Title of project: Utility of Abdominal Ultrasound in the Evaluation of Children with Blunt Trauma

Sponsored by: Emergency Medical Services for Children (1 H34MC19682-01-00)

non-IND Protocol

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DRAFT Version 2.0
October 28, 2010
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PROTOCOL TEAM ROSTER

Chair James F. Holmes

Co-Chairs Nathan Kuppermann

Statistician(s) Dan Tancredi, PhD
STUDY MANAGEMENT

Abbreviations in protocol:
ED = emergency department
FAST = Focused Assessment Sonography for Trauma
RC = research coordinator
UCDMC = University of California Davis, Medical Center
US = ultrasound
Utility of Abdominal Ultrasound in the Evaluation of Children with Blunt Trauma

**Title**

**DESIGN** Randomized Controlled Trial

**DURATION** Three Years

**SAMPLE SIZE** 925

**POPULATION** Patients < 18 years old with blunt torso trauma

**STRATIFICATION** *(not applicable)*

**REGIMEN OR INTERVENTION** FAST examination (Abdominal US examination in trauma patients)

**SUBSTUDIES**

- Impact of FAST on Clinician impression of intra-abdominal injury
- Validation of scoring systems for the FAST examination
1.0 HYPOTHESIS AND STUDY OBJECTIVES

1.1 **Hypothesis**: We hypothesize that an ED evaluation strategy that includes the FAST examination will improve the clinical management of children with blunt torso trauma.

1.2 **Primary Objective(s)**: To evaluate a clinical pathway that includes the FAST examination in children with blunt abdominal trauma.

1.3 **Secondary Objectives**: To evaluate the cost effectiveness of a clinical pathway that includes the FAST examination in children with blunt abdominal trauma.

2.0 INTRODUCTION

2.1 **Background**

Traumatic injury is the fifth leading cause of death in the United States but the leading cause of death during childhood. More than 28,000 individuals younger than 24 years of age died from traumatic injuries in 2006. Although injuries to the central nervous system are the leading cause of traumatic death, hemorrhage into the thoracic or abdominal cavity is the second most frequent cause, accounting for 30% of all traumatic deaths.

Abdominal ultrasound (US) has also evolved as a diagnostic test for the evaluation for intra-abdominal injury, but it is used primarily in injured adults. Advantages of abdominal US (compared to CT) include: bedside availability during initial ED evaluation/resuscitation, rapid (3-5 minutes) completion and data acquisition, ability for serial examinations, performance and interpretation by both ED physicians and surgeons, and lack of radiation exposure. Although the sensitivity of US for detecting intra-abdominal injury is not as great as that of CT, its sensitivity for injuries requiring therapy is quite similar to abdominal CT and its use as a screening test in the evaluation of the trauma patient may significantly improve clinical care.

The Institute of Medicine considers research on the “clinical aspects of emergency care” in children a high priority topic, identifying specifically issues in treatment of children with intra-abdominal injuries and variation in provision of care to children with such injuries. Furthermore, the Pediatric Emergency Care Applied Research Network (PECARN) has identified “best practices in patient care” and “practice protocols” as top areas for future research in pediatric emergency medicine. This proposal focuses on improving the safety and efficiency of the evaluation of children suffering from blunt abdominal trauma.
2.2 Rationale

Evidence from randomized, controlled trials in adult trauma patients indicates that implementation of an initial ED evaluation strategy, including immediate abdominal US, results in improved clinical parameters (decreased complications and hospital length of stay), safely decreased abdominal CT use, and decreased hospital costs. However, due to lack of definitive evidence (including the complete absence of randomized, controlled trials in children), abdominal US is not routinely used in the initial ED evaluation of children with blunt abdominal trauma. A survey of United States pediatric ED physicians indicates that <15% use abdominal US to screen children with trauma for intra-abdominal injuries, similar to the rate of US use in a current observational study of pediatric abdominal trauma in the PECARN, in which the key investigators of this proposal (J.H. and N.K.) are involved. The primary objective of this proposed study addresses this gap in scientific knowledge by proposing a randomized, controlled trial of US use in the evaluation of children with blunt abdominal trauma. We will use rigorous methodology and a large sample size to identify with great confidence whether a strategy using abdominal US in the initial ED evaluation of injured children will improve care and promote the safety of traumatized children. If this study demonstrates the clinical utility of an evaluation strategy using abdominal US, the injured children evaluated for intra-abdominal injuries across the United States and their families and society at large would stand to benefit.

