STUDY PROTOCOL:

The Holographic Standardized Patient: Using Mixed Reality to Reduce Barriers to Crisis Simulation in Acute Care

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Background and Rationale:

The current state-of-the-art in medical simulation and assessment is mannequin based and reliant on highly specialized personnel, equipment, and dedicated space. Costs are exorbitant and therefore access is limited[1]. Health care facilities and educational institutions without such a model are unable to participate in high fidelity medical simulation for initial training, continuing medical education, and assessment purposes. Simulation centres are also limited to trainees able to easily reach their facilities, which means lost potential revenue and impact. In addition, in-person evaluation is also vulnerable to disruption from the current pandemic, and alternatives are needed which allow evaluation[2].

We have created a prototype platform, HoloSIM[3,4], which disrupts this model. HoloSIM is a mixed reality platform consisting of laptop- or tablet-based instructor software and Microsoft Hololens 2 headset-based student software. The Microsoft Hololens 2 allows for mixed reality: spatially stable, interactable, and animated holograms inserted into a user's workspace (See Figure 1).

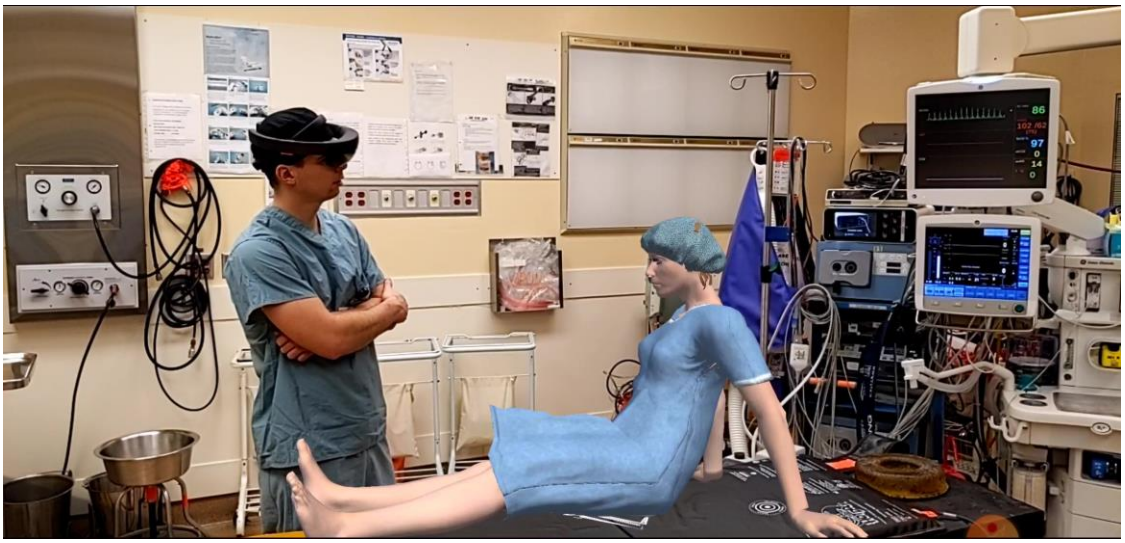

Figure 1: HoloSIM allows instructors to view a composite video of students interacting with the mixed reality learning environment. Follow this link to see a video of a prototype HoloSIM mixed reality learning environment (as experienced by a student).

This permits the augmentation of existing operating rooms and training spaces with holographic (i.e. virtual) equipment and patients. In addition, ubiquitous resources such as cardiopulmonary resuscitation (CPR) training mannequins may be extended to have animations, interactivity, and dynamic visual features as required.

