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Institutional Review Board

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June 16, 2023

Shannon Castle, MD
Surgery Dept.
Valley Children's Healthcare
9300 Valley Children's Place
Madera, CA 93636

Initial Approval – Expedited Review

HSC2553 – Performance of prediction rules for pediatric blunt trauma in trauma centers without current guidelines: a retrospective study

Study Risk Assignment: Minimal Risk

Approval Date: June 16, 2023

Expiration Date: None

Dear Dr. Castle:

All documents for the above-referenced study were reviewed and approved via expedited review on June 16, 2023.

The study was approved in accordance with regulations found at 45CFR46.110(5). Your request for a waiver of consent was approved in accordance with regulations at 45CFR46.116(f)(1).

A waiver of HIPAA Authorization is acceptable for the conduct of the study.

1. The study procedures do not adversely affect the rights and welfare of the individuals and pose minimal risk to their privacy, based on, at least, the presence of the following elements:
 - a. An adequate plan to protect the identifiers from improper use and disclosure;
 - b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless a health or research justification for retaining the identifiers was provided or such retention is otherwise required by law;
 - c. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule;
2. The research could not practicably be conducted without the waiver; and
3. The research could not practicably be conducted without access to and use of the protected health information.

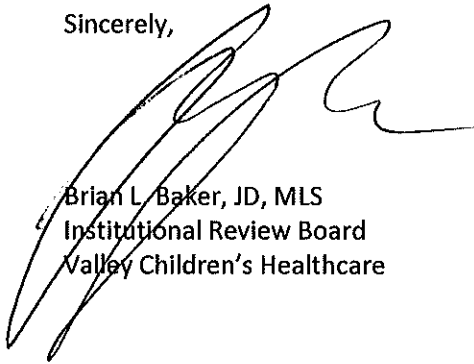
In the future, if you wish to make subsequent changes to the study, they must be re-approved by the IRB prior to implementation of the changes.

It has been determined that this study does not require future continuing review, per the regulatory criteria set forth in 45CFR46.109(f)(1). Changes to the study must be reported promptly so the IRB can determine whether the protocol still meets this regulatory criteria, and all mandatory reporting obligations are still in effect. In the future, if you wish to make subsequent changes to the study, they must be re-approved by the IRB prior to implementation of the changes.

Please notify the board immediately of any proposed changes to the protocol, amendments, revisions, or any unanticipated problems involving risks to subjects or others in the protocol. If there are any serious or unexpected adverse events, please send a written response, as to your opinion whether it was study-related and whether it is safe to continue the study.

To ensure adherence to good clinical practice, the IRB may audit your study in the future. If you have questions, please do not hesitate to contact the IRB at (559) 353-5171. As soon as the study closes, please inform the IRB immediately with a summary report and submit a Study Retirement Form.

Sincerely,

A handwritten signature in black ink, appearing to read 'Brian L. Baker', is written over the typed name and title.

Brian L. Baker, JD, MLS
Institutional Review Board
Valley Children's Healthcare

Documents reviewed in support of this application:

- IRB application 04/12/2023
- Study protocol outline from Children's Hospital of Orange County
- Request for waiver of patient authorization for the use of PHI in research 03/03/2023



Eastern Association for the Surgery of Trauma
Advancing Science, Fostering Relationships, and Building Careers

EAST MULTICENTER STUDY DATA COLLECTION TOOL

Multicenter Study: Performance of prediction rules for pediatric blunt trauma in centers without current guidelines: a retrospective study

Enrolling Center: _____
Enrolling Co-investigator: _____

Center data (to be submitted once for each center):

ACS-verified trauma center. YES / NO

Level (Check one): I _____ II _____ III _____ IV _____

Formal pediatric imaging guidelines for imaging in Head injury YES / NO

If Yes, which guideline _____

Formal pediatric imaging guidelines for Chest imaging YES / NO

Formal pediatric imaging guidelines for Abdominal imaging YES / NO

If Yes, which guideline _____

Demographics / Injury Variables:

From trauma registry, to be submitted as trauma registry output file:

age, sex, race, ethnicity, BMI, Injury Severity Score, Abbreviated Injury Scores for each region, Glasgow Coma Score, initial vital signs, imaging codes, diagnoses during admission (ICD-9 or ICD-10), operations during admission, ICU length of stay, hospital length of stay, discharge disposition, and mortality.

