**ImPACTS Outpatient**

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**Table of Contents:**

**Study Schema**

1. **Background**
2. **Rationale and Specific Aims**
3. **Inclusion/Exclusion Criteria**
4. **Enrollment/Randomization**
5. **Study Procedures**
6. **Reporting of Adverse Events or Unanticipated Problems Involving Risk to Participants or Others**
7. **Study Withdrawal/Discontinuation**
8. **Statistical Considerations**
9. **Privacy/Confidentiality Issues**
10. **Follow-up and Record Retention**
11. **Background**

Children with potentially life-threatening illnesses are sometimes brought to their primary care pediatrician’s office, which often serve as the child’s medical home. Estimates of how often emergently ill children are taken to primary care offices vary widely, with numbers ranging from 1-2 a year to up to multiple patients seen weekly. While the frequency of these events remains somewhat in question, it is well established that pediatric primary care offices are ill prepared to care for emergencies, with multiple studies reporting wide variation in the available equipment, supplies, and level of preparedness for these patients despite the existence of established recommendations from the American Academy of Pediatrics (AAP).

Academic Medical Centers (AMCs) with specialized pediatric providers and resources are committed to ensuring optimal health outcomes for all children in the US. In order to achieve this goal, AMCs need to expand their influence beyond their own institutions to support community practices and provide a continuum of care, starting with patients’ entry points to medical care.

ImPACTS (Improving Pediatric Acute Care through Simulation) is a collaborative improvement program that aims to improve pediatric acute care, whenever it’s needed, wherever it's needed in United States. ImPACTS has established an effective collaborative model between community emergency departments and multiple AMCs serving as “SPOKES” and “HUBS” respectively. This model was successful in improving the structure and process of acute care provided in these SPOKES in simulated setting. We seek to adapt this methodology with pediatric outpatient practices serving as “SPOKES.”

1. **Rationale and Specific Aims**

Pediatric primary care providers establish long-lasting relationships based on trust with patients and their families. As such, families will sometimes present with their emergently ill children to these practices rather than taking them to an unfamiliar emergency department. These outpatient offices, however, are often not prepared to care for emergencies in an ideal way due to inconsistencies in staff experience, equipment, training, and exposure to these events. The AAP has recognized this potential gap in care, and has published recommendations regarding practice readiness and how to improve upon it.

This project aims to improve outcomes of emergently ill pediatric patients presenting to outpatient offices by improving preparedness for pediatric emergencies through a collaborative program between these offices and the AMC. We will achieve this through a collaborative network between the state AMC and outpatient offices using simulation as an assessment and improvement tool~~.~~

**Aim 1:** To evaluate the impact of our intervention on the emergency preparedness of participating pediatric outpatient practices as measured by percent adherence to existing AAP guidelines.

**H1:** An improvement in readiness, measured by scoring on validated checklists regarding equipment/supply availability and provider performance, will be noted between the first and follow-up assessment. Participating practices will also be expected to complete action items provided to the in response to their initial evaluations over the expected period of time.

**Aim 2: T**o evaluate the impact of our intervention on the structure and process of care provided to simulated emergently ill patients in pediatric outpatient offices.

**H2:** Enrolled practices will be evaluated multiple times, both before and after interventions, while caring for simulated emergently ill pediatric patients. Specific aspects of their performance that will be evaluated include their teamwork, use of necessary supplies/equipment, and communication.

**Aim 3 (Optional/Exploratory):** To identify common themes/trends regarding barriers to providing high quality care to emergently ill pediatric patients in outpatient offices.

**H3:** AMCs participating in this aim will record and review structured debriefings after simulated emergencies, as well as self-reported reports of practice performance in actual emergencies of participating practices for common issues or themes.

1. **Inclusion/Exclusion Criteria:**

Inclusion criteria:

* “Hub” Academic Medical Centers
* “Spoke” Outpatient medical practices that care for pediatric patients.

