# ClinicalTrials.gov – Study Protocol and Statistical Analysis Plan

**Title: Improving Family-Centered Pediatric Trauma Care: The Standard of Care Versus the Virtual Pediatric Trauma Center**
**NCT Number: NCT04469036**
**Document Date: 09/22/2022**

## Protocol Title

Title: *Virtual Pediatric Trauma Center*

Protocol Version Date: *2022-09-22*

# 1) Objectives

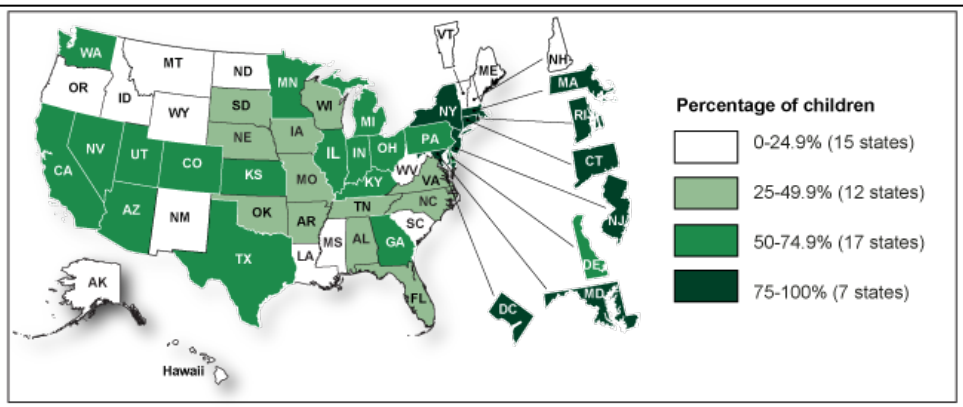
- **Aim #1a:** To compare the parent/family experience of care and distress at 3-days and 30-days following a childhood injury requiring an emergency department visit in a non-pediatric trauma center under the current standard model of care and the VPTC model of care.
    - Null Hypothesis: Measures of parent/family experience of care and measures of distress will be similar between the two models of care.
- **Aim #1b:** To compare the frequency of potentially avoidable transfers (PAT) and transfers in a non-pediatric trauma center under the current standard model of care and the VPTC model of care.
    - Null hypothesis: Frequency of PATs and transfers will be similar between the two models of care.
- **Aim #2:** To compare 30-day healthcare utilization between injured children cared for under the current standard model of care and the VPTC model of care.
    - Null Hypothesis: Hospitalizations, re-hospitalizations, primary and specialty care visits will be similar between the two models of care.
- **Aim #3:** To compare the out-of-pocket costs and financial burdens experienced by parents/families at 3-days and 30-days following a childhood injury requiring an emergency department visit in a non-pediatric trauma center under the current standard model of care and the VPTC model of care.
    - Null Hypothesis: Out-of-pocket costs and financial burdens for parent/families will be similar between the two models of care.

# 2) Background

The American College of Surgeons Committee on Trauma (ACS-COT) has been committed to improving the care provided to injured patients since 1922. An essential component of their efforts has been the creation of minimum standards for trauma facilities and a tiered trauma care system. As detailed in the ACS-COT published guidelines, *Resources for Optimal Care of the Injured Patient*,[1] these standards outline the five levels of trauma facilities that define varying levels of commitment, readiness, resources, policies, patient care, and performance improvement.[1] A Level I trauma center is the highest designation and is only granted to hospitals that are able to provide the highest level of care to all injured patients. The ACS-COT Trauma Center Verification process has been instrumental in improving outcomes among injured children and adults, and has become the national model of trauma care coordination as well as the prototype for trauma care on an international level.[2,3]

While the regionalization of trauma care has resulted in improved outcomes,[4,5] the ***current standard of care*** has created disparities in access for patients injured in geographically isolated locations. When children living in remote communities are injured and present to a non-pediatric trauma center emergency department (ED), they are transferred to the regionalized Level I pediatric trauma center.[6] In more than half of the states in the US, a majority of children live more than 30 miles from a designated Level I pediatric trauma center. Currently, there are *more than 41 million children in the US that have poor access to care, living more than 30 miles from a pediatric trauma center, and it is these children who would benefit the most from a re-engineered system of care that addresses the disparities in access for injured children.*[7,8]

**Estimated Percentage of Children With Adequate Access to Pediatric Trauma Care, Living within 30 Miles of a Pediatric Trauma Center, by State**




