This is to certify that the amendment to the research proposal entitled:
Small Bowel Perforation after Blunt Abdominal Trauma: Diagnosis, Morbidity, and Mortality

Submitted by: Samir Fakhry
Department: SURGERY DIVISION LEADS - MUSC

for consideration has been reviewed by IRB-II - Medical University of South Carolina and approved with respect to the study of human subjects as adequately protecting the rights and welfare of individuals involved, employing adequate methods of securing informed consent from these individuals and not involving undue risk in the light of potential benefits to be derived therefrom. No IRB member who has a conflicting interest was involved in the review or approval of this amendment, except to provide information as requested by the IRB. If this amendment required a change in the currently approved Informed Consent, then all previous Informed Consent documents should be marked obsolete.

Approval Date: 5/24/2016

Amendment Type: Expedited

Chair IRB II,
Susan Sonne, Pharm D

Electronic Signature: This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.
Amendment Approval of Full Board or Expedited Research

6/3/2016

Institutional Review Board for Human Research (IRB)
Office of Research Integrity (ORI)
Medical University of South Carolina

Harborview Office Tower
19 Hagood Ave., Suite 601, MSC857
Charleston, SC 29425-8570
Federal Wide Assurance # 1888

APPROVAL: Protocol: MS2_Pro00052179
MUSC Amendment #: Ame2_Pro00052179
Amendment Title: Amendment 2 for IRB Study #Pro00052179- Clarify Trauma Activation for Controls & number

This is to certify that the amendment to the research proposal entitled:
Small Bowel Perforation after Blunt Abdominal Trauma: Diagnosis, Morbidity, and Mortality

Submitted by: Samir Fakhry
Department: SURGERY DIVISION LEADS - MUSC

for consideration has been reviewed by IRB-II - Medical University of South Carolina and approved with respect to the study of human subjects as adequately protecting the rights and welfare of individuals involved, employing adequate methods of securing informed consent from these individuals and not involving undue risk in the light of potential benefits to be derived therefrom. No IRB member who has a conflicting interest was involved in the review or approval of this amendment, except to provide information as requested by the IRB. If this amendment required a change in the currently approved Informed Consent, then all previous Informed Consent documents should be marked obsolete.

Approval Date: 6/1/2016

Amendment Type: Expedited

Chair IRB II,
Susan Sonne, Pharm D

*Electronic Signature: This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*
Institutional Review Board for Human Research (IRB)
Office of Research Integrity (ORI)
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APPROVAL:
This is to certify that the research proposal Pro00052179 entitled:
Small Bowel Perforation after Blunt Abdominal Trauma: Diagnosis, Morbidity, and Mortality
Submitted by: Samir Fakhry
Department: SURGERY DIVISION LEADS - MUSC

For consideration has been reviewed by IRB-II - Medical University of South Carolina and approved with respect to the study of human subjects as adequately protecting the rights and welfare of the individuals involved, employing adequately methods of securing informed consent from these individuals and not involving undue risk in the light of potential benefits to be derived therefrom. Additionally, the Institutional Review Board for Human Research (IRB) recommends approval of the investigator's request for Waiver of Consent pursuant to 45 CFR 46.116(d) because the research involves no more than minimal risk to the subject, the waiver will not adversely affect the rights and welfare of the subjects, and the research could not be practicably carried out without the waiver. The Institutional Review Board for Human Research (IRB) also recommends approval of the investigator's request for a HIPAA Waiver of Authorization, as it appears that the criteria of the Privacy Rule have been satisfied. The HIPAA Waiver of Authorization was reviewed under expedited review procedures. No IRB member who has a conflicting interest was involved in the review or approval of this study, except to provide information as requested by the IRB.

Original Approval Date: 3/14/2016
Approval Expiration: 3/13/2017
Type: Expedited

Chairman, IRB-II - Medical University of South Carolina
Susan Sonne

Statement of Principal Investigator:
As previously signed and certified, I understand that approval of this research involving human subjects is contingent upon my agreement:

1. To report to the Institutional Review Board for Human Research (IRB) any adverse events or research related injuries which might occur in relation to the human research. I have read and will comply with IRB reporting requirements for adverse events.
2. To submit in writing for prior IRB approval any alterations to the plan of human research.
3. To submit timely continuing review reports of this research as requested by the IRB.
4. To maintain copies of all pertinent information related to the research activities in this project, including copies of informed consent agreements obtained from all participants.
5. To notify the IRB immediately upon the termination of this project, and/or the departure of the principal investigator from this Institution and the project.

*Electronic Signature: This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*
Table of Contents

Hospital Information

In-Hospital Case Information
HOSPITAL INFORMATION
(Data need to be entered one time only)
HOSPITAL CODE

Definition
A unique de-identifying letter assigned to each hospital individually by the lead site.

Field Values
• A capital alphabet letter.

Additional Information
• This field is required.

ACS TRAUMA CENTER DESIGNATION

Definition
American College of Surgeons (ACS) ranking for the Trauma Center where the patient received definitive treatment

Field Values
I  II  III  Undesignated

Additional Information
• This field is required.

STATE TRAUMA CENTER LEVEL

Definition
State Trauma Center status where the patient received definitive treatment

Field Values
I  II  III  IV  V  Unspecified  Non-US

Additional Information
• This field only applies to hospitals in USA.

TYPE OF MEDICAL CENTER

Definition
Please choose the description that best fits your medical center

Field Values
Academic medical center  Nongovernment not-for-profit community hospital
Investor-owned/for-profit community hospital  State or local government community hospital
Other

Additional Information
• This field is required.
TRAUMA TEAM

Definition
Choose any that attend your trauma activations.

Field Values
Resident
Mid-level providers (ie, Physician Assistants or Advanced Practice Nurses)
Neither

Additional Information
• This field is required.

NUMBER OF INPATIENT TRAUMA ADMISSIONS

Definition
The number of adult (18 years+) trauma cases admitted as inpatients to the hospital during the period from 10/1/13 through 9/30/15 (this includes 23-hour observation)

Field Values
Numerical value (integer)

Additional Information
• This field is required.

NUMBER OF TRAUMA ACTIVATIONS

Definition
The number of adult (18+) trauma alerts activated during the period from 10/1/13 through 9/30/15

Field Values
Numerical value (integer)

Additional Information
• This field is required.

NUMBER OF TRAUMA ACTIVATIONS WITH BLUNT MECHANISM

Definition
The number of adult (18+) trauma alerts activated with a blunt mechanism of injury during the period from 10/1/13 through 9/30/15

Field Values
Numerical value (integer)

Additional Information
• This field is required.
NUMBER OF TRAUMA ACTIVATIONS WITH BLUNT MECHANISM WITH AN ABDOMINAL CT SCAN IN THE ED

Definition
The number of adult (18+) trauma alerts activated with a blunt mechanism of injury who had an abdominal CT scan in the ED during the period from 10/1/13 through 9/30/15

Field Values
Numerical value (integer)

Additional Information
• This field is required.

HOSPITAL PROTOCOL FOR A 2ND CT SCAN

Definition
Is there a hospital policy or protocol for a 2nd Abdominal CT scan in blunt trauma?

Field Values
YES NO

Additional Information
• This field is required.
IN-HOSPITAL PATIENT INFORMATION
ASSIGNED PATIENT ID

Definition
A unique de-identifying number assigned to subjects by each site

Field Values
Numerical Value

Additional Information
- The value will be automatically generated.

AGE

Definition
The patient’s age at the time of injury.

Field Values
<18  18-89  >89

Additional Information
- Collected as a whole number in years only.
- An alert window will pop-up if you chose [<18] years (exclusion criterion)
- A new field will pop up if you chose [18-89] (conditional)
- This field is required.

Data Source Hierarchy
1. ED Admission Form
2. Billing Sheet / Medical Records Coding Summary Sheet
3. EMS Run Sheet
4. Triage Form / Trauma Flow Sheet
5. ED Nurses’ Notes

DID THE PATIENT HAVE A DUODENAL INJURY?

Definition
Did the patient have any duodenal perforation during this encounter?

Field Values
Yes    No

Additional Information
- An alert window will pop-up if you chose [Yes] (exclusion criterion).
- This field is required.

Data Source Hierarchy
1. Operative Notes
2. Problems List
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Discharge Notes
MECHANISM OF INJURY

Definition
The mechanism (or external factor) that caused the injury event.

