

Feasibility and Acceptability of a low-cost, mobile telemedicine platform for remote assessment of children transported by ambulance

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1 List of Abbreviations

Abbreviation	Abbreviation definition
EMS	Emergency Medical Services
BCH	Boston Children's Hospital
BMC	Boston Medical Center

2 Protocol Summary

Title:	Feasibility and Acceptability of a low-cost, mobile telemedicine platform for remote assessment of children transported by ambulance
Population:	<ol style="list-style-type: none"> 1) Clinically stable children aged <18 years (n=20) being transferred by ambulance from acute care facilities in Massachusetts and adjacent New England states by the BCH Critical Care Transport Team for acute respiratory illness from any cause. 2) Up to 6 total providers who will participate in the study assessments.
Intervention:	Prehospital teleconsultation (intervention) – Transport team personnel in moving ambulances will use Zoom Pro video-conferencing software on tablet computers as a low-cost mobile telemedicine platform (prototype platform) for synchronous video communication with remote physicians for the purpose of medical direction.
Objectives:	The primary objective is to test if it is feasible for a remote physician to assess the presence of respiratory distress in a child in a moving ambulance using the prototype platform.
Design/Methodology:	<p>We will conduct an open-label, nonrandomized, pilot feasibility trial of children with respiratory distress transported by the BCH Critical Care Transport Team that also serves BMC. Transport providers will initiate a video-call from the ambulance to one of two medical control physicians who will be at a geographically distant location. The remote medical control physician will assess each child subject using streaming video from the prototype platform to test video quality, an important feasibility measure. The remote medical control physician and the transport team member at the patient bedside in the ambulance will score a brief checklist to measure the presence of visible signs of respiratory distress simultaneously. It takes approximately 15 seconds to score the checklist.</p> <p>We will measure feasibility (primary outcomes) by assessing agreement in assessments of respiratory distress by providers in the ambulance (transport team personnel) with those in the hospital (remote medical control physicians). We will measure acceptability, video quality, audio quality, video-call connection success, success of tablet mount strategies, various transport time intervals, and</p>

	potential adverse events (secondary outcomes) on two brief questionnaires administered to users after each call. In this pilot study, we will not test efficacy; all decision making will occur according to usual care protocols.
Total Study Duration:	12 months
Subject Participation Duration:	5 minutes or less

3 Background/Rationale & Purpose

3.1 Background Information

In the United States, Emergency Medical Services (EMS) transport approximately 8 million children to hospitals per year, of which 10-14% require life-saving care outside hospitals.^{1,2} EMS encounters with critically ill and injured children are prone to errors and preventable harm with life-threatening consequences.³⁻⁷ Improving the safety of prehospital emergency care for children remains an unmet national priority.

Teleconsultation, or the use of video telecommunications technology to deliver expert recommendations for care remotely, has been used to improve the safety and quality of emergency care for children in hospital-based acute care settings by providing real-time access to remote pediatric physician experts experienced in the care of seriously ill children.⁸⁻¹¹ Whether this intervention can benefit sick and injured children in the prehospital setting is unknown. The EMS 2050 Agenda for Future Systems has proposed integrating digital health technologies to improve the safety and quality of prehospital care.¹² Despite advances in mobile technology, few U.S. EMS systems use video for any application, even for adults.^{13,14} The paucity of prehospital efficacy trials involving children has limited adoption and use of this intervention by the EMS community.

In prior simulation studies, we found high intervention acceptance among key stakeholder groups (pediatric emergency physicians and paramedics) and demonstrated that it was feasible to integrate video communication into prehospital clinical workflows involving critical care delivery in high-risk pediatric scenarios (preliminary data). These initial simulation studies were conducted in a controlled prehospital setting in static ambulances using infant simulator manikins to minimize risk to children and providers. Demonstrating feasibility and acceptability with real children in moving ambulances is the next step to build the necessary evidence base to support future planned prehospital efficacy trials with children.

This study will be conducted in compliance with the protocol, applicable regulatory requirements, and policies and procedures of the Boston Medical Center and BU Medical Campus Human Research Protection Program.

3.2 Rationale and Purpose

In the United States today, most EMS systems use standardized care protocols with standing orders followed by physician consultation via radio or telephone if needed. These physician-provider interactions rely on audio-only technologies and occur after most care events are completed. Adding video would allow the remote physician to view the patient, scene, and care events, which could enhance their ability to assess a child and guide care remotely. Thus, teleconsultation could improve outcomes by improving clinical decision-making and intervention timeliness, and reducing prehospital medical errors related to

medication administration and performance of critical procedures in sick children. This study is part of an NIH-funded phased research plan to develop teleconsultation as an efficacious prehospital patient safety intervention for children.

Teleconsultation with low-cost, commercially available mobile platforms (e.g., video-conferencing applications on mobile and tablet devices) has been used to assess and treat adults with stroke and myocardial infarction as examples of time-sensitive critical illnesses in the prehospital setting. Severe respiratory illness is a leading cause of EMS activation and transportation for children. Whether it is feasible or acceptable to use similar technology to assess critically ill children with respiratory distress remotely in moving ambulances is unknown. Children, particularly infants, are physically smaller so clinical signs and pertinent exam findings (e.g., use of accessory respiratory muscles) may be more difficult to see by tablet device cameras when patients are secured for safe transportation. Broadband connections may be harder to maintain to stream video, and environment noise and limited lighting may be additional confounders.

