

#### EAST MULTICENTER STUDY DATA COLLECTION TOOL

Multicenter Study: Anticoagulation in Emergency General Surgery: Who bleeds more? (ACES Trial)

Enrolling Center:\_\_\_\_\_

Patient Number:\_\_\_\_\_

The following sheets are for annotation. All data will be entered electronically at each site into REDCap for secure/encrypted electronic sharing with the coordinating site.

#### **Demographics (3-53):**

Age\_\_\_\_ Sex\_\_\_\_ Race: White Black Asian Hispanic or Latino Native Hawaiian Other

#### 6-21. Past Medical History (Circle all that apply)

Diabetes Mellitus	Liver disease	AIDS
Chronic Kidney Disease	Atrial Fibrillation	Congestive Heart Failure
Myocardial Infarction	Chronic Pulmonary Disease	Peripheral Vascular disease
Stroke	Dementia	Hemiplegia
Rheumatic or Connective tissue disorder	Peptic Ulcer Disease	Chemotherapy
Cancer		

#### 22. Anti-Coagulant:

Dabigatran Rivaroxaban Apixaban Warfarin

23. Anti-Platelet (Circle all that apply): Aspirin 81mg Aspirin 325mg Clopidogrel Ticagrelor

24-51. Lab values/Pre-operative exam (use worst value prior to index operation): Vital Signs: Tmax: \_\_\_\_\_°C HR: \_\_\_\_ bpm RR: \_\_\_\_\_/min SBP: \_\_\_\_\_mmHg MAP: \_\_\_\_mmHg Glasgow Coma Scale (3-15): \_\_\_\_ Intubated: YES NO

Continuous Vasopressors YES NO If YES, please specify:

WBCx10³/µL	Hgbg/dL	Hct%	Platelet10 <sup>3</sup> / µL
pH	Base Excmmol/L	PT	PTT
INR	Fibrinogen	Creatininemg/dL	Bilirubinmg/ dL
Lactate mmol/L			

#### Thromboelastogram (TEG):

R Time	K Time	Alpha Angle	Max	Lysis @30 Min
min	min	degrees	Amplitude	%
			mm	

#### ROTEM:

CT seconds	CFTseco	onds	Alpha Angle degrees	MCF mm	A10 mm
LI30 %	ML %				

#### 52. Indication for operation (Circle One):

Obstruction	Hernia	Ischemia
Diverticulitis	Infectious Colitis	Pancreatitis
Appendicitis	Cholecystitis	Bleeding
Intestinal Arterial Ischemia of Bowel	Peptic Ulcer disease (gastric or duodenal)	Other

53. AAST Organ-Specific EGS Grade (Circle One): I II III IV V N/A

### Management Variables (54-76)

*54-55. Pre-operative Variables* Date and Time of last dose of anticoagulant/antiplatelet Date: \_\_\_/\_\_/ Time: \_\_\_\_ If unknown time: AM or PM

 Date and Time in OR

 Date:
 /\_\_\_/

 Time:
 \_\_\_\_\_

### 56. Type of reversal products administered prior to start of index operation (Circle all that apply):

Tranexamic acid	Fresh Frozen Plasma
Prothrombin complex concentrate	Factor 7
Platelets	Vitamin K
Idarucizumab	Andexanet Alfa
Other	

### 57. Time to administration of targeted reversal agent prior to start of the index operation:

Dabigatran/Pradaxa→ Idarucizumab	Date and Time administered
	Date:// Time:
Rivaroxaban/Xarelto or Apixaban	Date and Time administered
Eliquis→ Andexanet Alfa	Date:// Time:
Warfarin/Coumadin→ Fresh Frozen	Date and Time administered
Plasma	Date:// Time:
$\rightarrow$ Vitamin K	Date and Time administered
	Date:// Time:
Clopridogrel/Plavix or	Date and Time administered
ticagrelor/Brilinta $\rightarrow$ Platelets	Date:// Time:

#### 58-59. Intra-Operative Variables (index operation):

Length of index operation: \_\_\_\_\_minutes

#### Surgical approach (Circle One):

#### 60-65. Total Intra-op blood products/Fluid given:

PRBCunits	FFPunits	Plateletspacks
Cryounits	Non-blood ColloidmL	CrystaloidmL

#### 66. Estimated Blood Loss: \_\_\_\_mL

#### 67. Intra-operative reversal agents (Circle all that apply):

Tranexamic acid	Fresh Frozen Plasma
Prothrombin complex concentrate	Factor 7
1	
Distalata	Other
Platelets	Other
Idarucizumab	Andexanet Alfa
Taur deizannae	i indexanet i ind
Other	

#### 68. Intra-operative hemostatic agents used (Circle all that apply):

Surgicel	Combat Gauze	Nu-Knit	Thrombin gel/spray
Other			

#### 69. World Health Organization 5 point bleeding scale (circle one): 0 1 2 3 4

# 70-72. Intra-operative physiology:YESNOHypotension (single measurement of SBP <90mmHg):</td>YESNOVasopressor therapy (IV infusion at any time intra-op):YESNOHypothermia (single body temperature recording <36°C):</td>YESNO

## 73-76. Damage control/open abdomen (proceed to Outcomes if fascia closed at index operation):

Indication for open abdomen (circle best that applies):

Coagulopathy	Contamination burden	Shock
Abdominal Compartment syndrome	Second look	Other

Total number of operations prior to fascia	l/mesh/sk	in closure (i	ndex operation =1)
Primary fascial closure achieved:	YES	NO	
Skin closed at time of fascial closure:	YES	NO	

#### **Outcomes (77-106):**

#### 77-87. Intra-abdominal complication (Check all that apply, include post-operative day)

Intra-abdominal abscess (organ-	Post-operative day diagnosed
space)	
Superficial surgical site infection	Post-operative day diagnosed
Deep-incisional surgical site	Post-operative day diagnosed
infection	
Enteric fistula	Post-operative day diagnosed
Fascial dehiscence	Post-operative day diagnosed
Intra-abdominal hematoma	Post-operative day diagnosed
Superficial hematoma	Post-operative day diagnosed
Deep-incisional hematoma	Post-operative day diagnosed

Need for unplanned operative intervention for one or more of the above (*Circle one*): YES NO Need for placement of a percutaneous drain for one or more of the above (*Circle one*): YES NO Need for ultrasound guided aspiration for one or more of the above (*Circle one*): YES NO

88-94. Other Complications (circle all that apply):

Acute Renal Failure	ARDS	Deep Vein	Transfusion
		Thrombosis	Reaction
Myocardial	Stroke	Pulmonary	
Infarction		Embolism	

### 95-98. Post-operative blood products (administered within 72 hours of index operation):

PRBCunits	FFPunits	Plateletspacks
Cryounits	Other	

#### 99. Post-operative reversal agents given (circle all that apply):

Tranexamic acid	Fresh Frozen Plasma
Prothrombin complex concentrate	Factor 7
Platelets	Other

#### 100-102. Other Post-operative variables:

DVT prophylaxis started:

Therapeutic anticoagulation started:

Antiplatelet therapy

### *103-104. Discharge Parameters:* Hospital LOS:

ICU LOS:

Hospital day \_\_\_\_\_

Hospital day \_\_\_\_\_

Hospital day \_\_\_\_\_

\_\_\_\_Days

\_\_\_\_Days

#### 105-106. Disposition (Circle one):

Home	Acute Rehab	Skilled nursing facility	Hospice
Against medical advice	Morgue		

If Morgue, indicate the primary cause of death as indicated on the death certificate: \_\_\_\_\_



#### EAST MULTICENTER STUDY DATA DICTIONARY

Anticoagulation in EGS (ACES TRIAL) – Data Dictionary

Data Entry Points and appropriate definitions / clarifications:

1. Enrolling center	A de-identifying letter assigned by the PI to each site
2. Patient number	A de-identifying number assigned by each site to each
	patient

