**Study Title:** Pediatric Cervical Spine Clearance: A Multicenter Prospective Observational Study

**Short Title:** C-Spine WTA WPSRC

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# ABBREVIATIONS

| | |
|---|---|
| **C-collar** | Cervical Collar |
| **C-spine** | Cervical Spine |
| **CT** | Computed Tomography |
| **DOB** | Date of Birth |
| **GCS** | Glasgow Coma Scale |
| **HIPAA** | Health Insurance Portability and Accountability Act of 1966 |
| **IRB** | Institutional Review Board |
| **ISS** | Injury Severity Score |
| **IQR** | Interquartile Range |
| **LOS** | Length of Stay |
| **MRI** | Magnetic Resonance Imaging |
| **MRN** | Medical Record Number |
| **NEXUS** | National Emergency X-Radiography Utilization Study |
| **NPV** | Negative Predictive Value |
| **NTDB** | National Trauma Data Bank |
| **PCSCWG** | Pediatric Cervical Spine Clearance Working Group |
| **PHI** | Protected Health Information |
| **PPV** | Positive Predictive Value |
| **SD** | Standard Deviation |
| **XR** | X-radiation, X-rays |

# ABSTRACT

Context:  (Background)

Cervical spine injury occurs in about 1% of pediatric patients after blunt trauma. (1–3) Early diagnosis facilitates treatment and mitigates the risk of further injury in the hospital. Guidelines for C-spine clearance in adults rely on CT scan alone, however practice guidelines in children are less well defined and MRI is often performed despite no clear evidence that it is superior to plain radiographs or CT scan.

Objectives: (primary and important secondary objectives)

The primary objective is to determine the sensitivity, specificity, positive and negative predictive value of plain radiographs and CT scan for detection of clinically significant injuries.

Study Design:

A prospective multicenter observational trial at adult and pediatric trauma centers will be performed. All children <18 with CT scans or XRs of the C-spine after blunt trauma will be included and followed to discharge.  Clinically significant injuries include those requiring surgical stabilization, halo, or rigid cervical or cervical-thoracic orthosis placement.

Setting/Participants:

This is a prospective multicenter observational study that will be conducted at the 10-participating children's hospitals in the Western Pediatric Surgery Research Consortium. Western Trauma Association member hospitals will also enroll, for a total of approximately 25-50 sites.

We anticipate an n of 22,600 participants across all sites.

Study participants include all pediatric trauma patients, <18 years old, who underwent cervical CT scan or plain cervical radiographs for suspected C-spine injury.

Study Measures:

The primary outcome measures are the sensitivity and sensitivity of C-spine CT scan or plain C-spine radiograph to detect clinically significant C-spine injuries.  Clinically significant injuries are defined as those requiring surgical stabilization, halo, or rigid cervical or cervical-thoracic orthosis placement.

The data will be collected through prospective chart review, no PHI identifiers that will be recorded.  No specimens will be obtained.

# 1    BACKGROUND INFORMATION AND RATIONALE

## 1.1    Introduction

Cervical spine injury occurs in about 1% of pediatric patients after blunt trauma. (1–3) Early diagnosis facilitates treatment and mitigates the likelihood of iatrogenic worsening of neurologic status or missed injuries, both of which can be clinically devastating and costly. The NEXUS low risk criteria have been used for clearance of the cervical spine in awake, evaluable pediatric patients without neck pain, neurologic deficits or distracting injuries. (1) In pediatric patients who fail the NEXUS criteria, imaging is performed. Depending on the size, age, and neurologic status of the patient either plain films or a CT scan of the cervical spine is utilized. In appropriate pediatric patients, the lack of arthritis and decreased soft tissue mass makes plain XRs sensitive and specific with the benefit of decreased radiation. However, expert consensus does recommend immediate CT scan for patients with suspected c spine injury and a GCS <9 and or with a GCS <14 without anticipation of improvement over the first 48hours. (5) In addition to diagnosis of clinically significant cervical spine injuries, the efficient clearance of patients without significant injury is important to prevent iatrogenic complications such as pressure ulceration and to avoid unnecessary patient discomfort. (4)