The objective of this study is to test whether it is feasible to use low-cost mobile technology to assess the presence of acute respiratory distress in children in moving ambulances. We will conduct an open-label, non-randomized pilot feasibility trial of children with respiratory distress transported by the BCH Critical Care transport team to sample an enriched population of eligible children (because EMS pediatric transports are infrequent), and leverage specialty teams experienced in the care of sick children in the prehospital setting to minimize risks to children and providers when introducing new technology in high-stakes clinical settings. We hypothesize that remote respiratory assessment of children by medical control physicians (expert physicians) using the prototype teleconsultation platform is technically feasible during ambulance transports and acceptable to physicians and transport providers. We will use the results of this trial and a fully powered simulation trial to assess intervention efficacy (R01 proposal pending NIH scientific review) to prepare for a future real-world prehospital efficacy trial testing the efficacy/effectiveness of teleconsultation as a prehospital patient safety intervention for children.

4 Objectives

4.1 Study Objectives

The primary objective is to test the feasibility of using low-cost mobile technology to assess the presence of acute respiratory distress in a child in a moving ambulance.

The secondary objectives are to assess the acceptability of using the prototype platform to conduct remote patient assessment; the adequacy of audio and video quality during teleconsultation encounters; the success of establishing video-call connections within a maximum of 2 attempts; the success of tablet mount strategies; and the impact on transport time intervals as time delay is a potential adverse effect.

4.2 Study Outcome Measures

4.2.1 Primary Outcome Measures

Agreement in global assessment of respiratory distress: Each child subject will be assessed concurrently by a remote medical control physician from a geographically separate location (e.g., in the hospital) and a transport provider in the ambulance. The medical control physician will assess the child via real-time

streaming video using the HIPAA-compliant Zoom Pro web application pre-loaded on a tablet device (prototype teleconsultation platform). The transport provider will assess the child in-person at the patient bedside in the ambulance. The remote medical control physician and the transport provider will score digital versions of the validated *Respiratory Observation Checklist* independently while assessing the child. The checklist measures 9 observable signs and 1 global measure of acute respiratory distress and has been validated for use in hospital-based emergency settings. The primary outcome, *agreement in global assessment of respiratory distress*, will range from 0 to 1.0, where 0 is no agreement and 1.0 is perfect agreement between remote physicians performing video assessment and transport providers performing in-person assessment. We will use the following scale to categorize agreement: 0.01-0.20=none to slight, 0.21-0.40=fair, 0.41-0.60=moderate, 0.61-0.80=substantial, and 0.81-1.0=almost perfect agreement.

Time Frame: Checklist data will be collected for each enrolled child during the 6-month study period.

4.2.2 Secondary Outcome Measures

1. Total Usability Score: This will be measured by the *Telehealth Usability Questionnaire* (TUQ). The 21-item TUQ is a validated measure of key usability characteristics of telehealth platforms. Users (physicians and transport providers) rate each item on a 7-point Likert-scale (1=disagree to 7=agree) in 6 domains (usefulness, ease of use and learnability, interface quality, interaction quality, reliability, and satisfaction and future use). The investigators modified this questionnaire to specifically address usability in the prehospital setting. The total usability score is the total mean score for all 21 questions (maximum possible score=7). Higher scores indicate greater usability. We will report the mean total usability score and standard deviation for all transports.

Time Frame: 6 months

2. Video quality: This will be measured by TUQ items #11 and #14 within the “Interaction Quality” domain. Users rate each item on a 7-point Likert-scale (1=disagree to 7=agree), so scores will range from 1 to 7. We will report the mean score and standard deviation for each item.

Time Frame: 6 months

3. Audio quality: This will be measured by TUQ items #12 and #13 within the “Interaction Quality” domain. Users rate each item on a 7-point Likert-scale (1=disagree to 7=agree), so scores will range from 1 to 7. We will report the mean score and standard deviation for each item.

Time Frame: 6 months

4. Success of video-call connection: This is the number of attempts transport team providers make to successfully connect with the medical control physician via video-call. We define success of video-call connection as ≤ 2 attempts to achieve a video-call connection.

Time Frame: 6 months

5. Success of tablet mount strategy: Study investigators will note any problems with tablet mounts in the ambulance cabin (e.g., location makes call activation difficult), as well as specific qualitative comments

from participants regarding tablet mount strategy. This outcome will be reported as the proportion of calls without any problem related to the tablet mount strategy.

Time Frame: 6 months

6. Proportion of calls with adequate video quality for assessment: This will be measured as the proportion of video-calls where clinicians are able to observe all 10 items on the *Respiratory Observation Checklist*.

Time Frame: 6 months

7. Time to arrival at referring facility: This is the time interval (minutes) from when BCH receives the patient transport request from the referring facility to the time the transport team arrives at the referring facility. This will be abstracted from transport records.

