria:** Report the patient’s most recent weight documented in the medical record in either pounds (lbs.) or kilograms (kg) within the 30 days prior to the principal operative procedure or at the time the patient is being considered a candidate for surgery.

**Options:**

- Enter value
  - Select pounds/kilograms
- Enter date for Weight Closest to Surgery, if known.
  - Select “Unknown” if the date of Weight Closest to Surgery is not known.
- Select “Unknown” if the Weight Closest to Surgery is not known.
Diabetes Mellitus Requiring Therapy with Non-Insulin Agents or Insulin [Preop]

Variable Name: Diabetes Mellitus Requiring Therapy with Non-Insulin Agents or Insulin

Intent of Variable: To differentiate three groups of patients with respect to diabetes: those not requiring therapy or controlled by diet alone, those requiring a non-insulin agent, and those requiring insulin. This should reflect how the patient is treated on a chronic basis prior to admission, not how they are managed in the hospital immediately prior to surgery. The diabetic who comes in and is sick, who has been treated with oral agents may need coverage with a sliding scale. This does not qualify as a diabetic treated with insulin. Diabetes may put a patient at increased risk for infection, delayed wound healing, renal and cardiac dysfunction.

Definition: Diabetes mellitus is a metabolic disorder of the pancreas whereby the individual requires careful monitoring of diet or regular dosages of exogenous parenteral insulin or a non-insulin anti-diabetic agent to prevent hyperglycemia/metabolic acidosis.

Criteria: Report the treatment regimen of the patient’s chronic, long-term management (treated > 2 weeks) within the 30 days prior to the principal operative procedure or at the time the patient is being considered a candidate for surgery.

- **No:** No diagnosis of diabetes or diabetes controlled by diet alone.
- **Non-Insulin:** A diagnosis of diabetes requiring therapy with a non-insulin anti-diabetic agent (such as oral agents or other non-insulin agents).
- **Insulin:** A diagnosis of diabetes requiring daily insulin therapy.

Options:
- No
- Non-Insulin
- Insulin

Scenarios to Clarify (Assign Variable):
- Patients with insulin resistance (e.g., polycystic ovarian syndrome, metabolic syndrome, pre-diabetes) that routinely take anti-diabetic agents.
- Patients prescribed oral or insulin treatment and are noncompliant.

Scenarios to Clarify (Do Not Assign Variable):
- Diabetes controlled by diet alone.

Notes:
- If the patient requires treatment with both non-insulin and insulin, assign insulin.
**Current Smoker within One Year**

**Variable Name:** Current Smoker within One Year

**Intent of Variable:** To capture a patient who has smoked cigarettes at any point within the 12 months prior to surgery. The use of cigarettes may have negative cardiopulmonary effects, increase risk for stroke, delay wound healing, along with increased anesthesia risk and venous thromboembolism (VTE).

**Definition:** A current smoker has smoked cigarettes at any point within the 12 months prior to admission for surgery. This does not include the use of cigars, pipes, chewing tobacco, marijuana, mechanical/electronic cigarettes, or hookah.

**Criteria:** The patient has smoked cigarettes within the 12 months prior to admission for the principal operative procedure.

**Options:**
- Yes
- No

**Scenarios to Clarify (Do Not Assign Variable):**
- If the patient smokes mechanical/electronic cigarettes.
**Functional Health Status**

**Variable Name:** Functional Health Status

**Intent of Variable:** To capture the best physical functional status/level of self-care as demonstrated by the patient prior to the onset of acute illness. This may indicate a chronic/underlying disease state that may impact the patient’s risk.

**Definition:** Activities of daily living (ADLs) are defined as “the activities usually performed in the course of a normal day in a person’s life.” ADLs include: bathing, feeding, dressing, toileting, and mobility.

**Criteria:** Report the best functional status demonstrated by the patient within the 30 days prior to the principal operative procedure or at the time the patient is being considered a candidate for surgery. Report the level of functional health status as defined by the following criteria:

- **Independent:** The patient does not require assistance from another person for any activities of daily living. This includes a person who is able to function independently with prosthetics, equipment, or devices.

- **Partially dependent:** The patient requires some assistance from another person for activities of daily living. This includes a person who utilizes prosthetics, equipment, or devices but still requires some assistance from another person for ADLs.

- **Totally dependent:** The patient requires total assistance for all activities of daily living.

- **Unknown:** If unable to ascertain the functional status prior to surgery, report as unknown.

**Options:**
- Independent
- Partially dependent
- Totally dependent
- Unknown

**Notes:**

- If there is a change in the patient’s functional status, (e.g., improvement to worsening) within the 30 days prior to surgery or at the time the patient is being considered a candidate for surgery, report the patient’s best functional status.

- All patients with psychiatric illnesses should be evaluated for their ability to function with or without assistance with ADLs, just as the non-psychiatric patient.
For instance if a patient with schizophrenia is able to care for him/herself without the assistance of nursing care, he/she is considered independent.
Pulmonary

History of Severe COPD

Variable Name: History of Severe COPD

Intent of Variable: To capture patients who suffer from severe Chronic Obstructive Pulmonary Disease (COPD). This may impact the patient’s outcome or ability to recover postoperatively. COPD may have negative cardiopulmonary effects, end organ dysfunction, and anesthesia risks.

Definition: “...COPD [emphysema and/or chronic bronchitis/bronchiectasis/bronchiolitis obliterans organizing pneumonia (BOOP)] is a progressive disease that makes it hard to breathe. ‘Progressive’ means the disease gets worse over time. ‘COPD can cause coughing that produces large amounts of mucus . . ., wheezing, shortness of breath, chest tightness, and other symptoms’ (National Heart Lung and Blood Institute, 2010) ‡.”

Criteria: Medical record must document that there is a historical or current diagnosis of COPD AND at least one of the following within the 30 days prior to the principal operative procedure or at the time the patient is being considered as a candidate for surgery:

- Functional disability from COPD (e.g., dyspnea at rest, inability to perform ADLs).

  OR

- Requires chronic bronchodilator therapy with oral or inhaled agents or other medication specifically targeted to this disease.

  OR

- Hospitalization in the past for treatment of COPD.

  OR

- An FEV1 of <75% of predicted on a prior pulmonary function test (PFT)*.

Options:

- Yes
- No

Scenarios to Clarify (Do Not Assign Variable):
• Patients whose only pulmonary disease is asthma, an acute and chronic inflammatory disease of the airways resulting in bronchospasm.
• Patients with diffuse interstitial fibrosis, sarcoidosis, or silicosis.
• Use of PRN bronchodilator therapy does not meet criterion of chronic bronchodilator.

Notes:

• *Utilize post bronchodilator values, if available
Oxygen Dependent

**Variable Name:** Oxygen Dependent

**Intent of Variable:** To capture patients who utilize oxygen therapy prior to the principal operative procedure.

**Definition:** The use of oxygen therapy (outside of a clinical setting) per physician instruction.

**Criteria:** Use of home oxygen for any reason, per physician instruction, required as oxygen therapy within the 30 days prior to the principal operative procedure or at the time the patient is being considered a candidate for surgery.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- Patients who are required to use home oxygen therapy per physician instructions, but are non-compliant.
- Patients who are prescribed oxygen therapy prn.
History of Pulmonary Embolism

Variable Name: History of Pulmonary Embolism

Intent of Variable: To capture patients with a history of pulmonary embolism.

Definition: Lodging of a blood clot in a pulmonary artery or segmental branch with subsequent obstruction of blood supply to the lung parenchyma.

Criteria: The patient has a documented history of pulmonary embolism that was treated either with anticoagulation therapy or placement of mechanical interruption (e.g., Greenfield Filter).

Options:

- Yes
- No
Obstructive Sleep Apnea Requiring CPAP/BiPAP (or Similar Technology) [Preop]

**Variable Name:** Obstructive Sleep Apnea Requiring CPAP/BiPAP (or similar technology)

**Intent of Variable:** To capture patients who require positive pressure ventilation while sleeping.

**Definition:** The most common type of sleep apnea is obstructive sleep apnea. During deep sleep, as the airway muscles relax, the airway collapses and the patient cannot move air. The brain eventually senses that the patient is not breathing and the patient awakes enough to breathe again, often with a loud snort or choking sound.

**Criteria:** A patient with a documented diagnosis of sleep apnea as documented by a sleep study and/or they use CPAP or BiPAP (or similar technology) as prescribed by a physician.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- A patient who is supposed to use CPAP/BiPAP (or similar technology) per physician instructions, but do not or are unable to tolerate it.
- A patient that is planning to or has had an uvuloplasty or other surgical correction of sleep apnea.

**Scenarios to Clarify (Do Not Assign Variable):**
- If a patient has symptoms that are minimal enough not to require the use of CPAP or BiPAP (or similar technology).
Gastrointestinal

Gastroesophageal Reflux Disease (GERD) Requiring Medication (within 30 Days Prior to Surgery) [Preop]

**Variable Name:** Gastroesophageal Reflux Disease (GERD) Requiring Medication (within 30 days prior to surgery)

**Intent of Variable:** To capture those patients who have a preoperative condition of GERD.

**Definition:** GERD results from a failure of the anti-reflux barrier, allowing the contents of the stomach back into the esophagus. The most common symptom is heartburn.

**Criteria:** A patient with the diagnosis of GERD in which they regularly take prescribed or over-the-counter medication within 30 days of the principal operative procedure.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- Patients who take proton pump inhibitors (PPI) or histamine (H2) receptor blockers.

**Scenarios to Clarify (Do Not Assign Variable):**
- Patients who experience occasional symptoms or treat their heartburn on a PRN basis.
- Patients who utilize antacids other than PPIs or H2 blockers.
- Patients who do not have a diagnosis of GERD.
Musculoskeletal

Is the Patient's Ambulation Limited Most or all of the Time

Variable Name: Is the Patient's Ambulation Limited Most or all of the Time

Intent of Variable: To capture patients with limited ambulation.

Definition: A patient who requires assistive devices for ambulation most or all of the time.

Criteria: A disability which requires the regular use of a scooter, wheelchair, or other such medical devices to assist in mobility.

Options:
- Yes
- No

Scenarios to Clarify (Assign Variable):
- The patient is dependent upon a home lift device or elevator to negotiate stairs.

Scenarios to Clarify (Do Not Assign Variable):
- A patient that does not regularly use such a device or if they prefer to use an elevator or lift, but could otherwise negotiate one flight of stairs.
Cardiac

History of Myocardial Infarction

Variable Name: History of Myocardial Infarction

Intent of Variable: To capture patients who have a history of myocardial infarction.

Definition: Blockage of blood flow to the heart causing damage or death to part of the heart muscle.

Criteria: A history of myocardial infarction must be documented in the patient’s medical record.

Options:
- Yes
- No
Previous PCI/PTCA

**Variable Name:** Previous PCI/PTCA

**Intent of Variable:** To capture patients who have undergone percutaneous coronary intervention (PCI) or percutaneous transluminal coronary angioplasty (PTCA) at any time prior to the principal operative procedure.

**Definition:** A nonsurgical procedure in which a catheter is inserted through the skin in the groin and advanced through the femoral arterial and into the coronary arteries using fluoroscopy. PTCA encompasses balloons, stents, and other modifications to the catheter tip, including devices that can cut out plaque and thus open up the narrowed artery.

**Criteria:** At any time prior to the principal operative procedure has undergone a PCI, PTCA, balloon dilatation, stent placement, or any attempted PCI or PTCA.

**Options:**
- Yes
- No

**Scenarios to Clarify (Do Not Assign Variable):**
- Those patients who have had valvuloplasty procedures.
- A patient who has a history of cardiac ablation.
- Patients with a history of a pacemaker/AICD.
- Patients with a history of cardiac catheterization or cardiac angiography without an intervention.
Previous Cardiac Surgery

Variable Name: Previous Cardiac Surgery

Intent of Variable: To capture those patients that have undergone any major cardiac surgical procedure(s) performed either as an “off-pump” repair or utilizing cardiopulmonary bypass.

Definition: Surgical procedures performed on the heart and great vessels.

Criteria: Any major cardiac surgical procedure performed either as an “off-pump” repair or utilizing cardiopulmonary bypass.

Options:

- Yes
- No

Scenarios to Clarify (Assign Variable):

- Coronary artery bypass graft surgery (CABG)
- Valve replacement or repair (AVR, MVR)
- Repair of atrial or ventricular septal defects (ASD, PFO, VSD)
- Great thoracic vessel repair
- Cardiac transplant
- Left ventricular Aneurysmectomy
- Insertion of ventricular assist devices (LVAD, BiVAD)

Scenarios to Clarify (Do Not Assign Variable):

- Do not include insertion of pacemaker or automatic implantable cardioverter defibrillator (AICD).
- A patient who has a history of cardiac ablation.
Hypertension Requiring Medication [Preop]

Variable Name: Hypertension Requiring Medication

Intent of Variable: To capture patients with a diagnosis of hypertension severe enough that medication is or should be prescribed. This condition may impact the patient's risk for cerebrovascular, renal, and cardiac disease.

Definition: "Hypertension (HTN) is the term used to describe high blood pressure. Blood pressure is a measurement of the force against the walls of your arteries as your heart pumps blood through your body. High blood pressure (hypertension) is when your blood pressure is 140/90 mmHg or above most of the time." (MedlinePlus, April 2012)

Criteria: The diagnosis of HTN must be documented in the patient’s medical record and the condition is severe enough that it requires antihypertensive medication, within 30 days prior to the principal operative procedure or at the time the patient is being considered as a candidate for surgery. The patient must have been receiving or required long-term treatment of their chronic hypertension for > 2 weeks.

Options:
- Yes
- No

Scenarios to Clarify (Assign Variable):
- Patients who are prescribed antihypertensive medications and are noncompliant

Scenarios to Clarify (Do Not Assign Variable):
- Patients who receive a onetime dose of antihypertensive medication or who have not been prescribed or required treatment for > 2 weeks.
- HTN controlled by diet alone.
- Patients diagnosed with Pulmonary Hypertension.

Notes:
- Pulmonary Hypertension without a diagnosis of Systemic Hypertension should not be assigned.
- Examples of antihypertensive medications include: diuretics, beta blockers, ACE inhibitors, and/or calcium channel blockers.
**Number of Anti-Hypertensive Medications**

**Variable Name:** Number of Anti-Hypertensive Medications

**Intent of Variable:** To capture the number of anti-hypertensive medications prescribed to a patient.

**Definition:** A patient that has hypertension and is being treated with medication(s), list the numbers of antihypertensive medications that they are taking.

**Criteria:** Antihypertensive medications include diuretics, beta blockers, ACE inhibitors, angiotensin receptor blockers, calcium channel blockers, vasodilators, etc.

**Options:** Enter number of medications.

**Notes:**

- If a patient is taking a pill that contains more than one medication, document the number of medications rather than the number of pills.
- If a patient has been diagnosed with hypertension and requires medication but is refusing medication or is noncompliant, enter “0.”
**Hyperlipidemia Requiring Medication [Preop]**

**Variable Name:** Hyperlipidemia Requiring Medication

**Intent of Variable:** To capture patients who have a preoperative risk factor of an increased cholesterol levels.

**Definition:** Hyperlipidemia is an increased level of triglycerides, LDL cholesterol, or an unfavorable LDL/HDL ratio, that puts a patient at risk for subsequent cardiovascular disease.

**Criteria:** The patient has a diagnosis of hyperlipidemia and at least one of the following:

- Is taking daily medications for the treatment of hyperlipidemia.
- Had a history of hyperlipidemia and received treatment with medications prior to weight-loss or dietary modification.

**Options:**

- Yes
- No

**Scenarios to Clarify (Assign Variable):**

- Patients who are taking daily medications such as, statins, niacin, or gemfibrozil for the treatment of hyperlipidemia.

**Scenarios to Clarify (Do Not Assign Variable):**

- Patients who are taking over the counter medications such as, fish oil, or homeopathic medications.
Vascular

Vein Thrombosis Requiring Therapy [Preop]

Variable Name: Vein Thrombosis Requiring Therapy

Intent of Variable: To capture those patients who have a history of a blood clot or thrombus within the venous system.

Definition: A blood clot (thrombus) that forms within a vein.

Criteria: The patient has a history of a blood clot or thrombus in the venous system, which may be coupled with inflammation. They have been treated with anticoagulation therapy, placement of a vena cava filter, and/or clipping of the vena cava.

Options:

- Yes
- No

Scenarios to Clarify (Assign Variable):

- Assign if the patient has a history of vein thrombosis requiring therapy, such as thrombolysis or clot extraction.
Venous Stasis

Variable Name: Venous Stasis

Intent of Variable: To capture patients with poor venous circulation of the lower extremities, both superficial and deep systems, which would result in delayed wound healing of the lower extremities.

Definition: Venous stasis is a condition where there is poor venous circulation of the lower extremities of either the superficial or deep systems. Venous stasis disease can be suggested by reddish-brown changes to the pre-tibial region and can lead to lower extremity ulcers or wounds that are difficult to heal.

Criteria: The patient must have at least one of the following:

- Venous stasis documented as a condition.
- Reddish-brown changes to the pre-tibial region.
- History of lower extremity venous stasis ulcers.
- Regularly wears or should wear compressive stockings of the lower extremity/extremities as a treatment for venous insufficiency.

Options:

- Yes
- No

Scenarios to Clarify (Do Not Assign Variable):

- Varicose veins or spider veins alone do not classify a patient as having venous stasis disease.
- Documentation of venous insufficiency alone.

Notes:

- Varicose veins may be associated with concomitant venous stasis disease.
Does the patient have an IVC filter?

Variable Name: Does the patient have an IVC filter?

Intent of Variable: To capture prophylactic or therapeutic placement of an IVC filter preoperatively in patients undergoing bariatric or metabolic surgery.

Definition: A vena cava filter is a small metal device inserted into the inferior vena cava (the large vein that takes blood back to the heart) to prevent a blood clot from entering the lungs. A blood clot in the lungs is called a pulmonary embolism (PE). A pulmonary embolism is caused by a thrombosis in a deep vein (DVT).

Criteria: Report if the patient has an IVC filter placed prior to the principal operative procedure.

Options:

- Yes
  - IVC Filter Timing
    - IVC filter placed in anticipation of the metabolic or bariatric procedure
    - IVC filter was pre-existing
    - Unknown

- No

Scenarios to Clarify (Assign Variable):

- This may be noted as a Greenfield filter.

Notes:

- Please keep in mind that IVC filter placement can be temporary or permanent.
Renal

Currently Requiring or On Dialysis [Preop]

Variable Name: Currently Requiring or On Dialysis

Intent of Variable: To capture patients who have demonstrated renal compromise severe enough to require dialysis within two weeks prior to surgery. This would indicate end organ failure/dysfunction and may cause physiologic changes such as electrolyte imbalances and metabolic/hematologic abnormalities.

Definition: A clinical condition associated with the decline of kidney function severe enough requiring dialysis.

Criteria: Acute or chronic renal failure requiring treatment with peritoneal dialysis, hemodialysis, hemofiltration, hemodiafiltration, or ultrafiltration, within two weeks prior to the principal operative procedure. The medical record must document that such a treatment was indicated.

Options:

- Yes
- No

Scenarios to Clarify (Assign Variable):

- A patient requires dialysis, but refuses it.
- A patient whose physical condition is documented in the medical record as warranting dialysis preoperatively and is unable to undergo dialysis due to the need for surgery.
- A dialysis catheter that is placed during the principal operative procedure and used for dialysis or filtration within 14 days following placement; this reflects a situation where dialysis was indicated prior to surgery.

Scenarios to Clarify (Do Not Assign Variable):

- A dialysis catheter that is placed during the principal operative procedure but not used for dialysis or filtration within 14 days following placement; this reflects a situation where dialysis was not indicated prior to surgery.
Renal Insufficiency [Preop]

**Variable Name:** Renal Insufficiency

**Intent of Variable:** To capture those patients who have an elevated preoperative creatinine without a need for dialysis.

**Definition:** The reduced capacity of the kidney to perform its function as evidenced by a creatinine of greater than 2 mg/dl but with no requirement for dialysis.

**Criteria:** The patient has a creatinine greater than 2 mg/dl but has not undergone any treatment with dialysis. Utilize the creatinine value if drawn within 90 days prior to the principal operative procedure. Utilize the creatinine value drawn closest to the documented Procedure/Surgery Start date and time (PST).

**Options:**

- Yes
- No
**Nutritional/Immune/Oncology/Other**

**Steroid/Immunosuppressant Use for a Chronic Condition**

**Variable Name:** Steroid/Immunosuppressant Use for a Chronic Condition

**Intent of Variable:** To capture patients who are receiving long-term pharmaceutical immunosuppressants which may lead to delayed wound healing, postoperative infection, and other effects. A short immunosuppressant course, one-time pulse or short taper would not qualify. Long-interval injections of long-acting agents (e.g., monthly) that are part of an ongoing regimen would qualify.

**Definition:** Corticosteroids and other immunosuppressants are utilized to decrease the body’s inflammatory response and can inhibit various portions of the immune system.

**Criteria:** Patient has required the regular administration of oral or parenteral corticosteroid medications or immunosuppressant medications, for a chronic medical condition, within the 30 days prior to the principal operative procedure, or at the time the patient is being considered as a candidate for surgery. A one-time pulse, limited short course, or a taper of less than 10 days duration **would not qualify.** Long-interval injections of long-acting agents (e.g., monthly) that are part of an ongoing regimen **would qualify.**

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- Patient has a diagnosis of Crohn’s Disease and receives a dose of infliximab 7 weeks prior to the Principal Operative Procedure and has an active order to receive one dose of Infliximab every 8 weeks.
- Corticosteroid therapy of 10 cumulative days or greater in the 30 days prior to surgery. The days do not need to be consecutive.

**Scenarios to Clarify (Do Not Assign Variable):**
- Topical corticosteroids applied to the skin or corticosteroids administered by inhalation or rectally.
- Short course steroids, pulse, or taper (duration 10 days or less) in the 30 days prior to surgery.
  - “Pulse dose” is intravenous administration of a high dose of steroids given over a short period of time or intermittently.
Chemotherapy alone does not meet criteria (while these medications may have immunosuppressant properties, these medications are not classified as steroids or immunosuppressants).

Notes:

- Examples of corticosteroid medications include, but are not limited to prednisone and Decadron.
- Examples of chronic medical conditions include, but are not limited to: COPD, asthma, rheumatologic disease, rheumatoid arthritis, and inflammatory bowel disease.
- Examples of patients who may take immunosuppressant medications include those on chemotherapy, transplant patients or patients with chronic inflammatory conditions.
- Drugs prescribed to treat HIV would not be assigned unless they are classified as Steroids or Immunosuppressants.

**Immunosuppressant medications may include:**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Generic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellcept</td>
<td>Mycophenolate Mofetil</td>
</tr>
<tr>
<td>Enbrel</td>
<td>Etanercept</td>
</tr>
<tr>
<td>Humira</td>
<td>Adalimumab</td>
</tr>
<tr>
<td>Imuran</td>
<td>Azathioprine</td>
</tr>
<tr>
<td>Neoral</td>
<td>Cyclosporine</td>
</tr>
<tr>
<td>Prograf</td>
<td>Tacrolimus</td>
</tr>
<tr>
<td>Rapamune</td>
<td>Sirolimus</td>
</tr>
<tr>
<td>Remicade</td>
<td>Infliximab</td>
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<tr>
<td>----------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Sandimmune</td>
<td>Cyclosporine</td>
</tr>
<tr>
<td>Tysabri</td>
<td>Natalizumab</td>
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<tr>
<td>Rheumatrex</td>
<td>Methotrexate</td>
</tr>
<tr>
<td>Cimzia</td>
<td>Certolizumab Pegol</td>
</tr>
<tr>
<td>Cosentyx</td>
<td>Secukinumab</td>
</tr>
<tr>
<td>Stelara</td>
<td>Ustekinumab</td>
</tr>
</tbody>
</table>

*This list is NOT inclusive.*
Therapeutic Anticoagulation

Variable Name: Therapeutic Anticoagulation

Intent of Variable: To capture those patients who require therapeutic anticoagulation pre-operatively.

Definition: Certain patients require therapeutic anticoagulation for a myriad of conditions such as hypercoaguable state, vein thrombosis, or pulmonary embolism (PE), heart abnormalities (e.g., atrial fibrillation, valve replacement, ventricular aneurysm, and low ejection fraction), vascular disease (carotid or peripheral vascular disease), etc.

Criteria: Patient requires anticoagulation therapy at any time within the 30 days prior to the principal operative procedure, or at the time the patient is being considered as a candidate for surgery.

Options:
- Yes
- No

Scenarios to Clarify (Assign Variable):
- The patient was taking a medication for therapeutic anticoagulation preoperatively, even if these medications were ceased.

Scenarios to Clarify (Do Not Assign Variable):
- The patient is only taking Aspirin.
- Any anticoagulation medication that was first started on the day of surgery or was prescribed prophylactically for surgery.

Notes:

Below is a non-exhaustive list of medications that can affect the patient’s risk for bleeding.

Anticoagulants

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic</th>
</tr>
</thead>
</table>


<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arixtra</td>
<td>Fondaparinux</td>
</tr>
<tr>
<td>Coumadin</td>
<td>Warfarin</td>
</tr>
<tr>
<td>Fragmin</td>
<td>Dalteparin</td>
</tr>
<tr>
<td>Heparin –</td>
<td>standard or</td>
</tr>
<tr>
<td></td>
<td>unfractionated</td>
</tr>
<tr>
<td>Heparin-</td>
<td>Low molecular</td>
</tr>
<tr>
<td></td>
<td>weight</td>
</tr>
<tr>
<td>Lovenox</td>
<td>Enoxaparin</td>
</tr>
<tr>
<td></td>
<td>Pentasaccaride</td>
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<tr>
<td></td>
<td>APC</td>
</tr>
<tr>
<td></td>
<td>Ximelagatran</td>
</tr>
<tr>
<td>Trental</td>
<td>Pentoxifylline</td>
</tr>
<tr>
<td>Xarelto</td>
<td>Rivaroxaban</td>
</tr>
<tr>
<td>Eliquis</td>
<td>Apixaban</td>
</tr>
</tbody>
</table>

**Antiplatelet Agents**
Aggrastat  Tirofiban
Aggrenox  ASA/Dipyridamole
Agrylin    Anagrelide HCL
Integrilin  Eptifibatide
Persantine  Dipyridamole
Plavix     Clopidogrel
Pletal     Cilostazol
ReoPro     Abciximab
Ticlid     Ticlopidine
Effient    Prasugrel
Brilinta   Ticagrelor

**Thrombin Inhibitors**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiomax</td>
<td>Bevalirudin</td>
</tr>
<tr>
<td>Brand Name</td>
<td>Active Ingredient</td>
</tr>
<tr>
<td>---------------------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td>Argatroban, Novastan</td>
<td>Argatroban</td>
</tr>
<tr>
<td>Refludan</td>
<td>Lepirudin, Hirudin</td>
</tr>
<tr>
<td>Xigris</td>
<td>Drotrecogin alpha</td>
</tr>
<tr>
<td>Pradaxa</td>
<td>Dabigatran</td>
</tr>
</tbody>
</table>
Previous Obesity Surgery/Foregut Surgery

Variable Name: Previous Obesity Surgery/Foregut Surgery

Intent of Variable: To capture those patients who have a history of obesity or foregut surgery.