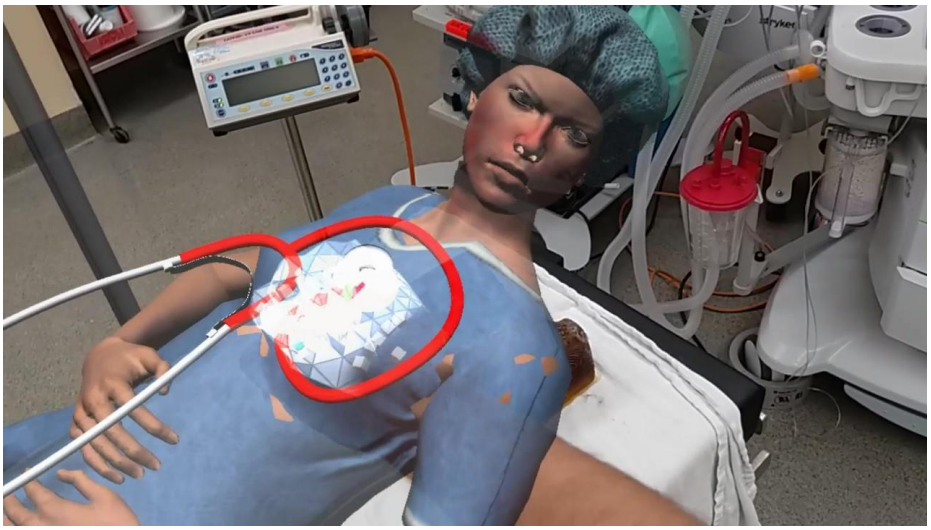

Figure 2: This image depicts the student's mixed reality view of a holographic patient with the symptoms of anaphylaxis (red facial rash and new wheeze). Breath sounds are auscultated by moving a holographic stethoscope over the correct area of the virtual patient. Follow this link to see a simulated patient experiencing anaphylaxis.

Telesimulation capable platforms are defined as being capable of controlling medical simulations for education, training, and assessment at off-site locations[5]. A wide variety of medical emergencies can be initiated using the HoloSIM instructor software, and then monitored/controlled from any distance using a high-speed internet connection. There are no reports, to our knowledge, of a mixed reality telesimulation-capable platform such as HoloSIM. However, the platforms usability, desired frequency and subject matter of use, and the barriers to adoption require investigation.

Though infrequent, anaphylaxis is a high risk and complex crisis seen in all acute care specialties; this scenario requires a focused examination and rapid decisive action, which presents a challenge for trainees[6]. Failure to effectively identify and treat anaphylaxis can lead to severe patient harms. We have therefore selected it as an archetypal medical crisis model to test the effectiveness of HoloSIM in learner acquisition of technical and nontechnical skills, scenario related declarative knowledge, as well as learner perceptions of this novel assessment method.

Mixed reality technology could potentially create infinite numbers of immersive clinical scenarios. By validating its effectiveness as an educational and assessment tool with this study we aim to demonstrate its feasibility in enhancing medical education curricula. This modality could provide a lower cost learning and assessment platform that can align with any context-specific clinical practice and professional development. With the telesimulation abilities allowing it to be applied locally and internationally, this solution may advance clinical teaching and assessment in a wide-ranging manner. Therefore, the use of a mixed reality high fidelity simulation model may allow for significant cost savings and increased access to simulation training and evaluation both within, and outside of, academic centres.

Hypothesis/Research Questions:

In this study we propose to refine and evaluate an innovative holographic medical crisis simulation technique which can be used both as an assessment tool and for teaching technical and nontechnical skills in a novel simulation curriculum.

Two main research questions will be addressed:

1. Does the novel simulation platform have sufficient usability for regular teaching and assessment use?
2. Is a mixed reality simulation platform curriculum non-inferior to the current teaching and assessment standard of high-fidelity mannequin-based crisis simulation in terms of student acquisition of technical and non-technical skills?