Time Frame: 6 months

8. Scene time: This is the time interval (minutes) from when the BCH transport team arrives at the referring facility to when the transport team leaves the referring facility. This will be abstracted from transport records.

Time Frame: 6 months

9. Time to arrival at destination facility: This is the time interval (minutes) from when the BCH transport team leaves the referring facility to the time of arrival at BCH/BMC (the destination facility). This will be abstracted from transport records.

Time Frame: 6 months

10. Total transport time: This time interval encompasses the time from when the transport team is dispatched to the referring facility to when they arrive at the destination (receiving facility). This will be abstracted from transport records.

Time Frame: 6 months

4.2.3 Exploratory Outcome Measures

There are no exploratory outcome measures.

5 Study Design

This is an open-label, nonrandomized, pilot feasibility trial to field test the feasibility and acceptability of using low-cost mobile technology to assess children remotely in moving ambulances. The study population will include clinically stable children (aged <18 years) from the New England region who are being transported by the BCH critical care team between hospitals for treatment of severe respiratory illness from any cause. We will mount tablet devices with Zoom Pro software in the cabin of both BCH ambulances. The tablet devices will utilize the secure wireless network used by BCH. Transport providers will initiate a video-call from the ambulance to the remote medical control physician. The physician will view streamed video to assess the child remotely. The physician and transport provider will each complete

a brief checklist to independently score the presence or absence of observable signs of respiratory distress. We will assess agreement in assessments of respiratory distress between transport providers in the ambulance and remote physicians in the hospital (primary outcome). We will also measure acceptability (total usability score) and various feasibility measures (secondary outcomes: video-call connection success; ease of making/receiving video-calls; adequate audio and video quality; and transport and treatment time intervals) on brief questionnaires administered to users (transport nurses and physicians) after each call. All data will be entered directly into web versions of each questionnaire and checklist tool using REDCap, a secure web platform for data collection and management hosted by Boston University.

6 Potential Risks and Benefits

6.1 Risks

The primary risk to participants is *loss of confidentiality*. We do not anticipate any reasonably foreseeable physical, psychological, legal, social, or financial risks as no treatment decisions will be made based on the intervention, participation in the study is anticipated to last <5 minutes, no video data will be recorded, and we will only recruit patients with stable illness who do not require immediate life-saving interventions during transportation. Therefore, there is minimal risk to subjects because of their participation in this research.

We will minimize risks because:

- Prior to child subject enrollment, we will first test the feasibility of using the teleconsultation equipment and completing video calls using infant manikins with study team members in moving ambulances. This will allow us to modify technology or equipment as necessary to ensure video-calls can be made successfully before involving child subjects. This will minimize the risk of equipment failure.
- We will only enroll children whose respiratory illness is not immediately life-threatening (i.e. requiring active bag-valve-mask ventilation, tracheal intubation, or cardiopulmonary resuscitation by the team in the ambulance during transportation). Only transported children who require supplemental oxygen, non-invasive ventilation, respiratory medications (e.g., albuterol), or are stabilized on invasive mechanical ventilation prior to initiating ambulance transportation will be eligible. This is to minimize any risks to subjects related to intervention feasibility testing. We will first confirm that the platform is efficient and provides clearly visible and accurate clinical data to the medical control physician and can be used in diverse geographic locations in Massachusetts and New England. Although prehospital teleconsultation with a pediatric expert may ultimately be most effective for critically ill children, it is important to initially study the intervention in sick children who are clinically stable for transportation. This is to minimize problems with connectivity or data transmission and ensure that system function is optimal and physician use of the scoring tool does not detract from care delivery.
- All data collection will be conducted using HIPAA compliant and encrypted technology. We will not record or store the actual clinical encounter. Although there could be a potential risk to confidentiality if the teleconsultation connection security was compromised, we will use a secure connection and devices that are used in current clinical practice that should minimize this risk.
- Only ID coded data will be provided to study investigators. This will minimize risks to loss of confidentiality.

6.2 Potential Benefits

The potential long-term benefits of knowledge gained by this study outweigh its risks. All children enrolled in this study will receive prehospital care consistent with the current standard. The prototype teleconsultation platform, which will be available to all participants, could potentially provide a direct benefit to the child subjects because a video connection could assist the medical control physician in more accurate remote assessment of a child, and ultimately provide better and earlier access to diagnosis and treatment, and enhance transitions of care between prehospital and hospital settings. There is also potential to gain generalizable knowledge as this intervention could be particularly important in areas with limited access to pediatric expertise, such as rural or otherwise underserved communities.

6.3 Analysis of Risks in Relation to Benefits

Adding streaming video to the usual mode of radio or telephone-based communication does not increase the probability or magnitude of harm within the communication mode itself for several reasons. First, in simulated prehospital settings, we found that prehospital providers in stationary ambulances could establish a video call with a remote physician at a geographically distant location on the first attempt in <30 seconds. Second, each video call is anticipated to last 1-3 minutes to allow the medical control physician and transport provider adequate time to score a brief checklist. Third, we will only enroll patients that do not require active care during transportation. Thus, study participation and intervention use are not anticipated to cause harms such as delayed transportation or alter care delivery. Last, while the study physicians are the Medical Directors for the BCH transport team, they will *not* be the medical control physicians on-call who are responsible for providing actual patient care. Transport providers will be instructed to use their usual modes and procedures for communicating with on-call medical control physicians for clinical care delivery.

