A guide to the NSQIP-IBD variables for SCRs

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Who should be considered for these 5 variables

- Any patient with Inflammatory bowel disease undergoing surgery:
  - **Ulcerative colitis**
    - ICD-9: 556.*
    - ICD-10: K51.*
  - **Crohn's Disease**
    - ICD-9: 555.*
    - ICD-10: K50.*
  - **Indeterminate Colitis (IBD undetermined)**
    - ICD-9: 558.9
    - ICD-10: K52.3
      - ICD-10 here is specific to IBD-U, ICD-9 includes other forms of non UC colitis
  - There are many subcategories for these diagnoses – please include any or all subdiagnoses with these roots.

Variables (New as of 9/26/23)

- IBD Diagnosis (IBDDx): What IBD diagnosis has been assigned to the patient
- a. Crohn's Disease (K50.*)
- b. Ulcerative Colitis (K51.*)
- c. Indeterminate Colitis (IBD-NOS – K52.3)

IBDDx

- Purpose: While many patients will have their IBD diagnosis as the preop diagnosis for surgery, some might have cancer or bowel obstruction, etc. This allows us to avoid relying solely on ICD-10 coding for data analysis.

- Foreseeable issues: For patients who have multiple IBD diagnoses in the chart, please use the “Postop diagnosis” in the operative report for the surgeon.

- Where to locate this information: **Operative report,** preop H&P, anesthesia record

Variables

- Ileostomy formation (**Ileost**): Please indicate if an ileostomy was created at the time of the procedure.

  a. None: No ileostomy

  b. New ileostomy: Patient did not have an ileostomy prior to surgery and completed surgery with an ileostomy

  c. Ileostomy from prior is unaltered: Patient had an ileostomy prior to surgery which remained unaltered after surgery

  d. Conversion of end ileostomy to loop: Patient had an end ileostomy prior to surgery and had formation of a loop ileostomy during surgery.

  e. Other ileostomy revision: All other ileostomy transitions

Ileost

- Purpose: Several CPT codes commonly used for IBD surgery include the phrase “with or without ileostomy”. This will clarify the patient's ileostomy status **at the end of the procedure.**

- Foreseeable issues :
  - The conversion of one type of ileostomy to another can be confusing. This primarily applies to patients undergoing completion proctectomy with IPAA after having previously had a subtotal colectomy

- Where to locate this information:
  - Operative report
    - Definitely in the body
    - Often in the list of procedures performed

Variables

- Biologic agent 60 days prior to surgery (**BioMed**): Was the patient on a biologic agent at any point over the 60 day period prior to surgery? This includes but is not limited to the list of biologics from the subsequent BioMed variable (next slide).
  - **a. No**
  - **b. Yes**
  - **c. Unable to determine**

These will be the biologic agents you may come across at this point in time. See the subsequent list for a more complete list of biologics

New **BioMed** (New 3/1/20, update 9/26/23, Update 5/25/25)

- Biologic agent 60 days prior to surgery (**BioMed**): Was the patient on a biologic agent at any point over the 60 day period prior to surgery? If so, please select the agent from the list below. If the patient is on a clinical trial medication that is not FDA approved, please select "other":
  a. No Biologic agent
  b. Infliximab (Remicaid, Inflectra, Renflexis, Ixifi, Avsola)
  c. Adalimumab (Humira, Hyrimox, Cyletz, Amjevita)
  d. Certolizumab Pegol (Cimzia)
  e. Golimumab (Simponi)
  f. Vedolizumab (Entyvio)
  g. Natalizumab (Tysabri)
  h. Ustekinumab (Stellara, Wezlana)
  i. Tofacitinib (Xeljanz)
  j. Upadacitinib (Rinvoq)
  k. Risankizumab (Skyrizi)
  l. Ozanimod (Zeposia)
  m. Mirikizumab (Omvoh)
  n. Guselkumab (Treymfaya)
  o. Other
  p. More than one of the above agents
  q. Unable to determine

Biomed

- Purpose: Biologic therapies are monoclonal antibodies or small molecules which impair immune responses. There is extensive controversy about whether they contribute to postoperative complications. This will allow us to capture the administration of these medications .
- Foreseeable issues :
  - These medications are often administered infrequently (every few weeks or months).
    - Last dose is the important one.
  - Which medications qualify:
    - See variable stem
- Where to locate this information:
  - Preop H&P
  - **Last note from GI (particularly if it is within 60 days)**
  - MAR – Medication administration record
  - Anesthesia record
  - Operative report
  - Medication reconciliation – Preop or at discharge
  - Infusion center records – Infliximab, Vedolizumab, and ustekinumab are administered at infusion centers

Variables

- Immune modulation 60 days prior to surgery (**ImmMod**): Was the patient taking immune modulation therapy at any point over the 60 day period prior to surgery. This includes: 6-mercaptopurine (6-MP, Purinethol, Purixan), Azathioprine (Imuran, AZA), Methotrexate (MTX, Trexall, Rasuvo, Methotrexate LPF Sodium, Folex PFS)
  - **a. No**
  - **b. Yes**
  - **c. Unable to determine**

Unlike biologic agents, there aren't a lot of new thiopurines coming out. This list should remain fairly static.

New **ImmMod** (New 3/1/20)

- Immune modulation 60 days prior to surgery (**ImmMod**): Was the patient taking immune modulation therapy at any point over the 60 day period prior to surgery? If so, please select the agent from the list below.
  a. No Immune modulation
  b. 6-mercaptopurine (6-MP, Purinethol, Purixan)
  c. Azathioprine (Imuran, AZA)
  d. Methotrexate (MTX, Trexall, Rasuvo, Methotrexate LPF Sodium, Folex PFS)
  e. Unable to Determine

Immnod

- Purpose: Immune modulation also suppresses immune responses. There is some controversy about whether they contribute to postoperative complications. This will allow us to capture the administration of these medications .
- Foreseeable issues :
  - Which medications qualify:
    - See variable stem
  - These medications tend to be taken daily or weekly so should be easier to capture.
- Where to locate this information:
  - Preop H&P
  - **Last note from GI (particularly if it is within 60 days)**
  - MAR – Medication administration record
  - Anesthesia record
  - Operative report
  - Medication reconciliation – Preop or at discharge

Variables

- Colonic Dysplasia (**Dyspl**): For patients undergoing colectomy only, did the patient have known dysplasia prior to the surgery or was there dysplasia found in the surgical specimen? For patients found to have both high and low grade dysplasia, please list high grade. Please answer not applicable if colectomy was not performed.

  a. Unable to determine

  b. No Dysplasia

  c. Low grade Dysplasia

  d. High Grade Dysplasia

  e. Colorectal Cancer: With or without previously identified dysplasia

  f. Not Applicable : If patient did not have a colectomy

Dyspl

- Purpose: Patient's operated on for dysplasia are often considered to have less severe disease than other indications which may affect outcomes. This is usually not included in the preoperative diagnosis of the pt.
- Foreseeable issues :
  - Degree of dysplasia – May be conflicting information between preop diagnosis and operative pathology. Use the highest
    - None < Low Grade < High Grade < Carcinoma (cancer, adenocarcinoma)
  - What if its not in the final pathology report?
    - Usually just sampling problems as the pathologist cannot examine the entire specimen. If pt had dysplasia preop, final path will not downgrade.
- Where to locate this information:
  - Operative dictation – body
  - Brief op note
  - **Final pathology report**
  - Preop H&P
  - Discharge summary

IPAA

IPAA (IPAA) For patients undergoing proctectomy, was there an ileal pouch anal anastomosis created during this surgery?