#### Demographics

<b>3.</b> A	Age	Age of the patient enrolled in the study
4. 5	Sex	Sex of the patient enrolled in the study
<b>5.</b> F	Race	Race of the patient enrolled in the study

#### Past Medical History: Select all that apply

i det med i en	
6. Diabetes Mellitus	Includes all patients with diabetes treated with insulin or oral hypoglycemic agents, but not diet alone. End organ-damage includes retinopathy, neuropathy, nephropathy, or brittle diabetes. Select NO if patient is controlled with diet-modification alone. Diabetes during pregnancy alone should not be counted
7. Liver disease	Mild disease includes chronic hepatitis (B or C) or cirrhosis without portal hypertension. Moderate disease consists of cirrhosis with portal hypertension, but without bleeding. Severe disease consists of patients with ascites, chronic jaundice, portal hypertension, a history of variceal bleeding, or those with prior liver transplant.
8. AIDS	Acquired immune deficiency syndrome includes patients with definite or probable AIDS. Does not include those who are HIV positive, asymptomatic, and well-managed with medical therapy
9. Chronic kidney disease	Baseline elevation of serum creatinine ≥3.0 mg/dL, need for outpatient hemodialysis, or prior renal transplant.
<b>10.</b> Congestive heart failure	Heart failure in which the heart is unable to maintain adequate circulation of blood in the bodily tissues or to pump out the venous blood returned. This includes patients who have had exertional or paroxysmal nocturnal dyspnea and who have responded symptomatically (or on physical examination) to digitalis, diuretics, or afterload reducing agents. Additionally, chest x-ray showing pulmonary vascular redistribution would qualify.
11. Myocardial infarction	Documented history of a myocardial infarction. Should not be based solely on EGK changes

<b>12.</b> Chronic pulmonary disease	Chronic pulmonary disease includes patients with asthma, chronic bronchitis, emphysema, and other chronic lung disease who have ongoing symptoms such as dyspnea or cough with mild or moderate activity. This includes patients who are dyspneic with slight activity, with or without treatment and those who are dyspneic with moderate activity despite treatment, as well as patients who are dyspneic at rest, despite treatment, those who require constant oxygen, those with CO2 retention, and those with a baseline PO2 below 50 Torr.
<b>13.</b> Peripheral vascular disease	Peripheral vascular disease includes patients with intermittent claudication or those who had a bypass for arterial insufficiency, those with gangrene or acute arterial insufficiency, and those with a treated or untreated aortic aneurysm (6 cm or larger).
14. Stroke	Stroke includes patients with a documented history of an intracerebral hemorrhage or thrombus. Transient ischemia attacks should be included in this population
15. Dementia	Dementia includes patients with moderate to severe chronic cognitive deficit resulting in impaired function from any cause.
16. Hemiplegia	Hemiplegia includes patients who have documented weakness or paralysis after stroke or transient ischemic attack
<b>17.</b> Rheumatic or Connective tissue disorder	Rheumatologic disease includes patients with systemic lupus erythematous, polymyositis, mixed connective tissue disease, rheumatoid arthritis, polymyositis, polymyalgia rheumatic, vasculitis, sarcoidosis, Sjögrens syndrome, or any other systemic vasculitis.
<b>18.</b> Peptic ulcer disease	Peptic ulcer disease includes patients who have required treatment for ulcer disease, including those who have bled from peptic ulcers
<b>19.</b> Cancer	Lymphoma includes patients with Hodgkins, lymphosarcoma, Waldenstrom's macroglobulinemia, myeloma, and other lymphomas. Leukemia includes patients with acute and chronic myelogenous leukemia, acute and chronic lymphocytic leukemia, and polycythemia vera. Solid tumor consists of patients with solid tumors including breast, colon, lung, prostate, melanoma, stomach, etc. Specify which solid tumor the patient had. Indicate whether the patient had a metastatic solid tumor
20. Chemotherapy	Pt enrolled is currently receiving chemotherapy
<b>21.</b> Atrial fibrillation	An abnormal, irregular heart rhythm in which electrical signals are generated chaotically throughout the atria.
22. Anticoagulant use	The current use of Dabigatran/Pradaxa, Rivaroxaban/Xarelto, Apixaban/Eliquis for any cause. The current use of warfarin/Coumadin at any goal INR
23. Anti-platelet use	The current use of aspirin (specify dose), Clopidogrel/Plavix, or ticagrelor/Brilinta for any cause. Circle all that apply

