

3/9/18

Case Report Forms

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General Instructions:

- Enter all dates in **MM/DD/YY** format. Enter all times in **HH:MM** using 24hr clock format.
- Print additional form pages if needed. Label additional form pages using a decimal point followed by sequential numbers. (Example: Page 5.01, 5.02)
- Use the following codes in data fields with unknown values:

NA = Not Applicable (e-CRF Code – 995)	ND = Not Detectable (e-CRF Code – 996)	NK = Unknown (e-CRF Code – 997)
NP = Not Palpable (e-CRF Code – 998)	NR = Not Recorded/Not Done (e-CRF Code – 999)	

Form 1: Verification of Eligibility/Screening & Demographics

Inclusion Criteria: *(To be eligible, all questions must be answered "YES")*

- | | | |
|---|------------------------------|-----------------------------|
| 1. Age (Est. ≥ 16 yr.) | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Evidence of sustained high mechanism blunt abdominal trauma* | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Abdominal CT scan performed prior to surgical intervention | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 4. Radiographic suspicion of bowel or mesenteric injury | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 5. Admitted to adult trauma service | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Exclusion Criteria: *(To be eligible, all questions must be answered "NO")*

- | | | |
|--|------------------------------|-----------------------------|
| 1. <u>Prisoners, defined as those who have been directly admitted from a correctional facility</u> | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
|--|------------------------------|-----------------------------|

***High Mechanism of Injuries include: MVC, MCC, ATV, bicycle, and auto-pedestrian**

Form 2: Emergency Department Information

1. Injury date/time known: Date: ___/___/___ Time: ___:___
 (mm/dd/yy) (24hr Clock in hh:mm)
 Estimated Yes No Unknown/Not Available

2. ED Arrival: Date: ___/___/___ Time: ___:___ **(TIME ZERO)**
 (mm/dd/yy) (24hr Clock in hh:mm)

3. First available vital signs & GCS obtained upon arrival to ED:

Blood Pressure (mmHg)		Pulse (beats/min)	Respiratory Rate (breaths/min)
Systolic	Diastolic		
_____	_____	_____	_____
	Palpable	Palpable	
	Yes / No	Yes / No	

GCS		Height	Weight	BMI
Record Component Scores / GCS Total Score		(cm)	(kg)	
E: ___ V: ___ M: ___	_____	_____	_____	_____
<input type="checkbox"/> Not Recorded				

3. Mechanism of Injury:

- Blunt Injury** (Select all that apply)
- MVC – Motorcycle MVC
 - MVC – Bicycle Bicycle
 - MVC – Pedestrian ATV
 - Motorcycle

4. Admission FAST done? Yes No

Results: Positive Negative Equivocal

If positive, select area: Abdominal Cardiac Both

5. Admission Labs (as obtained per Standard of Care guidelines)

Hemoglobin (g/dL): _____
 WBC: _____
 Bands: _____
 Base Deficit: _____
 Lactic Acid: _____

6. Abdominal Physical Exam Findings (check all that apply):

- peritonitis
- tender to palpation
- abdominal seat belt sign
- normal exam
- other

7. Emergency Department Disposition:

Date and Time of decision for abdominal operation:

Date: ___/___/___ Time: ___:___

Time patient departed the ED: ___:___

Location patient transferred to:

- OR (Proceed to form 6 to complete OR information)
- Hybrid OR (Proceed to form 6 to complete OR information)
- IR
- ICU
- IMU
- Floor
- COU
- PACU
- Morgue
- Other _____

Form 3: Operating Room Information

Date & time of arrival to OR: ___/___/___ : ___:___

Abdominal Operation: (Check type)

- Diagnostic Laparoscopy
- Exploratory Laparotomy
- Dx Lap converted to Open

Reason for operation: (Check all that apply)

- Failed trial of initial non-operative management
- Peritonitis
- Suspicion for BBMI on CT scan
- Abdominal operation for other injury (not bowel or mesentery)
- Repeat CT scan findings
- Other Define: _____

Operative Procedure

- Repair
- Resection with anastomosis
- Resection with anastomosis and protective stoma
- Resection and left in discontinuity
- Closure of mesenteric injury
- Ligation of mesenteric vessel
- Resection with stoma

**If a procedure is checked above, subject is considered as "+BBMI group"

No intervention on bowel or mesentery - if this procedure is checked, subject is considered as "No BBMI group"

Operative Findings

- Ischemic bowel Location - small bowel or colon
- Full thickness perforation Location - small bowel or colon
- Serosal tear > 50% circumference Location - small bowel or colon
- Serosal tear < 50% circumference Location - small bowel or colon
- Mesenteric injury - full thickness
- Mesenteric injury - partial thickness
- Actively bleeding mesenteric vessel

Was the fascia closed at the index operation? Yes No

If no, what additional procedures were performed? _____

Was the skin closed? Yes No

Form 4: Outcome Data (Initial Hospitalization through discharge)

Demographic Information:

a. Gender: Male Female Unknown

b. Age _____ Unknown ↓

If age is unknown, select the age group that best describes the subjects.