- **Yes**
- **No**
- **Not applicable**

- We have discussed what an IPAA involves in the past, but if there are any questions, please do not hesitate to send them my way.
- This includes any configuration = J- and S- pouches
- Generally is CPT: 45113, 44158, 44211, 45397, but occasionally there are other inappropriate codes
- Key here is that cpt 45397 is often used a surrogate for laparoscopic or robotic completion proctectomy with IPAA even though the definition of this code is for a partial proctectomy with colonic J-pouch. This will help us understand which of these cases are actually IPAAs

Variables (New 9/26/23)

Anastomosis Technique (AnastTech): Please select the method in which an anastomosis was created. Please include even if anastomosis is created with a proximal diversion.

a. **Not applicable**: No anastomosis

b. **Stapled side to side**: Linear stapler joins the bowel. Common enterotomy can be stapled or sewn

c. **Hand sewn**: Bowel transected and is sewn together (Please exclude Kono-S technique from this answer). No stapler employed to join the bowel

d. **Kono-S**: Bowel is stapled off and linear incisions are made on each end and sewn together, mesentery is spared, supporting column employed (primarily used in Crohn's disease, Surgeon will state Kono-S technique)

e. **Stapled End to End**: Circular stapler is used to anastomose in linear fashion to distal segment (common in IPAA or low pelvic anastomoses)

f. **Mucosectomy with hand sewing**: A mucosal sleeve is dissected out to the top of the anorectal ring and the pouch is sewn to the dentate line. Only in IPAA

g. **Multiple Anastomoses**: Answer for any patient receiving more than 1 anastomosis regardless of technique. Do not list technique

h. **Other**: Other technique not listed above

i. **Unable to Determine**

AnastTech

- Purpose: Significant debate in the community about anastomotic technique in a variety of scenarios. This will at least help demonstrate safety profiles as new techniques are adopted.

- Foreseeable issues: Lots of variations on techniques, so we tried to keep this as simple as possible. Will outline on subsequent slides. The techniques included are the most common, anything else can be listed as “other technique”. We are not recording anastomotic technique if multiple anastomoses are made
  - While an ileal pouch has many staple lines, only the connection between the IPAA and the anus counts as the anastomosis.

- Where to locate this information: Operative report. Should be spelled out clearly

AnastTech

- **Stapled side to side**: Linear stapler joins the bowel.
  - Common enterotomy can be stapled or sewn
  - Isoperistaltic, antiperistaltic
  - Extracorporeal or intracorporeal
  - Will see linear stapler names such as: GIA, endoGIA, Echelon, Proximate, Signia
  - Almost any small bowel or colon anastomosis may employ this
- **Hand Sewn:** Bowel transected and is sewn together
  - Please exclude Kono-S technique from this answer.
  - No stapler employed to join the bowel.
    - May have been used to separate, generally staple line will be removed
  - Otherwise any orientation or feature is included aside from Kono-S, or as the distal anastomosis for an IPAA (**mucosectomy with hand sewing**)
  - Can be in any anastomotic setting

AnastTech

- **Kono-S**: Bowel is stapled off and linear incisions are made on each end and sewn together, mesentery is spared, supporting column employed
  - Primarily used in Crohn's disease
  - Surgeon will state Kono-S technique
    - If the surgeon does not specifically state that they are forming a Kono-S anastomosis then it is not likely this technique

AnastTech – Pelvic anastomoses

- **Stapled End to End**: Circular stapler is used to anastomose in linear fashion to distal segment
  - Any orientation, end to end, end to side, side to side will create the stapled end to end configuration, key is circular stapler
  - Common in IPAA or low pelvic anastomoses (coloproctostomy, ileoproctostomy)
  - Staplers used: **EEA**, echelon circular, DST.
    - See term such as “anvil” or “spike” for the creation of the anastomosis

- **Mucosectomy with hand sewing**: A mucosal sleeve is dissected out to the top of the anorectal ring and the pouch is sewn to the dentate line.
  - Only in IPAA
  - Should be clearly dictated as this technique

How to process the deidentified reports to enable central data collection

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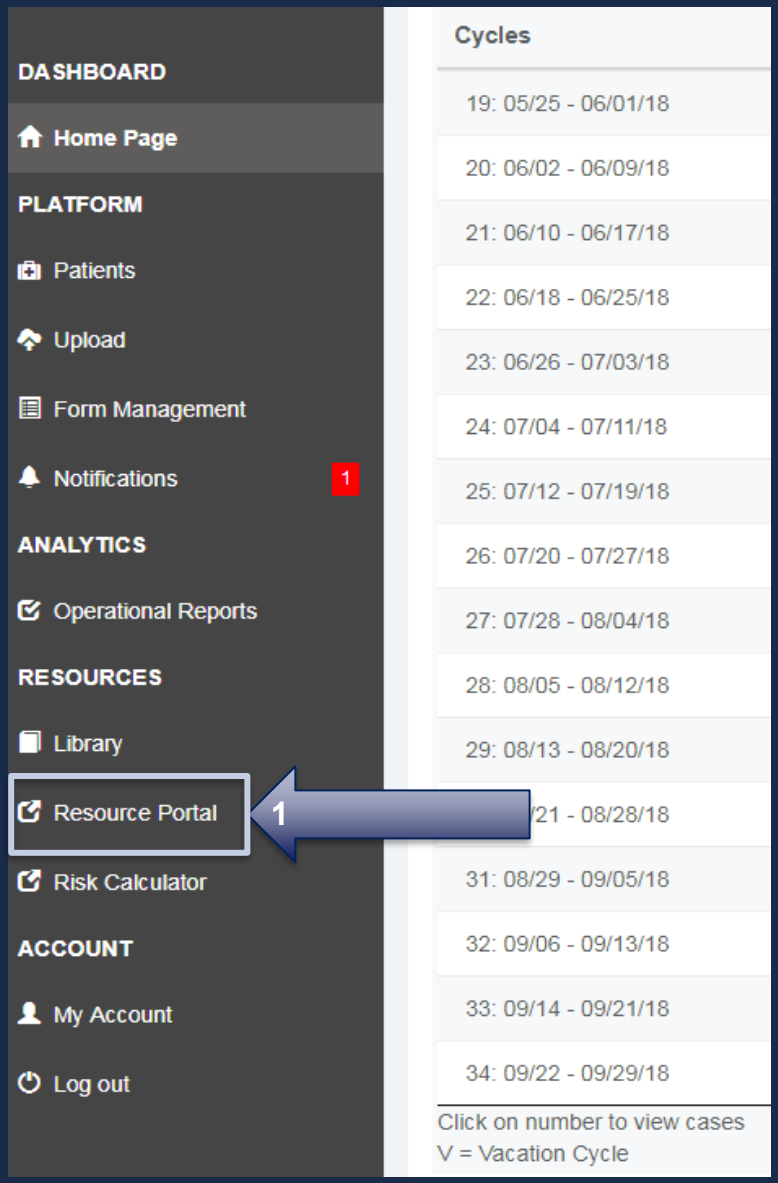
1.) Click on the **Resource Portal** within the NSQIP database