Lab values/Pre-operative exam: (Use worst value prior to index operation)

24. Vital signs	Indicate TMAX (° C), heart rate (HR; beats/minute),

	respiratory rate (RR; respirations/minute), systolic
	blood pressure (SBP; mmHg), and mean arterial
	pressure (MAP; mmHg)
25. Glasgow coma scale	Numerical value for Glasgow Coma Scale (3-15).
26. Continuous vasopressor infusion	Select YES if the patient required a continuous
·	vasopressor infusion to maintain a target mean arterial
	pressure. Include the use of any of the following
	agents: noreninenhrine, vasopressin, donamine
	dobutamine neosynenbrine milrinone eninenbrine
	Indicate which agent(s) was used
	Numerical which ageni(s) was used.
	/uL)
<b>28.</b> Hgb	Numerical value for hemoglobin (g/dL)
<b>29.</b> Hct	Numerical value for hematocrit (%)
<b>30.</b> Platelet count	Numerical value for platelet count (x103 /µL).
<b>31.</b> pH	Numerical value for arteria blood pH. If no pH was
•	obtained enter 999- do not enter 0
32. Base excess	Enter the numerical value for the arterial base excess
	(mmol/l) If no base excess was obtained enter 999-
	do not enter 0
22 Logisto	Numerical value for leastete (mmal/L). If no Leastete was
<b>33.</b> Laciale	Numerical value for lactate (mmor/L). If no Lactate was
04 DT	Obtained, enter 999 – do not enter o.
	Numerical value for prothrombin time
35. PTI	Numerical value for partial thromooplastin time
<b>36.</b> INR	Numerical value for International Normalized Ratio
	(INR)
37. Fibrinogen	Numerical value for fibrinogen. If no fibrinogen was
	obtained, enter 999- do not enter 0
38. Creatinine	Numerical value for creatinine (mg/dL); enter 999 if
	patient is receiving preoperative renal replacement
	therapy.
<b>39.</b> Bilirubin	Numerical value for bilirubin (mg/dL). If no bilirubin was
	obtained, enter 999- do not enter 0
<b>40</b> . R Time	Enter the numerical value for the R time (min) from the
	thromboelastogram (TEG). If no TEG was obtained
	enter 999- do not enter 0
11 K Timo	Enter the numerical value for the K time (min) from the
41. K 1111e	threm be least array (TEO) If no TEO was abtained
	thromboelastogram (IEG). If no IEG was obtained,
	enter 999- do not enter 0
<b>42.</b> Alpha angle	Enter the numerical value for the alpha angle (degrees)
	from the thromboelastogram (TEG). If no TEG was
	obtained, enter 999- do not enter 0.
43. Max amplitude	Enter the numerical value for the max amplitude (mm)
·····	from the thromboelastogram (TEG). If no TEG was
	obtained enter 999- do not enter 0
11 Lycis at 30 minutes	Enter the numerical value for the lysis at 30 minutes
	(0) from the thrembed betagram (TEC). If no TEC was
	(%) nom the thromboelastogram (TEG). If no TEG was
	obtained, enter 999- do not enter U
45. OT	
<b>45.</b> CT	Enter the numerical value for the clotting time
<b>45.</b> CT	(seconds) from the ROTEM If no ROTEM was
<b>45.</b> CT	(seconds) from the ROTEM If no ROTEM was obtained enter 999, do not enter 0
<b>45.</b> CT <b>46.</b> CFT	(seconds) from the ROTEM If no ROTEM was obtained enter 999, do not enter 0 Enter the numerical value for the clot formation time
45. CT 46. CFT	(seconds) from the ROTEM If no ROTEM was obtained enter 999, do not enter 0 Enter the numerical value for the clot formation time (seconds) from the ROTME. If no ROTEM was
45. CT 46. CFT	<ul> <li>Enter the numerical value for the clotting time (seconds) from the ROTEM If no ROTEM was obtained enter 999, do not enter 0</li> <li>Enter the numerical value for the clot formation time (seconds) from the ROTME. If no ROTEM was obtained enter 999, do not enter 0</li> </ul>
45. CT 46. CFT	<ul> <li>Enter the numerical value for the clotting time (seconds) from the ROTEM If no ROTEM was obtained enter 999, do not enter 0</li> <li>Enter the numerical value for the clot formation time (seconds) from the ROTME. If no ROTEM was obtained enter 999, do not enter 0</li> <li>Enter the numerical value for the clobe angle (mm)</li> </ul>

