**Variable Name**: **Date of Birth**

**Intent of Variable:** To be able to calculate patient's age at the time of the Primary 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)
- Enter year only (yyyy)

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

-

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

-

**Notes:**

- The MRN/IDN and Date of Birth are the two required fields used to establish the patient in the MBSAQIP database.
- The database will not accept patients under 5 years of age.

**Variable Name**: **Sex**

**Intent of Variable:** To capture sex for purpose of analysis. Sex can confer differential risk.

**Definition:** Distinguish between male, female, or non-binary.

**Criteria:** Report the patient's sex as per the medical record.

**Options:**

- Male
- Female
- Non-binary

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

-

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

-

**Notes:**

- For patients who do not identify as male or female, please utilize the non-binary option.

**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.
- **Some Other Race**: A person having origins which are not listed in a category above
- **Unknown/Not Reported:** if documentation does not state patient's race, report as Unknown/Not Reported.

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

**Options (choose all that apply):**

- White
- Black or African American
- American Indian or Alaska Native
- Native Hawaiian or Other Pacific Islander
- Asian
- Some Other Race
    - Indicate other race (text field)
- Unknown/Not Reported

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

-

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

-

**Notes:**

- Categories are consistent with the US Census Bureau
- 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."
- Hispanic/Latino Ethnicity is a separate variable (listed below) where you can report the patient's 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

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

-

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

-

**Notes:**

- Race is required in addition to this data element.

**Variable Name**: **Procedure Date**

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

**Definition:** The date the patient enters the procedure room or surgical suite for the Primary Procedure, Reoperation, or Intervention.

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

**Options:**

- Enter date (mm/dd/yyyy)
- Enter month and year (mm/yyyy)
- Enter year (yyyy)

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

- If multiple procedures were completed under the same anesthetic, please capture the date that the first procedure was started.

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

-

**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.
- Subsequently the operative date fields are prepopulated from this date, but finish date can be modified if needed.
- If you are capturing a Reoperation or Intervention and the procedure occurred at an outside facility, capture the date of the procedure for the Procedure Date (if you are unsure of the date that the patient entered the procedure room or surgical suite).

**Variable Name: Procedure Type**

**Intent of Variable:** To identify the procedure type that was completed.

**Definition:**

- An **Initial** procedure refers to a patient's primary metabolic and bariatric procedure. This option will generate a new Case Form.
- A **Conversion** refers to a metabolic and bariatric procedure being converted to another type of metabolic and bariatric procedure. This option will generate a new Case Form.
- A **Revision** is change to a current metabolic and bariatric procedure for repair or improvement of the existing metabolic and bariatric anatomy. This option will generate a new Case Form.
- A **Reoperation** refers to a surgery that occurs following a metabolic and bariatric surgery. This option will generate a Reoperation Event Form.
- An **Intervention** refers to a procedure completed following a metabolic and bariatric surgery in which, at minimum, sedation was given for the procedure. This option will generate an Intervention Event Form.

**Criteria:** Identify the procedure type for the procedure being entered into the MBSAQIP registry.

**Options:**

- Initial
- Conversion
- Revision
- Reoperation
- Intervention

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

-

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

-

**Notes:**

- Please choose **Reoperation** in the following scenarios:
    - A surgery that does not involve the metabolic and bariatric anatomy within 30 days of a Primary Procedure
    - A surgery which involves the metabolic and bariatric anatomy but was not completed to maintain current weight loss or increase future weight loss
    - A surgery which involves the metabolic and bariatric anatomy but was not completed at your site
    - A surgery completed at your site but does not require to be captured as a new case per Appendix B
- Please choose **Intervention** in the following scenarios:
    - Any procedure which was performed endoscopically (e.g. EGD)

**Variable Name**: **Primary Procedure**

**Intent of Variable:** To assist in determining which procedure and corresponding CPT® (Current Procedural Terminology) code will be the primary MBSAQIP abstracted procedure. This procedure is considered the primary focus assessment.

**Definition**: See specific criteria below.

**Criteria:** Provide the CPT® code of the Primary Procedure.

**Options:**

- Enter value
- Procedure Notes are optional

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

- Assign most complex metabolic and bariatric surgical procedure

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

-

**Notes:**

- 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.
- A **Procedure notes** section is provided for additional comments to be utilized at the site's discretion. This allows for further description of the procedure or patient conditions which may have been experienced during this surgical encounter.

**Variable Name: Initial Procedure Description**

**Intent of Variable:** To capture initial, primary metabolic and bariatric procedures which do not have specific CPT® codes assigned by the American Medical Association (AMA).

**Definition:** Bariatric or metabolic procedures which do not have a specific CPT® code. This field is required for initial cases with an unlisted Procedure CPT® Code (43659 or 43999). This field is optional for initial cases with any other included CPT® code.

**Criteria:** Capture the primary bariatric or metabolic procedure performed for weight loss or metabolic purposes which does not have a specific CPT® code.

**Options:**

- Endoscopic gastroplasty
- Intragastric balloon placement
- Laparoscopic biliopancreatic diversion
- Laparoscopic biliopancreatic diversion with duodenal switch
- Percutaneous gastric drainage device placement
- Single anastomosis duodeno-ileal bypass/Loop duodenal switch
- Single anastomosis gastric bypass
- Other (not listed)

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

- For AspireAssist®, please choose Percutaneous gastric drainage device placement
- Choose "Other" if the CPT code entered for the procedure does not indicate the specific procedure performed and one of the more specific options is not appropriate.
- Required if 43659 or 43999 is entered for the Primary Procedure CPT®.

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

- CPT code for the case indicates the procedure performed.

**Notes:**

- If you choose "Revision" or "Conversion" for the "Procedure Type" variable, then this variable will be disabled.

**Variable Name: Previous Procedure**

**Intent of Variable:** To identify any metabolic and bariatric procedures the patient had completed prior to entering the OR for the Primary Procedure.

**Definition:** A Conversion refers to a procedure being converted to another type of metabolic and bariatric procedure. The previous procedure refers to the patient's most recent metabolic and bariatric procedure completed. This field is required when Conversion is chosen for Procedure Type.

**Criteria:** Identify any metabolic and bariatric procedures the patient had prior to entering the OR for the Primary Procedure.

**Options** (select all that apply)**:**

- Adjustable gastric banding
- Biliopancreatic diversion
- Biliopancreatic diversion with duodenal switch
- Gastric stapling (not vertical banded gastroplasty)
- Intragastric balloon
- Percutaneous gastric drainage device placement
- Ring (Fobi or Silastic) procedure
- Roux-en-Y gastric bypass
- Single anastomosis duodeno-ileal bypass / Loop duodenal switch
- Single anastomosis gastric bypass
- Sleeve gastrectomy
- Vagal nerve blocking therapy
- Vertical banded gastroplasty
- Other endoluminal procedure (not listed)
- Other (not listed)

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

- Capture all that apply
- For AspireAssist®, please choose Percutaneous gastric drainage device placement

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

- Patient has a history of a partial gastrectomy that was completed due to stomach cancer.
- Patient has a history of a partial gastrectomy that was completed due to an automobile accident.

**Notes:**

- If you choose "Initial" or "Revision" for the "Procedure Type" variable, then this variable will be disabled

**Variable Name**: **Current Primary Procedure**

**Intent of Variable:** To identify the metabolic and bariatric procedure which is the primary MBSAQIP abstracted procedure. This procedure is considered the primary focus of the case.

**Definition**: A Conversion refers to a procedure being converted to another type of metabolic and bariatric procedure. The current Primary Procedure refers to the procedure which is considered the primary focus of the case. This field is required when Conversion is chosen for Procedure Type.

**Criteria:** Identify the metabolic and bariatric procedure which is the primary MBSAQIP abstracted procedure for this case.

**Options:**

- Biliopancreatic diversion
- Biliopancreatic diversion with duodenal switch
- Roux-en-Y gastric bypass
- Roux-en-Y distal gastric bypass
- Single anastomosis duodeno-ileal bypass / Loop duodenal switch
- Single anastomosis gastric bypass
- Sleeve gastrectomy
- Other (not listed)

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

- 

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

- 

**Notes:**

- If you choose “Initial” or “Revision” for the “Procedure Type” variable, then this variable will be disabled

**Variable Name**: **Revisions**

**Intent of Variable:** To identify the metabolic and bariatric revision procedure which is the primary MBSAQIP abstracted procedure. This procedure is considered the primary focus of the case.

**Definition**: A Revision is change to a current metabolic and bariatric procedure for repair or improvement of the existing metabolic and bariatric anatomy. This field is required when Revision is chosen for Procedure Type.

**Criteria:** Identify the option which most accurately describes the metabolic and bariatric revision procedure, which is the primary MBSAQIP abstracted procedure for this case.

**Options:**

- Adjustable gastric band, port, and/or tubing revision
- Adjustable gastric banding over Roux-en-Y gastric bypass
- Biliopancreatic diversion with or without duodenal switch revision
- Biliopancreatic diversion common channel lengthening
- Gastrectomy
- Gastric pouch or stoma plication or revision
- Roux-en-Y gastric bypass revision
- Roux-en-Y limb lengthening
- Single anastomosis duodeno-ileal bypass / Loop duodenal switch revision
- Sleeve gastrectomy revision (Re-sleeve)
- Other (not listed)

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

-

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

-

**Notes:**

- If you choose “Initial” or “Conversion” for the “Procedure Type” variable, then this variable will be disabled

**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 primary procedure must be performed during the hospital admission for the diagnosis.

**AND**

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

**Notes:**
-

**Variable Name: Final Indication**

**Intent of Variable:** To capture the indication for the Primary Procedure.

**Definition:** Revisions and Conversions of metabolic and bariatric procedures may be completed for many reasons.

**Criteria:** Please capture the indication or postoperative diagnosis for the Primary Procedure.

**Options:**

Anatomic

- Adhesions
- Anastomotic or staple line leak
- Gastrointestinal tract bleeding
- Gastrointestinal tract fistula
- Gastrointestinal tract perforation
- Gastrointestinal tract stricture or obstruction
- Gastrointestinal tract ulcer without perforation
- Mechanical malfunction

Pathophysiologic

- Abdominal pain
- Dumping syndrome
- Dysphagia
- Fluid, electrolyte, or nutritional depletion
- Gastroesophageal reflux disease (GERD)
- Hypoglycemia
- Inadequate weight loss
- Nausea and/or vomiting
- Patient intolerance
- Patient non-compliance
- Persistent comorbidities
- Weight gain
- Other (not listed)

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

-

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

-

**Notes:**

- If multiple postoperative diagnoses or indications are given for a procedure, please follow-up with the surgeon of record for the case or the MBS Director to determine the indication for the procedure.
- If you choose “Initial” for “Procedure Type” then this variable will be disabled

**Variable Name**: **Other Procedures**

**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 Primary Procedure. In some cases, additional captured CPT® codes might be analyzed separately from the Primary 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 Primary 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):**

- A metabolic and bariatric surgeon and his/her team perform multiple procedures under the same anesthetic. Enter the most complex metabolic or bariatric procedure as the Primary Procedure and additional procedures as "Other" procedures
    - Example: A bariatric surgeon and his/her team perform a sleeve gastrectomy and cholecystectomy. Capture the sleeve gastrectomy as the primary procedure and capture the cholecystectomy as an "Other" procedure.
- Invasive procedures performed at the time of the primary procedure
    - Bronchoscopy (not performed by anesthesia)
    - Esophagogastroduodenoscopy (EGD) if not bundled with primary procedure
    - Ureteral Stent placement

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

- Imaging performed during the Primary Procedure, such as x-ray or CT scans
- Anesthesia procedures
- Central line placement
- Sheath placement
- Transesophageal echocardiogram (TEE)

**Notes:**

- If a Laparoscopic procedure is converted to an Open procedure, the laparoscopic portion will not be included as an "Other." For example, if the primary procedure was a colectomy and was initiated via the laparoscopic approach and then a determination was made to convert to an open approach due to extensive disease, you would code the open approach as the primary procedure only.
- ACS advises each MBSCR to discuss and develop an internal process for determining the other surgical procedure with their MBS 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.
- An Other Procedure Notes section is provided for additional comments to be utilized at the site's discretion. This allows for further description of the procedure or patient conditions which may have been experienced during this surgical encounter.

**Variable Name**: **Concurrent Procedures**

**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 Primary Procedure. In some cases, additional captured CPT® codes might be analyzed separately from the Primary 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 Primary 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):**

- A metabolic and bariatric surgeon and his/her team perform a bariatric and metabolic procedure. A different surgeon performs a non-metabolic and non-bariatric procedure under the same anesthetic. Enter the bariatric or metabolic procedure as the Primary Procedure and non-metabolic and non-bariatric procedure as the "Concurrent" procedure, as two different surgeons performed procedures under the same anesthetic.
    - Example: Bariatric surgery performs a sleeve gastrectomy. Under the same anesthesia event, a plastic surgery completes a panniculectomy. Capture the sleeve gastrectomy as the Primary Procedure and the panniculectomy as a "Concurrent" procedure.
- Invasive procedures performed at the time of the primary procedure
    - Bronchoscopy (not performed by anesthesia)
    - Esophagogastroduodenoscopy (EGD) if not bundled with primary procedure
    - Ureteral Stent placement

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

- Imaging performed during the Primary 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 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.
- A Concurrent Procedure Notes section is provided for additional comments to be utilized at the site's discretion. This allows for further description of the procedure or patient conditions which may have been experienced during this surgical encounter.

**Variable Name: Stapler Used/Anastomosis Completed**

**Intent of Variable:** To identify cases involving the use of a surgical stapler for the anastomosis or resection of the GI tract, or creation of a new anastomosis, involving the metabolic and bariatric anatomy.

**Definition:** Surgical staplers are used to cut and anastomose portions of the GI tract. Anastomoses are surgical connections between two structures of the GI tract.

**Criteria:** A surgical stapler was used for an anastomosis or resection of the GI tract involving the metabolic and bariatric anatomy, or if there was creation of a new anastomosis, involving the metabolic and bariatric anatomy.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- 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
- Hand-sewn anastomosis

**Scenarios to Clarify (Do Not Assign Variable):**
- 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
- Creation or revision of an anastomosis distal or proximal to the metabolic and bariatric anatomy
- Stapling of the GI tract distal or proximal to the metabolic and bariatric anatomy

**Notes:**
- Look for key words such as GIA, TIA, ENDOPATH®, the use of staple “re-loads” (such as “Blue Re-load” or “Green Re-load”)

**Variable Name: Hospital Admission Date/Time**

**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 Primary Procedure.

**Options:**

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

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

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

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**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.