For patients with a negative CT scan, the utility of MRI remains controversial. The additional diagnostic yield of a cervical MRI in patients who have a negative CT and are unevaluable or have residual midline cervical spine tenderness in particular is unclear. There are institutional studies that advocate for MRI (6,7) and against it. (8) The practice of obtaining an MRI is currently common and recommended by expert consensus. (5) MRI has been shown to have a high rate of false positives without detection of previously missed clinically significant injuries. (8) Adult guidelines have concluded that high quality CT scan alone, without the addition of MRI, is sufficient for cervical spine clearance in the obtunded adult. (9) The purpose of this study is to prospectively evaluate the sensitivity and specificity of CT and XR for the detection of clinically significant pediatric cervical spine injury in a multicenter observational study.

## 1.2    Relevant Literature and Data

C-spine injuries have a low incidence in pediatric populations. Within the pediatric cohort (n = 3065) of a prospective multicenter study (The National Emergency X-Radiography Utilization Study/NEXUS), the incidence of C-spine injuries was found to be 0.98%. (1) Furthermore, a retrospective review of the National Trauma Data Bank (NTDB) between 2002 and 2006 found an incidence of 1.3% for C-spine injuries in pediatric patients. (2) In a similar retrospective review of the NTDB between 2001 and 2005, an incidence of 1.59% was found for C-spine injuries in patients younger than three. (3) Although the occurrence of cervical spine injuries is quite low, the complications may be drastic, and identifying such injuries early through appropriate examination and imaging is of high importance. A list of five criteria was developed from the NEXUS study as an imaging screening tool for patients having experienced blunt cervical trauma (criteria include absence of the following: midline cervical tenderness, altered level of alertness, evidence of intoxication, focal neurological deficit, and presence of painful distracting injury). Imaging can be avoided in patients

meeting those criteria. (1) The NEXUS criteria was found to apply well in pediatric populations and can be used to guide further imaging decisions (although the authors of the study did caution against application in infants and toddlers due a low sample size in the cohort). (1) If the five criteria are not met, children can either undergo plain film radiography or CT imaging based on the contextual factors. A study at the University of Utah comparing the sensitivity and sensitivity of four imaging modalities (radiographs, flexion extension radiographs, CT, and MRI) found that plain cervical spine radiographs were both highly sensitive (100%) and specific (95%) in imaging C-spine injuries. They further note that while CT or radiographs could be used as primary screening methods, CT may be better due to higher anatomical detail. (10) Further literature also supports CT as the first choice imaging in certain patient presentations. The Pediatric Cervical Spine Clearance Working Group (PCSCWG) Algorithm notes that with a GCS of 9-13, if the patient has the potential to improve to a GCS of 14 or 15, plain radiographs will suffice; without potential for improvement, a CT should be taken. With a GCS <=8, a CT is necessary. With a GCS of 14 or 15, either the c-spine be cleared, or a plain radiograph should be taken based on history and physical exam findings. (5)

If patients have a negative CT, an MRI may be taken, although the usefulness of this additional imaging modality is contested. A review and published guidelines from the Eastern Association for the Surgery of Trauma recommends that a negative CT scan alone is enough for cervical collar removal due to the high negative predictive value of CT imaging (100% for an unstable injury and 91% for a stable injury). They further note that additional imaging such as MRI increases patient risk and likely results in similar clinical outcomes as CT scanning alone. (6) This study, however, was specific to the adult obtunded blunt trauma patient. A retrospective chart review at St. Louis Children's Hospital from 2002 to 2012 found that in children with a GCS of <=8, MRI did not successfully detect unstable C-spine injuries after a negative CT. (9)

