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IRB Protocol for CRR Course

Title of Project: Evaluation of Consequence Validity of a Concise Instrument for Formative Assessment of Team Leader Performance During Pediatric Resuscitations

Study Purpose and Rationale

Brief background:

Pediatric resuscitations are infrequent, but high-stakes events, providing scarce opportunities for trainees to achieve proficiency in leading these scenarios[1-6]. Teamwork and leadership are critical to success in resuscitations, and formative feedback is critical to develop these skills[7-13].

Simulation is increasingly used as a tool to increase trainee resuscitation experience, skills and teamwork[14-17]. Prompt feedback is a vital component of simulation-based medical education, often guided by standardized assessment instruments[16-19]. However, standardized assessments of resuscitation leader performance are lacking. Many existing instruments do not focus on individual team leader performance, but rather the performance of the entire team[20-25]. Other instruments that have been created evaluate the individual performance of pediatric resuscitation team leaders in the research setting, but may be cumbersome or require extensive training to use, thus limiting their practical use in the clinical or educational environment[23-29].

We developed the Concise Assessment of Leader Management (CALM) instrument as a short, user-friendly tool designed to provide formative feedback to leaders of simulated pediatric resuscitation scenarios, and published the initial validation study which supported content and internal structure (reliability) validity[30].

Aim:

We aim to establish consequence validity of a previously published scoring instrument, the CALM instrument, designed to provide formative feedback to leaders of simulated pediatric resuscitations. We hypothesize that higher CALM scores will correlate with better clinical outcomes.

Study Design and Statistical Analysis

Study design:

This is a prospective validation study to assess consequence validity using Messick's framework of validity[31]. The CALM instrument will be used to score leaders of resuscitations in videos of resuscitations from the VIPER (Videography In Pediatric Emergency Resuscitation) Collaborative. Outcome data including mortality, completion and timing of basic critical assessments and interventions (monitor application, primary survey completion, vascular access, respiratory support), completion and timing of tasks related to tracheal intubation, chest compression performance (as measured by a combination of video review and feedback device measurement) will also be abstracted from the VIPER Collaborative Database.

Statistical analysis:

Continuous data will be described as means with standard deviations, or as medians and interquartile ranges, and will be compared using Unpaired T-tests or Wilcoxon-Rank-Sum tests, as appropriate. Categorical data will be described as counts (frequencies), and will be compared using Chi-Squared analysis or Fisher's exact test, if needed.

Study Procedures, Drugs, Devices or Questionnaires

No procedures, drugs, devices or questionnaires will be studied.

Study Subjects

There are two populations of study subjects in this study: the patients and the healthcare providers.

Patients:
Patients will be included in this study if they receive team-based resuscitative care in the resuscitation area of the Emergency Department (ED), which includes either tracheal intubation (attempted with or without success) and/or chest compressions, and the care is recorded by existing videorecording systems in the ED. They will be excluded from the study if the care provided in the resuscitation area does not include either chest compressions or at least one attempt at tracheal intubation, or the care is not captured by videorecording.

Heathcare providers:
Healthcare providers will be included in this study if they participate in the care of children receiving team-based resuscitative care in the resuscitation area of the ED and the care is recorded by existing videorecording systems in the ED. They will be excluded from the study if the care provided in the resuscitation area does not include either chest compressions or at least one attempt at tracheal intubation, or the care is not captured by videorecording.

Recruitment of Subjects
All videorecorded patient events are surveilled by clinical staff at each of the VIPER sites. Eligible subjects will be retrospectively identified during this surveillance, and dates and times of the relevant events will be distributed to local study team members by e-mail. Video review will be performed by study personnel at each of the VIPER Collaborative sites according to their respective Quality Improvement (QI) programs, within the time frame of video retention specified at each site. Each IRB at the VIPER sites which are actively collecting data have approved waiver of informed consents for both the patients and healthcare providers, based on the conditions that the research involves no more than minimal risk to the subjects, the waiver does not adversely affect the rights and welfare of the subjects, the research could not practicably be carried out without the waiver, and whenever appropriate the subjects will be provided with additional pertinent information after participation.

Confidentiality of Study Data
All data and records generated during this study will be kept confidential in accordance with institutional policies and HIPAA. Data will be managed and stored on the research-focused electronic web-based data capture system, REDCap. Identifiable information entered into REDCap for patients includes date of visit and date of birth, which will be used to calculate an age in days. Reports exported from REDCap database will only include the calculated age field and not the dates. Identifiable information entered into REDCap for healthcare providers includes a coded identification (ID) number. A separate master key linking names to ID numbers will be maintained in a locked office at each site's PI. Only ID numbers will be entered into REDCap. Video images of both patients and healthcare providers are reviewed by study personnel as the source of data collection. These videos are automatically destroyed according to the existing policies and procedures at each site, and are not retained longer for any additional purpose for this study.

Potential Risks, Benefits, and Alternative Therapies
The potential risk is no greater than minimal. Patients will receive standard of care in each respective emergency department, and there will be no alterations in care due to the study. The videorecordings will not be retained for longer than is the retention period allowed by each site according to the QI programs. Risk to healthcare providers include psychologic effects of video review and resultant clinical feedback, however this is already conducted in a systematic fashion at each site as part of their existing QI programs and this process will not be altered as a part of the study. There are no potential direct benefits of study participation, however eventual benefits include ongoing quality improvements of resuscitative care in emergency departments.

Compensation and Costs to Subjects

There will be no compensation or cost to subjects.

Minors as Research Subjects
This study poses no more than minimal risk to pediatric patients (subjects), as it does not alter the care provided during the resuscitation. A waiver of assent for the pediatric patients has also been approved by the IRB at each site due to their critical illness which results in limited capacity, such that they cannot be reasonably consulted.

Radiation or Radioactive Substances
There is no increased risk of exposure to radiation or radioactive substances in this study.

Resources

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