We propose a randomized, controlled clinical trial of abdominal US during the initial ED evaluation of children with blunt abdominal trauma. Currently, there is ample observational data on the performance of abdominal US in children with blunt abdominal trauma to suggest potential clinical utility of a strategy using abdominal US in the initial evaluation of children with blunt abdominal trauma. Despite this observational evidence, trauma abdominal US has not achieved widespread acceptance for use in evaluating injured children. The primary barrier preventing implementation of abdominal US in the initial evaluation of injured children is the lack of a randomized, controlled trial demonstrating utility and safety. We will conduct such a trial with sufficient sample size and methodologic rigor to provide Level 1 evidence regarding the safety and utility of an ED evaluation strategy including abdominal US.

3.0 STUDY DESIGN
Randomized controlled trial

4.0 SELECTION AND ENROLLMENT OF SUBJECTS

4.1 Inclusion Criteria

Children younger than 18 years with blunt abdominal trauma presenting to the
participating ED within 24 hours of the traumatic event will be eligible. Inclusion criteria include any one of the following:

- Blunt torso trauma resulting from a significant mechanism of injury
  - Motor vehicle collision: greater than 60 mph, ejection, or rollover
  - Automobile versus pedestrian/bicycle: automobile speed > 25 mph
  - Falls greater than 20 feet in height
  - Crush injury to the torso
  - Physical assault involving the abdomen
- Decreased level of consciousness (Glasgow Coma Scale score < 15 or below age-appropriate behavior) in association with blunt torso trauma
- Blunt traumatic event with any of the following (regardless of the mechanism):
  - Extremity paralysis
  - Multiple long bone fractures (e.g., tibia and humerus fracture)
- History and physical examination suggestive of intra-abdominal injury following blunt torso trauma of any mechanism (including mechanisms of injury of less severity than mentioned above)

4.2 Exclusion Criteria

Patients will be excluded for any of the following:

- Hypotension (Hemodynamic instability): Patients are excluded for prehospital or initial ED hypotension. This is because the standard evaluation of these patients involves immediate abdominal ultrasound based on prior work by our group. Hypotension is determined based upon the patient’s age. We will continue to provide the standard of care which involves radiology performing the FAST examination to those patients who are hypotensive.
- Prehospital GCS score ≤ 8.
- Penetrating trauma: Patients who are victims of stab or gunshot wounds
- Traumatic injury occurring > 24 hours prior to the time of presentation to the ED
- Transfer of the patient to the UCDMC ED from an outside facility with abdominal CT scan, diagnostic peritoneal lavage, or laparotomy previously performed
- Patients with known disease processes resulting in intraperitoneal fluid including liver failure and the presence of ventriculoperitoneal shunts
- Presence of abdominal seat belt sign
4.3 Study Enrollment Procedures

4.3.1 Prisoner Participation

Prisoners are not included.

4.3.2 Randomization/Registration

Patients meeting enrollment criteria will be randomized to the US arm or no-US arm using computer-generated randomization in blocks of 20. This will ensure that for each 20 enrolled patients, 10 will be enrolled into the US arm, and that confounding variables (either known or unknown), will likely be equally distributed between study arms. To ensure allocation concealment, opaque envelopes created by the research coordinator (RC) and available in the ED will reveal the random assignment and contain the appropriate data collection form.

5.0 STUDY TREATMENT (OR INTERVENTION)

5.1 Regimens (or Intervention), Administration, and Duration

All ED physicians who are participating in this study are required by the UCDMC ED to be certified in performing abdominal US for trauma (i.e. the FAST examination) based on guidelines established by the American College of Emergency Physicians. All US examinations will be performed by the faculty physician and recorded on the US hard drive.

On occasion, based on perceived clinical necessity, the faculty physician caring for a patient in the no-US arm may perform a US. This will be permitted by study protocol, as we cannot allow the conduct of this study to interfere with patient care needs perceived by the faculty physician. We expect, however, that this will occur rarely at most because US is not currently routinely performed on hemodynamically stable pediatric trauma patients at UCDMC. Analysis, however, will be conducted on the basis of random US assignment (i.e., “intention to treat analysis”).