Definition: A history of any type of bariatric or metabolic surgery performed on the upper gastrointestinal tract prior to the principal operative procedure.

Criteria: The patient must have had a history of one of the following:

- If the patient has had any type of bariatric or metabolic surgery in the past, including vertical-banded gastroplasty, roux-en-Y gastric bypass surgery, laparoscopic gastric banding, biliopancreatic diversion with or without duodenal switch, duodenal switch, or any other type of weight-loss operation performed on the upper gastrointestinal tract.
- If the patient has had any type of surgery on the esophagus, stomach, duodenum or pancreas.

Options:

- Yes
- No

Scenarios to Clarify (Assign Variable):

- Patients who had a splenectomy.
- Patients with a history of paraesophageal or hiatal hernia repair.

Scenarios to Clarify (Do Not Assign Variable):

- Patients who have had surgery for small bowel obstruction (SBO) beyond the duodenum.
- Patients who had a cholecystectomy, liver surgery, appendectomy, hysterectomy, C-section, tubal ligation.
- EGD with dilation and/or biopsy.
- Patients with a history of surgery of the large intestines or colon.
Previous Organ Transplant

**Variable Name:** Previous Organ Transplant

**Intent of Variable:** To capture patients who have undergone a solid organ transplant procedure at any time prior to the principal operative procedure.

**Definition:** Patient was the recipient of a solid organ transplant prior to the principal operative procedure.

**Criteria:** A history of a solid organ transplant procedure is documented in the patient’s medical record.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- Patient is a recipient of a:
  - Heart
  - Liver
  - Kidney
  - Pancreas
  - Intestine
  - Lung

**Scenarios to Clarify (Do Not Assign Variable):**
- Patient is a recipient of a:
  - Corneal transplant
  - Vascular graft
  - Bone Graft
  - Bone Marrow
  - Islet Cell
  - Skin graft
Preoperative Labs

Preoperative Lab Value Information

Variable Name: Preoperative Lab Value Information

Intent of Variable: To capture patients with preoperative lab variances. Altered lab values may indicate an underlying disease process/state that may affect surgical outcomes.

Definition: Diagnostic blood tests performed to evaluate a patient’s physical status prior to the surgical visit or surgical procedure.

Criteria: All of the following preoperative lab values are to be reported if they are drawn within 90 days prior to the principal operative procedure. Report the lab value drawn closest to the documented principal operative procedure surgery start date and time.

- Albumin (Alb) (g/dl)
- Hematocrit (Hct) (%)
- Serum Creatinine (mg/dl)
- Hemoglobin A1c (HbA1c) (%)  

Options:

- Enter value
- Enter date (mm/dd/yyyy)
- Unknown

Notes:

- Report the lab value drawn closest to the documented Procedure/Surgery Start date and time (PST).
- If you have a value greater than or less than symbol with a numeric lab value, enter the numeric value only into the workstation, as the system will not capture symbols. For example, if a resulted value is >4 or <4 enter the value of “4” in the space provided.
- Decimals can be recorded.
Operative Information

First Assistant

Variable Name: First Assistant

Intent of Variable: To report the level of training for the First Assistant in a surgical procedure.

Definition: A trained medical professional that is scrubbed into the bariatric or metabolic surgical procedure that assists the primary surgeon during the case (e.g. opening, suturing, closing, etc.).

Criteria: Indicate the level of training for the First Assistant scrubbed in on the surgical procedure.

Options:

- None: A First Assistant was not scrubbed in during the case.
- Physician Assistant/Nurse Practitioner/Registered Nurse First Assist: A non-physician clinician/nurse practitioner licensed to practice medicine or a registered nurse trained as a first assist with a physician's supervision.
- Resident: A surgical resident who is between their 1st and 5th post-graduate year of surgical training.
- MIS Fellow: A Minimally Invasive Surgery fellow who is usually between their 6th and 9th year of post-graduate year of surgical training, specializing in minimally invasive surgery and/or bariatric or metabolic surgery.
- Attending – Weight-Loss Surgeon: A staff surgeon who is credentialed as a weight-loss surgeon.
- Attending – Other: A staff surgeon who is credentialed in any other type of surgery other than weight-loss surgery.

Scenarios to Clarify (Do Not Assign Variable):

- Certified Surgical Technologist First Assistants, Certified Surgical Technologists, and Surgical Assistants would not be assigned.
Emergency Case

Variable Name: Emergency Case

Intent of Variable: The intent is to identify a patient population with heightened surgical risk due to an ongoing acute process that is currently having a negative impact on the patient’s health and for which continued, potentially rapid deterioration could occur. The increased risk might be partly due to the fact that the procedure is being performed with limited preoperative preparation time and the surgical team does not necessarily have the ability to optimize the patient’s status. The emergency case variable is not intended to capture urgent/semi-elective/elective cases.

Definition: An emergency case is usually performed within a short interval of time between patient diagnosis or the onset of related preoperative symptomatology. Emergency status is determined by anesthesiologist and/or surgeon.

Criteria: The case must meet both of the following criteria, A AND B below:

A. The MBSAQIP principal operative procedure must be performed during the hospital admission for the diagnosis.

AND

A.

B. The surgeon and/or anesthesiologist must report the case as emergent.

A.

• In the case of a discrepancy in the assignment of this variable by the anesthesia and surgical teams, please consult with the attending surgeon to determine if the intent of this variable was met. The attending surgeon’s decision is definitive.

Options:

• Yes
• No

Scenarios to clarify (Assign Variable):

• Case assigned as an emergency case by the surgeon and/or anesthesiologist, even if due to backlog the patient must wait for an operating room to become available (the patient must be kept in the hospital and cannot be sent home).
  • Patient comes to ER for an anastomotic leak. Numerous traumas requiring emergent surgery take precedence and the patient must wait for surgery
later that day. If the surgeon or anesthesiologist designates the case as emergent in the operative record, then assign the variable.

Scenarios to Clarify (Do Not Assign Variable):

- Urgent/semi-elective cases are not considered emergencies.
- Patients who are discharged after diagnosis and return for an elective, semi-elective, or urgent procedure related to the diagnosis.
ASA Classification

Variable Name: ASA Classification

Intent of Variable: ASA class is intended to capture patient disease levels which affect the risk of anesthesia and surgery.

Definition: The American Society of Anesthesiology (ASA) Physical Status Classification of the patient’s present physical condition on a scale from 1-6 as it appears on the anesthesia record. The ASA Classifications are as follows:

- **ASA 1** – Normal healthy patient
- **ASA 2** – Patient with mild systemic disease
- **ASA 3** – Patient with severe systemic disease
- **ASA 4** – Patient with severe systemic disease that is a constant threat to life
- **ASA 5** – Moribund patient who is not expected to survive without the operation
- **ASA 6** – Declared brain-dead patient whose organs are being removed for donor purposes
  
  *(NOTE: ASA 6 cases are not accrued in MBASQIP)*
- **None Assigned** – For cases performed under local anesthesia that meet inclusion criteria but do not have an ASA class assigned, report as ‘none assigned’. For cases that are not local anesthesia cases, an ASA class must be assigned.

Criteria: Report the ASA category, 1 – 5, assigned to the patient as it appears on the anesthesia record.

Options:

- **ASA 1** – No Disturb
- **ASA 2** – Mild Disturb
- **ASA 3** – Severe Disturb
- **ASA 4** – Life Threat
- **ASA 5** – Moribund
- None Assigned

Notes:

- MBASQIP advises each SCR to discuss and develop an internal process for determining the ASA with their Bariatric director. MBASQIP is reluctant to mandate particular internal processes for each institution on this issue, but will attempt to assist institutions once internal resources have been involved.
- Some hospitals may note the ASA classification as the “Acuity Code.”
- If there is a second assessment available prior to anesthesia induction, report this most recent assessment.
Surgical Approach

Variable Name: Surgical Approach

Intent of Variable: To capture the initial operative approach of the bariatric or metabolic surgical procedure.

Definition: The initial operative approach of the bariatric or metabolic surgical procedure.

Criteria: The surgical approach first utilized by the surgeon as documented in the operative note. If the procedure was converted to another approach, please indicate the initial approach here.

Options:

- N.O.T.E.S. (Natural Orifice Transluminal Endoscopic Surgery) - approached through a natural orifice, not percutaneous.
- Single Incision – used a single small skin incision and no additional laparoscopic port outside of that one incision.
- Robotic Assisted – The use of robotic systems to aid in the surgical procedure.
- Conventional Laparoscopic (thoracoscopic) - a laparoscope was used to perform the procedure. List conventional laparoscopic approach even if incision is trocar enlarged to extract a specimen.
- Laparoscopic Assisted (thoracoscopic assisted) - a laparoscope was used, but an incision was made to do more than just remove specimen (e.g. extracorporeal anastomosis).
- Hand Assisted – in hand assisted laparoscopic surgery, the surgeon inserts a hand into the abdomen while pneumoperitoneum is maintained. The hand assists laparoscopic instruments and is helpful in complex laparoscopic cases.
- Open

Scenarios to Clarify (Do Not Assign Variable):

- For Robotic Assisted, do not include a mechanical or electrical device to hold the camera only.
Was the procedure converted to another approach?

**Variable Name:** Was the procedure converted to another approach?

**Intent of Variable:** To capture cases in which the initial operative surgical approach was converted to another approach.

**Definition:** The surgical approach for the principal operative procedure was converted to another approach.

**Criteria:** The final operative approach utilized by the surgeon for the principal operative procedure as documented in the operative note.

**Options:**
- Yes
  - If Yes, select the approach the procedure ended with:
    - Single Incision – used a single small skin incision and no additional laparoscopic port outside of that one incision.
    - Robotic Assisted – The use of robotic systems to aid in the surgical procedure.
    - Conventional Laparoscopic (thoracoscopic) - a laparoscope was used to perform the procedure. List conventional laparoscopic approach even if incision is trocar enlarged to extract a specimen.
    - Laparoscopic Assisted (thoracoscopic assisted) - a laparoscope was used, but an incision was made to do more than just remove specimen, (e.g. extracorporeal anastomosis).
    - Hand Assisted – in hand assisted laparoscopic surgery, the surgeon inserts a hand into the abdomen while pneumoperitoneum is maintained. The hand assists laparoscopic instruments and is helpful in complex laparoscopic cases.
  - Open
- No

**Scenarios to Clarify (Do Not Assign Variable):**
- If an additional surgical procedure was performed (e.g. hernia repair), assign the variable based on the bariatric or metabolic procedure(s) performed.
Was the Case Aborted?

Variable Name: Was the Case Aborted?

Intent of Variable: To capture bariatric or metabolic surgical procedures that were aborted after the surgical incision for the intended procedure was made.

Definition: If the intended bariatric or metabolic surgical procedure was not performed or was aborted, capture the intended procedure, if the CPT code meets inclusion criteria. If the intended procedure was not completed due to an intraoperative complication, the case (based upon intended procedure) should still be captured. If the case was aborted please provide explanation.

Criteria: The intended bariatric or metabolic surgical procedure which was not completed due to an intraoperative complication during the case.

Options:

- Yes
- No

Notes:

- If the case was aborted, please provide an explanation in the text box provided.
- Examples:
  - Patient enters the operating room for an open Roux-en-Y, patient codes during surgery; the procedure is stopped (aborted) to administer CPR. The patient expires in the operating room. This case would be reviewed as the open Roux-en-Y and the intraoperative occurrence of death would be assigned to the intended open Roux-en-Y procedure.
  - Patient enters the operating room for a laparoscopic sleeve gastrectomy. Upon starting the procedure, the surgeon encounters numerous adhesions which take several hours to remove. The surgeon ends up only performing the lysis of adhesions and elects not to perform the sleeve gastrectomy. This case would be reviewed as a sleeve gastrectomy as this was the intended procedure.
Drain Placed at Time of the Initial Operation?

Variable Name: Drain Placed at Time of the Initial Operation?

Intent of Variable: To capture intra-abdominal drains placed during the initial bariatric or metabolic surgical procedure.

Definition: A drain that is used to remove fluids that builds up in areas of the body after a surgical procedure.

Criteria: A drain that is inserted during the time of the initial bariatric or metabolic surgical procedure that exits the body from the intra-abdominal area.

Options:

- Yes
- No

Scenarios to Clarify (Assign Variable):

- Blake drain, Jackson-Pratt, Hemovac, or any other type of closed suction or open drain (e.g. Penrose).

Scenarios to Clarify (Do Not Assign Variable):

- Gastrostomy, jejunostomy, nasogastric, Dobhoff tubes, or other tubes coming from the mouth or nose.
Was a swallow study performed the day of or the day after the procedure?

Variable Name: Was a swallow study performed the day of or the day after the procedure?

Intent of Variable: To capture patients at risk for aspiration leading to postoperative occurrences.

Definition: A swallow study is an x-ray study which uses fluoroscopy and is viewed real-time. This study is used to evaluate the anatomy and function of the esophagus, stomach, and small intestine. A small amount of oral contrast is given to swallow. Using x-ray, the oral contrast is followed as it goes from the mouth to the small intestine. This study is usually performed by a radiologist.

Criteria: A swallow study was performed the day of (POD 0) or the day following (POD 1) the principal operative procedure.

Options:

- Yes, routine
- Yes, selective
- No

Scenarios to Clarify (Assign Variable):

- Done on the day of surgery or Postop day 1
- Modified barium swallow

Scenarios to Clarify (Do Not Assign Variable):

- Upper GI series
- Esophagram

Notes:

- A speech therapist can also perform the swallow study test.
- A routine Swallow Study would be one that is routinely performed after bariatric or metabolic procedures to assess the esophagus, stomach, and small intestine. It can be performed on the same day the bariatric or metabolic procedure was performed or the next day after the procedure.
- A selective Swallow Study would be one where the study is performed for an identified reason/issue other than one routinely done following the procedure.
Was the anastomosis checked with a provocative test to assess for leak?

Variable Name: Was the anastomosis checked with a provocative test to assess for leak?

Intent of Variable: To capture a leaking anastomosis and/or staple line during the initial bariatric or metabolic surgical procedure.

Definition: Utilization of various techniques to determine an anastomotic leak during the bariatric or metabolic surgical procedure.

Criteria: Insufflation of air or through an endoscope or nasogastric tube with the anastomosis under saline to look for bubbles initial bariatric or metabolic surgical procedure (as documented in the operative note).

OR

The installation of methylene blue (or other liquid) under pressure, while looking for a fluid leak as the bowel is clamped distal to the anastomosis during the initial bariatric or metabolic surgical procedure (as documented in the operative note).

Options:

- Yes
- No
- N/A (no stapling or anastomosis performed)

Scenarios to Clarify (Assign Variable):

- A provocative leak test was done and dictated in the operative report, whether or not there was a leak identified intra-operatively.

Scenarios to Clarify (Do Not Assign Variable):

- The assessment of the anastomosis/staple line was not done or only done without pressure distending the bowel in that region.
- A visual assessment (only) of the anastomosis was performed without distending the bowel.

Notes:
• Answer "N/A" if there is no anastomosis/staple line to test for a leak (for example, laparoscopic placement of an adjustable gastric band).
Procedure/Surgery Start Time (PST)

Variable Name: Procedure/Surgery Start Time (PST)

Intent of Variable: To capture the time the principal operative procedure has begun (e.g., incision for a surgical procedure). This variable is often used to determine total time of surgical procedure.

Definition: Time the procedure began (e.g., incision for a surgical procedure).

Criteria:

- Procedure start time is recorded on the anesthesia, nursing, or operative record.
- There must be a recorded start time.

Options:

- Date (mm/dd/yyyy)
- Time (hh:mm)
Procedure/Surgery Finish (PF)

Variable Name: Procedure/Surgery Finish (PF)

Intent of Variable: To capture the time when the physician/surgeons have completed all procedure-related activities on the patient. This variable is often used to determine total time of surgical procedure.

Definition: Time when the physician/surgeons have completed all procedure-related activities on the patient.

Criteria:

- Procedure finish time is recorded on the anesthesia, nursing, or operative record.
- There must be a recorded finish time.

Options:

- Date (mm/dd/yyyy)
- Time (hh:mm)

Notes:

- Should the patient expire in the operating room, indicate the time the patient was pronounced dead.
Gastric Sleeve

Bougie (or sizing device) size

Variable Name: Bougie (or sizing device) size

Intent of Variable: To capture the size of the device utilized to create the gastric sleeve.

Definition: See criteria below

Criteria: Please indicate bougie (or other sizing device, e.g. endoscope or OG tube) size in French or cm. Please note that you must enter a value or check “not documented” for case completion.

Options:

- Size
  - French (Fr)
  - Centimeters (CM)
- Unknown

Scenarios to Clarify (Assign Variable):

- Answer all questions if the case is assigned with CPT code 43775 as the principal operative procedure.

Scenarios to Clarify (Do Not Assign Variable):

- The principal operative procedure for the case is not 43775.
Distance from the Pylorus (in cm)

Variable Name: Distance from the Pylorus (in cm)

Intent of Variable: To capture the distance from the pylorus where the staple line is started.

Definition: See criteria below

Criteria: Enter the distance from the pylorus where the staple line is started.

Options:

- Distance from the pylorus in cm
- Not Documented

Scenarios to Clarify (Assign Variable):

- Answer all questions if the case is assigned with CPT code 43775 as the principal operative procedure.

Scenarios to Clarify (Do Not Assign Variable):

- The principal operative procedure for the case is not 43775.

Notes:

- A value must be entered or check “not documented” for case completion.
Staple Line Reinforcement

Variable Name: Staple Line Reinforcement

Intent of Variable: To identify if a staple line reinforcement product was utilized for the case.

Definition: See criteria below

Criteria: Document whether or not a staple line reinforcement product was used.

Options:

- Yes, if mentioned it was used.
- No, not documented or not used.

Scenarios to Clarify (Assign Variable):

- Answer all questions if the case is assigned with CPT code 43775 as the principal operative procedure.
- Assign if bio-absorbable products, collagen mesh, Peri Strips®, etc. were used. Some examples that you may see are Biodesign® and Seamguard®.

Scenarios to Clarify (Do Not Assign Variable):

- The principal operative procedure for the case is not 43775.
- Do not assign if Evicel®, Surgicel®, fibrin glue, Seprafilm®, clips, Ligaclips®, and/or sutures were used.
Oversew

Variable Name: Oversew

Intent of Variable: To identify if a majority of the suture line was oversewn.

Definition: See criteria below

Criteria: Document whether or not all or the majority of the staple line was sutured.

Options:

- Yes, if oversew all or majority of staple line.
- No, if no oversewing or if only limited oversewing of bleeders or notches between staple fires only or if not documented.

Scenarios to Clarify (Assign Variable):

- Answer all questions if the case is assigned with CPT code 43775 as the principal operative procedure.

Scenarios to Clarify (Do Not Assign Variable):

- The principal operative procedure for the case is not 43775.
Other Procedures

Other Procedure

Variable Name: Other Procedure

Intent of Variable: To capture additional surgical procedures performed by the same surgical team (e.g. under direction of the same surgical attending) under the same anesthetic, which have CPT® codes different from that of the Principal Operative Procedure. In some cases, additional captured CPT® codes might be analyzed separately from the principal operative procedure code. This makes it in the best interest of the program to capture all relevant CPT® codes.

Definition: An additional surgical procedure performed by the same surgical team, under the same anesthetic which has a CPT® code different from that of the Principal Operative Procedure.

Criteria:

- Any additional CPT® code is eligible for this variable, regardless of whether it is on the MBSAQIP Bariatric CPT® Code Inclusion List.

Options:

- Enter CPT® Code
- Enter Procedure Description (optional)

Scenarios to Clarify (Assign Variable):

- Dr. Smith is a bariatric surgeon and his team performs a sleeve gastrectomy and cholecystectomy; enter the cholecystectomy as an “other” procedure, as the same surgical team performed all of the procedures listed under the same anesthetic.
- Ureteral Stent placement

Scenarios to Clarify (Do Not Assign Variable):

- Imaging performed during the principal operative procedure, such as x ray or CT scan
- Anesthesia Procedures
- Central line placement
- Sheath Placement
- Transesophageal Echocardiogram (TEE)

Notes:
• ACS advises each MBSCR to discuss and develop an internal process for determining the other surgical procedure with their Bariatric Director. ACS is reluctant to mandate particular internal processes for each institution on this issue, but will attempt to assist institutions once internal resources have been involved.

• To signify that a bilateral procedure was performed enter the CPT code as the Principal Operative Procedure and again as an “Other” or “Concurrent Procedure.”
Concurrent Procedure

Variable Name: Concurrent Procedure

Intent of Variable: To capture concurrent surgical procedures performed by a different surgical team (e.g. under direction of a different surgical attending) and under the same anesthetic which have CPT® codes different from that of the Principal Operative Procedure. In some cases, additional captured CPT® codes might be analyzed separately from the principal operative procedure code. This makes it in the best interest of the program to capture all relevant CPT® codes.

Definition: A surgical procedure performed by a different surgical team or surgeon, under the same anesthetic which has a CPT® code different* from that of the Principal Operative Procedure.

*Certain CPT® codes can be billed for a patient more than one time reflecting repeated performance of a particular procedure. In such cases the codes could be considered different.

Criteria:

- Any additional CPT® code is eligible for this variable, regardless of whether it is on the MBSAQIP Bariatric CPT® Code Inclusion List.

Options:

- Enter CPT® Code
- Enter Procedure Description (optional)

Scenarios to Clarify (Assign Variable):

- Dr. Smith is a bariatric surgeon whose team performs a Sleeve Gastrectomy and Dr. Doe is a GYN surgeon who performs a tubal ligation. Enter the bariatric or metabolic procedure as the principal operative procedure and the other as a “concurrent” procedure, as two different surgical attending’s performed procedures under the same anesthetic.
- Ureteral Stent placement

Scenarios to Clarify (Do Not Assign Variable):

- Imaging performed during the principal operative procedure, such as x ray or CT scan
- Anesthesia Procedures
- Central line placement
- Sheath Placement
- Transesophageal Echocardiogram (TEE)
Notes:

- To signify that a bilateral procedure was performed enter the CPT code as the Principal Operative Procedure and again as an “Other” or “Concurrent Procedure.”
- ACS advises each MBSCR to discuss and develop an internal process for determining the concurrent surgical procedure with their Bariatric Director. ACS is reluctant to mandate particular internal processes for each institution on this issue, but will attempt to assist institutions once internal resources have been involved.
Is this a Stapling Procedure? (Bariatric Stapling Procedures)

Variable Name: Is this a Stapling Procedure? (Bariatric Stapling Procedures)

Intent of Variable: To identify cases involving the use of a surgical stapler for the anastomosis or resection of any portion of the GI tract.

Definition: Surgical Staplers are used to cut and anastomose portions of the GI tract.

Criteria: Identify if a stapler was used for anastomosis or resection of any part of the GI tract.

Options:

- Yes
- No

Scenarios to Clarify (Assign Variable): (Key words to identify a gastric bariatric stapling, but not limited to)

- Roux-En Y Gastric Bypass (RYGB)
- Biliopancreatic Diversion with or without Duodenal Switch (BPD-DS)
- Sleeve Gastrectomy/Vertical Sleeve Gastrectomy
- Vertical Banded Gastroplasty
- Small Bowel Resection or Revision of the Anastomosis
- Resection with Stapler with Hand Sutured Anastomosis

Scenarios to Clarify (Do Not Assign Variable): (Key words to identify non- stapling bariatric or metabolic gastric procedures, but not limited to)

- Restrictive Gastric Band/ Adjustable Gastric Banding (AGB)
- Laparoscopic Greater Curvature Plication (LGCP)
- Laparoscopic Gastric Plication (LGP)
- Lysis of Adhesions (Enterolysis)
- Reduction of Internal Hernia without Bowel Resection

Notes:

- A gastric bypass anastomosis that is hand sutured would qualify for this variable.
- Look for key words such as GIA, TIA, ENDOPATH®, the use of staple “re-loads” (such as “Blue Re-load” or “Green Re-load”).
Postoperative Occurrences

Present at Time of Surgery (PATOS)

Variable Name: Present at Time of Surgery (PATOS)

Intent: Present at the time of surgery (PATOS) modifiers preclude the assigned postoperative event from being counted as a postoperative occurrence in modeling.

Definition: PATOS captures a condition or diagnosis that the patient has at the time of the start of or during the principal operative procedure (in other words, it is present preoperatively). Included conditions or diagnoses are limited to the following:

- Wound Occurrence: superficial, deep, organ/space
- Pneumonia
- On Ventilator > 48 hours
- UTI
- Sepsis
- Septic Shock

Criteria: The case must meet the following criteria, A AND B below:

A. The corresponding postoperative occurrence is assigned.

AND

B. The case meets the PATOS criteria for inclusion as detailed in the criteria section specific to each of these occurrences.

Notes:

- PATOS criteria are frequently less stringent than criteria for a preoperative risk factor or postoperative occurrence. This means at times PATOS can be assigned to a postoperative occurrence despite the fact that criteria for a preoperative risk factor may not be met.
Wound Occurrences

Variable Name: Wound Occurrences

NOTE: If the patient is readmitted, has a reoperation, or has died from a wound infection, such as a superficial, deep or organ/space SSI, please also document this as the “Most Likely Reason” in the 30 Day Follow-up section of the MBSAQIP database.