This study is the first known research initiative aiming to demonstrate that a mixed reality simulation training and assessment solution is usable and can improve decision making skills and management in a complex crisis scenario. *We hypothesize the HoloSIM platform is non-inferior to traditional mannequin-based simulation in acquiring and assessing technical and non-technical skills in a model life threatening health condition (e.g. anaphylaxis).*

Research Design and Methodology

Platform design:
We have created the prototype HoloSIM mixed reality simulation platform utilizing an iterative development process through resident morning teaching rounds over the past year. Immersed in the mixed reality simulations, learners undertake the decision-making steps in managing the medical care for a patient with an acute medical crisis. They then navigate through the scenarios that—by instructor control—provide feedback depending on their actions in the form of either the patient's hemodynamic changes, verbal prompts from the holographic patient in the scenario, or a holographic medical team confederate. We have designed the HoloSIM 'student experience' for use with typical Hololens controls of intuitive hand gestures and directing visual gaze towards holographic areas of interest. A limited set of dialogue, facial expressions, animations, clothing, skin visual cues, auscultations, physical exam findings, holographic confederates, and patient monitor physiologic changes have been incorporated to date. However, the underlying prototype program structure has been designed to allow this catalogue to be rapidly and easily expanded, allowing the software to be used to simulate a practically limitless variety of crisis scenarios.

Overall Experimental Strategy and Workflow:
The success of this proposal rests on our ability to optimize and adapt the HoloSIM platform to educate and assess acute care medical residents; the two research questions will be addressed by separate study phases. In the first phase of the study, the focus will be on software/scenario development and usability testing of the student and instructor experience. In the second study phase the HoloSIM platform will be incorporated into a

novel anaphylaxis education and assessment curriculum for acute care residents with the impact on technical and nontechnical skills, scenario related declarative knowledge, as well as learner perceptions of the novel assessment tool evaluated by randomized control trial.

First Research Question (Study Phase I): Software/Scenario Development and its Usability Evaluation

To address *the first research question*, throughout the first study phase we will follow best practices in software development for optimizing medical education software usability to maximize the impact of the final software[7]. By doing so the project development team will:

- Ensure participation from all target user groups as both instructors and students.
- Test usability iteratively and systematically with the product under development, not solely with the final product. Testing will occur *in situ* when possible, within unused clinical areas which participants typically use as clinical and teaching workspaces.
- Use a broad representation of participants in terms of technological as well as simulation teaching experience.

Upon receiving institutional research ethics approval, an initial two-month piloting period will allow the creation of two mixed reality anaphylaxis scenarios. The first scenario will be drawn from a recent trial of a telesimulation compatible mannequin based simulation system[8], which is similar to other anaphylaxis scenarios used in Critical Care, Anesthesia, and Emergency Medicine literature[9],[10],[11]. The second scenario[10] involves different inciting events, patient characteristics, hemodynamics, and environmental stimuli. However, the same core anaphylaxis management concepts are required. These scenarios will then be piloted on medical students, residents, staff anesthesiologists, and other experts in the field not involved in the study.

Recruitment and Study Groups:

Participants from acute care postgraduate training programs at Sunnybrook Health Sciences Centre, a tertiary academic institution, will be recruited for 1-hour sessions via email invitation. Consent will be obtained via REDCap at the time of recruitment, as well as a questionnaire to survey demographic information and previous experience with simulation and immersive reality technologies. This will include resident learners of all levels, recruited to use the software in the student role while paired with staff physicians (i.e. instructors/assessors) from the same specialty using the software in the instructor role, drawn together from the same fields of Anesthesiology (Group 1), Internal Medicine (Group 2), Critical Care Medicine (Group 3), or Emergency Medicine (Group 4).

Instructors will be informed two weeks in advance that the session content will include time for orientation to mixed reality, free experimentation, an anaphylaxis scenario, as well as a scenario of their choosing drawn from a study generated database of publicly available peer reviewed content within their specialty[12],[13],[14].

Usability evaluation:

The pairings will use HoloSIM to conduct medical crisis simulations in both a structured and unstructured manner. Usability will be assessed in an ethnographic manner[15] using audio recorded semi-structured interviews with thematic analysis. Usability will also be assessed via the System Usability Scale(SUS)[16], a widely cited, validated, and industry standard Likert scale questionnaire (see Supplementary Figure 4) utilized across a variety of software platforms[17]. No validated tools exist to specifically assess mixed reality software, however a comprehensive multidomain Likert questionnaire, will be administered (previously developed to assess a mixed reality medical simulation learning tool[18]) to students to delineate factors that enhance or limit learning via the Hololens 2 headset and HoloSIM. Additional Likert items will assess the participants age, previous experience with simulation-based teaching, and their desired frequency of future use of the platform.