Field Values

- Blunt (specify below)
- Penetrating

MVC (Motor Vehicle Collision )  MVC (Motorcycle Crash)
Auto vs. Pedestrian  Sports
Fall  Other

Assault

Additional Information

- You can either choose blunt or penetrating mode.
- An alert window will pop-up if you chose [Penetrating] (exclusion criterion).
- The value should describe the main reason a patient is admitted to the hospital.
- The value [Other] should only be used if the injury does not fit into one of the listed categories.
- A new field will pop up if you chose [Other].
- If the patient suffered more than one injury mechanism, chose the mechanism most closely associated with the reason for the abdominal injury.
- The maximum number of choices that may be reported for an individual patient is 1.
- This field is required.

Data Source Hierarchy

1. EMS Run Sheet
2. Triage Form / Trauma Flow Sheet
3. Billing Sheet / Medical Records Coding Summary Sheet
4. ED Nurses’ Notes
5. ER and ICU Records
6. Physician History and Physical
DID THE PATIENT HAVE ANY REGIONAL AIS > 2? (OTHER THAN FOR SBP)

**Definition**
Did the patient have any regional AIS > 2? (AIS SCORE FOR THE SMALL BOWEL PERFORATION DOES NOT COUNT).

**Field Values**
- YES
- NO

**Additional Information**
- An alert window will pop-up if you chose [Yes] (exclusion criterion).
- This field is required.

**Data Source Hierarchy**
1. ED Admission Form
2. Billing Sheet / Medical Records Coding Summary Sheet
3. EMS Run Sheet
4. Triage Form / Trauma Flow Sheet
5. ED Nurses' Notes

DID THE PATIENT HAVE AN ICD-9 PROCEDURE (OR CPT) CODE FOR SMALL BOWEL SURGERY?

**Definition**
Did the patient have an ICD-9 Procedure code of 45.61, 45.62, 45.90, 45.91, 45.93, or 46.73 (or a CPT code of 44120, 44121, 44202, 44203, 44602, 44603, or 44130)?

**Field Values**
- YES
- NO

**Additional Information**
- This field is required.
- This field is conditional.
- A new field will pop up accordingly.

**Data Source Hierarchy**
1. Operative Notes
2. Problems List
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Discharge Notes
DID THE PATIENT HAVE AN ABDOMINAL CT SCAN FOR BLUNT TRAUMA WITHIN THE INITIAL 6 HOURS?

**Definition**
Did the patient have an initial pre-operative abdominal CT scan in the ED or Hospital?

**Field Values**
- YES
- NO

**Additional Information**
- This field is **required**.
- If there was no CT done within 6 hours at your facility, BUT the patient was transferred to your ED from another ED, and 1) an abdominal CT scan was done in the 1st ED, and 2) you have the results, then the response is ‘YES’.
- A new field will pop up accordingly.

**Data Source Hierarchy**
1. ED Admission Form
2. Billing Sheet / Medical Records Coding Summary Sheet
3. EMS Run Sheet
4. Triage Form / Trauma Flow Sheet
5. Radiology Report
6. ED Nurses’ Notes

DID THE PATIENT HAVE A DOCUMENTED SMALL BOWEL PERFORATION IN THE OPERATIVE REPORT?

**Definition**
Did the patient have a small bowel perforation documented in the operative report?

**Field Values**
- YES
- NO

**Additional Information**
- This field is **required**.
- This field is **conditional**.
- A new field will pop up accordingly.

**Data Source Hierarchy**
1. Operative Notes
2. Problems List
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Discharge Notes
WAS THIS A TRAUMA ACTIVATION?

Definition
Patient arrived in ED as a trauma alert or activation.

Field Values
Yes          No

Additional Information
• An alert window will pop-up if you chose [No] (exclusion criterion).
• This field is required.
• If [Yes], a new field will pop-up (conditional).
• This field is conditional.

Data Source Hierarchy
1. ED Admission Form
2. Billing Sheet / Medical Records Coding Summary Sheet
3. EMS Run Sheet
4. Triage Form / Trauma Flow Sheet
5. ED Nurses’ Notes

DID THE PATIENT HAVE AN ABDOMINAL AIS >2?

Definition
Was the patient’s abdominal AIS score greater than 2?.

Field Values

Additional Information
• This field is conditional.
• The value will be automatically generated.

DID THE PATIENT HAVE AN ABDOMINAL SURGERY?

Definition
Abdominal surgery would include any operation with access to the peritoneal cavity.

Field Values
YES          NO

Additional Information
• This field is conditional.
• The value will be automatically generated.
AIS HEAD

**Definition**
The Abbreviated Injury Scale (AIS) severity codes that reflect the patient’s injuries to the head.

**Field Values**
Numerical Value (limited to integers 1-6)

**Additional Information**
- An alert window will pop-up if it was >2 (exclusion criterion).

**Data Source Hierarchy**
1. Trauma Registry
2. Hospital Discharge Summary
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Trauma Flow Sheet
5. Physician History and Physical
6. ER and ICU Records

AIS FACE

**Definition**
The Abbreviated Injury Scale (AIS) severity codes that reflect the patient’s injuries to the face.

**Field Values**
Numerical Value (limited to integers 1-6)

**Additional Information**
- An alert window will pop-up if it was >2 (exclusion criterion).

**Data Source Hierarchy**
1. Trauma Registry
2. Hospital Discharge Summary
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Trauma Flow Sheet
5. Physician History and Physical
6. ER and ICU Records
AIS NECK

Definition
The Abbreviated Injury Scale (AIS) severity codes that reflect the patient’s injuries to the neck.

Field Values
Numerical Value (limited to integers 1-6)

Additional Information
- An alert window will pop-up if it was >2 (exclusion criterion).

Data Source Hierarchy
1. Trauma Registry
2. Hospital Discharge Summary
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Trauma Flow Sheet
5. Physician History and Physical
6. ER and ICU Records

AIS THORAX

Definition
The Abbreviated Injury Scale (AIS) severity codes that reflect the patient’s injuries to the chest.

Field Values
Numerical Value (limited to integers 1-6)

Additional Information
An alert window will pop-up if it was >2 (exclusion criterion).

Data Source Hierarchy
1. Trauma Registry
2. Hospital Discharge Summary
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Trauma Flow Sheet
5. Physician History and Physical
6. ER and ICU Records
AIS ABDOMEN

**Definition**
The Abbreviated Injury Scale (AIS) severity codes that reflect the patient’s injuries to the abdomen OTHER THAN THE SMALL BOWEL PERFORATION.

**Field Values**
Numerical Value (limited to integers 1-6)

**Additional Information**
- An alert window will pop-up if it was >2 (exclusion criterion), unless the patient had a small bowel perforation.

**Data Source Hierarchy**
1. Trauma Registry
2. Hospital Discharge Summary
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Trauma Flow Sheet
5. Physician History and Physical
6. ER and ICU Records

AIS SPINE

**Definition**
The Abbreviated Injury Scale (AIS) severity codes that reflect the patient’s injuries to the spine.

**Field Values**
Numerical Value (limited to integers 1-6)

**Additional Information**
- An alert window will pop-up if it was >2 (exclusion criterion).

**Data Source Hierarchy**
1. Trauma Registry
2. Hospital Discharge Summary
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Trauma Flow Sheet
5. Physician History and Physical
6. ER and ICU Records
AIS UPPER EXTREMITY

**Definition**
The Abbreviated Injury Scale (AIS) severity codes that reflect the patient’s injuries to the upper extremity.

**Field Values**
Numerical Value (limited to integers 1-6)

**Additional Information**
An alert window will pop-up if it was >2 (exclusion criterion).

**Data Source Hierarchy**
1. Trauma Registry
2. Hospital Discharge Summary
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Trauma Flow Sheet
5. Physician History and Physical
6. ER and ICU Records

AIS LOWER EXTREMITY

**Definition**
The Abbreviated Injury Scale (AIS) severity codes that reflect the patient’s injuries to the lower extremity.

**Field Values**
Numerical Value (limited to integers 1-6)

**Additional Information**
- An alert window will pop-up if it was >2 (exclusion criterion).

**Data Source Hierarchy**
1. Trauma Registry
2. Hospital Discharge Summary
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Trauma Flow Sheet
5. Physician History and Physical
6. ER and ICU Records
AIS UNSPECIFIED

Definition
The Abbreviated Injury Scale (AIS) severity codes that reflect the patient’s injuries to other areas.