SSI Guidance

Surgical Wound Closure - The following information will assist in differentiating three clinical scenarios with respect to wound closure. This will assist in matching MBSAQIP data to other data systems. This also allows more relevant classification of postoperative infections.

A. All layers of incision (deep and superficial) are fully closed by some means. Often referred to as “Incision Primarily Closed.” This category includes complex reconstructive cases where autologous grafts or biologic or synthetic materials are used to reconstruct the closure of the site, as long as the reconstruction is ultimately covered or closed at the skin level. For example, biologic dermal grafts might be used to reconstruct fascial closure of an abdominal hernia, and would still be included in this category. Furthermore, if an incision is described as being “loosely closed” at the skin, or closed with “wicks” employed in the skin, the case would still be included in this category.

B. Only deep layers of incision are closed; superficial layers are left open. For example, for a laparotomy this would occur when the fascial layers are closed but the skin and subcutaneous tissues are left open (usually due to concerns about infection). The wound may or may not be described as "packed" with gauze or other material. Furthermore, if an incision is described as only the superficial layer being opened with no entry into the deep layers (e.g. I&D of superficial layers only), the case would be included in this category.

C. No layers of the incision are surgically closed. For example, for a laparotomy with findings of catastrophic bowel infarction, the fascia might not even be closed. Often such “open abdomen” cases are simply covered with plastic or other synthetic material. At times such cases are re-explored one or more times, and ultimately re-approximation of the abdominal wall might or might not be undertaken. Sometimes these wounds are allowed to granulate and heal by secondary intention, or might be covered with skin allografts or other biologic material at a subsequent operation.

Notes:
• Assign the surgical wound closure that applies when the patient leaves the operating room from the principal operative procedure.

• If there were multiple incisions or access sites involved in the principal operative procedure, choose the closure corresponding to the most complete level of closure of any incision.

• Assign “All layers of incision (deep and superficial) fully closed” in the following example settings:
  o Laparoscopic Colectomy with hand-assist incision and three port sites, all closed primarily.
  o Laparoscopic Colectomy with hand-assist incision and three port sites, port sites closed but hand site open. In such a situation, the port sites have the potential for developing superficial, deep, or organ space infection. The hand incision site has the potential for only developing deep or organ space infection (since skin was left opened). Should the patient develop any SSI, assign in accordance with the SSI variable definition.
  o If there were multiple incisions or access sites involved in the principal operative procedure with some entry sites primarily closed and others were left open…assign All layers of incision (deep and superficial) are fully closed by some means.
  o If there is no incision to close… assign “All layers of incision (deep and superficial) are fully closed by some means.”
  o If a drain is placed during the principal operative procedure and the incision is otherwise re-approximated….“All layers of incision (deep and superficial) are fully closed by some means.”
  o Puncture site where pressure is held to “close” the wound….assign “All layers of incision (deep and superficial) are fully closed by some means.”

• Placement of a wound vac does not constitute closure of a surgical wound.

• To clarify terms: “Closed Primarily” means closed during the original surgery. If a wound is not “Closed Primarily” it can either "Closed Secondarily" at some later date, or be described as “healing by secondary intention,” meaning that it is allowed to granulate on its own and scab over and heal without ever undergoing deliberate surgical closure. Again, guidance is to classify the surgical wound closure that applies when the patient leaves the operating room from the principal operative procedure.
Superficial Incisional SSI

Variable Name: Superficial Incisional SSI

Intent of Variable: To capture the occurrence of infection that does not meet the more severe criteria of deep incisional SSI or organ/space SSI.

Definition: Superficial incisional SSI is an infection that involves only skin or subcutaneous tissue of the surgical incision.

Criteria: An infection that occurs within 30 days after the principal operative procedure AND the infection involves only skin or subcutaneous tissue of the incision AND at least ONE of the following:

A. Purulent drainage, with or without laboratory confirmation, from the superficial incision.
B. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
C. Superficial incision is deliberately opened by a physician or advanced practitioner (see note below).

AND

At least one of the following signs or symptoms of infection:

- pain or tenderness
- localized swelling
- redness
- heat

If the patient meets criterion C and the surgical incision is cultured, a negative culture result would exclude the assignment of Superficial SSI based on criterion C only.

NOTE: Please also refer to Appendix F - Superficial Incisional SSI Algorithm posted to the Resource Portal, Program Resources Tab, ACS MBSAQIP Operations Manual, for additional guidance in assigning a Superficial SSI to a case utilizing criterion C.

D. Diagnosis of superficial incisional SSI by a physician or advanced practitioner.

Options:

- Select “Superficial Incisional SSI” from the dropdown menu.
- Enter date (mm/dd/yyyy).
• Comments (optional).

Scenarios to clarify (Assign Variable):

• Superficial SSI which occurs at a drain site, in which the drain was placed during the principal operative procedure.
• If the patient meets criteria A or D, a negative culture of the surgical incision will not affect the assignment of this occurrence.

Scenarios to clarify (Do Not Assign Variable):

• Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).
• Infected burn wound.
• Incisional SSI that extends into the fascia and muscle layers (see Deep Incisional SSI).
• If wound closure for the principal operative procedure is documented as “superficial layers are left open” or “no layers closed.”
• Report infection that involves both superficial and deep incision sites as Deep Incisional SSI.
• A diagnosis of "cellulitis" alone does not meet criteria to assign a Superficial Incisional SSI if this is in reference to an inflammatory response at the surgical site.
  o If cellulitis is treated with antibiotics this would be considered a diagnosis of an infection.

Notes:

• Only SSIs at the incision site of the principal operative procedure should be assessed. Incision sites for “other” or “concurrent” procedures, if they are in distinctly different anatomical sites should not be assessed. If there is question as to whether or not an incision site was an integral portion of the principal operative procedure, include this site in your SSI assessment. Please note: a single principal operative procedure can have more than one incision.
• Criteria will be assigned when modifying terms such as “possible,” “probable,” “evolving,” “highly suspicious,” or “suggestive” are used to describe an infection, in conjunction with otherwise meeting criteria.
• A positive fungal result would meet criteria as a positive culture.
• A Gram Stain result is not considered a culture and cannot be utilized as criterion to assign this post-operative occurrence.
• When bilateral procedures are performed (e.g. bilateral mastectomy, TKA), both sides need to be assessed for occurrences even if the CPT code for the primary procedure represents only one side.
• Can be assigned multiple times within the 30 day postop period each time criteria is met.
Superficial Incisional SSI – PATOS

Variable Name: Superficial Incisional SSI – PATOS

Intent of Variable: To identify patients who enter the operating room with evidence or suspicion of an existing superficial infection at the surgical site. Present at the time of surgery (PATOS) modifiers preclude the assigned postoperative event from being counted as a postoperative occurrence in modeling.

Definition: Evidence/suspicion of an active superficial infection (e.g., skin / subcutaneous) noted at the time the patient enters the operating room or intra-operatively for the principal operative procedure.

Criteria: The case must meet the following criteria, A AND B below:

A. Superficial Incisional SSI is assigned as a postoperative occurrence.

AND

B. Evidence or suspicion of a superficial infection found at the intended surgical site. This must be noted preoperatively or found intra-operatively at the surgical site and may include an open wound, cellulitis (erythema, tenderness AND swelling), or wound infection.

Options:

- Yes
- No
- Comments (optional)

Scenarios to clarify (Assign Variable):

- A postop superficial infection is assigned; Intra-operatively during the surgical “time out,” cellulitis is noted at the intended surgical site prior to incision.

Scenarios to clarify (Do Not Assign Variable):

- If a superficial SSI has not been assigned as a postop occurrence.

Notes:

- If a Superficial Incisional SSI is assigned as a postoperative occurrence -- only Superficial Incisional SSI PATOS can be assigned if the patient meets criteria for
Superficial Incisional PATOS. [Cannot assign Deep Incisional or Organ/Space PATOS unless the corresponding postoperative occurrence is assigned]

- PATOS criteria are frequently less stringent than criteria for a preoperative risk factor or postoperative occurrence. This means at times PATOS can be assigned to a postoperative occurrence despite the fact that criteria for a preoperative risk factor may not be met.
Deep Incisional SSI

Variable Name: Deep Incisional SSI

Intent of Variable: To capture the occurrence of infection that does not meet the criteria of superficial incisional SSI or organ/space SSI. These infections are typically more severe than the superficial SSI category.

Definition: Deep Incisional SSI is an infection which involves deep soft tissues. Deep soft tissues are typically any tissue beneath skin and immediate subcutaneous fat, for example fascial and muscle layers.

Criteria: An infection that occurs at the surgical site within 30 days after the principal operative procedure AND involves deep soft tissues AND at least ONE of the following:

A. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
B. A deep incision spontaneously dehisces or is deliberately opened by a physician or advanced practitioner when the patient has at least one of the following signs or symptoms: fever (greater than 38°C), localized pain, or tenderness, unless the site is culture-negative.
C. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
D. Diagnosis of a deep incision SSI by a physician or advanced practitioner.

Options:

• Select “Deep Incisional SSI” from the dropdown menu
• Enter date (mm/dd/yyyy)
• Comments (optional)

Scenarios to clarify (Assign Variable):

• Report an infection that involves both superficial and deep incision sites as deep incisional SSI.

Notes:

• Only an SSI at the incision site of the principal operative procedure should only be assessed. Incision sites for “other” or “concurrent” procedures, if they are in distinctly different anatomical sites should not be assessed. If there is question as to whether or not an incision site was an integral portion of the principal operative procedure, include this site in your SSI assessment.
• Criteria will be assigned when modifying terms such as “possible,” “probable,”
“evolving,” “highly suspicious,” or “suggestive” are used to describe an infection,
in conjunction with otherwise meeting criteria.
• A positive fungal result would meet criteria as a positive culture.
• When bilateral procedures are performed (e.g. bilateral mastectomy, TKA), both
sides need to be assessed for occurrences even if the CPT code for the primary
procedure represents only one side.
• Can be assigned multiple times within the 30 day postop period each time criteria
is met.
Deep Incisional SSI – PATOS

Variable Name: Deep Incisional SSI – PATOS

Intent of Variable: To identify patients who enter the operating room with evidence or suspicion of a deep infection at the surgical site. Present at the time of surgery (PATOS) modifiers preclude the assigned postoperative event from being counted as a postoperative occurrence in modeling.

Definition: Evidence/suspicion of an active deep layer infection (e.g., muscle and fascial layers) noted at the time the patient enters the operating room or intra-operatively for the principal operative procedure.

Criteria: The case must meet the following criteria, A AND B below:

A. Deep Incisional SSI is assigned as a postoperative occurrence.

AND

B. Evidence or suspicion of a deep infection (e.g., muscle and fascial layers) found at the intended surgical site. This must be noted preoperatively or found intra-operatively at the surgical site and may include an open wound, cellulitis (erythema, tenderness AND swelling), or wound infection.

Options:

- Yes
- No
- Comments (optional)

Scenarios to clarify (Do Not Assign Variable):

- Deep incisional SSI has not been assigned as a postop occurrence.
- Iatrogenic injuries that occur during the principal operative procedure with no other evidence of infection.

Notes:

- If a Deep Incisional SSI is assigned as a postoperative occurrence, then -- only Deep Incisional SSI PATOS can be assigned if the patient meets criteria for Deep Incisional SSI PATOS [ Cannot assign Superficial or Organ/Space PATOS ].
- PATOS criteria are frequently less stringent than criteria for a preoperative risk factor or postoperative occurrence. This means at times PATOS can be assigned
to a postoperative occurrence despite the fact that criteria for a preoperative risk factor may not be met.

- In instances where criteria for deep SSI was met due to an intraoperative event (e.g. iatrogenic injury) PATOS would not be assigned.
Organ/Space SSI

**Variable Name:** Organ/Space SSI

**Intent of Variable:** To capture the occurrence of infection that does not meet the criteria of superficial incisional SSI or deep incisional SSI. This category of infection is typically the most severe and is more likely to require procedural intervention.

**Definition:** Organ/Space SSI is an infection that involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation.

**Criteria:** An infection that occurs within 30 days after the principal operative procedure AND involves any of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during the operation AND at least ONE of the following:

- A. Purulent drainage from a drain that is placed through a stab wound into the organ/space. This does not apply to drains placed during the principal operative procedure, which are continually in place, with continual evidence of drainage/infection since the time of the principal operative procedure.
- B. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.
- C. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, by histopathologic or radiologic examination. (Please see note)

**NOTE:** If criterion C is met, please also refer to Appendix F Organ/Space SSI Algorithm posted to the Resource Portal, Program Resources Tab, ACS MBSAQIP Operations Manual, for additional guidance in assigning an Organ/Space SSI to a case.

- D. Diagnosis of an organ/space SSI by a physician or advanced practitioner.

**Options:**

- Select “Organ/Space SSI” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)
Scenarios to clarify (Assign Variable):

- Anastomotic leaks involving the GI tract or which involve enteric contents.
- Anastomotic leaks involving the GU tract which involve evidence of an active infection (e.g. elevated WBC/fever attributed to the leak, diagnosis by a physician or advanced practitioner, collection or leak is culture positive).
- Injury to intestine (e.g. enterotomy, iatrogenic injury) which results in a postoperative leak of enteric contents into the abdomen.

Scenarios to clarify (Do Not Assign Variable):

- Fistulas alone, unless they independently meet the other criteria listed above
- C diff in isolation (a positive culture without any other signs and symptoms of infection)
- A bile leak alone, unless the bile is leaking from the G.I tract (small intestine)

Notes:

- Only SSIs at the incision site of the principal operative procedure should be assessed. Incision sites for “other” or “concurrent” procedures that are in distinctly different anatomical sites should not be assessed. If there is question as to whether or not an incision site was an integral portion of the principal operative procedure, then include this site in your SSI assessment.
- Criteria will be assigned when modifying terms such as “possible,” “probable,” “evolving,” “highly suspicious,” or “suggestive” are used to describe an infection, in conjunction with otherwise meeting criteria.
- A positive fungal result would meet criteria as a positive culture.
- A Gram Stain result is not considered a culture and cannot be utilized as criterion to assign this post-operative occurrence.
- An SSI can only be assigned at or below the level of closure.
- When bilateral procedures are performed (e.g. bilateral mastectomy, TKA), both sides need to be assessed for occurrences even if the CPT code for the primary procedure represents only one side.
- Can be assigned multiple times within the 30 day postop period each time criteria is met.
Organ/Space SSI – PATOS

Variable Name: Organ/Space SSI – PATOS

Intent of Variable: To identify patients who enter the operating room with evidence or suspicion of an organ/space infection at the surgical site. Present at the time of surgery (PATOS) modifiers preclude the assigned postoperative event from being counted as a postoperative occurrence in modeling.

Definition: Evidence/suspicion of an active organ/space infection noted at the time the patient enters the operating room or intra-operatively for the principal operative procedure.

Criteria: The case must meet the following criteria, A AND B below:

A. Organ/space SSI is assigned as a postoperative occurrence.

AND

B. Evidence or suspicion of an abscess or other infection involving the organ or space manipulated during the operation. This must be noted preoperatively or found intra-operatively in the surgical space.

Options:

- Yes
- No
- Comments (optional)

Scenarios to clarify (Do Not Assign Variable):

- Organ/Space SSI has not been assigned as a postop occurrence.
- Enterotomies or iatrogenic injuries that occur during the principal operative procedure with no other evidence of infection.

Notes:

- If an Organ/Space SSI is assigned as a postoperative occurrence—only Organ/Space SSI PATOS can be assigned if the patient meets criteria for Organ/Space SSI PATOS [Cannot assign Superficial or Deep PATOS].
- PATOS criteria are frequently less stringent than criteria for a preoperative risk factor or postoperative occurrence. This means at times PATOS can be assigned to a postoperative occurrence despite the fact that criteria for a preoperative risk factor may not be met.
• In instances where criteria for Organ/Space SSI was met due to an intraoperative event (e.g. enterotomy, iatrogenic injury) PATOS would not be assigned.
Wound Disruption

Variable Name: Wound Disruption

Intent of Variable: To capture cases where the integrity of the surgical closure has been compromised.

Definition: The spontaneous reopening of a previously surgically closed wound.

Criteria: A spontaneous reopening of a surgically closed wound that occurs within 30 days after the principal operative procedure AND the primary loss of the integrity of fascial closure (or whatever closure was performed in the absence of fascial closure).

Options:

- Select “Wound Disruption” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)

Scenarios to clarify (Assign Variable):

- Tissue flap coverage where the surgical incisions, which were closed, have lost the integrity of closure.

Scenarios to clarify (Do Not Assign Variable):

- An ostomy with a small separation around it.

Notes:

- If a wound is closed in a subsequent procedure within the 30 day postop period, assign disruption based on this closure.
- When bilateral procedures are performed (e.g. bilateral mastectomy, TKA), both sides need to be assessed for occurrences even if the CPT code for the primary procedure represents only one side.
- Can be assigned multiple times within the 30 day postop period each time criteria is met.
Respiratory Occurrences

Pneumonia

Variable Name: Pneumonia

Intent of Variable: To identify patient(s) that developed an ongoing infectious process involving the lung(s) postoperatively affecting their physiology as described.

Definition: Pneumonia is an infection of one or both lungs caused by bacteria, viruses, fungi, or aspiration. Pneumonia can be community acquired or acquired in a healthcare setting. For more information about pneumonia definition, please see CDC document http://www.cdc.gov/nhsn/PDFs/pscManual/6pscVAPcurrent.pdf.

Criteria: The case must meet Radiology (A) criteria AND ONE of the following TWO Signs/Symptoms/Laboratory (B) scenarios as listed below within the 30 days after the principal operative procedure.

A. Radiology:

ONE chest radiological exam (x-ray or CT)* demonstrating at least ONE of the following:

- Infiltrate
- Consolidation
- Opacity
- Cavitation
- Pneumonia, possible, probable, suspicious for pneumonia

OR

- A diagnosis of pneumonia is rendered by a physician or advanced practitioner based on the findings demonstrated on a chest radiological exam (x-ray or CT).

*Two imaging tests are required for patients with underlying pulmonary or cardiac disease (e.g., respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease).

*See notes section below.

B. Signs/Symptoms/Laboratory:
SCENARIO #1
At least **ONE** of the following:

- Fever (>38°C or >100.4°F) with no other recognized cause
- Leukopenia (<4000 WBC/mm3) or leukocytosis (≥12,000 WBC/mm3)
- For adults ≥ 70 years old, altered mental status with no other recognized cause

**AND**

At least **ONE** of the following:

- 5% Bronchoalveolar lavage (BAL) -obtained cells contain intracellular bacteria on direct microscopic exam (e.g., Gram stain)
- Positive growth in blood culture not related to another source of infection
- Positive growth in culture of pleural fluid
- Positive quantitative culture from minimally contaminated lower respiratory tract (LRT) specimen (e.g. BAL or protected specimen brushing)

**OR**

SCENARIO #2
At least **ONE** of the following:

- Fever (>38°C or >100.4°F) with no other recognized cause
- Leukopenia (<4000 WBC/mm3) or leukocytosis (≥12,000 WBC/mm3)
- For adults ≥ 70 years old, altered mental status with no other recognized cause

**AND**

At least **TWO** of the following:

- New onset of purulent sputum, or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements
- New onset or worsening cough, dyspnea or tachypnea
- Rales (crackles) or rhonchi
- Worsening gas exchange (e.g. O2 desaturations (e.g., PaO2/FiO2 ≤ 240), increased oxygen requirements, or increased ventilator demand)
Options:

- Select “Pneumonia” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)

Scenarios to clarify (Assign Variable):

- When pneumonia criteria are met and the patient has aspiration pneumonitis or aspiration pneumonia.
- Clearly defined description of airspace disease (such as “suspicious for aspiration or infection”) would meet radiological criteria.

Scenarios to clarify (Do Not Assign Variable):

- Documentation of undefined airspace disease and densities on an x-ray would not qualify. Airspace disease may be referring to infection. If this is not clearly defined by the radiologist this description cannot be used. Densities may be referring to tumors rather than evidence of infection.
- A sputum culture is not considered a lower respiratory tract (LRT) specimen and cannot be utilized to assign pneumonia.
- Pneumonia progressing to another lobe is not a new pneumonia.
- At the time of care, if the physician or advanced practitioner documents that the patient does not have pneumonia and treats the patient for a noninfectious pulmonary process (e.g. pulmonary edema, pleural effusion, pulmonary hemorrhage, atelectasis) and subsequent serial radiographs demonstrate a rapid decrease or resolution in the positive radiological findings.

Notes:

- If serial radiological exams are assessed, the occurrence should be assigned on the date the patient first met all of the criteria of the definition (e.g., if the patient meets all PNA criteria on the day of the first x-ray, assign this date to the occurrence).
- In patients with underlying pulmonary or cardiac disease (e.g., respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, chronic obstructive pulmonary disease, CHF, valvular disease), two or more serial chest radiological exams (X-ray or CT) are required.
  - The two exams should both confirm the diagnosis or the first exam can serve as a baseline exam and allows the second exam to establish the definitive new diagnosis.
  - A preoperative X-ray used as a baseline must have been obtained within 30 days of the principal operative procedure or at the time the patient is being considered a candidate for surgery.
  - Postoperative serial radiological exams should be taken no less than 12 hours apart, but not more than 7 days apart.
• Multiple X-rays taken at the time but from different positions (e.g. posteroanterior, anteroposterior, and lateral) are not considered serial chest radiological exams.
• A positive fungal result would meet criteria as a positive culture.
• Can be assigned multiple times within the 30 day postop period each time criteria is met.
Pneumonia – PATOS

Variable Name: Pneumonia – PATOS

Intent of Variable: To identify patients who enter the operating room with evidence of pneumonia or symptoms that are highly suggestive or suspicious of pneumonia. PATOS modifiers preclude the assigned postoperative event from being counted as a postoperative occurrence in the Semiannual Report (SAR) modeling.

Definition: Evidence/suspicion of active pneumonia noted at the time the patient enters the operating room or intra-operatively for the principal operative procedure.

Criteria: The case must meet the following criteria, A AND B below:

A. Pneumonia is assigned as a postoperative occurrence.

AND

B. Preoperative data are highly suggestive or suspicious of pneumonia.

Options:

- Yes
- No
- Comments (optional)

Scenarios to clarify (Assign Variable):

- Preoperative diagnosis by a physician or advanced practitioner of pneumonia on the day of surgery.
- Preoperative diagnosis of pneumonia (day of surgery or prior) with patient undergoing treatment at time of surgery.
- Preoperative X-ray results stating pneumonia and patient being treated at time of surgery.
- Patient being treated for pneumonia at the time of surgery.

Scenarios to clarify (Do Not Assign Variable):

- Pneumonia has not been assigned as a postop occurrence.

Notes:

- PATOS criteria are frequently less stringent than criteria for a preoperative risk factor or postoperative occurrence. This means at times PATOS can be assigned
to a postoperative occurrence despite the fact that criteria for a preoperative risk factor may not be met.
Intraoperative or Postoperative Unplanned Intubation

Variable Name: Intraoperative or Postoperative Unplanned Intubation

Intent of Variable: The variable intent is to capture all unplanned intubations for any reason/cause, including, but not limited to, unplanned intubations for refractory hypotension, cardiac arrest, and inability to protect airway.

Definition: The placement of an endotracheal tube or other similar breathing tube [Laryngeal Mask Airway (LMA), nasotracheal tube, etc.] and ventilator support.

Criteria: An unplanned intubation must be noted intra-operatively or within 30 days after the principal operative procedure AND the following criteria, A AND B below:

A. Patient required placement of an endotracheal tube or other similar breathing tube.

[Laryngeal Mask Airway (LMA), nasotracheal tube, etc.]

AND

B. Patient required ventilator support, which was not intended or planned.

Options:

- Select “Unplanned Intubation” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)

Scenarios to clarify (Assign Variable):

- Patients who were intubated for their surgery, an unplanned intubation occurs after the patient has been extubated.
- Accidental self extubation requiring reintubation.
- For patients who were not intubated for the principal operative procedure or a return to the operating room, intubation at any time after their surgery is complete.
- Emergency tracheostomy.
- If patient is intubated and hand ventilated.

Scenarios to clarify (Do Not Assign Variable):

- CPAP, BiPAP, etc.
- Patients undergoing time off the ventilator during weaning trial and who fail the trial and are placed back on the ventilator.
• Intubations for an unplanned return to the operating room would not be assigned, as the intubation is planned, it is the return to the operating room which is unplanned. For patients who were intubated for a return to the operating room for a surgical procedure, unplanned intubation occurs after they have been extubated after surgery.

• Intraoperative conversion from local or MAC anesthesia to general anesthesia, during the Principal Operative Procedure, with placement of a breathing tube and ventilator support, secondary to the patient not tolerating local or MAC anesthesia, in the absence of an emergency would not be assigned.

  • **Example:** Patient undergoes an inguinal hernia repair under MAC, but, patient doesn’t tolerate the procedure well and is not cooperating; anesthesia switches to general and the patient is intubated. This scenario would not be assigned as an unplanned intubation; it is considered part of the normal safe management of anesthesia for the case.

• If the patient required placement of an endotracheal tube or other similar breathing tube and refused placement of the tube.

**Notes:**

• Patients with a chronic/long-term tracheostomy who are on and off the ventilator would not be assigned, unless the tracheostomy tube itself is removed and the patient requires reintubation (endotracheal or a new tracheostomy tube) or an emergency tracheostomy.

• Can be assigned multiple times within the 30 day postop period each time criteria is met.
**Intraoperative/Postoperative Pulmonary Embolism**

**Variable Name:** Intraoperative/Postoperative Pulmonary Embolism

**Intent of Variable:** The identification of a new blood clot in a pulmonary artery causing obstruction (complete or partial) of the blood supply to the lungs. However, since there are not always preoperative studies proving that a clot or thrombus was not present preoperatively, the technical specification of the variable requires only a “new diagnosis” - in other words the clot or thrombus was not previously known.

**Definition:** Lodging of a blood clot in the pulmonary artery with subsequent obstruction of blood supply to the lung parenchyma. The blood clots usually originate from the deep leg veins or the pelvic venous system.

**Criteria:** A pulmonary embolism must be noted during or within 30 days after the principal operative procedure **AND** the following criteria, A **AND** B below:

A. New diagnosis of a new blood clot in a pulmonary artery.

**AND**

B. The patient has a V-Q scan interpreted as high probability of pulmonary embolism or a positive CT exam, TEE, pulmonary arteriogram, CT angiogram, or any other definitive imaging modality (including direct pathology examination such as autopsy).