An iterative process will be undertaken to improve the user experience of participants in both the student and instructor roles through the aid of rapid prototyping, each session prompting refinement and feature addition both pre and post. Significant feature and crisis scenario addition based on user feedback is expected as well as efforts related to discovery and remedy of software errors/failures. We expect the final product educational and assessment software will provide a unique opportunity for knowledge and skills acquisition as well as assessment in a variety of clinically relevant training scenarios. As the medium of mixed reality is in its infancy, we will also learn potential accessibility issues and barriers to use.

The study team and all academic collaborators are committed to the principles of Free and Open Access Medical education (FOAM[19]) with regards to HoloSIM. All software code and resources developed related to this grant will be made freely available via our website[3] and the software repository github[20]. This will enable other groups to modify or adapt our work as per their needs.

Study conduct and data collection/management:
A total of 6 sessions within each specialty will be planned (24 sessions with 48 total participants), or until interim analysis demonstrates thematic saturation. This is in keeping with data demonstrating 5-6 of any type of user is typically enough to reveal 95% of usability issues[21].

Statistical Analysis:
SUS and mixed reality specific questionnaire results will be compiled in aggregate and descriptive statistics will be presented as frequencies. For the items of the SUS, the score will be calculated using Brooke's standard scoring method[16].

Second Research Question (Study Phase II): Evaluation of the novel mixed reality based anaphylaxis curriculum as a teaching and assessment tool

In the second study phase the HoloSIM platform will be incorporated into a novel anaphylaxis education and assessment curriculum and evaluated by randomized control trial. The primary outcome will be the impact on technical and nontechnical skill

acquisition as assessed by performance checklist; secondary outcomes include the scenario related declarative knowledge assessed by multiple choice quiz, as well as learner perceptions of the mixed reality assessment tool as measured by questionnaire. The nature, timing, and validity of these measurement tools is outlined below.

Recruitment and study workflow:
Acute care residents will be recruited and consented for a randomized control trial via email invitation and REDCap software[22]. Participants will be asked to complete baseline measurements of simulation, anaphylaxis management, and immersive device (virtual reality or mixed reality) experience.

Randomization and Study Groups
Randomization will be accomplished at the time of consent, to one of the two groups: A) HoloSIM based simulation (Intervention) or B) mannequin-based simulation (Control). Both groups will require students to learn and practice decision-making concepts for the management of anaphylaxis using their assigned modality (HoloSIM or traditional mannequin). Randomization will be stratified by specialty, as there is a potential for training background as a bias. We have chosen not to stratify by training level, due to data that both staff physicians and residents of all levels frequently have delayed or missed management steps when undergoing anaphylaxis simulations[6].

Sample Size Calculation and Feasibility:
Power analysis was conducted in SealedEnvelope[23] running an analysis for continuous outcome non-inferiority trial using a power of 0.9, alpha level of 0.05, and standard deviation calculated using RevMan[24] software from a previous study[9] utilizing the same anaphylaxis checklist evaluation tool. A non-inferiority limit of 3 out of a possible 45 total checklist points, equal to one major checklist criterion, was determined by investigator consensus to be significant. The items on the checklist are similar to those previously validated in earlier anaphylaxis simulation studies[10],[25]. The required sample size was calculated as 28. We consider this feasible as an estimated 20 new residents rotate through the included services each month. To compensate for a 10-20% loss to follow-up and increased robustness for secondary outcomes, we will recruit a total of 40 participants (20 in each group) over a period of 12 months.

We have chosen a noninferiority comparison as we believe a finding of comparable efficacy for the HoloSIM platform in light of its potential advantages in telesimulation capabilities, scenario flexibility of mixed reality, and potential for cost effectiveness would be significant.