**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.

**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:**

- Home/Permanent Residence
- Acute Care Hospital
- Other Facility
- Expired
- Against Medical Advice (AMA)
- Unknown

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

- See CMS-MBSAQIP Discharge Destination Crosswalk (Appendix I)

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

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**Notes:**

- See CMS-MBSAQIP Discharge Destination Crosswalk (Appendix I)
- Examples of Home/Permanent Residence would include: home, assisted living, group home, homeless, prison
- Examples of Other Facilities would include: temporary rehab, temporary stay in a skilled nursing facility
- For patients who are discharged to a nursing home/skilled nursing facility that will be their permanent residence, select "Home/Permanent Residence."
- For patients who are discharged to a nursing home/skilled nursing facility/rehabilitation facility to convalesce following the primary procedure, the nursing home/skilled nursing facility/rehabilitation facility would be considered an "Other Facility."
- If a patient is discharged to an independent living community, select "Home/Permanent Residence."
- If a patient is discharged to their home with Home Hospice services, select "Home/Permanent Residence."
- If a patient is discharged to another facility to provide Hospice services, select "Other Facility."
- If a patient is discharged/transferred to another hospital, select "Acute Care Hospital."

**Variable Name: Medical Specialist**

**Intent of Variable:** To capture the medical specialty of the physician performing the Primary Procedure.

**Definition:** See criteria below.

**Criteria:** Select the medical specialty of the physician performing the Primary Procedure.

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

- Metabolic and bariatric surgeon
- General surgeon
- Gastroenterologist
- Interventional radiologist
- Other

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

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

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**Notes:**

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**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 Primary Procedure or at the time the patient is being considered a candidate for surgery.

**Options:**

- Enter value
    - Select centimeters/inches
- Unknown

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

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

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**Notes:**

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**Variable Name**: **Highest Recorded Weight**

**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 Primary Procedure.

**Definition:** The highest amount a patient weighs as documented by the bariatric center or bariatric specialist's office within one year prior to the Primary Procedure.

**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 Primary Procedure.

**Options:**

- Enter value
    - Select pounds/kilograms
- Enter date for Highest Recorded Weight

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

- A weight taken preoperatively on the day of the Primary Procedure
- A weight taken during a pre-op anesthesia visit for the Primary Procedure

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

- A weight that is 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.
- Please note, BMI is calculated in the registry based on height and weight
- Please refer to Appendix G- Provider Assessment table for additional guidance

**Variable Name**: **Weight Closest to Procedure**

**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 Primary 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 Procedure

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

- Weight obtained during preoperative telehealth assessment (via phone or video)

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

-

**Notes:**

- Please refer to Appendix G- Provider Assessment table for additional guidance

**Variable Name**: **Risk Calculator Used**

**Intent of Variable:** To capture whether a metabolic and bariatric provider utilized the MBSAQIP Bariatric Surgical Risk/Benefit Calculator during a preoperative visit and reviewed the results with the patient.

**Definition:** The MBSAQIP Bariatric Surgical Risk/Benefit Calculator provides metabolic and bariatric surgeons and their patients with accurate, patient-specific information to guide surgical decision making and informed consent. The patient's preoperative information is entered and the tool provides estimates regarding the patient's risk of postoperative complications, remission of weight-related comorbidities, and weight loss for each of four primary bariatric surgical procedures.

The calculator can predict the patient's body mass index (BMI), weight, and total weight change percentage trajectories up to one year after a surgical procedure. To assist with understanding the predictions, the calculator provides a summary report designed for patients to share the information with their families and other multidisciplinary team members involved in their care.

**Criteria:** A metabolic and bariatric provider utilized the MBSAQIP Bariatric Surgical Risk/Benefit Calculator and reviewed the results with the patient during a preoperative visit.

**Options:**

- Yes
- No

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

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

- Other surgical risk calculator used

**Notes:**

- The MBSAQIP surgical risk/benefit calculator is available at: https://riskcalculator.facs.org/bariatric/

**Variable Name: Substance Abuse Screening Completed**

**Intent of Variable:** To capture whether a metabolic and bariatric provider or center screened the patient for substance abuse use disorder (SUD) during a preoperative visit.

**Definition:** Substance abuse screening entails assessing a patient for substance use behaviors that are associated with increased risk of SUD using standardized assessment tools. Screening quickly assesses the severity of substance use and identifies the need for potential intervention.

**Criteria:** A metabolic and bariatric provider or center screened for substance abuse during a preoperative visit utilizing standardized assessment tools.

**Options:**

- Yes
- No

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

- Screening to Brief Intervention (S2BI)
- Brief Screener for Alcohol, Tobacco, and other Drugs (BSTAD)
- Tobacco, Alcohol, Prescription medication, and other Substance use (TAPS)
- NIDA Drug Use Screening Tool: Quick Screen (NMASSIST)
- Screening, Brief Intervention and Referral to Treatment (SBIRT)
- Substance use/abuse screening or assessment completed by a behavioral health provider.

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

- Urine drug/alcohol screen
- Blood drug/alcohol screen
- Social History on History and Physical

**Notes:**

- This variable captures clinical information on those patients who received a systematic substance use screening at the time of their preoperative history and physical . Sites may satisfy this measure by administering a substance use assessment instrument at the time of the patient's preoperative history and physical or anytime during the preoperative evaluation phase by the multidisciplinary team (e.g., the psychological or behavioral health assessment). Providers should apply clinical judgment should their patients require substance use interventions, based on the following assessment areas:
    - Tobacco use component: Patients whose providers screened them for tobacco use and who received tobacco cessation intervention if identified as a tobacco user.
    - Unhealthy alcohol use component: Patients whose providers screened them for unhealthy alcohol use using a systematic screening method and who received treatment if identified as an unhealthy alcohol user.
    - Drug use component (nonmedical prescription drug use and illicit drug use): Patients whose providers screened them for nonmedical prescription drug use and illicit drug use by using a systematic screening method and who received treatment if identified as a nonmedical prescription or illicit drug user.

**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 Primary 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

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

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

**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.

**Variable Name**: **Current Smoker**

**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 Primary Procedure.

**Options:**

- Yes
- No

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

-

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

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**Notes:**

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**Variable Name: Diabetes Mellitus**

**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. 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 Primary 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
- Yes, non-insulin
- Yes, 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.
- A current/active diagnosis of gestational diabetes would be utilized as a diagnosis to assign Diabetes Mellitus.
- A patient with diabetes who has chronically been treated with oral agents may require additional coverage with a sliding scale while being treated in the hospital. If the patient receives the sliding scale for 2 weeks or less, this does not qualify as a diabetic treated with insulin. This would be assigned as "Non-Insulin."
- A patient with diabetes who utilizes a sliding scale insulin for long-term management (>2 weeks) would be assigned as "Insulin."

**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.

**Variable Name**: **Immunosuppressive Therapy**

**Intent of Variable:** To capture patients who are receiving immunosuppressive therapy which may predispose these patients to delayed wound healing, postoperative infection, and other effects. The medications collected include: corticosteroid, anti-rejection/transplant immunosuppressant, Synthetic DMARD, Biologic DMARD and Other.

**Definition:** Immunosuppressants are utilized to decrease the body's inflammatory response and can inhibit various portions of the immune system.

- **Corticosteroids** are stress hormones that are used to decrease the body's inflammatory process for patients with inflammatory disorders, autoimmune diseases and/or hematological cancers.[1]
- **Anti-rejection/transplant immunosuppressant drugs** weaken the immune system's response to foreign material to avoid rejection of the transplanted organ/tissue.[2] These medications can be used for immune-based therapy in non-transplant patients. These agents will be classified in this category whether or not the indication is post-transplant vs other condition.
- **Disease-modifying antirheumatic drugs (DMARDs)**/Disease modifying drugs (DMDs) are a class of drugs used to interfere with critical pathways in the inflammatory cascade to help treat inflammatory conditions such as rheumatoid arthritis, psoriatic arthritis, systemic lupus, inflammatory bowel disease. These medications can be further broken down by Synthetic (conventional) DMARDs and Biologic DMARDs/DMDs. [3]
- **Other:** This option is utilized for immune-based medications that are not included in one of the above categories but have known substantial side effects or actions of immunosuppression.

**Criteria:** The patient receives administration of oral or parenteral corticosteroids, anti-rejection/transplant immunosuppressants, DMARDs/DMDs or other immunosuppressant medications AND meets ONE of the following criterion points (A or B):

A. The medication is being taken for at least 10 days cumulatively within the 30 days prior to the primary procedure.

OR

B. Receives a longer-acting immunosuppressive agent that is part of a regimen (e.g., weekly, monthly) that **is active*** at the time of the primary procedure or the medication **is active*** for at least 10 total days within the 30 days prior to the primary procedure.

***Note:** To calculate "active" time, use the patient's specific prescribing interval for the medication. For example, an injection prescribed every six weeks would be considered active for six weeks from administration.

**Options:**

- Yes
- No

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

- A patient receives a dose of Infliximab 7 weeks prior to the primary procedure and has an active order to receive one dose of Infliximab every 8 weeks. This would meet for Criteria B.
- Prednisone administration of 10 cumulative days or greater in the 30 days prior to the primary procedure. The days do not need to be consecutive. This would meet for Criteria A.
- A patient with no transplant history receives tacrolimus (Prograf) daily for interstitial lung disease for the past two weeks. Non-transplant patients taking these types of medications are assigned.

- A patient has an order to begin regular weekly injections of Etanercept (Enbrel). The patient's first dose is four days prior to the primary procedure. This meets for Criteria B as an interval injection that is part of a regimen that is active at the time of the primary procedure.
- A patient is prescribed weekly oral methotrexate as an ongoing regimen for the last year. The patient had no interruptions in regimen and the last dose was five days prior to the primary procedure. This meets Criteria B as a longer-acting immunosuppressive agent that is part of a regimen that is considered active at the time of the primary procedure.

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

- Topical medications applied to the skin, eyes, or mucous membranes (e.g., hydrocortisone ointment or cyclosporine ophthalmic emulsion).
- Medications administered rectally or by inhalation (e.g., budesonide enema or fluticasone inhaler).
- Localized corticosteroids injections.
- Mineralocorticoids, such as aldosterone.
- Gonadocorticoids, such as testosterone, estrogens.
- Antiretroviral medications targeted for HIV.
- Stress dose steroid injections given by anesthesia prior to the primary procedure.

**Notes:**

**Corticosteroids:**

| Generic | Brand |
|---|---|
| Betamethasone | Celestone, Celestone Soluspan, Betaject |
| Budesonide | Entocort EC, Uceris |
| Cortisone acetate | Adreson, Cortison, Cortisone, Cortone, Cortistab, Cortisyl |
| Dexamethasone | Baycadron, Decadron, Dekpak, Zema-Pak |
| Deflazacort | Emflaza |
| Fludrocortisone acetate | Florinef Acetate |
| Methylprednisolone | Medrol, Duralone, Medralone, M-Prednisol, Solu-Medrol |
| Hydrocortisone | Cortef |
| Prednisone | Deltasone, Meticorten, Orasone |
| Prednisolone | Pediapred, FloPred, Orapred, Orapred ODT, Millipred, Millipred DP, Prelone Syrup, Veripred 20 |
| Triamcinolone | Zilretta, Kenalog-40, Azmacort, Kenalog-10 |

**Anti-rejection/transplant immunosuppressants:**

| Generic | Brand |
|---|---|
| Anti-thymocyte globulin | Thymoglobulin |
| Antithymocyte globulin equine, lymphocyte immune globulin | ATGAM, ATG equine |
| Antithymocyte globulin rabbit | ATG rabbit |

| | |
|---|---|
| Azathioprine | Imuran, Azasan |
| Basiliximab | Simulect |
| Belatacept | Nulojix |
| Cyclosporine | Neoral, Sandimmune, Gengraf |
| Daclizumab | Zenapax |
| Everolimus | Afinitor, Zortress |
| Muromonab-CD3 | Orthoclone OKT3 |
| Mycophenolic acid | Myfortic |
| Mycophenolate mofetil | CellCept |
| Sirolimus | Rapamune |
| Tacrolimus | Prograf, Astagraf XL, FK506, Envarsus XR, ~~Protopic,~~ Hecoria |

**Synthetic DMARDs/DMDs:**

| **Generic** | **Brand** |
|---|---|
| Apremilast | Otezla |
| Baricitinib | Olumiant |
| Bortezomib | Velcade |
| Chloroquine | Aralen |
| Dimethyl fumarate | Tecfidera |
| Fingolimod | Gilenya |
| Glatiramer acetate | Copaxone, Glatopa |
| Gold salts (sodium aurothiomalate, auranofin) | Ridaura, Myocrisin |
| Hydroxychloroquine (Hydroxychloroquine Sulfate) | Plaquenil |
| Leflunomide | Arava |
| Lenalidomide | Revlimid |
| Methotrexate | Rheumatrex, Otrexup (PF), Xatmep, Trexall, Rasuvo, RediTrex |
| Mitoxantrone | Novantrone |
| Penicillamine | Depen Titratabs, Cuprimine |
| Sulfasalazine | Azulfidine |
| Teriflunomide | Aubagio |
| Thalidomide | Thalomid |
| Tofacitinib | Xeljanz |
| Upadacitinib | Rinvoq |

**Biologic DMARDs/DMDs:**

| **Generic** | **Brand** |
|---|---|
| Abatacept | Orencia |
| Adalimumab | Humira |

| | |
|---|---|
| Alemtuzumab | Lemtrada, Campath, MabCampath |
| Anakinra | Kineret |
| Belimumab | Benlysta |
| Canakinumab | Ilaris |
| Certolizumab pegol | Cimzia |
| Eculizumab | Soliris |
| Etanercept | Enbrel |
| Etanercept-szzs | Erelzi |
| Etanercept-ykro | Eticovo |
| .Golimumab | Simponi |
| Guselkumab | Tremfya |
| Infliximab | Remicade |
| Infliximab-abda | Renflexis |
| Infliximab-axxq | Avsola |
| infliximab-dyyb | Inflectra |
| infliximab-qbtx | Ixifi |
| Interferon beta-1a | Avonex, REBIF |
| Interferon beta-1ab | EXTAVIA |
| Interferon beta-1b | Betaseron |
| Ixekizumab | Taltz |
| Mepolizumab | Nucala |
| Natalizumab | Tysabri |
| Ocrelizumab | Ocrevus |
| Ofatumumab | Arzerra, Kesimpta |
| peginterferon beta-1a | Plegridy |
| Risankizumab-rzaa | Skyrizi |
| Rituximab | Rituxan |
| Sarilumab | Kevzara |
| Secukinumab | Cosentyx |
| Tocilizumab | Actemra |
| Ustekinumab | Stelara |
| Vedolizumab | Entyvio |

**Other:**

| **Generic** | **Brand** |
|---|---|
| Carboplatin | Paraplatin |
| Cisplatin | Platinol®, Platinol®-AQ |
| Chlorambucil | Leukeran |
| Cyclophosphamide | Cytoxan |
| Docetaxel | Taxotere, Docefrez |
| fluorouracil (5FU) | |

| | |
|---|---|
| Gemcitabine | Gemzar |
| Ibrutinib | Imbruvica |
| Imatinib Mesylate | Gleevec |
| Irinotecan Hydrochloride | Camptosar |
| Mercaptopurine/ 6-mercaptopurine | (6-MP), Purinethol, Purixan |
| Nitrogen mustard | Mustargen |
| Oxaliplatin | Eloxatin |
| Palbociclib | Ibrance |
| Ruxolitinib | Jakafi |
| Tasigna® | nilotinib |
| Taxol | Paclitaxel |
| Verzenio | abemaciclib |
| FOLFIRI (combination drug) | |
| FOLFOX (combination drug) | |

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4662771/
[2] https://transplantliving.org/after-the-transplant/preventing-rejection/types-of-immunosuppressants/
[3] https://www.ncbi.nlm.nih.gov/books/NBK507863/

**Variable Name: Preop COVID-19 Diagnosis**

**Intent of Variable:** Identify patients with an active diagnosis of lab-confirmed or suspected COVID-19 preoperatively.

