By selecting Parkland as a study site, you acknowledge that you must obtain prior performance site approval from Parkland before beginning research at Parkland. The performance site approval is complete in Velos. More information about the performance site approval process can be found [here](#).

**Site Activities**: *(select all that apply)*

- Recruitment: [ ]
- Procedures: [ ]
- Resources: [ ]

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<th>Active: [ ]</th>
<th>ID: 3</th>
<th>Sort Order: 55</th>
<th>Is Umbrella Site: [ ]</th>
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<td><strong>Velos Code</strong>: 181</td>
<td><strong>Institution</strong>: Parkland Health &amp; Hospital System</td>
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EAST MULTICENTER STUDY
DATA COLLECTION TOOL

Multicenter Study: Primary Repair versus Resection for AAST Grade I and II Colon Injuries: Does the Type of Repair Really Matter?

Site ID: __________________________
Enrolling Center: __________________________
Enrolling Co-investigator: __________________________

Demographics:

Admission date: ______  Patient number: ______  Age: ______  Gender: ______  Race: ______
BMI: ______

Pre-hospital comorbidities (check all that apply):

Hypertension: ______
Diabetes mellitus: ______
   ______ If yes, type (insulin dependent, non-insulin dependent, unsure)
Peripheral vascular disease: ______
Coronary artery disease: ______
Current smoker: ______
Alcohol abuse: ______
Substance abuse: ______
CVA: ______
COPD: ______
Cirrhosis: ______
Chronic kidney disease: ______
ESRD: ______
Current steroid use: ______
Current chemotherapy: ______
HIV/AIDS: ______

Admission Physiology:

HR: ______  ED SBP: ______  ED MAP: ______  ED RR: ______  ED Temp: ______  ED GCS (total): ______
Intubated (Y/N): ______  ISS: ______  AIS Abdomen: ______

Mechanism of injury (check one):

Blunt: ______
MVC: ______
MCC: ______
Fall: ______
Assault: ______
Ped vs. auto: _____
Other: _____

Penetrating:
GSW: _____
Stab: _____
Other: _____

Admission Labs:

Operative Variables:
Time to OR > 6 hours (Y/N): _____ AAST grade of colon injury (I or II): _____
Location of colon injury: ____________________ Fecal contamination (mild, moderate, severe): ____________
Mechanism of repair (primary or resection with anastomosis): ___________________
_________ If resection, stapled or handsewn?
Open abdomen (Y/N): _____ Total # abdominal surgeries: _____

Other intra-abdominal injuries (check all that apply):
Small bowel: _____
Stomach: _____
Pancreas: _____
Diaphragm: _____
Liver: _____
Spleen: _____
Gallbladder: _____
Kidney: _____
Bladder: _____
Other: _____

MTP activation (Y/N): _____ Total # PRBCs 1st 24 hours: _____ Total # FFP 1st 24 hours: _____
Total # platelets 1st 24 hours: _____ Total # cryo 1st 24 hours: _____ TXA (Y/N): _____
Antibiotic prophylaxis (single vs combination): ______________
Names of antibiotic(s): ______________

Outcomes:
Hospital LOS: _____ ICU LOS: _____ Ventilator days: _____

Hospital Disposition (check one):
Home: _____
LTAC: _____
SNF: _____
Inpatient rehab: _____
Morgue: _____
Other: _____

30-Day Mortality (Y/N): ___
Complications: (check all that apply)
MI: _____
ARDS: _____
Sepsis: _____
SSI: _____ If yes, superficial, deep, or organ space?
UTI: _____
Bacteremia: _____
Pneumonia: _____
Anastomotic leak: _____
Fascial dehiscence: _____
ECF development: _____
Unplanned trip to the OR: _____ If yes, operation performed?
Unplanned ICU admission: _____ If yes, reason?
## Standard Study Questions

<table>
<thead>
<tr>
<th>Entry space</th>
<th>Definition / Instructions</th>
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<tbody>
<tr>
<td>Site ID</td>
<td>Each site’s assigned number</td>
</tr>
<tr>
<td>Enrolling Center</td>
<td>Name of institution where patient was treated</td>
</tr>
<tr>
<td>Enrolling Co-Investigator</td>
<td>Name of investigator entering in patient data</td>
</tr>
</tbody>
</table>