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2.) Under **Reports**, Click on **Case Details & Custom Fields Report**

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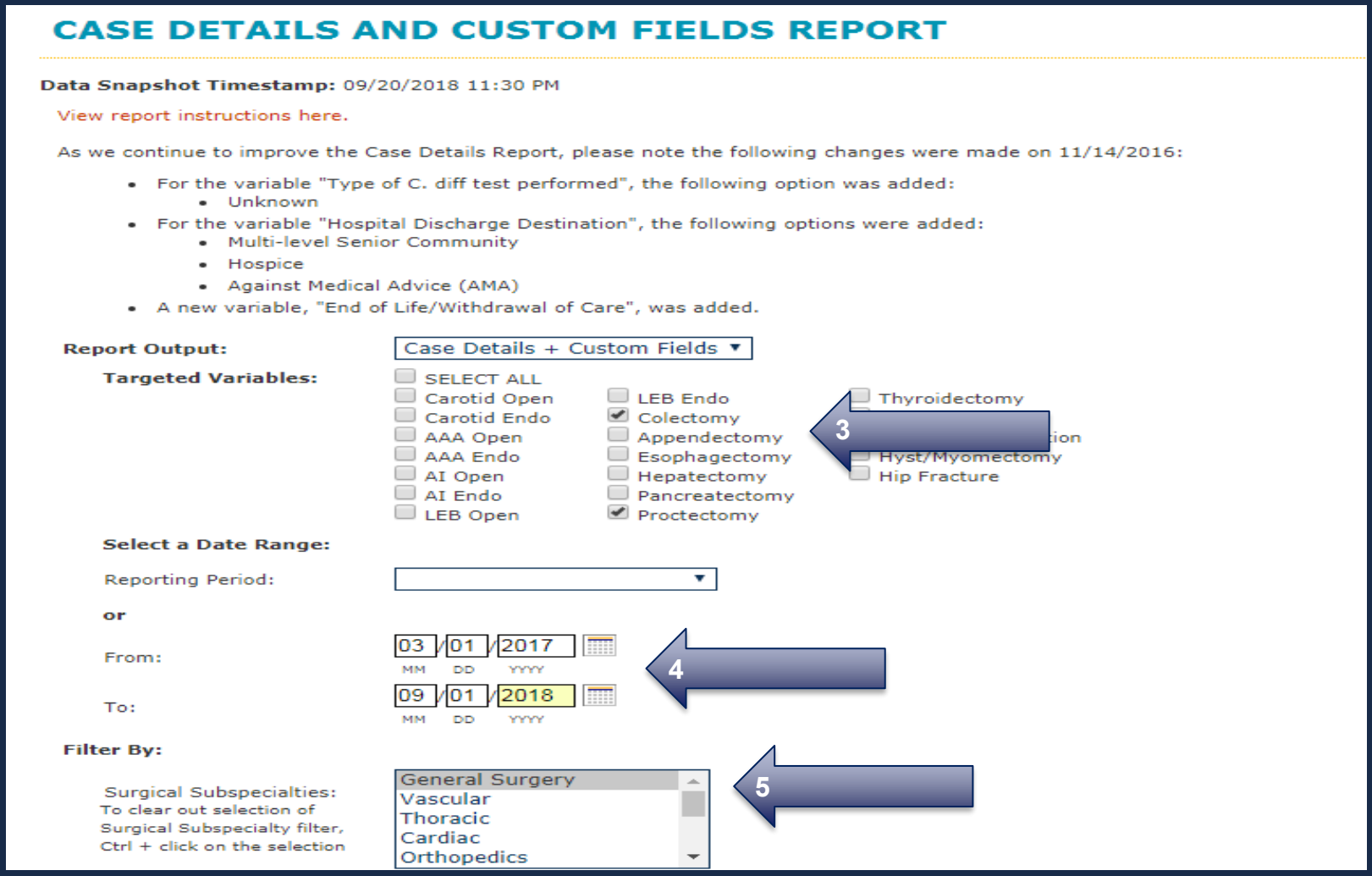
3.) Ensure **Target Variables** for **Colectomy** and **Proctectomy** are selected

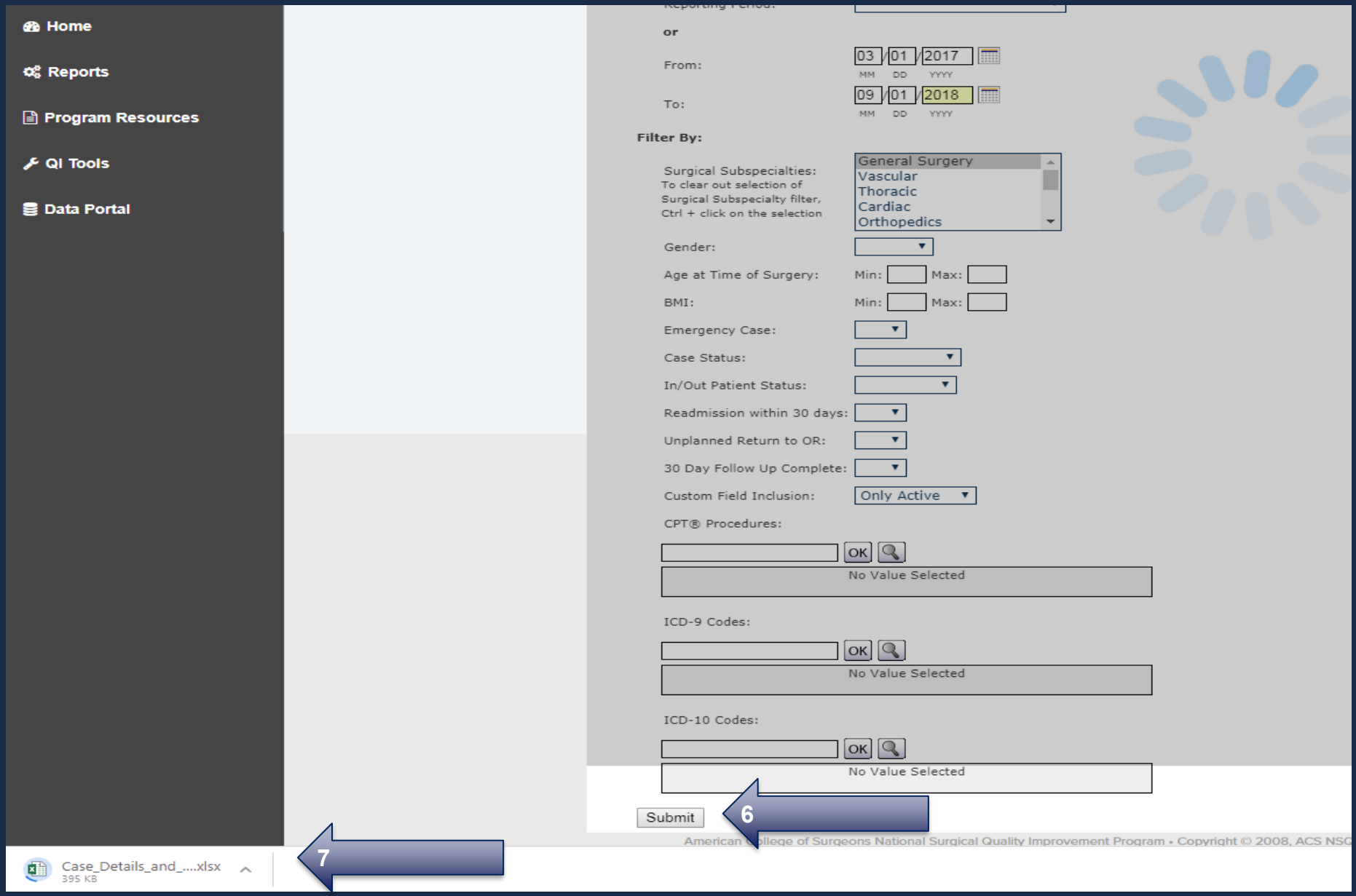
4.) Enter Date Range of interest.

