

FP.1.a.ii Provide an example of how you align the Fellowship Program activities to the simulation program mission and/or vision.

Our fellowship program started in 2018, with our first fellow's training experience being the academic/fiscal year '19 (i.e. July 2018-June 2019). Our second fellow thus began her training in fiscal year '20. **As an example of how her fellowship activities align with mission and vision as a Center, below is her IRB-approved research protocol.** In this project, our fellow worked closely with our application developers and created a novel trainer using virtual reality and augmented reality concepts. Additionally, she built a task trainer to evaluate gains in knowledge and skill within performance of a digital block for local finger anesthesia. She has completed enrollment, despite interruptions by COVID-19 pandemic, and her data is currently being extracted by video-based review. This is a great example of how her *innovation in simulation-based healthcare education and research* aligns perfectly with our vision and mission statements.

Study Title: A novel augmented reality digital block task trainer for practicing pediatric clinicians

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Abstract

Many physicians providing care in the pediatric emergency medicine and urgent care settings are trained solely in pediatrics. Procedural training in pediatrics faces many challenges, and medical simulation has become a popular method to address many of these challenges. Current simulation methods, however, have not consistently demonstrated improved patient outcomes and are difficult to standardize across multiple facilitators and institutions. Virtual and augmented reality are promising solutions to standardize simulation for procedural training while also adding realism, but there is little experience using these modalities in pediatrics. Over 12 to 18 months, our prospective, assessment-based study will evaluate the impact of an augmented reality task trainer for digital blocks on the improvement and maintenance of procedural knowledge and skill of pediatric providers working in pediatric emergency and urgent care settings. We will also assess the impact that performing digital blocks clinically has on the maintenance of procedural knowledge and skill within this same cohort of providers.

Purpose of Study

To help achieve standardized pediatric procedural training, this project intends to develop an augmented reality simulator for digital blocks, a common procedure performed by pediatric physicians and nurse practitioners working in the emergency and urgent care settings. The *long-term goal* of this work is to improve the clinical performance and safety of this and other pediatric procedures, thus improving care of pediatric patients in these settings. As a first step towards this goal, we have the following *short-term aims* for this study:

Specific aim 1: To improve procedural knowledge and skill within a cohort of pediatric providers (i.e. clinical staff physicians, residents, advanced practice nurses) who care for patients in the pediatric emergency department and urgent care settings. Our *hypothesis* is that enrollment in an augmented reality-based simulation course will translate to improved knowledge and skill compared to baseline, as measured by using a procedural checklist instrument.

Specific aim 2: To maintain procedural knowledge and skill within this cohort of providers. Our *hypothesis* is that enrollment in an augmented reality-based simulation course will translate to retained knowledge and skill compared to baseline and post-training time points, as measured by a procedural checklist instrument.

Specific aim 3: To assess the impact that digital blocks performed clinically during the study period have on maintenance of the procedural knowledge and skill within this cohort of providers. Our hypothesis is that providers who perform digital blocks in the clinical setting more frequently are more apt to maintain procedural knowledge and skill compared to providers who perform digital blocks in the clinical setting less frequently. To allow analysis for this correlation, we will track the number of digital blocks performed clinically by this cohort during the study period.

Background

Pediatric emergency medicine and urgent care medicine are procedure-heavy specialties within the field of pediatrics, yet many physicians providing care in these environments are solely trained in general pediatrics. While the Accreditation Council for Graduate Medical Education (ACGME) mandates that pediatric residency graduates are competent in the majority of procedures required for these environments, training methods and approaches to assessment are determined by each individual residency program (ACGME, 2017). Traditionally, procedural training has followed an apprenticeship model which leads to great variation in the quality and effectiveness of residency training. Also, changes in residency work hours, greater emphasis on patient safety, and especially the growth of pediatric fellowship programs has increased the concern that there are not as many opportunities for hands-on, bedside procedural training for pediatric residents. In light of these challenges, medical simulation has become increasingly popular as a method to improve procedural competency.

Medical simulation is a well-established method of addressing gaps in procedural training. In pediatrics, simulation-based training has been used in resuscitation training, team building, and procedural skill training. Evidence has shown that simulation-based training increases the medical knowledge and confidence level of participants, however, in pediatrics there is not as much evidence of improved patient outcomes with simulation training (Weinberg, 2009). Kessler, et al. demonstrated increased success in obtaining cerebrospinal fluid during lumbar puncture for pediatric residents at a single center who completed simulation training with audiovisual training compared to residents who completed audiovisual training alone (Kessler, 2011). However, when expanded to a multi-center trial, there was no statistical difference between participants who completed simulation training and those who did not. The authors postulate that differences in trainers or training equipment across institutions may have contributed to the lack of improved clinical outcome seen after simulation training, despite efforts to standardize training across institutions (Kessler, 2013).

