

PROTOCOL: SimuVersity Medical Center: Pain and opioid management training in diverse patient populations

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1.0 Objectives / Specific Aims

This study aims to compare the effectiveness of the new educational activity/game (a novel, engaging digital-training plus interaction with virtual patients to practice skills) in meeting clinical learning objectives and outcomes compared to traditional didactic (powerpoint slide-based training and text-base case scenarios) approaches to provider and student education and satisfaction.

2.0 Background

2.1 RATIONAL

Management of chronic pain and opioid use/misuse is challenging for clinicians and students, especially when working with diverse and underserved patient populations, and very few low-cost, flexible, highly-engaging, and effective learning resources are available to help the healthcare workforce best learn to manage these unique health concerns. Gamification holds promise as a user-friendly, fun, engaging and effective teaching strategy, especially for healthcare applications. SimuVersity Medical Center is an immersive 3D gaming platform that will engage students and practicing clinicians in a unique and captivating learning experience focused on pain and opioid management in diverse patient groups.

2.2 Preliminary and Prior Work

Preliminary Data and Prior Work Demonstrating Feasibility: Prior tools have been developed and successfully implemented by the Investigators in the healthcare space, demonstrating the feasibility of gamified teaching tools for health professionals, as well as the ability of the team to operationalize the proposed SimuVersity platform. The Sloppy Mountain Medical Center game, developed by the PI, provides an engaging tool to help “teach” team-building and interprofessionalism. The game is designed to challenge students with a set of engaging tasks that demand effective communication, leadership skills, efficient collaboration, and interprofessional cooperation. The Sloppy Mountain Medical Center activity was used as part of the curriculum for four Interprofessional Day’s at MUSC (2018, 2019, 2020, 2121). A total of 3909 MUSC students played the game during that timeframe. Players indicated that after gameplay they were better able to:

- 1) identify challenges and solutions associated with communicating complicated information to each other in a clear and concise manner
92% (Agree)
- 2) appreciate the challenge and importance of seeking information from all available sources, working as a team to solve problems
93% (Agree)

- 3) value listening and responding to the needs of other team members in order to solve problems collectively
93% (Agree)
- 4) develop strategies to communicate their own needs to the team in a clear and assertive manner in service of overall team success
89% (Agree)
- 5) appreciate the importance of monitoring team progress and providing task-relevant support and assistance to other team members
94% (Agree)

This PI-developed MUSC game (along with another developed by the PI; “Crisis in NewSugarton”) is licensed by Palmetto Innovative Education for commercial distribution. To date, 8 other US graduate health education institutions use this game annually as part of their interprofessional curriculum. The Sloppy Mountain game project demonstrates the experience of the PI in the development and large-scale implementation of educational software for health professional students. Further, it shows the feasibility of the current proposal.

2.3 Background

Overview: Management of chronic pain and opioid use/misuse is challenging for clinicians and students, especially when working with diverse and underserved patient populations. Very few low-cost, flexible, highly-engaging and effective learning resources are available to help the healthcare workforce best learn to manage these unique health concerns. Gamification holds promise as a user-friendly, fun, engaging and effective teaching strategy, especially for healthcare applications.

Chronic Pain: Chronic pain exerts an enormous personal and economic burden, affecting more than 30% of people worldwide.¹ Pain is the main reason why people seek medical care, with three of the top ten reasons being osteoarthritis, back pain, and headaches.² Among the four leading causes of years lost to disability, three are chronic pain conditions.³ Prevalence rates of chronic pain vary between 11% and 40%, with a study by the US CDC estimating the point prevalence at 20%.⁴ The economic costs of chronic pain are substantial, costing between \$560 and \$635 billion per year in medical costs and lost productivity.⁶ Numerous, relatively novel treatment options are available for chronic pain management however, many students and clinicians are unaware of all of the options and their accompanying efficacy data, so there are many missed opportunities for referrals to effective programs and treatments. Additional training is needed to elevate healthcare providers’ pain management knowledge and patient interaction skills.