However, evidence also supports the use of MRI in the context of a negative CT. A retrospective chart review of pediatric patients with potential C-spine injury found that when MRI was used in patients not yet cleared after 72 hours, time to cervical spine clearance significantly decreased, and both average ICU stay and average hospital stay trended to decrease. (8) The PCSCWG Algorithm recommends that MRI be used after a negative CT scan in pediatric patients with a GCS <=8 and in children with suspected abusive head trauma. (5) MRI is limited, however, by a significant false positive rate. The PCSCWG indicated that the high false positive rate of MRI along with limited machine availability, need for sedation, and high cost precluded MRI from serving as a primary screening tool. (5) The University of Utah study similarly found that MRI had a high false positive rate compared to other imaging techniques (100% sensitivity and 74% specificity). (10)

In addition to diagnosis of injury, rapid clearance is important to prevent collar associated pressure injuries. Pressure injuries can commonly occur with immobilization devices and be a cause of significant discomfort to the patient. A systematic review noted an incidence ranging from 6.8% to 38% for collar associated pressure ulcers in patients with spinal immobilization devices (backboard, vacuum mattress, cervical collar, lateral headblock, and straps). (4)

Extensive studies have been conducted on the value of MRI scanning standalone or in addition to CT. Literature on similar comparisons between CT and plain radiographs is not as extensive. General guidelines do outline conditions in which CT or radiographs should be conducted and in what succession, but further exploration into the efficacy of these imaging modalities in detecting clinically significant injuries is warranted.

## 1.3    Compliance Statement

This study will be conducted in full accordance all applicable Phoenix Children's Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46, and the HIPAA Privacy Rule. Any episode of noncompliance will be documented.

The investigator(s) will perform the study in accordance with this protocol, will obtain consent/assent/HIPAA authorization (unless waivers are granted), and will report unexpected problems in accordance with the Phoenix Children's IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

## 2    STUDY OBJECTIVES

## 2.1    Primary Objective (or Aim)

Specific Aim 1: Determine test characteristics (sensitivity, specificity, PPV, NPV) for CT and plain films of the c-spine in diagnosing clinically significant C-spine injury requiring intervention in the adolescent population.

We hypothesize that CT is highly sensitive and specific for clinically significant C-spine injury in the adolescent (12-17years) population.

## 2.2    Secondary Objectives (or Aim)

Specific Aim 2: Determine test characteristics (sensitivity, specificity, PPV, NPV) for CT and plain films of the C-spine in diagnosing clinically significant C-spine injury in the pediatric population

We hypothesize that CT is highly sensitive and specific for clinically significant C-spine injury in the pediatric (0-11) population, however due to morphological differences and lack of bone and ligamentous maturation we believe that CT will be less accurate for detecting clinically cervical spine injuries in the pediatric population in comparison to the adolescent population.

Specific Aim 3: Determine test characteristics (sensitivity, specificity, PPV, NPV) for MRI c-spine in diagnosing clinically significant C-spine injury requiring intervention in the adolescent population.

Specific Aim 4: Determine test characteristics (sensitivity, specificity, PPV, NPV) for MRI and plain films of the C-spine in diagnosing clinically significant C-spine injury in the pediatric population

## 3    INVESTIGATIONAL PLAN

### 3.1    General Description of Study

A prospective multicenter observational study to determine the sensitivity, specificity, positive and negative predictive value of CT for clinically significant injuries requiring surgical stabilization, halo, or rigid cervical or cervical-thoracic orthosis placement.

### 3.2    Study Duration, Enrollment and Number of Sites

#### 3.2.1    Date Range of Study

The study will begin on November 1, 2022 and end in 2028 with an expected 3 year study enrollment period.

#### 3.2.2    Total Number of Study Sites/Total Number of Subjects Projected

This is a prospective multicenter observational study that will be conducted at the 10-participating children's hospitals in the Western Pediatric Surgery Research Consortium. Western Trauma Association member hospitals will also enroll, for a total of approximately 25-50 sites.  This is a prospective multicenter observational study with an anticipated n of 22,600 participants across all sites.  We anticipate Phoenix Children's will enroll 300-500 patients annually, or 900-1,500 patients total.