	from the ROTEM If no ROTEM was obtained enter
	999, do not enter 0
48. MCF	Enter the numerical value for the max clot firmness (mm) from the ROTEM If no ROTEM was obtained enter 999, do not enter 0
<b>49.</b> A10	Enter the numerical value for the amplitude 10 minute after clot time (mm) from the ROTEM If no ROTEM was obtained enter 999, do not enter 0
<b>50.</b> LI30	Enter the numerical value for the lysis index 30 minutes after clotting time (%) from the ROTEM. If no ROTEM was obtained enter 999, do not enter 0
51. ML	Enter the numerical value for the maximum lysis (%) from the ROTEM. If no ROTEM was obtained enter 999, do not enter 0.

#### Indication for operation

<b>52.</b> Diagnosis	Single choice for best description of diagnosis. Choose from: obstruction, hernia, ischemia, diverticulitis, infectious colitis, pancreatitis, appendicitis, cholecystitis, bleeding, intestinal arterial ischemia of bowel, peptic ulcer disease, other. Please specify "other"
<b>53.</b> AAST Organ-Specific EGS Grade for Anatomic Severity of Disease	For diagnoses of diverticulitis, obstruction, ischemic bowel, hernia, infectious colitis, appendicitis, pancreatitis, cholecystitis, intestinal arterial ischemia of the bowel, or peptic ulcer disease indicate the AAST grade. Please specify grade based on operative findings as outlined below.

Grade	AAST Disease Grade Description	Intestinal obstruction (Small and large bowel)	Ischemic Bowel	Diverticulitis
I	Disease confined to the organ with minimal abnormality	Partial obstruction	Ischemia without tissue loss	Colonic inflammation
II	Confined to the organ with severe abnormality	Complete obstruction without bowel ischemia	Ischemia with mucosal ulceration only- no transmural infarction	Colon microperforation or pericolic phlegmon without abscess
III	Local extension beyond the organ	Complete obstruction, bowel ischemic but viable	Segmental transmural infarction without perforation	Localized pericolic abscess
IV	Regional extension beyond the organ	Complete obstruction with gangrenous bowel OR perforation with local spillage	Segmental transmural infarction with perforation	Distant abscesses
V	Widespread extension beyond the organ	Perforation with diffuse peritoneal contamination	Pan-intestinal infarction	Free colonic perforation with generalized peritonitis