Bedside US examinations will be performed on patients randomized to the US arm by the ED physicians providing care to the patient. As previously described, these physicians will be certified in trauma US prior to the start of the study as required by the Department of Emergency Medicine at UCDMC. US examinations will be performed using a portable US scanner with 3.5 MHz and 5.0 MHz curvilinear transducers. We will
adhere to the US protocol for the detection of intraperitoneal fluid (FAST examination). This protocol includes views of Morison’s pouch (right upper quadrant), splenorenal fossa (left upper quadrant), and long and short axis of the pelvis. There will be no attempt to image the solid organs, as this is not routine in the standard FAST examination. All US examinations will be uploaded and backed up at the central Department of Emergency Medicine ultrasound server. Image archival will be through password protected Osirix image data management software. ED clinicians caring for the patients will make bedside interpretations and record them on the data collection forms. For purposes of analysis, bedside US examinations will be classified as positive if any intraperitoneal fluid is identified and classified as negative if no such fluid is noted. The ED clinician will also document the location of fluid on all positive examinations.

**US interpretation verification process:** For the purposes of this study, all US examinations will also be presented for interpretation to a single, experienced ED ultrasonographer (John Rose, MD) co-investigator who is trained in ED ultrasound, the Director of ED Ultrasonography, and a Registered Diagnostic Medical Sonographer (RDMS). Dr. Rose will evaluate the archived US images (masked to all clinical data) as “positive” for intraperitoneal fluid or “negative” for intraperitoneal fluid, as described above. These will be performed within one week of the image being obtained. The interpretation of the US by the study ultrasonographer will be recorded on a separate data collection form (“blinded US interpretation”). Any discrepancies between the interpretation of Dr. Rose and the caring ED clinician will be notified to either James Holmes, MD (Study PI) or Nathan Kuppermann, MD (study Co-PI).

In addition, the study radiologist (Sandra Gorges) will review US examinations. This radiologist co-investigator will review the US images for the presence or absence of intraperitoneal fluid in a method similar to that of the ED physician ultrasonographer. Dr. Gorges will confirm any discrepancies identified by Dr. Rose.

**Patient follow-up procedures:**

1. *Hospitalized patients:* Patients will be hospitalized at the discretion of the treating physicians. Data from each patient’s electronic medical record will be collected for determination of outcome status.

2. *Patients discharged home from the ED:* The guardians/parents/responsible family member of all patients will receive an information sheet describing the study. This information sheet will notify guardians of patients discharged from the ED that they will be contacted by telephone by the RC one to two weeks after the ED visit. The RC will complete this telephone survey in order to document any possible missed intra-abdominal injuries (as determined by return visit to a healthcare facility during which an intra-abdominal injury is documented). If we are unable to contact the patient’s guardian after six telephone follow-up attempts extending to three months after the initial ED visit, we will review the patient’s electronic medical records and ED and trauma continuous quality improvement records to identify any study patients with possible missed intra-
abdominal injuries.

Missed eligible patients: Although we anticipate that most (90% based on prior studies) eligible patients will be enrolled in the study, it is inevitable that some eligible patients will inadvertently be missed. These patients will be identified by the RC on review of the ED patient log and basic information about these patients will be documented on a separate data collection form. This will allow some general comparisons between enrolled and missed patients in order to assess the possibility of enrollment bias.

Data entry (and confidentiality): The RC will review data form completion and accuracy, and retrieve missing information from the patient medical record, if applicable. The study data collection forms will be kept in a locked cabinet in a locked office in the Emergency Medicine offices. The data collection forms will not have the patient name or medical record number (these will be kept separately on a separate piece of paper (also locked in a cabinet in a locked office). All data will be stored on computers that are password protected. The data will be disconnected from the medical record number once data collection is completed.
6.0 STATISTICAL CONSIDERATIONS

6.1 Endpoints
1) Time in ED (measured in hours)
2) Number of abdominal CT scans performed (whole number)
3) Missed intra-abdominal injuries (whole number)
4) Costs for care (measured in US dollars)

6.2 Randomization and Stratification
Block randomization in blocks of 20 (10 randomized to each arm).

6.3 Sample Size and Accrual

_The sample size is 925 patients with blunt torso trauma._

7.0 DATA COLLECTION AND MONITORING AND ADVERSE EVENT REPORTING

7.1 Records to Be Kept

Data collection forms (DCF)s will be provided for each subject. Subjects will have a patient identification number placed over their medical record numbers on the data collection forms. Subjects will be identified by patient identification number.

7.2 Expedited Adverse Event Reporting to

We will report all adverse events to the IRB. A serious adverse event will include a missed intra-abdominal injury (identified after the child is discharged from UC Davis) and this will be reported immediately to the IRB. An adverse event will include an abdominal ultrasound examination identified incorrectly by the examining physician in the ED. This will be considered to occur when both Dr. Rose and Dr. Gorges are independently in agreement that the study was interpreted incorrectly. These events will also be reported to the IRB.