1. **Enrollment/Randomization:**

SPOKE and HUB sites will voluntarily join ImPACTS through a set of collaborative agreements.

1. **Study Procedures:**

***Study Phases:***

1. **Baseline Emergency Readiness and Quality Assessment**

This initial site visit involves the HUB team going to each participating SPOKE site to conduct

1. Pediatric Outpatient Readiness Survey (PORS) (Appendix 1)
2. In situ simulations: The HUB team will conduct two simulations: respiratory distress (represented either by asthma or bronchiolitis) and seizure. Additionally, clinical teamwork scale CTS will be used to assess overall team dynamics and communication during each simulated scenario.

This data will be logged in using this link:

<https://survey.az1.qualtrics.com/jfe/form/SV_5jsXuCc5Lgj3JQh>

1. **Gap Analysis, Action items, and Action Plans**

This phase will consist of:

1. Report outs with action items

Standardized “ImPACTS report outs” will be sent out to the SPOKEs from the HUB. Additionally, ImPACTS will support the HUB team as they interact with the SPOKE leads to review the report out score and select action items to be completed throughout the study period.

1. Ongoing interaction (HUB to SPOKEs)

All outgoing communications (from HUB to SPOKEs) will be scheduled at approximately 2 and 4 month intervals using conference call or on-site visit. The discussions will include updates on implementation of action items, any difficulties encountered, or newly identified educational needs.

Incoming interactions (from SPOKE to HUB) will be encouraged and will happen based on the need of each SPOKE for further assistance or input from the HUB.

1. Repeated follow-up in person visit

A follow-up visit to the SPOKE will be conducted by the same methods as described above to provide re-assessments of the PORS and simulation-based performance 6 months following the baseline assessment.

1. Post-visit Trends Analysis (Optional)

Structured debriefing will be recorded after all in-situ simulation sessions administered by AMCs participating in AIM 3. It will be analyzed for common themes or trends regarding barriers or difficulties to excelling in these scenarios.

SPOKEs working with AMCs participating in AIM 3 will also be encouraged to document their performance in any real clinical emergencies during the study period and report any perceived difficulties, barriers, or gaps in education. They will be provided a tool to assist with this based on the structured debriefing described above. No patient identifying information will be reported.

**HUB ImPACTS Team:**

The team will be recruited from an academic medical center at each region/state and aims to include providers from different medical backgrounds (EM, ICU, and critical care transport) and professions (RN, MD, DO, APRN, PA).

**Participant Team:**

Each team will consist of pediatric outpatient office staff including physicians, nurses, ancillary office staff, and others.

**Simulation Sessions:**

Staff expected to participate in the simulation should mimic the site’s normal assigned tasks and workflow. This will vary slightly based on each SPOKE’s normal staffing and assignments. Additionally, the location of in-situ simulation will be either in a patient room or the waiting room of the practice. Practices will be expected to provide their own supplies and equipment, but the simulation team will have all necessary equipment available to replace the SPOKE’s supplies prior to use as to prevent them from incurring costs due to this study.

**Simulators:**

We will use a variety of simulators for the project based on each HUB’s equipment. These will include a 7 kg infant/toddler (SimBaby) and a 20 kg child (Sim Junior/Megacode Kid).

**Video:**

All simulation sessions will be videotaped using B-Line Medical “SimCapture.” All videos will be stored in the central memory of B-Line or uploaded to this system if a HUB uses another method to record video. A random sample of 10% of the cases will be reviewed by a blinded individual to compare the scores to each HUB’s score for the case.

**Audio:**

Audio recordings of the structured debriefing sessions will be recorded and stored in the central memory of B-Line, or uploaded to this system if a HUB uses another method to record audio. These recordings will be reviewed for common themes/trends regarding barriers to providing ideal care in emergencies.