5.) To Narrow Search, Filter to show **General Surgery** Only

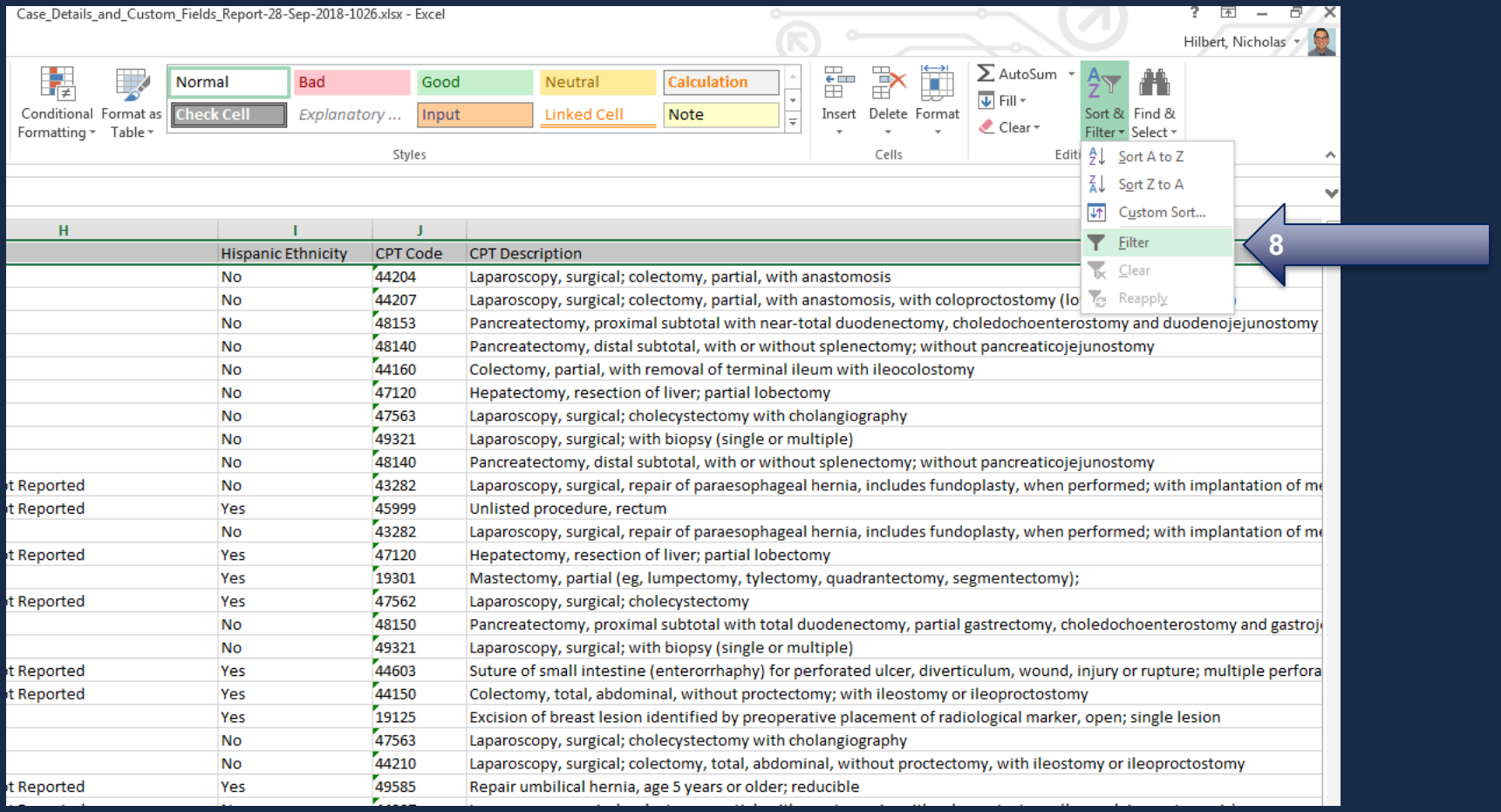


6.) Select **Submit** to download Excel Report

7.) Open Excel File labeled **Case_Details_and_Custom_Fields_Report…**



8.) **Select/Highlight** Very Top Row of Excel *and* enable filtering of data by Selecting **Filter**