8.0 HUMAN SUBJECTS

8.1 Institutional Review Board (IRB) Review and Informed Consent

This protocol and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight of the study.
8.2 Study Discontinuation

The study may be discontinued at any time by the IRB, the investigators, the Data Safety Monitoring Board, or the funding agency. The Data Safety Monitoring Board will review data two times during patient enrollment (per the DSMB charter).

9.0 PUBLICATION OF RESEARCH FINDINGS

Publication of the results of this trial will be governed by routine publication policies.
15.0 REFERENCES

Sample Size Calculations

During the 33-month period from May 2007 to January 2010, we enrolled 1,491 patients with blunt abdominal trauma at UCDMC (91.0% of eligible patients) into the current PECARN multicenter blunt abdominal trauma study (this is an observational study to derive an intra-abdominal injury prediction rule). Thus, 45.2 patients/month were enrolled. Furthermore, the PECARN multicenter study had less stringent enrollment criteria than that developed for the current proposal. Thus, we anticipate somewhat fewer eligible patients for the currently proposed study. By evaluating those patients enrolled into the PECARN study, we anticipate that at least 35 patients/month will meet the currently proposed study's inclusion/exclusion criteria. Due to a variety of reasons, it is likely that not all patients will be enrolled. For the current study proposal, we ultimately anticipate enrolling an average of 32 patients/month (90% capture rate).

For the purpose of the sample size calculation, our primary outcome measures are abdominal CT rate (Specific Aim 1a), length of stay in the ED (Specific Aim 1b) and medical costs (Specific Aim 2). All sample size calculations that follow assume an alpha error of 0.05, under two-sided hypothesis testing, and beta error of 0.20 (power = 80%).

**Specific Aim 1a:** To compare the rates of abdominal CT scanning in those children in the US study arm versus those in the study arm not undergoing US during their initial evaluation. We would consider US to lead to a clinically important reduction in the rate of CT use if the absolute decrease in CT rate were at least 10 percentage points. Based on our current enrollment in the PECARN observational abdominal trauma study, the current baseline CT rate among eligible patients at UCDMC is 59.6%. Therefore, assuming an equal number of patients assigned per arm, we estimate our sample size based on a rate of abdominal CT use of 60% in the no-US arm and 50% in the US arm (i.e., minimal clinically important difference to detect).

<table>
<thead>
<tr>
<th>Variable</th>
<th>no-US arm</th>
<th>US arm</th>
<th>Sample size needed per arm</th>
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<tbody>
<tr>
<td>CT Rate</td>
<td>60%</td>
<td>50%</td>
<td>388</td>
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</table>

Thus, for Specific Aim #1a, we would require 388 patients per arm or 776 total patients. At an enrollment rate of 32 patients per month, this would require 24.25 months of patient enrollment.

**Specific Aim 1b:** To compare the time to ED disposition in those children undergoing US examinations versus those not undergoing such examinations during their initial evaluation.

We performed a sample size calculation based on time spent in the ED before disposition (hospitalization or discharge). For this calculation, we considered one hour to be a clinically important difference to detect time to disposition between the study arms. To perform this sample size calculation, we gathered data on trauma admissions and discharges at the study site over a 12-month period. Trauma patients admitted had
a mean time in the ED of 8.1 hours (standard deviation (SD) = 4 hours). Patients discharged to home had a mean time in the ED of 5.1 hours (SD = 3 hours).

**Table 3: Sample Size for Aim 1b:**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Expected mean (SD)</th>
<th>Mean (SD) in US arm deemed a clinically important reduction (1 hr)</th>
<th>Sample size per arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time in ED (hospitalized patients)</td>
<td>8 (4) hours</td>
<td>7 (4) hours</td>
<td>252</td>
</tr>
<tr>
<td>Time in ED (discharged patients)</td>
<td>5 (3) hours</td>
<td>4 (3) hours</td>
<td>142</td>
</tr>
</tbody>
</table>

Thus, for Specific Aim #1b, we would require 504 admitted patients and 284 discharged patients (788 total patients) to detect a one-hour difference in ED stay between arms. Based on our current pediatric trauma data, among eligible patients, 60% are admitted to the hospital. Thus, 19 admitted patients and 13 discharged patients would be enrolled/month. Therefore, we will require 26.5 months of patient enrollment to reach the sample size for admitted patients and 21.8 months for discharged patients.