Sources: GAO analysis of American Trauma Society and U.S. Census Bureau data (data); Map Resources (map). | GAO-17-334

Because the current regionalization of trauma centers has created disparities in access, many pediatric trauma experts, including health policy makers, health services researchers, and front line clinicians, have advocated for the use of telemedicine so that the Level I pediatric trauma center expertise can be transmitted to the receiving EDs where a majority of pediatric trauma patients initially present.[9-12] This ***newer system of care*** has been commonly referred to as the "Virtual Pediatric Trauma Center" (VPTC) and is increasingly used by many hospitals and EDs throughout the country.[12,13] The VPTC creates a model of care that connects EDs in non-Level I trauma centers using telemedicine to bring expert pediatric trauma care to the bedside of injured children, no matter which hospital the patient presents to first. While this newer model of care enables participation of parents/families in the initial trauma care, there is conflicting and limited literature comparing this model to the current standard of care as it relates to parent/family-experience and distress, healthcare utilization, and financial impact on parents/families.[14]

## 3) Inclusion and Exclusion Criteria

### Inclusion

- Pediatric patients (<18 years old) with an acute injury at the time of a transfer consultation call to UC Davis Trauma Surgery, Orthopedic Surgery, or Neurosurgery from eleven outside emergency departments*
- Parents/guardians of the above patients will be contacted to complete surveys

*Adventist Health Lodi, Adventist Health Rideout, Marshall Medical Center, Mayers Memorial Hospital, Mercy Medical Center Redding, Mercy Methodist Hospital, Mercy San Juan Medical Center, Oroville Hospital, Tahoe Forest Hospital, Woodland Memorial Hospital, Barton Memorial Hospital

**ExclusionThe following patients will be excluded from recruitment for survey completion but included in the dataset:**

- Pediatric patients who are wards of the state
- Pediatric patients who die before the 3-day survey is administered
- Pediatric patients receiving cardiopulmonary resuscitation prior to presentation to either the outside or UC Davis emergency department

## 4) Study Timelines

Data will be abstracted for all patients with transfer center consultations from eligible emergency departments* between November 30th, 2020 and March 31st, 2024.

Parents/guardians of eligible patients will be contacted within 3-days of the eligible emergency department visit to complete the first survey. They will then be asked to complete surveys at 30-, 60-, and 90-days after the eligible emergency department visit. They will be given until 104 days after the eligible emergency department visit to complete the final survey.

The study team will complete primary analyses by May 31st, 2023.

## 5) Study Endpoints

Transfer consultation data will be collected until March 31st, 2024.

Surveys will be collected until March 14th, 2023.

## 6) Procedures Involved

**Systems Level Intervention**

To compare our parent, family, community and provider informed outcomes between the current standard of care and the VPTC, we will use a prospective stepped-wedge trial design,[62] which has important advantages over alternative designs. First, with the stepped-wedge design, changes in the quality and standards of pediatric trauma care over time can be accounted for, unlike a simple pre-test, post-test study design where

changes in care could be confounded by temporal changes and secular trends. Second, in common with a cluster randomized design, and in contrast to patient-randomized designs, our design minimizes contamination bias that could arise among researchers and participants when patients at the same site have been concurrently randomized to two different models of care. In addition, the stepped-wedge design has an important statistical power advantage over a parallel-groups cluster-randomized trial. The latter design suffers a loss of statistical power that arises from within-cluster correlation (ICC), even when ICC is as modest as 5%, a typical value for process-of-care outcomes.[63] The presence of positive intra-cluster correlation has the opposite effect in a stepped-wedge design, because in that design, the contrast of interest is a "within-cluster" contrast, so that the cluster serves as its own control, increasing the effective sample size and resulting statistical power.[64]

After a six-month pre-implementation period, the study will begin with all hospitals beginning in the standard of care condition and with patients enrolled for 13 consecutive 8-week periods. At the end of each of the 8-week periods, one hospital ED will switch to the VPTC model of care condition, according to its randomly assigned enumeration. Following the 2-year (13 x 8 weeks) data collection period, there will be a six-month post-implementation period for data analysis and dissemination.

