A Two-Phase Mixed Methods Project Illustrating Development of a Virtual Human Intervention to Teach Advanced Communication Skills and a Subsequent Blinded Mixed Methods Trial to Test the Intervention for Effectiveness

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ABSTRACT

Given growing interest in advanced applications of mixed methods research, we illustrate a multiphase, mixed methods program of research involving multidisciplinary collaboration to create a computer simulation using virtual humans to teach advanced communication skills, and to test the simulation in an educational trial. Phase I comprised 3 parts. Part I involved designing, building, testing, and refining a prototype called MPathic-VR. Four focus groups informed a blueprint used in Part II to develop the prototype. In Part III, focus groups; quantitative efficacy/feasibility testing; qualitative interviews/quantitative assessments; and the results, confirmed the feasibility of using the MPathic-VR program in medical education, and yielded critical design information for further development. Phase II comprised 2 parts: expanding features of MPathic-VR and testing its effectiveness. Part I involved 3 aims: incorporating additional competencies, creating a framework for streamlining virtual human development, and creating an automated after action review. A Part II mixed methods single-blinded, multisite, randomized controlled trial demonstrated that compared to controls, MPathic-VR-exposed students improved their performance with each successive encounter with the communication modules. They achieved statistically significantly higher composite scores from evaluators in a realistic clinical scenario held at a delayed interval after the training. They scored higher attitudinal scores about their experiences, and valued learning nonverbal communication skills, receiving immediate feedback and experiencing simulated emotionally-charged clinical encounters. This article illustrates a program of research used to develop an intervention and then test it, and applying mixed methods research to the development of complex virtual human technology through collaboration across multiple disciplines.

KEYWORDS

Mixed methods; program of research; simulation; virtual humans

Although a growing body of literature illustrates applications of mixed methods research designs, few authors have published illustrations of mixed methods integration in their programs of research (Crabtree et al., 2011). To address this gap in the literature, we introduce a program of research that sought a solution for the difficulty of teaching communication skills to medical learners. This topic is of great importance as doctor-patient communication has been characterized as the most important component of the doctor-patient relationship; yet,
teaching communication skills effectively has been found to be difficult. Poor communication is one of the most frequently identified root causes of sentinel events identified by the Joint Commission (The Joint Commission, 2007; Ziv, Wolpe, Small, & Glick, 2003), which accredits health organizations in the United States. Poor communication is a prime contributor to preventable medical error, and is estimated to result in 400,000 deaths annually, preventable harm to 4 million to 8 million patients annually, and has an economic impact of $735 billion to $980 billion annually (Andel, Davidow, Hollander, & Moreno, 2012; James, 2013).

Although medical educators have utilized a number of mechanisms to teach communication skills, the effectiveness of these approaches have been mixed (Berkhof, Van Rijssen, Schellart, Anema, & Van der Beek, 2011). The use of simulation and virtual human technology in health sciences education has received increasing attention as a mechanism to help prepare health professional students to develop skills prior to applying them to patients (Colletti, Gruppen, Barclay, & Stern, 2001; Kleinsmith, Rivera-Gutierrez, Finney, Cendan, & Lok, 2015; C. Lane & Rollnick, 2007; H. C. Lane, Hays, Core, & Auerbach, 2013). Here, we illustrate a narrative of how a very large and highly multidisciplinary team worked together to build and test a virtual human computer system to teach communication skills using mixed methods research. Based on the acronym of the grant, the system is called Modeling Professional Attitudes and Teaching Humanistic Communication in Virtual Reality (MPathic-VR).

This article is divided into four major sections. Section I illustrates the central role of designs for integration in mixed methods research and the need for illustrations of programs of research. Section II includes a brief review of the status of mixed methods research in several major fields that directly relate to this project, and a funding mechanism called the Small Business Innovation Research (SBIR) program. Section III describes the approach taken in the MPathic-VR project, including pre-grant submission studies establishing the importance of the work, as well as the Phase I and Phase II of the study. Section IV provides a discussion of the implications of this project relative to methodological innovation.