Grade	Hernia (Internal or Abdominal Wall)	Pancreatitis	Infectious Colitis	Appendicitis
1	Reducible	Acute edematous pancreatitis	Mucosal disease with positive cultures or other	Acutely inflamed appendix, intact

					confirmatory		
II	Incarcerated without bowel ischemia		Phlegmon OR peripancratic fluid collection or hemorrhage		Localized colon thickening by radiographic imaging OR pseudomembra on endoscopy	wall nes	Gangrenous appendix, intact
111	Incarcerated with bowel ischemia but viable		Sterile necrosis		Colon wall thickening with ascites OR diffu colonic dilation diffuse coalescin pseudomembra	ise OR ng nes	Perforated appendix with local contamination
IV	Incarcerated with gangrenous bowel OR perforation with local spillage		Infected necrosis or abscess		Localized colon necrosis with or without perforat or abscess	ic ion	Perforated appendix with periappendiceal phlegmon or abscess
V	Incarcerated with perforation and diffuse peritoneal contamination		Extrapancreatic extension of necrosis involving adjacent organs, such as colonic necrosis		Diffuse transmu colonic necrosis or without perforation or abscess	ral with	Perforated appendix with generalized peritonitis
Grade	Intestinal Arterial Ischemia of the Bowel	Cholecystitis		Perfora Ulcer D or Duod	ted Peptic isease (Gastric denal)		
I	Bowel ischemia without tissue loss	Acute cholecystitis		Micrope peritonit	rforation without		
11	Bowel ischemia with mucosal ulceration only, without transmural infarction	Gallbladder empyema or gangrenous cholecystitis or emphysematous cholecystitis		Contain with loca	ed perforation alized peritonitis		
III	Segmental transmural bowel infarction without perforation	Gallbladder perforation with local contamination		Perforat localized localized in lesse	ion with d peritonitis and d fluid collection r sac or RUQ		
IV	Segmental transmural bowel infarction with perforation	Gallbladder perforation with pericholecystitic abscess or gastrointestinal fistula		Free pe peritonit	rforation with is		
V	Pan-intestinal infarction	Gallb with g perito	Gallbladder perforation with generalized peritonitis		ion with al destruction etration into t organs and zed peritonitis		

#### Management Variables Pre-Operative Variables

54. Date and time of last documented dose of	Enter the date and time of the patients last recorded
anticoagulant/antiplatelet	administration of anticoagulant/antiplatelet. If an
	approximate time is unknown document if it was taken
	in the AM or PM. If no time line is known enter "999"
	under Time. DD/MM/YY

<b>55.</b> Date and time in OR	Enter the date and time the patient arrived in the OR DD/MM/YY
<b>56.</b> Type of reversal products administered before OR	Select all reversal agents that were administered before the patient went to the operating room. If no reversal agents given, enter "none" under other
<b>57.</b> Time to administration of targeted reversal agent prior to start of index operation	Enter the date and time that the targeted reversal agent was first administered. If this is unknown or they did not receive a targeted reversal agent, enter "999"

#### Intra-Operative Variables

58. Length of operation	Enter in minutes the duration of the operation
59. Surgical approach	Select one: Open, Laparoscopic, Laparoscopic
	converted to Open

### **OR Blood Products/Fluids administered:** How many units or mL of each of the following did the patient receive intraoperatively

60. PRBC	Numerical value for the units of packed red blood cells transfused
61. FFP	Numerical value for the units of fresh frozen plasma transfused
62. Platelets	Numerical value for the packs of platelets transfused
<b>63.</b> Cryo	Numerical value for the units of cryoprecipitate transfused
64. Non-blood colloid	Numerical value for non-blood colloid transfused (albumin, hespan, hextend, other colloid; mL)
65. Crystalloid	Numerical value for all crystalloid administered
66. Estimated blood loss	Numerical value for the total amount of blood loss in the operating room (mL)
67. Reversal products administered intra-op	Select all reversal agents that were administered before the patient went to the operating room. If no reversal agents given, enter "none" under other
68. Hemostatic products used intra-op	Select all hemostatic agents that were used during the operative procedure. If no agents were used enter "none" under other
<b>69.</b> World Health Organization 5 point bleeding scale	Indicate the WHO bleeding scale based on the operative findings as outlined below

Grade	
0	No blood loss
1	Petechial bleeding- spontaneous hematoma in skin or soft tissue, positive stool occult blood test
2	Mild blood loss- melanotic stool, hematemesis, visible blood in body cavity fluid, bleeding at invasive sites
3	Gross blood loss- bleeding requiring red blood cell transfusion over routine transfusion needs, bleeding associated with moderate hemodynamic instability
4	Debilitating blood loss – bleeding associated with severe hemodynamic instability, fatal bleeding