**Definition:** COVID-19 is a novel coronavirus with clinical features ranging from mild disease with non-specific signs and symptoms of acute respiratory illness, to severe pneumonia with respiratory failure and septic shock.[1]

**Criteria:**

- Select "No" for patients without an active diagnosis of COVID-19 within 14 days prior to the primary procedure. This includes all situations where COVID-19 was never mentioned nor considered.
- Select "Yes, lab-confirmed diagnosis" for those patients with an active diagnosis of COVID-19 within 14 days prior to the primary procedure which is confirmed by laboratory testing. Lab testing could be performed before or after the primary procedure to confirm the preoperative diagnosis.
- Select "Yes, suspected diagnosis" for those patients with an active clinical or epidemiological diagnosis of COVID-19 within 14 days prior to the primary procedure when laboratory confirmation was not performed, was inconclusive, or was negative but a suspected diagnosis was maintained (and indicated in the medical record).

**Options:**

- No
- Yes, lab-confirmed diagnosis (or ICD-10 code U07.1)
- Yes, suspected diagnosis (or ICD-10 code U07.2)

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

- If preoperative testing is negative or inconclusive, but there is still suspicion for active COVID-19 infection within 14 days prior to the primary procedure, assign "Yes, suspected diagnosis." The suspected diagnosis must be mentioned after the negative or inconclusive result.

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

- If a patient who is initially under investigation for COVID-19 is then deemed to not meet the threshold for probable infection or for testing preoperatively by infectious disease, infection control, or hospital protocol, assign "No" for this variable.
- A positive serological (antibody) test, alone, without a suspected current or active diagnosis of COVID-19 would be assigned "No." It can reflect a prior infection.

**Notes:**

- ICD-10 Diagnosis Codes U07.1 and U07.2 can be utilized as diagnoses for this variable.[2]
- For the purposes of this variable, lab-confirmed diagnoses are based on molecular (real-time reverse transcription polymerase chain reaction (rRT-PCR)) testing, rather than serological (antibody) testing.

[1] "Healthcare Professionals: Frequently Asked Questions and Answers/', Centers for Disease Control and Prevention, 22 Mar. 2020, https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html

[2] For additional information on these ICD-10 Diagnosis Codes please refer to the following link on the World Health Organization's website: https://www.who.int/classifications/icd/covid19/en/

**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 Primary 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 $FEV_1$ of <75% of predicted on a **prior** pulmonary function test (PFT)*

**Options:**

- Yes
- No

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

- Patients with a diagnosis of COPD, who are prescribed chronic bronchodilator therapy with oral or inhaled agents or other medication specifically targeted to this disease, but are non-compliant with taking the medication

**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.

‡ *National Heart Lung and Blood Institute*. (2010). Retrieved May 29, 2012 from http://www.nhlbi.nih.gov/health/health-topics/topics/copd/

**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

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

-

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

-

**Notes:**

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**Variable Name**: **Sleep Apnea**

**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 diagnosis of sleep apnea as documented by a sleep study and 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).
- Patients who use an oral appliance.

**Notes:**

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**Variable Name: GERD**

**Intent of Variable:** To capture those patients who have a preoperative condition of Gastroesophageal Reflux Disease (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 Primary 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

**Notes:**

-

**Variable Name: Previous Foregut Surgery**

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

**Definition:** A history of any type of surgery performed on the upper gastrointestinal tract prior to the Primary Procedure, which may indicate increased surgical complexity.

**Criteria:** Indicate if the patient had surgery on the esophagus, stomach, duodenum, spleen, or pancreas.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- Patients with a history of paraesophageal or hiatal hernia repair
- Patients with a history of an adjustable gastric band

**Scenarios to Clarify (Do Not Assign Variable):**
- Patients who had an intraluminal procedure such as an intragastric balloon, TransPyloric® shuttle, or EndoBarrier®
- 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, or colon resection
- EGD with dilation and/or biopsy
- Patients with a history of surgery of the large intestines or colon
- Ventral hernia repair, incisional hernia repair, umbilical hernia repair, inguinal hernia repair, internal hernia repair

**Notes:**
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**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

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

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

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**Notes:**

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**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 Primary 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 Primary Procedure, the patient has undergone a PCI, PTCA, balloon dilatation, stent placement, or any attempted PCI or PTCA.

**Options:**

- Yes
- No

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

-

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

- Patient with a history of valvuloplasty procedure.
- Patient with a history of cardiac ablation.
- Patient with a history of a pacemaker/AICD.
- Patient with a history of cardiac catheterization or cardiac angiography without an intervention.

**Notes:**

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**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)
- Transcatheter valve replacement or repair (TAVR. TAVI, TMVR, TMVI)

**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.

**Notes:**

-

**Variable Name: Hypertension**

**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 Primary 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, calcium channel blockers.

§ MedlinePlus. (2012). Retrieved May 29, 2012 from http://www.nlm.nih.gov/medlineplus/ency/article/000468.htm

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

**Intent of Variable:** To capture the number of anti-hypertensive medications prescribed to a patient prior to surgery for bariatric or metabolic disorders.

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

**Criteria:** The patient has HTN and is being treated with medication; list the number of antihypertensive medications that they are taking, within 30 days prior to the Primary Procedure or at the time the patient is being considered as a candidate for surgery.

**Options:**

- 0
- 1
- 2
- 3 or more

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

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

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

-

**Notes:**

- If a patient is taking a pill that contains a combination of medications, 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.”

**Variable Name: Hyperlipidemia**

**Intent of Variable:** To capture patients who have a preoperative risk factor of 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 gemfiberozil for the treatment of hyperlipidemia.
- Patients who are prescribed antihyperlipidemia medications and are noncompliant.
- Diagnoses of high triglycerides, hypertriglyceridemia, high cholesterol, hypercholesterolemia, dyslipidemia, elevated LDL, hyperglyceridemia, hyperlipoproteinemia and are treated.

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

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

**Notes:**

-

**Variable Name: Preop Venous Thrombosis Requiring Therapy**

**Intent of Variable:** To capture those patients who have a history of a blood clot (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 (thrombus) in the venous system, which may be coupled with inflammation **AND** has 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

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

-

**Notes:**

-

**Variable Name: Therapeutic Anticoagulation**

**Intent of Variable:** To capture those patients who require therapeutic anticoagulants, antiplatelets, or thrombin inhibitors pre-operatively.

**Definition:** Patients that require therapeutic anticoagulants, antiplatelets, or thrombin inhibitors for 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 therapeutic anticoagulants, antiplatelets, or thrombin inhibitors at any time within the 30 days prior to the Primary 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 is initiated on the day of surgery.
- Any anticoagulation medication prescribed prophylactically for surgery.

**Notes:**
- Below is a non-exhaustive list of medications that can affect a patient's risk for bleeding.

**Anticoagulants**

| Brand Name | Generic |
|---|---|
| Arixtra | Fondaparinux |
| Coumadin | Warfarin |
| Fragmin | Dalteparin |
| Heparin – standard or unfractionated | |
| Heparin- Low molecular weight | |
| Lovenox | Enoxaparin |
| | Pentasaccaride |
| | APC |
| | Ximelagatran |
| Trental | Pentoxifylline |
| Xarelto | Rivaroxaban |
| Eliquis | Apixaban |

**Antiplatelet Agents**

| Brand Name | Generic |
|---|---|
| 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**

| Brand Name | Generic |
|---|---|
| Angiomax | Bevalirudin |
| Argatroban, Novastan | Argatroban |
| Refludan | Lepirudin, Hirudin |
| Xigris | Drotrecogin alpha |
| Pradaxa | Dabigatran |

**Variable Name: Venous Stasis**

**Intent of Variable:** To capture patients with poor venous circulation of the lower extremities, both superficial and deep systems, which can 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 at any time within the 30 days prior to the Primary Procedure, or at the time the patient is being considered as a candidate for surgery:

- 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 (Assign Variable):**

-

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

- Varicose veins or spider veins.
- Documentation of venous insufficiency alone.

**Notes:**

- Varicose veins may be associated with concomitant venous stasis disease.

**Variable Name: IVC Filter**

**Intent of Variable:** To capture prophylactic or therapeutic placement of an inferior vena cava (IVC) filter preoperatively in patients undergoing bariatric or metabolic surgery.

**Definition:** An IVC 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 Primary 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

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

-

**Notes:**

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

**Variable Name**: **Currently Requiring/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 Primary 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 Primary 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 Primary 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.

**Notes:**

-

**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 Primary Procedure. Utilize the creatinine value drawn closest to the documented Procedure/Surgery Start date and time (PST).

**Options:**

- Yes
- No

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

-

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

-

**Notes:**

-

**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 Primary Procedure.

**Criteria:** All of the following preoperative lab values are to be reported if they are drawn within 180 days prior to the Primary Procedure. Report the lab value drawn closest to the documented Primary 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

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

-

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

-

**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

**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 I – No Disturb
- ASA II – Mild Disturb
- ASA III – Severe Disturb
- ASA IV – Life Threat
- ASA V– Moribund
- None Assigned

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

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

**Notes:**
- MBASQIP advises each MBSCR 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.

**Variable Name**: **Intragastric Balloon 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:** The principal anesthesia technique used during the intragastric balloon case as documented by the anesthesia provider or registered 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.
- Local
- None
- Other

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

- 

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

- 

**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.”

**Variable Name: Intragastric Balloon Type**

**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 primary procedure is the placement of an intragastric balloon, please select the type of balloon used.

**Options:**

- Absorbable
- Adjustable
- Air-Filled
- Fluid-Filled

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

-

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

-

**Notes:**

- If absorbable and air or fluid-filled, please choose "Absorbable."
- If adjustable and air or fluid-filled, please choose "Adjustable"

**Variable Name: Procedural 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. Endoscopic indicates that the procedure was primarily performed with use of an endoscope and may have been completed through a natural orifice. Laparoscopic indicates that trocars were placed and a laparoscope was utilized for the procedure. An open procedure indicates that the surgery was completed via laparotomy. Robotic Assisted indicates the use of robotic systems to aid in a portion of the Primary 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. Indicate if a robotic assist was utilized for any portion of the Primary Procedure.

**Options:**

- Endoscopic
- Laparoscopic
- Open

**And indicate if robotic assist was utilized during the primary procedure:**

- Robotic Assist
    - Yes
    - No

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

-

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

- For Robotic Assisted, **do not** include a mechanical or electrical device to hold the camera only.
- Surgical approach for any "Other" or "Concurrent" procedures not integral to the Primary Procedure.

**Notes:**

- For laparoscopic cases with a robot used, please choose Laparoscopic for Procedural Approach and Yes for Robotic Assist.

**Variable Name: 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 Primary Procedure was converted to another approach. Endoscopic indicates that the procedure was primarily performed with use of an endoscope and may have been completed through a natural orifice. Laparoscopic indicates that trocars were placed and a laparoscope was utilized for the procedure. An open procedure indicates that the surgery was completed via laparotomy. Robotic Assisted indicates the use of robotic systems to aid in a portion of the Primary Procedure.

**Criteria:** A procedure converted to another approach. Indicate the final operative approach utilized by the surgeon for the Primary Procedure as documented in the operative note, and if a robotic assist was utilized for any portion of the Primary Procedure.

**Options:**

- Yes
- No

If Yes, choose final operative approach:

- Endoscopic
- Laparoscopic
- Open

If Yes, choose if there was a robotic assist used for the final operative approach:

  - Yes
  - No

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

-

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

- For Robotic Assisted, **do not** include a mechanical or electrical device to hold the camera only.
- Surgical approach for any "Other" or "Concurrent" procedures not integral to the Primary Procedure.

**Notes:**

- For laparoscopic cases with a robot used, please choose Laparoscopic for Procedural Approach and Yes for Robotic Assist.

**Variable Name: Drain Placed**

**Intent of Variable:** To capture the placement of an intra-abdominal drain at the time of the Primary Procedure.

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

**Criteria:** Indicate if an intra-abdominal drain was placed during the Primary Procedure.

**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.

**Notes:**

-

**Variable Name: Anastomosis/Staple Line Leak Test**

**Intent of Variable:** To capture if the anastomosis or staple line was checked with a leak test.

**Definition**: Various techniques are utilized to determine if there is a leak at an anastomotic or staple line during the metabolic and bariatric procedure.

**Criteria**: A leak test performed on the staple line or anastomosis is described in the operative report or brief operative note.