Section I: Designs as Key Components of Integration in MMR Designs

On the spectrum of mixed methods research designs, there are two major design categories. One, the “emerging design” approach, and the other, a planned design or fixed approach (Creswell & Plano Clark, 2011). In the emerging design approach, the researcher listens to the data, and allows subsequent research steps and planning—qualitative, quantitative, or mixed—to be determined based upon emerging issues. On the other pole resides a structured approach, which involves the researcher choosing a specific design based on study purposes and questions, and mapping out a clear plan for the mixed methods investigation. Practically speaking, very few researchers work at either extreme end of the spectrum.

One advantage of the structured/calculated/specific approach is the opportunity to think clearly about how integration could occur in advance during each step of the research process. Arguably, a key reason many researchers do not achieve integration stems from the lack of a clear plan for how integration will occur at the design level. If the first thoughts of integration arise only after the qualitative and quantitative data have been collected and analyzed, integration will be more challenging. Certainly, work undertaken with an emerging design can have very sophisticated approaches to integration at multiple levels; however, a clear mixed methods research design at the start facilitates thinking proactively about integration throughout.

Mixed Methods Designs Categories

Leech and Onwuegbuzie (2009) provide an extensive typology of mixed methods research designs, and Plano Clark and Ivankova (2016) provide five design typologies that have been proposed by major authors from different fields. Creswell (2015), one of the most highly published mixed methods methodologists in the field, refers to basic and advanced mixed methods designs. More recently, Creswell and Plano Clark (2018) refer to these as core design and complex applications of core designs. There are three core designs, a convergent (also known as concurrent, parallel) design and two sequential designs. With convergent designs, qualitative and quantitative data are collected and analyzed in a similar timeframe. When qualitative data are collected first to explore a phenomenon that are then examined in a broader way with quantitative methods, Creswell (2015) calls this an exploratory sequential design. When an initial assessment of a phenomenon is conducted with a quantitative strand that is then followed with a qualitative strand conducted to explain, Creswell refers to this as an explanatory sequential design.
Advanced Mixed Methods Research Frameworks

Although a core mixed methods research design is an endeavor usually more complex than a single or a monomethod approach, many researchers use even more sophisticated designs. When using some combination of core designs, they have been referred to as “advanced applications” (Plano Clark & Ivankova, 2016, p. 136), “advanced designs” (Creswell, 2015, p. 41), “advanced frameworks” (Fetters, Curry, & Creswell, 2013, p. 4) “multistrand (complex) MMR designs” (Nastasi & Hitchcock, 2016, p. 43), and complex applications of core designs (Creswell & Plano Clark, 2018, p. 101). Here, we will refer to these as advanced frameworks. We do not favor the term complex because it suggests that core designs are not complex—core designs are more complicated than monomethod designs. Multistrand merely says there are many strands without more clarity. The designation framework also brings in the concept of the lens or emphasis. Advanced design suggests there is something more fixed when, in fact, these more sophisticated approaches may have many different iterations, although all have a unifying framework or lens. Fetters et al. (2013) described four major advanced frameworks as: multistage, intervention, case study, and participatory. They characterized the defining feature of these designs as occurring in multiple stages and specifically as having, “three or more stages when there is a sequential component, or two or more stages when there is a convergent component; these differences distinguish the multistage framework from basic mixed methods designs” (p. 4).

Programs of Research

Programs of research move beyond advanced frameworks as they involve multiple advanced frameworks that are linked together in a sustained program of research. We define a mixed methods program of research as the linking of multiple mixed methods studies in a meaningful way, usually through sustained research on a single topic or related topics, and through collaboration of experienced researchers and research teams. Crabtree et al. (2011) report on their experience of 15 years with six major funded projects. In their extended program of research, they studied more than 350 primary care practices in a process that unfolded across six major studies as an interdependent developmental progression of multimethod observational and intervention studies. They describe the value of sustained research over time as cumulative and synergistic learning that arises from using a longitudinal, collaborative, mixed methods developmental design. Although describing their work as a “Program of Research,” they never provide a definition of this term. Statistics Canada (StatCan) defines a program of research as

A sustained research enterprise that includes one or more projects or other components, and which is shaped by broad objectives for the advancement of knowledge. It might be undertaken primarily by one investigator and encompassed within a single research career, or it could mobilize a team of researchers during a specific period. In pursuit of the overall objectives, specific approaches and methods are advanced, adopted and modified as the research proceeds and as findings are made and reported. (2017, p. 1)

Despite interest in programs of research, there are relatively few examples of programs of research in the published literature. The two phases of the MPathic-VR research process qualify it as a program of research because the overall process linked two major mixed methods frameworks.