#### Intra-operative physiology: Indicate whether the following criteria were met at any time intra-operatively

70. Hypotension	Select YES if there was at least one episode of SBP <
	90mmHg
<b>71.</b> Vasopressor therapy	Select YES if any of the following agents were used as
	continuous infusions: norepinephrine, vasopressin,

	dopamine, dobutamine, neosynephrine, milrinone, epinephrine
72. Hypothermia	Select YES if the patient's body temperature was below
	36.0°C for at least one recorded time point

#### Damage control/open abdomen: Proceed to outcomes if fascia closed at index operation

<b>73.</b> Indication for open abdomen	Select based on operative note documentation: coagulopathy, contamination burden, shock, abdominal compartment syndrome, to facilitate a second look (ie- early re-exploration for bowel viability), other. Please specify if OTHER is chosen
<b>74.</b> Total number of surgical operations	Total number of surgical operations until closure achieved. Index operation = 1. Do not include procedures done by radiologists or interventional radiologists
<b>75.</b> Primary fascial closure	Select YES if primary fascial closure was achieved during the hospital course
76. Skin closed at time of fascial closure	Select YEST if skin was closed at the time of fascial closure

#### Outcomes

**Intra-abdominal complications:** Check all that apply and document the post-operative day that the complication first occurred

77. Intra-abdominal abscess	Infection occurs within 30 days of the operation if no implant is left in place or within 1 year if implant is in place and involves any part of the body deeper than the fascial/muscle layers, that is opened or manipulated during the operative procedure, and patient has at least one of the following: 1. Purulent drainage from a drain that is placed into the organ/space. (e.g., closed suction drainage system, open drain, T-tube drain, CT guided drain) 2. Organisms are identified from an aseptically- obtained fluid or tissue in the organ/space by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment 3. An abscess or other evidence of infection involving the organ/space detected on gross anatomical or radiographic examination. May be diagnosed through a combination of clinical indicators such as pain or peritonitis and biochemical markers such as fever or tachycardia WITH either intraoperative findings OR radiologic studies showing fluid collections or gas-containing collections
<ul><li>78. Superficial surgical site infection</li><li>79. Doop incicional surgical site infection</li></ul>	Infection occurs within 30 days of the operation and involves only skin and subcutaneous tissue of the incision with at least one of the following: 1. Purulent drainage from the incision 2. Organisms isolated from an aseptically obtained fluid culture or tissue from the superficial incision 3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture negative.
19. Deep-incisional surgical site intection	Infection occurs within 30 days of the operation if no