Virtual and augmented reality (VR and AR, respectively) have the potential to reduce differences in simulation training across facilitators and training locations. VR, which can be defined as a computer-generated environment that uses audio and/or visual output to simulate a

real or imaginary world for the user, may allow for more realistic training environments and can solve the logistical issues of obtaining training equipment. VR also allows for standardized evaluation and assessment (Mantovani, 2003). However, physical realism is also an important component of procedural task training that allows for the development of muscle memory and spatial awareness. Even with the use of simulators with high visual realism, physical realism is not always achieved (Shefrin, 2015). A disadvantage of using VR for procedural training is that all of the learning is in the digital world, and the physical realism of the simulation is lost. Using AR, which uses a virtual overlay that is displayed over the real environment, yields many of the same advantages of using VR with the added benefit of being able to combine the virtual world with the physical, thus improving the overall realism of the simulation. There are many AR applications that have been developed and validated as reliable training methods, however the majority of these applications have been developed for adult surgical fields. There is also very little data on whether these training modalities improve patient outcomes (Barsom, 2016).

Study Design

This will be a prospective assessment-based study of simulation-based training provided via a hands-on AR task trainer. The population for this study will be non-emergency trained pediatric providers who work in the emergency department and urgent care settings of an academic pediatric institution. Enrollment will be based on recruitment of volunteers. The intervention will be an augmented reality task trainer for digital blocks. There will not be a traditional “control group” who do not receive the intervention and are compared to this intervention group. Instead the participants are their own control group in the before-after design. The *primary outcome* will be participant performance of a simulated digital block, measured before and after the intervention. *Secondary outcomes* will be performance of participants longitudinally after the intervention and the correlation of performance over time with the number of times a digital block was performed clinically.

Preliminary work

Through a survey of emergency room clinical staff physicians, nurse practitioners, and third year pediatric residents we sought to identify minor procedures clinicians feel least trained to perform independently. A 19-question survey was developed by study investigators and piloted within a small cohort of clinical staff physicians and nurse practitioners for ease of use, clarity of questions, time for completion, and missing information. Feedback was obtained and the survey was revised, resulting in a final 19-question survey. The survey was delivered online via Survey Monkey® to clinical staff physicians, nurse practitioners, and third year pediatric residents at our institution, which we believed was a representative sampling of a cohort similar to intended participants in the current study proposal. Participants reported that they were least comfortable with nailbed repair and simple reduction of finger dislocation. Since successfully performing a digital block is a crucial component of both of these procedures, and is also a component of other minor procedures typically within the scope of practice for this cohort, we chose this procedure as the study procedure in which to initially test our hypothesis.

Duration

This study is expected to take approximately 15 months to complete. The development of the AR task trainer and course piloting will take approximately 6 months, followed by a 2-3 month period of enrollment, during which participants will complete the intervention. Maintenance assessments will be conducted at 1, 3, and 6 months post-intervention. Data analysis is expected to take 3-6 months, with dissemination of results taking an additional 2-3 months.

Selection and Recruitment of Participants

All participants will be current clinical staff physicians and APRNs working at Cincinnati Children's Hospital Medical Center in all emergency department and urgent care locations. We will enroll a convenience sample, as the selection of participants will be based on availability and willingness to participate in the initial training session and assessment as well as the 1, 3, and 6 month follow-ups. There are a total of 22 clinical staff physicians and 21 APRNs who work in these locations and would potentially be eligible.

Inclusion criterion: Clinical staff physicians and APRNs who manage patients in one of our emergency department or urgent care settings.

Exclusion criterion: Clinical staff physicians and APRNs who do not perform the study procedure(s) as a part of their work duties will be excluded from the study.

Process of Obtaining Consent

Providers who are eligible for the study will receive an email inviting them to participate in the study, and will be notified upon invitation that participation is completely voluntary. Reminder emails will be sent to all eligible providers once weekly for a total of 3 weeks to maximize the number of participants. Given the need for the assessment and training equipment, as well as the video recording, these sessions will be planned for either the Oak or Old Research Building simulation lab settings. Similar to the motion capture project, these will be 1-on-1 sessions. We anticipate the initial assessment and training session will take 1 hour and the follow up assessments will take at most 30 minutes. Thus, we plan to schedule session blocks where up to 4 participants can train across a 4-hour lab block. We will have them sign up for the sessions ahead of time. Upon arrival to the training session, participants will receive a written study information sheet containing all elements of informed consent and will have the opportunity to ask clarifying questions. This study will request a Waiver of Documentation of Consent from the Institutional Review Board (IRB) as this study is minimal risk and involves only educational procedures for which written informed consent is not typically required.