Section II: Developments in Mixed Methods Research in the Fields Contributing to the Development of the MPathic-VR Research Program

Development of MPathic-VR drew from expertise in multiple fields, especially medical education, simulation, virtual human programming, and business. Here, we review the status and development of mixed methods research in these fields, and the funding mechanism that enabled the MPathic-VR team to conduct this research.

Mixed Methods Research in Education

Considering the relative quantitative orientation and preference for quantitative research in the field of education, Johnson and Onwuegbuzie (2004) issued a call for incorporating mixed methods into educational research. Raudenbush (2005) has noted the need for moving beyond experiments for finding solutions to problems. Spillane et al. (2010) moved beyond the call for mixed methods approaches by conducting a mixed methods study
where they combined cognitive interviews about principals’ activities and qualitative observations with structured quantitative observations. Although Schifferdecker and Reed (2009) is well cited for the promotion of MMR quality guidelines, they only reference conceptual work regarding MMR for trials. In short, relatively little has been written about the use of mixed methods in educational randomized controlled trials (RCTs).

**Use of Simulation in Health Sciences Education**

In light of the conflicting goals of providing optimal patient care, and the necessity for health professional trainees to hone their skills on live patients, academicians have noted the potential benefits of simulation (Ziv et al., 2003). The use of simulations has grown dramatically in health sciences education (McGaghie, Issenberg, Petrusa, & Scalese, 2010; Scalese, Obeso, & Issenberg, 2008), particularly relative to procedural-based skills, such as in nursing, nurse midwifery (Murray, Grant, Howarth, & Leigh, 2008), and anesthesia (Morgan & Cleave-Hogg, 2002). Despite the potential utility of mixed methods research in simulation research, and the call for creating such applications (Rieber, 2005), relatively few empirical mixed methods studies involving simulation research in healthcare settings could be found. Although not involving computer simulation, Beischel (2013) used mixed methods research to test high-fidelity simulation in nursing education research when she tested a hypothetical model describing the effects of learning variables on anxiety and cognitive learning. Arnold, Johnson, Tucker, Chesak, and Dierkhising (2013) have compared the effects of three simulation methodologies (low-fidelity, non-interactive computer-based, and full-scale) on the outcomes of emergency response knowledge, confidence, satisfaction and self-confidence with learning, and performance.

**Conceptual Basis for Mixed Methods Research Using Virtual Human Simulation**

Dondlinger (2007) conducted a literature review of educational video game design elements and emphasized the value of interactivity, although there was only mention of virtual reality as part of the search criteria for studies included. In related work, Cheng and Tsai (2013) addressed the potential utility of mixed methods in science learning studies using augmented reality. Standards of best practices for simulation in nursing have been published in 2015, but these do not speak to interactive simulations other than a mention of use with virtual reality (Lioce et al., 2015).

**Empirical Studies Using Mixed Methods Research for Virtual Human Research in Simulations**

There have been limited direct applications of mixed methods in virtual reality research. Vottero (2014) demonstrated proof-of-concept for replicating complex health care environments through the use of a virtual reality simulation for medical administration. Feldon and Kafai (2008) used stroke counts, surveys, interviews, and ethnographic observations in a mixed methods research study to analyze users’ avatar-related activities in a virtual world of an informal science website. At a more general level, Venkatesh, Brown, and Bala (2013) used two cases to consider aspects of mixed methods research applied to information science research. A significant barrier to developing sophisticated interventions using virtual human simulation is the cost of research and development, which might require a business model.

**Applications of Mixed Methods and Business Research**

Mixed methods research has gained a foothold in business research. For example, Cameron and Molina-Azorin (2011), who examined empirical articles published across seven business and management fields, documented that 76% were quantitative in nature, whereas 14% were mixed methods and 10% were qualitative. Using content analysis, Harrison (2013) examined 2,072 articles published between 1990 and 2010 in the *Journal of Business Research*. Although 25 published mixed methods research studies were identified, none reported clear mixed methods procedures, nor was there any citation from the mixed methods research literature. Molina-Azorín and López-Gamero (2016) reviewed the application of mixed methods research in environmental management by examining 340 articles published over a 10-year period in the journal *Business Strategy and the Environment* and found there had been 26 (7.6%) mixed methods research studies published. Despite a mixed methods research presence, there remains relatively few published studies using mixed methods research.
The SBIR Funding Program - A Grant Mechanism to Bring Elements of Medical Education, Simulation, and Virtual Humans Together