	implant is left in place or within 1 year if implant is in place and infection appears to be related to the operation. Infection involves deep soft tissues (fascial and muscle layers) of the incision with at least one of the following: 1. Purulent drainage from deep incision but not from the organ/space component of the surgical site 2. A deep incision spontaneously dehisces or is deliberately opened when the patient has at least one of the following signs or symptoms: fever (body temperature >380 C), localized pain or tenderness 3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation or radiographic examination
<b>80.</b> Enteric fistula	Enterocutaneous or entero-atmospheric fistula: Clinical diagnosis, defined as free communication between the skin or outside surface of an open abdomen and any portion of the GI tract.
81. Fascial dehiscence	Separation of the surgical wound at the level of the fascia. May be clinically OR radiographically diagnosed.
82. Intra-abdominal hematoma	Bleeding within the abdominal cavity occurring within 30 days of the operation or other procedure involving the abdomen (ie- drain placement, paracentesis).
83. Superficial hematoma	Bleeding that occurs at the site of the operation and involves only the layers of the skin
84. Deep-incisional hematoma	Bleeding that occurs at the site of the operation and involves the deep soft tissue (fascial and muscle layers) of the incision.
85. Need for unplanned operative intervention	Select YES if the patient required unplanned re-operative intervention for one of these complications (77-84).
<b>86.</b> Need for placement of a percutaneous drain	Select YES if the patient required unplanned placement of a percutaneous drain for one of these complications (77- 84).
87. Need for ultrasound guided aspiration	Select YES if the patient required unplanned ultrasound guided aspiration for one of these complications (77-84).
Other Complications: Select all that apply	
88. Acute renal failure	Post-operative elevation of serum creatinine ≥ 2.0 mg/dL in a patient without antecedent renal dysfunction OR acute need for renal replacement therapy.
89. Acute respiratory distress syndrome	Mild ARDS: The PaO <sub>2</sub> /FiO <sub>2</sub> is > 200 mmHg, but $\leq$ 300 mmHg, on a ventilator with a positive end-expiratory pressure (PEEP) or continuous positive airway pressure $\geq$ 5 cm H <sub>2</sub> O. Moderate ARDS: The PaO <sub>2</sub> / FiO <sub>2</sub> is > 100 mmHg, but $\leq$ 200 mmHg, on a ventilator with a PEEP $\geq$ 5 cm H <sub>2</sub> O. Severe ARDS: The PaO <sub>2</sub> / FiO <sub>2</sub> is $\leq$ 100 mmHg on a ventilator with a PEEP $\geq$ 5 cm H <sub>2</sub> O. Presence of one or more thrombi in the deep veins. Can
	Tresence of one of more unofficition in the deep vehills. Call

include upper or lower extremity as diagnosed by

Indicate if the patient had a documented blood transfusion

Detection of a rise of cardiac biomarker values (preferably

troponin) with at least one of the following: - Symptoms of ischemia - New or presumed new significant ST-segment changes or new left bundle branch block - New Q waves

ultrasound or CT scan

reaction

**91.** Transfusion reaction

92. Myocardial infarction

	in the EKG - Imaging evidence of new loss of viable
	myocardium or new regional wall motion abnormality - Identification of intracoronary thrombus
<b>93.</b> Stroke	Confirmed stroke (hemorrhagic or thrombotic) confirmed by MRI or CT scan
94. Pulmonary embolism	Evidence of a clot within the pulmonary system and confirmed with imaging (i.e CT, V/Q scan)

Post-Operative Variables Post-operative blood products: How many units or mL of each of the following did the patient receive within 72 hours of the index operation

95. PRBC	Numerical value for the units of packed red blood cells transfused
96. FFP	Numerical value for the units of fresh frozen plasma transfused
97. Platelets	Numerical value for the packs of platelets transfused
<b>98.</b> Cryo	Numerical value for the units of cryoprecipitate transfused
<b>99.</b> Reversal agent administered post-operatively	Select all reversal agents that were administered before the patient went to the operating room. If no reversal agents given, enter "none" under other
<b>100.</b> DVT prophylaxis	Indicate the day from index operation that DVT prophylaxis was started. Enter 999 if DVT prophylaxis was not started or the patient was placed on therapeutic anticoagulation
<b>101.</b> Therapeutic anticoagulation	Indicate the day from index operation that therapeutic anticoagulation was started. Enter 999 if the patient was not placed on therapeutic anticoagulation was not
<b>102.</b> Antiplatelet therapy	Indicate the day from index operation that antiplatelet therapy was started. Enter 999 if antiplatelet therapy was not started

**Discharge parameters:** Note: for calculation of days, refer to day of admission as hospital day number 1. (ICU = Intensive Care Unit, LOS = length of stay)

103. Hospital LOS	Free text entry for number of consecutive hospitalized days
104. ICU LOS	Free text entry of number of consecutive days spent in ICU.
<b>105.</b> Discharge Disposition	Select from the following: home, acute care facility, skilled nursing facility, other healthcare facility, hospice, left against medical advice, deceased.
<b>106.</b> If morgue, indicate cause of death	If the patient's discharge disposition was morgue, free text the primary cause of death as indicated on the death certificate