## Demographics

<table>
<thead>
<tr>
<th>Entry space</th>
<th>Definition / Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admission Date</td>
<td>Date of hospital admission</td>
</tr>
<tr>
<td>Record Number</td>
<td>6-digit number starting with site ID (2-001, 2-002 etc.)</td>
</tr>
<tr>
<td>Age</td>
<td>Age of patient enrolled in years</td>
</tr>
<tr>
<td>Gender</td>
<td>Gender of patient enrolled</td>
</tr>
<tr>
<td>Race</td>
<td>Racial categories (per NIH standards)</td>
</tr>
<tr>
<td></td>
<td>American Indian or Alaskan Native</td>
</tr>
<tr>
<td></td>
<td>Asian</td>
</tr>
<tr>
<td></td>
<td>Black or African American</td>
</tr>
<tr>
<td></td>
<td>Native Hawaiian or Other Pacific Islander</td>
</tr>
<tr>
<td></td>
<td>White</td>
</tr>
<tr>
<td>BMI</td>
<td>Body mass index, calculated from height and weight (kg/cm²)</td>
</tr>
</tbody>
</table>

## Pre-hospital comorbidities (check all that apply)

<table>
<thead>
<tr>
<th>Entry space</th>
<th>Definition / Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>Abnormally high blood pressure</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>A long-term metabolic disorder characterized by high blood sugar, insulin resistance, and relative lack of insulin</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>A circulation disorder characterized by narrowing or blockage of blood vessels</td>
</tr>
</tbody>
</table>
Coronary artery disease
An impedance or blockage of one or more blood vessels that supplies blood to the heart

Current smoker
If patient is an active smoker at the time of initial presentation, check yes

Alcohol abuse
A pattern of drinking that results in harm to one’s health, interpersonal relationships, or ability to work

Substance abuse
The harmful or hazardous use of psychoactive substances, including illicit drugs

CVA
Impaired blood flow to the brain due to an artery blockage or rupture that leads to the death of brain cells caused by lack of oxygen

COPD
Long-term lung disorder that results in pulmonary compromise

Cirrhosis
Moderate to severe liver disease and dysfunction that has associated findings such as portal hypertension, ascites, encephalopathy, or variceal disease

Chronic kidney disease
Moderate to severe kidney disease defined as a decreased GFR

ESRD
End-stage renal disease requiring dialysis

Current steroid use
Current use of any steroid medication at the time of admission

Current chemotherapy
Currently on chemotherapy for any reason at the time of admission

HIV/AIDS
Human immunodeficiency virus (HIV) damages the immune system and can progress to acquired immunodeficiency syndrome (AIDS) which eventually leads to immune system failure

Admission Physiology

ED HR
First heart rate at time of presentation (BPM)

ED SBP
First systolic blood pressure at time of presentation (mmHg)

ED MAP
First mean arterial pressure at time of presentation (mmHg)

ED RR
First respiratory rate at time of presentation

ED temp
First temperature at time of presentation (Celsius)

Intubated
Patient was intubated by pre-hospital providers or required intubation in the emergency department

ISS
Injury severity score, numerical value

AIS abdomen
Abbreviated injury score, numerical value for abdominal region

Mechanism of Injury (check one)

Blunt
Single choice for best description of blunt mechanism. Options include:
MVC
Peds (pedestrian) vs. auto
Fall
Assault
MCC (Motorcycle Collision / Crash)
Other

Penetrating Single choice for best description of penetrating mechanism. Options include:

GSW (gunshot wound)
Stab
Other

Admission Labs

Hgb First hemoglobin (g/dL)
Hct First hematocrit (%)
pH First pH value (arterial preferred, venous acceptable if no arterial value available)
Base deficit First base deficit on an arterial blood gas (mEq/L)
Lactate First lactate (mmol/L)

Operative Variables

Time to OR > 6 hours Check yes if patient was taken to the operating room more than 6 hours after time of presentation
AAST grade of colon injury (I or II) Defined by the AAST Injury Scoring Scale
I: Hematoma- contusion or hematoma without devascularization
II: Laceration- partial thickness, no perforation
II: Laceration- laceration <50% of circumference

Location of colon injury List location of colon injury. Options include:
Cecum
Ascending colon
Hepatic flexure
Transverse colon
Splenic flexure
Descending colon
Sigmoid colon

Fecal contamination Found in the operative report, defined as mild, moderate, or severe

Mechanism of repair Primary repair (suture repair) or resection with anastomosis. If patient underwent resection with anastomosis, please note if they had a handsewn anastomosis or a stapled anastomosis

Open abdomen Temporary abdominal closure after initial trauma laparotomy

Total # abdominal surgeries Total number of intra-abdominal operations the patient underwent throughout their hospitalization
Other intra-abdominal injuries (check all that apply)

- Small bowel: Associated small bowel injury
- Stomach: Associated gastric injury
- Pancreas: Associated pancreatic injury
- Diaphragm: Associated diaphragmatic injury
- Liver: Associated liver injury
- Spleen: Associated splenic injury
- Gallbladder: Associated injury to the gallbladder
- Kidney: Associated renal injury
- Bladder: Associated bladder injury
- Other