The planning, feasibility testing, and further development and evaluation of the MPathic-VR computer required significant budgetary support. Here, we introduce the funding mechanism that supported the project, the SBIR program. In the United States, the SBIR program encourages domestic small businesses to engage in Federal-funded Research/Research and Development (R/R&D) that has commercialization potential (SBIR, 2017). There are three phases possible in an SBIR program. Phase I awards should establish technical merit, feasibility, commercial potential, and performance of the business. Phase II awards should continue research and development and show evidence of the technical merit and commercial potential. Phase III involves further commercialization efforts but additional resources are not provided (SBIR, 2017).

Section III: The MPathic-VR Phase I and Phase II Projects

Prior to submission of our SBIR Phase I research, we conducted two studies, both involving the administration of structured surveys. The first study concerned medical student interest in new media (Kron, Gjerde, Sen, & Fetters, 2010) and the second study concerned nursing student interest in new media (Lynch-Sauer et al., 2011).

Pilot Study 1: Medical Student Interest in New Media

In the first study, we surveyed medical students at the University of Wisconsin-Madison and University of Michigan (UM) (Kron et al., 2010). Of the 217 respondents, 53% were women. Most respondents liked the idea of using technology to enhance healthcare education (98%), believed that education should make better use of new media technologies (96%), and believed that video games can have educational value (80%). Even medical student respondents, who did not play video games, held favorable views about the use of video games and new media in medical education.

Pilot Study 2: Nursing Student Interest in New Media

We investigated undergraduate and graduate nursing students’ experience with computer games and new media, attitudes toward various instructional styles and methods, and the role that computer games and new media technologies might play in nursing education (Lynch-Sauer et al., 2011). Of the 218 respondents, 39% of undergraduates and 22% of graduates reported playing games. Regardless of experience with game play, an overwhelming majority (94%) liked the idea of using technology to enhance nursing education, and 88% believed that nursing education should make better use of computer games and new media technology (Lynch-Sauer et al., 2011). This research illustrated the very high level of interest in the kind of technology the team was eager to develop. These pre-submission data were valued as a customer validation, a part of market validation—testing a product concept against a potential target market.

Overview of the MPathic-VR Program of Research

An overview of the two Phases and Aims of the MPathic-VR program of research is illustrated in Figure 1. Phase I illustrates the intervention development, and Phase II represents the procedures for the implementation of a randomized controlled trial.

Phase I, Aim 1: “Design the Blueprint for the Prototype”

Phase I, Aim 1 had five sub-aims: (a) develop criteria to assess user performance; (b) draft the script for the “Breaking Bad News” scenario; (c) design the virtual patient character; (d) design the virtual reality environment and the user interface to enable users and the virtual patient to interact; and (e) perform a formative evaluation of script, character, interface, and environment with focus groups and integrate focus group feedback into the blueprint (Figure 2).
Figure 1. Overview of the primary data collection procedures in the two-phase mixed methods program of investigation.

Figure 2. Overview of procedures used to develop a virtual human intervention.
The MPathic-VR team completed the following research and development relative to the aforementioned aims: (a) The team evaluated different methods for digitally capturing a human actor’s performance, chose one, and used it to automate the performance of the virtual human character; (b) The team evaluated and fine-tuned voice recognition software for use in the program to allow learners to converse with the virtual human character; (c) The team developed a means of interaction between the human and virtual human that permitted learner assessment because this was not possible using free-form speech. Part of this process involved creating a finite number of dialogue choices. These were constructed so that it would be difficult to see any difference between them superficially; to choose between them, a learner would have to understand their pedagogical content, and the extent to which this did or did not conform to evidence-based learning principles related to doctor-patient interaction in the context of breaking bad news. The MPathic-VR team settled on three choices as being optimal; (d) A novel interactive narrative scripting format was developed that incorporated dialogue choices, a scoring rubric, and integrated nonverbal behavior notation. Facial expression assessments were based on the Facial Action Coding System (FACS) developed by Ekman and Friesen (1975, 1976, 1978). The script was also designed to feel natural and allowed for a variety of outcomes based on user choices; and (e) The MPathic-VR team developed an introductory sequence that quickly sets up the action with minimal exposition.