### 3.3    Study Population

#### 3.3.1    Inclusion Criteria

1.  Any participant less than 18 years with cervical spine image (XR or CT) after blunt force trauma.

#### 3.3.2    Exclusion Criteria

1.  Any participant greater than 18 years.
2.  Any participant with CT scan from outside facilities in poor quality and not repeated at Phoenix Children's (<63-channel, cuts >3mm, no reformats, motion artifact)

# 4  STUDY PROCEDURES

## 4.1  Data Sources/Collection

The data will be collected from the electrical medical record and stored in REDCap as deidentified data

### 4.1.1  Case Identification

All patients admitted to trauma service with cervical spine images after a blunt force trauma will be reviewed prospectively for potential inclusion.

### 4.1.2  Data sources

All data will be extracted from the electronic medical records.

## 4.2  Data Elements to Be Abstracted

### 4.2.1  Data Source 1

- Month/year of admissions
- Age
- Gender
- Zip Code
- Vital Signs
- Admission Exam
- Mechanism of Injury
- Past Medical History
- Imaging results
- Treatment for C-spine injury
- Discharge Disposition
- Length of stay
- ISS
- Other Injuries

### 4.2.2  Data Source 2

N/A

### 4.2.3  Data Source 3 (e.g. Pathology)

N/A

# 5  STATISTICAL CONSIDERATIONS

## 5.1  Primary and Secondary Endpoints

The primary outcome of this study to determine if with a 1% incidence of cervical spine injure, CT is non-inferior to MRI for detecting clinically significant injuries.

## 5.2    Measures to Avoid Bias

This is a prospective, observational chart review with specific elements to be abstracted from the medical record, based on the data collection form. Investigators or study personal performing the chart review will discuss and come to an agreement on how to address any discrepancies in documentation in the medical record.

Data Auditing plan:

1) Following enrollment of the first 10 patients, participating sites will be contacted/contact the primary site research team to review the REDCap for each of these patients. If inadequacies are identified the site will be instructed on how to input REDCap variables.
2) After the participating site have enrolled 100 patients, the primary site research team will query 5% of their enrollments at random. The participating site will review the assigned cases. If incorrect data input is identified an action plan will be made to address these inadequacies.
3) After half of the patients are enrolled, each site will be assigned 25 cases to review. If incorrect data input is identified an action plan will be made to address these inadequacies.

## 5.3    Statistical Methods

The data will be analyzed by a statistician at the primary site once data collection has been completed. The data will be analyzed with descriptive statistics and multivariate regression analysis, as appropriate.

Categorical values were compared using the Fisher exact test or Pearson $\chi^2$ test, as appropriate. Continuous variables were compared using an unpaired, 2-tailed t test. Descriptive statistics were used to characterize the study population. Mean with SD or range and median with IQR were used to characterize age, Injury Severity Score, systolic blood pressure, heart rate, and Glasgow Coma Scale score. Using a criterion standard of the final diagnosis at the time of discharge, which included the results of all imaging and operative findings as the criterion standard, sensitivity, specificity, NPV, and PPV for CT scan in the diagnosis of clinically significant C-spine injury were calculated.

## 5.4    Sample Size and Power

This is a prospective, observational chart review with a sample size of 22,600 participants. Once IRB approval has been met, we will gain access to the database.

Ultimately, the objective is to determine the sensitivity of CT scan for identifying pediatric cervical spine injury and determine if it is equivalent to MRI. There's precedence in the adult population that CT scan is equivalent to MRI for detecting C-spine injuries. It is imperative that CT scan has a very high sensitivity (99%) for detecting such injuries as missed injuries could be catastrophic.

The plan is to study two distinct pediatric populations, less than 12 years of age and 12-17 age. The following power calculations correspond to a single group and thus must be doubled to accurate study both groups.

We do not believe it is important to have a dropout-inflated enrollment sample size as this is a non-consenting study and all the data will be obtained prior to patient discharge. Therefore, we believe the sample size will reflect the actual enrollment size. For a sensitivity of 99%, there is a very precise 95% CI of 95%-100% with 11,300 patients per age group.