The main risk to subjects is loss of confidentiality of patient data. All study data forms will be identified with a unique study ID number which will be linked to a master-code list that contains all study ID numbers and direct subject identifiers (medical record number). The BCH nursing supervisor who conducts daily review of BCH transport record for the purpose of quality assurance will maintain this secure, password-protected crosswalk separately from study files and will be the sole study team member with access to this information. This individual will abstract limited patient demographic data (age, sex, race/ethnicity, comorbid medical conditions), physical exam findings (initial vital signs), reason for transportation (primary diagnosis), and transport encounter details (referring facility, destination facility, date, transport time intervals) from electronic transport medical records of enrolled child subjects directly into a REDCap database that will be shared with study investigators. Further, we do not anticipate psychological, legal, social, financial, or physical risks even in the unlikely event that loss of confidentiality were to occur. Thus, the potential societal benefits from the knowledge gained by conducting this study outweigh the potential minimal risks to subject related to loss of confidentiality.

7 Study Subject Selection

7.1 Subject Inclusion Criteria

To be eligible to participate in this study, a child subject must meet all the following criteria:

- Children, aged <18 years, from the New England region who are transported by the Boston Children Hospital for respiratory illness from any cause AND

- Clinically stable for transportation [e.g., need supplemental oxygen, medications, or are stable on mechanical ventilation] AND
- Have English speaking parents/guardians to participate in the verbal consent process.

Medical providers and transport personnel (n=4) are also human subjects but also have volunteered for this role as study personnel.

7.2 Subject Exclusion Criteria

A child who meets any of the following criteria will be excluded from participation in this study:

- Children with non-respiratory complaints
- Children whose illness is anticipated by transport providers to be acutely life-threatening during transportation [e.g., requiring emergency resuscitation procedures in the ambulance]
- Children with non-English speaking parents or guardians who cannot participate in the verbal consent process required for this study.
- Minors who are wards of the state, as verbal consent cannot be obtained in a timely manner.

8 Study Intervention

In this study, teleconsultation is a behavioral intervention to enhance interdisciplinary communication in the prehospital setting using commercially available mobile technology. Transport providers will use Zoom Pro© video-conferencing software (Zoom Video Communications, Inc.), on iPad Pro© tablet devices (Apple Inc.) as a scalable, low-cost teleconsultation platform (prototype platform) for synchronous communication with remote physicians using on-demand, real-time, streaming video interactions to enhance patient assessment and medical direction. One tablet device will be mounted and stored in the ambulance cabin, while the second device will be hand-held by the physician. Zoom Pro is a HIPAA-compliant software used by BCH and BMC in clinical and non-clinical settings. BMC will provide the tablet devices and mounting equipment, and the institutional Zoom Pro license for installation and use in two BCH critical care ambulances.

Each child subject will be exposed to the intervention only once during the transport encounter to complete scoring of the primary outcome measure (*Respiratory Observation Checklist*) which is anticipated to take <5 minutes.

9 Recruitment and Retention Procedures

9.1.1 Recruitment Procedures

The critical care transport team on a typical interfacility ambulance transport consists of two nurses and one paramedic. We have identified two transport nurses who have volunteered to serve as BCH study team members.

Child subjects who meet eligibility criteria will be identified by one of the two transport nurses. The transport nurse will screen the child for eligibility for participation after they have completed their initial

field assessment and patient care is transferred to the BCH team by the referring facility. In most interfacility transports, the parent or guardian accompanies the child (patient) and the transport nurse in the ambulance cabin for the duration of the transport from the referring facility to the receiving facility (BCH or BMC). Recruitment will occur in the ambulance only if a parent/guardian is present, and after the transport team has secured the patient within the ambulance cabin and completed all necessary patient care. As the provider of the transport service, BCH will be the sole recruiting site.

9.1.2 Retention Procedures

Retention strategies are not required as the participants will only be retained in the study for the duration of the interfacility ambulance transport to the receiving hospital. As the BCH Critical Care Transport Team serves the New England region, the duration of a given transport can range from minutes to hours based on the geographic distance between facilities.

10 Screening Procedures

There are no screening procedures beyond what is described above in Section 9.1.1.

11 Consent Procedures

Child subjects

For child subjects, we will use a verbal *Consent Script* and a printed *Parent Permission Form* that has been abbreviated for an *Alteration of Consent*. The consent script will be read by one of the two transport nurses indicating that they will be contacting a study physician using a video-conference platform and that the video of their child will not be recorded.

The parent/guardian will have the opportunity to ask questions prior to providing consent. The transport nurse will document the parent/guardian's response to this consent discussion (Yes/No) in a REDCap consent data form. After the verbal consent discussion, the transport nurse will provide the parent/guardian a printed paper copy of the *Parent Permission Form* which includes the consent script, confidentiality risks and protections, and contact information for the study investigators and the IRB of record.