**Options:**

- Select “Pulmonary Embolism” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)

**Scenarios to clarify (Do Not Assign Variable):**

- Pulmonary emboli diagnosed prior to the principal operative procedure.
- Cement PE (if this diagnosis is definitive)
- Fat PE (if this diagnosis is definitive)

**Notes:**

- Can only be assigned once within the 30 day postop period.
On Ventilator > 48 Hours

**Variable Name:** On Ventilator > 48 Hours

**Intent of Variable:** To capture patients who have a total cumulative duration of ventilator-assisted respirations greater than 48 hours during the postoperative hospitalization and any subsequent hospitalizations within 30 days after principal operative procedure.

**Definition:** Total cumulative time of ventilator-assisted respirations exceeding 48 hours.

**Criteria:** The total CUMULATIVE time a patient is receiving ventilator support, exceeding 48 hours within 30 days after the principal operative procedure.

**Options:**

- Select “On Ventilator > 48 hours” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)

**Scenarios to clarify (Assign Variable):**

- If the patient was discharged from the operating room intubated and remains on ventilator support more than 48 hours, assign the date 48 hours from the “Patient Out of Room” time.
- If the patient is on the ventilator for greater than 48 hours (cumulatively) postoperatively, regardless of ventilator status preoperatively.
- If the patient was readmitted and placed on ventilation for greater than 48 hours (cumulatively) postoperatively, within the 30 day timeframe.
- If the patient is extubated in the operating room and requires intubation at any point within 30 days, the date recorded should be the point at which the 48 cumulative hours have been reached.

**Scenarios to clarify (Do Not Assign Variable):**

- CPAP, BiPAP, etc. if patient is not intubated.
- Cumulative time periods during weaning trials off the ventilator.
- Time the patient spends intubated during any return to the operating room, while the patient is in the operating room suite, within the 30 day postoperative timeframe, does not count in the cumulative time to assign the variable. Time intubated during a return to operating room reflects the proper safe management of the patient for the reoperation; it does not necessarily reflect respiratory failure/insufficiency requiring vent support.

**Notes:**
• Can only be assigned once within the 30-day postop period.
On Ventilator > 48 Hours – PATOS

Variable Name: On Ventilator > 48 Hours – PATOS

Intent of Variable: To identify patients who are either: 1) intubated and receiving mechanical ventilator support upon entering the operating room, or 2) requires an unplanned intubation intraoperatively prior to the initiation of anesthesia for the principal operative procedure. Present at the time of surgery (PATOS) modifiers preclude the assigned postoperative event from being counted as a postoperative occurrence in the Semiannual Report (SAR) modeling.

Definition: To identify patients who are intubated and receiving mechanical ventilator support upon entering the operating room for the principal operative procedure or requires an unplanned intubation intraoperatively prior to the initiation of anesthesia for the principal operative procedure.

Criteria: The case must meet the following criteria, A AND B below:

A. On the Ventilator > 48 Hours is assigned as a postoperative occurrence

AND

B. One of the following scenarios (1 or 2):

1. The patient is intubated and receiving mechanical ventilator support upon entering the operating room.

OR

2. The patient requires an unplanned intubation intraoperatively prior to the initiation of anesthesia for the principal operative procedure.

Options:

- Yes
- No
- Comments (optional)

Scenarios to clarify (Do Not Assign Variable):

- CPAP, BiPAP, etc.
- Patients who required intubation and ventilator support at some point prior to the principal operative procedure, but who are not intubated and receiving ventilator support prior to the initiation of anesthesia for the principal operative procedure.
Notes:

- PATOS criteria are frequently less stringent than criteria for a preoperative risk factor or postoperative occurrence. This means at times PATOS can be assigned to a postoperative occurrence despite the fact that criteria for a preoperative risk factor may not be met.
Urinary Tract Occurrences

Progressive Renal Insufficiency/Acute Renal Failure Requiring Dialysis [Postop]

Variable Name: Progressive Renal Insufficiency/Acute Renal Failure Requiring Dialysis

Intent of Variable: To identify the patient with significant renal compromise at their most severe renal insufficiency/failure stage.

Definition:

Progressive Renal Insufficiency: the reduced capacity of the kidney(s) to perform its function in comparison to the preoperative state.

Acute Renal Failure Requiring Dialysis: A clinical condition associated with significant decline of kidney function in comparison to the preoperative state.

Criteria: The following criteria A or B below must be met within 30 days after the principal operative procedure, reporting the most severe level (Criterion B):

A. Progressive Renal Insufficiency: A rise in creatinine of >2 mg/dl from preoperative value, but with no requirement for preoperative (within the 2 week timeframe prior to surgery) or postoperative dialysis.

OR

B. Acute Renal Failure Requiring Dialysis: In a patient who did not require dialysis preoperatively (within the 2 week timeframe prior to surgery), worsening of renal dysfunction postoperatively requiring dialysis.

Options:

- Select “Progressive Renal Insufficiency” or “Acute Renal Failure” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)

Scenarios to clarify (Assign Variable):

- Acute Renal Failure Requiring Dialysis:
If the patient refuses a recommendation for dialysis, you would answer "Yes" to this variable because the patient required dialysis.
Hemodialysis, peritoneal dialysis, hemofiltration, hemodiafiltration, or ultrafiltration all qualify.

Scenarios to clarify (Do Not Assign Variable):

- Acute Renal Failure Requiring Dialysis:
  - Placement of a dialysis catheter is indicative of the need for dialysis preoperatively, if used within 14 days of placement.

Notes:

- The preoperative creatinine level that should be utilized when assigning the postoperative occurrence of "progressive renal insufficiency" should be taken closest to the surgery start time, but no greater than 90 days prior to surgery.
- Acute Renal Failure requiring dialysis is the most severe level.
- Can only be assigned once within the 30 day postop period.
**Urinary Tract Infection**

**Variable Name:** Urinary Tract Infection

**Intent of Variable:** To identify patient(s) who developed a symptomatic urinary tract infection postoperatively 30 days after the principal operative procedure.

**Definition:** An infection in the urinary tract (kidneys, ureters, bladder, and urethra).

**Criteria:** Must be noted within 30 days after the principal operative procedure AND patient must meet **ONE** of the following A or B below:

**A.** **ONE** of the following six criteria:

- fever (>38°C or 100.4°F)
- urgency
- frequency
- dysuria
- suprapubic tenderness
- costovertebral angle pain or tenderness

**AND**

- A urine culture of >100,000 colonies/ml urine with no more than two species of organisms. Signs and symptoms should be reported within 72 hours prior to a urine culture being sent or 24 hours after the culture was sent.

**OR**

**B.** **TWO** of the following six criteria:

- fever (>38°C or 100.4°F)
- urgency
- frequency
- dysuria
- suprapublic tenderness
- costovertebral angle pain or tenderness

**AND**

At least **one** of the following:

- Two urine cultures with repeated isolation of the same uropathogen with >100 colonies/mL in non-voided specimen. Signs and symptoms should be reported
within 72 hours prior to a urine culture being sent or 24 hours after the culture was sent.

- Urine culture with < 100,000 colonies/ml urine of single uropathogen in patient being treated with appropriate antimicrobial therapy. Signs and symptoms should be reported within 72 hours prior to a urine culture being sent or 24 hours after the culture was sent.
- Physician or advanced practitioner diagnosis
- A physician or advance practitioner institutes appropriate antimicrobial therapy.

[Please make sure to refer to the additional notes below]

Options:

- Select “Urinary Tract Infection” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)

Scenarios to clarify (Do Not Assign Variable):

- Asymptomatic UTI which are treated or untreated.
- Patients with Foley catheters who do not display signs or symptoms.

Notes:

- In order to assign a postoperative UTI, signs and symptoms should be reported within 72 hours prior to a urine culture being sent or 24 hours after the culture was sent.
- The CDC provides the following guidance: Laboratory cultures reported as “mixed flora” represent at least 2 species of organisms. Therefore an additional organism recovered from the same culture, would represent > 2 species of microorganisms. Such a specimen cannot be used to meet the UTI criteria.
- A positive fungal result would meet criteria as a positive culture.
- Can be assigned multiple times within the 30 day postop period each time criteria is met.
UTI – PATOS

Variable Name: UTI – PATOS

Intent of Variable: To identify patients who enter the operating room with symptomatic UTI or preoperative evidence that is highly suggestive or suspicious of a urinary tract infection (symptomatic or asymptomatic). Present at the time of surgery (PATOS) modifiers preclude the assigned postoperative event from being counted as a postoperative occurrence in modeling.

Definition: Evidence/suspicion of an active urinary tract infection noted at the time the patient enters the operating room or intra-operatively for the principal operative procedure.

Criteria: The case must meet the following criteria, A AND B below:

A. A Urinary Tract Infection (UTI) is assigned as a postoperative occurrence.

AND

B. One of the following scenarios (1 or 2):
   1. Preoperative evidence of a symptomatic UTI that had not started treatment or is currently undergoing treatment.

   OR

   2. Preoperative evidence was highly suggestive or suspicious of a UTI (symptomatic or asymptomatic) at the time of surgery.

Options:

- Yes
- No
- Comments (optional)

Scenarios to clarify (Assign Variable):

- Results from a sterile urine culture obtained at the start of the principal operative can be utilized for evidence.

Notes:

- PATOS criteria are frequently less stringent than criteria for a preoperative risk factor or postoperative occurrence. This means at times PATOS can be assigned to a postoperative occurrence despite the fact that criteria for a preoperative risk factor may not be met.
Central Nervous System Occurrences

Intraoperative/Postoperative Stroke/Cerebral Vascular Accident (CVA)

Variable Name: Intraoperative/Postoperative Stroke/Cerebral Vascular Accident (CVA)

Intent of Variable: To identify patient(s) who developed an acute cerebral vascular accident or acute stroke during or after surgery affecting their physiology as described.

Definition: An interruption or severe reduction of blood supply to the brain resulting in severe dysfunction.

Criteria: The following criteria, A or B below must be met within 30 days after the principal operative procedure.

A. There is motor, sensory, or cognitive dysfunction which persists for 24 hours or more in the setting of a suspected stroke.

OR

B. If a specific timeframe for the dysfunction is not documented in the medical record, but there is a diagnosis of a stroke, assign the occurrence, unless documentation specifically states that the motor, sensory, or cognitive dysfunction resolved within 24 hours.

Options:

- Select “CVA” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)

Scenarios to clarify (Assign Variable):

- A hemorrhagic stroke with motor, sensory, or cognitive dysfunction which persists for 24 hours or more.
- A new subdural hematoma with motor, sensory, or cognitive dysfunction which persists for 24 hours or more.

Scenarios to clarify (Do Not Assign Variable):

- A stroke/CVA is ruled out by a physician and a different reason is documented at the time of care for postoperative motor, sensory, and/or cognitive dysfunction, such as a brain tumor, cranial nerve injury, or encephalopathy. Information documented retrospectively in a discharge summary or follow up visit note would not be utilized.
Notes:

- Can be assigned multiple times within the 30 day postop period each time criteria is met.
**Cardiac Occurrences**

**Intraoperative or Postoperative Cardiac Arrest Requiring CPR**

**Variable Name:** Intraoperative or Postoperative Cardiac Arrest Requiring CPR

**Intent of Variable:** To identify patient(s) who experienced a cardiac arrest or dysfunction and required the initiation of CPR.

**Definition:** The absence of cardiac rhythm or presence of a cardiac rhythm requiring the initiation of cardiopulmonary resuscitation.

**Criteria:** Cardiac Arrest Requiring CPR must be noted intraoperatively or within 30 days after the principal operative procedure **AND** one of the following three scenarios (A or B or C) below:

A. The absence of a cardiac rhythm or presence of cardiac rhythm requiring the initiation of chest compressions.

**OR**

B. Patients in pulseless VT or V-Fib in which defibrillation is performed with or without chest compressions.

**OR**

C. Patients with automatic implantable cardioverter defibrillator (AICD) that fires and the patient has loss of consciousness.

**Options:**
- Select “Cardiac Arrest Requiring CPR” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)

**Scenarios to clarify (Assign Variable):**
- PEA (pulseless electrical activity) arrests requiring chest compressions.
- Patient receives open cardiac massage.

**Scenarios to clarify (Do Not Assign Variable):**
- Patients who might receive initial ACLS medications, but do not proceed to the initiation of chest compressions (except for VT or V-Fib as noted above).
• Patients with a DNR status; keep in mind that you would report the death of a patient who is a DNR and has a cardiac arrest.

Notes:

• Can be assigned multiple times within the 30 day postop period each time criteria is met.
Intraoperative or Postoperative Myocardial Infarction

Variable Name: Intraoperative or Postoperative Myocardial Infarction

Intent of Variable: To identify patient(s) who sustain an acute myocardial infarction (intraop or postop) affecting their physiology as described.

Definition: Reduction of blood flow to the heart causing damage or death to part of the heart muscle.

Criteria: The following criteria A, B, or C below must be met during or within 30 days after the primary procedure:

A. Documentation of ECG changes indicative of acute MI (one or more of the following three):
   1. ST elevation > 1 mm in two or more contiguous leads
   2. New left bundle branch block
   3. New q-wave in two or more contiguous leads

   OR

B. New elevation in troponin greater than three times the regular upper level of the reference range in the setting of suspected myocardial ischemia.

   OR

C. A Physician or advance practitioner diagnosis of myocardial infarction.

Options:
- Select “Myocardial Infarction” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)

Scenarios to clarify (Assign Variable):
- Diagnosis of demand ischemia along with any troponin elevation.
- Documentation of a Non-STEMI or NSTEMI is a diagnosis of a myocardial infarction.

Scenarios to clarify (Do Not Assign Variable):
- A diagnosis of MI is rendered, however, cardiology is consulted and renders an official opinion that signs and symptoms are unrelated to an MI.
Notes:

- The article on which the MBSAQIP MI criteria are based {Journal of the American College of Cardiology. 2012; 60(16): 1583-1598} can be referenced at the following website: http://www.onlinejacc.org/content/60/16/1581
- This table can be found in the article mentioned above. Please note that all types of MI noted are assigned.

Table 2- Universal Classification of Myocardial Infarction

Type 1: Spontaneous myocardial infarction

Spontaneous myocardial infarction related to atherosclerotic plaque rupture, ulceration, assuring, erosion, or dissection with resulting intraluminal thrombus in one or more of the coronary arteries leading to decreased myocardial blood flow or distal platelet emboli with ensuing myocyte necrosis. The patient may have underlying severe CAD but on occasion non-obstructive or no CAD.

Type 2: Myocardial infarction secondary to an ischemic imbalance

In instances of myocardial injury with necrosis where a condition other than CAD contributes to an imbalance between myocardial oxygen supply and/or demand, e.g. coronary endothelial dysfunction, coronary artery spasm, coronary embolism, tachy-/brady-arrhythmias, anemia, respiratory failure, hypotension, and hypertension with or without LVH.

Type 3: Myocardial infarction resulting in death when biomarker values are unavailable

Cardiac death with symptoms suggestive of myocardial ischemia and presumed new ischemic ECG changes or new LBBB, but death occurring before blood samples could be obtained, before cardiac biomarker could rise, or in rare cases cardiac biomarkers were not collected.

Type 4a: Myocardial infarction related to percutaneous coronary intervention (PCI)

Myocardial infarction associated with PCI is arbitrarily defined by elevation of cTn values 5 x 99th percentile URL in patients with normal baseline values (99th percentile URL) or a rise of cTn values 20% if the baseline values are elevated and are stable or falling. In addition, either (i) symptoms suggestive of myocardial ischemia, or (ii) new ischemic ECG changes or new LBBB, or (iii) angiographic loss of patency of a major coronary artery or a side branch or persistent slow- or no-flow or embolization, or (iv) imaging demonstration of new loss of viable myocardium or new regional wall motion abnormality are required.
**Type 4b: Myocardial infarction related to stent thrombosis**

Myocardial infarction associated with stent thrombosis is detected by coronary angiography or autopsy in the setting of myocardial ischemia and with a rise and/or fall of cardiac biomarkers values with at least one value above the 99th percentile URL.

**Type 5: Myocardial infarction related to coronary artery bypass grafting (CABG)**

Myocardial infarction associated with CABG is arbitrarily defined by elevation of cardiac biomarker values 10 x 99th percentile URL in patients with normal baseline cTn values (99th percentile URL). In addition, either (i) new pathological Q waves or new LBBB, or (ii) angiographic documented new graft or new native coronary artery occlusion, or (iii) imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.

- Can be assigned multiple times within the 30 day postop period each time criteria is met.
Other Surgical Occurrences

Transfusion Intra/Postop (RBC within the First 72 Hrs of Surgery Start Time)

Variable Name: Transfusion Intra/Postop (RBC within the First 72 Hrs of Surgery Start Time)

Intent of Variable: To identify those patients for whom it was deemed to be in the patient’s best interest to transfuse blood products (specifically red blood cell & whole blood products) or reinfuse autologous red blood cell or cell-saver products, and to quantify the units utilized/initiated during the principal operative procedure and up to 72 hours postoperatively.

Definition: Transfusion of red blood cells, whole blood, autologous blood, and cell-saver products.

Criteria: Indicate the number of units of red blood cells or whole blood (autologous blood, cell-saver products) utilized/initiated from the principal operative procedure surgical start time up to and including 72 hours postoperatively.

Options:

- Select “Transfusion Intraop/Postop (72 h from surgery start time)” from the dropdown menu.
- Enter the number of Units Utilized/Initiated within 72 hours from surgery start time (1-200).
- Enter date of initial transfusion (mm/dd/yyyy).
- Comments (optional)

Scenarios to clarify (Assign Variable):

- If the patient receives shed blood, autologous blood, cell-saver blood, other reinfusion products such as Constavac or Pleurovac, intraoperatively or postoperatively, then count this blood in terms of equivalent units (see notes below).

Scenarios to clarify (Do Not Assign Variable):

- Intraoperative blood to prime the bypass pump for CABG is not shed blood and should not be included as cell-saver blood.
- Blood initiated prior to the surgical start time and continuing intraoperatively and/or postoperative would not be assigned as an intraoperative/postoperative occurrence.
- Transfusions of fresh frozen plasma (FFP), platelets, or volume expanders (e.g., crystalloids or colloids).
Notes:

- If greater than 200 units are given, enter “200.”
- For shed blood, autologous blood, cell saver, or other reinfusion products (Constavac or Pleurovac), every 500 mL’s of fluid will equal 1 unit of packed cells.
  - If less than 250 mL of cell saver is transfused, you would not record this value. If there are 250mL, or more of cell saver, round up to 1 unit. Please use the table below to assist in determining number of units given;

<table>
<thead>
<tr>
<th>Volume Range</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>1500-1749mL</td>
<td>3 units</td>
</tr>
<tr>
<td>1250-1499mL</td>
<td>3 units</td>
</tr>
<tr>
<td>1000-1249mL</td>
<td>2 units</td>
</tr>
<tr>
<td>750-999mL</td>
<td>2 units</td>
</tr>
<tr>
<td>500-749mL</td>
<td>1 unit</td>
</tr>
<tr>
<td>250-499mL</td>
<td>1 unit</td>
</tr>
<tr>
<td>0-249mL</td>
<td>0 units</td>
</tr>
</tbody>
</table>

- The blood may be given for any reason.
- Record the number of units given or initiated. Record the date the first transfusion was initially started (intra-operatively or postoperatively).
- For a transfusion initiated intraoperatively, when the principal operative procedure crosses over 2 days enter the date the procedure ended.
- Can only be assigned once within the 30 day postop period.
Vein Thrombosis Requiring Therapy [Postop]

Variable Name: Vein Thrombosis Requiring Therapy

Intent of Variable: To identify patient(s) that developed a new blood clot or thrombus within the venous system postoperatively affecting their physiology and requiring treatment as described. However, since there are not always preoperative studies proving that a clot or thrombus was not present preoperatively, the technical specification of the variable requires only a “new diagnosis” - in other words the clot or thrombus was not previously known.

Definition: New diagnosis of blood clot or thrombus within the venous system (superficial or deep) which may be coupled with inflammation and requires treatment.

Criteria: Must be noted within 30 days after the principal operative procedure AND one of the following A or B below:

A. New Diagnosis of a [new] venous thrombosis (superficial or deep), confirmed by a duplex, venogram, CT scan, or any other definitive imaging modality (including direct pathology examination such as autopsy) AND the patient must be treated. Treatment includes anticoagulation therapy, placement of a vena cava filter, clipping of the vena cava, or thrombectomy. If the record indicates that treatment was warranted but there was no additional appropriate treatment option available, this would meet treatment criteria.

OR

B. As per (A) above, but the patient or decision maker has refused treatment. There must be documentation in the medical record of the [patient’s] refusal of treatment.

Options:

- Select “Vein Thrombosis Requiring Therapy” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)

Scenarios to clarify (Assign Variable):

- Internal jugular (IJ) clots
- Cephalic Vein clots
- Portal vein clots
• Patient requires therapy, but refuses.
• Chronic venous thrombosis present preoperatively, which are also noted postoperatively with evidence of new progression.
• If the patient is already on an anticoagulant, a new thrombus is noted and the medical professional caring for the patient documents that the current anticoagulant is sufficient to treat the new thrombus.

Scenarios to clarify (Do Not Assign Variable):

• Chronic venous thrombosis present preoperatively, which are also noted postoperatively but without evidence of new progression.
• If only an intravenous catheter is thrombosed and the vein is not.
• Arterial clots
• Aspirin alone does not constitute treatment sufficient to assign vein thrombosis requiring therapy.

Notes:

• Can only be assigned once within the 30 day postop period.
Postoperative Clostridium *difficile* (*C. diff*) Colitis

**Variable Name:** Postoperative Clostridium *difficile* (*C. diff*) Colitis

**Intent of Variable:** To identify patients who develop *C. difficile* colitis within 30 days after the principal operative procedure and did not have an active *C. diff* infection at the time of the principal operative procedure.

**Definition:** *C. difficile* colitis is diarrhea of varying severity, from mild to fulminant and life-threatening. It results from a disturbance of the normal bacterial flora of the colon and colonization by *C. difficile* which releases toxins (A&B) that cause mucosal inflammation and damage.

**Criteria:**

No active *C. diff* infection (including diagnosis or treatment) at the time of the principal operative procedure and at least one of the following:

1. There is documentation in the medical record of a positive *C. difficile* laboratory in the 30 day postoperative period.

   **OR**

2. There is documentation in the record that the patient is receiving current treatment for *C. difficile*.

**Options:** You must first select “yes” to “Was there a postoperative occurrence?” Then select “*C. diff*” from the drop down menu and complete the additional questions.

- Select *C. difficile* from the dropdown menu and complete the additional questions.
  - Date of occurrence (mm/dd/yyyy)
- Answer “Type of *C. Diff* Test Performed.”
  1. Toxin
  2. DNA
  3. Other - *C. diff*
  4. Other - Non *C. diff*
  5. Unknown
  6. None

- Answer “Result of *C. diff* Test” (if selected options 1-4 above)
  1. Positive
2. Negative

- Answer “Was the patient given Treatment for C. diff?”
  1. Yes
  2. No

- Answer “Did the Patient have diarrhea/loose stools?”
  1. Yes
  2. No

**Scenarios to Clarify (Assign Variable):**

- Document the date all criteria is met for options selected.

**Notes:**

- Do not assign if patient is treated for C. diff, but the initial C.diff test comes back negative and then the treatment is discontinued within 24 hours of the negative result.
- Laboratory assays may include:
  - Stool culture
  - Glutamate dehydrogenase EIA or latex agglutination
  - PCR assay,
  - Stool cytotoxin test
  - EIA for toxins A&B
- Treatments may include:
  - Oral and/or IV antibiotics
  - Fecal enemas
  - Surgical treatment for fulminant/uncontrolled C. diff colitis
- Can only be assigned once per 30 days.
Sepsis

Variable Name: Sepsis

Intent of Variable: To capture the patient who has developed an acute infectious process postoperatively affecting their physiology as described.

Definition: Sepsis takes a variety of forms and spans from relatively mild physiologic abnormalities to septic shock.

Sepsis: Sepsis is the systemic response to infection.

Septic Shock: Sepsis is considered severe when it is associated with organ and/or circulatory dysfunction.

Criteria: Report the most significant level using the criteria below: Septic shock is more severe than sepsis. Criteria must be noted within 30 days after the principal operative procedure. Report this variable if the criteria below are met.

A. **Five Clinical Signs of SIRS (need two):**

1. Temp >38°C (100.4°F) or < 36°C (96.8°F)
2. HR >90 bpm
3. RR >20 breaths/min or PaCO2 <32 mmHg (<4.3 kPa)
4. WBC >12,000 cell/mm3, <4000 cells/mm3, or >10% immature (band) forms
5. Anion gap acidosis: this is defined by either: (check with your Lab on calculation)
   a. [Na + K] – [Cl + HCO3 (or serum CO2)]. If this number is greater than 16, then an anion gap acidosis is present.
   b. Na – [Cl + HCO3 (or serum CO2)]. If this number is greater than 12, then an anion gap acidosis is present.

AND

B. **Sepsis: Either scenario 1, 2, 3, or 4:**

**Scenario 1: Following the principal operative procedure or a reoperation**

The patient must meet SIRS criteria (any two of the five) and One of the following:

a. Positive blood culture
b. Clinical documentation of purulence or positive culture from any site for which there is correlating physician or advanced practitioner documentation that the site was thought to be the acute cause of the septic picture
OR

Scenario 2: Immediately following and up to 8 hours after the principal operative procedure or a reoperation

Immediately following and up to 8 hours after the principal operative procedure or reoperation an elevated heart rate and elevated respiratory rate together will not satisfy SIRS criteria. SIRS criteria must be met utilizing at least one criterion of temperature, leukocyte count, or anion gap acidosis if an elevated heart rate or elevated respirations is used.