**Options:**

- Yes
- No

**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.
- Insufflation of air through an endoscope or nasogastric tube with the anastomosis under saline to look for bubbles (as documented in the operative note).
- The installation of methylene blue (or other liquid) under pressure, while looking for a fluid leak as the bowel is clamped (as documented in the operative note).
- A leak test is completed via a ViSiGi 3D™.

**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) was performed.

**Notes:**

-

**Variable Name**: **Procedure/Surgery Start**

**Intent of Variable:** To capture the date and time the Primary 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 date and 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)

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

-

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

-

**Notes:**

- This time would include Other and Concurrent Procedures
- This time would not include anesthesia activities prior to the surgical start time

**Variable Name**: **Procedure/Surgery Finish**

**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)

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

-

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

-

**Notes:**

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

**Variable Name: VTE Prophylaxis**

**Intent of Variable:** To capture the method(s) prescribed for the patient to prevent venous thromboembolism (VTE) of the lower extremities/legs of the patient.

**Definition:** Mechanical methods commonly employed following the Primary Procedure, including the wearing of "ted hose" to the lower extremities, and/or the use of compression devices to one or both of the lower extremities commonly referred to as SCDs and PCDs. Early ambulation within 24 hours following the Primary Procedure would also be included. Pharmacological methods commonly employed include intravenous, subcutaneous and oral administration of anticoagulants.

**Criteria**: Please indicate the method(s) prescribed for the patient to prevent venous thromboembolism (VTE) of the lower extremities/legs of the patient.

**Options:**

- Mechanical only (as defined above)
- Pharmacologic only (as defined above)
- Mechanical and pharmacologic
- None

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

-

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

-

**Notes:**

- Early ambulation within 24 hours must be documented, not just ordered.
- A standing order/pathway/order set including the measures above would meet criteria for postoperative VTE prophylaxis

**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 Primary Procedure **AND** the infection involves only skin or subcutaneous tissue of the incision /sites integral to the Primary Procedure **AND** at least **ONE** of the following:

- Purulent drainage, with or without laboratory confirmation, from the superficial incision.
- Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
- 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.*
- 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 Primary Procedure.
- If the patient meets criteria A or D, a negative culture of the surgical incision will not affect the assignment of this occurrence.
- If a diagnosis of cellulitis is treated with oral/IV/IM antimicrobial therapy, this would be considered a diagnosis of an infection, meeting criterion D.
- Some examples of purulence meeting criterion A include green drainage (unless attributed to a bile leak), phlegmon, or abscess identified in the superficial layers.
- If antimicrobials are ordered with an indication for possible/probable infection, this would meet Criterion D, as a diagnosis of infection.

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

- Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration) which does not require oral/IV/IM antimicrobial therapy.
- Infected burn wound
- A diagnosis of cellulitis alone without treatment does not meet criterion D to assign a Superficial Incisional SSI. This implies a non-infectious inflammatory response at the surgical site.

**Notes:**

- An SSI can only be assigned at or below the level of closure.
- Only one SSI occurrence is assigned during the 30-day postoperative timeframe.
    - If multiple incision sites or layers of the same surgical incision (of the primary procedure or an integral procedure) meet criteria, assign only one SSI occurrence during the 30-day postoperative timeframe, and assign at the deepest level (Superficial Incisional, Deep Incisional or Organ/Space).
- When a diagnosis of an infection is made and/or antimicrobial treatment is initiated based on any diagnostic test, this test would be utilized to assign this occurrence. Examples include but are not limited to point of care testing (e.g. Gram stain, rapid strep, whiff test) or a culture collected from a drain, but only in conjunction with a diagnosis of infection being made and recorded or treatment being initiated.
- If a diagnosis of an inflammatory condition (e.g. "-itis", cellulitis, vaginitis, etc.), is treated with oral/IV/IM antimicrobials, this treatment is considered to reflect a diagnosis of an infection, meeting criterion D.
- If a patient is already on an antimicrobial and an advanced provider documents that the current antimicrobial is sufficient to treat the new/additional infectious process, this would be considered antimicrobial treatment and would be utilized to assign an occurrence. If adjustments are made to an existing treatment regimen based on the new/additional infectious process, this would be considered treatment and utilized to assign the occurrence.
- If there is an SSI diagnosis by an advanced provider (other than the surgeon of record*) or a report of purulence by another advanced provider (other than the surgeon of record*) or patient, such information can be over-ruled by the surgeon of record* when all of the following are met:
    - The surgeon of record* assessed the patient's infection site in-person or via telehealth with video/photo capability within 2 calendar days of the diagnosis or report of purulence.
    - The surgeon of record* definitively documents, at the time of care, that there was no sign of infection. Retrospective documentation beyond the time window above would not be utilized.
    - All treatment for this diagnosis (including any antibiotics) was discontinued immediately by the provider when the "corrective" encounter occurred, if previously initiated.

  *For the purposes of this Note, "Surgeon of record" refers to the surgeon who performed the primary procedure, and includes any advanced provider in the same practice or on the same surgical care team who may be covering for or working with the surgeon.
  If all three of these points are met, the MBSCR would not assign the occurrence.
- Only SSIs at the incision site of the Primary Procedure or a site integral to the Primary Procedure should be assessed. Non-integral 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 Primary Procedure, include this site in your SSI assessment. Please note: a single Primary 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
- 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.

**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 Primary 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:**
- Information identified only on a pathology report cannot be utilized to apply PATOS to a postoperative SSI occurrence.
- 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.

**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 /sites integral to the Primary Procedure within 30 days after the Primary 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):**
- Other evidence of infection such as green drainage (unless attributed to a bile leak), phlegmon, or abscess identified in the deep layers would meet Criterion A.
- If antimicrobials are ordered with an indication for possible/probable infection, this would meet Criterion D, as a diagnosis of infection.

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

**Notes:**
- An SSI can only be assigned at or below the level of closure
- Only one SSI occurrence is assigned during the 30-day postoperative timeframe.
    - If multiple incision sites or layers of the same surgical incision (of the primary procedure or an integral procedure) meet criteria, assign only one SSI occurrence during the 30-day postoperative timeframe, and assign at the deepest level (Superficial Incisional, Deep Incisional or Organ/Space).
- When a diagnosis of an infection is made and/or antimicrobial treatment is initiated based on any diagnostic test, this test would be utilized to assign this occurrence. Examples include but are not limited to point of care testing (e.g. Gram stain, rapid strep, whiff test) or a culture collected from a drain, but only in conjunction with a diagnosis of infection being made and recorded or treatment being initiated.
- If a diagnosis of an inflammatory condition (e.g. “-itis”, cellulitis, etc.), is treated with oral/IV/IM antimicrobials, this treatment is considered to reflect a diagnosis of an infection, meeting criterion D.

- If a patient is already on an antimicrobial and an advanced provider documents that the current antimicrobial is sufficient to treat the new/additional infectious process, this would be considered antimicrobial treatment and would be utilized to assign an occurrence. If adjustments are made to an existing treatment regimen based on the new/additional infectious process, this would be considered treatment and utilized to assign the occurrence.
- If there is an SSI diagnosis by an advanced provider (other than the surgeon of record*) or a report of purulence by another advanced provider (other than the surgeon of record*) or patient, such information can be over-ruled by the surgeon of record* when all of the following are met:
    - The surgeon of record* assessed the patient's infection site in-person or via telehealth with video/photo capability within 2 calendar days of the diagnosis or report of purulence.
    - The surgeon of record* definitively documents, at the time of care, that there was no sign of infection. Retrospective documentation beyond the time window above would not be utilized.
    - All treatment for this diagnosis (including any antibiotics) was discontinued immediately by the provider when the "corrective" encounter occurred, if previously initiated.

  *For the purposes of this Note, "Surgeon of record" refers to the surgeon who performed the primary procedure, and includes any advanced provider in the same practice or on the same surgical care team who may be covering for or working with the surgeon.
  If all three of these points are met, the MBSCR would not assign the occurrence.
- Only an SSI at the incision site of the Primary Procedure or a site integral to the Primary 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 Primary 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.

**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 Primary 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 (Assign Variable):**
-

**Scenarios to clarify (Do Not Assign Variable):**
- Deep incisional SSI has not been assigned as a postop occurrence.
- Iatrogenic injuries that occur during the Primary Procedure with no other evidence of infection.

**Notes:**
- Information identified only on a pathology report cannot be utilized to apply PATOS to a postoperative SSI occurrence.
- 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.

**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 the Primary Procedure.

**Criteria:** An infection that occurs within 30 days after the Primary Procedure **AND** involves any of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during the Primary Procedure, including sites integral to the Primary Procedure, **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 Primary Procedure, which are continually in place, with continual evidence of drainage/infection since the time of the Primary 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/staple line leaks involving the GI tract.
- Injury to intestine (e.g. enterotomy, iatrogenic injury, perforation).
- Other evidence of infection such as green drainage (unless attributed to a bile leak), phlegmon, or abscess identified in the organ/space would meet Criterion A.
- If antimicrobials are ordered with an indication for possible/probable infection, this would meet Criterion D, as a diagnosis of infection.

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

- Fistulas alone, unless they independently meet the other criteria listed above
- A bile leak alone, unless the bile is leaking from the G.I tract (small intestine)

**Notes:**

- An SSI can only be assigned at or below the level of closure.

- Only one SSI occurrence is assigned during the 30-day postoperative timeframe.
    - If multiple incision sites or layers of the same surgical incision (of the primary procedure or an integral procedure) meet criteria, assign only one SSI occurrence during the 30-day postoperative timeframe, and assign at the deepest level (Superficial Incisional, Deep Incisional or Organ/Space).
- When a diagnosis of an infection is made and/or antimicrobial treatment is initiated based on any diagnostic test, this test would be utilized to assign this occurrence. Examples include but are not limited to point of care testing (e.g. Gram stain, rapid strep, whiff test) or a culture collected from a drain, but only in conjunction with a diagnosis of infection being made and recorded or treatment being initiated.
- If a diagnosis of an inflammatory condition (e.g. "-itis", peritonitis, etc.), is treated with oral/IV/IM antimicrobials, this is considered a diagnosis of an infection, meeting criterion D. See above
    - Exception: A gastrointestinal intraluminal infection (gastritis, enteritis, or colitis) would not meet criteria to assign an Organ/Space SSI regardless of treatment. Please note, *Clostridium difficile* colitis infections are captured under the "Clostridium Difficile (C.diff) Colitis" variable.
- If a patient is already on an antimicrobial and an advanced provider documents that the current antimicrobial is sufficient to treat the new/additional infectious process, this would be considered antimicrobial treatment and would be utilized to assign an occurrence. If adjustments are made to an existing treatment regimen based on the new/additional infectious process, this would be considered treatment and utilized to assign the occurrence.
- If there is an SSI diagnosis by an advanced provider (other than the surgeon of record*) or a report of purulence by another advanced provider (other than the surgeon of record*) or patient, such information can be over-ruled by the surgeon of record* when all of the following are met:
    - The surgeon of record* assessed the patient's infection site in-person or via telehealth with video/photo capability within 2 calendar days of the diagnosis or report of purulence.
    - The surgeon of record* definitively documents, at the time of care, that there was no sign of infection. Retrospective documentation beyond the time window above would not be utilized.
    - All treatment for this diagnosis (including any antibiotics) was discontinued immediately by the provider when the "corrective" encounter occurred, if previously initiated.

  *For the purposes of this Note, "Surgeon of record" refers to the surgeon who performed the primary procedure, and includes any advanced provider in the same practice or on the same surgical care team who may be covering for or working with the surgeon.

  If all three of these points are met, the MBSCR would not assign the occurrence.
- Only SSIs at the incision site of the Primary 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 Primary 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.
- If an Organ/Space SSI occurrence is assigned, the "Anastomotic or Staple Line Leak" variable will be activated and must be answered.

**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 Primary 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 (Assign Variable):**
-

**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 Primary Procedure with no other evidence of infection.

**Notes:**
- Information identified only on a pathology report cannot be utilized to apply PATOS to a postoperative SSI occurrence.
- 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 intra-operative event (e.g. enterotomy, iatrogenic injury) PATOS would not be assigned.

**Variable Name**: **Anastomotic/Staple Line Leak**

**Intent of Variable:** To determine if an assigned Organ/Space SSI is due to a leak of endoluminal contents through an anastomosis or staple line from the metabolic and bariatric procedure.

**Definition:** A leak of endoluminal contents through an anastomosis or staple line from the metabolic and bariatric procedure occurred. This could include air, fluid, GI contents, contrast material, or the presence of an infection/abscess thought to be related to an anastomosis.

**Criteria:** An Organ/Space SSI must be assigned AND was due to a leak of endoluminal contents through an anastomosis or staple line from the metabolic and bariatric procedure AND one of the following:

- Reoperation due to a leak
- Intervention due to a leak

**Options:**

- Yes
- No

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

- Drainage of leak (e.g. Interventional Radiology drainage)
- Placement of a drain due to a leak
- Placement of a stent due to a leak
- Leak noted on reoperation

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

- A leak is definitively ruled out during a reoperation.
- The patient is treated with antibiotics only.
- Leak or possible leak noted on radiologic study but not confirmed via reoperation or intervention.

**Notes:**

- If the patient developed a leak of endoluminal contents through an anastomosis or staple line assign an Organ/Space SSI to the case. The Anastomotic or Staple Line Leak field will then be activated when the occurrence of Organ/Space SSI is assigned, and you would select “Yes” for this variable.
- If an anastomotic or staple line leak of the gastrointestinal tract is associated with an additional procedure, do not assign if metabolic and bariatric anatomy is not involved.
    - Example: A Roux-en-Y gastric bypass and a colectomy are completed under a single anesthesia event. The anastomosis from colectomy site is noted to have a leak. This would not be assigned for the Anastomotic or Staple Line Leak, as this does not involve the metabolic and bariatric anatomy.
- Only one SSI occurrence is assigned during the 30-day postoperative timeframe.

**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 Primary Procedure **AND** a 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.
- Anastomotic leaks.
- A surgical wound that is intentionally reopened by an advanced provider.

**Notes:**

- If the wound is left open at the time of the primary procedure and is subsequently closed within the 30-day postoperative period, begin assessing that specific surgical site for a wound disruption after it is closed.
- For abdominal procedures where the abdominal cavity is not entered (e.g., port change), fascial disruption is not required in order to assign this occurrence, as the fascial layers are not incised during the primary procedure. The occurrence would be assigned if there was a spontaneous disruption or dehiscence of all layers of the surgical wound, or a spontaneous disruption or dehiscence of part of the surgical wound that required intervention for closure.
- Assign variable once during the 30-day postoperative timeframe.