Field Values
Numerical Value (limited to integers 1-6)

Additional Information
An alert window will pop-up if it was >2 (exclusion criterion).

Data Source Hierarchy
1. Trauma Registry
2. Hospital Discharge Summary
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Trauma Flow Sheet
5. Physician History and Physical
6. ER and ICU Records

WHAT IS YOUR BEST ESTIMATE OF THE TIME BETWEEN INJURY AND ARRIVAL AT THE ED?

Definition
The approximate time between injury and arrival to the hospital. This would be arrival at the 1st ED if the patient was later transferred to your facility’s ED.

Field Values
< 1 hour ~ 1 hour ~ 2 hours ~ 3 hours
~ 4 hours ~ 5 hours ~ 6 hours > 6 hours

Additional Information
- Day of the injury will always be Day 0.

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Hospital Discharge Summary
WAS THE PATIENT A TRANSFER?

Definition
Had the patient been received initially by another hospital and transferred to your ED for definitive treatment?

Field Values
YES NO

Additional Information
- If the patient was a transfer, new fields will pop-up (conditional).
- This field is required.

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Hospital Discharge Summary

PRE-TRANSFER ACS TRAUMA CENTER DESIGNATION

Definition
American College of Surgeons (ACS) ranking for the Trauma Center where the patient received initial treatment

Field Values
I II III Undesignated

Additional Information
- This field is conditional.

PRE-TRANSFER STATE TRAUMA CENTER LEVEL

Definition
State Trauma Center status where the patient received initial treatment

Field Values
I II III IV V Unspecified Non-US

Additional Information
- This field only applies to hospitals in USA.
- This field is conditional.
PRE-TRANSFER DAY OF ADMISSION TO ED

Definition
The day the patient arrived to the ED at the initial trauma center.

Field Values
0 1 2 3

Additional Information
- This field in conditional.

Data Source Hierarchy
1. Transfer notes
2. ED Record
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Hospital Discharge Summary

PRE-TRANSFER ADMIT TIME TO ED

Definition
The time the patient arrived to the ED at the initial trauma center.

Field Values
- Relevant value for data element (00:00 to 23:59).

Additional Information
- This field in conditional.
- Collected as HH:MM using military time (00:00 = 12 am = midnight).

Data Source Hierarchy
1. Transfer notes
2. ED Record
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Hospital Discharge Summary

PRE-TRANSFER ADMISSION GLASGOW COMA SCORE

Definition
GCS done in the Trauma Center where the patient initially was received

Field Values
3 through 15 and 2T through 10T.

Additional Information
- This field is conditional.

Data Source Hierarchy
1. Transfer notes
2. ED Record
PRE-TRANSFER ADMISSION PHYSICAL EXAMINATION FINDINGS

**Definition**
Findings of physical examination done in the Trauma Center where the patient initially was received

**Field Values**
- None
- Abdominal Tenderness
- Abdominal Distention
- Peritoneal Signs
- Seat belt sign/bruising
- Other

**Additional Information**
- This field is conditional.
- Multiple selections are enabled.
- Check all relevant boxes

**Data Source Hierarchy**
1. Transfer notes
2. ED Record
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Hospital Discharge Summary

PRE-TRANSFER ADMISSION SYSTOLIC BLOOD PRESSURE

**Definition**
Initial systolic blood pressure recorded at the Trauma Center where the patient initially was received

**Field Values**
- Numerical Value (0 to 399).

**Additional Information**
- This field is conditional.
- Units are mmHg.

**Data Source Hierarchy**
1. Transfer notes
2. ED Record
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Hospital Discharge Summary
PRE-TRANSFER ADMISSION DIASTOLIC BLOOD PRESSURE

**Definition**
Initial diastolic blood pressure recorded at the Trauma Center where the patient initially was received

**Field Values**
Numerical Value (0 to 199).

**Additional Information**
- This field is *conditional*.
- Units are mmHg.

**Data Source Hierarchy**
1. Transfer notes
2. ED Record
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Hospital Discharge Summary

PRE-TRANSFER ADMISSION HEART RATE

**Definition**
Initial heart rate recorded at the Trauma Center where the patient initially was received

**Field Values**
Numerical Value (0 to 300).

**Additional Information**
- This field is *conditional*.
- Units are beats per minute.

**Data Source Hierarchy**
1. Transfer notes
2. ED Record
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Hospital Discharge Summary

PRE-TRANSFER ADMISSION TEMPERATURE

**Definition**
Initial patient’s temperature recorded at the Trauma Center where the patient initially was received

**Field Values**
Numerical Value (29 °C to 42 °C).

**Additional Information**
- This field is *conditional*.
- Units are Celsius.
Data Source Hierarchy
1. Transfer notes
2. ED Record
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Hospital Discharge Summary

PRE-TRANSFER ADMISSION RESPIRATORY RATE

Definition
Initial respiratory rate recorded at the Trauma Center where the patient initially was received

Field Values
Numerical Value (0 to 40).

Additional Information
- This field is conditional.
- Units are breaths per minute.

Data Source Hierarchy
1. Transfer notes
2. ED Record
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Hospital Discharge Summary

GENDER

Definition
The patient’s sex.

Field Values
Male       Female

Additional Information
- Patients who have undergone a surgical and/or hormonal sex reassignment should be coded using the current assignment.
- This field is required.

Data Source Hierarchy
1. ED Admission Form
2. Billing Sheet / Medical Records Coding Summary Sheet
3. EMS Run Sheet
4. Triage Form / Trauma Flow Sheet
5. ED Nurses' Notes
RACE

Definition
The patient’s race.

Field Values
White Native American
African-American Pacific Islander
Asian Mixed Race
Other Unknown

Additional Information
• If more than one race listed, please choose ‘Mixed race’.

Data Source Hierarchy
1. ED Admission Form
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Triage Form / Trauma Flow Sheet
4. EMS Run Sheet
5. ED Nurses’ Notes

ETHNICITY

Definition
The patient’s ethnicity.

Field Values
Hispanic Non-Hispanic Unknown

Additional Information
• N/A

Data Source Hierarchy
1. ED Admission Form
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Triage Form / Trauma Flow Sheet
4. EMS Run Sheet
5. ED Nurses’ Notes
PAYER STATUS

Definition
The patient’s payer status and insurance type.

Field Values
- Private/commercial/HMO
- Medicare
- Medicaid
- Military (active duty/retired/dependent/VA)
- Worker’s Compensation
- Uninsured/self-pay
- Other

Additional Information
- N/A

Data Source Hierarchy
1. Billing Sheet / Medical Records Coding Summary Sheet

DIAGNOSES

Definition
The patient’s diagnoses.

Field Values
ICD-9-CM Codes

Additional Information
- List all ICD-9-CM diagnosis codes for this admission.

Data Source Hierarchy
1. ED Admission Form
2. EMS Run Sheet
3. ED Nurses’ Notes

DAY OF ADMISSION TO ED

Definition
The day the patient arrived to the ED or hospital (if direct transfer from another hospital) where the patient had definitive treatment.

Field Values
Day 0    Day 1    Day 2    Day 3

Additional Information
- If the patient was brought directly to the ED, enter 'Day 0'. If patient was transferred from another hospital, chose 'Day 0' if the patient was received before midnight the day of injury, or enter 'Day 1' if the patient was received after midnight, etc.
- This field is required.

**Data Source Hierarchy**
1. Transfer notes
2. Triage Form / Trauma Flow Sheet
3. ED Record
4. Hospital Discharge Summary

**ADMISSION TIME TO ED**

**Definition**
The time the patient arrived to the ED/hospital where the patient had definitive treatment.

**Field Values**
- Relevant value for data element (00:00 to 23:59).

**Additional Information**
- If the patient was brought to the ED, enter time patient arrived at ED. If patient was directly admitted to the hospital, enter time patient was admitted to the hospital.
- Collected as HH:MM using military time (00:00 = 12 am = midnight).
- This field is required.