Study Conduct and Data Collection:

Group A (Intervention). Participants randomized to Group A will arrive on day 0 to be given an orientation to the immersive HoloSIM platform. When they feel accustomed to its technical aspects an anaphylaxis management scenario will be initiated[10].

Group B (Control). Participants randomized to Group B will be assigned to mannequin-based scenario practice, which is the current gold standard in medical education and

assessment. Similar to the HoloSIM group, participants will arrive on day 0 to be given an orientation to the mannequin-based simulation environment so that they feel accustomed to its technical aspects. The anaphylaxis management scenario will match the HoloSIM environment and sequence of events.

All participants will receive learning objectives and a handout with educational content previously developed by a panel of allergists[26] and be asked to review it approximately 48 hours prior to the intervention simulation session.

Participants will have access to the same handouts provided at the time on enrollment for debriefing after each practice session, as well as an instructor led debrief. All participants will then complete a validated assessment of learning satisfaction tool, the Modified Simulation Effectiveness Tool (SET-M, see Supplementary Figure 5) [27]; if HoloSIM is utilized, participants will complete usability questionnaires as in the first study phase.

Study follow-up:
We will invite participants to return one month later to assess the impact of the intervention with a validated anaphylaxis knowledge test developed by allergists for use with the same curriculum included in our study[26] and a mannequin-based anaphylaxis assessment scenario, the parameters of which were piloted in the first study stage utilizing HoloSIM[28]. Participants from the intervention group (Group A) will be oriented to the mannequin simulation environment prior to managing the scenario as they will not have had previous exposure to this modality. All participant sessions will be video recorded and evaluated by two trained assessors. Scoring of the assessment scenario will involve a weighted checklist (See Supplementary Figure 6) of critical events similar to other validated anaphylaxis scoring tools[10] and used in a previous similar trial[28]. Scores in percentage points will be averaged between assessors, with a significant deviation being referred to a third assessor.

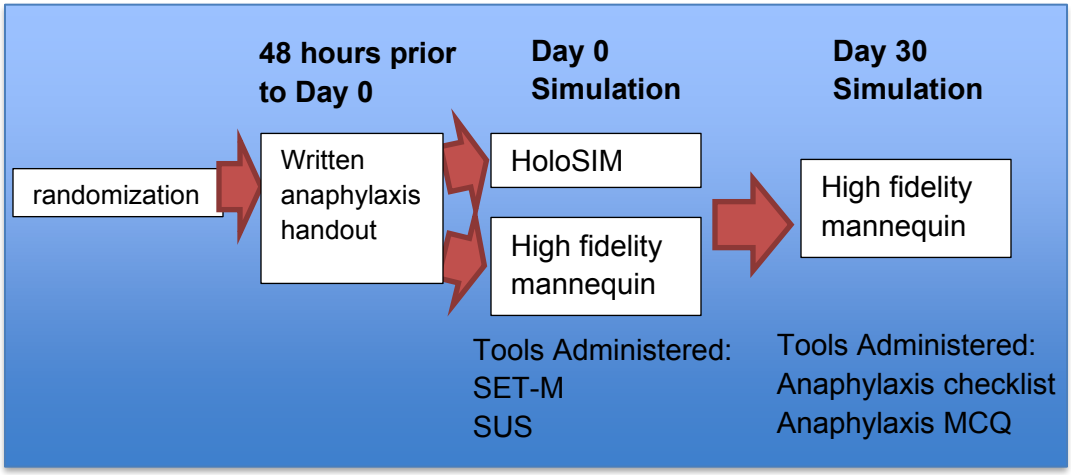

Figure 3: Study Design

Study limitations:

We understand that participants in Group B (Control) will be learning on and then assessed using the same modality (mannequin-based simulation), which creates an advantage for these participants. However, practice and assessments cannot be done on live patients, and the current gold standard is mannequin-based simulation training. Thus, there are no alternatives but to compare HoloSIM to mannequin-based simulation.