See below:

Confidence Intervals for One-Sample Sensitivity

**Numeric Results for Two-Sided Confidence Intervals for One-Sample Sensitivity**

Confidence Interval Formula: Exact (Clopper-Pearson)

| Confidence of Level | Sample Size (N) | Target Width | Actual Width | Sensitivity | Lower Limit | Upper Limit | Prevalence | Number Positives |
|---|---|---|---|---|---|---|---|---|
| 0.950 | 59300 | 0.050 | 0.050 | 0.900 | 0.873 | 0.923 | 0.010 | 593 |
| 0.950 | 33400 | 0.050 | 0.050 | 0.950 | 0.921 | 0.971 | 0.010 | 334 |
| 0.950 | 11300 | 0.050 | 0.050 | 0.990 | 0.950 | 1.000 | 0.010 | 113 |
| 0.950 | 15800 | 0.100 | 0.100 | 0.900 | 0.842 | 0.942 | 0.010 | 158 |
| 0.950 | 9400 | 0.100 | 0.100 | 0.950 | 0.884 | 0.984 | 0.010 | 94 |
| 0.950 | 4400 | 0.100 | 0.099 | 0.990 | 0.901 | 1.000 | 0.010 | 44 |
| 0.950 | 7400 | 0.150 | 0.150 | 0.900 | 0.808 | 0.958 | 0.010 | 74 |
| 0.950 | 4700 | 0.150 | 0.148 | 0.950 | 0.844 | 0.992 | 0.010 | 47 |
| 0.950 | 2700 | 0.150 | 0.146 | 0.990 | 0.854 | 1.000 | 0.010 | 27 |
| 0.950 | 4400 | 0.200 | 0.198 | 0.900 | 0.772 | 0.970 | 0.010 | 44 |
| 0.950 | 2900 | 0.200 | 0.197 | 0.950 | 0.799 | 0.997 | 0.010 | 29 |
| 0.950 | 1900 | 0.200 | 0.194 | 0.990 | 0.806 | 1.000 | 0.010 | 19 |

**Report Definitions**
Confidence level is the proportion of confidence intervals (constructed with this same confidence level, sample size, etc.) that would contain the population sensitivity.

N is the size of the sample drawn from the population.
Width is the distance from the lower limit to the upper limit.
Target Width is the value of the width that is entered into the procedure.
Actual Width is the value of the width that is obtained from the procedure.
Sensitivity is the assumed sample sensitivity, or true positive rate.
Lower Limit is the lower limit of the confidence interval.
Upper Limit is the upper limit of the confidence interval.
Prevalence is the assumed overall proportion of individuals with a positive condition.
Number of Positives is calculated as the Sample Size times the Prevalence with appropriate rounding. The Number of Positives is the count upon which the confidence interval width calculation is based.
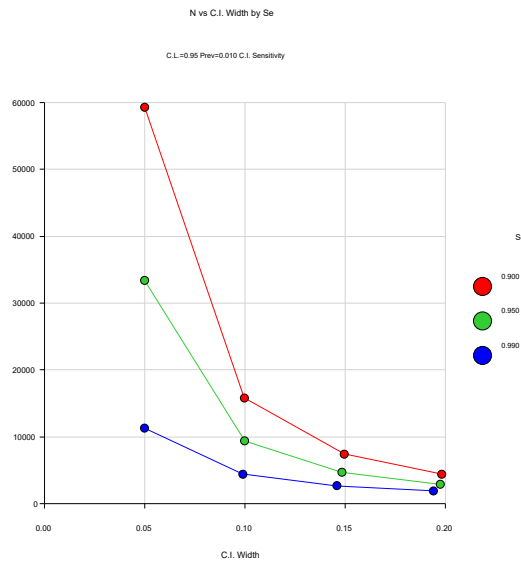


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## 6 STUDY ADMINISTRATION

### 6.1 Data Collection and Management

All study records will be kept in a secure area and confidentiality will be maintained within legal limits. Data will be compiled on the HIPAA-secure REDCap database maintained by the research team on the University of Utah REDCap instance. Working data will be de-identified and the master list of participants will be password-protected on the secure server K-drive. Only members of the research team have access to the folder in K-drive. The identifiers and other data will be destroyed 21 years after completion and closing of the study.