Data to be collected and inputted into RedCap:

Patient identifier _____

Mechanism of initial injury:

Blunt: YES / NO

Admission Lab values:

WBC: _____ Hemoglobin: _____ Hct: _____ Creatinine: _____ LDH: _____ AST: _____
ALT: _____ Amylase: _____ Lipase: _____

Intervention:

Intubated (Circle one) : YES / NO

History and exam (Circle one):

Decreased breath sounds YES / NO

Thoracic wall trauma YES / NO

Vomiting YES / NO

Complaint of abdominal pain YES / NO

Abdominal tenderness YES / NO

Abdominal wall trauma, tenderness or distension YES / NO

2 years or older:

Signs of basilar skull fracture (hemotympanum, otorrhea, clear rhinorrhea, bruising under eyes or over mastoid) YES / NO

Altered mental status (agitation, somnolence, slow response, repetitive questions) YES / NO

Loss of consciousness YES / NO

Severe headache YES / NO

Severe mechanism of injury (Fall > 5 ft, MVA with ejection, rollover or fatality, bike/ped vs vehicle without helmet, struck by high impact object) YES / NO

Younger than 2 years:

Palpable skull fracture YES / NO

Scalp hematoma (excluding frontal) YES / NO

Altered mental status (agitation, somnolence, slow response, repetitive questions) YES / NO

Loss of consciousness > 5 seconds YES / NO

Not acting normally per parent YES / NO

Severe mechanism of injury (Fall > 3 ft, MVA with ejection, rollover or fatality, bike/ped vs vehicle without helmet, struck by high impact object) YES / NO

Imaging on admission:

CXR done YES / NO

Abnormal YES / NO

Findings _____

CT abdomen/pelvis done YES / NO

Abnormal YES / NO

Findings _____

CT head done YES / NO

Abnormal YES / NO

Findings _____

FAST done YES / NO

If done (Circle one) : POSITIVE FAST / NEGATIVE FAST





Eastern Association for the Surgery of Trauma
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**EAST MULTICENTER STUDY
DATA DICTIONARY**

Performance of prediction rules for pediatric blunt trauma in centers without current guidelines

– Data Dictionary

Data Entry Points and appropriate definitions / clarifications:

Entry space	Definition / Instructions
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Mechanism of initial Injury

Blunt	Single choice for best description of blunt mechanism (if penetrating mechanism proceed to next data point) Options include: MVC, Auto vs. Peds (Pedestrian), Fall, Assault, MCC (Motorcycle Collision / Crash) Machinery Other
Penetrating	Single choice for best description of penetrating mechanism. Options include: GSW (Gunshot wound) Shotgun (Shotgun wound) Stab (Stab Wound) Other
ISS	Numerical value for calculated ISS (ISS = Injury Severity Score)
AIS Head	Numerical Value for AIS body region = Head (AIS = Abbreviated Injury Score)

Admission Lab Values

WBC	Admission white blood cell number value (x10 ³ /microliter)
Hemoglobin	Admission Hemoglobin value (g/dL)
Hematocrit	Admission hematocrit (%)
Creatinine	Admission creatinine (mg/dL)
LDH	Admission lactate dehydrogenase (U/L)
AST	Admission aspartate transaminase (U/L)
ALT	Admission alanine transaminase (U/L)
Amylase	Admission amylase (U/L)
Lipase.	Admission lipase (U/L)

Intervention:

Intubated Choose YES if the patient is intubated at the time of initial exam

History and Exam: For each, document YES if either the trauma flowsheet OR the documented history and physical documents the following findings or history:

Decreased breath sounds	Decreased breath sounds on one or both sides of the chest
Thoracic wall trauma	Any bruising, abrasion, laceration or deformity to chest wall
Vomiting	Vomiting prior to presentation or in trauma bay
Complaint of abdominal pain	Patient complaint of abdominal pain
Abdominal wall trauma or distension	Any documented bruising, abrasion, discoloration, laceration to abdomen, or documentation of abdominal distension

2 years or older:

Signs of basilar skull fracture	Documented hemotympanum (may be documented as blood behind TM), otorrhea (any documentation of clear fluid from ear), rhinorrhea (any documentation of clear fluid from nose) bruising under eyes or under mastoid
Altered mental status	Any documentation of agitation, somnolence, slow response, repetitive questions, or documentation saying "altered mental status"
Loss of consciousness	Any documentation indicating loss of consciousness after trauma, either in field or in hospital. Includes documentation saying "+LOC" or "LOC"
Severe headache	Any documentation of severe or "bad" headache, head pain
Severe mechanism of injury	Fall > 5 ft, MVA with ejection, rollover or fatality, bicycle or pedestrian

struck by vehicle without helmet, struck by high impact object

Younger than 2 years:

Palpable skull fracture	Documentation that any clinician can feel a skull fracture on patient.
Scalp hematoma	Any non-frontal hematoma on scalp.
Altered mental status	Any documentation of agitation, somnolence, slow response, repetitive questions, or documentation saying "altered mental status"
Loss of consciousness > 5 seconds	Any documentation indicating loss of consciousness after trauma for greater than 5 seconds, either in field or in hospital. Includes documentation saying "+LOC" or "LOC"
Not acting normally per parent	Any documentation (triage, trauma flowsheet, history and physical) that says caregiver or parent says child not acting normally
Severe mechanism of injury	Fall > 3 ft, MVA with ejection, rollover or fatality, bicycle or pedestrian struck by vehicle without helmet, struck by high impact object

Imaging on admission:

CXR done	Choose YES if a chest radiograph was performed at time of initial evaluation
Abnormal	If any abnormal finding on initial chest radiograph performed at initial evaluation, choose YES
Findings	If any abnormal finding(s) on chest radiograph, free text finding
CT abdomen/pelvis done	Choose YES if computed tomography of the abdomen AND pelvis was performed at the time of initial evaluation
Abnormal	If any abnormal finding on initial computed tomography of the abdomen AND pelvis choose YES
Findings	If any abnormal finding(s) on computed tomography of the abdomen and pelvis, free text finding(s)
CT head done	Choose YES if a computed tomography of the head/brain was performed at time of initial evaluation
Abnormal	If any abnormal finding on initial computed tomography of the head/brain performed at initial evaluation, choose YES
Findings	If any abnormal finding(s) on computed tomography of the head/brain, free text finding(s)
FAST done	Choose YES if a Focused Assessment with Sonography for Trauma exam was performed at the time of initial evaluation
If done, positive/negative	Documentation of a "positive" FAST including free fluid in cardiac, right upper quadrant, left upper quadrant, or pelvic windows. This may be on a formal radiology read or documented in the trauma flowsheet or chart.



Type of temporary closure utilized continued...

bridge such as IV bag)

Type of device	Type of device utilized, if NPWT (negative pressure wound therapy) employed. Check for those that apply: Options include: KCI (copyright) product Non-commercial apparatus (includes "poor man's vac" or cassette drape / towel / occlusive dressing construction
Type of KCI product	Name of KCI (copyright) product utilized if appropriate. If not utilized, leave blank
Other type of temporary	Free text utilized to describe NON-Vaccum assisted
Closure	closures (ex. Towel clip, or non-Wittman patch

Post-operative course

Fluid requirements first 24 hours after surgery

Colloid (cc)	Free text entry of total colloid requirements within first 24 hours of surgery. For this section, colloids include all blood products as well as non-blood product colloids (ex. Albumin, hespan, hexend) (in cc)
Crystalloid (cc)	Free text entry of total crystalloids infused in the 24 hours following surgery (in cc)
Total fluids (cc)	Total colloid and crystalloid infused the first 24 hours after surgery (in cc)