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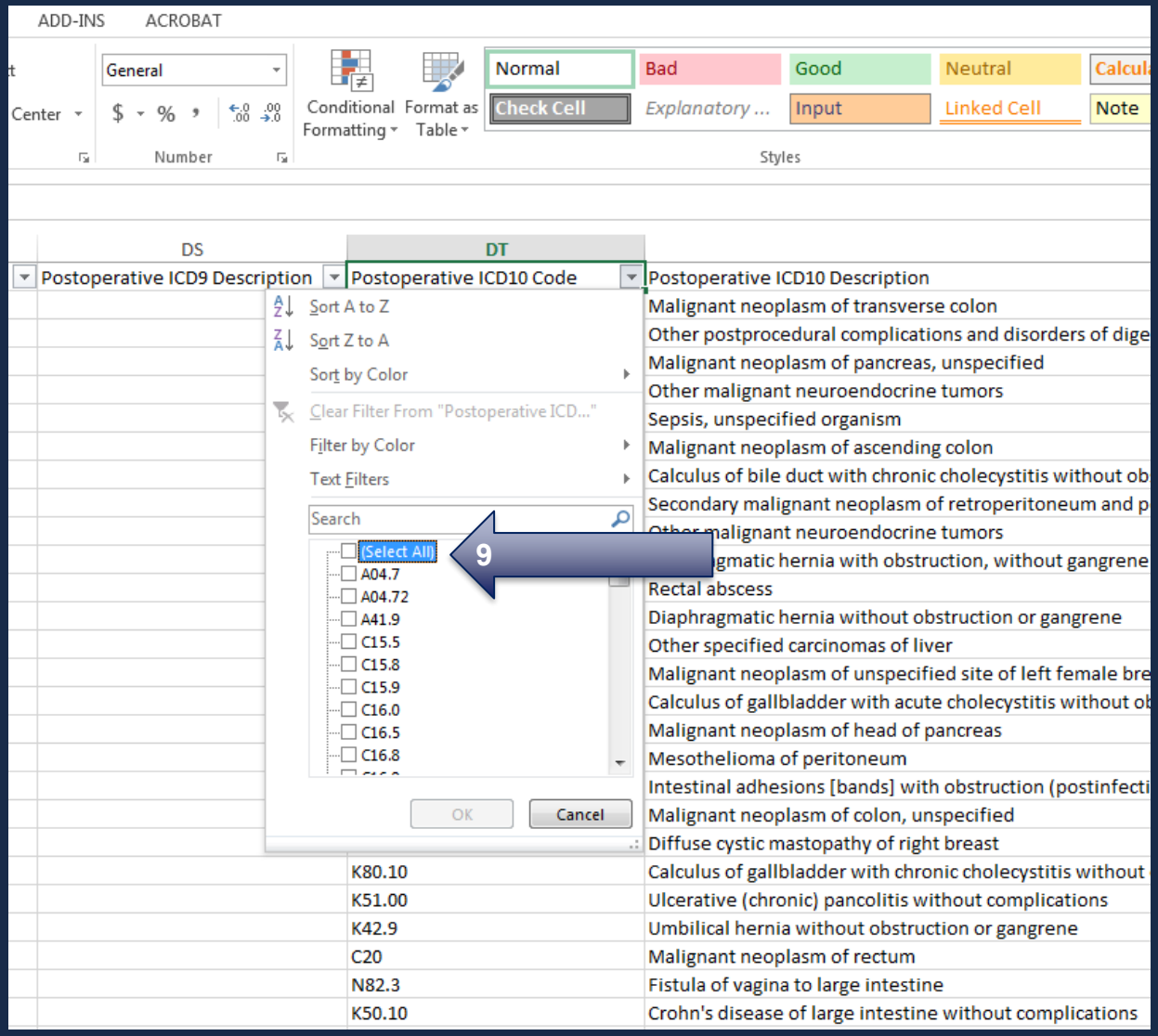
9.) Scroll over to the **Postoperative ICD10 Code and** Uncheck Select All



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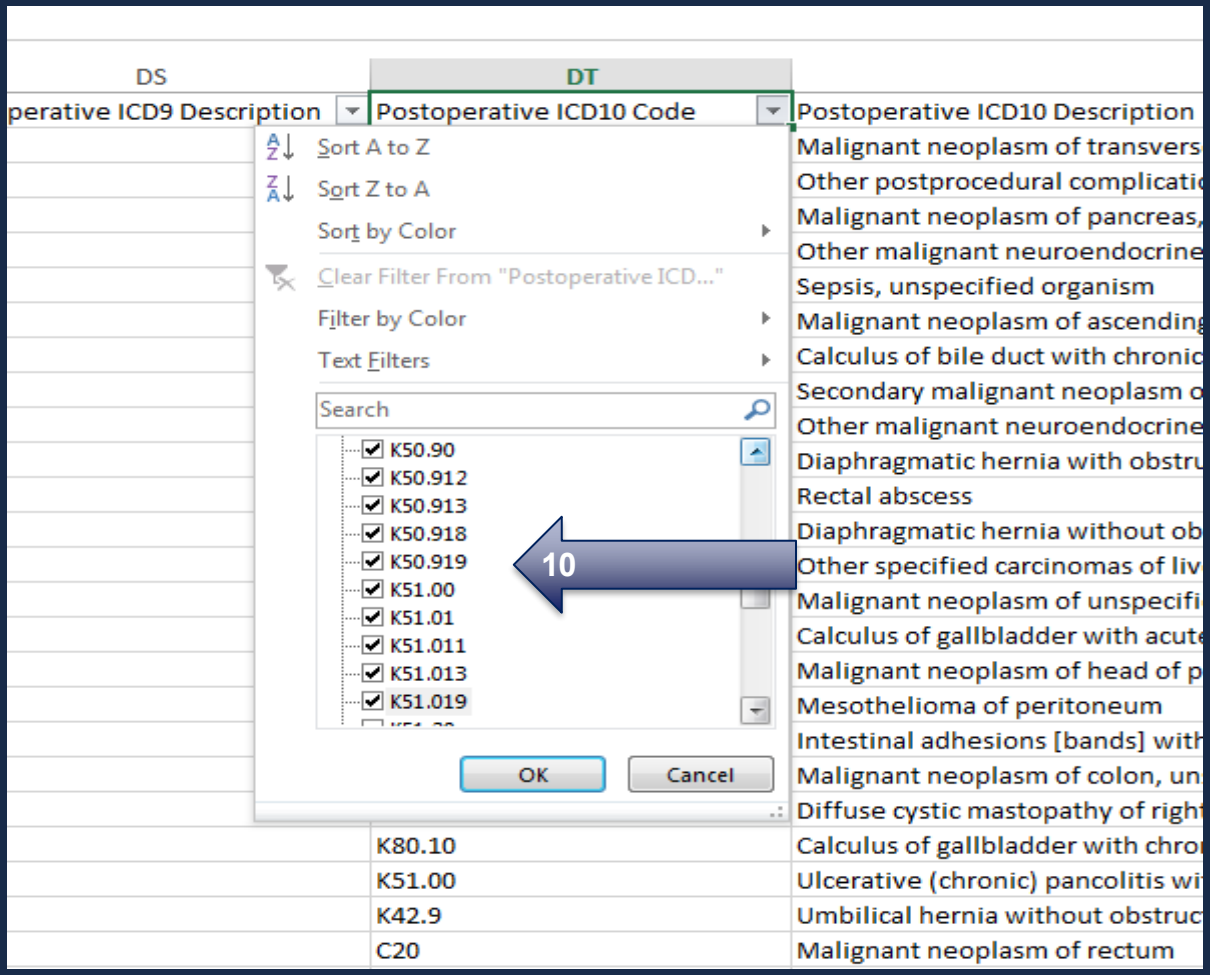
10.) Filter/Select to show only the ICD10 Codes involved in the IBD Collaborative