Creation of the Virtual Patient, Environment and User Interface

The MPathic-VR team also designed the virtual patient, environment, and interface. This included the following six tasks: (a) creating a detailed, written character sheet with a full back story; (b) creating a series of four two-dimensional (2D), stylized sketches of the patient character, ranging from cartoon-like pencil sketches to highly realistic drawings, to determine which style would best promote empathic engagement (See Figure 3); (c) developing a short, audition version of the “Breaking Bad News” script and obtaining audition tapes from 25 voiceover actresses; this number was cut by the development team to five candidates; (d) obtaining feedback on the script, sketches, and voices from four focus groups of medical students and medical experts at two medical schools; (e) designing the virtual reality environment based on a photographic study of an actual emergency department; and (f) designing the user interface.

Figure 3. Four character sketches as developed for the virtual human Robin. Copyright by Medical Cyberworlds, Inc. Figures, pictures and photos may not be reproduced without permission.

Findings from the Formative Evaluation

We conducted a formative evaluation to develop the script, voice samples, and character design. To do this, we conducted four focus group sessions at the University of Michigan and University of Virginia (UVA) with a total of 41 participants for this component of the MPathic-VR project. At each location, one focus group was held with M3 and M4 students and one focus group with medical education experts. Below, we discuss the development and use of the focus group findings in the development of the script, voice samples, and the character designs.

Script

To check the working script for face validity, it was read to focus group participants. Overall, participants believed that the script was credible. Educators thought that the script was dramatic and effective. All focus group
participants believed that the patient dialogue was realistic. Learner dialogue responses were constructed so that it would be difficult to see any difference between them superficially; to be able to differentiate, one would have to understand the extent to which the response did or did not conform to evidence-based learning principles for effective doctor-patient communication in the setting of Breaking Bad News. Educators and students agreed it would be better to present additional variations among the potential responses to allow for more “personalization.” Educators and students believed that choices containing jargon or bashing other physicians were obviously wrong and should be replaced.

**Voice**

After review of the script, a series of voice sample auditions for the patient character was played for focus group participants. Five actresses (A through E) reading a portion of the script were played for focus group participants. The participants found two performances, Actresses D and E, to be most compelling, and their specific feedback (both verbal and quantitative, using 100-point visual-analogue scales) informed the ultimate selection of Actress D.

**Character Design**

The final MPathic-VR element that was tested in the focus group sessions was a series of four head-and-shoulders, poster-sized, stylistically distinct sketches of the patient character. The sketches were (a) Design A: highly stylized (i.e., cartoon-like pencil sketch); (b) Design B: moderately stylized; (c) Design C: minimally stylized—the format that ultimately became the main virtual human protagonist; and (d) Design D: realistic, where all the relative proportions of facial and body features were correct, and no features were exaggerated (Figure 3). This, in itself, was groundbreaking research because, at the time of Phase I development, there was no identifiable literature informing the fidelity or other characteristics required for a virtual character that would enable it to best elicit an emotional reaction and promote empathic engagement with learners, although subsequent researchers have explored this (Volante et al., 2016).

Focus group participants chose the design they liked best and the one they liked least. Although participants did not like Design A or B, they found features of both Designs C and D to be appealing. Based on feedback (both verbal and quantitative, using 100-point visual-analogue scales) about design specifics and the character description, the participants provided detailed suggestions that guided a design that informed the final, 2-D drawing of the MPathic-VR virtual patient and main protagonist, Robin, that was based largely on the minimally stylized Design C. An interesting observation was that all of the women panel members focused a lot of attention on Robin’s hair, to make sure that it was appropriate to her age, backstory, and the voices that they auditioned. In short, these results illustrate how a blueprint for the prototype was developed.

**Phase I, Aim 2: Build the MPathic-VR Prototype**

In accordance with Phase I, Aim 2, the MPathic-VR team built the MPathic-VR prototype based on the blueprint developed in Aim 1. This Phase II aim had seven sub-aims: (a) record script and create a normal paused dialog track, (b) prepare reference videotape of voice actor performing script, (c) complete character rigging and modeling of virtual patient, (d) animate virtual patient, (e) complete modeling of the three-dimensional virtual environment and its assets, (f) program user evaluation engine, and (g) program user interface. The completion of this aim was to generate a testable prototype. As noted below, development proceeded according to the sub-aims.