Fluid requirements 48 hours after surgery

Colloid (cc)	Free text entry of total colloid requirements within first
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	48 hours of surgery. For this section, colloids include all blood products as well as non-blood product colloids (ex. Albumin, hespan, hexextend) (in cc)	Interval between re-explorations	Free text entry of interval between re-explorations (in hours). If the time between these schedule interventions was variable as close an estimation as possible should be utilized. If these were planned at specific intervals (ex. Every 48 hours, every 72 hours) use these estimation values
Crystalloid (cc)	Free text entry of total crystalloids infused in the 48 hours following surgery (in cc)		
Total fluids (cc)	Free text entry of total colloid and crystalloid infused the first 48 hours after surgery (in cc)	Time to normalization of lactate	Free text time to normalization of lactate (defined for the purpose of our study as serum lactate <2.1 mmol/L) - In hours.
Time to first re-exploration (hours)	Free entry of time to first re-exploration after initial operation (in hours)	<u>Fluid requirements 48 hours after surgery</u>	<u>continued</u> ⋮
Total number of re-explorations	Free text entry of total number of re-explorations after initial operation	Post-operative antibiotics	Yes or No drop down menu. Post-operative antibiotics include any antibiotics administered

d after completion of initial surgical intervention as a **continued order** (either at dosing intervals – such as every 6 hours, or as a continuous infusion). Do not include in this or any of the other following three data free text areas any antibiotics started after any period of antibiotic free interval post-operatively.

post-operative antibiotics meeting above definition are continued.

Mechanical Ventilation

Ventilation mode post-operatively

Free text entry of ventilation mode utilized. Abbreviations appropriate (examples: SIMV for spontaneous intermittent mechanical ventilation, APRV, or CMV, etc)

Maximum peak airway pressure

Free text entry of peak airway pressure encountered at any point during the use of mechanical ventilation post-operatively (mm/Hg)

Type

Free text entry – Type of antibiotic utilized (tradename or generic name)

Dosing interval

Dose and interval of antibiotic utilized as a continued order after operation (ex. 3.375 gm q6h interval)

Initiation of enteral feeding

Free text entry of day of enteral feeding initiation in days (day of admission = hospital day #1)

(hospital day)

Duration of use (days)

Duration of antibiotic use (in days) that

Ileus

Yes or No drop down

menu. Did the patient develop ileus after feeding?

Feeding Intolerance

Yes or No drop down menu. Did patient develop feeding intolerance at any time after initiation of enteral feeding?

When did the patient reach goal enteral nutrition feeding?

Free text entry of hospital day patient reached goal enterla nutrition feeding rate as determined by care team (day of admission = hospital day #1)

Was a tracheostomy required?

Yes or no drop down menu. Did the patient undergo a trachesotomy

Hospital Day

Free text entry of hospital day trach required (leave blank if no trach required) – Day of admission = hospital day #1

Outcomes

Fascial closure attempted during

Yes or No dropdown menu.

patch to ultimately achieve subsequent primary re-approximation of native fascia

Initial hospitalization?

Fascial closure is defined as closure of the fascia, with or without bridging material between fascial edges (synthetic or biologic) over the enteric contents.

Synthetic Mesh = use of synthetic mesh fixated to fascial edges to restore abdominal domain

If yes, what type of closure

Type of closure (as defined above) utilized.

Biosynthetic / biologic Mesh = use of biosynthetic or biologic mesh fixated to fascial edges to restore abdominal domain

was utilized (check one that

Choose the ONE option that best describes the method utilized. Options include:

applies)

Primary fascial closure = primary re-approximation of native fascia in a serial or one-operation fashion

Seperattion of components = Surgical mobilization / division of the fascial planes of the anterior abdominal wall / muscular fascial to provide mobility required to facilitate primary re-approximation of the fascial edges

Wittman patch to primary closure = serial use of a Wittman

Type of synthetic mesh	Other Free text entry for description / brand name of synthetic mesh utilized to bridge fascial edges. Leave blank if none utilized		Covered initially with vac – skin closure same hospitalization (skin approximated in delayed fashion) Skin closure over biologic at initial closure operation
Type of biosynthetic / biologic	Free text entry for description / brand name of biosynthetic or biologic mesh utilized to bridge fascial edges. Leave blank if none utilized	Other	Free text entry to describe other outcome for open abdomen not described above
Mesh		When was fascial closure achieved (hospital day)	Free text entry for hospital day that fascial closure (as defined above) was achieved (date of admission = hospital day #1)
Type of management of biologic	Check those that apply only if biologic mesh utilized. Options include: Nothing selected = Unknown / Data not available		
Mesh	Covered with wound vac – discharged with vac	<u>Outcomes continued...</u> Results of fascial closure (check one that best applies)	Check box that best applies. Options include: Nothing selected =