MTP activation: Check yes if the massive transfusion protocol was initiated

- Total # PRBCs in 1st 24 hours: Total units of packed red blood cells given within 1st 24 hours of patient’s hospital course
- Total # FFP in 1st 24 hours: Total units of fresh frozen plasma given within 1st 24 hours of patient’s hospital course
- Total # platelets in 1st 24 hours: Total units of platelets given within 1st 24 hours of patient’s hospital course
- Total # cryo in 1st 24 hours: Total units of cryoprecipitate given within 1st 24 hours of patient’s hospital course
- TXA: Check yes if tranexamic acid was given
- Antibiotic prophylaxis: Antibiotics given at the start of the initial trauma laparotomy. Single drug therapy versus combination therapy with more than one agent
- Names of antibiotics: List the name(s) of the antibiotics given for prophylaxis in the operating room

Outcomes

- Hospital LOS: Free text entry for number of consecutive days patient hospitalized at initial admission (Day of admission = hospital day #1)
- ICU LOS: Free text entry for number of days patient required admission to the intensive care unit (Day of admission = hospital day #1)
- Ventilator days: Free text entry for number of days patient required mechanical ventilation (Day of admission = hospital day #1)

Hospital disposition: Select disposition of patient. Options include:
- Home
- Long term acute care facility
- Skilled nursing facility
- Inpatient rehabilitation facility
- Morgue
- Other
30-Day mortality  
Check if patient expired within 30 days after discharge

**Complications (check all that apply)**

**MI**  
Detection of a rise of cardiac biomarker values (preferably troponin) with at least one of the following: symptoms of ischemia, new or presume new significant ST-segment changes or new left bundle branch block, development of pathological Q waves in the EKG, imaging evidence of new loss of viable myocardium or new regional wall motion abnormality, identification of an intracoronary thrombus by angiography or autopsy

**ARDS**  
Defined as occurring within 1 week of a known clinical insult or new or worsening respiratory symptoms. Must have new bilateral opacities, edema not explained by a cardiac source, and impaired oxygenation defined as mild 200 mmHg < PaO2/FiO2 < 300 mmHg with PEEP or CPPA >=5 H2O, moderate 100 mmHg < PaO2/FiO2 < 200 mmHg with PEEP > 5 cm H2O, severe PaO2/FiO2 < 100 mmHg with PEEP or CPAP > 5 cm H2O

**Sepsis**  
Check if sepsis is documented during a patient’s hospital course  
Severe sepsis: sepsis with associated organ dysfunction  
Septic shock: sepsis with hypotension or hypoperfusion despite fluid resuscitation

**SSI**  
Defined as an infection occurring at the site of surgery within 30 days of the operation  
Superficial surgical site infection: infection occurring in the skin where the incision was made  
Deep surgical site infection: infection occurring in the tissue beneath the skin including the muscle and subcutaneous fat  
Organ space infection: infection in a body organ or in a space between organs

**UTI**  
Patient must have one of the following: positive urine culture that is >= 10⁵ microorganisms/mL of urine with no more than two species of microorganisms, or urine culture with 10 wbc/hpf

**Bacteremia**  
Defined as two positive blood cultures that were drawn simultaneously

**Pneumonia**  
Check if pneumonia reported during a patient’s hospital course. Confirmed by the presence of the following after 48 hours of hospitalization:  
- Purulent sputum  
- Associated systemic evidence of infection, WBC > 11,000 or < 4,000, fever > 100.4 degrees F / 38 degrees Celsius  
- Two or more serial chest radiographs with new or progressive and persistent infiltrate, consolidation, or cavitation  
- BAL with quantitative culture > 100,000 cfu/mL

**Anastomotic leak**  
Development of a defect of the intestinal wall at the anastomotic site (including suture line or staple line) leading to a communication between the intra and extraluminal compartments
<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fascial dehiscence</td>
<td>Separation of the fascial closure of an abdominal wound with the exposure of intraabdominal contents to the external environment</td>
</tr>
<tr>
<td>ECF development</td>
<td>Aberrant connection between the intra-abdominal tract and the skin</td>
</tr>
<tr>
<td>Unplanned trip to the OR</td>
<td>Patient taken back to the operating room for an unplanned reason. Free text operation(s) performed. Exclude pre-planned, staged, or procedures due to incidental findings</td>
</tr>
<tr>
<td>Unplanned ICU admission</td>
<td>Patient admitted to the intensive care unit for an unplanned reason or a decompensation. Free text reason for admission</td>
</tr>
</tbody>
</table>