Study Procedures

For **Aim 1** we plan to develop, implement and assess a simulation-based training course surrounding performance of the digital block.

After Informed Consent has been obtained, participants will be given a verbal orientation, which will include a statement of the session being a safe learning environment, and an overview of the AR task trainer for the digital block. Participants will also be given a hands-on orientation of the AR task trainer to reduce potential bias from unfamiliarity with the equipment. Prior to performance of the digital block, we will survey (Appendix 1) participants on their baseline comfort level and knowledge with performing a digital block. Participants will then perform the digital block on the AR task trainer. Their procedural skills will be assessed using a procedural checklist instrument (Appendix 2) to determine baseline performance. The instrument, as attached, was derived from multiple published resources and local expertise and will undergo piloting similar to Appendix 1.

After completing this baseline assessment, participants will then undergo virtual-based simulation training for the digital block. All training will take place through the virtual trainer to reduce variation in training received between participants. After this session, participants will be asked to perform a digital block on the AR task trainer again. This post-test performance will be assessed using the same procedural checklist instrument that was used for the baseline assessment.

For **Aim 2**, participants will return at 1, 3, and 6 months after the original training session. At each of these time points, participants will be refamiliarized with the AR task trainer, then asked

to perform a digital block on same AR task trainer as they did in the original study session. They will be assessed on their performance using the same procedural checklist instrument. After each assessment, enrolled providers will again be asked to report their comfort and knowledge with performing a digital block using the same survey instrument as used in the original training session.

For **Aim 3**, we will track the number of times digital blocks are performed in the clinical setting by each of the participants during the study period, concluding after the 6 month assessment. The procedures will be tracked through the electronic medical record system by running a report for each participant to search for all patient encounters that have been coded for diagnoses that usually require a digital block for the specified time period. We will NOT be assessing the quality of the digital block, just extracting the number of times a digital block was performed clinically. This data will be extracted at the provider level; no patient data will be collected.

Data Analysis/Methods

Outcomes of Interest

The primary outcome will be participant knowledge and skill after undergoing AR-based simulation training for digital blocks. Secondary outcomes will be participant comfort after completion of the AR-based simulation training, participant knowledge and skill 1-, 3-, and 6-months after training, and the clinical performance digital blocks through the 6-month assessment.

Measures of Outcome

To assess procedural knowledge and skill, we will use a procedural checklist instrument (Appendix 2). Despite thorough literature review, there is no published tool to assess performance in digital block. Thus, we underwent the process described above within the chosen construct to develop internal validity. The same instrument will be used to assess participant performance before, immediately after, and at 1-, 3-, and 6-months after training. To assess for improvement in comfort level with digital blocks, immediately after training we will use a short survey (Appendix 1).

Application of outcome measures

All digital block performances throughout the study will be video recorded using GoPro cameras and/or Simulation iQ recording software. The Center for Simulation and Research has extensive experience in video recording and video assessment with both recording options. The recording process will be piloted in combination with Appendix 2 to determine the most effective and thorough recording process and to insure that all elements of the checklist are discernable on video review. These videos will be assessed by a group of trained reviewers using Appendix 2. Prior to review, each video reviewer will be trained by an investigator who has extensive experience in simulation-based training and assessment, video review and reviewer training. This investigator will serve as the “gold standard” in the review process. The reviewer training will continue until there are no inconsistencies between reviewers, similar to prior studies by this investigative group (Couto, 2015; Lee, 2019). Once review commences, every 10th video will be co-reviewed by the investigator and discussed with the reviewer to prevent “drift.” If there are no discrepancies between reviewers, then the primary reviewer will proceed with his/her next 10 videos. If there are discrepancies, these will be discussed and agreement achieved and the process will be repeated one video at a time until consistency is achieved. The frequency of inconsistency for each review will be reported and tracked across the study. This process has been used in multiple published studies, with very low rates of discrepancies between reviewers. To reduce bias, the reviewers will not know whether the video is baseline, post-test

or delayed testing (1, 3 or 6-month). This will be accomplished by block randomizing the videos in blocks of ten. The assessment scores will be tracked for each participant throughout the study, and their performance after the training session (post-training assessment) will be compared to their performance prior to the training session (baseline assessment) to assess for skill gain. This same instrument will be used to assess participants at each of the follow up assessments, and each of these performances will be compared to the post-training performance to assess for maintenance of skill.

