Protocol

Title:	**Code Blue Outcomes & Process Improvement through Leadership Optimization using Teleintensivists-Simulation (COPILOT-Simulation)**
ClinicalTrials.gov ID:	NCT03000829
Study sites:	Alta View Medical Center, American Fork Hospital, Heber Valley Medical Center, Intermountain Medical Center, LDS Hospital, McKay-Dee Hospital, Park City Medical Center, Riverton Hospital, The Orthopedic Specialty Hospital
Principle investigator:	Ithan Peltan, MD, MSc
Sponsor:	Intermountain Research and Medical Foundation

PROTOCOL

Code Blue Outcomes & Process Improvement through Leadership Optimization using Teleintensivists-Simulation (COPILOT-Simulation)

Principle Investigator: Ithan Peltan, MD, MSc

Purpose of the Study: Our long-term goal is to improve patient outcomes after in-hospital cardiac arrest (IHCA), an event often referred to as a "Code Blue." The current project will evaluate the effect of telemedical consultation by an intensive care physician to assist local IHCA teams.

Research Questions: Does remote consultation by experienced intensivists "copilots" improve the quality of resuscitation delivered by IHCA teams?

Study summary: We will conduct a multicenter randomized trial using in-situ cardiac arrest simulations ("mock codes") to test the effect of adding a telemedical intensivist "copilot" to IHCA teams on chest compression quality, ACLS protocol adherence, team function, and provider experience.

Hypothesis: *Intensivist support of the IHCA team during mock codes improves chest compression quality.*

Background and Significance: Only 15-30% of patients who suffer in-hospital cardiac arrest (IHCA) survive to hospital discharge.[1,2] Factors associated with lower mortality and improved function include provision of high-quality, minimally-interrupted chest compressions, prompt administration of epinephrine, and swift defibrillation of eligible arrhythmias.[3-6] Unfortunately, resuscitation teams provide suboptimal care to 25-40% of IHCA victims, with significant variation in IHCA outcomes and process adherence documented between hospitals.[3,7] Resource limitations and less-experienced providers may explain lower IHCA at small hospitals and on nights and weekends.[8,9] Although educational and technological interventions may improve patient outcomes, the gap between optimal and actual resuscitation practice remains large.[1,10] Barriers to effective IHCA resuscitation countered by effective leadership include response teams' ad hoc formation and variable structure and member expertise.[11-13] Explicit leadership training improves processes of care and outcomes for IHCA resuscitation, but standard Advanced Cardiac Life Support (ACLS) training provides little instruction non-technical skills critical for high-functioning IHCA teams.[12,14,15] A dedicated, leadership-trained "copilot" on cardiac arrest resuscitation teams may improve IHCA outcomes by performing the same functions — parallel analysis, situational awareness augmentation, action checking, protocol verification, and error correction — for the resuscitation team leader that an airplane copilot provides the pilot during an in-flight emergency. Employing telemedical technology to involve the "copilot" physician will allow this role to be filled by an intensivist physician with particular expertise in care of critical illness and will provide long-term cost and resource efficiencies, particularly in smaller hospitals with fewer available physicians.

Research subjects: We will conduct mock codes at Intermountain Healthcare hospitals, specifically Intermountain Medical Center, LDS Hospital, Riverton Hospital, The Orthopedic Specialty Hospital, McKay-Dee Hospital, Park City Medical Center, and American Fork Hospital.

- Local IHCA team: Intermountain Healthcare employees, resident physicians, and affiliated care providers who are either designated members of each participating hospital's IHCA response

teams or act as voluntary responders to announced mock codes will be eligible to participate. The number of on-site participants for each simulated IHCA event is expected to average 15-25.

- Telemedical intensivist IHCA copilot: Board-certified or board-eligible critical care medicine physicians on the staff of the Intermountain Healthcare Telecritical Care Center will act as IHCA team copilot. The total number of expected participants is up to 30.

Recruitment:

- Local IHCA team: IHCA team activation will employ the participating hospital's standard mechanism. A sign posted outside the room used for the mock code will indicate that a video-recorded simulation is taking place. After completion of the simulation, participants will receive an information sheet about the study.
- Telemedical intensivist IHCA copilot: Eligible telemedical intensivists will be invited to participate by email and in person.