→ **K50.* (All)**

→ **K51.* (All)**

→ **K52.3**



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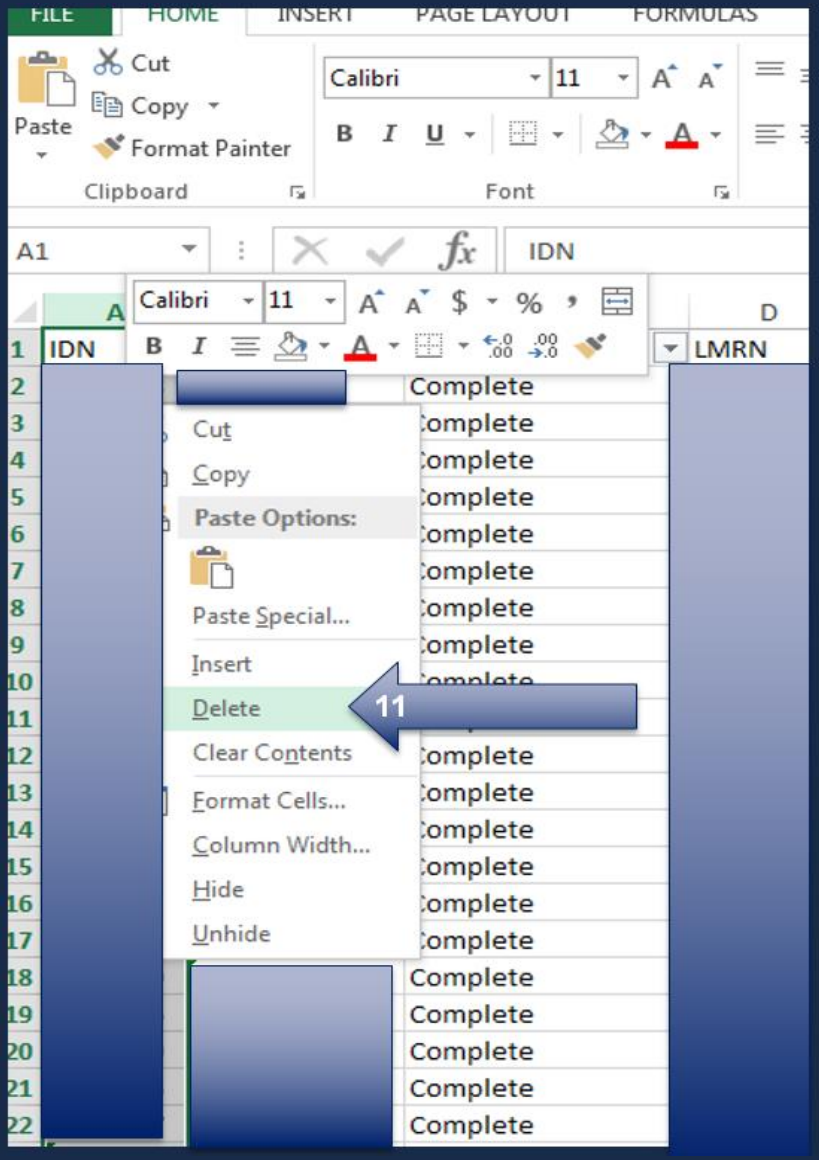
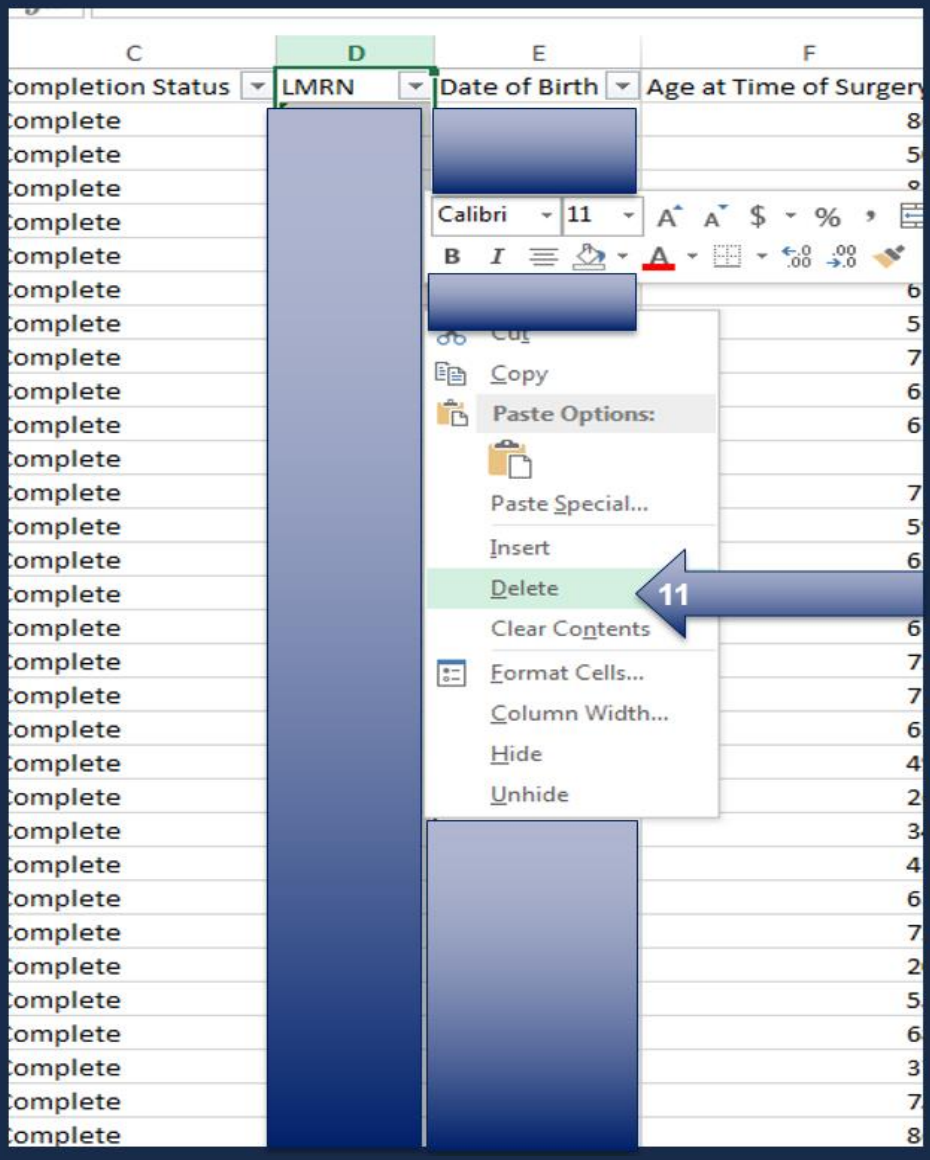
11.) Remove all Patient Identifier Columns (i.e. **IDN Column, LMRN Column, phone, e-mail address, etc.).**





12.) Once all patient identifier columns are removed, save Excel File and send To: **seisenstein@health.ucsd.edu**

Eliminated variables

These have been removed or replaced within the data set

Variables (replaced 9/26/23

- Ileal Pouch Anastomosis (**Mucos**): For an ileal pouch (CPT: 45113, 44158, 44211, 45397) created for ulcerative colitis, please describe the anastomotic technique.