Comfort level with performing a digital block independently will be assessed by a short survey administered at the beginning of the study prior to the simulation session, and again at each of the follow up assessments. Their responses prior to the first training session (baseline comfort) will be compared to their responses after the training session (post-training comfort) to assess for improvement in comfort level. The responses from the post-training session will be compared to the responses from each of the follow up assessments to assess maintenance of comfort level.

For **Aim 3**, we will run reports in the electronic medical record system (Epic) to obtain the number of digital blocks performed by each participant during the study period. For each participant this number will be compared to their follow up assessment scores to evaluate for any correlation of the number of clinical procedures performed with skill maintenance. The number of clinical procedures performed for all participants who demonstrated maintenance of skill (defined as scoring statistically at or above their post-test) will be compared to the number of clinical procedures performed by participants who did not demonstrate maintenance of skill (defined as scoring statistically below their post-test) to assess whether there is a correlation between the number of digital blocks performed by participants and maintenance of skill throughout the study period.

Data Analysis

Each study participant will be assessed using the procedural checklist at five points: pre- and post-training and 1-, 3-, and 6-months after training. Consequently, the outcome measures will be correlated. Descriptive frequencies will be generated and reported. The continuous variables (performance task measures, global performance assessment score, etc.) will be analyzed using one-way analysis of variance (ANOVA) for repeated measures. The assumption that variances at each time are not significantly different will be tested and if there is a significant departure from homogeneity, corrections (e.g., Greenhouse-Geisser) will be applied to ensure the F-ratio is interpretable. If the overall F value is significant we will conduct post hoc tests to determine where differences between each time comparison are significant. The overall assessment of success is a binary variable (i.e., yes/no) and Cochran's Q test is the appropriate statistic. If there is a significant result ($p < 0.05$) then multiple comparisons will be made using the McNemar test and to control for the potential increase of Type I error associated with multiple comparisons, the alpha value will be adjusted (e.g., Bonferroni correction).

Facilities and Performance Sites

Recruitment and enrollment will take place at Cincinnati Children's Hospital Medical Center (CCHMC) through the Division of Emergency Medicine at all clinical locations served. Orientation, training, all assessments, and data analysis will take place at the Center for Simulation and Research (CSR) located at the Oak Campus of CCHMC.

Potential Benefits

The participants will have the direct benefit of receiving education and training for digital blocks. The results of this study may be important in developing future procedural training exercises for providers, thus providing the potential downstream benefit of improved outcomes for patients who are receiving digital blocks.

Potential Risks, Discomforts, Inconveniences and Precautions

There is a risk of breach of confidentiality for participants. Each participant will be assigned a random ID number for the purpose of tracking and comparison of scores across the various assessments that only the investigators will be able to link to them. This same ID number will be used to link participants performances to their clinical data obtained from Epic. The surveys collected during the study will be handled in the same manner as the assessment, using the random ID number for purposes of tracking and comparison across time, as well as linking with the simulation-based assessments and clinical exposure. All participant related data will be stored on password-protected servers and only members of the study team will have access to them. All hard copies of study documents will be kept in locked cabinets. No information regarding an individual's performance will be released to the Division of Emergency Medicine leadership.

Due to the nature of the assessment, participants are at potential risk of psychological discomfort and physical risk during the simulated procedure. We anticipate that these risks are acceptably minimal with the establishment of a safe learning environment during orientation and with universal precautions during performance of the digital block. There is also potential risk that participants may feel bad about their performance at any of the assessments. All instructors for the course will have undergone simulation-based education facilitator training, which will reduce this risk to participants.

As there is an augmented reality component to the study, there is a small risk of simulator sickness. As augmented reality still allows for visual balance from the physical environment and there is limited visual movement during the procedure, there is significantly reduced risk of simulator sickness in study participants as compared to virtual reality environments (Duh, 2001).

Risk/Benefit Analysis

We believe the potential benefits to the participants and future patients outweigh the potential risks of breach of confidentiality and discomfort during the study.

Data Safety and Monitoring

A Data Safety and Monitoring plan will not be required as there is no more than minimal risk to the participants and no risk to any patients.

Privacy and Confidentiality

Participants' data will only be tracked through a randomly assigned ID number, and no personal identifying demographics will be collected. This same ID number will be used to link participants performances to their clinical data obtained from Epic. All participant-related data will be stored on password-protected servers and only members of the study team will have access to them. All hard copies of study documents will be kept in locked cabinets. No information regarding an individual's performance will be released to the Division of Emergency Medicine leadership.

Cost of Participation

There is no cost for participation in this study.

Payment for Participation

Participants will not be paid for participation in the study.

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