Stepped-Wedge Trial Design:

| Hospital | 6-Month Period | 8-Week Periods | | | | | | | | | | | | | 6-Month Period |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Pre-Implementation | Standard of Care | One of ten hospitals is randomized to VPTC according to stratification | | | | | | | | | Full VPTC | | | Data Analysis |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
| 1 | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | | | | |
| 5 | | | | | | | | | | | | | | | |
| 6 | | | | | | | | | | | | | | | |
| 7 | | | | | | | | | | | | | | | |
| 8 | | | | | | | | | | | | | | | |
| 9 | | | | | | | | | | | | | | | |
| 10 | | | | | | | | | | | | | | | |

Pre-implementation
Standard of care
VPTC
Data analysis

Of note, after starting the study, one of the hospitals declined to further participate and will be replaced by another similar hospital. The replacement protocol has been approved by the senior statistician on the project.

In order to ensure that we can fully evaluate this **systems level intervention** we will abstract the following variables from the UC Davis EMR: Sending hospital, Glascow Coma Score (GCS) at time of consultation & at time of departure from OSH, encounter number, outcome of the transfer center call, time of transfer call, reasons for transfer, which trauma/ortho/neuro/other specialist took call, mode of transport, length and frequency of OR visit , ICD-10-CM/PCS codes, CPT codes, Epic imaging order codes, admitting service, critical care use, specific UCD provider completing telehealth visit, type of primary service admitted, disposition, location and time of discharge; Patient characteristics: MRN, patient name, age,

race/ethnicity, sex, language, insurance, parent/guardian phone/e-mail, home address

**Parent/Guardian Survey**

Parents/guardians of patients from above will be approached either by StudyPages, phone, e-mail, or in-person and asked to complete surveys (either electronic, via REDCap, or phone (entered directly into REDCap by a study team member)) at 3-, 30-, 60-, and 90-days after the after the eligible emergency department visit.

The surveys will contain no identifying information and are attached in IRBNet.

The primary risk to this study is loss of confidentiality. All information will be stored in REDCap, StudyPages, or in password protected databases on secure UC Davis servers.

Retrospective Data Entry

Upon approval of 3/18/2021 protocol version, Barton Memorial Hospital patients will be entered into REDCap dating back to 11/30/2020. Depending on the patient's survey timeline, research staff will recruit patients to complete their prospective 3-, 30-, 60-, 90- day surveys.

## 7) Data and/or Specimen Management and Confidentiality

☒ I understand that if this study involves the use of the UC Davis Health Electronic Health Record (EMR/EPIC) also contains the clinical data for Marshall Medical Center (MMC). I understand that MMC patient data cannot be accessed for research purposes and that I must take the necessary steps to ensure that MMC data is not accessed, used, or disclosed for UC Davis Health research purposes.

☐ I undersand that if this study involves use of UC Davis students' educational records (including records in the PI's own possession such as course exams/assignments), I must consult with the Registrar's office to see if all requirements of the Family Educational Rights and Privacy Act (FERPA) are satisfied.

This study is evaluating a systems-level intervention; a system-level intervention means that we are doing an intervention on how we deliver healthcare. In other words, our intervention is a test of change to the healthcare system. Because we are doing a systems level intervention, we need to evaluate outcomes on all the eligible patient transfer consultations. Our outcomes include transfers and potentially avoidable transfers. We therefore need to know if all the transfers, among our eligible patients were "avoidable or potentially avoidable" or not. The outcome data (and our research study) would be not useful if we can only gather data the patients who were consented. It is not feasible to get consent from every patient's parent.

Doing a systems intervention and only evaluating the outcomes on the patients who return a HIPAA authorization would make the study not valid. It is therefore not possible

to do the research without the waiver, because a systems intervention study requires evaluating the outcomes on all the patients involved in order to be valid.

In summary, rationale for the waiver of HIPAA and waiver of consent for the data abstraction include: (1) The use or disclosure of protected health care information involves no more than minimal risk; (2) the research could not practicably be conducted without the waiver or alteration; and (3) the research could not practicably be conducted without access to and use of the PHI.

All study personnel involved in this proposed project have received Human Subjects Protection and HIPAA education.