**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 Primary 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/mm$^3$) **or** leukocytosis (≥12,000 WBC/mm$^3$)
- 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 or corresponding semi-quantitative culture from minimally contaminated lower respiratory tract (LRT) specimen (specifically, BAL, protected specimen brushing, endotracheal aspirate) or lung tissue specimen. Organisms identified could include bacteria, viruses, or fungi.
- Virus, *Bordetella, Legionella, Chlamydia* or *Mycoplasma* identified from respiratory secretions or tissue by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment.

**OR**

SCENARIO #2

At least **ONE** of the following:

- Fever (>38°C or >100.4°F) with no other recognized cause
- Leukopenia (<4000 WBC/mm$^3$) or leukocytosis (≥12,000 WBC/mm$^3$)
- 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. $O_2$ desaturations (e.g., $PaO_2/FiO_2 \leq 240$), 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):**

- Aspiration pneumonitis or aspiration pneumonia are types of pneumonia that would be captured for this variable, if all criteria are met.
- 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:
    - A physician or advanced provider documents that the patient does not have pneumonia or indicates that the patient's symptomatology/imaging results are due to a noninfectious condition (e.g., pulmonary edema, pleural effusion, pulmonary hemorrhage, atelectasis).

  AND

    - The patient is not treated for an infectious pulmonary process (e.g. antimicrobials are not prescribed) OR if antimicrobial treatment was started empirically for a potential pulmonary process (pending culture or non-culture based microbiologic test results), and the antimicrobial treatment is discontinued by the provider within 24 hours of a negative result

  If both of these points (1 AND 2) are met, the MBSCR would not assign the occurrence.

**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 which may be difficult to differentiate from pneumonia on a radiologic exam (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 Primary 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 same 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 are met.

**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 intraoperatively for the Primary 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.

**Variable Name: 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 Primary 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 Primary 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 Primary 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 intragastric balloon placement 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 revision.
- Can be assigned multiple times within the 30-day postop period each time criteria are met.

**Variable Name**: **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 Primary 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 (Assign Variable):**

-

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

- Pulmonary emboli diagnosed prior to the Primary Procedure
- Cement PE (if this diagnosis is definitive)
- Fat PE (if this diagnosis is definitive)

**Notes:**

- Assign variable once during the 30-day postoperative timeframe.

**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 Primary 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 Primary 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:**

- Assign variable once during the 30-day postoperative timeframe.

**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 Primary 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 Primary Procedure **or** requires an unplanned intubation intraoperatively prior to the initiation of anesthesia for the Primary Procedure.

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

A. On 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 Primary Procedure.

**Options:**

- Yes
- No
- Comments (optional)

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

-

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

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

**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 Primary 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, continuous renal replacement therapies (CRRT), 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 take 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.

**Variable Name**: **Urinary Tract Infection**

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

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

**Criteria:** Must be noted within 30 days after the Primary 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
- suprapubic 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 advanced practitioner institutes appropriate antimicrobial therapy.

**Options:**
- Select “Urinary tract infection” from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)

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

- 

**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.
- A culture obtained from an ileal conduit or neobladder would not be utilized to assign a UTI.

**Notes:**

- Lower abdominal pain or bladder or pelvic discomfort (with no other recognized cause) are examples of symptoms that can be used as suprapubic tenderness. Generalized “abdominal pain” in the medical record is not to be interpreted as suprapubic tenderness as there are many causes of abdominal pain and this symptom is too general.
- Left or right lower back or flank pain (with no other recognized cause) are examples of symptoms that can be used as costovertebral angle pain or tenderness. Generalized "low back pain" is not to be interpreted as costovertebral angle pain or tenderness.
- Documentation of new or worsening nocturia (with no other recognized cause) can be used as frequency.
- 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 are met

**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 Primary 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 primary can be utilized for evidence.

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

-

**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.

**Variable Name**: **Stroke/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 Primary 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 "Stroke/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:**

- Assign variable once during the 30-day postoperative timeframe.

**Variable Name**: **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:** The following criteria, A, B or C below, must be noted intraoperatively or within 30 days after the Primary Procedure:

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

**or**

B. Patients in V-Fib or pulseless VT 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).
- Patient 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 are met

**Variable Name**: **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 (including high sensitivity troponin assays) greater than three times the regular upper level of the reference range in the setting of suspected myocardial ischemia

**or**

C. A Physician or advanced 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 above the regular upper level of the reference range (including high sensitivity troponin assays).
- 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:**

- For assistance in determining the normal reference range for troponin assays performed at your hospital, please contact your hospital lab.
- The Fourth Universal Definition of Myocardial Infarction (2018) consensus document notes that with the implementation new high-sensitivity troponin (hs-cTn) assays, the frequency of MI diagnosis will increase when compared to use of traditional troponin assays. The American College of Surgeons is taking current evidence into account and is currently working on a redesign of this variable.[3]
- The article on which the MBSAQIP MI criteria are based {Journal of the American College of Cardiology. 2012; 60(16): 1583-1598} and can be referenced at the following website: http://www.onlinejacc.org/content/60/16/1581

[3] Journal of the American College of Cardiology Volume 72, Issue 18, October 2018 DOI: 10.1016/j.jacc.2018.08.1038

- 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.

- Assign variable once during the 30-day postoperative timeframe.

**Variable Name: Blood Transfusion**

**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 Primary Procedure and up to 72 hours from the surgical start time, 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 Primary Procedure surgical start time up to and including 72 hours from the surgical start time, postoperatively.

**Options:**

- Select "Blood transfusion" from the dropdown menu.
- Enter the number of Blood Units Transfused
- 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).
- If packed red blood cells, also known as PRBCs or simply "packed cells," are administered to the patient, each bag is considered one unit, regardless of the total volume of fluid transfused.

**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 such as Constavac or Pleurovac, every 500 mLs of fluid will equal 1 unit of packed cells.
    - If less than 250 mL of cell-saver is transfused, round down, this would not constitute a unit and would not be reported.
    - If there are 250mL, or more of cell-saver, round up to 1 unit. The blood may be given for **any** reason. Use the table below to assist in determining number of units given:

| | |
|---|---|
| 1500-1749mL | 3 units |
| 1250-1499mL | 3 units |
| 1000-1249mL | 2 units |
| 750-999mL | 2 units |
| 500-749mL | 1 unit |
| 250-499mL | 1 unit |
| 0-249mL | 0 units |

*This table should only be utilized for shed blood, autologous blood, cell-saver blood, other reinfusion products.

- 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 Primary Procedure crosses over 2 days, enter the date the procedure ended.
- Assign variable once during the 30-day postoperative timeframe.

**Variable Name**: **Postop Venous 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 Primary 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:**

- Assign variable once during the 30-day postoperative timeframe.

**Variable Name: C. diff Colitis**

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

**Definition:** C. diff. colitis manifests as 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. diff. which releases toxins (A&B) that cause mucosal inflammation and damage. Active infection is differentiated from colonization by symptomatology. A colonized patient exhibits no symptoms but may have a positive C. diff stool test.

**Criteria:** No active C. diff infection at the time of the primary procedure*, and the following criteria, **A <u>and</u> B,** must be met within the 30-day postoperative timeframe:

A. **ONE** of the following symptoms indicating active infection, must be noted:
- Diarrhea or loose stool
- Suspicion or evidence of an ileus or intestinal obstruction

**<u>AND</u>**

B. **ONE** of the following criteria must be noted:
- A diagnosis of C. diff infection by an advanced provider
- The patient is prescribed treatment for C. diff, or for suspected C. diff

** Please see the Scenarios to Clarify (Do Not Assign) and Notes section*

**Options:**
- Yes
- No

**If Yes:**
- Date of occurrence (mm/dd/yyyy)
- Answer "Was the patient diagnosed with C. diff?"
  1. Yes
  2. No
- Answer "Was the patient given treatment for C. diff?"
  1. Yes
  2. No
- Answer "Tests performed that resulted positive?" "Tests performed that resulted negative?". *Select all that apply.*
  1. Enzyme immunoassay (EIA) for GDH
  2. Enzyme immunoassay (EIA) for Toxin A/B
  3. Antigen test (GDH assay)
  4. Cell culture cytotoxicity assay
  5. Polymerase chain reaction (PCR)
  6. Nucleic Acid Amplification Tests (NAAT)
  7. DNA Amplification (DNA-A)
  8. Loop-Mediated Isothermal Amplification (LAMP)
  9. Toxigenic Stool Culture
  10. Other (free text option)

11. Unknown (some unidentified test was performed)
12. None (no testing was performed)

*Evaluate only those tests performed in the 30-day postoperative timeframe. If it is not obvious that a test was performed, mark None. Unknown would be utilized when a test was documented as being performed, but it is unknown which type of test was performed.*

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

- A diagnosis or evidence on endoscopic exam of pseudomembranous colitis would meet criteria to assign the occurrence.

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

- *Do not assign the occurrence if at the time of the primary procedure or within 10 days prior to the primary procedure:
  - The patient was being treated for C. diff
  - The patient had an active diagnosis of C. diff
- Do not assign if a patient is treated for C. diff, but an initial C. diff test comes back negative and then the treatment is discontinued within 24 hours of the negative result.

**Notes:**

- *A diagnosis of “historical”, “history of”, or “past colonization of” (or other terminology reflecting a history but not active infection of) C. diff at the time of the primary procedure would not negate assignment of this occurrence if all postoperative criteria are met.
- Assign variable once during the 30-day postoperative timeframe. Treatments may include:
  - Oral and/or IV antibiotics
  - Fecal enemas
- Surgical treatment for fulminant/uncontrolled C. diff colitis

**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 (e.g., bacterial, viral, fungal).

**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 Primary Procedure**.** Report this variable if the criteria below are met.

**A. <u>Five Clinical Signs of SIRS (need two):</u>**

- Temp >38°C (100.4°F) or < 36°C (96.8°F)
- HR >90 bpm
- RR >20 breaths/min or $PaCO_2$ <32 mmHg (<4.3 kPa)
- WBC >12,000 cell/$mm^3$, <4000 cells/$mm^3$, or >10% immature (band) forms
- Anion gap acidosis: this is defined by either: (check with your Lab on calculation)
    - [Na + K] – [Cl + $HCO_3$ (or serum $CO_2$)]. If this number is greater than 16, then an anion gap acidosis is present
    - Na – [Cl + $HCO_3$ (or serum $CO_2$)]. If this number is greater than 12, then an anion gap acidosis is present

**<u>AND</u>**

**B. <u>Sepsis: Either scenario 1, 2, 3, or 4:</u>**

**Scenario 1: Following the Primary Procedure or a reoperation**

The patient must meet SIRS criteria (any two of the five) **and ONE** of the following:

- Positive blood culture
- Clinical documentation of purulence from any site for which there is correlating physician or advanced practitioner documentation that the site was thought to be the **<u>acute</u>** cause of the septic picture
- A positive test result of bacteria, fungus, or virus from any appropriately obtained specimen, representing any medical condition or any site for which there is correlating physician or advanced provider's documentation that the condition/site was thought to be the acute cause of the septic picture.
    - Test examples include cultures and non-culture based microbiologic testing methods (e.g., PCR/nucleic acid or antigen testing).

**<u>or</u>**

**Scenario 2: Immediately following and up to 8 hours after the Primary Procedure or a reoperation**

Immediately following and up to 8 hours after the Primary 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 Primary Procedure or reoperation:

- Confirmed ischemic/infarcted bowel (for instance requiring resection)
- Purulence in the operative site
- Enteric/gastric contents in the operative site
- Positive intraoperative culture

**or**

**Scenario 3: 8- 48 hours after the Primary Procedure**

The patient must meet SIRS criteria (any two of the five) between 8 and 48 hours after the Primary Procedure **AND** one of the following findings during the Primary Procedure:

- Confirmed ischemic/infarcted bowel (for instance requiring resection)
- Purulence in the operative site
- Enteric/gastric contents in the operative site
- 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:

- Confirmed ischemic/infarcted bowel (for instance requiring resection)
- Purulence in the operative site
- Enteric/gastric contents in the operative site
- 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.
- The presence of necrotizing fasciitis (or other necrotizing soft tissue infections), 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:**

- Findings of ischemic/infarcted bowel, purulence, or perforation(s) noted only on a pathology report that returns postoperatively would not meet intraoperative infectious criteria for Sepsis. The surgeon would need to report the ischemic/infarcted bowel, purulence, or perforation(s) as intraoperative findings in the operative report.
- Report only the most significant level of Sepsis or Septic Shock.
- Assign variable once during the 30-day postoperative timeframe.

**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 Primary Procedure.

**Options:**
- Yes
- No
- Comments (Optional)

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

**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:**
- Information identified only on a pathology report cannot be utilized to apply PATOS to the postoperative occurrence, Sepsis.
- 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.

**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 Primary 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 (Assign Variable):**
-

**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.

**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 Primary 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 Primary Procedure.

**Options:**
- Yes
- No
- Comments (Optional)

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

**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.

**Variable Name: Unplanned Admission to ICU**

**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 or at the time of the primary procedure.

**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 which was not planned prior to or at the time of the primary procedure.

**Options:**

- Select "Unplanned admission to ICU" from the dropdown menu
  - Enter date (mm/dd/yyyy)
- Comments (optional)

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

- Examples of ICU include SICU, MICU, NSICU, CVICU, CCU, etc.
- The decision was made to admit the patient to the ICU after leaving the OR following the primary procedure.

**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 or intraoperatively.

**Notes:**

- Assign variable once during the 30-day postoperative timeframe.

**Variable Name: Gastrointestinal Tract Bleeding**

**Intent of Variable:** To capture bleeding of the any portion of the gastrointestinal tract within the 30-day postoperative period.

**Definition:** Bleeding of any portion of the gastrointestinal tract. This may be at a staple line, anastomosis, enterotomy, or ulcer. Bleeding in the early postoperative period after metabolic and bariatric surgery is a rare complication. Occasionally, bleeding can be problematic, resulting in significant postoperative morbidity or even mortality.