We anticipate that most minor subjects will be infants or young children who are not developmentally capable of providing assent, or minors who are cognitively impaired due to underlying chronic conditions. Nevertheless, the transport nurse conducting the consent discussion with the parent/guardian will obtain and document assent from all minor subjects who can understand what participation in the study involves unless otherwise prohibited by the severity of the child's clinical condition.

While the transport nurse will only attempt to recruit the patient once, the parent/guardian will have the opportunity to consider participation for the duration of the transportation prior to arrival at the receiving facility assuming the patient's clinical condition (eligibility) is unchanged.

Parents/guardians can decline to participate and elect to remove their child's data at any point.

Transport nurses and physicians

For transport nurses and physicians, we will present a brief *Exempt Information Sheet* prior to filling out the post-call questionnaires. This brief paragraph will be presented electronically via REDCap. They will provide their opinions on the technology and report any problems with the video call. If they agree, they will proceed to complete an electronic version of the post-call questionnaire. Because there are only four people involved, and they are all voluntary study team members or volunteered to work on this project, it is not feasible or necessary for them to be anonymous. We will keep their name and date of the study encounter so that we can pair data measuring agreement in assessment between providers (primary outcome) with the presence or absence of any technology failures.

12 Study Procedures

Event	Study team member(s) responsible	Data form	Time
Screening	Transport nurse screens for eligibility		Based on dispatch call information, after initial clinical assessment of patient prior to initiating transport to receiving facility (beginning of clinical encounter)
	Transport nursing supervisor maintains log	Screening log (Excel)	After transport completed (end of clinical encounter)
Recruitment, consent	Transport nurse recruits, consents	Parent Permission Form (REDCap)	During transport in ambulance
Enrollment	Transport nurse enrolls consented child	Parent Permission Form (REDCap)	During transport in ambulance
	Transport nursing supervisor maintains log	Recruitment/Enrollment log (Excel)	After transport completed
Study encounter	Transport nurse assesses patient at bedside, scores checklist	Respiratory Observation Checklist (REDCap)	During video-call in ambulance (study encounter)
	Remote physician assesses patient remotely via video, scores checklist	Respiratory Observation Checklist (REDCap)	
Post-call user ratings, call characteristics	Transport nurse rates platform, reports any technical issues with call	Post-call questionnaire (REDCap)	After transport completed (within 24 hours after end of clinical encounter)
	Remote physician rates platform, reports any technical issues with call	Post-call questionnaire (REDCap)	After video-call completed (end of study encounter)
Patient, transport characteristics	Transport nursing supervisor abstracts patient, transport clinical	Patient, transport questionnaire (REDCap)	After transport completed (within 1

	encounter data from electronic medical record		week after end of clinical encounter)
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We will use the following study procedures for each enrolled subject (see Table above):

1. **Establish video-call connection:** After obtaining consent, the transport nurse will initiate a two-way video-call from the ambulance to the remote study physician using the prototype teleconsultation platform on a tablet device mounted in the ambulance cabin. This marks the beginning of the study encounter. The remote physician will answer the call on a separate handheld tablet device to establish the video call connection.
2. **Confirm study ID:** The transport nurse will confirm the study ID number with the remote physician to ensure outcome data are paired correctly.
3. **Optimize video-call conditions:** If requested by the remote physician, the transport nurse will adjust the position of the tablet device to optimize view of the child. We will mount the tablet device within arm distance of the transport nurse so it can be safely adjusted in a moving ambulance without removing safety restraints.
4. **Blinded outcome assessment:** The remote physician will use streaming video to assess the child remotely while the transport nurse will use direct observation to assess the child at the bedside in the ambulance. The remote physician and the transport nurse will then score digital versions of the Respiratory Observation Checklist independently in REDCap data forms using their smart phones. The remote physician and transport nurse will be blinded to all outcome assessment. The transport nurse will then end the two-way video-call. This marks the end of the study encounter. The total duration of the study encounter is anticipated to last <5 minutes.
In the event of call failure (inadequate video quality to conduct remote assessment) or call disconnection, the transport nurse will make up to 2 additional attempts to complete a video-call successfully for a total of 3 attempts. The transport nurse will determine the timing of each additional attempt based on patient care needs and expected duration of the transport.
5. **Post-call questionnaires:** After each study encounter, the remote physician and transport nurse will complete a brief post-call questionnaire to rate the usability of the prototype platform (Telehealth Usability Questionnaire) and input video-call feasibility data (frequency of attempts; problems with the platform, call quality, tablet mounting strategy; and any perceived adverse events). This questionnaire takes 5-10 minutes to complete. Whenever feasible, remote physicians will complete the questionnaire immediately after the *study* encounter ends, and transport nurses immediately after *clinical* encounter ends (to minimize interference with patient care). If this is not feasible, providers will be encouraged to complete the questionnaire within 24 hours.
6. **Screening, recruitment, and enrollment logs:** After the end of the clinical transport encounter, the transport nurse will provide the transport nursing supervisor with the patient medical record number for screened patients who were eligible for inclusion and approached for recruitment and consent; and study ID number for enrolled patients. The transport nursing supervisor will record and maintain the crosswalk of master codes linking patient medical record numbers and study ID numbers in a secure, password-protected electronic database with limited access.
7. **Electronic medical record data abstraction:** The transport nursing supervisor reviews all clinical transport encounters daily for quality assurance as part of routine care. The transport nursing supervisor will review the electronic medical record for each enrolled patient to abstract limited patient demographic information, vital signs, illness severity data, the primary diagnosis, reason for transportation, comorbid conditions, facility names, and transport time intervals. They will enter this

data directly into a REDCap data form without any identifying patient information other than the study ID number. This data form is anticipated to take 15 minutes to complete.