Information not available	Other	Free text entry for use if re-exploration required for a reason falling in the "Other" category above
No complication		
Re-exploration required		

Re-exploration required for:

Drop down menu outlining reasons for re-exploration. If no re-exploration was required, leave blank. Options include:

Abdominal compartment syndrome (defined as elevated abdominal pressures requiring re-exploration)

Abdominal sepsis (defined as intra-abdominal infection requiring re-exploration for infectious cause)

Dehiscence / early repair failure

Other

Complications (check all that apply and list hospital day encountered)

NOTE = for calculation of all complication days, day of admission = hospital day #1

Definitions of complications included in this section:

Enteric fistula	Check if applies. Defined as free communication between the skin or outside surface of an open abdomen and any portion of the enteric tract
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Hospital Acquired Pneumonia	Check if applies. Definition below.
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Hospital Acquired Pneumonia: Confirmed by the presence of the following after 48 hours of hospitalization:

1. purulent sputum
2. associated systemic evidence of infection:
 - a. WBC > 11,000 or < 4,000
 - b. Fever > 100.4 degrees F / 38 degrees Celsius

3. Two or more serial chest radiographs with new or progressive and persistent infiltrate, consolidation or cavitation.
4. BAL, mini-BAL or sterile endotracheal specimen with:
 - a. Limited number of epithelial cells
 - b. WBC (2-3+)
 - c. Dominant organism(s) identified on gram stain or culture with quantitative culture > 100,000 cfu/mL

BSI Check if applies. BSI = Blood stream infection.

Defined as positive cultures obtained from blood culture.

VAP Check if applies. VAP = Ventilator-associated pneumonia.

Definition below.

VAP: Hospital acquired pneumonia (as defined above) occurring in a patient who was intubated and ventilated at the time of or within 48 hours before onset of pneumonia.

Catheter-associated UTI Check if applies. UTI = Urinary tract infection. Definition below:

Catheter-associated UTI: All criteria must be met:

1. Patient has had an indwelling urinary catheter within 7 days before urinary culture.
2. Positive urine culture, that is $\geq 10^5$ microorganisms/ml of urine with no more than two species of microorganisms
3. Urine culture has 10wbc/hpf

Sepsis Check if applies. Definition below.

Sepsis:

Has a confirmed infectious process AND two or more of the following:

1. Body temperature < 36 degrees Celsius (97 F) or > 38 C (100 F)
2. Heart rate > 100 bpm
3. Respiratory rate > 20 breaths per minute or, on blood gas, PaCO₂ of less

4. White blood cell count > 4,000 cells/mm³ or > 12,000 cells/mm³ or greater than 10% and forms (immature wbc) than 32 mm Hg

Intra-abdominal abscess / sepsis Check if applies. Defined as intra-abdominal abscess or abdominal source for sepsis

DVT / PE Check if applies. DVT = Deep Vein Thrombosis PE = Pulmonary embolism. Diagnosis must be confirmed radiographically (Ultrasound, Computed tomography, venography, etc.)

Acute Renal Failure Check if applies. Defined for the purpose of this study as elevation of serum creatinine greater or equal to 2.0 mg/dL during hospitalization in patient without antecedent renal dysfunction.

ALI / ARDS Check if applies. ALI = Acute Lung Injury ARDS = Acute respiratory distress syndrome. Definition(s) below:

ALI / ARDS: ARDNet definitions will be utilized – (ALI PaO₂/FiO₂ < 300; ARDS – PaO₂/FiO₂ < 200; either must have appropriate radiographic findings)

Hospital LOS (days) Free text entry for number of consecutive days patient hospitalized at initial admission (Day of admission = hospital day #1) LOS = Length of Stay

ICU LOS (days) Free text entry of number of consecutive days patient required ICU admission (ICU = Intensive Care Unit, LOS = Length of Stay) - Day of admission = hospital day #1

Duration of Mechanical entry for total number of days patient Ventilation (days) mechanical ventilation (Day of admission = hospital day #1)	Free text required
Mortality menu. Yes or No. Did patient expire hospitalization?	Drop down during initial
Mortality within 48 hours of menu – yes or no. Did patient expire Admission hours of admission?	Drop down within 48