**Specific Aim 1c:** *To identify if an ED evaluation strategy with abdominal US results in more cases of missed or delayed diagnosis of clinically-important intra-abdominal injuries than a strategy not employing US.*

In the current PECARN observational blunt abdominal trauma study, there have been no delays in diagnosis (i.e., patients diagnosed with intra-abdominal injury in the hospital after ED disposition) among the 100 patients with intra-abdominal injuries at UCDMC, and no patients with missed intra-abdominal injuries have been identified. Although these outcomes are very important, they are of insufficient frequency to be used for sample size determination. We will simply identify and report any cases of missed or delayed diagnoses in both the US arm and no-US arm.

**Specific Aim #2:** *To evaluate the cost-effectiveness ratios of US and no-US evaluation strategies in children with blunt abdominal trauma.*

We performed a sample size calculation to identify a 15% reduction in costs per patient (what we determined to be a minimally clinical important difference) in the US arm. To perform this sample size calculation, we collected cost data for 18 consecutive pediatric trauma patients at UCDMC deemed eligible for the study. The mean cost for an eligible patient was $36,491 (SD = $29,537).

**Table 4: Sample Size for Aim 2:**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Expected mean (SD)</th>
<th>Mean (SD) in US arm deemed clinically important</th>
<th>Sample size needed per arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs</td>
<td>$36,491</td>
<td>$31,017</td>
<td>458</td>
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Thus, for Specific Aim #2, we would require 458 patients per arm or 916 total patients. At an enrollment rate of 32 patients/month, this would require 28.75 months of patient enrollment. Given the other sample size calculation, identifying a significant difference between arms in hospital costs will drive the sample size for this study. Thus, we will need to enroll patients for 28.75 months. We will plan for approximately 30 months of patient enrollment to ensure that we meet the planned sample size.

3.3 Project Evaluation/Data Analysis
We will explore the impact of US use on clinical outcomes and resource utilization by comparing the outcomes between arms using the statistical methods described below. The analysis will be performed on the primary outcome variable (as noted in the Specific Aims). We will also perform secondary analyses on the additional outcome variables.

Categorical variables:
1. **Specific Aim 1a**: Abdominal CT utilization rate will be compared between the cohort undergoing abdominal US and the cohort not undergoing abdominal US
2. **Specific Aim 1c**: We will identify any delayed diagnosis/missed intra-abdominal injury in the two cohorts.
3. Secondary analyses:
   a. Laparotomy rate between the two cohorts
   b. Hospitalization rates between the two cohorts

Continuous variables:
1. **Specific Aim 1b**: Time to ED disposition will be compared between the cohort undergoing abdominal US with the cohort not undergoing abdominal US
2. **Specific Aim 2**: Total patient costs will be compared among the cohort undergoing abdominal US with the cohort not undergoing abdominal US
3. Secondary analyses:
   a. Time from ED arrival to definitive diagnostic test among the two cohorts
   b. Hospital length of stay among the two cohorts
   c. Physician impression of intra-abdominal injury

Baseline demographic, clinical and laboratory data, and outcome measures will be compared between the two cohorts (US arm versus the no-US arm) using appropriate bivariate statistical methods to assess for parity between arms in known confounding variables (i.e., hypotension, pediatric trauma score). Ninety-five percent confidence intervals will be calculated for all measures of interest. All tests will be based on two-tailed alternatives. Probability values <0.05 will be considered statistically significant. Categorical data will be compared using chi-square testing or Fisher’s exact test in cases of small expected cell frequencies. Continuous data will be compared with Student’s t-test or Mann-Whitney U test (Wilcoxon rank-sum test) in cases of non-normally distributed data. The analysis of the time-to-ED disposition (Hypothesis 1b) will be stratified by disposition site (hospitalized versus discharged). Data analysis will be performed using STATA (StataCorp, College Station, TX).

This study will be a large, randomized clinical trial and we expect known and unknown confounders to be equally distributed between arms. It is possible, however, that
potential confounders will be distributed unequally between US and no-US arms. If this is the case, we will use multivariable regression methods (linear and non-linear as appropriate) to adjust for confounders and other important variables. Outcome measures to be analyzed in this way include the rate of abdominal CT utilization, time until abdominal CT for those imaged, time spent in ED until definite disposition, hospitalization and laparotomy rates, rate of missed or delayed diagnoses, and costs.