**Criteria:** Indicate if there was any bleeding of the gastrointestinal tract within the 30-day postoperative period **AND** one of the following:

- Readmission
- Reoperation
- Intervention
- Any blood transfusion
- Critical drop in BP and/or increase in heart rate that results in a transfer to a higher level of care or the administration of pressors

**Options:**

- Select "Gastrointestinal tract bleeding" from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)

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

- Blood given includes red blood cells, PRBCs, whole blood, autologous blood, and cell-saver products
- Bleeding from the omentum
- Hematoma found during reoperation would meet*

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

- *A hematoma is due to another definitive cause, which is not related to the GI tract anatomy
- Blood loss due to trauma (e.g. MVA)
- Blood loss not associated with a GI bleed
- Transfusions of fresh frozen plasma (FFP), platelets, or volume expanders (e.g., crystalloids or colloids)

**Notes:**

- Assign variable once during the 30-day postoperative timeframe.

**Variable Name: Bowel Obstruction**

**Intent of Variable:** To capture if the patient developed a bowel obstruction, either partial or complete, within the 30-day postoperative period.

**Definition:** Patients may develop a bowel obstruction, in which the gastrointestinal tract is partly or completely blocked, following metabolic and bariatric surgery. A bowel obstruction may be related to ileus, internal hernias, adhesions, or strictures.

**Criteria:** Indicate if the patient developed a bowel obstruction within the 30-day postoperative period AND one of the following:

- Readmission
- Reoperation
- Intervention
- Initial hospital stay ≥ 4 days primarily due to delayed bowel function
- NG placed, prolonged bowel rest, and/or reinstating NPO status any time on or after POD 4

**Options:**

- Select "Bowel obstruction" from the dropdown menu
- Enter date (mm/dd/yyyy)
- Comments (optional)

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

-

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

**Notes:**

- If the patient is made NPO for another procedure, after the Primary Procedure (e.g. return to the OR, IR, etc.), the time the patient is NPO for the procedure does not count. However, if the patient remains NPO for this additional procedure, for 24 hours or more, the Prolonged Postoperative NPO or NGT Use variable would be assigned.
- Assign variable once during the 30-day postoperative timeframe.

**Variable Name: New Postop COVID-19 Diagnosis**

**Intent of Variable:** Identify patients with a **new** postoperative diagnosis of lab-confirmed or suspected COVID-19.

**Definition:** COVID-19 is a novel coronavirus with clinical features ranging from mild disease with non-specific signs and symptoms of acute respiratory illness, to severe pneumonia with respiratory failure and septic shock.[4]

**Criteria:**

- Select "No" for patients without a new diagnosis of COVID-19 within 30 days following the primary procedure. This includes all situations where COVID-19 was never mentioned nor considered.
- Select "Yes, lab-confirmed diagnosis" for those patients with a new diagnosis of COVID-19 within 30 days following the primary procedure which is confirmed by laboratory testing, with the test sent to the lab by day 30 (result can return later).
- Select "Yes, suspected diagnosis" for those patients with a new clinical or epidemiological diagnosis of COVID-19 within 30 days following the primary procedure when laboratory confirmation was not performed, was inconclusive, or was negative but a suspected diagnosis was maintained (and indicated in the medical record).

**Options:**

- No
- Yes, lab-confirmed diagnosis (or ICD-10 code U07.1)
- Yes, suspected diagnosis (or ICD-10 code U07.2)

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

-

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

- If the patient had an active preoperative COVID-19 diagnosis (lab-confirmed or suspected) within 14 days prior to the primary procedure, assign "No" to this postoperative occurrence. These patients would be assigned the preoperative risk factor of "Preop COVID-19 Diagnosis."
- If a patient who is initially under investigation for COVID-19 within the 30-day postoperative timeframe is then deemed to not meet the threshold for probable infection or for testing by infectious disease, infection control, or hospital protocol, assign "No" to this postoperative occurrence.
- A positive serological (antibody) test, alone, without a suspected current or active diagnosis of COVID-19 would be assigned "No." It can reflect a prior infection.

**Notes:**

- ICD-10 Diagnosis Codes U07.1 and U07.2 can be utilized as diagnoses for this variable.[5]
- For the purposes of this variable, lab-confirmed diagnoses are based on molecular (real-time reverse transcription polymerase chain reaction (rRT-PCR)) testing, rather than serological (antibody) testing.

[4] "Healthcare Professionals: Frequently Asked Questions and Answers/' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 22 Mar. 2020, https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html

[5] For additional information on these ICD-10 Diagnosis Codes please refer to the following link on the World Health Organization's website: https://www.who.int/classifications/icd/covid19/en/

**Variable Name: IV Treatment as an Outpatient**

**Intent of Variable:** To capture if the patient received IV fluids or IV medication as an outpatient within the 30 day postoperative timeframe for nausea and vomiting, fluid, electrolyte, or nutritional depletion in an outpatient setting.

**Definition**: The outpatient setting is utilized to infuse the patient with IV fluids and to administer IV medications.

**Criteria:** Indicate if the patient received IV fluids or IV medication as an outpatient within the 30 day postoperative timeframe for nausea and vomiting, fluid, electrolyte, or nutritional depletion.

**Options:**

- Yes
    - If yes, select the number of visits:
        - 1
        - 2
        - 3
        - 4
        - 5 or more
- 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.
- Capture only fluids given in the outpatient setting. Do not capture fluids given in the ED, as this would be captured under the Emergency Department (ED) Visit variable.
- Standard IV orders without a diagnosis of nausea and vomiting, fluid, electrolyte, or nutritional depletion would not be assigned.

**Notes:**

-

**Variable Name: Emergency Department (ED) Visits**

**Intent of Variable:** To capture emergency department (ED) visits within the 30 day postoperative timeframe that does not result in an inpatient admission.

**Definition**: The patient was seen in the ED and criteria are not met to assign a Readmission.

**Criteria:** Any ED visits within the 30 day postoperative timeframe which does not meet criteria to assign a Readmission.

**Options:**

- Yes
  - If yes, please capture:
    - Visit date
    - Discharge diagnosis for the ED visit (please refer to Appendix J)
- No

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

- Visits to Urgent Care Centers which function as EDs 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:**

- Please enter information for each visit to the ED.

**Variable Name: Morbidity Occurrences, Events, and Mortality Data Captured**

**Intent of Variable:** To capture morbidity, event, and mortality data through the 30th day after the Primary Procedure. Sites must consistently capture morbidity, event, and mortality data through the 30th day after the Primary Procedure on a minimum of 80 % of the cases submitted to the Program. Sites with morbidity, event, and mortality data capture rates of less than 80% will not be included in the Semiannual Report (SAR).

**Definition:** Follow-up data is essential to evaluate outcomes of metabolic and bariatric procedures. Accurate follow-up data enables the comparison of outcomes data between sites at the national level. The MBSAQIP requires the reporting of morbidity, event, and mortality data up to and including the 30th day after the Primary Procedure on all cases entered into the Program.

**Criteria:** A minimum of two (2) attempts should be made to contact the patient.

**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 Primary Procedure is considered full 30-day follow-up as no additional follow-up can be obtained.
- A patient sees a nurse affiliated with the center, occupational therapist, or physical therapist on or after postoperative day 30.

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

- A patient sees a dietician on or after postoperative day 30.
- The patient did not complete a post-operative office visit between postoperative day 30 and postoperative day 90 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:**

- Methods to obtain 30-day follow-up include, but are not limited to:
  - Physician assessment on or beyond postoperative day 30
  - Nurse practitioner assessment on or beyond postoperative day 30
  - Physician assistant assessment on or beyond postoperative day 30
  - Assessment by a clinical nurse specialist with experience, training, or certification in the care of metabolic and bariatric patients on or beyond postoperative day 30
  - Supervised registered nurse with experience, training, or certification in the care of metabolic and bariatric patients on or beyond postoperative day 30
  - Patient or patient's family on or beyond postoperative day 30
  - Death certificates
  - Internet sources (such as death index, patient locator software, obituary listings)
  - Communication with other medical facilities on or beyond postoperative day 30
- 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 Primary 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 and Appendix G – Provider Assessment Table

**Variable Name: Weight Closest to Day 30**

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

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

**Criteria:** The patient's weight documented in the medical record in either pounds (lbs.) or kilograms (kg) within the 30 day postoperative timeframe closest to postoperative day 30.

**Options:**

- Enter Value
  - Select pounds/kilograms
  - Enter Date
- Weight Not Obtained

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

- A weight documented by an appropriate provider during a phone, telemedicine, or telehealth assessment may be captured.

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

- A weight obtained during an assessment or call beyond postoperative day 30

**Notes:**

- BMI will auto-populate based on the weight entered and the height previously documented.
- Please refer to Appendix G- Provider Assessment table for additional guidance

**Variable Name: Physical Assessment Completed**

**Intent of the Variable**: To capture if the patient had a physical assessment between postoperative day 1 and postoperative day 30.

**Definition:** Following metabolic and bariatric surgery, all patients should be seen within the 30 day postoperative time frame.

**Criteria:** The patient had a physical assessment between postoperative day 1 and postoperative day 30.

**Options:**

- Yes
- No

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

- This may be an inpatient or outpatient assessment
- This assessment may be completed during the initial inpatient stay
- Must be completed by a provider which can perform a physical assessment
- A physical assessment may be completed via telehealth or phone by an appropriate provider
- An assessment with an RN or Clinical Nurse Specialist

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

- Physical assessment completed on or beyond postoperative day 31
- Assessment completed by dietician or nutritionist

**Notes:**

- Appropriate Providers include:
    - Physician
    - Nurse practitioner
    - Physician assistant
    - Clinical nurse specialist with experience, training, or certification in the care of metabolic and bariatric patients
    - Supervised registered nurse with experience, training, or certification in the care of metabolic and bariatric patient's assessment
- Please refer to Appendix G- Provider Assessment table for additional guidance

**Variable Name**: **Readmission**

**Intent:** To capture readmission(s) that occurred following a metabolic and bariatric procedure.

**Definition:** Patients who were discharged from their index hospital stay or encounter (whether inpatient or outpatient basis) after their primary procedure, and are subsequently formally admitted by a qualified practitioner as an inpatient to an acute care bed, or have a subsequent hospital (or facility-based) encounter (receiving outpatient, emergency department or observation services) that crosses at least two midnights.

**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:** Enter each hospital readmission separately.

- Readmission at your site
  - Yes
  - No
- Readmission Date (mm/dd/yyyy; if not at your site mm/yyyy or yyyy also available)
- Discharge Date (mm/dd/yyyy if not at your site mm/yyyy or yyyy also available)
- Unplanned Readmission (If within 30 days of the Primary Procedure) –see next page for additional guidance
  - Yes
  - No
- Discharge Diagnosis (please refer to Appendix J)

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

- For the Discharge Diagnosis, capture the primary discharge diagnosis for that stay.
- Assign Unplanned Readmission if there is no documentation prior to or at the time of the primary procedure that the patient would require a Readmission.
- Any readmission which meets criteria within 30 days of a case form
- A related readmission more than 30 days following a case, if your site is following the patient out long-term
- A related readmission more than 30 days following a Reoperation or Intervention event form, if your site is following the patient out long-term

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

- Do not capture emergency room visits that did not meet admission criteria above.
- Do not assign Unplanned Readmission if the Readmission was due to primary procedure that the patient would require a Readmission.
- Do not capture a patient who is transferred from their index encounter at your acute care site directly to another acute care site, as 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 a patient is transferred from your acute care site directly to another acute care site, the admission to the other site would not be assigned as an additional 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.
- After the 30-day follow-up timeframe, only capture Readmissions related to the bariatric or metabolic

procedure.

- Do not capture an unrelated readmission more than 30 days following any case or event form
- Do not capture a related readmission more than 30 days following a case form, if your site is NOT following the patient out long-term
- Do not capture a related readmission more than 30 days following a Reoperation or Intervention event form, if your site is NOT following the patient out long-term
- Do not capture a readmission which occurs in conjunction with a procedure captured on a case form in the MBSAQIP registry for your site. (The case forms will capture the readmission.)

**For DOD and international sites only:**

- 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 NSQIP 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 hours should be rare). In considering this NSQIP 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**.**
- An inpatient readmission is assigned regardless of the length of stay. The two-midnight rule applies to outpatient/observation services.
- All readmissions that meet criteria within the 30-day postoperative timeframe would be entered into the registry.
- A readmission comments section is provided for additional notes to be utilized at the site's discretion.

**Variable Name: Unplanned Readmission**

**Intent of Variable:** To indicate if a readmission which occurred within 30 days of the Primary Procedure was unplanned.

**Definition:** A Readmission that was not planned at the time of the primary procedure. The "Unplanned" qualifier is meant to reflect that there was no prior documentation in any available records, before or during - primary procedure, that this readmission was part of a plan of care for the patient.

**Criteria:** If within 30 days of the Primary Procedure, was this an unplanned readmission?

**Options:**

- Yes
- No

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

- Answer "Yes" if the documentation was completed following the Primary Procedure (for example in a postprocedural progress note)

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

- Answer "No" if there is mention in the operative note or operative report that the patient may require a readmission
- Answer "No" if there is mention in the operative note or operative report that the patient may require a reoperation for which the patient was readmitted

**Notes:**

- Do not utilize information from a standard surgical consent form
- Do not utilize information from the H&P in which the physician is documenting information for the surgical consent form
- Readmissions due to pathology results from the primary procedure would be considered planned.
    - For example, if during the primary procedure, pathology is obtained that later results positive for cancer and the patient is readmitted to the hospital for chemotherapy in response to these pathology results, this readmission would be considered planned.

**Variable Name: Performed at Your Site**

**Intent of Variable:** To identify whether the procedure was completed at the site where the data is being entered.

**Definition:** Only procedures completed at your site should be entered as new cases.

**Criteria:** Indicate if the procedure was performed at your site.

**Options:**

- Yes
- No

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

-

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

- Procedure was completed at another hospital or facility within your healthcare system

**Notes:**

- If you choose "No" for this question, you will have the option to capture the procedure as a Reoperation or Intervention.

**Variable Name: To Maintain or for Future Weight Loss**

**Intent of Variable:** To determine if a procedure was completed to maintain current weight loss or for future weight loss.

**Definition:** Metabolic and bariatric procedures are completed to maintain weight loss or for future weight loss purposes.

**Criteria:** Please indicate if the procedure was completed either to maintain current weight loss **or** for future weight loss.

