A Simulation-Based Randomized, Controlled, Multicenter Trial to Test the Efficacy of Augmented Reality Software on Prehospital Pediatric Medication Administration Accuracy. The Augmenting the On-Scene Medic (ATOM) study

Study Protocol

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This protocol version has been provided by the study team to provide additional information on the study to the reader.

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1. **Protocol Title:** A Simulation-Based, Randomized, Controlled, Multicenter Trial to Test the Efficacy of Augmented Reality Software on Prehospital Pediatric Medication Administration Accuracy. The Augmenting the On-Scene Medic Study (ATOM)

   Short Title: Augmenting the On-Scene Medic (ATOM)

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4. **Objectives**

   Primary: To assess the effect of augmented reality software delivered via a head mounted display (HMD) for prehospital pediatric medication administration (PMA) dosing accuracy.

   Secondary: To assess the effect of augmented reality software on errors of omission and commission

   Hypothesis: Use of augmented reality software, developed via human-centered design thinking, will reduce PMA errors made by EMS paramedics compared to usual practice with existing cognitive aids.

5. **Background and Rationale**

   Research examining the quality of care provided by Emergency Medical Services (EMS) has shown that errors with serious consequences occur at high rates.[1] Numerous studies have shown that pediatric patients are at significantly higher risk to experience medical errors in EMS.[2–6] One aspect of pediatric care shown to have extraordinarily high rates of error is pediatric medication administration (PMA). Studies have shown an overall medication error rate of 31% during EMS pediatric care[3,4,7,8] with some medications having error rates over 60%.[7] In 2021, 1,263,959 children aged 12 and younger were treated by EMS and received one or more drugs.[9] Based on a 31% medication error rate, an estimated 391,827 (31%) of those children received an incorrect drug dose with many possibly suffering an adverse drug event.[7] This number of pediatric patients receiving an incorrect dose in EMS is enough to fill the University of Michigan Stadium, the largest football stadium in the United States, over 3.5 times. This alarming data has led to strategies aimed at reducing these errors which have had limited success.

   In comparison to the hospital setting, little effort has been made to decrease errors in EMS. A California EMS quality improvement initiative targeting pediatric epinephrine dosing errors reduced error rates from 60% to 35%.[8] This study's interventions were an EMS pediatric drug reference with doses in milligrams, encouragement of use of the Broselow-Luten Tape, a length-based pediatric weight estimation tool, and the requirement that the paramedic consult a physician via radio after the first dose was delivered for dose confirmation. This rigorous study demonstrated significant improvement. However, even with the interventions,

an error rate of 35% still occurred. Some weaknesses of this study were: it only focused on a single drug and excluded the many other drugs that EMS providers administer to children, it did not describe a needs assessment of the paramedics, root cause analysis (RCA) of errors, failure modes and effects analysis (FMEA) of the drug administration process or testing that includes direct observation or simulation of the interventions for efficacy and unintended consequences prior to implementation. By not evaluating the systems for error causes and failure modes prior to implementation, the causes of the remaining 35% of errors were never discovered.

A recent study describes the results of 142 pediatric patient simulations with 16 EMS agencies in Michigan.[7] These took place after implementation of an EMS-specific pediatric drug dosing reference (PDR) with doses listed in milliliters. PDR use by all paramedics is mandated in Michigan, including psychomotor biennial training on PDR use and PMA. After implementation, 31.2% of all drug doses were still incorrect. The changes in incorrect dosing pre and post PDR implementation were epinephrine in cardiac arrest: Pre-75%, Post-27% (32% of post errors were ten-fold overdoses), benzodiazepine doses for seizures: Pre-76%, Post-34%. Prior to PDR implementation, based on the aforementioned database study 94.6% of opioid doses were incorrect, with 89% being under doses.[10] After PDR implementation, the opioid error rate decreased to 35% incorrect, but 80% of incorrect doses were overdoses, with the median overdose being 5 times the correct dose.[7] While previously studied interventions have reduced the error rates for prehospital medication administration, there remains an overall error rate of 31-35%.[3,7,8] Studies that demonstrate reduced errors have several significant limitations including focus on a single drug, lack of direct observation, lack of paramedic needs assessment, lack of FMEA analysis of drug administration procedures, and lack of testing of interventions to determine efficacy and unintended consequences prior to implementation. Additionally, many of the error types discovered in observational studies are not addressed through the current design of cognitive aids. This has resulted in this abnormally high error rate continuing unchecked.

The errors that occur during PMA call out for cognitive support aids that are more dynamic. Dynamic cognitive aids are usually electronic and can offer step-by-step support through changing interactive display options.[13] This combines features of multiple cognitive aid designs, such as reference lists, calculation devices, and procedural checklists. Furthermore, dynamic cognitive aids can read objects in the environment, such as medication labels.[12] This allows for an interactive experience for the user that supports their performance in multiple ways.

One evolving technology for implementing dynamic cognitive aids are head-mounted displays (HMD). These devices project an interactive display into the user's field of view while allowing continuous visibility of the surrounding environment. Outside of healthcare, research from numerous disciplines, including aviation and manufacturing, have shown significant improvement in efficiency and reduction in errors using applications with HMDs.[14-19] Although there is limited research regarding their use in EMS, other disciplines in healthcare have shown dramatic improvement in accuracy and lower error rates with use of HMD applications.[20-23] These studies have seen error reductions of 34% to as high as 66%.[21,24-28] One of the most widely utilized HMDs is the Microsoft HoloLens. Currently on its second edition (HoloLens 2), the device can read objects in the user's field of view and use that information to display crucial instructions the user needs to perform a certain task.

The headset can remain in a shelf in kiosk mode, which allows a user to put it on and quickly launch an application in seconds with the tap of a button. Depending on the application being used, the user can interact with the displays through hand gestures, a hand-held clicker, or even voice commands.[29]

6. **Setting:**
The setting for this research will be the Western Michigan Homer Stryker M.D. School of Medicine and the Western Michigan University. Simulation scenarios will be conducted in our mobile pediatric simulation trailer, with high-fidelity pediatric simulators. The trailer will be taken to seven different EMS agencies in Michigan and Indiana.

7. **Resources Available**
Personnel: Research coordinator, investigators, data analysts, simulation technician/specialists.

Equipment: simulation trailer with 4 camera audio/video recording system using Avigilon AV Software, four HoloLens 2s, sham medications, syringes (1, 3, 5, 10 ml), three-way stopcocks, IV catheters (22 and 24 gauge), EZ IO drill with all three sizes of needles, anchoring devices and extension tubing, 1L and 500mL bags of NS, IV tubing.

Human patient simulators: Gaumard Super Tory with Microsoft Surface computer to run the simulator and a separate Microsoft Surface computer to project vital signs. Gaumard Hal Jr. with Microsoft Surface computer to run the simulator and a separate Microsoft Surface computer to project vital signs.

8. **Study Design**
This is a block-randomized, controlled, parallel group, unblinded, simulation-based, multicenter trial involving Emergency Medical Services (EMS) crews in Michigan and Indiana. Subject EMS crews will be randomized within each agency to have an equal number of experimental and control crews in each agency thereby accounting for inter-agency variation. Experimental group crews will use the augmented reality software and control group crews will use their usual references and do their usual practice for PMA.

   a) **Number of EMS agencies**
   This study will be a multicenter study performed with seven EMS agencies, six in Michigan and one in Indiana.

   b) **Number of subjects**
   Eighty-four EMS crews, twelve at each agency, are planned to be randomized. We expect a 20% decline rate leaving a total of 33 crews in each arm. Rationale for sample size is included in the section labeled Sample size.

   c) **Estimated study duration**
   Enrollment for this study will take place over sixteen weeks, April through July 2025.

   d) **Subject eligibility**

Investigators will maintain a log that includes demographic information about each identified subject, as well as outcome of the screening process (enrolled, reason for ineligibility, refusal to consent).

e) Randomization

This RCT will employ block randomization by agency to ensure balance between the control (usual practice) and experimental (augmented reality) arms, thereby accounting for potential between-agency and intra-agency variations. Specifically, within each agency, crews will be randomized in a 1:1 ratio to yield 6 control crews and 6 experimental crews per agency. Study team members will not know crew randomization assignment until the evening before the simulation session. Study team will not know crew scenario order until the morning of the simulation session. Crews will not be told of their assignment until after they are consented.