## 6.2    Confidentiality

To protect against the risk for loss of privacy due to breach of confidentiality, study data will be collected and maintained as per the safeguards described under data collection and management. All data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy and all research personnel will not use the data and records for any purpose other than conducting the study.

## 6.3    Regulatory and Ethical Considerations

### 6.3.1    Risk Assessment

The potential risk to participating in this study is the loss of confidentiality (privacy). However, we have taken many steps to protect all private information. All records will be stored on a secure institutional server that requires prior authorization to access as well as further authorization needed to access files associated with this study. Only research staff members will have access to the research files.

### 6.3.2    Potential Benefits of Study Participation

There is no direct benefit for participants at this time, however there may be benefits to them in the future. This will benefit society as a whole because it could create a new guideline for C-collar removal. This could prevent pressure ulcers as well as improve comfort and ease of nursing care.

### 6.3.3    Risk-Benefit Assessment

This study is no greater than minimal risk, so the potential benefits outweigh the negligible risks. The greatest risk is the potential for loss of confidentiality, however there are steps in place to protect all private information.

## 6.4    Informed Consent/Assent and HIPAA Authorization

### 6.4.1    Waiver of Consent

We are requesting a waiver of written informed consent as the research involves minimal risk to participants and is a prospective, observational chart review of data within the medical record that will be collected as part of standard of care. There will also be no additional treatments or diagnostic imaging required for this study. This study does not involve personal contact, and a waiver of consent would not adversely affect the rights and welfare of participants as data from the medical record that will be collected as part of standard of care is being used. Safeguards to protect confidentiality are in place as detailed in 6.1, and data will be reported in aggregate with no identifying information or PHI.

Furthermore, the risk of cervical spine injury in the pediatric population is estimated to be less than 0.1% of patients that suffer blunt force trauma. In order to truly establish the accuracy of CT scan and plain radiographs for the detection of c-spine injury, it is imperative to capture all patients. This includes patients that may present and leave the hospital during nighttime and weekend hours when there is limited staff present, making it impractical to consent and capture every study subject.

Additionally, the cognitive and emotional burden of undergoing the consent process during a traumatic event is a real and measurable effect according to AMA Journal of Ethics, which states that continual insistence on obtaining an informed consent would distract from other important ethical obligations (13). Given that we do not intend to collect PHI the risk associated with obtaining consent outweigh the risk of collecting non-PHI data prospectively.

### 6.4.2   Waiver of Assent

We are requesting a waiver of assent as the research involves minimal risk to participants, is a prospective, observational chart review of data within the medical record that will be collected as part of standard of care, and no additional treatments or diagnostic imaging will be required, for the reasons stated in 6.4.1.

### 6.4.3   Waiver of HIPAA Authorization

We are requesting a waiver of HIPAA as access to protected health information is necessary to identify study participants and the data required for this study is only available in medical records. The research could not be practically carried out without a waiver. As detailed in 6.1, measures to protect data confidentiality will be undertaken. Only de-identified data will be used for working data.

### 6.5   Payment to Subjects/Families

### 6.5.1   Reimbursement for travel, parking and meals

N/A

### 6.5.2   Payments to parent for time and inconvenience

N/A

### 6.5.3   Payments to subject for time, effort and inconvenience

N/A

### 6.5.4   Gifts

N/A

## 7   SAFETY MANAGEMENT

N/A – this is a prospective, observational chart review involving data in medical record that will be collected as part of standard of care, and no additional treatments or diagnostic imaging will be required. There is no personal contact with, or active clinical care being provided to study participants.

### 7.1   Clinical Adverse Events

N/A

## 7.2  Adverse Event Reporting

N/A

## 8  PUBLICATION

The results of this study will be compiled for presentation at academic conferences and/or manuscript publication in a peer-reviewed journal. We plan to eventually submit to Western Trauma Association.

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# APPENDIX

N/A