  a. Not applicable : No ileal pouch anastomosis

  b. Double staple: Circular stapler is used to anastomose the ileal pouch to a rectal cuff

  c. Mucosectomy with hand sewing: The mucosal sleeve is dissected out to the top of the anorectal ring and the pouch is sewn to the dentate line

  d. Hand Sewn without mucosectomy: The ileal pouch is sewn by hand to a residual rectal cuff without performing a mucosectomy

  e. Other: Other technique not listed above

#4 Mucos

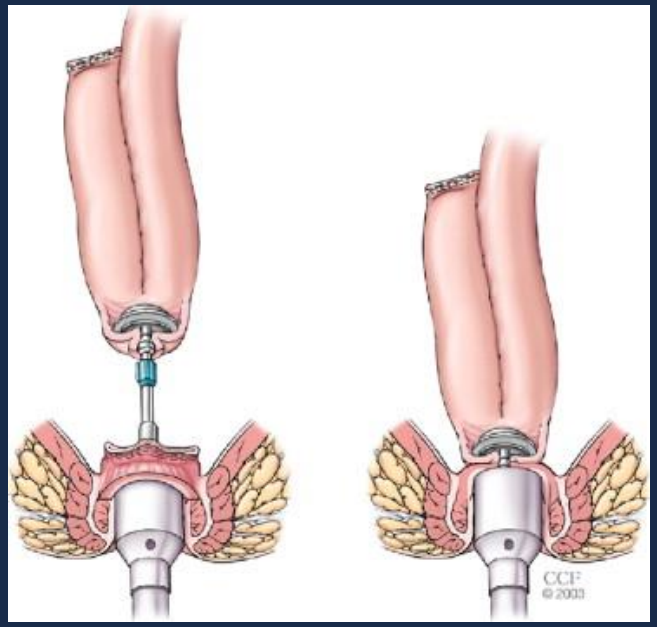
- Purpose: The anastomotic technique for an ileal pouch has been implicated in both functional outcomes and the risk of postoperative complications. This is not currently captured via standard CPT codes.
- Foreseeable issues :
  - This should only be used for patients undergoing IPAA surgery for UC.
    - Only CPT: 45113, 44158, 44211, 45397
    - Not Crohn's disease at this time
- Where to locate this information:
  - Operative report
    - Definitely in the body
    - Often in the list of procedures performed

Key words/phrases

- Stapled:
  - EEA stapler
  - ILS stapler
  - Circular stapler
  - Anvil or spike
  - Rectal Cuff
  - “Surgical Donuts”
- Mucosectomy w/ hand sewn:
  - Mucosal sleeve
  - Elevate mucosa
  - Lonestar device/retractor
  - May often be 2 teams for this technique
  - Pouchotomy

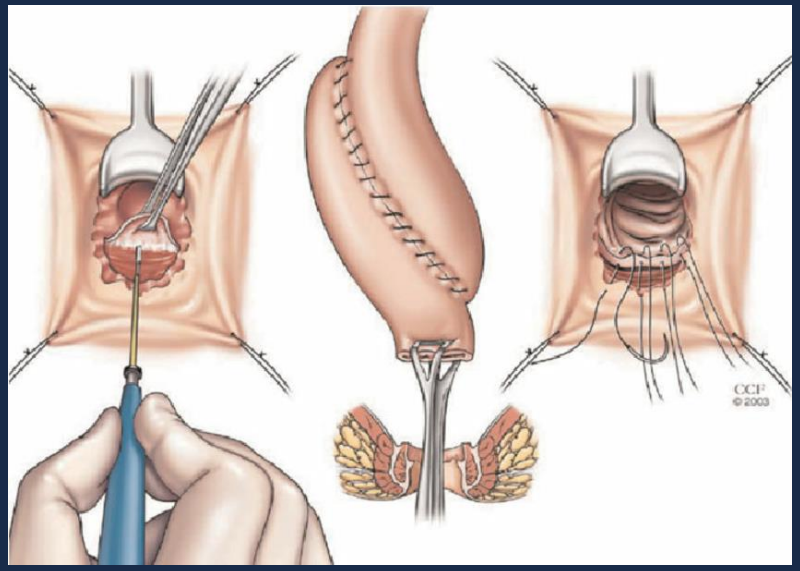
Stapled circular anastomosis – Example from an operative report

- The anus was sequentially dilated using EEA sizers, and an EEA 29 stapler was brought to the level of the rectal cuff staple line. The spike was brought out. It was married to the anvil and the pouch. The pouch was inspected. There was noted to be no twisting, and there was no herniation of bowel underneath the mesentery. All of the small bowel was on the left side of the patient's abdomen. The anvil and the stapler were brought together, fired, and removed. The donuts were inspected and noted to be intact circumferentially.
- EEA is also known as an ILS stapler



Mucosectomy – example from an operative report

- The mucosectomy was begun transanally by placing the lonestar retractor and instilling 0.5% Marcaine with epinephrine circumferentially around the dentate line to elevate the mucosa. The mucosa was incised sharply and the dissection was carried down into the plane between the internal sphincter muscle and the rectal mucosa circumferentially reflecting down the internal sphincter muscle, ensuring that it was not injured. This portion of the procedure was carried up and above the levators in the submucosal plane and once we were up and above the levators, we encountered the abdominal team's dissection plane and the two were joined.



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Hand sewing the anastomosis – Example from an operative report

- We were ultimately able to get the pouch to reach and the most dependent portion of the pouch was grasped. A pouchotomy was created and this was sutured into place at the dentate line with an interrupted 3-0 Vicryl suture. All 4 cardinal points were sutured in using 3-0 Vicryl sutures at the dentate line and we then completed the anastomosis with numerous interrupted 3-0 Vicryl sutures circumferentially.

Variable: DVT Location

1. Deep vein thrombosis Location (DVTLoc): For those patients who developed deep vein thromboses (DVT) postoperatively, where was their DVT located? For patients with DVTs prior to surgery please list as present prior to surgery. If a patient with a DVT prior to surgery develops a new or worsening DVT please also include as present prior to surgery. Please also exclude superficial thrombophlebitis and DVTs below the knee as these do not require therapeutic anticoagulation. Pulmonary Embolus (PE) should be answered separately in the PULMEMBOL question.

1. Not applicable
2. Preoperative DVT present prior to surgery
3. Lower extremity deep venous thrombosis
4. Upper extremity deep venous thrombosis
5. Mesenteric venous thrombosis – including Portal, Inferior and Superior Mesenteric, and Splenic Veins.
6. Cerebral venous sinus
7. More than 1 location of DVT (multiple mesenteric vessels will be considered 1 site)
8. Other location
9. Unable to Determine

DVT Location

- **Importance of variable:** While NSQIP already records a Yes/No on this as well as a PE, it would be helpful to learn the patterns of venous thromboembolus.
- **Key Issue #1:** Which VTEs are important?
  - We can all agree on LE and UE DVT, PE, mesenteric vein thrombosis. Do we care about the specificity of rare DVTs when we're unlikely to see more than a few of them through the course of the study? I looked at a lot of guidelines and there aren't really any thorough recommendations about who to anticoagulate. After talking to the SCRs we expect PE to be picked up in its own section. This will just be for DVTs.
- Where to find this:
  - Discharge Summary
  - Imaging reports
  - Post discharge notes

Variable: 30 Day Bleeding Requiring Transfusion

2. Occurrences Bleeding Transfusions 30 Days(OTHBLEED30): Starting at 72 hours after the procedure ends until 30 days after completion of the surgery, did the patient require a transfusion of at least 1 unit packed red blood cells? Select if a transfusion was given due to bleeding. Examples of indicators which may require a transfusion includes post-operative anemia, wound hematoma, retroperitoneal hematoma, active bleeding from wound or puncture site, upper or lower GI bleeding, or any other bleeding that is deemed clinically relevant.