**Options**:

- Yes
- No

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

- Initial metabolic and bariatric procedures
- Bariatric conversions or revisions
- Assign "Yes" for Preoperative diagnoses for **Initial procedures** including:
  - Obesity
  - (high) BMI
  - Diabetes mellitus
  - Hypertension
  - Hyperlipidemia
  - Sleep apnea
  - Metabolic syndrome
- Assign "Yes" if a patient has a **history** of metabolic and bariatric surgery, and the **Revision** or **Conversion** procedure has a preoperative diagnosis including:
  - Obesity
  - Weight gain
  - (high) BMI
  - Diabetes mellitus
  - Hypertension
  - Hyperlipidemia
  - Sleep apnea
  - GERD
  - Metabolic syndrome

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

- Assign "No" for Reoperations due to a complication
- Assign "No" if a patient has a history of metabolic and bariatric surgery, and the Revision or Conversion procedure has a preoperative diagnosis including:
  - Ulcer (gastric, anastomotic, duodenal, jejunal)
  - GI Perforation
  - GI bleeding
  - Band slippage or mechanical malfunction
  - GI stricture
  - Intussectption
  - Volvulus

- Hernia (internal, incisional, hiatal, paraesophageal)
- Mesenteric defect
- Fistula (e.g. gastrogastric, gastrocutaneous, enterocutaneous)
- Gastroparesis
- Nausea, vomiting, food intake intolerance
- Malnutrition
- Excessive weight loss

**Notes:**

- If you choose "No" for this question, the only options available to capture this procedure will be Reoperation or Intervention.

**Variable Name: Reoperation**

**Intent of Variable:** To capture any reoperations performed within 30 days of the assessed bariatric or metabolic surgical procedure. Beyond postoperative day 30, only related procedures would be captured as a Reoperation.

**Definition**: Any reoperations performed within 30 days of the assessed bariatric or metabolic surgical procedure. Create one Reoperation Event Form in the database for each encounter in the operating room (OR), procedure room, or other venue; even if more than one procedure was performed during that encounter.

**Criteria:** A reoperation would only be entered in the MBSAQIP database at a minimum, procedural sedation or anesthesia was required for the procedure or if a metabolic or bariatric related procedure was performed.

**Options:**

- Choose Reoperation as the Procedure Type on the Interim Screen

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

- Exploration with drain placement
- AICD or pacemaker insertion
- Laparoscopic LINX placement or removal
- Bedside surgical procedures (e.g. laparotomy completed at bedside for patient too ill to take to the OR)

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

- Gastric adjustable band adjustments, such as band fills or deflations.

**Notes:**

- If both a Reoperation and Intervention were completed during one anesthesia event or trip to the OR/ Procedure room, base the procedure type on the most complex metabolic and bariatric procedure completed. If no bariatric-related procedures were performed, enter the most complex procedure completed. Enter all additional procedures and interventions performed during the anesthesia event or trip to the OR/ Procedure room into the text field for the reoperation.
    - Example: Patient has an incisional hernia repair at a trocar site from a prior metabolic and bariatric procedure, and an EGD with stent placement for an anastomotic stricture at the gastrojejunal anastomosis. This would be captured on a Reoperation event form as the incisional hernia repair was the most complex metabolic and bariatric related procedure performed. The EGD with stent placement would be captured in the notes section of the Reoperation event form.
    - Example: Patient has a carpal tunnel release and EGD with stent placement for an anastomotic stricture at the gastrojejunal anastomosis. This would be captured in an Intervention event form as this was the most complex metabolic and bariatric procedure performed.
    - Patient has a carpal tunnel release and an EGD with findings within normal limits during the 1 year follow-up timeframe. This would not be captured in the registry.

**Variable Name: Unplanned Reoperation** (Reoperation form)

**Intent of Variable:** To capture any procedures that occurred prior to midnight of POD 30 which were unplanned at the time of the primary procedure.

**Definition:** A Reoperation that was not planned at the time of the primary procedure. The "Unplanned" qualifier is meant to reflect that there was no prior documentation in any available records, before or during the primary procedure (operative report), that this reoperation was part of a plan of care for the patient.

**Criteria:** Indicate if this was an unplanned reoperation If completed within 30 days of the Primary Procedure.

**Options:**

- Yes
- No

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

- Answer "Yes" if the documentation was completed following the Primary Procedure (for example in a postprocedural progress note)

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

- Answer "No" if there is mention in the operative note or operative report that the patient may require a reoperation

**Notes:**

- Do not utilize information from a standard surgical consent form
- Do not utilize information from the H&P in which the physician is documenting information for the surgical consent form
- A Reoperation comments section is provided for additional notes to be utilized at the site's discretion.

**Variable Name**: **Emergency Case** (Reoperation form)

**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. Yes was answered to "Was this Procedure Performed at Your Site?"

**AND**

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

- 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.

**Notes:**
-

**Variable Name: Stapler Used or Anastomosis Completed** (Reoperation form)

**Intent of Variable:** To identify reoperative cases involving the use of a surgical stapler for the anastomosis or resection of the GI tract, or creation of a new anastomosis, involving the metabolic and bariatric anatomy.

**Definition:** Surgical staplers are used to cut and anastomose portions of the GI tract. Anastomoses are surgical connections between two structures of the GI tract.

**Criteria:** A surgical stapler was used during a reoperation for an anastomosis or resection of the GI tract involving the metabolic and bariatric anatomy, OR if there was creation of a new anastomosis, involving the metabolic and bariatric anatomy.

**Options:**
- Yes
- No

**Scenarios to Clarify (Assign Variable):**
- 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
- Hand-sewn anastomosis

**Scenarios to Clarify (Do Not Assign Variable):**
- 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
- Creation or revision of an anastomosis distal or proximal to the metabolic and bariatric anatomy
- Stapling of the GI tract distal or proximal to the metabolic and bariatric anatomy

**Notes:**
- Look for key words such as GIA, TIA, ENDOPATH®, the use of staple “re-loads” (such as “Blue Re-load” “Green Re-load” or “Black Re-load”).

**Variable Name: Final Surgical Approach** (Reoperation form)

**Intent of Variable:** To capture the final operative approach of the reoperation.

**Definition:** The final operative approach of the reoperation. Endoscopic indicates that the procedure was primarily performed with use of an endoscope and may have been completed through a natural orifice. Laparoscopic indicates that trocars were placed and a laparoscope was utilized for the procedure. An open procedure indicates that the surgery was completed via laparotomy. Robotic Assisted indicates the use of robotic systems to aid in a portion of the reoperation.

**Criteria:** The final surgical approach utilized by the surgeon as documented in the operative note for the reoperation. If the procedure was converted to another approach, indicate the final approach here. Also indicate if a robotic assist was utilized for any portion of the reoperation.

**Options:**

- Endoscopic
- Laparoscopic
- Open

- Robotic Assist
    - Yes
    - No

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

-

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

- For Robotic Assisted, **do not** include a mechanical or electrical device to hold the camera only.
- Surgical approach for any procedures completed which were not related to the metabolic and bariatric procedure/anatomy.

**Notes:**

- For laparoscopic cases with a robot used, please choose Laparoscopic for Procedural Approach and Yes for Robotic Assist.

**Variable Name: Postprocedural Diagnosis** (Reoperation form)

**Intent of Variable:** To capture the indication for reoperation.

**Definition**: The postoperative diagnosis accurately reflects the reason that the reoperation was performed.

**Criteria:** Postoperative or postprocedural diagnosis which represents the most accurate single diagnosis of the patient's reason for the reoperation.

**Options:**

- Select the most appropriate postoperative or postprocedural diagnosis from the drop down menu.

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

-

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

-

**Notes:**

- Please refer to Appendix J - Diagnosis List for the complete list of diagnoses.

**Variable Name: Reoperation Type** (Reoperation form)

**Intent of Variable:** To capture any reoperations performed within the follow-up timeframe.
**Definition:** A reoperation which was completed after the patient left the operating room following the Primary Procedure.

**Criteria:** 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:**

| Options | Examples |
|---|---|
| Adjustable gastric band, port, and/or tubing revision | Repositioning port; repositioning band; repositioning tubing; remove and replace port; band; and/or tubing |
| Adjustable gastric banding over roux-en-Y bypass | Band placed on gastric pouch of patient with existing Roux-en-Y gastric bypass anatomy |
| Biliopancreatic diversion with or without duodenal switch revision | Revision of biliopancreatic limb; Anastomotic revision |
| Biliopancreatic diversion common channel lengthening | Common channel limb lengthening completed for patient with BDP |
| Feeding tube placement (G-tube or J-tube) (laparoscopic or open) | Gastrostomy tube placed laparoscopic or open; Jejunostomy tube placed laparoscopic or open. (If placed via endoscopy- capture on Intervention event form) |
| Gastrectomy | Partial gastrectomy or completion gastrectomy for any MBS procedure (**except** sleeve gastrectomy) |
| Gastric pouch or stoma plication or revision | Plication of gastric pouch, plication of stoma/anastomosis; revision of gastric pouch (due to dilation); stoma revision (due to dilation) |
| Gastrointestinal tract repair (involving metabolic or bariatric surgery anatomy) | Perforated marginal ulcer repair, perforated gastric pouch repair, leaking staple line repair; perforated stomach ulcer repair; perforated GI tract repair involving MBS anatomy |
| Hernia repair (involving metabolic or bariatric surgery anatomy) | Hiatal hernia repair; Paraesophageal hernia repair; Incisional hernia repair (incision site from prior metabolic and bariatric surgery); Internal hernia repair |
| Roux-en-Y gastric bypass revision | Revision of GJ anastomosis, Revision of JJ anastomosis, Pouch Revision |
| Roux-en-Y limb lengthening | Lengthening of the roux limb |
| Sleeve gastrectomy revision (Re-sleeve) | Revision of a gastric sleeve; Gastric sleeve staple line revision |
| Single anastomosis duodeno-ileal bypass / Loop duodenal switch revision | Single anastomosis duodeno-ileal bypass (SADI) revision; Loop duodenal switch revision |
| Takedown or reversal of metabolic or bariatric procedure | Lap band, port, or tubing removal; intragastric balloon removal; vbloc removal; gastroplasty |

| | |
|---|---|
| | takedown; gastric bypass or duodenal switch takedown; Fobi or silastic ring removal (with NO OTHER metabolic and bariatric procedure completed under the same anesthesia event) |
| Other abdominal procedure involving metabolic or bariatric anatomy (not listed) | Miniloop gastric bypass revision; Pyloroplasty; Entreopexy; Gastropexy; Gastrorrhaphy; Reduction of intussectption; Reduction of volvulus |
| Other investigational (not listed) | An investigational procedure completed on metabolic and bariatric anatomy |
| Other abdominal NOT involving metabolic or bariatric anatomy (not listed) | Exploratory laparotomy; Diagnostic Laparoscopy; Cholecystectomy; Splenectomy; Liver surgery, resection or repair of bowel distal to metabolic and bariatric anatomy; Colectomy; |
| Other (not listed) | Any non-abdominal procedure or surgery. |

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

- 

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

- If any of the above procedures are completed at your site, and more than 30 days have elapsed since a prior case was captured in the registry for the patient, and the procedure was completed for continuing or maintaining weight loss, the procedure would be captured as a new case.

**Notes:**

- If both a Reoperation and Intervention were completed during one anesthesia event or trip to the OR/ Procedure room, base the procedure type on the most complex metabolic and bariatric procedure completed. If no bariatric-related procedures were performed, enter the most complex procedure 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.

**Variable Name: Conversions - Previous Metabolic and Bariatric Procedure** (Reoperation form)

**Intent of Variable:** To identify the metabolic and bariatric procedure the patient had completed prior to entering the operating room for the reoperation.

**Definition:** A conversion refers to a patient's anatomy being converted to another type of bariatric or metabolic procedure. The previous procedure refers to the patient's most recent metabolic and bariatric procedure completed.

**Criteria:** Identify metabolic and bariatric procedure the patient had prior to entering the operating room for the conversion.

**Options:**

- Adjustable gastric banding
- Biliopancreatic diversion
- Biliopancreatic diversion with duodenal switch
- Gastric stapling (not vertical banded gastroplasty)
- Intragastric balloon
- Single anastomosis gastric bypass
- Percutaneous gastric drainage device placement
- Ring (Fobi or Silastic) procedure
- Roux-en-Y gastric bypass
- Single anastomosis duodeno-ileal bypass / Loop duodenal switch
- Sleeve gastrectomy
- Vagal nerve blocking therapy
- Vertical banded gastroplasty
- Other endoluminal procedure (not listed)
- Other (not listed)

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

- If the patient has a history of multiple metabolic or bariatric procedures, please capture the most recent one completed prior to the Primary Procedure.
    - Patient has a history of an intragastric balloon insertion and removal, then went on to have an adjustable gastric band which was removed due to patient intolerance. In this scenario, you would choose Adjustable gastric banding.

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

- Patient has a history of a partial gastrectomy that was completed due to stomach cancer.
- Patient has a history of a partial gastrectomy that was completed due to an automobile accident.

**Notes:**

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**Variable Name**: **Conversions - Current Procedure** (Reoperation form)

**Intent of Variable:** To identify the metabolic and bariatric procedure which is completed during the reoperation.

**Definition**: A Conversion refers to a patient's anatomy being converted to another type of bariatric or metabolic procedure. The current procedure refers to the metabolic and bariatric procedure the patient has completed during the reoperation.

**Criteria:** Identify the metabolic and bariatric procedure which was completed during the reoperation.

**Options:**

- Biliopancreatic diversion
- Biliopancreatic diversion with duodenal switch
- Roux-en-Y gastric bypass
- Roux-en-Y distal gastric bypass
- Single anastomosis gastric bypass
- Single anastomosis duodeno-ileal bypass / Loop duodenal switch
- Sleeve gastrectomy
- Other

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

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

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**Notes:**

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**Variable Name: Intervention**

**Intent of Variable:** To capture any interventions performed within 30 days of the assessed bariatric or metabolic surgical procedure. Beyond postoperative day 30, only related procedures would be captured as an intervention.

**Definition:** An Intervention is a procedure if, at a minimum, procedural sedation or anesthesia was required for the procedure or a metabolic or bariatric related procedure was performed. Create one Intervention event form 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**:

- Choose Intervention as the Procedure Type on the Interim Screen

**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
- Only local anesthesia was utilized, and the procedure involved the metabolic and bariatric anatomy

**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.
- Only local anesthesia was utilized, and the procedure did **not** involve the metabolic and bariatric anatomy.