The patient must meet SIRS criteria as specified above AND one of the following findings during the Principal Operative Procedure or reoperation:

a. Confirmed ischemic/infarcted bowel (for instance requiring resection)
b. Purulence in the operative site
c. Enteric/gastric contents in the operative site
d. Positive intraoperative culture

OR

Scenario 3: 8-48 hours after the Principal Operative Procedure

The patient must meet SIRS criteria (any two of the five) between 8 and 48 hours after the Principal Operative Procedure AND one of the following findings during the Principal Operative Procedure:

a. Confirmed ischemic/infarcted bowel (for instance requiring resection)
b. Purulence in the operative site
c. Enteric/gastric contents in the operative site
d. Positive intraoperative culture

OR

Scenario 4: 48 hours before or 8-48 hours after a Reoperation

The patient must meet SIRS criteria (any two of the five) within 48 hours before or between 8 and 48 hours after a subsequent reoperation AND one of the following findings during a subsequent operation:

a. Confirmed ischemic/infarcted bowel (for instance requiring resection)
b. Purulence in the operative site
c. Enteric/gastric contents in the operative site
d. Positive intraoperative culture

Options:

- Select “Sepsis” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)

Scenarios to clarify (Assign Variable):

- The presence of pneumatosis along with the presence of SIRS.

Scenarios to clarify (Do Not Assign Variable):

- Patient meets SIRS criteria; however, they have only a positive culture from a chronic leg wound, which is otherwise unchanged in its chronic appearance.
- In cases where there is a documented explanation or evidence that the criteria being reviewed for SIRS (i.e. HR, RR, Temp) are likely due to a cause other than an inflammatory or infectious process, SIRS should not be assigned. For instance, if the patient’s heart rate and respiratory rate are elevated and the WBC, temperature, and anion gap were all normal and there is no other evidence of infection. Nursing and physician documentation state the patient is anxious about their diagnosis and concern for family. As there is no evidence of an ongoing inflammatory process, in this example, it is highly unlikely that the patient’s elevated heart rate and respiratory rate are due to SIRS and are more likely due to anxiety. Therefore, this case will not meet SIRS criteria.

Notes:

- Report only the most significant level of Sepsis or Septic Shock.
- A positive fungal result would meet criteria as a positive culture.
- Assign variable once during the 30 day postoperative timeframe.
Sepsis – PATOS

Variable Name: Sepsis – PATOS

Intent of Variable: To identify patients in which preoperative/intraoperative data are highly suggestive or suspicious of sepsis being present at time of surgery. Present at the time of surgery (PATOS) modifiers preclude the assigned postoperative event from being counted as a postoperative occurrence in modeling.

Definition: Evidence is highly suggestive or suspicious of a systemic response to infection preoperatively/ intraoperatively.

Criteria: The case must meet the following criteria, A AND B below:

A. Sepsis is noted as a postoperative occurrence.

AND

B. Preoperative/intraoperative evidence was highly suggestive or suspicious of sepsis at the time of the principal operative procedure.

Options:

- Yes
- No
- Comments (Optional)

Scenarios to clarify (Do Not Assign Variable):

- If the record indicates that sepsis was present at some point preoperatively but fully and definitively resolved prior to the time of surgery, then PATOS should not be chosen.
- Injury to intestine (e.g. enterotomy, iatrogenic injury) which results in a postoperative leak of enteric contents into the abdomen.

Notes:

- If postoperative “Sepsis” is assigned--only “PATOS Sepsis” can be assigned (provided that the patient meets criteria for PATOS Sepsis). Cannot assign “PATOS Septic shock” unless septic shock occurs postoperatively.
- PATOS criteria are frequently less stringent than criteria for the postoperative occurrence.
- Sepsis PATOS: If sepsis is noted as a postoperative outcome; select YES (for PATOS) if preoperative data are highly suggestive or suspicious of Sepsis or the
more severe level of Septic Shock being present at the time of surgery. If the record indicated that Sepsis or the more severe level of Septic Shock was present at some point preoperatively but fully and definitively resolved prior to the time of surgery, then PATOS should not be chosen.

- In instances where criteria for sepsis was met due to an intraoperative event (e.g. enterotomy, iatrogenic injury) PATOS would not be assigned.
Septic Shock

Variable Name: Septic Shock

Intent of Variable: To capture the patient who has developed an acute infectious process postoperatively affecting their physiology as described. Sepsis takes a variety of forms and spans from relatively mild physiologic abnormalities to septic shock.

Definition: Septic shock is more severe than sepsis as it is associated with organ and/or circulatory dysfunction.

Criteria: Criteria must be noted within 30 days after the principal operative procedure. Report this variable if the patient meets SIRS criteria (A) AND meets the criteria of Septic Shock below:

Report this variable if the patient meets both of the followings:

1. Sepsis criteria

   AND

2. Has documented organ and/or circulatory dysfunction.

   • Examples of organ dysfunction include oliguria, acute alteration in mental status, acute respiratory distress.
   • Examples of circulatory dysfunction include hypotension with requirement of inotropic or vasopressor agents.

Options:

   • Select “Septic Shock” from the dropdown menu
   • Enter date (mm/dd/yyyy)
   • Comments (optional)

Scenarios to clarify (Do Not Assign Variable):

   • Cardiogenic, neurogenic, distributive or hypovolemic shock, in the absence of meeting above criteria.

Notes:

   • Report only the most significant level of sepsis or septic shock.
   • Assign variable once during the 30 day postoperative timeframe.
Septic Shock – PATOS

Variable Name: Septic Shock – PATOS

Intent of Variable: To identify patients in which preoperative/intraoperative data are highly suggestive or suspicious of septic shock being present at time of surgery. Present at the time of surgery (PATOS) modifiers preclude the assigned postoperative event from being counted as a postoperative occurrence in modeling.

Definition: Evidence is highly suggestive or suspicious of a systemic response to infection with organ/circulatory dysfunction preoperatively/intraoperatively for the principal operative procedure.

Criteria: The case must meet the following criteria, A AND B below:

A. Septic Shock is noted as a postoperative occurrence.

AND

B. Preoperative/intraoperative evidence was highly suggestive or suspicious of septic shock at the time of the principal operative procedure.

Options:

- Yes
- No
- Comments (Optional)

Scenarios to clarify (Do Not Assign Variable):

- If the record indicates that septic shock was present at some point preoperatively but fully and definitively resolved prior to the time of surgery, then PATOS should not be chosen.
- Injury to intestine (e.g. enterotomy, iatrogenic injury) which results in a postoperative leak of enteric contents into the abdomen.

Notes:

- If postoperative “Septic shock” is assigned--only “PATOS septic shock” can be assigned (provided the patient meets criteria for PATOS septic shock). “PATOS sepsis” cannot assign because septic shock is the occurrence that is more severe and takes precedence over sepsis.
- In instances where criteria for septic shock was met due to an intraoperative event (e.g. enterotomy, iatrogenic injury) PATOS would not be assigned.
Other Postoperative Occurrence (ICD Code)*

Variable Name: Other Postoperative Occurrence (ICD Code)*

Intent of Variable: To capture postoperative occurrences not previously captured on a site by site basis.

Definition: Individual sites determine the use of this field.

Options:

- Select “Other (list ICD code)” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Enter ICD Code

Notes:

- These “other postoperative occurrences” will not be risk-adjusted for the semi-annual report (SAR). If this data needs to be analyzed, a data download report may be run.
Metabolic/Bariatric Postoperative Occurrences

Coma >24 Hours

Variable Name: Coma >24 Hours

Intent of Variable: To capture those patients who are unresponsive for a period of time greater than 24 hours post-operatively.

Definition: See criteria below

Criteria: Patient is unconscious, or postures to painful stimuli, or is unresponsive to all stimuli in the post-operative period.

Options:

- Yes
- No

Scenarios to Clarify (Do Not Assign Variable):

- Do not include drug-induced coma (e.g., Propofol, versed, precedex, pentobarbital IV infusions).
- Exclude transient disorientation or psychosis.

Notes:

- Assign variable once during the 30 day postoperative timeframe.
Peripheral Nerve Injury

**Variable Name:** Peripheral Nerve Injury

**Intent of Variable:** To capture those patients who have developed peripheral nerve damage post-operatively due to potential intra-operative positioning.

**Definition:** Peripheral nerve damage may result from damage to the nerve fibers, cell body, or myelin sheath during surgery.

**Criteria:** Peripheral nerve injuries which result in motor deficits to the cervical plexus, brachial plexus, ulnar plexus, lumbar-sacral plexus (sciatic nerve), peroneal nerve, and/or the femoral nerve.

**Options:**
- Yes
- No

**Notes:**
- Assign variable once during the 30 day postoperative timeframe.
Unplanned Admission to ICU within 30 Days

**Variable Name:** Unplanned Admission to ICU within 30 Days

**Intent of Variable:** To capture those patients who were admitted in the intensive care unit (ICU) at any time during the 30 days postoperatively and was not planned preoperatively.

**Definition:** An unplanned admission to the intensive care unit (ICU) at any time within the 30 day postoperative period.

**Criteria:** A patient that was admitted to the intensive care unit at any time within 30 days postoperatively.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- Examples of ICU include SICU, MICU, NSICU, CVICU, CCU, etc.

**Scenarios to Clarify (Do Not Assign Variable):**
- If the patient was never admitted to the ICU or if the decision to send to the ICU was made preoperatively.

**Notes:**
- Assign variable once during the 30 day postoperative timeframe.
Other Postoperative Occurrence (ICD Code)*

**Variable Name:** Other Postoperative Occurrence (ICD Code)*

**Intent of Variable:** To capture postoperative occurrences not previously captured on a site by site basis.

**Definition:** Individual sites determine the use of this field.

**Options:**

- Select “Other (list ICD code)” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Enter ICD Code

**Notes:**

- These “other postoperative occurrences” will not be risk-adjusted for the semi-annual report (SAR). If this data needs to be analyzed, a data download report may be run.
Discharge Information

Acute Hospital Discharge Date

Variable Name: Acute Hospital Discharge Date

Intent of variable: To capture the date on which the patient’s level of care reflects discharge from the acute level of care whether or not the patient leaves your institution.

Definition: The date when the patient is discharged or transferred from the acute hospital setting at your institution.

Criteria: Enter the date the patient is transferred or discharged from your hospital’s acute care setting.

Options:
- Enter Date (mm/dd/yyyy)

Scenarios to clarify (Assign Variable):
- Patient remains in institution but is transferred from acute to sub-acute care, assign the date of this transfer from acute care.
- Patient is transferred from the acute care setting of your institution to the acute care setting of another institution; assign the date of this transfer out of your institution as the discharge date from your hospital and enter discharge destination appropriately.

Scenarios to clarify (Do Not Assign Variable):
- The transfer from an intensive care unit to a regular acute medical/surgical floor is not a discharge from acute care.

Notes:
- If the patient remains in the acute hospital setting at 30 days, record as “still in-hospital at 30 days.”
- If the patient dies in the acute hospital setting, record the date of death as the hospital discharge date.
Hospital Discharge Destination

Variable Name: Hospital Discharge Destination

Intent of variable: To capture information that might be utilized to assess completeness of care episode or utilization of resources.

Definition: The place where the patient was discharged following their acute care stay.

Criteria: Choose the patient’s discharge destination from the following options.

Options:

- Skilled care, not home (e.g., transitional care unit, sub-acute hospital, ventilator bed, skilled nursing home)
- Unskilled facility, not home (e.g., nursing home or assisted facility-if not patient’s home preoperatively)
- Facility which was home (e.g., return to a chronic care, unskilled facility, or assisted living-which was the patient’s home preoperatively, prison)
- Home
- Separate acute care (e.g., transfer to another acute care facility)
- Rehab
- Expired
- Unknown

Notes:

- See CMS-MBSAQIP Discharge Destination Crosswalk in Appendix I
Still in Hospital > 30 Days

**Variable Name:** Still in Hospital > 30 Days

**Intent of Variable:** To indicate that the patient has not yet been discharged from the acute care setting at your institution within 30 days after the principal operative procedure. Postoperative day 30 represents the final day of follow-up for the patient, for any occurrence, except in-hospital death.

**Definition:** The patient remains in the acute care setting at your institution continuously for > 30 days after the principal operative procedure.

**Criteria:** Patient has a **continuous** stay in the acute care setting **at your institution** > 30 days after the principal operative procedure.

**Options:**
- Check box

**Scenarios to clarify (Do Not Assign Variable):**
- Patients discharged from the acute care setting at your institution, but remained in the hospital (rehab or hospice unit).
Death During Operation (Intraoperative Death) or Postoperative Death within 30 Days of Procedure

Variable Name: Death During Operation (Intraoperative Death) or Postoperative Death w/in 30 Days of Procedure

Intent of Variable: To capture any death that occurs at any point within 30 days after the principal operative procedure.

Definition: Any death, regardless of cause, noted during the intraoperative period or within 30 days after the principal operative procedure. The date the patient leaves the surgical suite is treated as POD 0. The intraoperative period is defined from the time the patient arrives in the operating room (Patient In Room time) to the time the patient is transported out of the operating room (Patient Out of Room time). Deaths occurring by midnight of POD 30 would be included.

Criteria: Death, regardless of cause, must be noted intraoperatively or within 30 days after the principal operative procedure AND one of the following three scenarios (A or B or C) below:

A. If the patient dies in the operating room, regardless of cause, enter the date of death for the patient.

OR

B. If patient enters the operating room and death, regardless of cause, occurs intraoperatively, but on the following day, document the actual date the death occurred, if different from the date the patient entered the operating room.

OR

C. If the patient dies within 30 days after the principal operative procedure, regardless of cause, in or out of the hospital, enter the date of death for the patient.

Options:

- Yes
- No

Notes:

- A death that occurs within 30 days after the principal operative procedure is considered full 30 day follow-up as no additional follow-up can be obtained.
Date of Death [30 Day]

Intent of Variable: To capture the date of death of the patient.

Definition: The date in which the patient expires.

Criteria: Enter date of death based on ONE of the following four scenarios (A, B, C, or D) below:

A. If the patient dies in the operating room, enter the date of death for the patient.

B. If patient enters the operating room and death occurs intraoperatively, but on the following day, document the actual date the death occurred if different from the date the patient entered the operating room.

C. If the patient dies within 30 days after the principal operative procedure, regardless of cause, in or out of the hospital, enter the date of death for the patient.

D. If patient was never discharged from the acute care setting, and remained in the hospital >30 days, and the death is related to the principal operative procedure or a postoperative complication enter the date of death.

E. If date of death is not reported assign “Unknown”.

Options:

- Enter date (mm/dd/yyyy)
- Unknown
Was the Death Likely Related to the Operation?

**Intent of Variable:** To determine if the death of the patient was related to the bariatric or metabolic surgical procedure or a related complication.

**Definition:** See criteria below

**Criteria:** Determine if the death of the patient’s death was related to the bariatric or metabolic surgical procedure or a related complication.

**Options:**

- Yes
- No
**Most Likely Cause of Death**

**Intent of Variable:** To capture the likely cause of death as related to the bariatric or metabolic surgical procedure.

**Definition:** See criteria below

**Criteria:** Enter the patient’s suspected cause of death as reported in the medical record or autopsy report.

**Options:** Select the most appropriate option from the drop down menu. (See notes section)

**Notes:**

<table>
<thead>
<tr>
<th>Most Likely Cause</th>
<th>Most Likely Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anastomotic/Staple Line Leak</td>
<td>Incisional Hernia</td>
</tr>
<tr>
<td>GI Perforation</td>
<td>Bleeding</td>
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<td>Pulmonary Embolism</td>
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<tr>
<td>Intestinal Obstruction</td>
<td>Pneumonia</td>
</tr>
<tr>
<td>Gastric Distention</td>
<td>Other Respiratory Failure</td>
</tr>
<tr>
<td>Fluid, electrolyte, or nutritional depletion</td>
<td>Infection/Fever</td>
</tr>
<tr>
<td>Anastomotic Ulcer</td>
<td>Band Slippage/Prolapse</td>
</tr>
<tr>
<td>Gastro-Gastric Fistula</td>
<td>Band Erosion</td>
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<tr>
<td>Gallstone Disease</td>
<td>LAGB – Port, Tubing or Band problem</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>Wound Infection/Evisceration</td>
<td>Bile Reflux Gastritis</td>
</tr>
<tr>
<td>Internal Hernia</td>
<td>Other</td>
</tr>
</tbody>
</table>
Was the Death Reviewed by the Bariatric Committee within 60 Days of Death? [30 Day]

Intent of Variable: To determine if the death of the patient was reviewed by the MBS (Bariatric) Committee within 60 Days of Death.

Definition: See criteria below

Criteria: If a mortality event occurred within 30 days of the principal operative procedure, regardless of cause, the site’s MBS (Bariatric) Committee reviewed the Death within 60 days of the occurrence.

Options:

- Yes
- No
Did the Patient Receive Treatment for Dehydration as an Outpatient?

**Intent of Variable:** To capture the number of treatments a patient received within the 30 day postoperative timeframe for nausea and vomiting, fluid, electrolyte, or nutritional depletion on an outpatient.

**Definition:** See criteria

**Criteria:** The patient receives outpatient therapy (fluids, medications, etc.) for the treatment of nausea and vomiting, fluid, electrolyte, or nutritional depletion within the 30 day postoperative timeframe.

**Options:**
- Yes
  - Select the number of treatments
- No

**Scenarios to Clarify (Assign Variable):**

- Patient received IV fluids or IV medications for the treatment of nausea and vomiting, fluid, electrolyte, or nutritional depletion.

**Scenarios to Clarify (Do Not Assign Variable):**

- Patient received oral or transdermal medications for the treatment of nausea and vomiting, fluid, electrolyte, or nutritional depletion.

**Notes:**

- If the patient was treated in the ED and not admitted, you would also assign “Was the Patient Seen in any Emergency Department (ED) which did not result in an Inpatient Admission?”
Was the Patient Seen in any Emergency Department (ED) Which Did Not Result in an Inpatient Admission?

**Intent of Variable:** To capture emergency department (ED) visits within the 30 day postoperative timeframe that does not result in an inpatient admission.

**Definition:** See criteria

**Criteria:** A patient is seen in the emergency department for any reason within the 30 day postoperative timeframe, but does not meet criteria for a "hospital readmission" per MBSAQIP definition.

**Options:**
- Yes
  - Select the number of times
- No

**Scenarios to Clarify (Assign Variable):**
- Visits to Urgent Care Centers which function as emergency departments should be counted. Each institution should determine whether affiliated and non-affiliated Urgent Care Centers fit this definition.

**Scenarios to Clarify (Do Not Assign Variable):**
- The patient meets MBSAQIP criteria for a “hospital readmission.” See variable criteria for full definition.

**Notes:**
- If the patient was treated for dehydration; nausea and/or vomiting; fluid, electrolyte, or nutritional depletion in the ED and not admitted, you would also assign “Did the Patient Receive Treatment for Dehydration (Nausea and Vomiting, Fluid, Electrolyte, or Nutritional Depletion) as an Outpatient?”
Hospital Readmissions

Did the Patient have a Hospital Readmission within 30 Days of the Principal Procedure?

Intent of Variable: To capture inpatient readmission(s) by midnight of POD 30 and distinguish between planned and unplanned readmissions at the time of the principal operative procedure; and to distinguish those that are likely related or unlikely related to adverse events following the principal operative procedure.

Definition: Patients who were discharged from their index hospital stay or encounter (whether inpatient or outpatient basis) after their principal operative procedure, and within 30 days of the principal operative procedure, are subsequently formally readmitted by a qualified practitioner as an inpatient to an acute care bed

OR

Otherwise have a subsequent hospital (or facility-based) encounter (receiving outpatient, emergency department, or observation services) that crosses at least two midnights.

Criteria: Were there any readmissions (to the same or another hospital), for any reason, within 30 days after the principal operative procedure as per the definition above.

Options:

• Yes

Enter each hospital readmission separately. For each admission enter the following:

• Readmission Date or Unknown
• Discharge Date or Unknown or N/A
• Information Source
  • Medical Record
  • Patient/Family Report
  • Other
• Was this readmission unplanned at the time of the principal procedure?
  • Yes
  • No
• Did this readmission occur at your hospital?
• Yes
• No
• Was this readmission likely related to a metabolic or bariatric procedure?
  • Yes
  • No
• Most Likely Reason (See notes section)
  • Choose from drop down menu
  • If the patient was readmitted for any reason not included in drop down menu, please select "Other."

• No

Scenarios to Clarify (Assign Variable):

• If a patient is admitted to an outside Emergency Department and you do not have access to this site’s orders, utilize the patient arrival date to that outside Emergency Department as the hospital stay or encounter start date when assessing for readmission.

Scenarios to Clarify (Do Not Assign Variable):

• Do not capture emergency room visits that did not meet criteria above.
• If a patient is transferred from your acute care site directly to another acute care site, this is not a readmission. An example of this would be a transfer to a higher level of care or for a procedure that cannot be done at your institution.
• If your site is a DOD or international site which does not utilize the “Outpatient” or “Observation” status designation, however, documentation indicates that the patient is being admitted for outpatient or observation services and the stay does not cross 2 midnights.

Notes:

• This definition follows the spirit of CMS's "two midnight" rule, though it differs in the sense that for MBSAQIP purposes, a two-midnight stay will definitely constitute a readmission (CMS does not require two-midnight stays to constitute inpatient admission, though it does provide guidance that outpatient or observational stays longer than 48 hrs should be rare). In considering this MBSAQIP definition, the following verbiage from CMS regarding Rule 1599F can also provide guidance:

  "...consider time the beneficiary spent receiving outpatient services (including observation services, treatments in the emergency department,
and procedures provided in the operating room or other treatment area) for purposes of determining whether the 2-midnight benchmark is [met]... the starting point for medical review purposes [should be] the time the patient starts receiving any services after arrival at the hospital." -CMS Rule

Thus, for MBSAQIP purposes, if a patient is in observation or receiving some combination of outpatient services this time counts against the two-midnight judgment.

- Multiple readmissions can be entered, similar to how multiple postoperative occurrences can be entered.
- A field is provided for readmission comments.
- Evaluate the reason for admission from the discharge summary in order to capture the most accurate single diagnosis of the patient’s primary discharge diagnosis.

<table>
<thead>
<tr>
<th>Most Likely Reason</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Nausea, Vomiting, Fluid, Electrolyte or Nutritional Depletion</td>
<td>Chest Pain (cardiac enzymes not required to be positive)</td>
</tr>
<tr>
<td>Anastomotic/Staple Line Leak</td>
<td>Myocardial Infarction</td>
</tr>
<tr>
<td>Anastomotic Ulcer</td>
<td>Abdominal Pain, Not Otherwise Specified</td>
</tr>
<tr>
<td>Band Slippage/Prolapse</td>
<td>Intestinal Obstruction</td>
</tr>
<tr>
<td>Band Erosion</td>
<td>Other Abdominal Sepsis (diverticulitis, pancreatitis, intra-abdominal abscess)</td>
</tr>
<tr>
<td>Bleeding</td>
<td>CVA</td>
</tr>
<tr>
<td>Gastric Distention</td>
<td>Psychiatric-Related</td>
</tr>
<tr>
<td>Gastro-Gastric Fistula</td>
<td>Nephrolithiasis</td>
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<td>Musculoskeletal Pain</td>
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<td>Other Respiratory Failure (including pleural effusions)</td>
<td>Other</td>
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<td>Pneumonia</td>
<td>Planned Surgery</td>
</tr>
<tr>
<td>Pulmonary Embolism</td>
<td>Vein Thrombosis Requiring Therapy</td>
</tr>
<tr>
<td>Shortness of Breath (without diagnosis of PE)</td>
<td></td>
</tr>
<tr>
<td>Cardiac, Not Otherwise Specified (arrhythmia, CHF)</td>
<td></td>
</tr>
</tbody>
</table>
Reoperations/Interventions Performed After the Principal Metabolic or Bariatric Procedure
Reoperations

Did the Patient have a Reoperation within the 30 Day Postoperative Period?

Intent of Variable: To capture any reoperations performed within 30 days of the assessed bariatric or metabolic surgical procedure.

Definition: Any reoperations performed within 30 days of the assessed bariatric or metabolic surgical procedure. Complete one reoperation entry in the database for each encounter in the operating room (OR); even if more than one procedure was performed during that encounter.

Criteria: A reoperation would only be entered in the MBSAQIP database if, at a minimum, procedural sedation or anesthesia was required for the procedure or if a metabolic or bariatric related procedure was performed.

Options:

- Yes
  - Was this reoperation unplanned at the time of the principal procedure?
    - Yes
    - No
  - Was this reoperation performed at your hospital?
    - Yes
    - No
  - Was this reoperation likely related to the metabolic or bariatric procedure?
    - Yes
    - No
  - Emergency Case?
    - Yes
    - No
  - Was this a stapling case?
    - Yes
    - No
  - Was this procedure a Revision/Conversion?
    - Yes
    - No
  - Was this procedure a mini-loop gastric bypass?
    - Yes
    - No
  - Was this procedure a gastric plication?
    - Yes
    - No
  - Was this procedure an endoscopic therapy?
    - Yes
    - No
Select the appropriate reoperation from the drop-down menu

- Operative Drain Placement
- Gastrostomy Tube (G-tube) Placement
- Jejunostomy Tube (J-tube) Placement
- Anastomotic Revision
- Band Removal
- Band Tubing or Port Revision
- Band Placement
- Internal Hernia Repair

- Incisional Hernia Repair
- Cholecystectomy
- Bowel Resection
- Re-exploration
- Tracheostomy (Open or Percutaneous)
- Other-Abdominal
- Other Reoperation

- CPT Code
  - Enter the CPT code assigned by your site for the reoperation
  - No

Scenarios to Clarify (Assign Variable):
  - Exploration with drain placement
  - AICD or pacemaker insertion
  - Laparoscopic LINX placement or removal

Scenarios to Clarify (Do Not Assign Variable):
• Gastric adjustable band adjustments, such as band fills or deflations.

**Notes:**

• If both a reoperation and intervention was completed during one anesthesia event or trip to the OR/Procedure room, capture this only as a single Reoperation. If no bariatric-related reoperations were performed, enter the most complex reoperation completed. Enter all additional procedures and interventions performed during the anesthesia event or trip to the OR/Procedure room into the text field for reoperations.
Was this reoperation unplanned at the time of the principal procedure?

**Intent of Variable:** To assist in determining if the reoperation was unplanned at the time of the principal operative procedure.

**Definition:** See criteria below

**Criteria:** Determine if the reoperation was unplanned at the time of the principal operative procedure.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- There is no documentation prior to or at the time of the principal operative procedure that indicates that the patient may require additional surgery.