Racial and Ethnic Disparities in Pain Management: Not all people are affected by chronic pain equally. Data from the CDC suggest higher prevalence rates in women, individuals from lower socioeconomic backgrounds, military veterans, and people residing in rural areas.⁴ Regarding race and ethnicity, studies are mixed, with most reporting higher prevalence in racial and ethnic minorities, such as African American people and indigenous populations.⁵ The burden of chronic pain and pain disparities in racial and ethnic minorities is multifaceted and includes patient and healthcare provider communication discrepancies, different attitudes and decision making, and access to pain medication and services.¹⁹ Providers’ diagnostic decisions and patient complaints of pain are handled less aggressively in racial and ethnic minorities.²⁰ Further, racial and ethnic minorities experience discrepancies and disruptions to recovery support services, including access to treatments such as naloxone.²¹ New educational tools,

such as the one proposed herein, will help providers and students learn to streamline patient care and decision-making by employing engaging, standardized, and empirically-supported training resources.

Opioids for Pain Management: While opioid therapy is a widely employed strategy for chronic pain management, a significant proportion of patients opioid therapy have suboptimal pain relief and/or poor functioning despite significant risks. Americans represent less than 5% of the world's population, but consume 80% of the global opioid supply⁷ with 9 million users of medical long-term opioid analgesics in the United States.^{7,9} Most studies report that less than half of patients experience a decrease in chronic pain with opioid therapy⁷. Systematic reviews report mixed functional outcomes with no conclusive evidence for improved physical, emotional or cognitive functioning in patients on opioids⁹. Frequently cited risks of opioid therapy include overdose, progression to misuse or addiction, and depression. Another clinically important risk of opioid therapy is physiologic opioid tolerance, which is common, can lessen effectiveness of opioid therapy, and lead to between-dose withdrawal symptoms (including pain, anxiety, craving) once dose escalation is stopped^{7,9}. This creates a clinical dilemma where patients on opioid therapy become physiologically dependent on a medication from which they are no longer gaining benefit but are still incurring risk. This situation is challenging for clinicians to effectively address and many need additional training in opioid management and patient-interaction strategies.

Talking to Patients about Pain and Opioids: Opioid therapy tapering and cessation is problematic, particularly if involuntary. Fears of withdrawal symptoms, abandonment or involuntary taper, and pain among those on opioid therapy make the decision to taper or transition from opioid therapy daunting.¹⁰ This leads to patient ambivalence and provider inertia, which can leave the patient “stuck” on a medication that is no longer effective yet conferring risk. Health care providers need additional education and guidance on how to have conversations with patients about opioids, pain treatment, opioid discontinuation, addiction and other topics that may be challenging to address with patients. The development of educational games will provide a more engaging and standardized tool to train clinicians and help streamline talking to patients about pain, opioid use, and other challenging topics.

Current Solutions: Training opportunities for interprofessional students and providers must be safe, low-stakes, high-impact, and dynamically-engaging if they are to nurture the development of collaborative and highly effective behaviors. Effective training demands receptive and engaged learners as well as immersive learning activities and experiences. Current training approaches in healthcare tend to focus primarily on didactic lectures and seminars with some, but lesser, emphasis on simulation scenarios. Simulation has many forms and can include non-human avatars often employed by simulation laboratories, or the use of standardized patient/actors. The use of prerecorded video lectures is common. However, expertise in unique and specialized content areas such as modern, empirically-supported interventions for pain and opioid misuse concerns tends not to be locally available for most healthcare students and practitioners. Learners often rely on institution-sponsored visiting expert speakers who tend to employ traditional didactic methods. However, training health professional students and practitioners via traditional didactic approaches falls short of engaging learners in a manner that promotes *application of knowledge*. The use of simulation

scenarios in either sim-laboratories or with standardized actor/patients is often employed to address this gap, however the expenses and logistical burdens of using sim-lab avatars or actors are considerable and often prohibitive. These approaches are limited by capacity, physical space and equipment restrictions, and expensive equipment, as well as by actor availability, and variability in actor quality. Further, bringing content experts to training facilities to lecture on select topics is often very expensive and inconvenient as well. Travel costs, speaker fees and coordination of provider/student availability to attend trainings are burdensome and suboptimal. Novel asynchronous digital technologies for learning are needed that better engage learners and provide simulation opportunities to help bridge the gap between didactic learning and clinical practice. Computer-based educational approaches can be hosted remotely and engage learners in the application of knowledge with lower costs, better outcomes, and higher levels of engagement and application skills than traditional methods.