1. No
2. Yes

30 day bleeding requiring transfusion

- **Importance of Variable:** NSQIP recently changed their bleeding variable to only cover the first 72 hours, so we would need to reintroduce this to ensure our most likely complication was recorded. This is essentially the old variable but it picks up where the current one leaves off.

- Where to find this information
  - Discharge Summary
  - Lab values (often you will see a type and cross around a transfusion)
  - Daily progress notes
  - After discharge – Look for infusion center notes, ED notes, or surgeon's notes

Variable: 30 Day Bleeding Requiring a Secondary Procedure

3. Occurrences Bleeding Intervention 30 Days (BleedInt): Was there an intervention required after surgery for postoperative bleeding or anemia? These procedures may include, but are not limited to: bedside suturing of bleeding, bedside evacuation of hematoma, percutaneous intervention for bleeding, endoscopic intervention for bleeding, reoperation for bleeding, or other interventions.

1. No
2. Yes

30 day bleeding requiring a secondary procedure

- **Importance of Variable:** Helps us to understand the severity of bleeding problems. All bleeding does not necessarily get transfused, so this may help pick up some misses as well.
- **Key Issue #1:** Since these incidents are fairly rare do we care what the specific intervention was or will a yes/no be adequate. This is taken from Vascular surgery NSQIP data set where they currently just look at yes/no, was there a procedure. We will proceed as they do.
- Where to find this
  - Discharge Summary
  - Operative or procedure notes (bedside, endoscopy, IR, OR, etc.)
  - Daily progress notes

Variable: Inpatient DVT Chemoprophylaxis

4. DVT chemoprophylaxis (DVTAgent): Starting 48 hours after surgery is completed, what was the chemoprophylaxis agent primarily used as an inpatient. Please note the medication which the patient received over the most days, however if the patient spent more days without chemoprophylaxis then list none. If patient had preoperative DVT, or were on preoperative anticoagulation for a preexisting condition, including but not limited to: atrial fibrillation, pulmonary embolus, artificial heart valve, or known hypercoagulability syndrome, please answer option "No prophylaxis, already on therapeutic anticoagulation". If the patient was bridged to warfarin with another agent for a condition existing prior to surgery such as those listed above, list "No prophylaxis, already on therapeutic anticoagulation". If the patient developed a DVT postoperatively please list the agent they were on prior to developing the DVT.

1. None
2. Unfractionated Heparin
3. Low Molecular Weight Heparin – including dalteparin, enoxaparin, and tinzaparin
4. Aspirin
5. Platelet inhibitors – including Clopidogrel, Prasugel, ticagrelor, Ticlopidine, others
6. Aspirin and platelet inhibitor
7. Direct Oral Anticoagulants - Including Argatroban, Bivalrudin, Dabigatran, Rivaroxaban, Apixaban, Edoxaban, others
8. Other
9. No prophylaxis, already on therapeutic anticoagulation
10. Unable to Determine

DVT chemoprophylaxis

- **Key Issue #1**: Which drugs do we include?
- We need to ensure anything that could potentially anticoagulated is captured. That includes ASA, Heparin (subQ and therapeutic), LMWH, NOACs, antiplatelet agents, and anything else. Warfarin is generally only used for therapeutic anticoagulation so we can exclude that agent. Most will likely fall into that group, but we need to be careful in selecting this data. Problems here include when patients switch meds during a hospitalization and if they also change meds between inpatient and outpatient settings. This will be for only the inpatient setting.
- **Key Issue #2**: Dosing of the medications?
- This can be quite complex and we opted to limit this to therapeutic vs prophylactic. That will be much easier for the SCRs and it would be a quick question. Otherwise there could be difficulties ensuring the right dosage was given to each patient. Therapeutic dosing is not helpful for this study, so can be omitted in a catch-all answer.

Variable: Discharge DVT Chemoprophylaxis

5. Discharge DVT chemoprophylaxis (DischAgent): Which agent was the patient prescribed after their discharge and up to 30 days postoperatively. If patient was on anticoagulation preoperatively, and discharged on therapeutic anticoagulation, please answer option “No prophylaxis, already on therapeutic anticoagulation”. If their medication was changed after discharge please list the one they spent the most time receiving based on intention to treat.

1. None
2. Unfractionated Heparin
3. Low Molecular Weight Heparin – including dalteparin, enoxaparin, and tinzaparin
4. Aspirin
5. Platelet inhibitors – including Clopidogrel, Prasugel, ticagrelor, Ticlopidine, others
6. Aspirin and platelet inhibitor
7. Direct Oral Anticoagulants - Including Argatroban, Bivalrudin, Dabigatran, Rivaroxaban, Apixaban, Edoxaban, others
8. Other
9. No prophylaxis, already on therapeutic anticoagulation
10. Unable to Determine

Discharge DVT chemoprophylaxis

- This includes the same medications as the prior list and essentially follows the same rules. This does not cover adherence to the regimen, just the medication itself.
- Where to find this
  - Discharge medication reconciliation
  - Post discharge office notes

Variable: Length of Time on Primary DVT Chemoprophylactic

6. Length of time on primary DVT chemoprophylactic agent (DVTMedTime): What day postoperatively did the patient's VTE chemoprophylaxis end? This is documented as postoperative day. Please include the days after discharge if the patient was discharged on chemoprophylaxis and it is clearly documented in post discharge notes, otherwise document the last day they received as an inpatient if not discharged on DVT chemoprophylaxis. If there is no clear documentation in the post discharge notes as to when the patient stopped their anticoagulation, please list the day that their post discharge chemoprophylaxis prescription was to end based on the patient's discharge instructions. If the patient is readmitted after discharge and there was a stoppage of chemoprophylaxis followed by a resumption while in the hospital please list the day the initial stoppage occurred. Please answer "None" if the patient did not start anticoagulation postoperatively and "therapeutic anticoagulation" if the patient was on therapeutic anticoagulation for a DVT or other condition such atrial fibrillation, pulmonary embolus, artificial heart valve, or known hypercoagulability syndrome present prior to surgery. If the patient developed a DVT after surgery please list this answer as the postoperative day that the patient developed their DVT (Should be the same as DOTHDVT answer).

1. None
2. <14 days
3. 14-31 days
4. >31 days
5. Therapeutic anticoagulation
6. Unable to determine

Length of time on primary DVT chemoprophylactic

- **Key Issue #1:** Compliance – this is almost impossible to track based on this study. We have to consider this an intention to treat study and realize that what makes a good chemoprophylactic agent is the ability of the patient to adhere to it after discharge. Those who can remember to ask in their post discharge notes will help to improve the fidelity of the data. We can potentially improve this with PROs, but will need to complete IRB approval prior to starting a subset of patients with PROs.
- **Key Issue #2:** Those that develop DVTs postop. Will list as intention to treat to ensure that these patients are listed in the long term prophylaxis group so as to not bias the results towards long term prophylaxis. For those that develop as in inpatient will list the day they switch from prophylactic to therapeutic as final day.
- Where to find this:
  - Discharge medication reconciliation
  - Postoperative office notes
  - Nursing communications after discharge