We acknowledge that no pretesting will be performed prior to the intervention, this is to avoid repeated exposure to anaphylaxis related content immediately prior to the intervention. However, we have randomized carefully to avoid bias.

Statistical analysis:
Demographic characteristics of participants will be summarized with appropriate measures of central tendency and dispersion (count/percent for categorical data). The mean checklist scores in each group will be presented as mean/standard deviation and inferential testing will be done with the t-test. The inter-assessor agreement will be measured using the interclass correlation coefficient (ICC).

I. APPENDICES

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Additional Figures:

Figure 4: System Usability Scale (SUS)

System Usability Scale (SUS)

Statement:	Rating				
	Strongly disagree	Disagree	Undecided	Agree	Strongly Agree
I think that I would like to use this system frequently					
I found the system unnecessarily complex					
I thought the system was easy to use					
I think that I would need the support of a technical person to be able to use this system					
I found the various functions in this system were well integrated					
I thought there was too much inconsistency in this system					
I would imagine that most people would learn to use this system very quickly					
I found the system very cumbersome to use					
I felt very confident using the system					
I needed to learn a lot of things before I could get going with this system					

Figure 5: Simulation Effectiveness Tool (SET-M)

Simulation Effectiveness Tool - Modified (SET-M)

After completing a simulated clinical experience, please respond to the following statements by circling your response.

PREBRIEFING:	**Strongly Agree**	**Somewhat Agree**	**Do Not Agree**
Prebriefing increased my confidence	3	2	1
Prebriefing was beneficial to my learning.	3	2	1
SCENARIO:			
I am better prepared to respond to changes in my patient's condition.	3	2	1
I developed a better understanding of the pathophysiology.	3	2	1
I am more confident of my nursing assessment skills.	3	2	1
I felt empowered to make clinical decisions.	3	2	1
I developed a better understanding of medications. (Leave blank if no medications in scenario)	3	2	1
I had the opportunity to practice my clinical decision making skills.	3	2	1
I am more confident in my ability to prioritize care and interventions	3	2	1
I am more confident in communicating with my patient.	3	2	1
I am more confident in my ability to teach patients about their illness and interventions.	3	2	1
I am more confident in my ability to report information to health care team.	3	2	1
I am more confident in providing interventions that foster patient safety.	3	2	1
I am more confident in using evidence-based practice to provide nursing care.	3	2	1
DEBRIEFING:			
Debriefing contributed to my learning.	3	2	1
Debriefing allowed me to verbalize my feelings before focusing on the scenario	3	2	1
Debriefing was valuable in helping me improve my clinical judgment.	3	2	1
Debriefing provided opportunities to self-reflect on my performance during simulation.	3	2	1
Debriefing was a constructive evaluation of the simulation.	3	2	1
What else would you like to say about today's simulated clinical experience?			

Figure 6: Anaphylaxis Checklist of Core Decision Making Steps

1. Score _____ (Out of 45)

History (10 points)

❑ Symptom duration [1]
❑ Inciting factors [2]
❑ Airway management questions (i.e. sob) [2]
❑ Other symptoms [1]
❑ Past medical history [1]
❑ Medications [1]
❑ Allergies [2]

Physical (15 points)

❑ Airway assessment [3]
❑ Breath sounds [3]
❑ Pulse oximetry [3]
❑ Respiratory rate [2]
❑ Cardiac exam [1]
❑ Blood pressure [1]
❑ Pulse [1]
❑ Extremity/skin [1]

Diagnostic evaluation (0 points)

Management (20 points)

❑ Epinephrine [3]
❑ Oxygen (mask or intubation) [3]
❑ H1 blocker [2]
❑ H2 blocker [1]
❑ Steroids [2]
❑ IV with fluids [3]
❑ Monitor [1]
❑ Albuterol nebs [1]
❑ Observation [1]
❑ Notify PMD [1]
❑ Bracelet [1]
❑ Epi-pen Rx [1]