**Project Facilities:**

This study will be conducted across the United States and be administered by collaborating HUBs outside of the Indiana area. In Indiana, Dr. Yuknis will conduct the protocol and in other sites the PI will be identified prior to enrollment and appropriate local HIC will be obtained. SPOKE and HUB sites will voluntarily join ImPACTS through a set of collaborative agreements (between SPOKE and “ImPACTS core” as well as HUBs and core). The ImPACTS core will provide a standardized protocol for SPOKEs to collaborate with HUBs. Participating SPOKEs will have access to quality improvement and educational content that can be shared by the HUB. The goal is to have all necessary resources, guidelines, and policies readily available in a centralized folder that can be accessed by HUB and SPOKE sites at any time. This project will not involve randomization.

**HUB recruitment, collaboration, and standardization:**

The HUB will complete training with the “ImPACTS core” using “Train the Trainer” to ensure standardization in the structure and process of this intervention, if it has not already completed this training during an earlier ImPACTS project. HUB team should include healthcare providers with a solid background in pediatric emergency/critical care medicine and simulation-based education. The team may include but not be limited to the following: pediatric emergency physicians, pediatric critical care physicians, nurses, respiratory therapists, and nurse practitioners. Each HUB will be provided a turnkey approach to collaborating with SPOKEs including QI/PI/clinical practice/education. Each HUB will identify at least three SPOKEs that will participate on a voluntary basis and commit to all elements of the program. Each SPOKE is to identify a physician and/or nurse as a champion for their location. This individual will coordinate the in person readiness assessment, the simulations, and all follow-up interactions with the HUB upon the initial agreement.

**Clinical Data:**

All self-reported clinical data regarding actual emergencies during the study period will be submitted in a de-identified manner via the same website where readiness survey and assessment results are submitted. No patient identifying information will be recorded. This data will be used only for identification of common themes regarding the care for pediatric emergencies in the primary care setting in order to better tailor interventions to improve that care.

1. **Reporting of Adverse Events or Unanticipated Problems Involving Risk to Participants or Others:**

Our study will be low risk as it is an observational pre-post study of an educational and supportive intervention for pediatric outpatient providers. The only direct risk to subjects involved is the potential breach of confidentiality of protected health information (PHI) from the minimal amount of observational, clinical data reported from actual emergencies during the study period. This risk is minimized by the lack of any patient-identifiable data being recorded.

1. **Study Withdrawal/Discontinuation:**

SPOKE participation in this study is entirely voluntary, as is HUB participation. Any SPOKE or HUB may withdraw from participation at any time.

1. **Statistical Considerations**

* **Pediatric Primary Care Readiness score outcomes**
* **Simulation case performance and CTS**
* **Completion rate of action items**
* **Identification of common themes/trends from debriefs/clinical data**

1. **Privacy/Confidentiality Issues:**

Data will be collected through videotapes, audiotapes, and online data collection forms. Subjects in the multidisciplinary team will be asked to complete a data collection instrument online using qualtrics: <https://survey.az1.qualtrics.com/jfe/form/SV_5jsXuCc5Lgj3JQh>. The data collection form will be maintained on a secure server that is password protected. SPOKEs reporting any clinical data will do so using a similar online instrument: <https://survey.az1.qualtrics.com/jfe/form/SV_5jsXuCc5Lgj3JQh>**,** which will be maintained on the same server.Videotapes and audiotapes of simulated scenarios and debriefing sessions will be processed and collected at each individual HUB and stored directly onto an encrypted server that is password protected. They will be uploaded to the secure video portal. Video and audio recordings reviewed by members of the review team will be maintained on the secure server and undergo destruction once review is completed. Each SPOKE will have a PORS survey completed to document a score. All items on checklists will be examined in person with the SPOKE “champion.” If the designated SPOKE “champion” is unsure or unable to identify an item, it will count as non-existent.

1. **Follow-up and Record Retention:**

The study will be conducted in the timeframe from 1/1/2019 – 1/1/2022. Records, data, and evaluations will be retained until the completion of the study.