Methods/Procedures:

- Study design: Randomized, multicenter, simulation-based clinical trial
- Intervention: Standardized consultation to IHCA team by off-site intensivist via two-way audiovisual link using a mobile telemedicine cart
- Control: Display of silent, pre-recorded, non-interactive videotape of an ICU physician. The on-site participants will be told that an intensive care physician is observing the mock code.
- Randomization: Each event will be randomly assigned to intervention or control using block randomization by hospital.
- Procedures:
    - All event will be randomly pre-assigned to intervention (participation via telemedicine link by a remote critical care physician) or control (prerecorded video of telemedicine physician displayed on mobile telemedicine cart).
    - A research coordinator will arrange a time for mock code with local hospital clinical leadership and Code Blue leadership. The remainder of the IHCA team will not be informed that the announced event is a simulation prior to team activation.
    - The research coordinator and an experienced simulation technician will set up simulation equipment in an unused patient care room on the general medical or surgical ward at the hospital, including video recording device and mobile telemedicine cart.
    - Research coordinator will obtain final confirmation with the on duty clinical leadership that simulation will not interfere with patient care.
    - The hospital's on duty IHCA resuscitation team will then be activated via the hospital's standard mechanism.
    - Upon arrival to the room, members of the designated IHCA team and other care providers will be informed via a posted sign that the event is a videorecorded research simulation. They will then begin participate in the simulation at their discretion.
    - We will adapt existing, tested cardiac arrest simulation scenarios for use in this study. While the provided case histories will describe patients of different ages, genders, and presenting complaints, all scenarios will feature cardiac rhythms demanding substantively identical resuscitative actions (Figure 1).
    - The telemedical link (or a control video) will be activated by the research coordinator after the arrival of the team lead or after five minutes have elapsed, whichever occurs first. At this time, the coordinator will also provide simple, brief, and scripted "just-in-

time" training to the mobile telemedicine cart and, for intervention events, the telemedical intensivist copilot.

- For mock codes randomized to intervention, critical care physicians with experience in telecritical care who consent to participate in this study will provide standardized consultation to the on-site team. These IHCA team "copilots" will advice and assistance to the on-site team leader including help with ensuring high-quality, minimally-interrupted chest compressions and prompt defibrillation, assisting situational awareness, encouraging etiologic evaluation, and promoting leadership behaviors.

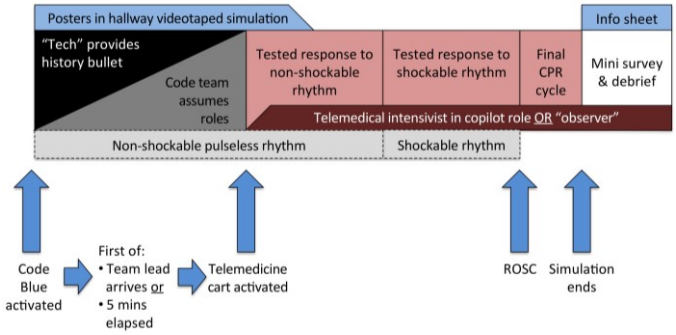

Figure 1. Unified structure for mock code scenarios. (ROSC: return of spontaneous circulation.)

- The event will be terminated when team performs an action that was pre-determined for the scenario to result in return of spontaneous circulation. The simulation will be terminated no later than 25 minutes after initiation if team fails to perform this pre-determined action. Most simulations are expected to last 10-12 minutes.
- After simulation termination, participants will complete a brief, anonymous questionnaire.
- Local code team leadership and/or the on-site code team leader will lead a debrief of the event. As needed, the research coordinator or simulation specialist will facilitate discussion of the simulation.
- In progress mock code simulations may be terminated by on-duty hospital clinical leadership or physician code team members if clinical care of patients requires.