The order of the three simulation scenarios will also be randomized, resulting in six possible permutations of their sequence (e.g., cardiac arrest first, followed by burn, then seizure). To counterbalance the design and further control for between-agency and between-crew variations while ensuring balanced exposure to scenario sequences, each of the six permutations will be assigned exactly once to the control arm and once to the experimental arm within each agency. Crews will not be told which scenario they will be participating in until they are given dispatch information just prior to the case starting.

Randomization to treatment arm (control vs. experimental) and scenario sequence permutation will be performed using a random number generator, specifically the Mersenne Twister (MT19937). To accommodate logistical constraints, restricted randomization will be applied such that no more than two experimental groups are scheduled per simulation day to ensure enough time to reset scenarios and to fully charge patient simulators and the HMDs.

The paramedic in the experimental crew will use the HMD application. For crews consisting of two paramedics, simple randomization using a mobile application (Roundom: Decision Maker, version 2.0.4) will be used to assign one paramedic to operate the HMD, which will take place after consent. Similarly, for control crews with two paramedics, using the same randomization method, one will be designated as the lead paramedic for the simulations after consent has been obtained. The randomization scheme will be concealed from the two study scenario observers until the start of each agency's simulation day.

Crews will either be temporarily removed from service by the agency, or will come in on their non-working day, at the discretion of the agency. Agencies will be compensated for the personnel time for the simulations. Four crews will go through the simulation scenarios each day. Each of the four crew slots will be randomized for each day. If a crew is not available for a given time slot, that crew slot will be dropped and recorded as excluded.

f) Inclusion and Exclusion Criteria

Inclusion criteria

Eligible participants will be licensed paramedics or EMTs authorized to practice within their agency.

Exclusion criteria

- Do not agree to participate (consent not given)
- Strabismus
- Severe astigmatism
- Vertigo
- Significant visual impairment
- Motion sickness
- Claustrophobia
- Screen-induced nausea/headache

g) Screen Failures

Subjects who fail exclusion screening will be tracked with the reason for failing screening and which group they are assigned to.

h) Subject Enrollment

Agencies will have crews consisting of paramedic/paramedic, paramedic/EMTA and paramedic/EMT. Both paramedic and EMT subjects will undergo written informed consent prior to any screening procedures. The paramedic of the crew will use the augmented reality software. For crews consisting of two paramedics, one will be randomly assigned to the augmented reality software. Crews and agencies participating in the trial will not have participated in preliminary simulations or usability testing during development of the application software. This will eliminate any possibility of contamination by communication about the project between members of the agency. Agencies who participate in preliminary simulations and usability testing will not be told identities of agencies participating in the RCT. This will also decrease the possibility of contamination by communication between members of agencies. In addition, all participants will sign a non-disclosure agreement and receive instruction on not discussing information about the study with other members of their agency or members of other agencies to decrease the possibility of contaminating the trial.

9. Study Procedures

a) Informed consent

Before participation in the trial, members of each crew will undergo informed consent by having the consent form (Appendix A) read to them by a member of the study team. The consent form will include information about the *Federal Certificate of Confidentiality* that covers the study and its protections and limitations. The crew members will be allowed to ask questions regarding the consent form and the study. If both members of the crew consent, they will be asked to sign a consent form and then will be given a copy of the consent form to retain for their personal records. If one or both members of the crew do not consent, they will be recorded as failing to consent and they will be excluded and logged as an excluded crew for the arm to which they were assigned.

b) Demographic Survey, non-disclosure agreement (NDA), and continuing education credit

Following consent, crew members will complete a demographic survey on an electronic tablet with internet connection directly linked to a Research Electronic Data Capture (REDCap) database, followed by an NDA form. The NDA form is used to discourage discussion of the trial between personnel of the same or different agencies and therefore prevent participant contamination. The demographic form will ask basic demographic information along with years of experience and pediatric experience. Crew members with an EMTA or Paramedic certification in Michigan are eligible for one continuing education credit for pediatric medication administration. Crew members eligible for this credit will be asked to sign an attendance form for the State of Michigan.

c) Simulation Instructions

Once each crew has completed their demographic survey, they will be read standardized instructions on how to participate in the simulation scenarios that includes: they will be using their usual equipment they would take into a pediatric call (monitor/defibrillator, first in bag, airway kit, IV start kit) including their drug box. Teams will be told that they will use a training drug box supplied by their agency instead of their duty drug box, but it will look, function and be stocked identically to their duty drug box. They are to draw up any medications they plan to give to the patient and hand the syringe off to one of the study team members in the simulation space. They will be given an orientation to how the simulation trailer is set up. The rear represents a small room in a house, and the middle represents an ambulance. If they desire to move the patient to the ambulance, they can pick the patient simulator up and move to the ambulance stretcher. They will be told that study team member (who will identify themselves) will play the role of the patient's parent who can answer questions about the patient. EMS crews will be instructed to take whatever equipment they would normally take to a patient's side into the simulation trailer.

Crews will be told that they are to do everything they would normally do in caring for a patient. This includes placing monitoring devices, obtaining IV or IO access, as indicated, and administering medications. They will be instructed on the procedures they can perform on the simulators. They can place oral airways and endotracheal tubes if desired (none of the agencies have supraglottic airways for pediatric patients in their scope of practice). They can place intraosseous access in designated areas of the simulators if desired. If they desire to place an IV, they can locate their target area and not poke the mannequin with the IV catheter. Instead, they should pull the needle from the IV catheter and tape the plastic catheter to the mannequin. When they administer a medication, they are to draw it up as they normally do, but instead of pushing the fluid through their IV or IO access, or administering it intramuscularly or intranasally, they are to hand the syringe off to a study team member.

They will be told that they can hook up whatever monitoring devices they desire for the simulated patient. However, the vital signs will not be displayed on their monitor but instead will be displayed on a monitor in the simulation space that will be shown to them by a study team member once the vital sign monitoring device(s) are connected to the simulated patient.

If a crew has a third member, such as an EMT in training or a paramedic in training, that team member will sign an NDA and be allowed to observe the simulations in the control

room, behind a closed door, of the simulation trailer and will not participate in the simulations. This person will not be able to communicate with the persons participating in the simulation.

d) Simulation Trailer

We will utilize a simulation trailer. It is approximately 22 feet in length and six feet wide divided into three sections. The rear represents a small room in a house. This section also has an entry door from which the crew will enter the simulation space, as well as a fold down ramp. There is fold-down section on the left rear wall that serves as a changing table/crib with a box underneath that serves as a chair. The middle section represents an ambulance and contains a stretcher, bench seat, airway seat (at the head of the stretcher), a set of upper cabinets and lower cabinets. The front-most section is the control room. This is separated from the rest of the trailer by a door and a wall with a large one-way mirror allowing visualization into the simulation space. There is a desk area that faces the simulation space and shelves that run along the left wall and the front wall. A computer and screen for the AV system and the computer for running the simulators are placed on the shelf facing the simulation space.

The trailer is climate controlled. It will be parked in the agency's apparatus bay during the simulations. It will be leveled with jacks that will prevent any swaying motion, so it is a stable platform.

e) Drug box stocking

We will utilize a training drug box or bag that matches the drug box or bag carried on an agency's ambulances. This will be stocked as it is found on an ambulance with the following changes: the study team will replace existing stock with study-supplied real epinephrine pre-filled syringes and sham fentanyl and midazolam vials. These will be the same size, color and concentration as those that are used by each agency. Experimental crews will have their pediatric length-based tape replaced with the study length-based tape that only has colored blocks with a unique barcode for each block. Their existing hard-copy pediatric drug dosing references will be removed. For experimental crews that use a phone app-based PMA reference, they will be told not to use that during the simulations and instead use the ATOM application on the HoloLens. Control groups will continue to have access to their usual PMA references and length-based tapes.

f) HoloLens training and training scenario

After receiving standardized participation instructions, experimental group EMS crews will undergo a standardized orientation to the HoloLens and study application conducted by two study team members. Prior to each training session, each HoloLens will be reset (e.g., previous holograms removed, recharged). Training will proceed in two phases.