Subjects will participate in the study for 5 minutes or less during with study activities will occur (patient assessment and scoring of respiratory distress). The total study duration will be 1 year, with 6 months to complete recruitment and enrollment and 6 months to complete data analysis and reporting.

Early termination: Any patient that has a change in clinical status that alters their eligibility for study participation after consent procedures are completed but prior to initiation of the study encounter will be terminated from the study.

Blinding: This is an open-label, nonrandomized study as the intervention cannot be masked or blinded. However, remote physicians and transport nurses will be blinded to each other's assessment as they will not communicate verbally while they assess a given patient and will score respiratory distress independently on separate electronic data forms. We do not require unblinding procedures, as no clinical decision-making will occur using remote video assessment. All clinical decision-making will occur using usual care processes and communication modes to contact the medical control physician on call (non-study physicians).

13 Assessment of Safety and Data Safety Monitoring Plan (DSMP)

13.1 Definitions for Safety Assessment

The following definitions will be used in the assessment of safety:

Adverse Event (AE) is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Serious Adverse Event (SAE) is any adverse event that

- (1) results in death;
- (2) is life-threatening;
- (3) results in inpatient hospitalization or prolongation of existing hospitalization;
- (4) results in a persistent or significant disability/incapacity;
- (5) results in a congenital anomaly/birth defect; or
- (6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

Life-threatening means that the event places the subject at immediate risk of death from the event as it occurred.

Unanticipated Problem is defined as an event, experience or outcome that meets **all three** of the following criteria:

- is unexpected; AND
- is related or possibly related to participation in the research; AND
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research

Unexpected means the nature, severity, or frequency of the event is not consistent with either:

- the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
- the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

13.2 Safety Review

Both the risks listed in Section 4.1 and unknown risks will be monitored as follows:

- Risk classification and recommended level of monitoring: This is a *minimal risk* study because the probability and magnitude of harm or discomfort anticipated for children participating in this research involving remote physical examination do not exceed those encountered during routine physical examination, and confidentiality is protected. Thus, the study can be monitored by the PI and does not require independent monitoring per NHLBI and BUMC IRB policy on minimal risk studies. We will use 3 mechanisms for PI notification. (1) BCH Transport Nurses providing clinical care in the ambulance and recruiting/enrolling children will notify the BCH Transport Nursing Supervisor and the BMC study PI within 48 hours if an AE occurs or is perceived to have occurred. (2) If either the transport nurse or the remote physician participating in the study indicates that an AE could have or did occur while entering data in the post-call questionnaire in REDCap, the REDCap database will send an automatic email alerting the study PI. (3) Finally, if the BCH Transport Nursing Supervisor identifies an AE during data abstraction from the medical record, they will notify the PI within 72 hours.
- Internal data monitoring: The PI will be responsible for internal monitoring of AE and UP in the study overall. The PI will delegate monitoring responsibility to the BCH Nursing Supervisor as this study team member has the appropriate qualifications, privileges, and access to patient data to serve as the medical monitor. The BCH Nursing Supervisor is uniquely situated to distinguish research-related events from non-research related events as they review all transport clinical encounters as part of routine care quality assurance and can consult the Medical Director when necessary. The BCH Nursing Supervisor and the study PI will meet at least monthly with flexibility based on recruitment and enrollment progress.
- UP, AE, and significant AE (SAE) definitions, classification and grading, and attribution: We will utilize all BUMC accepted definitions for UP, AE, and SAEs. UPs will be any incident, experience, or outcome that is unexpected, related/possibly related to intervention use, and places child subjects at a greater risk of harm than previously known or recognized. In clinical trials involving ill participants, events considered related to the natural history of the disease process (acute respiratory distress) are not

considered “unexpected”. Events that would typically not be reported as AEs include abnormal physical findings or vital signs expected in a child with acute respiratory distress (e.g., abnormal respiratory rate for age), fluctuations that are consistent with the natural course of illness (e.g., worsening respiratory distress during ambulance transportation), and hospitalization. Events that we will monitor include if intervention use impedes or delays patient care delivery, and if use of video causes unexpected emotional distress in a child subject or parent/guardian. AEs will be graded as “mild” if treatment is not required, “moderate” if resolved with treatment, or “severe” if professional medical attention is required to continue or return to normal activity. The BCH Transport Nursing Supervisor will assess each AE to assign grading. If needed, the Medical Director will assist the Transport Nursing Supervisor with AE classification. Attribution of AEs will utilize the BUMC IRB scale relating AE as definite, probable, possible, unlikely, or unrelated to the study intervention.