*Data Analysis Plan/Statistical Procedures:*

Regression analyses will be conducted within a generalized linear mixed model framework for multilevel data (patients nested within hospitals), with random effects for hospitals specified to account for unmeasured sources of between-unit heterogeneity.[65-67] A within-site time-varying binary indicator (VPTC vs. standard of care) will be included in the model to permit estimating the key contrasts of interest. For linear-normal mixed models (e.g., experience of care and distress), effect sizes will be adjusted mean differences; for binary and count outcomes fitted with logistic and Poisson regression models, respectively, effect sizes will be adjusted odds and rate ratios, respectively. For outcomes assessed at both 3-days and 30-days after injury, we anticipate estimating time point-specific contrasts of the VPTC vs. standard of care groups. To do this, models will also include a binary indicator for time point (3 day vs. 30 day) as well as interactions of time point with the time-varying treatment group indicator. Additional independent variables will include a parsimonious and pre-specified set of patient-level effects to account for study design effects and to improve the precision of estimated effects, accounting for known sources of heterogeneity.[66,68,69] To account for confounding by calendar time in our stepped-wedge design,[62] we will compute each patient's date at enrollment in the study and use fractional polynomial modeling to determine the order of polynomial (linear, quadratic, cubic, etc.) to specify the calendar date of enrollment effects, to account for temporal effects.[70] A senior health economist will conduct the economic analyses relevant to the financial burdens experienced by parent/family members. Additional details for each aim and outcome are provided below.

## 8) Data and/or Specimen Banking

N/A

## 9) Provisions to Monitor the Data to Ensure the Safety of Subjects

N/A

## 10) Withdrawal of Subjects

No patients will be withdrawn from this study without their consent.

## 11) Risks to Subjects

There is the potential risk of loss of confidentiality; however, for all data, only study personnel will have access to these materials. All data will be destroyed 7 years after completion of the study.

Because this specific intervention has never been tested at UC Davis (though telemedicine has been used in these emergency departments for many years for other pediatric patients), it is possible that there are unforeseen risks to the intervention. This is why monitoring the implementation outcomes are important—the study team will be closely observing the implementation for any unforeseen risks and will take immediate action if any risks are identified. Based on prior studies that have used this technology, it is highly unlikely that this intervention will cause any risk.

## 12) Potential Benefits to Subjects

Patients who receive a telemedicine consultation may find benefit.

## 13) Multi-Site Research

N/A

## 14) Community-Based Participatory Research

In preparation for the original proposal for this study, we conducted three meetings with community advisory boards, which laid the foundation for the study design and evaluation. For the resubmission of that proposal, we reconvened with members from each of these boards to focus more on parent/family-centered measures. Our team of clinical investigators, consortium hospital partners, as well as our two broadly representative community advisory boards, are confident that these two models of care can be effectively compared, and that the results will provide important solutions to problems facing families wanting to improve specialized trauma care for children. As highlighted in the PCORI Research Prioritization Topic Brief entitled, "Rural Trauma Care," improving rural trauma care is a "high-impact target."[15] Recent data derived on adult patients have documented the impact that telemedicine can have on clinical outcomes in a variety of trauma settings.[16-21] Having the core members of a regionalized Level I pediatric trauma center available virtually at the bedside of injured children has the potential to have a positive impact on the parent and family involvement in shared decision making, which may reduce unnecessary and financially burdensome transfers. *Alternatively, parents and families may prefer to err on the side of safety and have an injured child immediately transferred to the regional Level I pediatric trauma center, so delaying or avoiding the transfer of an injured child to a better equipped and staffed facility could result in increased parent/family distress, healthcare utilization, and out-of-pocket costs.* Hence, a rigorous comparison of the two prevailing models of care is needed to inform the choice between them.

## 15) Sharing of Results with Subjects

Results will not be shared with subjects.

## 16) Prior Approvals

N/A

## 17) Provisions to Protect the Privacy Interests of Subjects

All information will be kept in secure REDCap database and StudyPages.

Only members of the research team will have access to the data.

As described above, d**oing a systems intervention and only evaluating the outcomes on the patients who return a HIPAA authorization would make the study not valid. It is therefore not possible to do the research without the waiver, because a systems intervention study requires evaluating the outcomes on all the patients involved in order to be valid.** The rationale for the waiver of HIPAA and waiver of consent include: (1) The use or disclosure of protected health care information involves no more than minimal risk; (2) the research could not practicably be conducted without the waiver or alteration; and (3) the research could not practicably be conducted without access to and use of the PHI.