- Mock codes terminated in progress due to competing clinical priorities prior to simulated return of spontaneous circulation will be excluded from the final analysis. If this occurs, the simulation event may be rescheduled at the same hospital for a later date, with the rescheduled mock code assigned to the same study arm as the aborted mock code.
- If systematic problems interfering with study implementation, data collection, or interpretation are identified after study initiation, the study may be halted temporarily while the systematic issues are addressed. Affected events where data is invalid will be considered part of a roll-in phase of the study and will be excluded from data analysis. For each assigned to roll-in event status, we will schedule a make-up event at the affected hospital. Make-up events will be assigned to the same study arm as the roll-in event being replaced and will be interposed randomly with other events at the affected study site.
- Data collection: A research coordinator will be present at all mock codes. Besides study implementation duties, the coordinator will record team composition and function, processes of care, and leadership behaviors. Additional data will be obtained from (1) the simulator device, (2) the defibrillator device, (3) videotaped recording obtained via the mobile telemedicine carts, and (4) a brief questionnaire completed by IHCA team members upon completion of the mock code.
- The primary outcome for the study will be the fraction of time between activation of the telemedicine cart and beginning of the pulse check following the subsequent second full cycle of CPR that the IHCA team does not deliver chest compressions ("no-flow fraction"). Secondary outcomes are shown in Table 1.
    - On-site IHCA team members will complete a brief questionnaire (attached) to measure the subjective experience of individual and team function and — when applicable,

opinions about the simulated mock code. Some on-site study participants will also complete a short-form version of the State-Trait Anxiety Index (STAI)[16] validated for measurement of state anxiety (i.e. anxiety/stress at the time the questions are answered).[17] Some participants may complete the survey online using REDCap, a secure web application for building and managing online surveys and databases.[18]
    - Off-site IHCA team copilots will complete a brief questionnaire (attached). Most participants may complete the survey online using a version of this questionnaire implemented in REDCap.[18] Opinions about the procedure will also be elicited through post-study qualitative interviews.
    - ACLS protocol adherence and violations using a checklist adapted from previously validated research tools.[8,40]
    - Leadership behaviors will be evaluated according to a previously published taxonomy.[19]
    - Overall function of the IHCA team will also be evaluated using a previously validated instrument.[20,21]
- Number of simulation events and power analysis: Assuming a baseline no-flow percentage of 0.285,[10,22] a best-case no-flow fraction of 0.08 (protocol guidelines advise a single 10 second pause in chest compressions for a pulse and cardiac rhythm check every two minutes), and equipment malfunction or simulation termination precluding event analysis for 15% of mock codes, we will require 76 completed mock codes (38 in each arm) to achieve 80% power to detect a 31% relative decrease (9% absolute decrease) in the mean no-flow fraction.
- Study duration: The 76 planned mock codes will be divided between the 7-8 participating institutions. We expect to complete 2-6 simulations at each participating hospital every 2 months. Accounting for scheduling conflicts and expected intermissions during implementation of a new electronic medical record at some study hospitals, we expect study completion to require 18-24 months (and potentially up to 48 months) after simulations begin.

Informed consent ("copilot" physicians): Members of the research team will approach the eligible subjects by email (see attached) or in person at their workplace. Interested subjects will be consented by research team member(s) according to the Intermountain Healthcare Informed Consent Policy.

Table 1: Descriptive & outcome measures for randomized trial of telemedical intensivist IHCA team copilot

Variable	Data source	
	Primary	**Secondary**
Response team characteristics		
Response team structure	In-person observation	Video recording
Past experience of code team members	Questionnaire	
Primary outcome		
Fraction of pulseless time with no chest compressions*	Simulator mannequin	
Secondary outcomes		
Time from onset of shockable rhythm to defibrillation	Simulator mannequin	Defibrillator
~~Fraction of chest compressions in target depth range[23]*~~	~~Simulator mannequin~~	~~Defibrillator~~
Fraction of chest compressions with incomplete release*	Simulator mannequin	Defibrillator
~~Fraction of 30s segments with 8-12 breaths/minute[23]*~~	~~Simulator mannequin~~	~~Defibrillator~~
Fraction chest compressions at target rate (100-120/minute)*	Simulator mannequin	Defibrillator
Time to first dose of epinephrine	In-person observation	Video recording
ACLS protocol adherence fraction (using validated instrument)[24]	In-person observation	Video recording

ACLS protocol errors of commission, timing and omission [24]	In-person observation	Video recording
Team Emergency Assessment Measure (TEAM) score[20]	In-person observation	Video recording
Number and types of input by telemedical intensivist copilot	Video recording	In-person observation
On-site provider experience during mock-code	Questionnaire	
On-site provider satisfaction with telemedical intensivist copilot	Questionnaire	
On-site provider short-form State-Trait Anxiety Inventory score [16,17]	Questionnaire	
Off-site copilot experience during mock code	Questionnaire	Qualitative interview
Audiovisual connection or equipment problems (logistic or technical)	In-person observation	Questionnaire