- Reporting Responsibilities: All UP, AE, and SAEs will be reported by the PI to the IRB per BUMC policy.
- Emergency Actions: This trial cannot be blinded due to the nature of the intervention. However, we will deliberately exclude children when the transport team deems intervention use is not practical due to the child’s clinical condition (e.g., receiving cardiopulmonary resuscitation, requiring extensive monitoring or active therapeutic interventions during transportation) for the initial feasibility trial. Finally, in the rare and unlikely event that use of the study intervention results in a life-threatening delay in delivery of the standard of care for a child, the study will be suspended pending further review.

13.2.1 Multi-Site Safety Monitoring

This is a *collaborative study* with study team members located at two different sites. BCH study team members will perform data collection and outcome assessment, and BMC study team members will perform data analysis. This is not a multi-site study because the clinical protocol will be implemented at a single site (BCH) where participants will receive the intervention and be assessed for outcomes.

13.3 Reporting Plans

The Principal Investigator at BMC/BU Medical Campus will report Unanticipated Problems, safety monitors’ reports, and Adverse Events to the BMC/BU Medical Center IRB in accordance with IRB policies:

- Unanticipated Problems occurring the BCH site will be reported to the BMC/BU Medical Campus IRB within 7 days of the principal investigator learning of the event.
- Adverse Events (including Serious Adverse Events) will be reported in summary at the time of continuing review, along with a statement that the pattern of adverse events, in total, does not suggest that the research places subjects or others at a greater risk of harm than was previously known.

13.4 Stopping Rules

If a subject’s condition worsens during any point in the study encounter between recruitment and conduct of remote patient assessment by video, the subject will be withdrawn from active participation in the study. The BCH critical care transport team will immediately provide appropriate care using all usual protocols and procedures, including those for obtaining online medical direction. The study will be

stopped if rules are met for stopping, such difficulties interfacing with the intervention platform impedes or delays the standard of care during transportation.

14 Data Handling and Record Keeping

14.1 Confidentiality

- BCH study team members will perform all data collection. Only BCH transport nurses and the BCH transport nursing supervisor who provide routine care to the child subject will have access to identifiable patient data. BMC study team members will create all data collection and management tools using study record numbers (without identifiable patient information) and conduct all data analysis.
- All participants will be assigned a unique study code using REDCap. We will create a secure REDCap data form that includes the script for the verbal consent process. This data form can be accessed on by any mobile device with internet access, such as a smart phone. The transport nurse will read this script and select whether the parent/guardian consented to or declined study participation. When consent is obtained, a data form containing the respiratory observation checklist with a unique study ID number will be automatically generated. The transport nurse will provide the study ID number and the patient medical record number directly to the nursing supervisor at the end of the transport encounter via direct verbal communication or secure email.
- The master crosswalk that links study codes to participant medical record numbers will be held by the BCH transport team nursing supervisor as this individual reviews every transport record as part of routine care. The master crosswalk will be stored on a password protected computer in the nursing supervisor office at BCH for the duration of the study and then destroyed. The study PI will be responsible for ensuring that it is shredded or otherwise destroyed.
- Medical control physicians and transport team members will enter their independent assessments of respiratory distress directly into a secure, online REDCap database held at BMC (hosted by Boston University).
- The BCH Transport Team Nursing Supervisor will abstract patient and transport encounter data from the electronic medical record directly into a secure REDCap database held at BMC (hosted by Boston University).
- All REDCap data will be stored on a HIPAA compliant, password protected, secure cloud server maintained by BU/BMC with access limited to BMC study team members only. We will use data collection and management tools that meet HIPAA security rules to protect confidentiality and security of protected health information. All data will be kept for seven years after data analysis is complete and then destroyed.
- This trial has been registered on ClinicalTrials.gov and will be updated at least every 12 months or within 30 calendar days of change to protocol information, including recruitment status and primary completion date.

14.2 Study Documentation, Source Data, and Case Report Forms (CRFs)

We will not collect biological specimens. We will gather two types of data as detailed above in Section 14.1:

Participant data: We will collect data on the success of child subject recruitment and enrollment on the consent form. We will use transport medical records to abstract patient demographic information (age, sex, race/ethnicity), clinical encounter data (vital signs, illness severity, primary clinical diagnosis, and clinically relevant comorbid conditions), and transport data (referring facility location, time of video-call initiation to the physician, duration of the video-call, and all key transport and treatment time intervals). This data will be entered directly into REDCap. We will not record names, date of birth, social security numbers, or home address.

User ratings: Transport providers and medical control physicians (BCH study team members) will enter platform ratings and provide written qualitative comments directly into REDCap data forms.

See Section 18 Appendix for the following data collection forms:

- Patient and transport records_DATA FORM
- Videocall_DATA FORM
- Transport personnel TUQ
- Physician TUQ

14.3 Study Records Retention

As per Boston Medical Center and Boston University policy, we will retain study records for at least seven years after study completion.