**Data Source Hierarchy**
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Hospital Discharge Summary

**INJURY SEVERITY SCORE (ISS)**

**Definition**
The Injury Severity Score (ISS) that reflects the patient’s injuries.

**Field Values**
- Total ISS value for the constellation of injuries (1 to 75).

**Additional Information**
- This field is required.
- Entered as whole number.

**Data Source Hierarchy**
1. Trauma Registry
2. Hospital Discharge Summary
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Trauma Flow Sheet
5. Physician History and Physical
6. ER and ICU Records

ADMISSION PHYSICAL EXAMINATION FINDINGS

Definition
Findings of initial physical examination done in the Trauma Center where the patient had definitive treatment

Field Values
None   Abdominal Tenderness   Abdominal Distention
Peritoneal Signs   Seat belt sign/bruising   Other

Additional Information
- This field is required.
- Multiple selections are enabled.
- Check all relevant boxes

Data Source Hierarchy
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical

ADMISSION GLASGOW COMA SCORE

Definition
Initial GCS done in the Trauma Center where the patient had definitive treatment

Field Values
3 through 15 and 2T through 10T.

Additional Information

Data Source Hierarchy
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical
ADMISSION SYSTOLIC BLOOD PRESSURE

Definition
Initial systolic blood pressure recorded at the Trauma Center where the patient had definitive treatment

Field Values
Numerical Value (0 to 399).

Additional Information
- This field is required.
- Units are mmHg.

Data Source Hierarchy
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical

ADMISSION DIASTOLIC BLOOD PRESSURE

Definition
Initial diastolic blood pressure recorded at the Trauma Center where the patient had definitive treatment

Field Values
Numerical Value (0 to 199).

Additional Information
- This field is required.
- Units are mmHg.

Data Source Hierarchy
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical

ADMISSION HEART RATE

Definition
Initial heart rate recorded at the Trauma Center where the patient had definitive treatment

Field Values
Numerical Value (0 to 300).

Additional Information
• This field is required.
• Units are beats per minute.

Data Source Hierarchy
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical

ADMISSION TEMPERATURE

Definition
Initial temperature recorded at the Trauma Center where the patient had definitive treatment

Field Values
Numerical Value (29 °C to 42 °C).

Additional Information
• This field is required.
• Units are Celsius.

Data Source Hierarchy
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical

ADMISSION RESPIRATORY RATE

Definition
Initial respiratory rate recorded at the Trauma Center where the patient had definitive treatment

Field Values
Numerical Value (0 to 30).

Additional Information
• This field is required.
• Units are breaths per minute.

Data Source Hierarchy
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical

INITIAL LAB RESULTS

ARTERIAL pH

Definition
Initial arterial pH recorded after arrival.

Field Values
- Relevant value for data element (6.5-8.5).

Additional Information
- Enter value up to 2 decimal places.
- Try to ensure that the blood gas was arterial before recording the value.
- If no arterial blood gas was done please leave the data element blank – please do not enter 0.

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Laboratory reports

BASE DEFICIT

Definition
Initial base deficit recorded after arrival.

Field Values
- Relevant value for data element (-15 to +15).

Additional Information
- Only use integers for this data element.
- Units are mEq/L.
- Try to ensure that the blood gas was arterial before recording the value.
- If no arterial blood gas was done please leave the data element blank – please do not enter 0.
- If the patient had a base deficit, include a negative (-) sign prior to the integer. If the patient had a base excess include (+) sign prior to the integer.

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Laboratory reports
LACTATE

Definition
Initial lactate level recorded after arrival.

Field Values
- Relevant value for data element (0 to 8.0).

Additional Information
- Enter value up to 1 decimal place.
- Units are mmol/L.
- If no Lactate was done leave the data element blank – please do not enter 0.

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Laboratory reports

HCT

Definition
Initial hematocrit recorded after arrival.

Field Values
- Relevant value for data element (10 – 60)

Additional Information
- Only use integers for this data element.
- Units are %.

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Laboratory reports

HEMOGLOBIN

Definition
Initial hemoglobin level recorded after arrival.

Field Values
- Relevant value for data element (4.0 to 20.0)

Additional Information
- Enter up to 1 decimal place.
- Units are g/dl
Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Laboratory reports

WBC COUNT

Definition
Initial White Blood Cell count recorded after arrival.

Field Values
- Relevant value for data element (500 to 50,000)

Additional Information
- Only use integers for this data element
- Units are in micro-liter (mcL).

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Laboratory reports

SERUM AMYLASE

Definition
Initial serum amylase level recorded after arrival.

Field Values
- Relevant value for data element (0 to 5000)

Additional Information
- Only use integers for this data element.
- Units are units per liter (IU/L).

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Laboratory reports

SERUM LIPASE

Definition
Initial serum lipase level recorded after arrival.

Field Values
- Relevant value for data element (0 to 5000)
NUMBER OF PRE-OPERATIVE CT SCANS

Definition
Total number of relevant Abdominal CT scans done on patient pre-operatively and/or within the first 24 hours of admission (initial admission if it was a transfer)

Field Values
0  1  2  3

Additional Information
- This field is required.
- This field is conditional.
- New fields will pop up accordingly.

Data Source Hierarchy
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Radiology Reports
6. Physician History and Physical

FIRST CT SCAN DAY

Definition
The day the patient had the 1st abdominal CT scan for this injury in the ED/hospital where the patient had definitive treatment.

Field Values
0  1

Additional Information
- Enter ‘Day 0’ if the CT was done before midnight the day of injury, or enter ‘Day 1’ if the CT was done after midnight.
- This field is required.

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Hospital Discharge Summary

FIRST CT SCAN TIME

Definition
The time the patient had the 1st abdominal CT scan for this injury in the ED/hospital where the patient had definitive treatment.

Field Values
- Relevant value for data element (00:00 to 23:59).

Additional Information
- Collected as HH:MM using military time (00:00 = 12 am = midnight).
- This field is required.

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Hospital Discharge Summary

HOW MANY DETECTORS DOES THE FIRST CT SCANNER HAVE

Definition
The number of detectors in the multi-detector computed tomography scanner used for this patient

Field Values
4, 8, 16, 32, 64, >64

Additional Information
- This field is required.

Data Source Hierarchy
1. Dictated radiologist report.
2. Hospital radiology department log.
FIRST CT SCAN FINDINGS

**Definition**
Radiological findings recorded on the 1st abdominal CT scan for this injury.

**Field Values**

- No Abnormalities
- Free Fluid
- Free Air
- Bowel Wall Thickening
- Mesenteric Stranding
- Contrast Extravasation
- Solid Organ Injury
- Retroperitoneal Blood
- Chance Fracture
- Others

**Additional Information**
- This field is **required**.

**Data Source Hierarchy**

1. Radiology Reports
2. ER and ICU Records
3. Trauma Flow Sheet
4. Physician History and Physical
5. Hospital Discharge Summary
6. Billing Sheet / Medical Records Coding Summary Sheet

SECOND CT SCAN DAY

**Definition**
The day the patient had 2nd abdominal CT scan done either preoperatively, or prior to discharge for patients who did not have abdominal surgery.

**Field Values**

0
1

**Additional Information**
- Enter 'Day 0' if the CT was done before midnight the day of injury, or enter 'Day 1' if the CT was done after midnight.
- This field is **required**.

**Data Source Hierarchy**

1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Hospital Discharge Summary
SECOND CT SCAN TIME

**Definition**
The time the patient had the 2ND abdominal CT scan done either preoperatively or prior to discharge for patients who did not have abdominal surgery

**Field Values**
- Relevant value for data element (00:00 to 23:59).

**Additional Information**
- Collected as HH:MM using military time (00:00 = 12 am = midnight).
- This field is **required**.

**Data Source Hierarchy**
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Hospital Discharge Summary

HOW MANY DETECTORS DOES THE SECOND CT SCANNER HAVE

**Definition**
The number of detectors in the multi-detector computed tomography scanner used for this patient

**Field Values**
4, 8, 16, 32, 64, >64

**Additional Information**
- This field is **required**.

**Data Source Hierarchy**
1. Dictated radiologist report.
2. Hospital radiology department log.

SECOND CT SCAN FINDINGS

**Definition**
Radiological findings were recorded on the 2nd abdominal CT scan for this injury.

**Field Values**
- No Abnormalities
- Free Fluid
- Free Air
- Bowel Wall Thickening
- Mesenteric Stranding
- Contrast Extravasation
- Solid Organ Injury
- Retroperitoneal Blood
- Chance Fracture
- Others

**Additional Information**
• This field is **required**.

**Data Source Hierarchy**
1. Radiology Reports
2. ER and ICU Records
3. Trauma Flow Sheet
4. Physician History and Physical
5. Hospital Discharge Summary
6. Billing Sheet / Medical Records Coding Summary Sheet

**THIRD CT SCAN DAY**

**Definition**
The day the patient had the 3RD abdominal CT scan for this injury done pre-operatively in the ED/hospital where the patient had definitive treatment.