Phase 1: Crews will observe a complete demonstration of the HoloLens application from start to finish, including the delivery of two doses of 1mg/ml epinephrine, with one study team member role-playing the primary medic and another role-playing the partner. This demonstration will model correct use of the HoloLens, including eye-tracking calibration and fitting, activation of hologram buttons, navigation of the application interface, use of the study length-based tape, operation of the integrated barcode scanner, and progression through the application workflow. The demonstration will also include instruction on

recentering holograms, adjusting the visor, and understanding spatial positioning during movement. During the demonstration, study team members will also model expected partner-check behaviors, including talk-aloud and closed-loop communication, consistent with standard EMS communication practices and with the communication prompts embedded in the application.

Phase 2: Participating EMS crews will complete a supervised, hands-on orientation to the HoloLens and study application. During this phase, each crew member will calibrate and fit the HoloLens and perform a training scenario. This training scenario will allow the crew to practice interacting with hologram buttons, familiarize themselves with the application layout and capabilities, and rehearse partner-check interactions using talk-aloud and closed-loop communication. Crews will also verify that the HoloLens audio output is functioning properly and is audible in the training environment. This training will be limited to system orientation and communication practices and will not include instruction, guidance, or feedback regarding specific medical decision-making or treatment.

The practice scenario will be a 10-year-old child that weighs 70 pounds, per parent report if asked, and measures in the green color zone on the length-based tape, who is experiencing anaphylaxis and requires a dose of 1 mg/ml epinephrine intramuscularly. Crews will be allowed to determine weight by asking the parent, using the length-based tape or using age at their discretion. Experimental crews will use the HoloLens application to navigate through obtaining the patient's weight, drawing up the medication and administering it. Crews will be provided with a study length-based tape, vial of sham epinephrine, 1 milliliter syringe, and needles.

g) Control group training

After receiving standardized simulation instructions, control group crews will participate in the same practice scenario as the experimental group without using the HoloLens. The practice scenario will be a 10-year-old child that weighs 70 pounds, per parent report if asked, and measures in the green color zone on the length-based tape, who is experiencing anaphylaxis and requires a dose of 1mg/ml epinephrine intramuscularly. Crews will be allowed to determine weight by asking the parent, using the length-based tape or using age at their discretion. They will be able to use their usual pediatric drug reference(s) and length-based tape. Crews will be provided with a vial of epinephrine, 1 milliliter syringe and needle and asked to draw up and deliver the correct dose of epinephrine for the simulated patient. This approach ensures that both groups receive equivalent recent PMA exposure, controlling for any potential training effects unrelated to the assistive technology itself.

h) Sample size

To show superiority of the augmented reality software versus usual care, the study plan calls for 84 crews, 42 per study arm. Each crew administers six total drug doses over the three simulation scenarios, totaling 252 dose administrations in each arm. This sample size equates to a two-proportion superiority test with a 25% baseline pediatric medication administration error rate and an estimated 35% reduction using the HMD application, with alpha = 0.1, Power = 80%, and a participant/crew ineligible rate of 25%. The four

EMS agencies involved in application design and usability testing will be excluded from the RCT.

i) Compliance

Institutional Review Board

This study is approved as exempt by the Western Michigan University, Homer Stryker, MD School of Medicine Institutional Review Board (IRB). All study team members have completed Collaborative Institutional Training Initiative (CITI) modules on human subject research required by the IRB and will maintain these certifications throughout the study period.

Subject Confidentiality

All study team members are responsible for maintaining the confidentiality of study subjects.

- Confidentiality is covered by a Federal Certificate of Confidentiality. (See informed consent form provided in appendix A.)
- No identifiable data will be shared with subject's employer, management, supervisors or other employees.
- No supervisory, management or executive personnel of any of the agencies will be allowed to observe any of the simulations. No crew members will be allowed to observe another crew's simulations.

j) Simulation scenarios

Three pediatric scenarios will be presented to the crews using high-fidelity mannequins. The order of the scenario presentation will be randomized for each crew. The scenarios will be recorded with four, high resolution, zoom capable cameras (Avigilon, Inc) in the simulation trailer and audio recorded. Video recordings will be captured via four cameras, each with zoom capability, and one microphone on a password protected computer using Avigilon software which also has zoom capability. Each scenario will be scored with a case report form specific to the scenario. (Appendix B-D)

A large digital clock will be placed at the rear of the simulation trailer in view of one of the video cameras and will serve as the time reference for all crew activities.

Patient simulators will be wirelessly operated by a simulation specialist via a computer in the control room of the simulation trailer. The simulation specialist will be able to hear all conversation in the simulation space and will follow a script for changes in mannequin vital signs, cardiac rhythms, seizure activity, etc. for each simulation scenario.

Two study team members will observe crews in the simulation space and record actions using a scenario specific CRF. Study team members will not be blinded to whether a crew is in the control or experimental group due to the experimental group wearing the HoloLens and the control group not wearing the HoloLens. Study team member A will deliver the dispatch information to the crew outside the simulation trailer rear door and play the role of the parent. Study team member B will be inside

the simulation trailer prior to the simulation starting. During the simulation, study team member A will record actions taken by crews in the simulation space using the scenario specific CRF. Study team member B will observe in the study simulation space and record actions taken by crews in the simulation space using the scenario specific CRF.

Due to the cost of certain supplies and to reduce the financial impact of the study on the participating agencies, the study will supply certain items. These include an intraosseous drill and needles, bags of normal saline and IV extension tubing as well as 20- and 22-gauge IV catheters. All supplies supplied by the study team will be standardized (same brand and model) throughout the entire study. If a crew decides to obtain IO access, once they have located their own IO kit in their own equipment bag, a team member will state to them "We have an IO kit for you to use". They will then be handed the study IO kit that contains an IO drill, IO needles (infant, pediatric and adult) connection tubing and an anchoring device. If they decide to "hang a bag of fluids", once they locate their IV bag and extension tubing a study team member will state "We have an IV bag and tubing for you to use". They will then be handed the IV bag, with extension tubing connected, by a team member.

Teams will use their own IV catheters from their own equipment bags if they want to start IV access. IV access attempts will be deemed successful, on the first attempt, with that information communicated to the crew, on the first attempt.

Crew Time Management

A simulation session will include three separate sessions: prebrief, simulations (cardiac arrest, seizure, burn) and debrief. The prebrief and debrief will take place in a location separate from the simulations, such as a classroom at the agency and will be visually and sound separated from each other and the simulations. Crews will be scheduled at two-hour intervals. A crew can be undergoing prebrief and/or simulations while another crew is undergoing debrief.

Study Team members A and B will be responsible for prebrief, control group training scenario and simulations. Study Team members C and D will be responsible for HoloLens and application training for the experimental group. Study team members C, E, F and G will be responsible for debrief. Study team members B and H will be responsible for placing Empatica watches on participants and baseline data collection on cognitive load. A simulation specialist will be responsible for running the human patient simulators.

Upon completion of each scenario, all equipment will be repacked and expended equipment such as IV catheters and medication vials or syringes will be replaced. Correct repackaging of equipment and supplies will be confirmed by Team member A including that the existing PMA reference and length-based tape are available to the next group if they are a control group and removed if they are an experimental group. All crew equipment will be staged outside the rear door of the simulation trailer prior to each simulation scenario.