- Less than 15 years of age 15 to 19
 20 to 34 35 to 49
 50 to 65 > 65 years of age

c. Ethnicity: Not Hispanic or Latino Hispanic or Latino Unknown

d. Race: (Check all that apply)

- White American Indian/Alaskan Native/Aboriginal
 Asian Black/African American
 Native Hawaiian/other Pacific Islander
 Other (Specify): _____
 Not Noted/Unknown

Date of hospital discharge: ____/____/____ Remains Hospitalized on Day 30
(mm/dd/yy)

Total (cumulative) number of ICU days: ____

Total (cumulative) number of hospital days: ____

Bowel Injury Predictive Score (BIPS)

- WBC ≥17 Yes No
CT Scan grade of bowel and mesenteric injury = 4 Yes No
Abdominal Tenderness Yes No

Total Score (1 point for each “yes”) _____

Subject discharged to? (Select one)

- Home Long Term Care Facility Skilled Nursing Facility
 Rehabilitation Facility Hospice Acute Care Hospital
 Other, specify: _____ Morgue

Did patient die? Yes No

a. Date of Death: ___ / ___ / ___

b. Time of Death: ___ : ___

c. Cause of Death: (Check ALL that apply)

- Exsanguination / Hemorrhagic Shock
- Traumatic Brain Injury (TBI)
- Respiratory Failure
- Sepsis/Multiple Organ Failure (MOF)
- Cardiovascular Event
- Pulmonary Embolism
- Other, (Specify): _____
- Unknown

d. Was patient comfort care status at time of death? Yes No

Form 5: Complications Check here if there are NO Complications to report.
 (Record any of the following complications that occurred during the subject's hospitalization. Print additional pages as needed.)

COD	Complication	COD	Complication
1	Unplanned return to OR/IR	13	Septic Shock
2	Acute Kidney Injury (AKI)	14	Pneumonia (PNUI)
3	Acute Respiratory Distress Syndrome (ARDS)	15	Ventilator Associated Pneumonia (VAP)
4	Abdominal Compartment Syndrome (ACS)	16	Mesenteric Thrombosis
5	Open Abdominal Complications	17	Myocardial Infarction (MI)
6	Fascial dehiscence	18	Stroke or Cerebral Infarction
7	Enteric fistula	19	Deep Vein Thrombosis (DVT)
8	Bacteremia	20	Pulmonary Embolus
9	Surgical Site Infection (SSI)	21	Other (specify)
10	Urinary Tract Infection (UTI)		
11	Multiple Organ Failure (MOF)		
12	Sepsis		

↓

Code	Start Date (mm/dd/yy)	Stop Date (mm/dd/yy)	
	/ /	/ /	<input type="checkbox"/> Ongoing <input type="checkbox"/> Not Noted/Unknown
	/ /	/ /	<input type="checkbox"/> Ongoing <input type="checkbox"/> Not Noted/Unknown
	/ /	/ /	<input type="checkbox"/> Ongoing <input type="checkbox"/> Not Noted/Unknown
	/ /	/ /	<input type="checkbox"/> Ongoing <input type="checkbox"/> Not Noted/Unknown
	/ /	/ /	<input type="checkbox"/> Ongoing <input type="checkbox"/> Not Noted/Unknown
	/ /	/ /	<input type="checkbox"/> Ongoing <input type="checkbox"/> Not Noted/Unknown
	/ /	/ /	<input type="checkbox"/> Ongoing <input type="checkbox"/> Not Noted/Unknown

Refer to "Definitions of Complications Reported" in manual of operations for more information.

Site P.I. Name: _____	Signature: _____
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Form 6: Radiographic Review (Retrospective)

Admission CT scan

1. CT scan date and time ____/____/____ ____:____

2. CT scan protocol:

- No contrast
- IV only
- IV + PO

3. CT Scan findings of BHVI:

- Isolated mesenteric hematoma
- Isolated mesenteric contusion
- Grade 4 (mesenteric contusion or hematoma with associated bowel wall thickening or adjacent interloop injury)
- Active vascular or oral contrast extravasation or pneumoperitoneum

- Free peritoneal fluid

Form 7: Trauma Registry Data Form

1. Was subject data entered into the trauma registry? Yes No

2. Abbreviated Injury Scale (AIS) Score: **Check here** if the AIS Score was not noted/unknown.

ANATOMIC REGION	Head/ Neck	Abdomen
Score		

3. Injury Severity Score (ISS): __ __ **Check here** if the ISS Score was not noted/unknown.

4. Injuries

Record the **first** 15 discharge diagnostic and procedure codes below.

Discharge Diagnostic Codes (<i>xxx.xx format</i>)	
(1) _____ . _____	(8) _____ . _____
(2) _____ . _____	(10) _____ . _____
(3) _____ . _____	(11) _____ . _____
(4) _____ . _____	(12) _____ . _____
(5) _____ . _____	(13) _____ . _____
(6) _____ . _____	(14) _____ . _____
(7) _____ . _____	(15) _____ . _____
(8) _____ . _____	