**Field Values**
0     1

**Additional Information**
• Enter 'Day 0' if the CT was done before midnight the day of injury, or enter 'Day 1' if the CT was done after midnight.
• This field is **required**.

**Data Source Hierarchy**
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Hospital Discharge Summary

**THIRD CT SCAN TIME**

**Definition**
The time the patient had the 3RD abdominal CT scan for this injury done pre-operatively in the ED/hospital where the patient had definitive treatment.

**Field Values**
• Relevant value for data element (00:00 to 23:59).

**Additional Information**
• Collected as HH:MM using military time (00:00 = 12 am = midnight).
• This field is **required**.

**Data Source Hierarchy**
1. Triage Form / Trauma Flow Sheet
2. ED Record
HOW MANY DETECTORS DOES THE FIRST CT SCANNER HAVE

**Definition**
The number of detectors in the multi-detector computed tomography scanner used for this patient

**Field Values**
4, 8, 16, 32, 64, >64

**Additional Information**
- This field is required.

**Data Source Hierarchy**
1. Dictated radiologist report.
2. Hospital radiology department log.

THIRD CT SCAN FINDINGS

**Definition**
Radiological findings recorded on the 3rd abdominal CT scan for this injury.

**Field Values**
- No Abnormalities
- Free Fluid
- Free Air
- Bowel Wall Thickening
- Mesenteric Stranding
- Contrast Extravasation
- Solid Organ Injury
- Retroperitoneal Blood
- Chance Fracture
- Others

**Additional Information**
- This field is required.

**Data Source Hierarchy**
1. Radiology Reports
2. ER and ICU Records
3. Trauma Flow Sheet
4. Physician History and Physical
5. Hospital Discharge Summary
6. Billing Sheet / Medical Records Coding Summary Sheet
DIAGNOSTIC TESTS DONE OTHER THAN CT SCAN

**Definition**
Diagnostic tests and procedures used to diagnose abdominal trauma other than abdominal CT scan

**Field Values**
- None
- Chest x-ray
- Focused Abdominal Sonography in Trauma (FAST)
- Abdominal ultrasound
- Abdominal x-ray
- Diagnostic peritoneal lavage

**Additional Information**
- Multiple selections are enabled.
- Check all relevant boxes

**Data Source Hierarchy**
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical

DAY OF SURGERY

**Definition**
The day the patient had the initial abdominal surgery in the hospital where the patient had definitive treatment.

**Field Values**
- 0
- 1
- 2
- 3
- Other

**Additional Information**
- Enter ‘Day 0’ if the surgery was done before midnight the day of injury, enter ‘Day 1’ if the surgery was done after midnight, or enter the chronological day in the field of ‘Other’
- This field is **required**.
- This field in **conditional**.

**Data Source Hierarchy**
1. Operative Report
2. ER and ICU Records
3. Trauma Flow Sheet
4. Physician History and Physical
5. Hospital Discharge Summary
6. Billing Sheet / Medical Records Coding Summary Sheet
TIME OF SURGERY

**Definition**

The time the patient had the initial abdominal surgery in the hospital where the patient had definitive treatment.

**Field Values**

- Relevant value for data element (00:00 to 23:59).

**Additional Information**

- Collected as HH:MM using military time (00:00 = 12 am = midnight).
- This field is **required**.
- This field is **conditional**.

**Data Source Hierarchy**

1. Operative Report
2. Trauma Flow Sheet
3. Physician History and Physical
4. Hospital Discharge Summary
5. Billing Sheet / Medical Records Coding Summary Sheet

PRE-OPERATIVE PHYSICAL EXAMINATION FINDINGS (OR PRIOR TO DC FOR NONSURGICAL PATIENTS, IF PRESENT)

**Definition**

Findings of physical examination in the immediate pre-operative period. For patients who did not have surgery use findings prior to discharge, if present.

**Field Values**

- None
- Abdominal Tenderness
- Abdominal Distention
- Peritoneal Signs
- Seat belt sign/bruising
- Other

**Additional Information**

- This field is **required**.
- This field is **conditional**.
- Multiple selections are enabled.
- Check all relevant boxes.

**Data Source Hierarchy**

1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical
PRE-OPERATIVE SYSTOLIC BLOOD PRESSURE (OR PRIOR TO DC FOR NONSURGICAL PATIENTS, IF PRESENT)

**Definition**
Systolic blood pressure recorded in the immediate pre-operative period. For patients who did not have surgery use results prior to discharge, if present.

**Field Values**
Numerical Value (0 to 399).

**Additional Information**
- This field is **required**.
- This field is **conditional**.
- Units are mmHg.

**Data Source Hierarchy**
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical

PRE-OPERATIVE DIASTOLIC BLOOD PRESSURE (OR PRIOR TO DC FOR NONSURGICAL PATIENTS, IF PRESENT)

**Definition**
Diastolic blood pressure recorded in the immediate pre-operative period. For patients who did not have surgery use results prior to discharge, if present.

**Field Values**
Numerical Value (0 to 199).

**Additional Information**
- This field is **required**.
- This field is **conditional**.
- Units are mmHg.

**Data Source Hierarchy**
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical
PRE-OPERATIVE HEART RATE (OR PRIOR TO DC FOR NONSURGICAL PATIENTS, IF PRESENT)

**Definition**
Initial heart rate recorded in the immediate pre-operative period. For patients who did not have surgery use results prior to discharge, if present.

**Field Values**
Numerical Value (0 to 250).

**Additional Information**
- This field is required.
- This field is conditional.
- Units are beats per minute.

**Data Source Hierarchy**
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical

PRE-OPERATIVE TEMPERATURE (OR PRIOR TO DC FOR NONSURGICAL PATIENTS, IF PRESENT)

**Definition**
Initial patient’s temperature recorded in the immediate pre-operative period. For patients who did not have surgery use results prior to discharge, if present.

**Field Values**
Numerical Value (29 °C to 42 °C).

**Additional Information**
- This field is required.
- This field is conditional.

**Data Source Hierarchy**
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical

PRE-OPERATIVE RESPIRATORY RATE (OR PRIOR TO DC FOR NONSURGICAL PATIENTS, IF PRESENT)

**Definition**
Initial respiratory rate recorded in the immediate pre-operative period. For patients who did not have surgery use results prior to discharge, if present.
Field Values
   Numerical Value (0 to 30).

Additional Information
   • This field in required.
   • This field in conditional.
   • Units are breaths per minute.

Data Source Hierarchy
   1. ED Record
   2. Billing Sheet / Medical Records Coding Summary Sheet
   3. Hospital Discharge Summary
   4. ER and ICU Records
   5. Physician History and Physical

PRE-OPERATIVE LAB RESULTS [OR PRIOR TO DC FOR NONSURGICAL PATIENTS, IF PRESENT]

ARTERIAL pH

Definition
   Arterial pH recorded in the immediate pre-operative period. For patients who did not have surgery use results prior to discharge, if present.

Field Values
   • Relevant value for data element (6.5-8.5).

Additional Information
   • Enter value up to 2 decimal places.
   • Try to ensure that the blood gas was arterial before recording the value.
   • If no arterial blood gas was done please leave the data element blank – please do not enter 0.

Data Source Hierarchy
   1. Triage Form / Trauma Flow Sheet
   2. ED Record
   3. Laboratory reports

BASE DEFICIT

Definition
   Base deficit recorded in the immediate pre-operative period. For patients who did not have surgery use results prior to discharge, if present.

Field Values
   • Relevant value for data element (-15 to +15).

Additional Information
   • Only use integers for this data element.
   • Units are mEq/L.
• Try to ensure that the blood gas was arterial before recording the value.
• If no arterial blood gas was done please leave the data element blank – please do not enter 0.
• If the patient had a base deficit, include a negative (−) sign prior to the integer. If the patient had a base excess include (+) sign prior to the integer.