**Scenarios to Clarify (Do Not Assign Variable):**
- There is documentation prior to or at the time of the principal operative procedure that the patient may require additional surgery.
- Staged procedures.
Most Likely Reason for Reoperation/Intervention

Variable Name: Most Likely Reason for Reoperation or Intervention

Intent of Variable: To capture the likely reason for reoperation(s) and/or intervention(s).

Definition: See criteria below

Criteria: Evaluate the reason for the reoperation or intervention upon completion of the procedure in order to capture the most accurate single diagnosis of the patient’s reason for the reoperation or intervention (e.g., postoperative diagnosis).

Options:

- Select the most appropriate option from the drop down menu that reflects the postoperative diagnosis.
Date Performed

**Intent:** To capture the date of the reoperation or Intervention.

**Definition:** See criteria below

**Criteria:** Enter the date of the reoperation or intervention.

**Options:**
- Enter Date (mm/dd/yyyy)
- Unknown
Information Source

Intent: To capture the method in which the information regarding reoperation or interventions was obtained.

Definition: See criteria below.

Criteria: Select the method in which you learned about the reoperation or intervention.

Options:

- Medical Record
- Patient/Family Report
- Other
Interventions

Did the Patient have an Intervention within the 30 day Postoperative Period?

**Intent of Variable:** To capture any interventions performed within 30 days of the assessed bariatric or metabolic surgical procedure.

**Definition:** Any interventions performed within 30 days of the assessed bariatric or metabolic surgical procedure. Complete one intervention entry in the database for each encounter in the operating room (OR), procedure room, or endoscopy suite, even if more than one procedure was performed during that encounter.

**Criteria:** An intervention would only be entered in the MBSAQIP database if, at a minimum, procedural sedation or anesthesia was required for the procedure or a metabolic or bariatric related procedure was performed.

**Options:**

- **Yes**
  - Was intervention unplanned at the time of the principal procedure? (please see following pages for complete definition)
    - Yes
    - No
  - Was the intervention performed at your hospital?
    - Yes
    - No
  - Was the Intervention likely related to a Metabolic or Bariatric procedure? (please see following pages for complete definition)
    - Yes
    - No
  - Emergency Case
    - Yes
    - No
- **No**

**Scenarios to Clarify (Assign Variable):**

- Endoscopic cases (EGD, bronchoscopy, colonoscopy)
- Cystoscopy, ureteroscopy, hysteroscopy, lithotripsy, ERCP
- IVC filter Placement or removal
- Cardiac catheterization, percutaneous cardiac stent
- Placement of PEG tube or percutaneous J tube
- Chest tube placement
- Percutaneous drain placement
- Lumbar or epidural pain injections
- Stretta procedure
Scenarios to Clarify (Do Not Assign Variable):

- Gastric adjustable band adjustments, such as band fills or deflations completed in the office.
- Swallow studies, upper GI series, radiological studies.
- Non-metabolic-related or non-bariatric-related procedures in which no sedation was given.
Was this intervention unplanned at the time of the principal procedure?

**Intent of Variable:** To assist in determining if the intervention was unplanned at the time of the principal operative procedure.

**Definition:** See criteria below

**Criteria:** Indicate if the intervention was unplanned at the time of the principal operative procedure.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**

- There is no documentation prior to or at the time of the principal operative procedure that indicates that the patient may require additional surgery or interventions.

**Scenarios to Clarify (Do Not Assign Variable):**

- There is documentation prior to or at the time of the principal operative procedure that the patient may require additional surgery or interventions.
- Staged procedures.
**Intervention [30 Day]**

**Intent of Variable:** To capture any interventions performed within 30 days of the assessed bariatric or metabolic surgical procedure.

**Definition:** See criteria below

**Criteria:** Select the most complex bariatric-related intervention performed. If no bariatric-related intervention was completed, select the most complex intervention performed.

**Options:**

- Select the most appropriate option from the drop down menu. (See notes section)

- Diagnostic Endoscopy
- Therapeutic Endoscopy
  - With stent placement/retrieval
  - With dilation (no stent)
  - To control bleeding
  - Stoma resizing
  - Gastro-gastric fistula closure
  - Percutaneous endoscopic gastrostomy (PEG) tube placement
  - Band Removal
  - ECRP
  - Other Therapeutic Endoscopy
- Intraluminal Therapeutic Procedure
  - Planned/scheduled intragastric balloon removal per protocol
  - Intragastric balloon intolerance
  - Intragastric balloon rupture
  - Obstruction
  - Aspiration
  - Perforation
  - Bleeding
  - Gastric ulcer
- Balloon Brand
  - Elipse™ (Allurion Technologies)
  - Orbera™ (Apollo Endosurgery)
  - ReShape™ (ReShape Medical)
  - Spatz™ (Spatz)
  - Other
  - Unknown
- Placement of Percutaneous Drain
- Inferior Vena Cava Filter (IVC) Placement
- Inferior Vena Cava Filter (IVC) Retrieval
- Other Intervention

Notes:

- If multiple interventions were completed during one anesthesia event or trip to the OR/Procedure room, capture this as a single Intervention and choose the most complex bariatric-related intervention performed.
- If no bariatric-related interventions were performed, enter the most complex intervention completed. Enter all additional interventions performed into the text field for interventions.
- If both a reoperation and intervention was completed during one anesthesia event or trip to the OR/Procedure room, capture this only as a single Reoperation.
Most Likely Reason for Reoperation/Intervention

**Variable Name:** Most Likely Reason for Reoperation or Intervention

**Intent of Variable:** To capture the likely reason for reoperation(s) and/or intervention(s).

**Definition:** See criteria below

**Criteria:** Evaluate the reason for the reoperation or intervention upon completion of the procedure in order to capture the most accurate single diagnosis of the patient’s reason for the reoperation or intervention (e.g., postoperative diagnosis).

**Options:**

- Select the most appropriate option from the drop down menu that reflects the postoperative diagnosis.
Date Performed

Intent: To capture the date of the reoperation or Intervention.

Definition: See criteria below

Criteria: Enter the date of the reoperation or intervention.

Options:

- Enter Date (mm/dd/yyyy)
- Unknown
Information Source

Intent: To capture the method in which the information regarding reoperation or interventions was obtained.

Definition: See criteria below.

Criteria: Select the method in which you learned about the reoperation or intervention.

Options:

- Medical Record
- Patient/Family Report
- Other
Visit Period

Were you able to follow the patient for the full 30 days?

**Intent of Variable:** To capture mortality and morbidity data through the 30th day after the principal operative procedure. Sites must consistently complete full 30 day follow-up on a minimum of 80% of the cases submitted to the Program. Sites with complete 30 day follow-up rates of less than 80% will not be included in the Semiannual Report.

**Definition:** The MBSAQIP requires the reporting of mortality and morbidity data up to and including the 30th day after the principal operative procedure on all cases entered into the Program.

**Criteria:** A minimum of two (2) attempts should be made to contact the patient with one attempt by phone and one attempt by letter.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- The patient remained in the hospital for the full 30 day post-operative period AND the MBSCR was able to review the full hospital stay.
- A death that occurs within 30 days after the principal operative procedure is considered full 30 day follow-up as no additional follow-up can be obtained.
- A patient sees a dietician, nurse, or physical therapist and the note is signed off by a physician or advance practitioner affiliated with the center.

**Scenarios to Clarify (Do Not Assign Variable):**
- The patient did not complete a post-operative office visit and was not in the hospital for the full 30-day period.
- Documentation could not be reviewed for the full post-operative 30 day timeframe.

**Notes:**
- All reasonable attempts to obtain complete follow-up data should be made by the MBSCR and documented in this section. The MBSCR will incorporate some or all of the strategies for obtaining follow-up data recommended in the MBSAQIP Operations Manual: Appendix E – Policies & Procedures - 30 day Follow-up Policy.
If a patient returns a 30-day follow-up letter and reports that they developed one of the MBSAQIP postoperative occurrences within 30-days of the principal operative procedure, the patient or physician should be contacted to determine if they meet the criteria of the definition to assign the postoperative occurrence.

For additional information, please refer to Appendix E-30-Day Follow-up Guidelines.
What is the Assessment Date? [30 Day]

**Intent of the Variable:** To capture the date in which the physical assessment was completed within the 30 days following surgery.

**Definition:** See criteria below

**Criteria:** Enter the date the physical assessment was completed by a physician or advanced practitioner within the 30 days following surgery.

**Options:**
- Date (mm/dd/yyyy)
- Unknown

**Notes:**
- If you are not able to determine the date of the assessment, please check “Unknown.”
- If the assessment date by the provider is past POD 30, you would select “Unknown.”
- Enter the date of the visit with the provider closest to the end of the 30 day postoperative period.
Was an Exam Performed by a Bariatric Physician, Nurse Practitioner, or Physician’s Assistant?

**Intent of the Variable:** To capture the clinician who performed the postoperative examination within the 30 days following the principal operative procedure.

**Definition:** See criteria below

**Criteria:** The postoperative follow-up examination must be performed by a bariatric physician, nurse practitioner, physician’s assistant, or supervised registered nurse with experience, training, or certification in the care of the metabolic and bariatric surgery patient from the bariatric center or bariatric specialist’s office within the 30 days following the principal operative procedure.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- A visit with a registered nurse with experience, training, or certification in the care of the metabolic and bariatric surgery patient must be signed off by a bariatric physician or advanced practitioner affiliated with the center.

**Scenarios to Clarify (Do Not Assign Variable):**
- No follow-up examination was completed.
- A follow-up exam was performed by a physician who is not part of the bariatric center or bariatric specialist’s office.
Was the Patient Seen by Any Clinician?

Intent of the Variable: To capture patients who have follow up examination by clinicians other than the bariatric physician, nurse practitioner, or physician’s assistant within the 30 days following the principal operative procedure.

Definition: Patients who have follow up examination by clinicians other than the bariatric physician, nurse practitioner, or physician's assistant within the 30 days following the principal operative procedure.

Criteria: There was a visit with another clinician (e.g., RN without experience, training, or certification in the care of the metabolic and bariatric surgery patient, dietician, therapist) or if there is available documentation for a visit with any other clinician, such as a primary care physician within the 30 days following the principal operative procedure.

Options:

- Yes
- No

Scenarios to Clarify (Do Not Assign Variable):

- If the patient was seen both a Bariatric Physician, Nurse Practitioner, or Physician's Assistant, or RN with experience, training, or certification in the care of the metabolic and bariatric surgery patient, AND any other clinician. Please mark "Yes" for "was an Exam Performed by a Bariatric Physician, Nurse Practitioner, or Physician's Assistant" in this scenario.
General

Weight

**Intent of Variable:** To capture the weight of the patient to calculate the body mass index (BMI)

**Definition:** The amount a patient weighs.

**Criteria:** Report the patient’s weight documented in the medical record in either pounds (lbs.) or kilograms (kg).

**Options:**
- Enter Value
  - Select pounds/kilograms
  - Enter Date
- Unknown

**Scenarios to Clarify (Assign Variable):**
- Enter all weights taken at the bariatric center or bariatric specialist’s office within the long term follow-up period.
- If the patient did not have a weight taken at the bariatric center or bariatric specialist’s office, you may utilize a weight taken at another location (e.g. physician’s office, hospital).

**Scenarios to Clarify (Do Not Assign Variable):**
- Do not utilize patient reported weight.

**Notes:**
- Please utilize the measured weight versus the patient’s reported weight.
- BMI will auto-populate based on the weight and the height entered into the workstation.
Was Anticoagulation Initiated for Presumed/Confirmed Venous Thrombosis/PE? [30 Day]

**Intent of Variable:** To capture those patients who were started on anticoagulation therapy specifically for either a presumed or confirmed venous thrombosis or pulmonary embolism.

**Definition:** A medication(s) that acts to suppress, delay, or nullify blood coagulation.

**Criteria:** The patient must have been started on anticoagulation therapy postoperatively.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- For a venous thrombosis, the patient should have had a duplex, venogram, or CT scan documenting confirmation or suspicion of a venous thrombosis
- For a pulmonary embolism, the patient should have had a VQ scan, CT exam, TEE, pulmonary arteriogram, or CT angiogram, or any other definitive modality.

**Scenarios to Clarify (Do Not Assign Variable):**
- If the patient did not have a physical assessment completed within the 30 days following the principal operative procedure answer “no.”
- If this was not addressed at the time of the physical assessment answer “no.”
Was an Incisional Hernia Noted on Exam? [30 Day]

**Intent of Variable:** To capture those patients who have a *newly* documented incisional hernia.

**Definition:** An incisional hernia is a bulge or protrusion that occurs near or directly along a prior abdominal surgical incision.

**Criteria:** Diagnosis and documentation of a *new* incisional hernia at the incision site from the bariatric or metabolic surgical procedure.

**Options:**
- Yes
- No

**Scenarios to Clarify (Do Not Assign Variable):**
- If the patient did not have a physical assessment completed within the 30 days following the principal operative procedure answer “no.”
- If this was not addressed at the time of the physical assessment answer “no.”
Was an Operative Drain Still Present at 30 days? [30 Day]

**Intent of Variable:** To determine if a patient had drain placed during the bariatric or metabolic surgical procedure that is still present 30 days postoperatively.

**Definition:** Drains are placed to evacuate collections of pus, blood, or other fluids from a wound.

**Criteria:** An abdominal drain that was placed during the initial bariatric or metabolic surgical procedure (principal operative procedure) is present at postop day 30.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- Examples of drains include: Jackson-Pratt and Blake.

**Scenarios to Clarify (Do Not Assign Variable):**
- If no drain was placed during the bariatric or metabolic surgical procedure (e.g., lap gastric band placement).
- Drain was placed during a reoperation.
- If the patient did not have a physical assessment completed within the 30 days following the principal operative procedure answer “no.”
- If this was not addressed at the time of the physical assessment answer “no.”
Attempts by the Bariatric Center to Contact Patient

Was a Follow-up Appointment Made but Patient Did Not Show for Appointment?

Intent of Variable: To capture patient(s) who have made an appointment with the bariatric center of bariatric specialist for postoperative care after a bariatric or metabolic surgical procedure, but did not show for the appointment.

Definition: See criteria below

Criteria: An appointment is made for the patient at the bariatric center or bariatric specialist’s office and the patient did not show up for any appointment within that long term follow-up timeframe.

Options:

- Yes
- No

Scenarios to Clarify (Assign Variable):

- Any appointments are documented in the bariatric center’s or bariatric specialist’s office schedule, but the patient did not show up for the appointment.
- The patient set-up an appointment and later called and rescheduled appointment outside of the follow-up timeframe.
- The patient set-up an appointment and cancelled the appointment and did not reschedule within the follow-up timeframe.

Scenarios to Clarify (Do Not Assign Variable):

- The patient rescheduled their appointment and was seen by the bariatric center or bariatric specialist within that follow-up timeframe.

Notes:

- The bariatric center or bariatric specialist's office may cease attempts to contact patients after the patient is lost to follow-up or no-show for two consecutive follow-up periods.
Was a Phone Call Placed to the Patient?

**Intent of Variable:** To capture the attempts of the bariatric center or bariatric specialist’s office to contact the patient after bariatric or metabolic surgical procedures in order to set-up an appointment for a physical assessment within that long term follow-up timeframe.

**Definition:** See criteria below

**Criteria:** At a minimum, one phone call attempt is required for the program if the patient did not have a physical assessment completed within the follow-up timeframe.

**Options:**
- Once
- Twice
- Never

**Scenarios to Clarify (Assign Variable):**
- There is documentation in the medical record, bariatric center’s schedule, or bariatric specialist’s office as to a phone call by the bariatric center or bariatric specialist’s office personnel to the patient for a follow-up appointment.

**Notes:**
- Once an appointment is scheduled within that long term follow-up timeframe, no further contact attempts are required.
Was a Letter Sent to the Patient?

Intent of Variable: To capture the attempts of the bariatric center or bariatric specialist’s office to contact the patient after bariatric or metabolic surgical procedures in order to set-up an appointment for a physical assessment within that long term follow-up timeframe.

Definition: See criteria below

Criteria: At a minimum, one letter sent to the patient is required for the program if the patient did not have a physical assessment completed within the follow-up timeframe.

Options:

- Once
- Twice
- Never

Scenarios to Clarify (Assign Variable):

- There is documentation of a letter being sent to the patient by the bariatric center or bariatric specialist's office for a follow-up appointment.

Notes:

- An email would be considered a letter sent to the patient.
- Once an appointment is scheduled within that long term follow-up timeframe no further contact attempts are required.
Was the Patient's Care Transferred to Another Bariatric Specialist?

**Intent of Variable:** To capture patient(s) who have their postoperative care transferred to another bariatric center or bariatric specialist for postoperative care after a bariatric or metabolic surgical procedure.

**Definition:** See criteria below

**Criteria:** A patient who has care transferred to another bariatric center or bariatric specialist for postoperative care after a bariatric or metabolic surgical procedure due to geography (patient moves), patient request, etc.

**Options:**

- Yes
  - Please report the specialist's name and address.
- No

**Scenarios to Clarify (Assign Variable):**

- Transfer to a bariatric physician
- Transfer to a bariatric advanced practitioner

**Scenarios to Clarify (Do Not Assign Variable):**

- Transfer to general surgeon who does not perform bariatric surgery
- Transfer to primary care provider (PCP)

**Notes:**

- After marking that a patient has transferred care to another bariatric specialist, you would deselect the patient for long term follow-up in the data registry.
Is the Patient Refusing Follow-up?

**Intent of Variable:** To capture patient that refuse to follow-up with the bariatric center or bariatric specialist.

**Definition:** See criteria below

**Criteria:** There is documentation stating the patient either verbally or via letter or email is refusing follow-up care and/or follow-up visits.

**Options:**
- Yes
- No

**Notes:**
- After marking that a patient is refusing to follow-up, you would deselect the patient for long term follow-up in the data registry.
Contact Management

Patient Contact Management [30 Day]

Intent of Variable: To assist with MBSCR workflow management.

Definition: This field is used to assist the MBSCR in managing patient follow up activities.

Criteria: Enter the method(s) of completion for 30 day follow-up.

Options:

- Contact Date
- Contact Action
- Contact Results
- Notes

Notes:

- This field is utilized to document how your site obtained “full” 30 day follow-up and will be reviewed during a data integrity audit.
Long Term Follow Up

What is the Assessment Date? [Long Term]

**Intent of the Variable:** To capture the date in which the physical assessment was completed within the long term follow-up period.

**Definition:** See criteria below

**Criteria:** Enter the date the physical assessment was completed by a physician, advanced practitioner, or supervised registered nurse with experience, training, or certification in the care of the metabolic and bariatric surgery patient within the specific long term follow-up timeframe.

**Options:**

- Date (mm/dd/yyyy)
- Unknown

**Scenarios to Clarify (Assign Variable):**

- A visit with a registered nurse with experience, training, or certification in the care of the metabolic and bariatric surgery patient must be signed off by a bariatric physician or advanced practitioner affiliated with the center.

**Notes:**

- If you are not able to determine the date of the assessment, please check “Unknown.”
- Enter the date closest to the anniversary date of the surgery for that follow-up period. For example, for the 6 month follow-up, capture the physical assessment performed closest to 6 months after the date of the principal operative procedure.
Is the Patient Alive? [Long Term]

Intent of the Variable: To capture mortality information for the patient.

Definition: See criteria below

Criteria: Answer “Yes” if the patient is alive for this follow-up visit.

Options:
- Yes
- No

Scenarios to Clarify (Assign Variable):
- Answer “yes” if there is no definitive evidence that the patient is deceased.

Notes:
- If the patient has died, please complete Mortality Information.
Was an Exam Performed by a Bariatric Physician, Nurse Practitioner, or Physician’s Assistant?

**Intent of the Variable:** To capture the clinician who performed the postoperative examination within the 30 days following the principal operative procedure.

**Definition:** See criteria below

**Criteria:** The postoperative follow-up examination must be performed by a bariatric physician, nurse practitioner, physician’s assistant, or supervised registered nurse with experience, training, or certification in the care of the metabolic and bariatric surgery patient from the bariatric center or bariatric specialist’s office within the 30 days following the principal operative procedure.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- A visit with a registered nurse with experience, training, or certification in the care of the metabolic and bariatric surgery patient must be signed off by a bariatric physician or advanced practitioner affiliated with the center.

**Scenarios to Clarify (Do Not Assign Variable):**
- No follow-up examination was completed.
- A follow-up exam was performed by a physician who is not part of the bariatric center or bariatric specialist’s office.
Was the Patient Seen by Any Clinician?

**Intent of the Variable:** To capture patients who have follow up examination by clinicians other than the bariatric physician, nurse practitioner, or physician’s assistant within the 30 days following the principal operative procedure.

**Definition:** Patients who have follow up examination by clinicians other than the bariatric physician, nurse practitioner, or physician’s assistant within the 30 days following the principal operative procedure.

**Criteria:** There was a visit with another clinician (e.g., RN without experience, training, or certification in the care of the metabolic and bariatric surgery patient, dietician, therapist) or if there is available documentation for a visit with any other clinician, such as a primary care physician within the 30 days following the principal operative procedure.

**Options:**
- Yes
- No

**Scenarios to Clarify (Do Not Assign Variable):**
- If the patient was seen both a Bariatric Physician, Nurse Practitioner, or Physician's Assistant, or RN with experience, training, or certification in the care of the metabolic and bariatric surgery patient, AND any other clinician. Please mark "Yes" for "was an Exam Performed by a Bariatric Physician, Nurse Practitioner, or Physician's Assistant" in this scenario.
General

Height [Long Term]

Intent of Variable: To capture the height of the patient to calculate body mass index (BMI).

Definition: The height of a patient.

Criteria: Report the patient’s height documented in the medical record in either inches (in) or centimeters (cm).

Options:

- Enter value
  - Select centimeters/inches
- Unknown
Weight

**Intent of Variable:** To capture the weight of the patient to calculate the body mass index (BMI)

**Definition:** The amount a patient weighs.

**Criteria:** Report the patient’s weight documented in the medical record in either pounds (lbs.) or kilograms (kg).

**Options:**
- Enter Value
  - Select pounds/kilograms
  - Enter Date
- Unknown

**Scenarios to Clarify (Assign Variable):**
- Enter all weights taken at the bariatric center or bariatric specialist’s office within the long term follow-up period.
- If the patient did not have a weight taken at the bariatric center or bariatric specialist’s office, you may utilize a weight taken at another location (e.g. physician’s office, hospital).

**Scenarios to Clarify (Do Not Assign Variable):**
- Do not utilize patient reported weight.

**Notes:**
- Please utilize the measured weight versus the patient’s reported weight.
- BMI will auto-populate based on the weight and the height entered into the workstation.
Was Anticoagulation Initiated for Presumed/Confirmed Venous Thrombosis/PE? [Long Term]

**Intent of Variable:** To capture those patients who were started on anticoagulation therapy specifically for either a presumed or confirmed venous thrombosis or pulmonary embolism.

**Definition:** A medication(s) that acts to suppress, delay, or nullify blood coagulation.

**Criteria:** The patient must have been started on anticoagulation therapy postoperatively.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- For a venous thrombosis, the patient should have had a duplex, venogram, or CT scan documenting confirmation or suspicion of a venous thrombosis.
- For a pulmonary embolism, the patient should have had a VQ scan, CT exam, TEE, pulmonary arteriogram, or CT angiogram, or any other definitive modality.

**Notes:**
- Capture if anticoagulation was initiated for presumed or confirmed Venous Thrombosis or PE at any time within the long term follow-up timeframe.
Was an Incisional Hernia Noted on Exam? [Long Term]

**Intent of Variable**: To capture those patients who have a **newly** documented incisional hernia.

**Definition**: An incisional hernia is a bulge or protrusion that occurs near or directly along a prior abdominal surgical incision.

**Criteria**: Diagnosis and documentation of a **new** incisional hernia at the incision site from the bariatric or metabolic surgical procedure.

**Options**:  
- Yes  
- No

**Notes**:  
- Capture if an incisional hernia was noted on exam at any time within the long term follow-up timeframe.
Comorbidity List

Sleep Apnea

Intent of Variable: To capture patients who currently have sleep apnea.

Definition: The most common type of sleep apnea is obstructive sleep apnea. During deep sleep, as the airway muscles relax, the airway collapses and the patient cannot move air. The brain eventually senses that the patient is not breathing and the patient awakes enough to breathe again, often with a loud snort or choking sound.

Criteria: Answer “Yes” if the patient has a diagnosis of sleep apnea and one or more of the following:

- Sleep apnea requiring CPAP or BiPAP (or similar technology) continuing from before Metabolic or Bariatric surgery.
- Documented new sleep apnea requiring CPAP or BiPAP (or similar technology).
- Planning to or have had an uvuloplasty or other surgical correction of sleep apnea since the time of the Metabolic or Bariatric surgery.

Options:

- Yes
- No
- Not Documented

Scenarios to Clarify (Assign Variable):

- A patient who is supposed to use CPAP/BiPAP (or similar technology) per physician instructions, but do not or are unable to tolerate it.

Scenarios to Clarify (Do Not Assign Variable):

- A patient who does not have a physician prescription for the use of CPAP/BiPAP (or similar technology).

Notes:

- Answer “Not Documented” if not assessed or addressed at the time of the physical assessment—even if there is not a history of sleep apnea prior to the metabolic or bariatric surgery.
Gastroesophageal Reflux Disease (GERD) Requiring Medication [Long Term]

**Intent of Variable:** To capture those patients who have GERD.

**Definition:** GERD results from a failure of the anti-reflux barrier, allowing the contents of the stomach back into the esophagus. The most common symptom is heartburn.

**Criteria:** Indicate if the patient had a diagnosis of GERD in which they regularly take prescribed or over-the-counter medication at the time of the physical assessment for the long term follow-up period.

**Options:**
- Yes
- No
- Not Documented

**Scenarios to Clarify (Assign Variable):**
- Patients who take proton pump inhibitors (PPI) or histamine (H2) receptor blockers.

**Scenarios to Clarify (Do Not Assign Variable):**
- Patients who experience occasional symptoms or treat their heartburn on a PRN basis.
- Patients who utilize antacids other than PPIs or H2 blockers.
- Patients who do not have a diagnosis of GERD.