* Outcome measured over (1) primary analysis window and from (2) activation of telemedicine cart; (3) "Code Blue" activation; and (4) from arrival of first resuscitation team member until simulation termination

Data analysis:

The primary analysis will include completed simulation where CPR quality data is complete and non-corruprted. Simulations for which equipment malfunction preclude measurement of compression quality will be excluded from analysis. Simulation events where malfunction of audiovisual recording equipment or major deviations during simulation implementation prevent accurate evaluation of resuscitation team performance and protocol will be excluded from analyses addressing these topics. Prematurely terminated simulation events and simulation events classified as run-in events will be excluded from all analyses.

Between-group comparisons for continuous variables will employ two-sided t-tests with unequal variance. Comparisons for binary or categorical variables will employ Fisher's exact test or chi-squared test as appropriate. Given clustering within simulations, between-group comparisons of of survey responses will employ multilevel logistic (for binary variables) or linear (for continuous variables) regression with a random effect for simulation event. Comparisons of Likert-style variables will use the rank-sum method described Datta/Satten.[28]

Sample size/power analysis: Assuming a baseline no-flow percentage of 0.285, a best-case no-flow fraction of 0.08 (protocol guidelines advise a single 10 second pause in chest compressions for a pulse and cardiac rhythm check every two minutes), and equipment malfunction or simulation termination precluding event analysis for 15% of mock codes, we will require 76 mock codes (38 in each arm) to achieve 80% power to detect a 31% relative decrease (9% absolute decrease) in the mean no-flow fraction. We therefore expect to enroll 1900 on-site IHCA team members as study subjects (although some participants may participate in >1 mock code).

Waiver of Informed Consent and HIPAA Authorization (for on-site IHCA team members):

We are requesting a waiver of informed consent and HIPAA authorization for on-site IHCA team study participants of this study. Participation in this study is similar to standard training for IHCA team members and involves no more than minimal risk to the subject. Individuals will be notified by means of a prominently displayed poster(s) that a simulation-based research project with video recording is in progress. Such notification will address individuals reasonable expectation of privacy. We will not use video recordings for any purposes except research, and digital video recordings will be stored securely and then transferred to a secure, approved server of the Intermountain network. We will not systematically collect individually identifiable information. The research therefore involves no more than minimal risk to the subjects; the only potential risk is a breach of confidentiality, and protections are in place to safeguard the data. Because risk is minimal, the waiver of consent and authorization will not adversely affect the rights or welfare of subjects.

The research could not practicably be carried out without the waiver of consent and authorization. Most hospitals have dozens or even hundreds of staff eligible to participate formally in IHCA responses. We would estimate that more than 2000 individuals are eligible for study participation. Team membership is also flexible, and the list of eligible IHCA team members for each hospital is expected to vary significantly over the 24 months of this study as staffing changes. Finally, for hospitals announcing IHCA team activations via a public address system, additional ad hoc participation by other staff is to be expected. For all of these reasons, we are unable to identify and consent in advance individuals who will participate in simulations. Moreover, including on IHCA simulation teams only those subjects for whom advance consent could be obtained would compromise the scientific validity of the study and preclude useful conclusions, as a large proportion of the data would be eliminated if obtaining consent were a requirement. Informed consent would markedly increase the response burden for participants, thereby reducing response rates and compromising study validity.

Similarly, obtaining consent after IHCA team activation and individual's arrival to the simulation site but prior to an individual beginning participation in the simulation is also not feasible. This would preclude the necessarily rapid formation of a IHCA response team and abolish the simulation's fidelity to actual cardiac arrest event, introducing significant bias into the results and compromising the scientific validity of the data obtained.

On-site participants in code simulations will be provided an information sheet about study participation at the time the simulation concludes.

Safeguards will be in place to protect subject identity. The data will be protected from improper use or disclosure. The study data will be kept on encrypted, password-protected computers. The data will only be accessible to members of the research team, and all members of the research team with access to identifiable data have completed Human Subjects Protections training and understand the importance of protecting subject privacy and confidentiality. These computers are Intermountain Healthcare devices, which are routinely used for storage of patient data and research data including subject identifiers. No individual subject data will be presented in any presentation, publication, or report related to this research. Data will be presented only in aggregate or as results of statistical analyses and will not include any individual-level data that could be traced to a particular subject.