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Laboratory reports

LACTATE

Definition
Lactate level recorded in the immediate pre-operative period. For patients who did not have surgery use results prior to discharge, if present.

Field Values
• Relevant value for data element (0 to 8.0).

Additional Information
• Enter value up to 1 decimal place.
• Units are mmol/L.
• If no Lactate was done leave the data element blank – please do not enter 0.

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Laboratory reports

HCT

Definition
Hematocrit recorded in the immediate pre-operative period. For patients who did not have surgery use results prior to discharge, if present.

Field Values
• Relevant value for data element (10 – 60)

Additional Information
• Only use integers for this data element.
• Units are %.

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Laboratory reports
HEMOGLOBIN

Definition
Hemoglobin level recorded in the immediate pre-operative period. For patients who did not have surgery use results prior to discharge, if present.

Field Values
- Relevant value for data element (4.0 to 20.0)

Additional Information
- Enter up to 1 decimal place.
- Units are g/dl

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Laboratory reports

WBC COUNT

Definition
White Blood Cell count recorded in the immediate pre-operative period. For patients who did not have surgery use results prior to discharge, if present.

Field Values
- Relevant value for data element (500 to 50,000)

Additional Information
- Only use integers for this data element
- Units are in micro-liter (mcL).

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Laboratory reports

SERUM AMYLASE

Definition
Serum Amylase level recorded in the immediate pre-operative period. For patients who did not have surgery use results prior to discharge, if present.

Field Values
- Relevant value for data element (0 to 5000)

Additional Information
- Only use integers for this data element.
- Units are units per liter (IU/L).

Data Source Hierarchy
1. Triage Form / Trauma Flow Sheet
SERUM LIPASE

**Definition**
Serum Lipase level recorded in the immediate pre-operative period. For patients who did not have surgery use results prior to discharge, if present.

**Field Values**
- Relevant value for data element (0 to 5000)

**Additional Information**
- Only use integers for this data element.
- Units are units per liter (IU/L).

**Data Source Hierarchy**
1. Triage Form / Trauma Flow Sheet
2. ED Record
3. Laboratory reports

INDICATION FOR SURGERY

**Definition**
The most important factors that led to the decision to perform surgery.

**Field Values**
- Free fluid without solid organ injury on CT scan
- Free air on CT scan
- Mesenteric hematoma/stranding on CT scan
- Bowel wall thickening on CT scan
- Abdominal pain
- Peritoneal Signs
- Deterioration of Vital Signs
- Sepsis
- Other (specify)

**Additional Information**
- Multiple selections are enabled.
- Check all relevant boxes
- This field is conditional.

**Data Source Hierarchy**
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical
INTRAOPERATIVE FINDINGS

Definition
The most important factors that led to the decision to perform surgery.

Field Values
Free fluid  Liver injury  Splenic injury
Mesenteric injury  Small Bowel Perforation  Others (specify)

Additional Information
- Multiple selections are enabled.
- Check all relevant boxes
- This field in conditional.
- Specify type of liver, splenic, or mesenteric injury.

Data Source Hierarchy
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical

TYPE OF FREE FLUID

Definition
Type of free fluid found during small bowel surgery.

Field Values
Blood  Bile  Other

Additional Information
- Multiple selections are enabled.
- Check all relevant boxes
- This field in conditional.

Data Source Hierarchy
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical
AMOUNT OF FREE FLUID

Definition
Amount of free fluid found during small bowel surgery.

Field Values
Number value (in milliliters)

Additional Information
• This field is conditional.

Data Source Hierarchy
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical

COMPLICATIONS

Definition
Complications that took place during the 30 days following surgery for bowel injury (or the 30 days following admission for patients without bowel injury).

Field Values
Wound Infection
Systemic Sepsis
ARDS
Venous Thrombo-embolism
Other

Intra-abdominal Abscess
Pneumonia
Acute Kidney Injury
Unplanned return to surgery

Additional Information
• Multiple selections are enabled.
• Check all relevant boxes

Data Source Hierarchy
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical

HOW MANY DAYS TOTAL WAS THE PATIENT IN AN ICU DURING THE STAY?

Definition
Number of days the patient spent in the ICU
Field Values
Numerical Value (whole numbers)

Additional Information
• This field is required.
• If patient had non-consecutive stays in the ICU, please add up days.
• Please put zero if patient was not admitted to an ICU

Data Source Hierarchy
1. Transfer notes
2. ED Record
3. Billing Sheet / Medical Records Coding Summary Sheet
4. Hospital Discharge Summary

DAY OF DISCHARGE

Definition
The day the patient was discharged from the hospital where the patient had definitive treatment.

Field Values
Numerical Value (whole numbers)

Additional Information
• Counting from Day 0, the day of injury.
• Enter ‘Day 0’ if the discharge was before midnight the day of injury, enter ‘Day 1’ if the discharge was done the next day, etc.
• This field is required.

Data Source Hierarchy
1. ER and ICU Records
2. Trauma Flow Sheet
3. Physician History and Physical
4. Hospital Discharge Summary
5. Billing Sheet / Medical Records Coding Summary Sheet

DISCHARGE & DISPOSITION

Definition
Status of the patient’s discharge or disposition

Field Values
Home
Inpatient Rehabilitation Facility
Nursing Home/Skilled Nursing Facility
Against Medical Advice
Hospice Facility
Death attributed to SBP
Death not attributed to SBP Other

Additional Information
- The maximum number of choices that may be reported for an individual patient is 1.
- Death is classified as attributed to a small bowel perforation (SBP) if a patient met all three of the following criteria: 1) a small bowel perforation was verified on operation/autopsy, 2) death was confirmed as involving peritoneal sepsis, and 3) the death was not directly attributable to or exacerbated by another injury or illness
- This field is required.

Data Source Hierarchy
1. Billing Sheet / Medical Records Coding Summary Sheet
2. Hospital Discharge Summary
3. Physician History and Physical

READMISSION

Definition
Has the patient been readmitted to the hospital for a related cause within 30 days after discharge?

Field Values
YES NO

Additional Information
- Readmission cause can be classified as related if it happened as a result of the trauma, surgery, under-management, or missed injuries.
- This field is required.

Data Source Hierarchy
1. ED Record
2. Billing Sheet / Medical Records Coding Summary Sheet
3. Hospital Discharge Summary
4. ER and ICU Records
5. Physician History and Physical

GENERAL NOTES

Use this field to fill-in any relevant notes not captured elsewhere.

END
Reliable diagnosis of Small Bowel Perforation (SBP) remains problematic (Mukhopadhyay 2009). CT sensitivity estimates range from 50% to 94%, but CT specificity decreased markedly as sensitivity increased, suggesting different standards in reading the CT scans (Fang JF 1999, Fakhry SM 2003, Mathonnet M 2003, Zissin R 2009). Additionally, the highest sensitivity value was calculated based on suggestive injuries; only 50% of patients met diagnostic criteria for SBP on CT scan (Sherck J 1994). Ultrasonography is useful when patients have intraperitoneal free air, but is not sensitive in the absence of that marker (Moriwaki Y 2009). Laparoscopy and peritoneal lavage are the most sensitive methods, with most sensitivity measured at 100%, but laparoscopy especially may not be feasible in all patients (Ceelen W 1995, Fang JF 1999, Mathonnet M 2003, Nicolau A E 2006). Since increased delay in surgical repair is associated with increased morbidity and mortality, improving sensitivity of existing examination methods is critical. Mortality increases from 13.0% with surgery within 8 hours to 30.8% when surgery is delayed for more than 24 hours. In addition, delay in surgery results in increased likelihood of wound infection, wound dehiscence, intra-abdominal abscess, ARDS, and sepsis (Fakhry SM 2003). Delay in surgery past 24 hours was also associated with increased hospital stay (Fang JF 1999). Overall, SBP has an average mortality of 10-15% (Fakhry SM 2000, Watts DD 2003).

The difficulty of diagnosing SBP through CT scan is increasingly well known. Newer data suggests that surgery in <24 hours is necessary in these patients, with surgery in <8 hours preferred (Fang JF 1999, Fakhry SM 2000). Although SBP is an urgent problem, these data suggest that small delays to use the more sensitive diagnostic method of laparoscopy could be beneficial, rather than relying on CT. This study intends to examine whether increased awareness of diagnostic difficulty has improved diagnosis methods and time to surgery.