15 Statistical Plan

15.1 Study Hypotheses

We hypothesize that we will have adequate agreement ($Kappa \geq 0.8$) between providers assessing the presence of acute respiratory distress in children using direct observation at the bedside (transport nurses) and video observation (remote medical control physicians).

15.2 Sample Size Determination

This study involves two populations:

(1) Child subjects ($n=20$) with respiratory distress who require ambulance transportation for hospitalization

(2) Transport nurses ($n=2$) and physicians ($n=2$) – These study personnel meet the definition of "human subjects" as they will provide their opinions and preferences in the TUQ.

CHILD SUBJECTS

After review of 12 months of BCH transport records, 400 (36%) of 1,121 children met eligibility criteria. We plan a 6-month study from October to March to maximize subject recruitment with respiratory illness and reasonably enroll at least 20 (10%) expected eligible subjects.

Number of children	Kappa (95% CI)
20	0.80 (0.54, 1.00)
40	0.80 (0.61, 1.00)

Table 1. Precision of estimates in interrater agreement in assessment of respiratory distress between bedside and remote providers assuming a 90% prevalence of assessed respiratory distress for raters in each location.

prevalence of assessed respiratory distress of 90% for raters in each location, the lower bound of a 95% confidence interval (CI) for a clinically relevant minimal kappa statistic of 0.8 is 0.54 with an upper bound of 1.0. In comparison, in a sample of 40 children, again assuming a prevalence of assessed respiratory distress of 90% for raters in each location, the lower bound of a 95% CI for a kappa statistic of 0.8 is 0.61 with an upper bound of 1.0. Thus, in samples of the size that we anticipate being able to evaluate for this trial, the widths of these confidence intervals for a clinically meaningful kappa of 0.80 are acceptably narrow (**Table 1**).

We will assess the agreement in assessments of respiratory distress by providers in the ambulance (transport nurses) with those in the hospital (remote medical control physicians). This is measured by the question “Patient in respiratory distress? Yes/No” on the 10-item Respiratory Observation Checklist. In a sample of 20 children being transported, assuming a

TRANSPORT NURSES & PHYSICIANS

The BCH Critical Care Transport Program has approximately 30 employees. We have identified 2 transport nurses, and 2 medical control physicians in the BCH Critical Care Transport Program who have volunteered to participate in this research. We anticipate on identifying up to 2 more. The physicians are the prior Medical Director (Dr. Monica Kleinman) and the current Medical Director (Dr. Jordan Rettig) of the Transport Program. Their specific clinical experience and expertise will support the validity of the outcomes.

We will sample two individuals within each group so we can assess interrater reliability from more than one pair of providers.

15.3 Statistical Methods

We will report descriptive statistics including means with SD for continuous variables (selected quantiles, if non-Gaussian), counts with proportions for categorical variables, and 95% CI for both.

We define the agreement threshold as Kappa ≥ 0.8 as this represents a clinically meaningful threshold of agreement between raters. We will refine the intervention for agreement ratings below this threshold, guided by low-scoring TUQ items that measure specific telehealth system attributes, and qualitative results. We will proceed to a future efficacy trial with children (non-simulated) if we demonstrate that children can be adequately assessed remotely to determine the presence or absence of acute respiratory distress via the low-cost mobile teleconsultation platform.

We will summarize the number of subjects approached and screened, number and reason ineligible, number declining participation, number enrolled, and estimated recruitment rate.

We will also summarize patient (age, sex, race/ethnicity, vital signs, illness severity, physical exam) and transport encounter characteristics (referral source, transport time intervals).

We will analyze written qualitative comments using the Technology Acceptance Model framework and grounded theory to identify themes. We will start with a set of conceptual categories using the Constant Comparative Method, apply these to data, and revise categories to reflect new concepts. This process will

generate the subsequent theory of intervention acceptance. To ensure coding validity, we will use two study team members for all coding. We will use critical review and team consensus to resolve coding discrepancies.

16 Ethics/Protection of Human Subjects

This study is to be conducted according to applicable US federal regulations and institutional policies (which are based in federal regulations, guidance, and ICH Good Clinical Practice guidelines).

This protocol and any amendments will be submitted to the Boston Medical Center and Boston University Medical Campus IRB for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator. A copy of the initial IRB approval letter will be provided to the sponsor before commencement of this study.

All subjects for this study will be provided a Parent Permission Form with Alteration of Consent describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. The consent form will be submitted with the protocol for review and approval by the IRB. The consent of a subject, using the IRB-approved consent form, must be obtained before that subject is submitted to any study procedure. Consent will be documented as required by the IRB.

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18 Appendix

18.1 Schedule of Events

Event	Transport encounter					24 hours post-transport	1 week post-transport
	Dispatch	Arrival at receiving facility	Patient preparation for transport	Transport in ambulance	Arrival at destination facility		
Screening	x		x				
Recruitment, consent				x			
Enrollment				x			
Remote and bedside respiratory assessment of child subject (study encounter)				x			
Post-call user ratings, call characteristics						x	
Patient, transport characteristics							x