

# **Imaging Gently – Imaging Guidelines Reduce Unnecessary CT scans in Pediatric Trauma Patients**

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## **1. STUDY OVERVIEW – PURPOSE AND BACKGROUND**

### **1.1. Purpose**

We aim to assess the effect of algorithm implementation on CT scan utilization and missed injury rate during pediatric blunt trauma activations at our institution. This project will also compare previously collected retrospective data (RSRB# 00067660) in combination with prospective data collection to determine if implementing institutionally approved imaging algorithms will reduce unnecessary CT scans compared to pre-intervention data. We hypothesize that by applying these algorithms, we will decrease our unnecessary CT scans by 25% without missing any clinically significant injuries.

### **1.2. Background**

Imaging studies, such as CT scans have been very valuable in the trauma field for identification and categorization of injuries, especially due to blunt trauma. As such, it has become popular to “pan-scan” patients to obtain imaging of the patient from head through pelvis and eliminate any concern for potential injury. While this may be acceptable in adults, this practice has the potential to place children at increased risk of radiation exposure. Compared to adults, children are at higher risk of radiation complications due to increased tissue radio-sensitivity and longer lifespan for potential radiation impact.<sup>1</sup> It has been estimated that 1 in 1000 children undergoing CT of the abdomen/pelvis will die from radiation-induced cancers.<sup>1</sup> Therefore, it has been proposed that standard imaging algorithms may decrease practice variability and unnecessary radiation exposure.<sup>2,3</sup> In a previous study, we evaluated current imaging practices at our institution and retrospectively applied institutionally developed and validated algorithms. The study demonstrated that fifty-two percent of CT scans already performed were not indicated by the imaging algorithms. CT scans that were not indicated identified no clinically significant injuries that would have changed the management of the patient. We concluded that application of imaging protocols could significantly reduce radiation exposure to pediatric trauma patients while not compromising the detection of clinically significant injuries. Following validation and approval of the algorithms by the involved provider teams, algorithm utilization for blunt pediatric traumas began in July 2017. The aim of this study is to evaluate the utilization and impact of these protocols prospectively to guide imaging and improve quality care in traumatically injured children.

## 2. CHARACTERISTICS OF THE RESEARCH POPULATION

### 2.1. Subject Characteristics

- a) **Number of Subjects:** We aim to enroll 122 patients from January 1, 2014 – December 31, 2016. These patients will represent our previous cohort of patients reviewed. In addition we aim to enroll 200 patients between January 1, 2017 – May 1, 2018 that will require retrospective review. Last we aim to enroll 600 patients between the years of May 2, 2018 – December 31<sup>st</sup>, 2023 for prospective review of application of the algorithms.
- b) **Gender and Age of Subjects:** Male and female patients less than 16 years of age will be included for study analysis.
- c) **Racial and Ethnic Origin:** Subjects of all ethnic and racial origins will be included (there are no exclusions).
- d) **Vulnerable Subjects:** Pediatric patients less than 16 years of age will be included in the study. This study will be a retrospective chart review for patients evaluated from January 1, 2017 – present and a prospective chart review of patients from present – December 31, 2023. We perceive minimal risk to patients enrolled in the study. No patients will be contacted for study completion as the algorithm implementation is occurring as part of standard clinical care in the trauma bay. Patient name, MRN, and date of admission will be collected initially from our trauma data set. They will be used to identify the trauma admission and collected pertinent data. All collected data will then be de-identified and assessed in aggregate, ultimately minimizing risk to patients.

### 2.2. Inclusion and Exclusion Criteria

- a) **Inclusion Criteria:**
  - a. Pediatric patients, less than 16 years of age, who have sustained blunt trauma and are evaluated at the University of Rochester Medical Center between January 1, 2014 – December 31, 2023.
- b) **Exclusion Criteria:**
  - a. Pediatric patients who have who have sustained penetrating trauma, non-accidental trauma, death before imaging, or proceeded directly to surgery will be excluded.

## 3. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT

### 3.1. Method Of Subject Identification And Recruitment

Pre-existing data collected as part of the University of Rochester Trauma Registry will be reviewed for eligible patients. Robert Dorman maintains the Pediatric Trauma Registry. He will provide the patient name, mrn, and date of admission which we will use to identify both the retrospective and prospective subjects enrolled.

### **3.2. Process of Consent**

We request a waiver of parental consent for this chart review as the target population is < 18 years of age. We are requesting a waiver of HIPAA authorization. The patients reviewed are involved in emergency situations where obtaining consent would not be feasible or appropriate. The algorithms are part of a Quality Improvement Project for the Pediatric Surgery Trauma team's protocol for trauma patient management upon presentation to the ED. They have been approved by the Golisano Children's Hospital and Strong Memorial Hospital's Clinical Councils for implementation. They are now considered standard of care for management of pediatric trauma patients at our institution.