**Record script and create a normal paused dialog track.** We casted a professional actress who was a member of the Screen Actors Guild to record the script, and an accomplished director to elicit several different performances for each of her lines. From this, we developed three paused dialog tracks. This involved cutting together the best three takes from among multiple reads to form three distinct beginning-to-end script readings with pauses separating each line of dialogue. The set that was judged the best according to the focus group results was used in the project.

**Prepare reference videotape of voice actor performing script.** As can be seen in Figure 4, the actress performed the script in a recording studio. Data points applied to the actress’ face were captured using a non-commercial, specially designed “helmet cam.” External reference video of the actress was also captured. The data points helped to automate the animation process; the external video served as a guide for animators. Performance data and video that corresponded to the selected paused dialogue track were used to create the
virtual human performance.

**Figure 4.** Data points applied to actress’s face (left); actress in recording studio wearing helmet-cam (right). Copyright by Medical Cyberworlds, Inc. Figures, pictures and photos may not be reproduced without permission.

**Complete character rigging and modeling of virtual patient.** We created a 2-D sketch of the patient character that incorporated the feedback provided by formative focus groups. This was then translated into a three-dimensional (3-D), volumetric model of the character (Figure 5).

**Figure 5.** Original 2-D sketch, 3-D, volumetric model of patient character that incorporates formative feedback. Copyright by Medical Cyberworlds, Inc. Figures, pictures and photos may not be reproduced without permission.

**Complete character rigging and modeling of virtual patient.** The virtual human then underwent rigging and modeling. This is the process of creating “bones, muscles, skin and sub-dermal coloring” and animation controls for the character, which supported nuanced, expressive performance.
Animate virtual patient. First, human performance data were used to create movement in the virtual human character (Figure 6). After each animated segment was created, Dr Paul Ekman, who along with Wallace Friesen developed the Facial Action Coding System, critiqued it (Ekman & Friesen, 1975, 1976, 1978). Dr Ekman, a renowned expert on facial expression, gave specific directions to character animators for changes to facial expression and other elements of the virtual human’s nonverbal communication. This combination of steps resulted in a virtual human capable of delivering highly nuanced, expressive, and consistent performance. Figure 7 shows the final character exhibiting a sampling of different emotional states.

Figure 6. Human performance data animating the face of the virtual human. Copyright by Medical Cyberworlds, Inc. Figures, pictures and photos may not be reproduced without permission.

Figure 7. Patient character displaying different emotional states. Copyright by Medical Cyberworlds, Inc. Figures, pictures and photos may not be reproduced without permission.

Complete modeling of the three-dimensional virtual environment and its assets. Professional photographers and artists under contract developed a virtual environment based on a photographic study graciously supported by the University of California, Los Angeles (UCLA) Emergency Department.

Program user assessment engine. The prototype included 18 exchanges between the learner and the virtual human patient. Each exchange included virtual human dialogue, and a set of three possible learner responses:
one optimal response and two suboptimal responses. As noted earlier, learner responses were constructed so that it would be difficult to see any difference between them superficially; to choose between them, a learner would have to understand the extent to which a response did or did not conform to evidence-based learning principles related to doctor-patient interaction in the context of breaking bad. The learner responses were first tested with a medical peer group to ensure that the learner responses were, in fact, indistinguishable superficially and could not be guessed based on common sense. To further gauge how the statements performed, the researchers also tested them with psychology graduate students working in the department of the third author. Each statement was selected approximately 33% of the time, making it unlikely that learners could select correct answers and obtain a high score purely by guessing.

Additional evaluation was based on chronemics, the time-flow of the learner-virtual human interaction. For example, in one exchange, learners who missed the fact that the virtual human was reddening and about to cry were penalized (+1) if they interrupted the virtual human at this crucial moment rather than allowing the virtual human adequate time to express her feelings. The text for each choice, the ranking of the choices, and the penalty values were reviewed by two subject matter experts with significant experience in communicating bad news.