Syringe review and dose determination: Once a crew has a medication drawn up into a syringe and is ready to administer it intramuscularly or intranasally (midazolam or fentanyl) or via IV or IO access (epinephrine, midazolam or fentanyl), they will be directed to hand the syringe to study team member A or B prior to any attempt to administer it or attach it to IV or IO access. The study team member will then grasp the syringe by the barrel with the administration tip held toward the ceiling and then gently place the syringe on the counter of the control room on a labeled surface with "Dose A" for the first dose and "Dose B" for the second dose. This process will be carried out for both doses in each scenario. If, for the cardiac arrest scenario, a crew decides to push medication directly out of the prefilled epinephrine syringe, they will be asked to gently squirt the medication into a cup made of low surface tension plastic. The first dose cup will be labeled "A" and the second dose cup will be labeled "B". These cups will be within easy reach of the study team members but hidden from the simulation participants.

Upon conclusion of the scenarios, team members A and B will go into the control room to evaluate the syringes and/or cups for the correct volume. This will be done out of sight and out of hearing range of the simulation participants. Because of the difficulty in differentiating air versus fluid, and the importance of documenting the exact volume of liquid and air in the syringe, this process will be carried out by consensus with team member A and B. Team member A will examine the syringes first and Team member B will examine the syringes second. This will not be done with each blinded to the other's interpretation and interrater reliability will not be calculated.

For syringes, team members will handle them carefully and avoid touching the plunger during examination. Each team member will examine the syringe individually using a bright light source and magnification via reading glasses. If there are air bubbles located at the bottom of the syringe or along the sides of the syringe, team member A will gently agitate the syringe, being careful to not force any fluid out of the syringe, by using a single finger to direct enough force to the syringe barrel to loosen the air bubble and allow it to float to the top of the syringe without causing any loss of fluid through the end of the syringe. After this, the graduations on the syringe will be used to determine the portion of fluid and any air in the syringe. This will be confirmed between team member A and B by consensus and then recorded by both on their case report forms. This method of dealing with the syringes from the hand off through to the examination of syringe volume has been practiced in the simulations used for research team education and usability testing (176 doses) before the RCT.

For doses pushed out of the prefilled syringe into a cup, team member A will ensure all the fluid is in a single drop in the bottom of the cup and that no fluid is on the sides of the cup. The fluid will then be drawn up into a 1 mL syringe (Exel brand Luer Lock) for volumes of 1 mL or less and a 5 mL syringe (Exel 5cc Luer lock) using a 20 mL needle until the meniscus is at the base of the injection port of the syringe (at the distal end of the graduated portion of the syringe prior to the injection barrel or needle tip of the syringe). Once all the fluid is collected, the graduations on the side of syringe will be used to determine the volume of fluid in the syringe. If the

dose is more than 5 ml, the remaining fluid will be drawn up in a 1mL syringe. This will be confirmed between team member A and B by consensus and then recorded by both on their case report forms.

Scenario One: Infant Cardiopulmonary Arrest
The crew will receive dispatch information outside of the simulation trailer prior to entering, from the study team member playing the role of the parent, of "You are responding to 100 Fremont Street for an infant that is not breathing." The study team member will then open the door to the simulation trailer and step inside with the crew following.

A Gaumard Super Tory simulator (Gaumard, Miami, FL) will be used. The patient will be found in a diaper only laying supine on a crib with a large stuffed animal and fluffy blanket with the mannequin's face turned toward and in contact with the stuffed animal mimicking a suffocation scenario. Upon entering the "patient's room", the study team member playing the parent will state "I put her down for her nap with her blanket and stuffed animal like I always do and I don't think she is breathing." If the crew asks if the parent knows the weight, they will respond, "They weighed 9 pounds at their checkup two weeks ago." The mannequin measures in the gray color zone for the study tape, Broselow-Luten Tape and Pedia Tape which may be used by crews to obtain weight. The parent will respond, if asked, that there is no past medical history, normal birth history, no recent fever, and no medications.

The mannequin represents a 1-month-old infant. The crew finds the infant to be cyanotic, with no limb motion, no respiratory activity and no pulse. The initial cardiac rhythm is asystole. After the first dose of epinephrine, the rhythm changes to a pulseless electrical activity (sinus bradycardia with a rate of ~50), BP will not be measurable, pulse ox will be 53% and end tidal CO2 will be 16mmHg. Vital signs will be displayed, if monitoring device(s) or defibrillator pads are attached to the mannequin, on a monitor in the simulation space that will be pointed out by the study member A playing the role of parent. After the crew starts compressions and ventilations, a study team member B will identify themselves as an EMT that has arrived on scene. They will state that they can help with compressions and ventilation. The study team member will then perform compressions, ventilations or both at the direction of the crew and will continue to do so until told to stop or switch role(s).

Crews can obtain intraosseous (IO) or IV access for medication administration. If the crew decides to obtain IO access, once they have pulled their IO device out of their equipment bag, they will be handed a study IO device (EZ-IO, Teleflex Morrisville, NC) that contains the drill and all three sizes of IO needles along with connection tubing and anchoring device. At this time, a study team member will point to the area on each leg where IO access can be obtained.

If epinephrine is drawn into a syringe, that syringe is to be handed off to a study team member instead of connected to the IV or IO access. If the crew wants to administer epinephrine directly from the manufacturers prefilled syringe, they will be provided a

plastic cup, with low surface tension plastic, to push their dose into. This cup will then be handed into the control room.

After a second dose of epinephrine, on the subsequent pulse check the study team member playing the role of parent will announce that there is a pulse and the scenario has concluded. At this time the HoloLens wearing paramedic (experimental group) or drug administering paramedic (control group) will be given a piece of paper with "Dose 1 _____mg" and "_____ml" and "Dose 2 _____mg" and "_____ml" on it and be instructed to write down the doses they delivered. Control crews can consult their PDR prior to writing down the doses. The study team will then replace all used items from the crew's equipment and medication bags (epinephrine preloaded syringes, IV tubing and fluids, IV catheters, IV start kits, syringes and any other expendable supplies) used during the scenario.

Scenario Two: Infant Seizure

The crew will receive dispatch information outside of the simulation trailer prior to entering, from the study team member playing the role of the parent, of "You are responding to 151 Sweet Street for an infant that is seizing." The study team member will then open the door to the simulation trailer and step inside with the crew following.

A Gaumard Super Tory mannequin (Gaumard, Miami, FL) will be used. The patient will be found in a diaper only laying supine on a crib with active seizure activity of the arms and legs by placing the mannequin settings to "jittery". Upon entering the "patient's room", the study team member playing the parent will state "She just started doing that five minutes ago." If the crew asks if the parent knows the weight, they will respond, "I don't know." If the crew asks for the patient's age, they will respond "6 months". If the crew measures the patient with a length-based tape, the study team member playing the parent will state "for the purposes of the simulation, the patient measures in the pink zone." The parent will respond, if asked, that there is no past medical history, normal birth history, no recent fever, and no medications. If the crew asks about the possibility of a poisoning or ingestion, the parent will state that that there is no concern.

Crews can obtain intraosseous (IO) or IV access for medication administration. If the crew decides to obtain IO access, once they have pulled their IO device out of their equipment bag, they will be handed a study IO device (EZ-IO Teleflex, Morrisville, NC) that contains the drill and all three sizes of IO needles (adult, child and infant) along with connection tubing and anchoring device. At this time, a study team member will point to the area on each leg where IO access can be obtained.

Vital signs will be displayed, if a monitoring device(s) is/are attached to the simulator, on a monitor in the simulation space that will be pointed out by the study member playing the role of parent. Initial vital signs will be heart rate 180, respiratory rate 40, oxygen saturation 94% on room air, blood pressure 90/60. If a point of care blood sugar is obtained, the study team member playing the parent will state that "the blood sugar is 80". If oxygen via mask or nasal canula is placed on the patient, the oxygen saturation will improve to 98%.

The patient will require two doses of midazolam for seizure cessation. Sixty seconds after the second dose of midazolam is administered, the seizure activity will stop, and the study team will announce that the scenario has concluded. At this time the HoloLens wearing paramedic (experimental group) or drug administering paramedic (control group) will be given a piece of paper with "Dose 1 _____mg" and "____ml" and "Dose 2 _____mg" and "_____ml" on it and be instructed to write down the doses they delivered. Control crews can consult their PDR prior to writing down the doses. The study team will then replace all used items from the crew's equipment and medication bags (midazolam vial(s), IV tubing and fluids, IV catheters, IV start kits, syringes and any other expendable supplies used during the scenario.