Gamification in Healthcare Education: As a method of teaching and learning, gamification is a relatively novel concept.¹² Coupled with the use of technology and online-based platforms, gamification appears to have the ability to transform the way both undergraduate and graduate students learn.^{12,13,17} While some studies suggest that learning outcomes are similar to that of traditional pedagogical approaches,^{15,17} others have shown significant improvements in learning outcomes and advantages to gamification in several clinical areas.^{13,14,16,17} Further, there is strong evidence that health professional students hold highly favorable views about the use of video games in higher education and that gamification significantly increases student engagement with the educational material and activities.^{13,15,17}

3.0 Interventions to be studied

SimuVersity Medical Center is an innovative platform solution to education and training in specialty topics in healthcare. This novel learning platform will permit learners to explore a 3D virtual hospital space and can interact with objects, virtual colleagues/trainers and virtual patients (imbued with artificial intelligence) to learn and practice new clinical skills. The platform is built for ease-of-use with simple character controls that non-game-savvy learners find intuitive and easy. The graphical interface is clean and clear and the software runs on all modern computing platforms. The control intervention consists of traditional powerpoint slide-based training and text-base case studies for review.

4.0 Study Endpoints

This study aims to compare the effectiveness of the new educational activity/game in meeting clinical learning objectives and outcomes compared to traditional learning management system approaches to provider and student education. Participation involves one 1- to 2-hour session (including training and case-based practice) and all measures will be self-report questionnaires administered immediately before and after training.

5.0 Inclusion and Exclusion Criteria/ Study Population

5.1 Inclusion Criteria

- Ages 18-80 years
- English-speaking
- Graduate-level health professional students and faculty at the Medical University of South Carolina
- Willingness and ability to volunteer to play the new educational game and complete questionnaires regarding satisfaction, knowledge acquisition, value, ease of use and ability to meet learning objectives

5.2 Exclusion Criteria

- None

6.0 Number of Subjects

90 participants

7.0 Setting

This study will be conducted virtually using a computer to access SimuVersity.

8.0 Recruitment Methods

Participants will be graduate-level health professional students and faculty volunteers from the Medical University of South Carolina. Participation in the game evaluation study will require approximately 1- to 2-hours. Email announcements from the Office of Interprofessional Initiatives will inform students and faculty about the opportunity to participate in this study. Flyers will also be hung on campus bulletin boards in the library and College student lounge areas. The training system(s) will be available online and can be accessed by volunteers on their own schedules.

The PI in his role as Assistant Provost for Interprofessional Initiatives and his team work closely with the student body and faculty regularly to test and evaluate new interprofessional course offerings, learning objective outcomes and program updates. The feedback provided by students and faculty has proven to be highly valuable in the development and refinement of MUSC's interprofessional curriculum which has an outstanding reputation (largely due to these evaluation efforts). Students and faculty find value and purpose in participating in our evaluation and focus groups because they get an early look at new educational technologies and are actively contributing to the curriculum that directly affects them and other students and faculty in their programs. There is a long track record of successful recruitment of student and faculty samples for program development in OII, and because this study requires only a single session, retention is not applicable.

Volunteer participation or lack thereof in this study will have no bearing on any professional or educational standing at MUSC in any way. Participation is anonymous and no identifying information will be stored or used for study purposes. All materials

related to this study opportunity will include a statement that participation will have no bearing on any professional or educational standing at MUSC.

Inclusion of Individuals Across the Lifespan

Any graduate-level health professional student or faculty member at the Medical University of South Carolina between the ages of 18 and 80 are eligible to volunteer and participate in our software evaluation study. This age range is wide enough to capture a generalizable and representative sample of our target population.

Inclusion of Women and Minorities

Any graduate-level health professional student or faculty member at the Medical University of South Carolina between the ages of 18 and 80 are eligible to volunteer and participate in our software evaluation study, regardless of sex, race or ethnicity. Efforts will be made to ensure that the recruited sample is representative of the population base rates for sex, race and ethnicity and that our groups are balanced across these key demographics using stratified bin randomization.

9.0 Consent Process

Participants will review an IRB-approved study information-statement electronically prior to participation in the study. This statement will include inclusion criteria, participation duration, anticipated risks and protections, study procedures, and remuneration details.

10.0 Study Design / Methods

10.1 Procedures:

SimuVersity Medical Center Overview: Participants randomly assigned to the experimental condition will learn new material through the SimuVersity Platform. The SimuVersity platform is a 3D virtual hospital with several special areas that can be explored by learners with their virtual first-person character. Once inside SimuVersity Medical Center, learners will engage with virtual coaches and trainers that will teach about current, empirically-supported interventions and assessments for a variety of types of chronic pain as well as opioid management considerations and strategies among diverse patient groups. They will also learn communication techniques based on recent research on motivational interviewing as well as about considerations and unique aspects of clinical care among patients from diverse backgrounds.