Specific Aims

1. Describe current methods trauma centers are using to diagnose non-duodenal SBP in patients with blunt abdominal trauma.
2. Describe current mortality and morbidity due to blunt near-isolated non-duodenal SBP.
3. Describe the current average time to surgery for patients with blunt near-isolated non-duodenal SBP.
4. Describe the frequency and utility of a second abdominal CT scan, and its association with time to surgery and incidence of post-operative complications in patients with blunt near-isolated non-duodenal SBP.
5. Determine the sensitivity and specificity of diagnostic findings for blunt near-isolated non-duodenal SBP.
6. Determine what percentages of codes 863.2, 863.20, 863.29, 863.3, 863.30 and 863.39 are being assigned to blunt versus penetrating mechanism.

B. RESEARCH DESIGN AND METHODS (including data analysis)

This study is an international multi-center study being led by Dr. Samir Fakhry at Medical University of South Carolina, through the Eastern Trauma Association. It will be a retrospective data collection study. Hospital-level data will be collected on trauma level, continent, presence of a protocol for a second CT in blunt abdominal trauma, type of trauma staffing, type of hospital, number of yearly adult trauma admissions, number of yearly adult trauma activations, number of yearly adult blunt trauma admissions, and approximate number of yearly adult blunt trauma admissions with suspected abdominal injury (ie, CT scan of the abdomen). Patients will be identified via medical records for inclusion in the study. Patient records will be screened for the inclusion and exclusion criteria mentioned below, data collection from the Trauma Registry and/or a review of the patient chart will include patient demographics, past medical history, injury related details, physiologic details, diagnostic tests and
findings, CT capability (i.e., 32, 64, 128 slice), surgical timing and results, complications, length of stay (LOS), intensive care unit (ICU) LOS, disposition, and return to hospital for related cause within 30 days.

1. Records/Data to be reviewed – At MUSC the study team will request the following from the Trauma Registry per year for the study time frame: the number of adult yearly trauma admissions, adult yearly trauma activations, adult yearly blunt mechanism admissions, and adult yearly trauma patients with an abdominal CT performed in the ED. All patient-level requests will consist of patients 18 years and older and without an ICD-9-CM code of 863.21 or 863.31. All data points may be collected from the Trauma Registry, patient charts, administrative data, or other, as available. PHI that may be collected include the patients’ hospital identification number, name, age, and dates (i.e., dates of injury, admission, abdominal CTs, surgery, discharge).

Three lists of patients will be requested from the Trauma registry:

1. Potential Cases
   A. All patients with the following criteria
      - 18 years or older,
      - Admitted from 10/1/13 through 9/30/15,
      - No ICD-9-CM code of 863.21 or 863.31,
      - A code for small bowel surgery (CPT=44120, 44121, 44202, 44203, 44602, 44603, or 44130; ICD-9 Procedure code=45.61, 45.62, 45.90, 45.91, 45.93, or 46.73),
      - Blunt mechanism only, and
      - All non-abdominal AIS scores are <3.
   B. Request the Trauma Registry send a list of patients meeting the above criteria with the following data points listed: hospital identification number &/or name, age, admission date & time, all ICD-9-CM diagnosis codes including E & V codes, all CPT or ICD-9 Procedure codes, mechanism of injury, date & time of initial abdominal CT (if done), admission status (whether transferred from another ED or not), AIS scores for all 9 body regions, and ISS.
   C. Abstract these patients’ charts.

      I. If patients had an abdominal CT within the initial 6 hours of arriving at the ED and had a surgical report stating the presence of non-duodenal small bowel perforation, with no other major operative findings requiring repair or resection, they are considered a Small Bowel Perforation (SBP) Case.

      II. If patients did not have an abdominal CT prior to going to surgery, and had a surgical report stating the presence of non-duodenal small bowel perforation, with no other major operative findings requiring repair or resection, they are considered a SBP Diagnosed without CT. If a patient in this group that did not have an abdominal CT at this hospital but had one within 6 hours of admission to an ED prior to the patient’s transfer to this ED and there are CT findings in the chart, that patient can be removed from this group and added to the SBP Cases.

      III. All other patients are discarded.

2. Potential Controls
   A. All patients with the following criteria
      - 18 years or older,
      - Admitted from 10/1/13 through 9/30/15,
      - No ICD-9-CM code of 863.21 or 863.31,
      - None of the codes for small bowel surgery (CPT=44120, 44121, 44202, 44203, 44602, 44603, or 44130; ICD-9 Procedure code=45.61, 45.62, 45.90, 45.91, 45.93, or 46.73),
      - Blunt mechanism only,
      - All AIS scores, including the abdominal region, are <3,
      - Was a trauma activation, and
      - Had an abdominal CT within the initial 6 hours of admission (or at the initial ED if the patient was transferred to your hospital, and you have the CT findings).
   B. Request the Trauma Registry send a list of patients meeting the above criteria with the following data points listed: hospital identification number &/or name, age, admission date & time, all ICD-9-CM diagnosis codes including E & V codes, all CPT or ICD-9 Procedure codes, mechanism of injury, date & time of initial abdominal CT, admission status (whether transferred from another ED or not), AIS scores for all 9 body regions, and ISS.
   C. Randomly choose twice as many of these charts to abstract as the number of SBP Cases.
   D. Abstract these patients’ charts.
I. If the patients met the listed criteria and they did not have abdominal surgery, they are considered the Controls.
II. If during abstraction a patient does not fulfill the above criteria, discard that patient and randomly choose another one.

3. SB injury coding and mechanism
A. All patients with the following criteria
   - 18 years or older,
   - Admitted from 10/1/13 through 9/30/15,
   - No ICD-9-CM code of 863.21 or 863.31, and
   - A code for small bowel surgery (CPT=44120, 44121, 44202, 44203, 44602, 44603, or 44130; ICD-9 Procedure code=45.61, 45.62, 45.90, 45.91, 45.93, or 46.73) and/or non-duodenal small bowel injury (863.2, 863.20, 863.29, 863.3, 863.30, or 863.39).
B. Request the Trauma Registry send a list of patients meeting the above criteria with the following data points listed: all CPT or ICD-9 Procedure codes, mechanism of injury (blunt, penetrating, other), and all ICD-9-CM diagnosis codes. No patient identifiers should be included.

2. Estimated number of records: Minimum of 260 cases and 520 frequency matched controls, plus whatever number of SBP with no abdominal CT. We anticipate a maximum of 1000 records for those groups. In addition, we anticipate the number of abbreviated records from the ‘SB injury coding and mechanism’ group not to exceed 10,000. We plan to recruit 100 trauma centers to join the study some of them will be international.

3. Date Range of Records to be included in this review from 10/1/2013 to 9/30/2015

4. Data analyses.
   1. Describe current methods trauma centers are using to diagnose non-duodenal SBP in patients with blunt abdominal trauma. Descriptive statistics will be used to evaluate the percentages of patients diagnosed via abdominal CT, Focused Assessment with Sonography in Trauma (FAST), abdominal ultrasound, x-ray, and/or diagnostic peritoneal lavage (DPL). Percentages of positive findings for each diagnostic modality, as well as physical exam, laboratory values, and vital signs (VS), will be calculated for patients with and without SBP.
   2. Describe current mortality and morbidity due to blunt near-isolated non-duodenal SBP. Calculate overall mortality rate of patients with SBP, mortality rates by time to surgery, overall morbidity rate as number of complications, and morbidity rate of types of complications,
   3. Describe the current average time to surgery for patients with blunt near-isolated non-duodenal SBP. Overall time to surgery will be calculated, as well as percentages of patients with SBP going to surgery in <8 hours, <16 hours, <24 hours, and ≥24 hours.
   4. Describe the frequency and utility of a second abdominal CT scan, and its association with time to surgery and incidence of post-operative complications in patients with blunt near-isolated non-duodenal SBP who did not go to surgery emergently (=within 4 hours) after an initial CT. Percentage of patients with SBP who had a 2nd abdominal CT scan prior to surgery, percentage with deteriorating physical exam pre-operatively and a 2nd CT scan, average pre-op lab values of patients with 2nd CT scan, and average pre-operative VS of patients with 2nd CT scan. A linear regression will be modeled with outcome of time to surgery and main independent binomial variable of the occurrence of a 2nd CT scan. Other independent variables may include admission and pre-operative VS, admission and pre-operative lab values, admission and pre-operative physical exam, comorbid conditions, gender, race, payer status, slice level of CT machine, and presence of a hospital protocol regarding a second CT scan. Since there is little in the way of pre-existing data on which to build a sample size calculation, we are using a ‘rule of thumb’ calculation of 10-20 observations per degree of freedom for a Cox regression, and assuming all continuous variables will have a linear relationship with the outcome of time to surgery. If we have a full model with 13 degrees of freedom, we would need a sample size range of 120 to 260 patients with a 2nd CT scan to compare to 120 to 260 with only one CT scan.
   5. Determine the sensitivity and specificity of the best combination of diagnostic findings for distinguishing SBP and no SBP in patients with blunt abdominal trauma and no other severe
injuries who had at least one abdominal CT. A multivariate logistic regression will be modeled with outcome of SBP or none, and using independent variables of all available diagnostic findings (ie, radiologic, laboratory, physical). Again, since there is little in the way of pre-existing data on which to build a sample size calculation, we are using a 'rule of thumb' calculation of 10-20 observations per degree of freedom multiplied by the inverse percent of expected events for a logistic regression. If we anticipate a full model with 26 degrees of freedom, we will need a sample size range of 260 to 520 patients with SBP to compare to at least 260 to 520 patients without SBP.