Risks: Both the off-site copilot and on-site study participants may find participation in simulated IHCA events stressful. This expected stress related to the simulation is similar to the stress participants would experience during performance of their routine job duties or routine training related to these duties. On-site participants will have an opportunity to discuss their experience during the simulation during post-event debriefings.

The only other risk involved with this study is a potential breach of confidentiality. There is a minimal risk of a privacy and confidentiality breach. However, this risk is low given the secured databases and computers that will be employed for data storage.

Benefits: It is unlikely that there will be any direct benefit to you as a result of participating in this study. Participation in simulated IHCA events may improve the skills used by both on-site IHCA team members and the telemedical copilot when managing actual patients suffering medical emergencies. Improved understanding of cardiac arrest resuscitation could improve outcomes for all patients suffering IHCA.

Compensation:

- On-site IHCA team member: A small snack/drink or similar token of appreciation, valued at $1-2 each, will be available for members of on-site code team after simulation completes
- Telemedical physician copilot: Fleece jacket, valued at approximately $35-50

Data Collection: A research coordinator will be present at all mock codes. Besides study implementation duties, the coordinator will record team composition and function, processes of care, and leadership behaviors. Additional data will be obtained from (1) the simulator device, (2) the defibrillator device, (3) review of video recording of simulation event, (4) a brief questionnaire completed by IHCA team members upon completion of the mock code, and (5) a brief questionnaire completed by the telemedical physician copilot.

Data elements for collection

- Telemedical critical care physician ("copilot")
  - Name
  - DOB
  - Email
  - Telephone
  - Race/ethnicity
  - Year completed medical school
  - Year completed post-graduate training
  - Date of first experience with telecritical care
  - Telecritical care shifts per year
  - Sex
  - Age
  - Credential type (MD vs DO)
  - Experience with in-person cardiac arrest events led
  - Date/time of each study simulation participation
  - Opinions about impact, utility, and feasibility of "copilot" interaction (survey)
  - Opinions about impact, utility, and feasibility of "copilot" interaction (post-participation qualitative interview)
- On-site code team participants
  - Event ID
  - Profession
  - Specialty (if physician)
  - Role on IHCA team
  - IHCA team participation frequency
  - Experience participating in mock code
  - Opinions about code team function during mock code
  - Opinions about impact, utility, and feasibility of "copilot" interaction
  - Short form State-Trait Anxiety Inventory[16,17]
- Simulation events (see also Table 1)
  - Location
  - Date/time of event
  - Participant numbers and professions
  - Simulation duration
  - Date/time of key response parameters (i.e. team leader arrival)
  - Date/time of key resuscitation events
  - CPR quality
  - Interventions by IHCA team
  - ACLS protocol adherence
  - ACLS protocol deviation & errors

- Etiology identification
- IHCA team function
- Debriefing (Y/N) and themes
- Telemedicine interface function
- Leadership behaviors by IHCA team leader

Privacy, Confidentiality and Data Management

Names, date of birth, email addresses, and telephone numbers of participating telemedicine critical care physicians will be maintained in a protected database on a protected computer and within the secure REDCap interface until completion of data collection and analysis. Individual identifiers will subsequently be deleted. We will not collect any individual identifiers for on-site IHCA team members. Paper questionnaires will be maintained securely in a locked office. All electronic subject and simulation data, including digital video recordings, will be kept in a protected database on a protected computer or server after transfer from collection devices. Video recordings will be viewed only be research staff and will be destroyed after completion of data collection and analysis. Information about physician and mid-level remuneration (name/remuneration value) will be provided to Intermountain compliance officials to comply with requirements for imposed by the federal Stark Law requiring tracking of non-montary compensation given to clinicians.

To comply with scientific journal data sharing requirements, deidentified and anonymized data from the proposed study may be shared with other researchers upon request. Deidentified and anonymized data may also be deposited to one or more research data repositories such as the Harvard Dataverse Network, the Dryad Digital Repository, or other data repository recommended by the specific journal in which study results are being published.

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Appendix:

- Post-simulation questionnaire for on-site IHCA team members
- Post-simulation questionnaire for telecritical care physicians
- State-Trait Anxiety inventory short form
- Telemedical critical care physician recruitment emails
- Informed consent for telemedical critical care physician
- Poster for display outside simulation room
- Information sheet for distribution to on-site IHCA team members after each simulation

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