Learners will interact with 4 (randomly chosen from 8) virtual patients from different racial/ethnic backgrounds with different pain conditions and varied opioid use concerns. Learners will have to apply the knowledge they have learned from the virtual coaches and trainers during these patient interactions. After each patient interaction is completed, the learner will receive feedback on the quality of their knowledge application. This unique, applied training experience will help students and clinicians

improve their clinical outcomes with patients from diverse backgrounds with a variety of pain and opioid use concerns.

Training and Coaching within SimuVersity: Learners will visit the learning resource room in the virtual hospital to interact with several virtual trainers and coaches. Learners will interact with multimedia presentations that cover learning objectives related to: 1) most common types of chronic pain and their etiologies, 2) empirically supported chronic pain treatment options including cognitive behavioral therapy for pain and opioid misuse, 3) opioid therapy strategies and considerations, 4) opioid taper and discontinuation strategies, 5) opioid misuse and abuse risks and etiologies, 6) assessment tools for pain and opioid misuse, 7) diversity considerations in pain and opioid management. Content details and format of the training materials will be developed during the award period by the team which includes experts in pain and opioid management, health disparities and diversity, pain and opioid risk assessment, and behavioral interventions to enhance patient adherence to treatment recommendations.

Clinical Cases for Learners to Apply New Knowledge: Virtual patients powered by AI will be used by students to practice newly learned techniques and apply knowledge. The cases will represent different racial/ethnic categories (e.g., African American, Hispanic, and Caucasian) with different pain conditions (e.g., Fibromyalgia, Chronic low back pain, Sickle Cell, Chronic migraine headache, Knee osteoarthritis), and different levels of opioid use/misuse. Learners will interact with the virtual patients by conducting pain and opioid assessments, clinical interviews, and virtual physical examinations. Learners will make treatment recommendations and referrals as warranted by each unique case. During virtual patient interactions, the patients will provide verbal and non-verbal signs that dynamically reflect the appropriateness of the actions taken by the learner in order to provide real-time feedback of learners' *application* of knowledge. Upon completion of each case, learners will be given a "report card" providing feedback on their choices of assessments, interview techniques, and treatment recommendations.

Control Condition: Participants randomly assigned to the control condition will view pre-developed powerpoint slides and read articles & case materials that contain identical content as those presented through the SimuVersity platform but without using the gamified learning setting. Participants will then review 4 written case studies and answer questions about strategies they would use when interviewing and recommending treatment plans to the patients in the case studies.

Training Materials: We will use the opioid management guidelines and diversity considerations from the Centers for Disease Control (CDC), Substance Abuse and Mental Health Services Administration (SAMHSA) and the Department of Health and Human Services (Think Cultural Health HHS). The didactic training module will be a stand-alone video and slide-based module and the primary areas of focus derived from the CDC guidelines include: 1. Determining whether or not to initiate opioids for pain, 2. Selecting opioids and determining dosages, 3. Deciding duration of initial opioid prescription and conducting follow-up, and 4. Assessing risk and addressing potential harms of opioid use. Learners will review CDC recommendations and data related to attending to health inequities; providing culturally and linguistically appropriate communication, including communication that is accessible to persons

with disabilities; and ensuring access to an appropriate, affordable, diversified, coordinated, and effective nonpharmacologic and pharmacologic pain management regimen for all persons. Think Cultural Health HHS's Cultural Competency Deployment materials will be integrated into the module along with SAMHSA's data and strategies to address opioid misuse and opioid use disorder in Black/African American Communities.

Cases will be developed using the AI case development interface developed by the PI at MUSC. We will use data, recommendations, and examples from the CDC, SAMHSA and Think Cultural Health materials to build the core case foundations and integrate them into 8 racially and ethnically diverse virtual patients. Participants will be randomly assigned to interact with 4 of these characters. In the control condition, the same cases will be used but will be presented in text format instead of the interactive AI patient platform.

This educational software is not a medical device.

1) The intended use is to teach health care providers about the recent scientific literature on pain and opioid management in diverse patient populations.

1a) The general purpose of the software is to educate health care providers about recent advances in pain & opioid management in diverse patient populations. This educational software does not diagnose, cure, mitigate, treat or prevent any disease or condition.