6. **Determine how often the codes 863.20, 863.29, 863.30 and 863.39 are being assigned to patients with small bowel injuries due to blunt versus penetrating mechanism.** A cross-frequency of mechanism (blunt or penetrating) by diagnosis code will be done for each diagnosis code of 863.20, 863.29, 863.30, and 863.39. In addition, we will determine what percentage of patients with a diagnosis code of perforated small bowel injury have a small bowel surgical code, and vice-versa (what percentage of patients with a small bowel surgical code have an 863 code).

Descriptive statistics will be calculated on hospital level data, Additional descriptive statistics will be calculated on rate of false negative CT scans.

**C. PROTECTION OF HUMAN SUBJECTS**

1. **HUMAN SUBJECTS INVOLVEMENT AND CHARACTERISTICS**

The study sample will be derived from patients admitted to the MUSC trauma center and other participating trauma centers, nationally and internationally.

**Inclusion criteria:**
All subjects must be ≥ 18 who suffered blunt trauma.

First Group (SBP Cases):
1. Had at least one abdominal CT done within the initial 6 hours
2. Had surgery for small bowel perforation

Second Group (Controls, frequency matched 2:1 for each case):
1. Had at least one abdominal CT done within the initial 6 hours
2. No abdominal surgery
3. Was a trauma activation

Third Group (SBP diagnosed without CT):
1. Had surgery for small bowel perforation
2. No abdominal CT done within the initial 6 hours

**Exclusion criteria:**
1. Duodenal injuries.
2. Abbreviated Injury Scale (AIS) of >2 for injuries other than perforated small bowel, including other intra-abdominal injuries.

Fourth Group (SB injury coding and mechanism) with inclusion criteria limited to ≥18 and exclusion criteria limited to duodenal injuries.
1. Was a trauma patient.
2. Had ICD-9-CM code for small bowel injury and/or a procedure code for small bowel surgery.

We plan to include persons of any gender or race who are eligible for the study.

2. **SOURCES OF MATERIALS**

No samples or materials will be obtained from patients. Patients' medical records will be accessed for collection of data. Patients included in the study will be maintained in a master patient list, and only study personnel will have access to the list.

All data will already exist in the patient medical record at the time of data collection and no new data, specimens, or samples will be collected from patients. De-identified data for all participating sites will be maintained in a in an
online, secure, REDCap database. The REDCap is password protected. Each site will have access to subjects enrolled from their site only. Only MUSC Study team will have access to the entire database, and will have the ability to monitor data input from each participating site. Research records will be entered into this computerized study database and will be assigned a unique ID code. Participating sites will be allowed to submit data to the main data base only after MUSC has received a copy of their IRB approval, or equivalent agencies’ approval for non-US centers. At MUSC a master key which links MUSC subjects’ names and PATCOMs with the codes for each research record will be maintained until the study has ended and all the information has been collected and verified with the hospital chart. This information will be stored on a password-protected MUSC server accessible only to study team members. Any hard copy information that may have PHI will be stored in a locked drawer or cabinet. Patient names and PATCOM numbers will not be entered in to the database. In addition, in lieu of dates, sites will count day of injury as day zero and all other dates as days from injury to preclude transmission of PHI.

3. RISKS AND BENEFITS (*modify below as needed)

-Risks: There are no physical risks associated with this study because there are no study-related interventions or interaction with the patients. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep each subject’s information confidential.

-Benefits: The subjects whose records are used are not likely to receive any benefit from the proposed research; however, future patients and clinicians may benefit from the knowledge gained.

4. ADEQUACY OF PROTECTION AGAINST RISKS

Confidentiality of Data:

Both here and at any participating site all paper research records will be stored in locked file cabinets and will be accessible only to research personnel. All electronic research records will be computer password protected and also accessible only to research personnel. Research records will be entered into a computerized study database and will be labeled with a code. A master key which links the subjects’ names with the codes for each research record will be maintained at the local investigative site until the study has ended and all the information has been collected and verified with the hospital chart. Subjects will not be identified in any presentations or publications based on the results of this research study.

All patient data will be de-identified prior to being entered into the database so that no identifiable information is to be submitted. To de-identify the data leaving MUSC and all participating sites, patients will be assigned a unique identifier at each site in lieu of name or medical record number, any patients with an age older than 89 will have their age entered as ‘>89’, and dates will be entered as days from injury, with injury date entered as zero.

Each site PI will have access to subjects enrolled from their site only. Only MUSC Study team will have access to the entire database, and will have the ability to monitor data input from each participating site. At least monthly, the number of subjects enrolled will be determined and the amount of missing data will be determined by the study team. To ensure consistency among sites regarding data entry, a study related data dictionary will be developed. These efforts will help to ensure that the data gathered as part of this study is of the highest quality possible.

Data will be stored for (6) years. It will be wiped from the server drive when no longer needed.

5. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

Small bowel perforation (SBP) is a rare complication of blunt abdominal trauma. Estimates of the frequency of small bowel trauma in blunt abdominal trauma range from 5 – 15% (Mathonnet M 2003) with perforation occurring in 1% or less of blunt abdominal traumas (Fakhry SM 2000, Watts DD 2003). The rarity of this type of injury, combined with the low sensitivity and specificity of many diagnostic tests and procedures, make this a difficult diagnosis, and require a large patient population to examine the problem. Delay in diagnosis of a SBP can result in serious complications and death, making timely diagnosis critical in the treatment of these patients.
D. REFERENCES/LITERATURE CITATIONS

List all references. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The reference should be limited to relevant and current literature. It is important to be concise and to select only those literature references pertinent to the proposed research.


**Blunt Trauma Mechanism**

- Age ≥ 18
- No Duodenal Perforation
- AIS ≤ 2 except for SBP

**Group 1a**
- SBP W/O CT
- SBP confirmed by operative report
- Yes
- No
- Discard

**Group 1b**
- SBP confirmed by operative report
- Yes
- No
- Discard

**Group 2**
- Abdominal AIS > 2
- Yes
- No
- Trauma Activation
- Yes
- No
- Discard

**Group 3**
- Abdominal CT-scan
- Yes
- No
- Abdominal Surgery
- Yes
- No
- Cargo

**Group 4**
- Send to MUSC all of:
  - CPT or ICD-9 Procedure codes
  - ICD-9-CM diagnosis codes
  - Mechanism of injury

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- Abdominal CT should be within the initial 6 hours of admission, OR at the initial ED if the patient was transferred to your hospital and you have the CT findings.
- Discard that patient and randomly choose another one from the pool.
- Patient should NOT have any other major abdominal finding requiring repair or resection.
- CPT=44120, 44121, 44202, 44602, 44603, or 44130; ICD-9 Procedure code=45.61, 45.62, 45.90, 45.91, 45.93, or 46.73; ICD-9-CM SBI codes=863.2, 863.20, 863.29, 863.3, 863.30, or 863.39
- Abdominal surgery would include any operation with access to the peritoneal cavity.