Scenario Three: Toddler Burn/Pain Management
The crew will receive dispatch information outside of the simulation trailer prior to entering, from the study team member playing the role of the parent, of "You are responding to 131 North Street for an eighteen-month-old with a burn." The study team member will then open the door to the simulation trailer and step inside with the crew following.

A Gaumard Pediatric HAL simulator (Gaumard, Miami, FL) will be used. The patient will be found sitting on a low chair wearing shorts but no shirt. The mannequin will have moulage on the chest demonstrating first and second degree burns with blisters. There will be a similar moulage to burn to the right lower leg and right upper arm. The burns cover approximately 5% total body surface area. Upon entering the "patient's room", the study team member playing the parent will state "I was boiling water for mac and cheese and turned away for a minute, and his older brother grabbed the pot handle and pulled the boiling water over on him." If the crew asks if the parent knows the weight, they will respond, "He weighed 24 pounds at his doctor's appointment last week." If the crew asks for the patient's age, they will respond "18 months". The mannequin measures in the purple zone on length-based tapes. The parent will respond, if asked, that there is no past medical history, normal birth history, no recent fever, and no medications.

Crews can obtain intraosseous (IO) or IV access for medication administration. If the crew decides to obtain IO access, once they have pulled their IO device out of their equipment bag, they will be handed a study IO device (EZ-IO Teleflex, Morrisville, NC) that contains the drill and all three sizes of IO needles (adult, child and infant) along with connection tubing and anchoring device. At this time, a study team member will point to the area on each leg where IO access can be obtained.

Vital signs will be displayed, if a monitoring device(s) is/are attached to the mannequin, on a monitor in the simulation space that will be pointed out by the study member playing the role of parent. Initial vital signs will be heart rate 160, respiratory rate 40, oxygen saturation 100% on room air, blood pressure 110/70.

The toddler is conscious, represented by eyes that are actively blinking and loud crying via a small portable Bluetooth speaker placed in the mannequin's pants pocket

linked to a looped recording of a toddler crying. The crying volume will be maintained until the patient receives a second dose of fentanyl.

The patient will require two doses of fentanyl for adequate pain management (indicated by crying cessation). If three minutes elapses after the first dose of fentanyl and there is no indication that a second dose will be given, the parent will state "I think his burn still really hurts, can you give him some more medicine?" If the crew decides not to give a second dose, the parent will not say anything further. Sixty seconds after the second dose of fentanyl is administered, the volume on the crying will be turned down to zero over 25 seconds. At that time the parent will state "I think he feels much better now" and announce that the scenario has concluded. At this time the HoloLens wearing paramedic (experimental group) or drug administering paramedic (control group) will be given a piece of paper with "Dose 1 _____mcg" and "_____ml" and "Dose 2 _____mcg" and "_____ml" on it and be instructed to write down the doses they delivered. Control crews can consult their PDR prior to writing down the doses. The study team will then replace all used items from the crew's equipment and medication bags (fentanyl vial(s), IV tubing and fluids, IV catheters, IV start kits, syringes and any other expendable supplies used during the scenario.

k) Cognitive Load Analysis

Both the control and experimental groups will be evaluated for cognitive load during scenarios using the Empatica 4 wristband. Crew members will wear the Empatica 4 wristband to collect biometric data, including heart rate variability and electrodermal activity/galvanic skin response (EDA). Baseline data will be measured while subjects take an operational span task test (Stroop Effect test) to examine working memory capacity and again during 5 minutes of relaxation to obtain baseline EDA measurements. During relaxation they will sit in a quiet area with soft, gentle music playing. The same music will be used for all participants. EDA data analysis will focus on critical decision-making points in both experimental and control groups and evaluate the increase or decrease of cognitive load of while using the HoloLens. Critical decision-making points include start of scenario, calculation of drug dosage(s), preparation of drug dosage(s), delivery of drug dosage(s), and end of scenario. Post simulations, participants will complete the Cognitive Load Assessment Scales in Simulation (CLAS) scale for a subjective measurement of cognitive load. Observer XT program (Noldus Observer XT, Noldus Media Recorder) will be used to synchronize the EDA data with simulation video recordings. The skin conductance response (SCR) component of EDA occurs as a peak in the EDA signal, between one to four seconds after stimulus presentation. Peak SCR amplitude will be used as the indicator of cognitive load. We will extract EDA data for the first five seconds after the start of each critical decision-making point. The EDA signal will be decomposed into SCR by performing continuous decomposition analysis using Ledalab software (Ledalab version 3 4.9). SCR amplitudes will be computed using PyEDA (PyEDA version 0.27.5). R (R version 4.2.0) will be used for statistical analysis with a p-value of less than 0.05 considered statistically significant. A linear mixed model will be used to compare the participants' cognitive load between subjective and objective measures.

l) Debriefing

Once a crew has completed all three scenarios, they will proceed to the debriefing area where they will first complete the System Usability Scale (SUS), User Experience Questionnaire (UEQ) and Cognitive Load Assessment Scales in Simulation. These will be administered via a tablet computer connected to Wi-Fi with a direct link to the study REDCap form. Each member of the crew for both the experimental and control group will complete each of the surveys.

Following completion of the three surveys, participants in both groups will be informed of any errors that occurred by Team member A or B and will be given a brief time to discuss them with the investigators.

As part of the debrief, participants will also be asked a small number of open-ended questions. These questions will invite participants to describe their overall experience with the system used in the scenario (HoloLens or usual PMA reference), to identify perceived strengths and weaknesses of that system, and to reflect on their confidence in having prepared and administered the correct medication dose in each scenario.

m) Video Review

Team members A and B, together, will review video of all three scenarios for each crew in their entirety. This will be done to confirm findings recorded in real time, except for drug doses, and times in which they occurred. This will be done from the same day the simulations occurred up to two weeks after. Team members will be able to zoom individual cameras as needed and reverse and replay sections of video as needed.

n) Data entry

Case report form data entry will be done by study team member I. Data will be directly entered from the master CRF into a REDCap form. Each scenario has its own CRF. Each crew will have a record generated for each scenario. All data regarding drug dosing ("drug" dose in ml, air dose in ml, and dose in mg) will require double data entry-each value will be entered twice. The REDCap form will automatically check to make sure both values are identical. If not, the form will generate a flag and not allow the data enterer to proceed any further until the difference between the two values is resolved.

o) Data review

Once all the data is entered, an excel spreadsheet will be generated from REDCap and these values will be compared to those on the master CRF for each scenario for each crew. If discrepancies are found between the REDCap data and the CRF, the REDCap data will be corrected to reflect the data on the master CRF. This will be carried out by three separate individuals reviewing the records. Once all three individuals have completed their review, a discussion will be held amongst them to ensure that the data is correct in REDCap and that all data entry errors or REDCap discrepancies have been found and corrected.

p) Study endpoints

The study will conclude with the final simulation of the final EMS agency.

q) Data management

A Research Electronic Data Capture (REDCap) database will be used for data collection and storage of survey data. Data will be entered by study subjects and collected in web-accessible REDCap surveys. Data exported from Research Electronic Data Capture will be de-identified and stored in the Western Michigan University School of Medicine Virtual Data Warehouse SharePoint Hub.

Only investigators and research staff are granted access to the secured data. Access control to data export for the study will be the responsibility of the investigators and/or data manager. Only study team members listed as key personnel in the IRB application will have access to the study-specific SharePoint folder. Data will not be moved from or stored outside of the SharePoint folder without notifying the VDW Data Manager.

r) Withdrawal of subjects

Subjects who fail screening will be tracked with the reason for failing screening and which group they are assigned to. Each of the four crew slots will be randomized for each day. If a crew is not available for a given time slot, that crew slot will be dropped and recorded as excluded.