**Notes:**
- Answer “Not Documented” if not assessed or addressed at the time of the physical assessment—even if there is not a history of GERD prior to the metabolic or bariatric surgery.
Hyperlipidemia Requiring Medication [Long Term]

**Intent of Variable:** To capture patients who have increased cholesterol levels.

**Definition:** Hyperlipidemia is an increased level of triglycerides, LDL cholesterol, or an unfavorable LDL/HDL ratio, that puts a patient at risk for subsequent cardiovascular disease.

**Criteria:** Determine if the patient is taking daily medication for a diagnosis and treatment of hyperlipidemia.

**Options:**
- Yes
- No
- Not Documented

**Scenarios to Clarify (Assign Variable):**
- Patients who are taking daily medications such as, statins, niacin, or gemfibrozil for the treatment of hyperlipidemia.

**Scenarios to Clarify (Do Not Assign Variable):**
- Patients who are taking over the counter medications such as, fish oil, or homeopathic medications.

**Notes:**
- Answer “Not Documented” if not assessed or addressed at the time of the physical assessment—even if there is not a history of hyperlipidemia prior to the metabolic or bariatric surgery.
Hypertension Requiring Medication [Long Term]

**Intent of Variable:** To capture patients with a diagnosis of hypertension severe enough that medication is or should be prescribed. This condition may impact the patient’s risk for cerebrovascular, renal and cardiac disease.

**Definition:** “Hypertension (HTN) is the term used to describe high blood pressure. Blood pressure is a measurement of the force against the walls of your arteries as your heart pumps blood through your body. High blood pressure (hypertension) is when your blood pressure is 140/90 mmHg or above most of the time.” (MedlinePlus, April 2012)*.

**Criteria:** The diagnosis of HTN must be documented in the patient’s medical record and the condition is severe enough that it requires antihypertensive medication.

**Options:**
- Yes
- No
- Not Documented (if not assessed)

**Scenarios to Clarify (Assign Variable):**
- Patients who are prescribed antihypertensives and are noncompliant.

**Scenarios to Clarify (Do Not Assign Variable):**
- Patients who receive a onetime does of antihypertensive medication or who have not been prescribed or required treatment for > 2 weeks.
- HTN controlled by diet alone.
- Patients taking antihypertensive medications with no diagnosis of hypertension.

**Notes:**
- Examples of antihypertensive medications include: diuretics, beta blockers, ACE inhibitors, calcium channel blockers.
- Answer “Not Documented” if not assessed or addressed at the time of the physical assessment—even if there is not a history of hypertension prior to the metabolic or bariatric surgery.
**Number of Anti-Hypertensive Medications**

**Variable Name:** Number of Anti-Hypertensive Medications

**Intent of Variable:** To capture the number of anti-hypertensive medications prescribed to a patient.

**Definition:** A patient that has hypertension and is being treated with medication(s), list the numbers of antihypertensive medications that they are taking.

**Criteria:** Antihypertensive medications include diuretics, beta blockers, ACE inhibitors, angiotensin receptor blockers, calcium channel blockers, vasodilators, etc.

**Options:** Enter number of medications.

**Notes:**

- If a patient is taking a pill that contains more than one medication, document the number of medications rather than the number of pills.
- If a patient has been diagnosed with hypertension and requires medication but is refusing medication or is noncompliant, enter “0.”
Diabetes Mellitus Requiring Therapy with Non-Insulin Agents or Insulin [Long Term]

Variable Name: Diabetes Mellitus Requiring Therapy with Non-Insulin Agents or Insulin

Intent of Variable: To differentiate three groups of patients with respect to diabetes: those not requiring therapy or controlled by diet alone, those requiring a non-insulin agent, and those requiring insulin. This should reflect how the patient is treated on a chronic basis prior to admission, not how they are managed in the hospital immediately prior to surgery. The diabetic who comes in and is sick, who has been treated with oral agents may need coverage with a sliding scale. This does not qualify as a diabetic treated with insulin. Diabetes may put a patient at increased risk for infection, delayed wound healing, renal and cardiac dysfunction.

Definition: Diabetes mellitus is a metabolic disorder of the pancreas whereby the individual requires careful monitoring of diet or regular dosages of exogenous parenteral insulin or a non-insulin anti-diabetic agent to prevent hyperglycemia/metabolic acidosis.

Criteria: Report the treatment regimen of the patient’s chronic, long-term management (treated > 2 weeks) of diabetes mellitus.

• No: No diagnosis of diabetes or diabetes controlled by diet alone.
• Non-Insulin: A diagnosis of diabetes requiring therapy with a non-insulin anti-diabetic agent (such as oral agents or other non-insulin agents).
• Insulin: A diagnosis of diabetes requiring daily insulin therapy.

Options:

• Yes
  
  • If “yes”, select current medication type:
    o Non-Insulin
    o Insulin

• No
• Not Documented

Scenarios to Clarify (Assign Variable):

• Patients with Insulin resistance (e.g., polycystic ovarian syndrome, metabolic syndrome, pre-diabetes) that routinely take anti-diabetic agents.
• Patients prescribed oral or insulin treatment and are noncompliant.

Scenarios to Clarify (Do Not Assign Variable):

• Diabetes controlled by diet alone.

Notes:
•

Answer “Not Documented” if not assessed or addressed at the time of the
physical assessment-even if there is not a history of Diabetes prior to the
metabolic or bariatric surgery.


# Attempts By the Bariatric Center to Contact Patient Section

## Long Term Follow-up Guidance

Requirements for Follow-up Attempts*

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<td>assessment</td>
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</table>

*patient is contacted and receives scheduled clinical assessment;
**Documentation of contact attempts is not required**

<table>
<thead>
<tr>
<th>No Show</th>
<th>Patient did not show up for scheduled clinical assessment or a clinical assessment was not scheduled; 2 attempts to contact the patient must be documented</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>Patient did not show up for scheduled clinical assessment or a clinical assessment was scheduled for 2 consecutive follow-up timeframes; no further attempts to contact the patient are required</td>
</tr>
</tbody>
</table>

*Please note that the table above provides a snapshot of possible follow-up scenarios. Attempts to follow patients annually should continue beyond the six-year follow-up period until the patient fails to show up for two consecutive follow-up periods.

To deselect the patient for long term follow-up one of the following scenarios must occur:

- The patient is lost to follow-up for two consecutive long term follow-up timeframes.
- The patient is a no-show for two consecutive long term follow-up timeframes.
- The patient is lost to follow-up for a long term follow-up timeframe and a no-show for next consecutive long term follow-up timeframe.
- The patient is a no-show for a long term follow-up timeframe and lost to follow-up for next consecutive long term follow-up timeframe.
- The patient refuses follow-up.
- The patient has transferred care to another bariatric provider or center.
- The patient expires (this is done automatically in the registry).
Was a Follow-up Appointment Made but Patient Did Not Show for Appointment?

**Intent of Variable:** To capture patient(s) who have made an appointment with the bariatric center of bariatric specialist for postoperative care after a bariatric or metabolic surgical procedure, but did not show for the appointment.

**Definition:** See criteria below

**Criteria:** An appointment is made for the patient at the bariatric center or bariatric specialist’s office and the patient did not show up for any appointment within that long term follow-up timeframe.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- Any appointments are documented in the bariatric center’s or bariatric specialist’s office schedule, but the patient did not show up for the appointment.
- The patient set-up an appointment and later called and rescheduled appointment outside of the follow-up timeframe.
- The patient set-up an appointment and cancelled the appointment and did not reschedule within the follow-up timeframe.

**Scenarios to Clarify (Do Not Assign Variable):**
- The patient rescheduled their appointment and was seen by the bariatric center or bariatric specialist within that follow-up timeframe.

**Notes:**
- The bariatric center or bariatric specialist's office may cease attempts to contact patients after the patient is lost to follow-up or no-show for two consecutive follow-up periods.
Was a Phone Call Placed to the Patient?

**Intent of Variable:** To capture the attempts of the bariatric center or bariatric specialist’s office to contact the patient after bariatric or metabolic surgical procedures in order to se-up an appointment for a physical assessment within that long term follow-up timeframe.

**Definition:** See criteria below

**Criteria:** At a minimum, one phone call attempt is required for the program if the patient did not have a physical assessment completed within the follow-up timeframe.

**Options:**

- Once
- Twice
- Never

**Scenarios to Clarify (Assign Variable):**

- There is documentation in the medical record, bariatric center’s schedule, or bariatric specialist’s office as to a phone call by the bariatric center or bariatric specialist's office personnel to the patient for a follow-up appointment.

**Notes:**

- Once an appointment is scheduled within that long term follow-up timeframe, no further contact attempts are required.
Was a Letter Sent to the Patient?

**Intent of Variable:** To capture the attempts of the bariatric center or bariatric specialist’s office to contact the patient after bariatric or metabolic surgical procedures in order to set-up an appointment for a physical assessment within that long term follow-up timeframe.

**Definition:** See criteria below

**Criteria:** At a minimum, one letter sent to the patient is required for the program if the patient did not have a physical assessment completed within the follow-up timeframe.

**Options:**
- Once
- Twice
- Never

**Scenarios to Clarify (Assign Variable):**
- There is documentation of a letter being sent to the patient by the bariatric center or bariatric specialist’s office for a follow-up appointment.

**Notes:**
- An email would be considered a letter sent to the patient.
- Once an appointment is scheduled within that long term follow-up timeframe no further contact attempts are required.
Was the Patient's Care Transferred to Another Bariatric Specialist?

**Intent of Variable:** To capture patient(s) who have their postoperative care transferred to another bariatric center or bariatric specialist for postoperative care after a bariatric or metabolic surgical procedure.

**Definition:** See criteria below

**Criteria:** A patient who has care transferred to another bariatric center or bariatric specialist for postoperative care after a bariatric or metabolic surgical procedure due to geography (patient moves), patient request, etc.

**Options:**
- Yes
  - Please report the specialist’s name and address.
- No

**Scenarios to Clarify (Assign Variable):**
- Transfer to a bariatric physician
- Transfer to a bariatric advanced practitioner

**Scenarios to Clarify (Do Not Assign Variable):**
- Transfer to general surgeon who does not perform bariatric surgery
- Transfer to primary care provider (PCP)

**Notes:**
- After marking that a patient has transferred care to another bariatric specialist, you would deselect the patient for long term follow-up in the data registry.
Is the Patient Refusing Follow-up?

**Intent of Variable:** To capture patient that refuse to follow-up with the bariatric center or bariatric specialist.

**Definition:** See criteria below

**Criteria:** There is documentation stating the patient either verbally or via letter or email is refusing follow-up care and/or follow-up visits.

**Options:**

- Yes
- No

**Notes:**

- After marking that a patient is refusing to follow-up, you would deselect the patient for long term follow-up in the data registry.
Is the Patient Lost to Follow-up? [Long Term]

Intent of Variable: To indicate that no patient contact was made within the follow-up timeframe.

Definition: See criteria below

Criteria: Answer “Yes” if there is documentation stating that patient contact attempts were made per policy and no appointment was scheduled for the patient within that long term follow-up timeframe.

Options:

- Yes
- No

Notes:

- The bariatric center or bariatric specialist’s office may cease attempts to contact patients after the patient is lost to follow-up for two consecutive follow-up period.
Mortality Information

Date of Death [Long Term]

Intent of Variable: To capture the date of a metabolic or bariatric surgical patient’s death.

Definition: See criteria below

Criteria: The date that the patient expired.

Options:

- Enter the patient’s date of death using the format mm/dd/yyyy.
- Unknown

Notes:

- If you are not able to determine the date of death, please choose “unknown.”
Was the Death Likely Related to the Operation?

**Intent of Variable:** To determine if the death of the patient was related to the bariatric or metabolic surgical procedure or a related complication.

**Definition:** See criteria below

**Criteria:** Determine if the death of the patient’s death was related to the bariatric or metabolic surgical procedure or a related complication.

**Options:**
- Yes
- No
**Most Likely Cause of Death**

**Intent of Variable:** To capture the likely cause of death as related to the bariatric or metabolic surgical procedure.

**Definition:** See criteria below

**Criteria:** Enter the patient’s suspected cause of death as reported in the medical record or autopsy report.

**Options:** Select the most appropriate option from the drop down menu. (See notes section)

**Notes:**

<table>
<thead>
<tr>
<th>Most Likely Cause</th>
<th>Most Likely Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anastomotic/Staple Line Leak</td>
<td>Incisional Hernia</td>
</tr>
<tr>
<td>GI Perforation</td>
<td>Bleeding</td>
</tr>
<tr>
<td>Other Abdominal Sepsis</td>
<td>Vein Thrombosis Requiring Therapy</td>
</tr>
<tr>
<td>Strictures/Stomal Obstruction</td>
<td>Pulmonary Embolism</td>
</tr>
<tr>
<td>Intestinal Obstruction</td>
<td>Pneumonia</td>
</tr>
<tr>
<td>Gastric Distention</td>
<td>Other Respiratory Failure</td>
</tr>
<tr>
<td>Fluid, electrolyte, or nutritional depletion</td>
<td>Infection/Fever</td>
</tr>
<tr>
<td>Anastomotic Ulcer</td>
<td>Band Slippage/Prolapse</td>
</tr>
<tr>
<td>Gastro-Gastric Fistula</td>
<td>Band Erosion</td>
</tr>
<tr>
<td>Gallstone Disease</td>
<td>LAGB – Port, Tubing or Band problem</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>Wound Infection/Evisceration</td>
<td>Bile Reflux Gastritis</td>
</tr>
<tr>
<td>Internal Hernia</td>
<td>Other</td>
</tr>
</tbody>
</table>
Hospital Readmissions

Did the Patient have a Hospital Readmission? [Long Term]

Intent: To capture readmission(s) that occurred within the long term follow-up postoperative time period.

Definition: See criteria below

Criteria: Patients who are formally admitted by a qualified practitioner as an inpatient to an acute care bed.

OR

Otherwise have a subsequent hospital (or facility-based) encounter (receiving outpatient or observation services) that crosses at least two midnights.

Options:

- Yes
  - Readmission Date or Unknown
  - Discharge Date or Unknown or N/A
  - Information Source
    - Medical Record
    - Other
  - Was this readmission likely related to a metabolic or bariatric procedure?
    - Yes
    - No
  - Most Likely Reason (See notes below)
    - Choose from drop down menu
- No

Scenarios to Clarify (Do Not Assign Variable):

- Do not capture emergency room visits that did not meet admission criteria above.
- After the end of the one year follow-up period, only capture readmissions related to the bariatric or metabolic procedure.

Notes:

- It is not necessary to capture unrelated readmissions after the one year follow-up period.
- most accurate single diagnosis of the patient’s reason for admission.
Reoperations/Interventions

Did the Patient have a Reoperation/Intervention? [Long Term]

It is not necessary to capture unrelated reoperations and interventions after the one year follow-up period.

Intent of Variable: To capture any surgical operations or interventions performed within the follow-up period of the assessed bariatric or metabolic surgical procedure. After the first year follow-up period following their bariatric or metabolic surgery, only capture the procedure if the reoperation or intervention is bariatric or metabolic related.

Definition: See criteria below

Criteria: A reoperation or intervention would only be entered in the MBSAQIP database if, at a minimum, procedural sedation or anesthesia was required for the procedure. It is not necessary to capture unrelated reoperations/interventions after the one year follow-up period.

Options:

- Yes
- No

Scenarios to Clarify (Do Not Assign Variable):

- Gastric adjustable band adjustments, such as band fills or deflations.

Notes:

- Complete one reoperation/intervention entry in the database for each encounter in the operating room even if more than one procedure/intervention was performed during that encounter.
  - Enter the most complex bariatric-related procedure as the reoperation. When no bariatric or metabolic related procedure is performed, enter the most complex procedure.
  - If multiple procedures were performed during a single encounter in the operating room, enter the additional procedures in the Comments text box field of the Reoperation variable.
Reoperations

Intent of Variable: To capture any reoperations performed within the long term follow-up timeframe.

Definition: See criteria below

Criteria: Select the most complex bariatric-related procedure performed during the reoperation. If no bariatric-related procedure was completed, select the most complex surgical procedure performed during the reoperation.

Options:
  - Select the most appropriate operative procedure from the drop down menu.

Notes:
  - If multiple surgical procedures were performed during the visit to the operating room for the reoperation, choose the most complex bariatric-related procedure performed. If no bariatric-related procedure was performed, enter the most complex surgical procedure completed. Enter all additional surgical procedures performed during the visit to the operating room for the reoperation into the text field for reoperations.
CPT code for Reoperation [Long Term]

**Intent:** Determine the CPT code for the reoperation as noted reported in the operating room report, operative note, operating room log, or surgical billing if the reoperation/intervention was noted to be “Other”.

**Definition:** See criteria below

**Criteria:** Provide the CPT® code of the reoperation when the “Other” option is chosen from the dropdown menu. Note the CPT® code as it is reported in the operative report, operative note, operating room log, or surgical billing. If the CPT® code is not known (for example: if a procedure is performed at an outside hospital) please check “Unknown”.

**Options:**
- Enter CPT code
- Unknown
Interventions [Long Term]

**Intent of Variable:** To capture any interventions performed within the long term follow-up timeframe.

**Definition:** See criteria below.

**Criteria:** Select the most complex bariatric-related intervention performed. If no bariatric-related intervention was completed, select the most complex intervention performed.

Select the most appropriate option from the drop down menu. (See notes section)

- Diagnostic Endoscopy
- Therapeutic Endoscopy
  - With stent placement/retrieval
  - With dilation (no stent)
  - To control bleeding
  - Stoma resizing
  - Gastro-gastric fistula closure
  - Percutaneous endoscopic gastrostomy (PEG) tube placement
  - Band Removal
  - ECRP
  - Other Therapeutic Endoscopy
- Intraluminal Therapeutic Procedure
  - Planned/scheduled intragastric balloon removal per protocol
  - Intragastric balloon intolerance
  - Intragastric balloon rupture
  - Obstruction
  - Aspiration
  - Perforation
  - Bleeding
  - Gastric ulcer
- Placement of Percutaneous Drain
- Inferior Vena Cava Filter (IVC) Placement
- Inferior Vena Cava Filter (IVC) Retrieval
- Other Intervention

**Scenarios to Clarify (Assign Variable):**

- Endoscopic cases (EGD, bronchoscopy, colonoscopy)
- Cystoscopy, ureteroscopy, hysteroscopy, lithotripsy, ECRP
- IVC filter Placement or removal
- Cardiac catheterization, percutaneous cardiac stent
- Placement of PEG tube or percutaneous J tube
- Chest tube placement
- Percutaneous drain placement
- Lumbar or epidural pain injections
- Stretta procedure

**Scenarios to Clarify (Do Not Assign Variable):**

- Gastric adjustable band adjustments, such as band fills or deflations, completed in the office.
- Swallow studies, upper GI series, radiologic studies
- Non-metabolic-related or non-bariatric-related procedures in which no sedation was given.

**Notes:**

- If multiple interventions were performed, choose the most complex bariatric-related intervention performed. If no bariatric-related interventions were performed, enter the most complex intervention completed. Enter all additional interventions performed into the text field for interventions.
- Please complete the drop down menu when “therapeutic endoscopy” is selected.
- Please complete the drop down menu when “Intraluminal Therapeutic Procedure” is selected.
**Most Likely Reason for Reoperation/Intervention**

**Variable Name:** Most Likely Reason for Reoperation or Intervention

**Intent of Variable:** To capture the likely reason for reoperation(s) and/or intervention(s).

**Definition:** See criteria below

**Criteria:** Evaluate the reason for the reoperation or intervention upon completion of the procedure in order to capture the most accurate single diagnosis of the patient’s reason for the reoperation or intervention (e.g., postoperative diagnosis).

**Options:**

- Select the most appropriate option from the drop down menu that reflects the postoperative diagnosis.
Date Performed

**Intent:** To capture the date of the reoperation or Intervention.

**Definition:** See criteria below

**Criteria:** Enter the date of the reoperation or intervention.

**Options:**
- Enter Date (mm/dd/yyyy)
- Unknown
Information Source

**Intent**: To capture the method in which the information regarding reoperation or interventions was obtained.

**Definition**: See criteria below.

**Criteria**: Select the method in which you learned about the reoperation or intervention.

**Options**:

- Medical Record
- Patient/Family Report
- Other
Was this Reoperation/Intervention Likely Related to a Bariatric or Metabolic Procedure? [Long Term]

**Intent of Variable:** Determine if the reoperation/intervention was likely related to the bariatric or metabolic surgical procedure.

**Definition:** See criteria below

**Criteria:** Any reoperation or intervention that is performed in relation to the bariatric or metabolic surgical procedure.

**Options:**
- Yes
- No
Contact Management

Patient Contact Management [Long Term]

Intent of Variable: To assist with MBSCR workflow management.

Definition: This field is used to assist the MBSCR in managing patient follow up activities. The intent of contact management is to document the attempts to schedule the patient for a physical assessment by the bariatric provider.

Criteria: Enter the method(s) of patient contact.

Options:

- Contact Date
- Contact Action
- Contact Results
- Notes

Notes:

- This field is required and will be audited during a site visit.
## Appendix A - CPT Code Inclusion List

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<th>Code 2</th>
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Appendix B - Case Inclusion and Follow-up Guidelines

Metabolic and bariatric procedures performed by Surgeons and Proceduralists must be entered into the MBSAQIP data registry.

### Procedure Descriptions

#### PRIMARY (no previous metabolic/bariatric procedure)

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<td>Biliopancreatic Diversion (With or Without Duodenal Switch)</td>
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</tr>
<tr>
<td>Gastric Band Placements</td>
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</tr>
<tr>
<td>Gastric Bypass with Roux-en-Y (Open or Laparoscopic)</td>
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</tr>
<tr>
<td>Gastric Plication (With or Without Banding)</td>
<td>X X</td>
</tr>
<tr>
<td>Gastroplasty, Vertical-Banded</td>
<td>X X</td>
</tr>
<tr>
<td>Mini-Gastric Bypass (Any Variation)</td>
<td>X X X</td>
</tr>
<tr>
<td><strong>Primary Endoscopic Procedures Completed for Metabolic/Bariatric Purposes Including:</strong></td>
<td></td>
</tr>
<tr>
<td>Gastric Imbrication, Intragastric Balloons, Vascular Embolization, Endoluminal Sleeves, and Endoluminal Stapling</td>
<td>X X X</td>
</tr>
<tr>
<td>Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy (&quot;Loop DS&quot;)</td>
<td>X X</td>
</tr>
<tr>
<td>Sleeve Gastrectomy (Open or Laparoscopic)</td>
<td>X X</td>
</tr>
<tr>
<td>Vaginal Nerve Block (e.g. VBLIC® Therapy)</td>
<td>X X</td>
</tr>
</tbody>
</table>

Reoperations and interventions subsequent to a metabolic and bariatric procedure (regardless of where the primary metabolic and bariatric procedure occurred) must be entered into the MBSAQIP data registry.

### REVISIONS/CONVERSIONS/OTHER PROCEDURES

(following a primary bariatric procedure: emergent or non-emergent)

<table>
<thead>
<tr>
<th>Procedure Description</th>
<th>AT YOUR CENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anastomotic Revision including Gastrojejunostomy, Jejunogastrostomy, and Gastrojejunostomy</td>
<td>X X X</td>
</tr>
<tr>
<td>Any Intervention Not Listed, in Which [at Minimum] Moderate Sedation Was Administered</td>
<td>X X X</td>
</tr>
<tr>
<td>Any Surgical Procedure Not Listed</td>
<td>X X X</td>
</tr>
<tr>
<td>Biliopancreatic Diversion (With or Without Duodenal Switch)</td>
<td>X X X</td>
</tr>
<tr>
<td>Cholecystectomy</td>
<td>X X X</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>X X X</td>
</tr>
<tr>
<td>Endoscopic Procedures Completed for Metabolic/Bariatric Purposes Including: Gastric Imbrication, Intragastric Balloons, Vascular Embolization, Endoluminal Sleeves, Endoluminal Stapling, Gastric Plication, Oversew, or Stoma Resizing</td>
<td>X X X</td>
</tr>
<tr>
<td><strong>Endoscopy, Diagnostic with Abnormal Findings</strong></td>
<td>X X X</td>
</tr>
<tr>
<td><strong>Endoscopy, Diagnostic with Findings Within Normal Limits</strong></td>
<td>X X X</td>
</tr>
<tr>
<td><strong>Endoscopy, Therapeutic: With Dilatation, Biopsy, Stent Placement, and/or Cauterization</strong></td>
<td>X X X</td>
</tr>
<tr>
<td>ERCP (Endoscopic Retrograde Cholangiopancreatography)</td>
<td>X X X</td>
</tr>
<tr>
<td><strong>Feeding Tube, Placement or Revision (G-tube or J-tube)</strong></td>
<td>X X X</td>
</tr>
<tr>
<td>Gastrectomy, Partial or Total</td>
<td>X X X</td>
</tr>
<tr>
<td>Gastrectomy, Partial or Total</td>
<td>X X X</td>
</tr>
<tr>
<td><strong>Gastric Band and/or Port Removal (Laparoscopic, Endoscopic, or Open)</strong></td>
<td>X X X</td>
</tr>
<tr>
<td><strong>Gastric Band and/or Port Revisions (Laparoscopic, Endoscopic, or Open)</strong></td>
<td>X X X</td>
</tr>
<tr>
<td><strong>Gastric Band and/or Port Removal (Laparoscopic, Endoscopic, or Open)</strong></td>
<td>X X X</td>
</tr>
<tr>
<td><strong>Gastric Band and/or Port Revisions (Laparoscopic, Endoscopic, or Open)</strong></td>
<td>X X X</td>
</tr>
</tbody>
</table>
### REVISIONS/CONVERSIONS/OTHER PROCEDURES
(following a primary bariatric procedure; emergent or non-emergent)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>X</th>
<th>X</th>
<th>X</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastric Bypass with Roux-en-Y (Open or Laparoscopic)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastric Plication (With or Without Banding)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastric Pouch Revision</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastric Stoma Plication</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastrolapasty, Vertical-Banded</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastrotomy, Suture of Perforated Duodenal of Gastric Ulcer, Wound, or Injury</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hernia Repair, Hiatal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hernia Repair, Incisional from the Incision Site of a Previous Metabolic/Bariatric Surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hernia Repair, Inguinal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hernia Repair, Intestinal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hernia Repair, Mesenteric (With or Without Volvulus)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hernia Repair, Paraesophageal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hernia Repairs (Umbilical, Ventral, Incisional) Not Related to the Incision or Port Sites from Previous Metabolic or Bariatric Procedures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incidental Finding of a Mesenteric Defect (e.g., Closure of Petersen's Defect)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intussusception Reduction, Involving the Anatomy of a Prior Metabolic/Bariatric Procedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laparoscopy, Diagnostic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laparotomy, Exploratory</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lysis of Adhesions, Adhesiolysis, Enterolysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marginal Ulcer, Revision or Repair, With or Without Perforation, Involving the Metabolic/Bariatric Anatomy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Revisions/Conversions/Other Procedures
(following a primary bariatric procedure; emergent or non-emergent)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>AT YOUR CENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mini-Gastric Bypass (Any Variation)</td>
<td>X X X †</td>
</tr>
<tr>
<td>Pancreatectomy or Plastic Surgery</td>
<td></td>
</tr>
<tr>
<td>Removal of Fobi Ring or Silastic Ring</td>
<td>X X §</td>
</tr>
<tr>
<td>Resection of the Large Bowel</td>
<td>&lt; 1 yr</td>
</tr>
<tr>
<td>Resection of the Small Bowel Beyond the Metabolic or Bariatric Anatomy</td>
<td>&lt; 1 yr</td>
</tr>
<tr>
<td>Resection of the Small Bowel Involving the Metabolic or Bariatric Anatomy</td>
<td>X X §</td>
</tr>
<tr>
<td>Reversals/Takedowns of a Primary Metabolic/Bariatric Procedure</td>
<td>X X §</td>
</tr>
<tr>
<td>Revision of Any Part of the Bariatric Procedure Not Done for Metabolic or</td>
<td></td>
</tr>
<tr>
<td>Bariatric Purposes (Trauma, Cancer)</td>
<td>&lt; 1 yr</td>
</tr>
<tr>
<td>Revision/Conversion Procedure; Any Variation, Non-investigational</td>
<td>X X X †</td>
</tr>
<tr>
<td>(Stapling or Non-stapling)</td>
<td></td>
</tr>
<tr>
<td>Single Anastomosis Duodenal-ileal Bypass with Sleeve Gastrectomy (“Loop DS”)</td>
<td>X X X †</td>
</tr>
<tr>
<td>Sleeve Gastrectomy (Open or Laparoscopic)</td>
<td>X X X †</td>
</tr>
<tr>
<td>Sleeve Gastrectomy Revision, (Re-sleeve) for Weight Gain or Sleeve Dilation</td>
<td>X X X §</td>
</tr>
<tr>
<td>Suture of Small Intestine Involving the Metabolic/Bariatric Anatomy for</td>
<td></td>
</tr>
<tr>
<td>Perforated Ulcer, Diverticulum, Wound, Injury or Rupture</td>
<td>X X §</td>
</tr>
<tr>
<td>Volvulus; Reduction, Involving the Anatomy of a Prior Metabolic/Bariatric</td>
<td></td>
</tr>
<tr>
<td>Procedure</td>
<td>X X §</td>
</tr>
</tbody>
</table>

*FDA Preapproval Trials*  
**Not Captured**

*Cases Aborted for Any Reason BEFORE the Surgical Incision or EGD*  
**Not Captured**

*Cases Aborted for Any Reason AFTER the Surgical Incision or EGD*  
X < 1 yr

---

**Legend:**

* Only for existing patients in the MBSAQIP data registry (i.e., patient had a previous metabolic or bariatric case entered into the data registry at your center that is being followed long-term).