## 18) Compensation for Research-Related Injury

N/A

## 19) Economic Burden to Subjects

N/A

## 20) Drugs or Devices

N/A

## 21) Review Requirements

**Are there any contractual obligations or other considerations that require IRB review of this research, or review at intervals other**

**than those required by the Common Rule or FDA? If yes, check box:**

☐ Yes

X No

**References**


1. American College of Surgeons. Committee on Trauma. *Resources for optimal care of the injured patient.* Chicago, Ill.: American College of Surgeons, Committee on Trauma; 2014.
2. MacKenzie EJ, Rivara FP, Jurkovich GJ, et al. A national evaluation of the effect of trauma-center care on mortality. *N Engl J Med.* 2006;354(4):366-378.
3. Cudnik MT, Newgard CD, Sayre MR, Steinberg SM. Level I versus Level II trauma centers: an outcomes-based assessment. *J Trauma.* 2009;66(5):1321-1326.
4. Brown JB, Rosengart MR, Billiar TR, Peitzman AB, Sperry JL. Geographic distribution of trauma centers and injury-related mortality in the United States. *J Trauma Acute Care Surg.* 2016;80(1):42-50.
5. Sasser SM, Hunt RC, Faul M, et al. Guidelines for field triage of injured patients: recommendations of the National Expert Panel on Field Triage, 2011. *MMWR Recomm Rep.* 2012;61(RR-1):1-20.
6. Gausche-Hill M, Ely M, Schmuhl P, et al. A national assessment of pediatric readiness of emergency departments. *JAMA Pediatr.* 2015;169(6):527-534.
7. Nance ML, Carr BG, Branas CC. Access to pediatric trauma care in the United States. *Arch Pediatr Adolesc Med.* 2009;163(6):512-518.
8. United States Government Accountability Office *Availability, Outcomes, and Federal Support Related to Pediatric Trauma Care.* 2017.
9. Fallat MG, B; Haley, K; Meredith, J; Mooney, D; Upperman, J; The Childress Summit II Work Groups. Proceedings of the second Childress Summit on pediatric trauma: Operationalizing the vision. *J Trauma Acute Care Surg.* 2016;81(4):795-801.

10. Gaines BH, K; McKenna, C; McMahon, M; Meredith, J; Mooney, D; Snow, S; Upperman, J; Childress Summit of the Pediatric Trauma Society Work Groups. Report from the Childress Summit of the Pediatric Trauma Society, April 22–24, 2013. *J Trauma Acute Care Surg.* 2014;77(3):504-509.
11. Segui-Gomez M, Chang DC, Paidas CN, Jurkovich GJ, Mackenzie EJ, Rivara FP. Pediatric trauma care: an overview of pediatric trauma systems and their practices in 18 US states. *J Pediatr Surg.* 2003;38(8):1162-1169.
12. Kim PT, Falcone RA, Jr. The use of telemedicine in the care of the pediatric trauma patient. *Semin Pediatr Surg.* 2017;26(1):47-53.
13. American Hospital Association Annual Survey Fact Sheet: Telehealth. https://www.aha.org/system/files/2018-01/fs-telehealth.pdf. Published 2018. Accessed.
14. Bashshur RL, Howell JD, Krupinski EA, Harms KM, Bashshur N, Doarn CR. The Empirical Foundations of Telemedicine Interventions in Primary Care. *Telemed J E Health.* 2016;22(5):342-375.
15. PCORI Scientific Program Area Rural Trauma Care. http://www.pcori.org/assets/PCORI-Addressing-Disparities-Topic-Brief-10-0416132.pdf. Published April 16, 2013. Accessed December 2015, 2015.
16. Esposito TJ, Sanddal ND, Dean JM, Hansen JD, Reynolds SA, Battan K. Analysis of preventable pediatric trauma deaths and inappropriate trauma care in Montana. *J Trauma.* 1999;47(2):243-251; discussion 251-243.
17. Lewis ER, Thomas CA, Wilson ML, Mbarika VW. Telemedicine in acute-phase injury management: a review of practice and advancements. *Telemed J E Health.* 2012;18(6):434-445.
18. Ricci MA, Caputo M, Amour J, et al. Telemedicine reduces discrepancies in rural trauma care. *Telemed J E Health.* 2003;9(1):3-11.
19. Rogers FB, Ricci M, Caputo M, et al. The use of telemedicine for real-time video consultation between trauma center and community hospital in a rural setting improves early trauma care: preliminary results. *J Trauma.* 2001;51(6):1037-1041.
20. Latifi R. Telepresence and telemedicine in trauma and emergency. *Stud Health Technol Inform.* 2008;131:275-280.
21. Lambrecht CJ. Telemedicine in trauma care: description of 100 trauma teleconsults. *Telemed J.* 1997;3(4):265-268.