10. Statistical Plan

a) Sample size determination

The study plan calls for 84 crews, 42 per study arm. Each crew administers six total drug doses over the three simulation scenarios, totaling 252 dose administrations in each arm. This sample size equates to a two-proportion superiority test with a 25% baseline PMA error rate and a 35% reduction using the HMD application, with alpha = 0.1, Power = 80%, and a participant/crew ineligibility rate of 25%. The four EMS agencies involved in application design and usability testing were excluded from the RCT.

b. Statistical Methods

For this study, data for all eligible study subjects will be considered. Missing value management is scrutinized at the variable (not case) level. Consequently, missing variable data will be excluded from analysis. Spurious measurements will be considered for possible verifiable correction and inclusion; failing satisfactory resolution, erroneous data will be excluded from statistical analyses.

1. Primary Analyses:

Demographics of all participants will be assessed via an electronic survey and will include:

- Age
- Race (self-reported)
- Ethnicity (self-reported)
- Sex
- Crew configuration
- Years of experience working in EMS

- Time since last pediatric course
- Number of pediatric calls in the last year
- Level of confidence in caring for high acuity pediatrics patients
- Comfort with technology
- EMS instructor status

These will be expressed as means (with Interquartile range for age), and percentages.

Drug dosing accuracy data will also be collected and expressed as means and percentages with 95% confidence intervals. To compare the proportion of medication errors between the HMD application (experimental group) and standard practice (control group), chi-square tests will be employed; if sample sizes are small Fisher's exact tests will be used. Additionally, relative risk of errors between the two groups will be assessed. Specific areas of analysis for both experimental and control groups include:

- Accuracy (defined as a >20% deviation from correct dose according to the reference used by the agency) of doses, per drug and overall
- Frequency of any overdose, per drug and overall
- Frequency of 10 times overdose, per drug and overall
- Frequency of underdose, per drug and overall
- Frequency of 10 times underdose, per drug and overall
- Median overdoses and underdoses per drug and overall, with IQR
- Errors of omission (e.g. omitting a drug dose, omitting a blood sugar check)
- Errors of commission (e.g. intubating a patient, giving the wrong concentration of drug)

2. Secondary Analyses:

Surveys will be used to assess cognitive load associated with the simulation and usability of the ATOM software and HMD. The following surveys will be utilized:

- (CLAS) Cognitive Load Assessment Scale in Simulation
- (SUS) System Usability Scale
- (UEQ) User-Experience Questionnaire

These surveys will be scored per their respective scoring instructions.

3. Supplementary Analyses:

Appropriate descriptive/summary statistics will be generated for additional variables of interest. Quantitative data will be represented as means or medians. Additional measures for numeric variables include location, spread, and shape of the underlying population distribution. Nominal and ordinal data will be reported as frequencies and percentages.

Descriptive/summary statistics will be illustrated via tabular formatting, as well as suitable charts and/or graphs. Confidence intervals will be reported at a 95% level of confidence, unless otherwise indicated. Significance / Inference testing will

employ a significance threshold of $\alpha \leq .05$, unless otherwise indicated. Additionally, suitable corrections for multiple testing will be applied when appropriate. All data will be cleaned, organized, and analyzed using SAS Proprietary Software Version 9.4 (SAS Institute, Cary, NC).

11. Risks to Subjects:

Real needles and medications are used during the simulation. Subjects have the same risk of injuring themselves with a needle as during a real case. However, there would be no exposure to infectious materials from patients.

Some people feel uncomfortable or stressed during patient simulations. Some are reluctant to analyze their own performance or critique the system in which they work. The research team will do its best to make subjects comfortable with the simulation and debriefing experience. A subject's responses will remain confidential. A subject's performance in the simulations will not be included in their work evaluations, nor will it affect their employment. All information will be kept confidential.

12. Potential Benefits to Subjects

By participating in this study, subjects will provide information to the investigators about the effectiveness of the augmented reality application in managing prehospital pediatric emergencies, system problems that limit their ability to perform your job, pitfalls that result in errors in the care of children, and ways to avoid errors in the future.

13. Provisions to Protect the Privacy Interests of Subjects

We will do everything possible to keep a subject's performance and answers confidential. Scoring forms and questionnaires will be locked up. Once they are assigned a code and combined with those of other participants, they will be destroyed. We will video record the simulations to improve the accuracy of our scoring and record participant responses. These recordings are not available to anyone except the investigators. They will be locked up and eventually erased to maintain subject confidentiality. Subjects will not be identified in any publication. We will not compare individual performances of paramedics with field data; only combined data will be used.

14. Provisions to Maintain the Confidentiality of Data

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify a subject in any action or suit unless the subject consents to it. The researchers also cannot provide them as evidence unless the subject agrees. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

15. Costs to Subjects

There are no costs for participating in this study. Because subjects are participating in this study during their shift, they will be paid their usual, hourly income per and by the EMS agency. However, they will not receive any additional compensation for their time. The investigators will not provide compensation for injuries that may occur during the session. This will be covered by the workers compensation coverage provided by each agency.

16. Sharing of Results with Subjects

The EMS crew will be provided with the drug dosage accuracy information during their debrief. Each agency administration will receive a deidentified composite of the error rate in their experimental and control group. Individuals will not be able to be identified from this data. Agencies do not have any information that identifies who was in the control versus experimental group.

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Appendix A:

Consent Form for Research

Title: Augmenting the On-Scene Medic (ATOM)
Final Phase SA 3: A Simulation Based Randomized Controlled Trial

Principal Investigator: John Hoyle, MD
Western Michigan University Homer Stryker M.D. School of Medicine

Funding by: Agency for Healthcare Research and Quality (AHRQ)

Introduction

We invite you to take part in a research study involving paramedics and EMTs. Your participation is entirely voluntary. Please ask one of the investigators to explain any part of the study you do not understand.

Purpose

The primary objective of this research study is to use simulated pediatric emergencies to 1) identify the pitfalls and problems in pediatric prehospital care that result in errors and 2) assess the effectiveness of a drug dosing safety system for EMS.

As part of the research, we may not tell you everything about the research procedures. At the conclusion of the study, we will provide you with that information.

Procedure

How do I qualify for this study?
You are eligible for this study if you meet the following criteria:

1. You are a licensed paramedic or EMT in one of the participating agencies.
2. You are currently authorized by the local medical control authority to practice within the local EMS system.
3. You have not attended one of the previous research simulation events offered by Dr. Hoyle and his team.

Approximately 312 paramedic/EMT and paramedic/paramedic teams are expected to participate in this simulation session across several agencies.

What do I have to do?
You will be participating in a simulation session today.

This session will last about 2-2 1/2 hours.

You will complete the following activities during this session:

1) You will complete a questionnaire that provides some basic information about you, such as your training, experience level, and your confidence with pediatric emergencies.

2) You will receive general information about the project and detailed instructions about this session, such as the capabilities of the simulators and how to use them, what to do during the simulation, and how to interact with actors who will play the roles of parents.

3) You and your team member(s) will manage different simulated pediatric emergencies. Each simulation will last about 10 minutes. The session will be video recorded.

4) You and your partner will share your general impression of the simulation with the investigators.

5) You will undergo a "facilitated debriefing." This interactive exercise consists of answering written questions and discussing your opinions and self-analysis with the investigator. You will a) help identify problems and pitfalls (including errors and "close-calls") that you encountered during the simulation; b) determine if the problems had any adverse consequences; c) look for contributory factors, such as equipment failure, equipment design limitations, excessive workload, communication failures, inadequate training or experience, and system factors and d) suggest solutions that would prevent problems in the future. The session will be audio recorded so that the investigators conducting the debriefing can play back the interview later. This method improves the accuracy of the debriefing.

Potential Benefits

By participating in this study, you will provide information to the investigators about effective and innovative methods of managing prehospital pediatric emergencies, system problems that limit your ability to perform your job, pitfalls that result in errors in the care of children, and ways to avoid errors in the future.