**Notes:**

- If both a Reoperation and Intervention were completed during one anesthesia event or trip to the OR/ Procedure room, base the procedure type on the most complex metabolic and bariatric procedure completed. If no bariatric-related procedures were performed, enter the most complex procedure 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.
    - Example: Patient has an incisional hernia repair at a trocar site from a prior metabolic and bariatric procedure, and an EGD with stent placement for an anastomotic stricture at the gastrojejunal anastomosis. This would be captured on a Reoperation event form as the incisional hernia repair was the most complex metabolic and bariatric related procedure performed. The EGD with stent placement would be captured in the notes section of the Reoperation event form.
    - Example: Patient has a carpal tunnel release and EGD with stent placement for an anastomotic stricture at the gastrojejunal anastomosis. This would be captured in an Intervention event form as this was the most complex metabolic and bariatric procedure performed.

- Patient has a carpal tunnel release and an EGD with findings within normal limits during the 1 year follow-up timeframe. This would not be captured in the registry.

**Variable Name: Unplanned Intervention** (Intervention form)

**Intent of Variable:** To capture any procedures that occurred prior to midnight of POD 30 which were unplanned at the time of the primary procedure.

**Definition:** An intervention that was not planned at the time of the primary procedure. The "Unplanned" qualifier is meant to reflect that there was no prior documentation in any available records, before or during the primary procedure (operative report), that this reoperation was part of a plan of care for the patient.

**Criteria:** Unplanned intervention within 30 days of the Primary Procedure.

**Options:**

- Yes
- No

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

- Answer "Yes" if the documentation was completed following the Primary Procedure (for example in a postprocedural progress note).

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

- Answer "No" if there is mention in the operative note or operative report that the patient may require an intervention.

**Notes:**

- Do not utilize information from a standard surgical consent form.
- Do not utilize information from the H&P in which the physician is documenting information for the surgical consent form.
- An Intervention comments section is provided for additional notes to be utilized at the site's discretion.

**Variable Name**: **Emergency Case** (Intervention form)

**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. Yes was answered to "Was this Procedure Performed at Your Site?"

**AND**

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

- 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.

**Notes:**
-

**Variable Name**: **Intragastric Balloon Anesthesia Type** (Intervention form)

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

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

**Criteria:** The principal anesthesia technique used during the intragastric balloon intervention 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

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

- 

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

- 

**Notes:**

- If the patient is given a regional/spinal or epidural and MAC, MAC anesthesia would take precedence.
- 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."

**Variable Name: Intragastric Balloon Type** (Intervention form)

**Intent of Variable:** To capture patients whose intervention involved an intragastric balloon.

**Definition:** An intervention in which an intragastric balloon is removed or placed in the patient's stomach to restrict the amount of oral intake.

**Criteria:** The type of intragastric balloon involved in the case.

**Options:**

- Absorbable
- Adjustable
- Air-filled
- Fluid-filled

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

- Removal of an intragastric balloon

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

-

**Notes:**

- If absorbable and air or fluid-filled, please choose "Absorbable."
- If adjustable and air or fluid-filled, please choose "Adjustable"

**Variable Name: Intervention Type** (Intervention form)

**Intent of Variable:** To capture any interventions performed within the follow-up timeframe.

**Definition:** An intervention which was completed after the patient left the operating room following the Primary Procedure.

**Criteria:** The most complex bariatric related procedure performed during the intervention. If no bariatric related procedure was completed, select the most complex intervention performed during that intervention.

**Options:**

- Diagnostic endoscopy
- Intragastric balloon placement
- Intragastric balloon adjustment
- Intragastric balloon removal
- Therapeutic endoscopy with dilation and/or stent placement
- Therapeutic endoscopy with stoma resizing
- Therapeutic endoscopy with gastric plication or oversew (pouch resizing)
- Therapeutic endoscopy with fistula closure
- Therapeutic endoscopy with band removal
- Therapeutic endoscopy with endoscopic gastroplasty
- Endoscopy with placement of percutaneous tube placement (G-tube, J-tube)
- Other Intervention (not listed)

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

- 

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

- 

**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 were completed during one anesthesia event or trip to the OR/ Procedure room, base the procedure type on the most complex metabolic and bariatric procedure completed. If no bariatric-related procedures were performed, enter the most complex procedure completed. Enter all additional procedures performed during the anesthesia event or trip to the OR/ Procedure room into the text field for the Intervention.

**Variable Name: Postprocedural Diagnosis** (Intervention form)

**Intent of Variable:** To capture the reason for the Intervention.

**Definition**: The postoperative diagnosis accurately reflects the reason that the Intervention was performed.

**Criteria:** The most accurate single diagnosis of the patient's reason for the Intervention (postoperative or postprocedural diagnosis).

**Options:**

- Select the most appropriate postoperative or postprocedural diagnosis from the drop down menu.

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

-

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

-

**Notes:**

- Please refer to Appendix J - Diagnosis List for the complete list of diagnoses.

**Variable Name: Date of Death**

**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

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

- If you are unsure of the specific date, please capture the month and year of the death.
- If you do not have the month, please capture the year of the death.

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

-

**Notes:**

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**Variable Name: Cause of Death**

**Intent of Variable:** To capture the likely cause of death.

**Definition**: Any death, regardless of cause, is captured.

**Criteria:** The patient's suspected cause of death as reported in the medical record or autopsy report.

**Options:** Select the most appropriate cause of death from the medical record or autopsy report.

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

- 

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

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**Notes:**

- Please refer to Appendix J - Diagnosis List for the complete list of diagnoses.
- Mortality comments are optional

| **Abdominal and Gastrointestinal** | |
|---|---|
| Abdominal pain, not otherwise specified | Abdominal pain without findings which meet more specific criteria |
| Adhesions | Bands of fibrous tissue form between abdominal tissues and organs |
| Anastomotic ulcer | Mucosal erosion at an anastomosis of the metabolic and bariatric anatomy; this may also be called a marginal ulcer or stomal ulcer. If there is an ulcer with bleeding, please choose "Gastrointestinal tract bleeding" |
| Anastomotic stricture | A narrowing of the anastomosis of the metabolic and bariatric anatomy |
| Anastomotic or staple line leak | A leak of endoluminal content through an anastomosis or staple line involving the metabolic and bariatric anatomy. If there is an anastomotic or staple line leak with bleeding, please choose "Gastrointestinal tract bleeding" |
| Band erosion | A gastric band erodes through the stomach |
| Band slippage or prolapse | Migration of the gastric band |
| Cholecystitis, cholelithiasis | Inflammation of the gallbladder or gall stones |
| Dumping syndrome | Rapid gastric emptying; when food moves from the stomach into the small bowel too quickly |
| Dysphagia | Difficulty swallowing or a sensation of food being stuck in the throat |
| Enterocutaneous fistula | An abnormal passage between the intestinal tract or stomach and the skin involving the metabolic and bariatric anatomy |
| Gastric distention | Enlargement of the stomach. If this is due to an obstruction, stenosis or other abdominal pathology on this list, then identify the more specific etiology |
| Gastroesophageal reflux disease (GERD) | Stomach acid frequently flows back into the esophagus causing irritation or erosion |
| Gastrointestinal stromal tumor (GIST) | Tumor that usually arises in the tissue of the stomach or small intestine, or less often in the large intestine, esophagus or rectum |
| Gastrointestinal tract bleeding | Bleeding of the GI tract involving the metabolic and bariatric anatomy. If there is an ulcer and/or perforation with bleeding, please choose this option. |
| Gastrointestinal tract fistula | An abnormal connection between part of the gastrointestinal tract and another organ or part of the GI tract involving the metabolic and bariatric anatomy |
| Gastrointestinal tract perforation | An unintentional hole (perforation) of the GI tract involving the metabolic and bariatric anatomy. If |

| | |
|---|---|
| | the perforation was found to be from an anastomosis or staple line, then choose "anastomotic/staple line leak", not GI perforation. If there is a GI tract perforation with bleeding, please choose "Gastrointestinal tract bleeding" |
| Gastrointestinal tract stricture or obstruction | A narrowing or blockage of the GI tract involving the metabolic and bariatric anatomy which may be related to technical issue, ischemia, or food impaction |
| Gastrointestinal tract ulcer without perforation | Mucosal erosion of the GI tract involving the metabolic and bariatric anatomy |
| Gastroparesis | Delayed gastric emptying; Slowed or stopped movement of food from the stomach to the small intestine without blockage |
| Gastritis | Inflammation of the lining of the stomach |
| Hiatal hernia | The stomach and the section of the esophagus that joins the stomach slide up into the chest through the opening in the diaphragm, may be called a sliding hiatal hernia |
| Internal hernia or mesenteric defect | Defect of the mesentery which may or may not have bowel herniating through it which involves the involving the metabolic and bariatric anatomy |
| Intussusception or volvulus | (Intussusception) A segment of intestine "telescoping" inside of another, causing an intestinal obstruction which involves the metabolic and bariatric anatomy. (Volvulus) A loop of intestine twists around itself and the mesentery that supports it, resulting in a bowel obstruction which involves the metabolic and bariatric anatomy. |
| Mechanical malfunction | Malfunction of the implant utilized for the metabolic and bariatric surgery (e.g. balloon, band, port, tubing, v-bloc, aspire assist port) |
| Other abdominal sepsis | An intra-abdominal infection (not thought to be related to an anastomotic/staple line leak or GI perforation). Choose this option if gram stain and/or culture of an intra-abdominal collection identifies pathogenic organisms or infection, or if operative intervention describes an infected field, or if an intervention was performed for presumed abdominal sepsis. |
| Oral intake intolerance | Difficulty or inability to ingest foods or liquids orally |
| Paraesophageal hernia | The esophagus and the stomach remains in their normal location but part or all of the stomach herniates through the hole in the diaphragm into the thorax next to the esophagus |
| Pouch stricture | A narrowing of the gastric pouch |

| | |
|---|---|
| Pouch dilation | Enlargement of the gastric pouch |
| Revision of metabolic or bariatric procedure for reason not otherwise listed (e.g. scheduled surgery) | A revision of the metabolic and bariatric procedure for any reason not listed, including planned, scheduled revisions and conversions |
| **Cardiac and Vascular** | |
| Cardiac, not otherwise specified (arrhythmias, CHF) | Cardiac diagnosis which is not listed here (e.g. arrhythmias, CHF) |
| Chest pain | Chest pain which does not meet a more specific listed reason |
| Myocardial infarction | Blockage of blood flow to the heart, which leads to tissue loss/tissue death |
| Vein thrombosis requiring therapy | A blood clot (thrombus) that forms within a vein |
| **CNS** | |
| CVA | Blood flow to a part of the brain is stopped either by a blockage or the rupture of a blood vessel; also called a stroke |
| Psychiatric-related | Mental health or mental illness (e.g. depression) |
| **Intragastric Balloon** | |
| Aspiration | Breathing in a foreign object (e.g. stomach content, food, stomach acid) in a patient with an intragastric balloon |
| Bleeding | Bleeding of the GI tract due to an intragastric balloon |
| Balloon rupture | Break or burst of an intragastric balloon |
| Gastric ulcer | Mucosal erosion of the GI tract in a patient with an intragastric balloon |
| Obstruction | Blockage of the GI tract due to an intragastric balloon |
| Perforation | A hole (perforation) of the GI tract due to an intragastric balloon |
| Planned removal per protocol | A scheduled balloon removal (to follow manufacturer recommendations) |
| **Metabolic** | |
| Excessive weight loss | Weight loss beyond what is expected from the metabolic and bariatric procedure |
| Hypoglycemia | Low blood glucose (blood sugar) |
| Inadequate weight loss | Weight loss which is less than what is expected from the metabolic and bariatric procedure |
| Nausea, vomiting, fluid, electrolyte, and/or nutritional depletion | Fluid, electrolyte or nutritional depletion is diagnosed. If vomiting or poor p.o. intake is related to an obstruction, stenosis or other abdominal pathology on this list, then identify that etiology |
| Persistent co-morbidities | Co-morbidity resolution which is less than what is expected from the metabolic and bariatric procedure |

| | |
|---|---|
| Weight gain | Weight gain or regain following a metabolic and bariatric procedure |
| **Respiratory** | |
| Other respiratory | Respiratory issue or condition which does not meet a more specific option |
| Pneumonia | An infection of one or both lungs caused by bacteria, viruses, fungi, or aspiration. |
| Pulmonary embolism | A blood clot in a pulmonary artery causing obstruction (complete or partial) of the blood supply to the lungs |
| Shortness of breath | Difficulty breathing. Also called dyspnea. If this condition is due to a pathology on this list, then identify that etiology |
| **Renal** | |
| Nephrolithiasis | Kidney stones |
| Renal failure | Abrupt or rapid decline in Kidney (renal) filtration function |
| Renal insufficiency | The reduced capacity of the kidney to perform its function, not severe enough for be diagnosed as renal failure |
| **Wound** | |
| Wound disruption | The opening or disruption of the surgical closure for a metabolic or bariatric procedure. This may be a superficial/ deep dehiscence or evisceration. If this is in conjunction with a wound infection, please choose “Wound Infection” |
| Incisional hernia | Protrusion of tissue that forms at the site of a surgical closure for a metabolic or bariatric procedure |
| Wound infection | Pathogenic organisms have invaded into viable tissue at the site of a surgical closure for a metabolic or bariatric procedure |
| **Other** | |
| Cancer | Any diagnosed cancer, leukemia, myeloma |
| Findings within normal limits | Postoperative or postprocedural diagnosis indicate findings within normal limits |
| Infection and/or fever (not meeting criteria for more specific reason) | Presence of a presumed or confirmed infection or fever. If a more definitive etiology for the infection is identified (e.g., “anastomotic/staple line leak”, “other abdominal sepsis”, “pneumonia”, “wound infection,” or “GI perforation”) then list that etiology. Examples include C. Diff and COVID-19. |
| Medication-related | Related to medication the patient is prescribed |
| Musculoskeletal pain | Pain that affects the muscles, ligaments and tendons, and bones |
| Other | Any reason not otherwise included in this list |

| | |
|---|---|
| Patient intolerance | Patient is unable to tolerate the metabolic and bariatric procedure in place |
| Patient non-compliance | Failure or refusal to comply or follow a prescribed course of treatment |
| Patient request | Patient requests the metabolic or bariatric procedure be revised, converted or reversed |
| Planned surgery (not metabolic or bariatric related) | Planned procedure which was not related to the metabolic or bariatric procedure |
| Traumatic injury (e.g. Motor vehicle accident, fall) | Physical injuries of sudden onset and severity which require immediate medical attention |