† For patients with multiple cases in the data registry at a center, one case per patient must be followed long-term.

§ These procedures do not require long-term follow-up, however, long-term follow-up is optional and at the discretion of the center.

< 1 yr Indicates a reoperation/intervention that is only captured when performed postoperatively through the end of the 1 year follow-up timeframe of the metabolic/bariatric procedure you are following out long-term.
Appendix C - Worksheets

Click on the links below to download the worksheets:

MBSAQIP Case Form Worksheet
MBSAQIP Long Term Follow Up Form Worksheet
Appendix D - Metabolic and Bariatric Surgical Clinical Reviewer (MBSCR) Annual Certification Policy

Purpose:
To measure the MBSCRs current level of knowledge and understanding of the MBSAQIP, including aspects such as case inclusion, variable definitions, and other program guidelines.

Policy:
In addition to the initial MBSCR training, MBSAQIP requires that all MBSCRs successfully complete an initial Certification Exam as well as an annual recertification Exam. Those who pass the Certification Exam demonstrate competency in the application of MBSAQIP’s rigorous data definitions.

Procedure:

Timing
The MBSCR annual Certification Exam will take place annually each September. The MBSAQIP MBSCR Certification Exam opens for MBSCRs on September 1 and will close September 30 of each year.

Preparation
All MBSCRs may study and retake the online training modules to prepare for the exam. Please contact mbsaqip@facs.org if you need assistance with access to the online training modules.

The online training modules may be accessed as often as necessary to prepare for the exam.
Communication

Initial Email - Two weeks prior to the availability of the MBSCR Certification Exam, an email will be sent from MBSAQIP reminding MBSCRs of the exam dates.

Commencement Email - Upon the Exam’s commencement date an email with instructions to take the MBSCR Certification Exam will be sent from MBSAQIP

Instructions will include:

- Exam website link
- Login information: username and password
- Who to contact for assistance:
  - Technical, IT, or other exam questions: MBSAQIP Team mbsaqip@facs.org

Guidelines

If you receive a passing score on the Exam, you will not be able to reenter the Exam to review the questions.

Permissible material which may be utilized to complete the Exam includes:

- All available written/online resources including the most recent Operations Manual and all Appendices
- Exception of possible content expertise:
  - You may not use the MBSAQIP Clinical Support Team, your site’s surgeons, or other MBSCRs.

Exam Disclaimer: At the beginning of the Exam all MBSCRs are required to complete the Exam disclaimer, which indicates that they will abide by the Exam rules and complete the Certification Exam in an individual manner using only MBSAQIP Materials and documents for reference as needed.

Exam Format

The MBSCR Certification Exam consists of 50 multiple choice questions.

To pass the Exam the MBSCR must score a minimum of 90%.

The Exam can be taken as many times as needed during the exam availability period to reach the require score of 90%.
The Exam should take approximately 2 hours to complete.

The Exam does not need to be completed in one session. The MBSCR may start and stop the Exam at any time and their progress will be saved.

Once the Exam is completed, a breakdown of areas in which questions were answered incorrectly will be provided.

To protect the integrity of the exam, you will not be provided with exact questions that were missed at the completion of the exam.

Following the end of the calendar year, MBSAQIP will post all Exam questions with rationale. MBSAQIP will not be able to provide individuals with specific questions that they missed on their exam.

New MBSCRs

In order to sit for the MBSCR Certification Exam the following requirements must be met:

- MBSAQIP online training modules 1-5-completed with minimum passing score of 90%.
- Active Workstation access.
- MBSCRs that do not complete and pass the online training modules will not be allowed to sit for the Certification Exam.
- If online training modules 1-5 are completed after June 30th of the exam year, the MBSCR will be eligible to sit for the exam the following year.

Failure to Pass

All current MBSCRs must take and pass the Certification Exam annually.

The MBSAQIP team will work with any user which does not successfully complete the Exam to determine the appropriate course of action.

If an MBSCR fails to complete and pass the initial or recertification Exam in the required timeframe, the MBSAQIP reserves the right to:

- Exclude the site’s data from the Semiannual Report (SAR).
- Change MBSCR workstation user status to read only.
- Recommend additional training for the MBSCR.
- Recommend replacement of the MBSCR at the site.
**Additional Information**

MBSCRs must follow all Exam directions; test scores will not be recalculated if Exam directions are not followed.

MBSCR Educational Opportunities: Exam results are compiled and are utilized to develop content for Ask MBSAQIP Clinical Support Hot Topics, Annual MBSAQIP Conference Sessions and bi-monthly educational questions which are posted to the MBSAQIP Resource Portal.
Appendix E - 30-Day Follow-up Guidelines

I. Purpose:

The purpose of this policy is to provide guidance to the Metabolic and Bariatric Surgical Clinical Reviewer (MBSCR) for the complete follow-up of patients 30 days after the primary procedure.

II. Policy:

A. MBSAQIP requires the reporting of mortality and morbidity data up to and including 30 days after the surgical procedure date on all cases entered into the MBSAQIP registry.

B. Prior to the case’s lock date, the MBSCR should perform all reasonable attempts to obtain 30-day morbidity and mortality data on the patient. The MBSCR may produce a report from the MBSAQIP registry listing the cases with incomplete follow-up and may perform an additional search of the hospital medical records as well as obituary information in an attempt to obtain 30-day mortality data. If follow-up is obtained, the MBSCR should edit the case and save it accordingly.

C. Completed cases entered into the MBSAQIP registry will not be removed from the database, even cases without full 30-day follow-up.

D. Sites must consistently complete full 30-day follow-up on a minimum of 80% of all of the cases entered into the MBSAQIP Registry and marked as “Complete,” per Semiannual Report time period. Sites with full 30-day follow-up rates of less than 80% will not be included in the Semiannual Report.

E. For patients that remain in acute care at your institution through postoperative day 30, follow-up is considered complete and morbidity and mortality data should be collected through the 30-day postoperative timeframe.

F. For patients that remain in the acute care setting at your institution and expire at any point during the postoperative timeframe (within the 30 days following the primary procedure), follow-up is considered complete.

III. Procedure:

The MBSCR will incorporate some or all of the following strategies to obtain follow-up data as is feasible at your institution. Please follow all privacy policies as required by your institution when attempting to obtain full 30-day follow-up.
A. For patients that are inpatient at your facility at or beyond postoperative day 30:

Review the medical record for documentation of postoperative occurrences.

B. For patients that have been discharged and have a follow-up visit between postoperative day 30 and the lock date:

Review the physician or advanced provider notes for documentation of postoperative occurrences. If a documented visit is not with the surgeon’s office or center, the documentation should include some reference to the primary procedure or recent hospitalization (as applicable).

1. Physical Therapy, Occupational Therapy, Speech Therapy, and other therapy provider notes from assessments occurring on or after postoperative day 30 may be utilized for full 30 day follow-up if the need for therapy is directly related to the primary procedure.

2. Documented telemedicine assessments on or after postoperative day 30 (with interactive telecommunications equipment that includes, at a minimum, audio and video equipment) completed by the surgeon’s office or center can be utilized for full 30 day follow-up. If the telemedicine assessment is not with the surgeon’s office or center, the documentation should include some reference to the primary procedure or recent hospitalization (if applicable).

3. If the patient had an in-person visit with a provider between postoperative day 1 and postoperative day 29, then a documented phone call, letter or email, on or after postoperative day 30 between the patient or a caregiver and an advanced provider at the surgeon’s office or center can be utilized for full 30-day follow-up as long as the patient’s postoperative course is addressed.

C. For patients that have been discharged and have follow-up visits with a physician or advanced provider on or between postoperative day 0 and postoperative day 29.

or

For patients that have not had a follow-up visit after the patient was discharged following the primary procedure.

The following actions may be taken:

0. A minimum of two attempts should be made to contact the patient or caregiver, one phone call or text message and one letter or email between postoperative day 30 and the lock date.

   a. If the initial attempt involves sending a letter or email, it is recommended to send it out on or shortly after postoperative day 30. The MBSCR should wait until approximately postoperative day 45 for the return of the letter or email before initiating a second
attempt to allow time for patient completion and return the communication.

1. Phone contact attempts can be made by non-MBSCRs working closely with the MBSCR. The MBSCR should provide any callers with a script or questionnaire to ensure that required information is obtained. The MBSCR is responsible for following up with any patient that reports an abnormal postoperative course.

2. Electronic health record communications through patient portals are acceptable forms of patient contact and would be considered an email contact attempt.

3. If the MBSCR was able to obtain follow-up data, s/he should:
   a. Mark “Yes” for “Were you able to follow the patient for the full 30 days?”
   b. Indicate the method(s) and the number of attempts that were utilized to obtain follow-up information for this patient.
   c. Record, at minimum, the attempt that satisfied full 30-day follow-up in the Contact Management section.
   d. In the comments text box of the Discharge tab, make note of any details of conversation or letter correspondence from the patient, in case of a future audit.
   e. Ensure/Verify the case is marked as “Complete.”
   f. Save and Exit Form.

4. If the MBSCR is unable to obtain follow-up data utilizing any of the above methods, s/he should:
   a. Mark “No” for “Were you able to follow the patient for the full 30 days?”
   b. Indicate the method(s) and the number of attempts that were utilized to perform due diligence for this patient.
   c. Ensure/Verify the case is marked as “Complete.”
   d. Save and Exit Form.
Appendix F - Algorithms

Superficial Incisional SSI Algorithm (Criterion C)
Additional clarification regarding criterion “C” of the Superficial Incisional SSI criteria:

Was one of the following present at the incision site for the principal operative procedure: pain or tenderness, or localized swelling, or redness, or heat AND was the superficial incision deliberately opened by the Surgeon?

Yes →

Was the incision cultured?

Yes →

Assign a Superficial Incisional SSI.

No →

Is there clear physician diagnosis of infection?

Yes →

Did an MD clearly document “No infection” or uninfected hematoma, seroma, or fluid collection?

No →

Do not assign a Superficial Incisional SSI based on criterion “C”. Return to criteria A, B, or D to see if criteria are met.

Yes →

Is a potential diagnosis of infection mentioned in the record despite being unknown or uncertain?

Yes →

Were antibiotics prescribed?

Yes →

Assign a Superficial Incisional SSI.

No →

Do not assign an SSI.

No →

Was the culture result positive?

Yes →

Assign a Superficial Incisional SSI.

No →

Do not assign an SSI.
Appendix G - Data Entry Workflow Algorithm

Use this decision tree tool to determine if a case should be entered into the data registry. Answer the questions one at a time and you will be guided to the recommendation.
Appendix H - Data Entry Audit Protocol

I. Purpose:

This audit plan will provide the structure and requirements for performing random and targeted clinical data integrity audits of MBSAQIP participating sites.

II. Background:

Data integrity audits are a valuable tool in validating the reliability of the data collected for the MBSAQIP. In addition, data integrity audit results have informed the Program’s educational and operational direction.

III. Policy:

a. All participating sites will be continuously monitored for certain variations over time that may be indicative of a degradation of data.

b. If the Program identifies a site where significant discrepancies across data occur, an audit may be more likely to be performed.

c. Audits will be performed remotely by members of the ACS Clinical Support team at ACS Headquarters in Chicago, Illinois. Audits typically take place between the standard work hours of 8 AM and 5 PM US Central time. However, if the site is not available during these hours, ACS will work with the site to come to a mutual agreement of the audit timeframe. In some cases, audits may take place outside of standard business hours for either the site or ACS.

d. While the vast majority of audits will be performed remotely, there may be times when MBSAQIP requires an on-site audit of a hospital. Hospitals will be notified a minimum of 10 days (typically 4-6 weeks) ahead of time if an on-site audit is required.

e. A data integrity audit will be performed on the site as a whole, not on individual MBSCRs at the site. The audit will evaluate data accuracy/validity as well as quality improvement processes within the institution.

f. It is the expectation that each audited site will have a disagreement rate of 5% or less over all variables evaluated, and may be held to more stringent levels of disagreement for critical variables at the discretion of MBSAQIP leadership.
g. If a site does not pass its audit, the MBSCR(s) may be required to complete additional training and/or the site may be subject to additional audits. In addition, site data may be prevented from entry into the program or from being included in the risk-adjusted Semiannual Report (SAR) until agreement thresholds are reached at the discretion of MBSAQIP leadership. In such an instance, the MBSAQIP Center’s accreditation may also be at risk.

h. If a site cancels a previously scheduled/confirmed audit within 72 hours of the audit, the site will be charged for any expenses incurred by MBSAQIP representatives in setting up the remote audit.

i. All sites that undergo an audit will receive a score of pass/fail or a score of incomplete if the hospital does not provide appropriate information/access for the audit.

IV. Prior to the Data Integrity Audit:

a. A site will be notified a minimum of 10 days (typically 4-6 weeks) prior to the audit date that an audit is required.

b. The MBSAQIP will provide the site with a list of cases for chart review. Case selection will be determined by MBSAQIP using advanced data analytics.

c. The MBSCR will request and obtain specified charts prior to the audit.

d. The remote audit can be performed one of three ways. 1) The auditors are given remote access to the hospital’s electronic medical record. This type of access is usually provided to site employees to access medical records offsite. 2) The auditors will conduct a secure webinar with the MBSCR to remotely access the MBSCR’s and/or other site computer to login to the medical record. 3) The MBSCR will upload complete scanned records to a secure portal so the auditors can perform the audit.

e. If the auditors are given remote access or are auditing via a secure webinar, the SCR will coordinate the acquisition of either remote access for the NSQIP auditors or ensure remote access to the SCR’s computer prior to the audit according to hospital policy.

f. The MBSAQIP will have a pre-audit meeting with the site’s MBSCR to ensure the access to the hospital’s records is established and working correctly.

V. During the Data Integrity Audit:

a. Each audit will be conducted over the course of 1-2 business days.

b. Any and all collected variables may be audited, but those most likely to be audited are the variables that most greatly impact the morbidity risk-adjusted models. Each variable will be evenly weighted.
c. The MBSAQIP chart review will be conducted in a private office at the ACS headquarters in Chicago, Illinois. Only members of the audit team will be allowed access to the office during the audit. The MBSCR may be asked to clarify information during the audit, but is not required to be available throughout the duration of the entire audit.

d. The data integrity audit will be performed in English and requires all information given to the auditors to be in English.

VI. After the Audit:

a. The audit team will compose a summary report of the data integrity audit, including the specific variable disagreements and any needed reeducation requirements. Special attention will also be paid to the site's follow up rates, certification exam results, and case study completion rate, where applicable.

b. The audit score will be pass/fail or incomplete.

c. The audit report will be reviewed by MBSAQIP leadership prior to being finalized.

d. The finalized audit report will be sent to the site's MBSCR(s), MBS Director and MBS Coordinator approximately 4 weeks following completion of the audit.

e. After receiving the finalized audit report, the site (if desired) may request an audit wrap up phone call with the MBSAQIP to discuss the information/findings contained within the report.
## Appendix I - Discharge Destination Crosswalk

### CMS – NSQIP Discharge Destination Crosswalk

<table>
<thead>
<tr>
<th>CMS #</th>
<th>CMS (Center for Medicare &amp; Medicaid Services) Destination Name</th>
<th>NSQIP #</th>
<th>NSQIP Destination Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Discharged to home care or self-care</td>
<td>4</td>
<td>Multi-level Senior Community</td>
</tr>
<tr>
<td>02</td>
<td>Discharged/transferred to a short term general hospital for inpatient care</td>
<td>5</td>
<td>Separate acute care</td>
</tr>
<tr>
<td>03</td>
<td>Discharged/transferred to skilled nursing facility (SNF) with Medicare certification in anticipation of skilled care</td>
<td>1, 3</td>
<td>Skilled care, not home (if not home preop) Facility which was home (if home preop)</td>
</tr>
<tr>
<td>04</td>
<td>Discharged/Transferred to an Intermediate Care Facility (ICF)</td>
<td>2, 3</td>
<td>Unskilled facility, not home (if not home preop) Facility which was home (if home preop)</td>
</tr>
<tr>
<td>05</td>
<td>Discharged/transferred to a designated cancer center or children’s hospital</td>
<td>5</td>
<td>Separate acute care</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Count</td>
<td>Location</td>
</tr>
<tr>
<td>------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-------</td>
<td>------------------------------</td>
</tr>
<tr>
<td>06</td>
<td>Discharged/Transferred to home under care of organized home health service organization in anticipation of covered skilled care</td>
<td>4</td>
<td>Home</td>
</tr>
<tr>
<td>07</td>
<td>Left against medical advice or discontinued care</td>
<td>8</td>
<td>Unknown</td>
</tr>
<tr>
<td>20</td>
<td>Expired</td>
<td>7</td>
<td>Expired</td>
</tr>
<tr>
<td>21</td>
<td>Discharged/Transferred to court/law enforcement</td>
<td>3</td>
<td>Facility which was home</td>
</tr>
<tr>
<td>43</td>
<td>Discharged/Transferred to a Federal Hospital (discharges and transfers to a government operated health care facility)</td>
<td>2</td>
<td>Unskilled facility, not home - If to VA nursing home (if not home preop)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>Facility which was home (if home preop)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5</td>
<td>Separate acute care - If to VA hospital</td>
</tr>
<tr>
<td>50</td>
<td>Hospice-home</td>
<td>4</td>
<td>Home</td>
</tr>
<tr>
<td>51</td>
<td>Hospice-medical facility providing hospice level of care</td>
<td>1</td>
<td>Skilled care, not home (if not home preop)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>Facility which was home (if home preop)</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Category</td>
<td>Notes</td>
</tr>
<tr>
<td>------</td>
<td>----------------------------------------------------------------------------</td>
<td>----------</td>
<td>-------</td>
</tr>
<tr>
<td>61</td>
<td>Discharged/transferred to hospital-based Medicare approved swing bed</td>
<td>1</td>
<td>Skilled care, not home</td>
</tr>
<tr>
<td>62</td>
<td>Discharged/transferred to an inpatient rehabilitation facility (IRF) including rehabilitation distinct part units of a hospital</td>
<td>6</td>
<td>Rehab</td>
</tr>
<tr>
<td>63</td>
<td>Discharged/transferred to a Medicare certified long term care hospital (LTCH)</td>
<td>1</td>
<td>Skilled care, not home (if not home preop)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>Facility which was home (if home preop)</td>
</tr>
<tr>
<td>64</td>
<td>Discharged/transferred to a nursing facility certified under Medicaid but not certified under Medicare</td>
<td>1</td>
<td>Skilled care, not home (if not home preop)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>Facility which was home (if home preop)</td>
</tr>
<tr>
<td>65</td>
<td>Discharged/transferred to a psychiatric hospital or psychiatric distinct part unit of a hospital</td>
<td>5</td>
<td>Separate Acute care</td>
</tr>
<tr>
<td>66</td>
<td>Discharged/transferred to a critical access hospital (CAH)</td>
<td>5</td>
<td>Separate acute care</td>
</tr>
<tr>
<td>70</td>
<td>Discharged/transferred to another type of health care institution not defined elsewhere in this code list</td>
<td>8</td>
<td>Unknown</td>
</tr>
<tr>
<td>82</td>
<td>Discharged/transferred to a short term general hospital for inpatient care with a</td>
<td>5</td>
<td>Separate acute</td>
</tr>
<tr>
<td></td>
<td>planned acute care hospital inpatient readmission</td>
<td></td>
<td>care</td>
</tr>
<tr>
<td>---</td>
<td>-------------------------------------------------------------------------------------------------------------------</td>
<td>---</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>83</td>
<td>Discharged/transferred to a skilled nursing facility (SNF) with Medicare certification with a planned acute care hospital inpatient readmission</td>
<td></td>
<td>Skilled care, not home (if not home preop)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>Facility which was home (if home preop)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>84</td>
<td>Discharged/transferred to a facility that provides custodial or supportive care with a planned acute care hospital inpatient readmission</td>
<td></td>
<td>Unskilled facility, not home (if not home preop)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2</td>
<td>Facility which was home (if home preop)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>85</td>
<td>Discharged/transferred to a designated cancer center or children's hospital with a planned acute care hospital inpatient readmission</td>
<td></td>
<td>Separate acute care</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>86</td>
<td>Discharged/transferred to home under care of organized home health service organization with a planned acute care hospital inpatient readmission</td>
<td></td>
<td>Home</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>87</td>
<td>Discharged/transferred to court/law enforcement with a planned acute care hospital inpatient readmission</td>
<td></td>
<td>Facility which was home</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>88</td>
<td>Discharged/transferred to a federal health care facility (discharges and transfers to a government operated health care facility) with a planned acute care hospital inpatient</td>
<td></td>
<td>Unskilled facility, not home - If to VA nursing home (if not home preop)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
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</tr>
<tr>
<td>Code</td>
<td>Readmission Details</td>
<td>Facility Details</td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>---------------------</td>
<td>------------------</td>
<td></td>
</tr>
<tr>
<td>89</td>
<td>Discharged/transfered to a hospital-based Medicare approved swing bed with a planned acute care hospital inpatient readmission</td>
<td>Skilled care, not home</td>
<td></td>
</tr>
<tr>
<td>90</td>
<td>Discharged/transfered to an inpatient rehabilitation facility (IRF) including rehabilitation distinct part units of a hospital with a planned acute care hospital inpatient readmission</td>
<td>Rehab</td>
<td></td>
</tr>
<tr>
<td>91</td>
<td>Discharged/transfered to a Medicare certified long term care hospital (LTCH) with a planned acute care hospital inpatient readmission</td>
<td>Skilled care, not home (if not home preop) Facility which was home (if home preop)</td>
<td></td>
</tr>
<tr>
<td>92</td>
<td>Discharged/transfered to nursing facility certified under Medicaid but not certified under Medicare with a planned acute care hospital inpatient readmission</td>
<td>Skilled care, not home (if not home preop) Facility which was home (if home preop)</td>
<td></td>
</tr>
<tr>
<td>93</td>
<td>Discharged/transfered to a psychiatric hospital/distinct part unit of a hospital with a planned acute care hospital inpatient readmission</td>
<td>Separate Acute care</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Discharge/Transfer Description</td>
<td>NSQIP Code</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>--------------------------------</td>
<td>------------</td>
<td>-------------</td>
</tr>
<tr>
<td>94</td>
<td>Discharged/transferred to a critical access hospital with a planned acute care hospital inpatient readmission</td>
<td>5</td>
<td>Separate acute care</td>
</tr>
<tr>
<td>95</td>
<td>Discharged/transferred to another type of health care institution not defined elsewhere in this code list with a planned acute care hospital inpatient readmission</td>
<td>8</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

**NSQIP Options**

1. Skilled care, not home (e.g., transitional care unit, subacute hospital, ventilator bed, skilled nursing home)
2. Unskilled facility, not home (e.g., nursing home or assisted facility-if not patient's home preoperatively)
3. Facility which was home (e.g., return to a chronic care, unskilled facility, or assisted living-which was the patient’s home)
4. Preoperatively, prison)
5. Home
6. Separate acute care (e.g., transfer to another acute care facility)
7. Rehab
8. Expired
9. Unknown