The study investigators will review the chart for events pertaining to the child's admission for traumatic injury only. Patient name, MRN, and date of admission will be collected initially from our trauma data set. This list will be used to find patients in eRecord. Once the data is collected from eRecord, all identifiers will be removed from the data set. We do not anticipate that any of the information we are recording would be felt to be particularly sensitive. We do not believe that subjects will be exposed to anything more than minimal risk. The guidelines have been approved by the Golisano Children's Hospital and Strong Memorial Hospital Clinical Council. The trauma program reviews all pediatric trauma patients. We monitor for missed injuries in order to determine if the imaging algorithms need to be modified.

## **4. METHODS AND STUDY PROCEDURES**

### **4.1. Study Procedures and Assessments**

This study is a retrospective chart review between January 1, 2014 – May 1, 2018 and prospective quality assurance between May 2, 2018 –December 31, 2023. Chart review has already been done for patients from January 1, 2014 – December 31, 2016. No more data will be collected for them. Their identifying information has been deleted.

The University of Rochester Medical Center trauma registry will be surveyed between the dates of January 1<sup>st</sup> 2017 – present for the retrospective portion and quarterly from present to December 31<sup>st</sup>, 2023 to identify pediatric patients under the age of 16 who sustained traumatic injuries. Patients who sustained blunt force trauma will be included for study analysis. Data pre-collected as part of the trauma registry will include data of birth, age of time of trauma, trauma level activated, mechanism of injury, data of evaluation and discharge, length of stay and medical record number. The medical record will initially be queried to allow for further data to be collected via eRecord including imaging studies obtained, radiation dose of each CT scan, injuries recorded

on physical exam and imaging, lab values obtained, and interventions/management during hospitalization (surgery, admission for observation, intubation, etc). Once this data is collected in a secure database patient identifiers such as medical record number and date of birth will be erased and not stored.

The institutionally developed, internally validated imaging protocols have been approved by faculty in Pediatric Emergency Medicine, Pediatric Surgery, Adult Trauma Surgery, Pediatric Radiology, Orthopedic Surgery, Neurosurgery, and Urology prior to implementation. They have been made available to the Surgery residents, Emergency Medicine residents, Emergency Room staff, and Emergency Medicine attendings. They are also available on the URM website. Provider and staff education has been already implemented and will continue as a recurrent process to ensure everyone is utilizing the algorithms appropriately.

The investigators will not have access to any subject identifiers after collecting the necessary information for the study. The data will initially be collected using the patients' name, mrn, and admission date to find them in EPIC. Once the chart is identified, the patient information will be de-identified prior to further analysis.

## **5. RISK/BENEFIT ASSESSMENT**

### **5.1. Risks to Subjects**

This study is of minimal risk to participants. Patients are at potential risk for loss of confidentiality. However, this risk is very unlikely given all collected data will be de-identified and assessed in aggregate. Additionally, data will be stored on a spreadsheet on the investigator's computer accessible only to the study team.

### **5.2. Benefits to Subjects**

This is a chart review and will not provide direct benefit to the subjects involved in the chart review.

## **6. CONFIDENTIALITY OF DATA AND INFORMATION STORAGE**

Collected data will be de-identified and assessed in aggregate. Research data will be stored on a spreadsheet on the investigator's computer and will be secured with username and password that will only be known to the investigators. The spreadsheet will be password protected and shared only with study personnel. The data will not contain any personal identifying information once it is gathered. Data will be kept indefinitely.

## **7. DATA ANALYSIS AND DATA MONITORING**

### **7.1. Planned Statistical Analysis**

The data will be analyzed for number of total CT scans obtained with breakdown by type (CT head, CT c-spine, CT chest, and CT abdomen/pelvis) and necessity of each image based on the established algorithm. We will establish the rate of not indicated images performed and any associated missed injuries. We will also determine if there is a difference in CT utilization following algorithm implementation compared to pre-algorithms.

## 8. REFERENCES

1. Streck CJ, Jewett BM, et al. Evaluation for intra-abdominal injury in children following blunt torso trauma. Can we reduce unnecessary abdominal ct by utilizing a clinical prediction model? *J Trauma Acute Care Surg.* 2012; 73 (2): .doi:10.1097/TA.0b013e31825840ab.
2. Holmes JF, Mao A, et al. Validation of a prediction rule for the identification of children with intra-abdominal injuries after blunt torso trauma. *Annals of Emergency Medicine.* 2009; 54 (4): 528-533.
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4. Kuppermann N, Holmes JF, Dayan PS, Hoyle JD Jr, Atabaki SM, Holubkov R, Nadel FM, Monroe D, Stanley RM, Borgialli DA, Badawy MK, Schunk JE, Quayle KS, Mahajan P, Lichenstein R, Lillis KA, Tunik MG, Jacobs ES, Callahan JM, Gorelick MH, Glass TF, Lee LK, Bachman MC, Cooper A, Powell EC, Gerardi MJ, Melville KA, Muizelaar JP, Wisner DH, Zuspan SJ, Dean JM, Wootton-Gorges SL; Pediatric Emergency Care Applied Research Network (PECARN). Identification of children at very low risk of clinically-important brain injuries after head trauma: a prospective cohort study. *Lancet.* 2009 Oct 3;374(9696):1160-70.