Potential Risks and Discomfort

The amount of time required to complete a session is about 2-2 ½ hours.

Real needles and medications are used during the simulation. You have the same risk of injuring yourself with a needle as you would during a real case. However, there would be no exposure to infectious materials from patients.

Some people feel uncomfortable or stressed during patient simulations. Some are reluctant to analyse their own performance or critique the system in which they work. We will do our best to

make you comfortable with the simulation and debriefing experience. Your responses will remain confidential.

Your performance in the simulations will not be included in your work evaluations, nor will it affect your employment. All information will be kept confidential.

Costs, Compensation, and Physical Injuries

There are no costs to you for participating in this study. Because you are participating in this study during your shift, you will be paid your usual, hourly income. However, you will not receive any additional compensation for your time. The investigators will not provide compensation if you injure yourself during the session.

Confidentiality

To encourage you to provide honest and forthright opinions about your own performance and about problems with your work environment and the system, you must keep everything that was said and done during this session completely confidential. Do not discuss the simulation with anyone once the session is over.

We will do everything possible to keep your performance and answers confidential. Scoring forms and questionnaires will be locked up. Once they are assigned a code and combined with those of other participants, they will be destroyed. We will video record the simulations to improve the accuracy of our scoring and record your responses. These recordings are not available to anyone except the investigators. They will be locked up and eventually erased to maintain your confidentiality. You will not be identified in any publication. We will not compare individual performances of paramedics with field data; only combined data will be used.
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from

willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Additional Information

Your participation is voluntary. You are free to withdraw at any time without affecting your employment status. The investigators have the right to withdraw you from the study without your consent.

This study was approved by the WMed Institutional Review Board (IRB). If you have any questions about the research, you may contact Dr. John Hoyle at 269-337-6600. If you have questions about your rights as a research subject, you may contact the representative of the IRB at 269-337-4345 or irb@med.wmich.edu.

Agreement to Participate

I have read the information above, have had the study fully explained to me, and have had all questions answered fully by an investigator before participating in the study. I voluntarily give my consent to participate in this study. By signing this form, I have not waived any of the legal rights that I would otherwise have as a participant in a research study.

Subject Name (print) _____ Date _____

Subject signature _____

Signature of investigator explaining the study
_____ Date _____

Appendix B:

Infant Cardiac Arrest Score Sheet

Start Time:

Skill Set	Skill Components Scoring Sheet	Evaluator Guide
Phase 1: Airway & Breathing Assessment	__ Initial assessment performed (pulse, breathing) Instructor will play role of parent Instructor script (as EMS comes through door): "I put my baby down for a nap about 20 minutes ago with his pillows and blankets. I came to check on him about 5 minutes ago and I don't think he's breathing" If EMS checks breathing: "there is no breathing" If EMS checks pulse: "there is no pulse" PMH: none, the child was born term with no complications. After EMS crew starts CPR and resuscitation, IF they call for additional crew people, one instructor can serve as an EMT/MFR who can do BVM and/or compressions.	Actor: 'My baby's not breathing' Starting rhythm: asystole *Instructor:* at the start of the scenario that "the infant's extremities and face are cyanotic." Parent will answer that they know the weight is 9 pounds Provide information about physical exam only if requested. *(*Paramedic can ask EMT partner or MFR to perform this step.)*
Circulation Assessment Circulation Management	__ Attach cardiac monitor electrodes to chest. * __ Begin compressions. * Time: _____ __ Perform compressions at 100-120/min., __ Compressions 15:2 breaths __ Use two thumb technique or two fingers if doing BVM and CPR alone __ Call for additional help.	

IV/IO access	__ Insert IV/IO Time: _____ Location: _____ __ Attach IV line to IV/IO needle. *	IV line is successful. If IO attempted, it is immediately successful. *Instructor* will state: "You got blood return immediately."
Phase 2: Initial Drug Therapy Card used: ☐ Gray Other _____ Epi correct dose 0.5 ml of 1:10,000 IO or IV	__ Obtain patient weight (4 kg or GREY) Method Used: Time: _____ __ Asked parent __ Broselow Tape __ Patient age __ Guess __ Other: _____ Method to obtain epi dose. Time: _____ ___ MI-MEDIC Cards ___ ATOM software ___ Broselow Tape ___ Memory of dose ___ Other Reference ___ Other _____ __Obtain allergies Give epinephrine 1:10,000 concentration Time Given: _____ Dose Given: ML_____ AIR (ML) _____ MG_____ Scale Wt: _____ Concentration(circle) 1:1000 1:10,000 Route Given (circle): IV IO IM Diluted? Y N ML Drug: _____ ML Diluent: _____ Drawn up into 1ml syringe from preloaded syringe using stopcock? Y N Syringe size: 1, 3, 5, 10 ml Syringe brand & type: _____ __ Check cardiac rhythm on monitor after epinephrine. __ Check pulse after epinephrine. *(absent)*	☐ Cross check ☐ Weight ☐ Card Error using tape? Y N ☐ Not at top of head ☐ Leg not straight ☐ Didn't measure at heel ☐ Tape not pulled tight ☐ Tape Upside down ☐ Tape folded over __other _____ ☐ Cross Check ☐ Weight ☐ Card ☐ Drug ☐ Concentration ☐ Expiration ☐ Calculation ☐ Dose in ml ☐ Volume in Syringe ☐ Air bubble Volume: _____ ☐ Allergies ☐ Closed loop communication ☐ Speaking milliliters etc. vs ml ☐ Any errors caught with comms/cross check? List:_____ _____

	When epinephrine is first given, change rhythm to pulseless electrical activity; rhythm = sinus bradycardia; rate ~ 50/min (pre-set)	
Repeat Drug Therapy Card used: ☐ Gray Other _____ Epi correct dose 0.5 ml of 1:10,000 IO or IV End Scenario	Repeat initial dose of epinephrine within 3-5 minutes of first dose: Method to obtain epi dose Time:_____ ___ MI-MEDIC Cards ___ HoloLens ___ Broselow Tape ___ Memory of dose ___ Other Reference ___ Other _____ Give epinephrine 1:10,000 concentration Time Given: _____ Dose Given: ML_____ AIR (ML) _____ MG_____ Scale Wt: _____ Concentration(circle) 1:1000 1:10,000 Route Given (circle): IV IO IM Diluted? Y N ML Drug: _____ ML Diluent: _____ Drawn up into 1ml syringe from preloaded syringe using stopcock? Y N Syringe size: 1, 3, 5, 10 ml Syringe brand & type: _____ __ Atropine given (incorrect action) __ Patient electrically paced (incorrect action) __ Patient intubated (incorrect action) End Time: _____	☐ Cross Check ☐ Weight ☐ Card ☐ Drug ☐ Concentration ☐ Expiration ☐ Calculation ☐ Dose in ml ☐ Volume in Syringe ☐ Air bubble Volume: _____ ☐ Allergies ☐ Closed loop communication ☐ Speaking milliliters etc. vs ml ☐ Any errors caught with comms/cross check? List: _____ _____ Scenario ends after second dose of epinephrine is administered

Appendix C:

Pain Management/Burn Score Sheet

Start Time:

Skill Set	Skill Components (Scoring Sheet)	Evaluator Guide
Phase 1 History	__Obtain weight (24 pounds per parent, Purple on Broselow tape) **Time:** _____ How weight was obtained: __ Asked Parent __ Broselow Tape __ Age __ Guess __ Other __Obtain vital signs **Time:** _____ __Obtain pain score (10) **Time:** _____ __Assess burn and look for burns elsewhere (burn covers approx. 4.5% of body surface area)	☐ Cross Check ☐ Weight ☐ Card Error using tape? Y N ☐ Not at top of head ☐ Leg not straight ☐ Didn't measure at heel ☐ Tape not pulled tight ☐ Tape Upside down ☐ Tape folded over __other _____ Initial pain score is 10
Phase 2 Medication Card used: ☐ Purple ☐ None ☐ Other _____ _ Correct doses: Fent ***IN/IV/IO*** 0.2 ml undiluted (10mcg) MS IV/IM/ 1ml diluted (1mg)	Method used to obtain opioid dose **Time:** _____ ___ MI-MEDIC Cards ___ ATOM Software ___ Broselow Tape ___ Memory of dose ___ Other Reference ___ Other_____ __Obtain allergies __Obtain IV access **Time:** _____ Give dose of opioid **Time** Given: _____ Drug Given: _____ Dose Given: mL _____ AIR (mL)_____ Mcg_____ Scale Wt: _____ Route Given (circle): IV IN IM IO Diluted Y N Dilution Correct? Y N ML Drug: _____ ML Diluent: _____ **Syringe size: 1, 3, 5, 10 ml**	☐ Cross Check ☐ Weight ☐ Card ☐ Drug ☐ Concentration ☐ Expiration ☐ Calculation ☐ Dose in ml ☐ Volume in Syringe ☐ Air bubble Air Volume: _____ ☐ Allergies ☐ Closed loop communication ☐ Speaking milliliters etc. vs ml ☐ Any errors caught with comms/cross check? List: _____ _____ If EMT-P does nothing to address pain, document and parent will state "Aren't you going to do anything about his pain?" Vitals will remain unchanged

If diluted: **Fent;** 2ml drug & 8ml of NS = 10mcg/ml Card used: ☐ Purple ☐ Other _____ Dilution: **Fent;** 2ml drug & 8ml of NS = 10mcg/ml **MS:** 1ml drug & 9ml NS = 1mg/ml Correct doses:	**Syringe brand & type:** _____ __Reassess pain 2-5 minutes after giving medication **Time:** _____ __Reassess VS **Time:** _____ __Prompted by Parent to give pain medicine? Y N Second Dose of opioid Method used to obtain dose **Time:** _____ ___ MI-MEDIC Cards ___ ATOM Software ___ Broselow Tape ___ Memory of dose ___ Other Reference ___ Other _____ **Time** Given: _____ Drug Given: _____ Dose Given: mL _____ AIR (mL) _____ Mcg_____ Scale Wt: _____ Route Given (circle): IV IN IM IO Diluted Y N Dilution Correct? Y N ML Drug: _____ ML Diluent: _____ **Syringe size: 1, 3, 5, 10 ml** **Syringe brand & type:** _____ __ _____ __Reassess pain 2-5 minutes after giving medication (<=3) **Time:** _____ __Reassess VS **Time:** _____	After first dose of pain med, child is still crying. If no reassessment of pain or no second dose of pain medicine, parent states "I think his burn still really hurts, can you give him some more medicine?" ☐ Cross Check ☐ Weight ☐ Card ☐ Drug ☐ Concentration ☐ Expiration ☐ Calculation ☐ Dose in ml ☐ Volume in Syringe ☐ **Air bubble** **Volume:** _____ ☐ Allergies ☐ Closed loop communication ☐ Speaking milliliters etc. mL ☐ Any errors caught with comms/cross check? List: _____ _____ After second dose of pain medicine, child has stopped crying and is content. Repeat VS HR 120, BP 90/60, RR 14 Sat 98%

Fent *IN* 0.2 ml undiluted (10mcg) **Fent *IV*** 1.0 ml diluted (10 mcg) **MS *IV/IM*** 1ml diluted (1mg) If diluted: **Fent;** 2ml drug & 8ml of NS = 10mcg/ml		
Scenario Ends	**Scenario ends Time:** _____	

Appendix D:

Infant Seizure Score Sheet

Start Time:

Skill Set	Skill Components Scoring Sheet	Evaluator Guide
Phase 1: Initial Assessment: *Appearance* *Breathing* *Circulation*	__ Recognize presence of seizure activity within 60 seconds. **Time: _____** __ Check pulse *(present; rate =180/min)* __ Check for respiratory rate (40). *(present)* __ Check O2 Sat (94%) *(Capillary refill normal; skin normal; skin turgor normal; eyes deviated left)*	Provide information about physical exam only if requested. If asked, father will not know the patient's weight. **IF BROSELOW TAPE IS USED, TELL MEDICS PT MEASURES *PINK***
Airway & Oxygen Vascular access	**Deliver oxygen** NC. NRB Liters: _____ **Time: _____** Obtain access __ IV-line Time**: _____** __ IO line. **Time: _____**	Record on computer when <u>oxygen</u> is applied. (O_2 sat changes automatically.) If an IO line is attempted, there is immediate blood return and normal flow. EMT provides cues.

Phase 2: Anticonvulsant Therapy **Card used:** ☐ Pink ☐ Other _____ Dilution 1 ml of drug added to 4 ml saline **Correct Dose:** Midazolam **IM:** 0.2 ml ***(UNDILUTED)*** Midazolam **IV/IO**: 0.4 ml ***(DILUTED)***	__ How was weight estimated? **Time:** ____ __ Asked Parent __ Broselow tape __ Age __ Guess __ Other _____ **Administer benzodiazepine:** Method used to obtain dose **Time:** _____ ___ MI-MEDIC Cards ___ ATOM Software ___ Broselow Tape ___ Memory of dose ___ Other Reference ___ Other _____ __Obtain allergies **Time Given: _____** **Drug Given: _____** **Dose Given: ML_____** **AIR (ML) _____** **MG: _____** **Scale Wt: _____** **Route Given (circle): IV IN IM IO** **Diluted Y N Dilution Correct? Y N** **ML Drug: _____** **ML Diluent: _____** Syringe size: 1, 3, 5, 10 ml Syringe brand & type: _____ __ **Test Glucose** Test glucose with dipstick. * **Time:** _____	☐ Cross Check ☐ Weight ☐ Card Error using tape? Y N ☐ Not at top of head ☐ Leg not straight ☐ Didn't measure at heel ☐ Tape not pulled tight ☐ Tape Upside down ☐ Tape folded over Other _____ ☐ Cross Check ☐ Weight ☐ Card ☐ Drug ☐ Concentration ☐ Expiration ☐ Calculation ☐ Dose in ml ☐ Volume in Syringe ☐ Air bubble Air Volume: _____ ☐ Allergies ☐ Closed loop communication ☐ Speaking milliliters etc vs ml ☐ Any errors caught with comms/cross check? List:_____ __ _____ _ Seizure will stop 60 seconds after second dose of midazolam

END Scenario	*(80 mg%)* **2nd dose?** **Time Given: _____** **Drug Given: _____** **Dose Given: ML_____** **AIR (ML) _____** **MG: _____** **Scale Wt: _____** **Route Given (circle): IV IN IM IO** **Diluted Y N Dilution Correct? Y N** **ML Drug: _____** **ML Diluent: _____** Syringe size: 1, 3, 5, 10 ml Syringe brand & type: _____ __ **END TIME: _____**	☐ Cross Check ☐ Weight ☐ Card ☐ Drug ☐ Concentration ☐ Expiration ☐ Calculation ☐ Dose in ml ☐ Volume in Syringe ☐ Air bubble Air Volume:_____ ☐ Allergies ☐ Closed loop communication ☐ Speaking milliliters etc. vs ml ☐ Any errors caught with comms/cross check? List: _____ _____ _ ☐ Seizure will end 60 seconds after second dose of midazolam whether it is correct or not.

Glossary

ABC Airway, Breathing, Circulation
ACLS Advanced Cardiac Life Support
CLAS Cognitive Load Assessment Scale in simulations
CPR Cardiopulmonary Resuscitation
CRF Case Report Form
EDA Electrodermal activity
EHR Electronic Health Record
EMS Emergency Medical Services
EMT Emergency Medical Technician
EMTA Emergency Medical Technician-Advanced
FMEA Failure Modes & Effects Analysis
HMD Head Mounted Display
MFR Medical First Responder
PARAMEDIC Emergency Medical Technician-Paramedic
PDR Pediatric Drug Dosing Reference
PMA Pediatric Medication Administration
SCR Skin Conductive Response
SUS System Usability Scale
UEQ User Experience Questionnaire
VDW Virtual Data Warehouse