1b) The intended population is healthcare providers/professionals.

2) Participants will watch a powerpoint-like presentation of the current literature on pain, opioid and diversity considerations. They then review case-studies that implement AI-powered virtual clinical cases to illustrate and practice key learning concepts.

3) We hope that our learning platform (digital presentation and virtual case study practice) will be more engaging and result in better knowledge than text-based learning and text-based case studies.

Participant Renumeration

Upon completion of the online, post-training questionnaires, participants will be presented with a unique renumeration webpage. They can choose to enter their email address on that secure page and the server will send an email directly to the Office of Interprofessional Initiatives front desk. Upon receipt, a link to a \$30 amazon gift card will be emailed to them. Participant data from the study will not be linked to their email address (which will be provided for renumeration purposes only).

10. 2 ASSESSMENT INSTRUMENTS AND OUTCOMES

Outcomes

- (1) Video Game Questionnaire
- (2) Pre- and post-training knowledge test
- (3) Post-Training Likert-type ratings of:
 - a. the perceived value of the learning experience
 - b. level of engagement
 - c. quality of the learning experience

- d. how well the stated learning objectives were met

10.3 STUDY INTERVENTIONS AND PROCEDURES

We will employ a between-subject, controlled investigation of the effectiveness and perceived value of the SimuVersity Medical Center learning platform. 60 students from MUSC's Colleges of Medicine, Nursing, Clinical Pharmacy, Health Professions, and Graduate Studies as well as 30 clinical faculty will be randomized (using a bin-randomization scheme implemented through a custom-randomizer developed using Visual BASIC) to undergo chronic pain and opioid management training using the SimuVersity Medical Center game VERSUS traditional text-based training and text-based case studies using the same content.

Participants will review the study information-statement electronically and then complete a knowledge test on opioid and pain management knowledge as well as diversity considerations in pain management. They will also complete questionnaires designed to assess video game experience and affinity. Participants will then be randomly assigned to play the new educational game or watch powerpoint slides and read case studies (educational control condition) derived from the same content as the game. Participants will then be asked to complete questionnaires designed to evaluate the training usefulness, ease-of-use, ability to meet stated learning objectives as well as re-complete the knowledge test.

11.0 Specimen Collection and Banking

There will be no specimen collection or banking.

12.0 Data Management

Stratified bin-randomization will be employed balancing for health professional specialty, age, sex, race/ethnicity, faculty vs student status, and gaming experience to ensure comparable samples. Data will be collected via digital surveys administered on MUSC's ip.musc.edu secure server and data will be stored in the password-protected MySQL database that lives on ip.musc.edu and is behind MUSC's firewall.

2x2 Mixed Modeling will be used to examine pre-post knowledge test scores between the two groups. Independent sample t-tests will be employed to compare the two groups across all other outcome measures (Holmes-corrected for multiple comparisons). In order to demonstrate that our approach to pain/opioid education is superior to traditional approaches, a medium effect-size (game vs control; Cohen's $d=0.6$) should be detectable. With 30 students and 15 faculty in each group, power to detect a medium effect size is good ($1-\beta = .80$; 2-tailed; $\alpha=.05$).

14.0 Withdrawal of Subjects

A participant can opt not to participate, if desired. Otherwise, participation is limited to one 1- to 2-hour session while they complete the activity. During that time

period, participants are able to stop participation at any time for any reason without consequence.

15.0 Risks to Subjects

General Risks:

-Loss of Confidentiality: There is the risk of breach of confidentiality. The research team has procedures in place to minimize the risk of any confidentiality breach. Participant data are stored in password-protected databases behind MUSC's firewall. Questionnaire data collected will be de-identified. No specific or general participant information will be left in public access areas. Research staff members have been given extensive training in maintaining confidentiality as well as HIPAA regulations.

16.0 Potential Benefits to Subjects or Others

Participants will be exposed to the latest empirically-supported knowledge and data on best practices for pain and opioid management in racially/culturally diverse patient populations. Participants will also get exposure to clinical case studies (either via virtual patient interactions or text-based case scenarios) to help with application of new knowledge. This knowledge and experience may improve their clinical skills and outcomes.

17.0 Sharing of Results with Subjects

Study results will only be shared with participants in aggregate/publication form.

18.0 Drugs or Devices

There are no drugs or devices for this study.

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