As can be seen from these activities, a great deal of effort was invested to create immersion in/engagement with the simulation experience by encouraging learners’ willing suspension of disbelief—that is, the cognitive choice that a learner makes to accept the simulation as genuine clinical experience (Muckler, 2017). In keeping with this, the user interface was made simple, intuitive, and free from distracting elements to minimize the risk of breaking suspension of disbelief (Dede, 1995, 2009; Dede, Salzman, Loftin, & Ash, 2000). The virtual human patient, dressed in an examination gown and sitting in an emergency room bay, was displayed on a computer screen. To maximize impact on learners, the patient was displayed full-screen. After the virtual human character spoke, three possible responses were displayed on the upper right-hand side of the screen. Placement was deliberate, and took two factors into account: (a) In print advertising, a number of researchers had found that readers of printed newspapers in the United States typically make their first fixation on the right page rather than on the left (Garcia & Stark, 1991; Holmqvist & Wartenberg, 2005); and (b) users scanning the text from left-to-right would, at the end of each line, return to the patient character, who was in the center of the screen. This would tend to minimize disruption in the connection between the virtual human and the user.

Phase I, Aim 3: Conduct Summative Evaluation of the Emotional Impact and Efficacy of the MPathic-VR Prototype

In accordance with Phase I, Aim 3, the MPathic-VR team conducted a summative evaluation of the emotional impact and efficacy of the MPathic-VR prototype in a pilot test with students and medical education experts at two medical schools. Building on the success of the voice and design of Robin, we sought input from medical education stakeholders who participated in Phase I for additional design elements. To test the emotional impact of the prototype, we conducted four focus groups—two at U-M and two at UVA. This was more focus groups than originally planned so as to be more exhaustive in the qualitative input. Two focus groups included naive (previously unexposed) medical students and two medical education experts. This enabled us to evaluate the feasibility of the system as an effective learning environment, and provided critical design information for developing a more complete Phase II product.

In a second evaluation to establish system efficacy, a sample of naïve medical students and naïve breaking bad news experts at UM and UVA used the prototype. We then compared their system-recorded scores in order to demonstrate that the MPathic-VR prototype was able to distinguish between levels of expertise. The overarching purpose of this aim was to evaluate the feasibility of the system as an effective learning environment, and provide critical design information for developing a more complete Phase II product. Consequently, we pilot-tested the prototype at U-M and UVA. The fully functional prototype was tested with first-year students, second-year students, third-year students, and fourth-year students; clinicians; and palliative care and medical education faculty. In the following section, we present the preliminary findings.

Demographics of Participants in the Summative Evaluation

During pilot testing, 148 individuals played the prototype: 77 (52%) from U-M and 71 (48%) from UVA. Breakdown of users included 60 (41%) medical students, 51 (33%) faculty, and 37 (25%) “friends” (e.g., colleagues, technicians, Information Technology [IT] administrators). Distribution of medical students was: M1: 12 (20%); M2: 18 (30%); M3: 12 (20%); and M4: 18 (30%). The faculty breakdown comprised 41 (80%) clinicians and 10
(20%) non-clinician educators, although 36 (71%) of the faculty sample reported full or considerable roles in medical education and 17 (33%) were considered breaking bad news experts based on role and reputation.

Performance on the Prototype

We developed and implemented a method for assessing learner performance. The mean MPathic-VR score for a sample of clinicians, educators, and breaking bad news experts was 15.31 out of 55. The mean score for the medical students was 16.81 out of 55. Scores of participants with complete data were analyzed to compare medical student (novices) \( n = 44 \) and a sub-group identified by their peers as breaking bad news/communications experts \( n = 17 \). The range of possible scores was 0 to 50, with lower scores reflecting better performance \( (0 = \text{perfect score}) \). The mean score for novices was 14.43 \( (SD = .637) \), and for experts it was 13.53 \( (SD = 1.252) \). These means were not statistically different from one another, even though an expert achieved the best score and a novice the poorest score. Based on comments from participants in the post-prototype use interviews, we believe that some participants were not clear that the point of interacting was to do their best, and that some were exploring different choices without intent to do well, for example, selecting the worst answers, to examine how the simulation worked rather than to perform their best. We also learned that some students did not understand that each possible response in an exchange was superficially similar but intrinsically distinct. Without understanding the underlying communication principles that ideally should have guided them to the best choices, they instead used communication style rather than substance as their performance yardstick.

Interviews with Target Users

Sixty of the participants \( (36 \text{ U-M}; 24 \text{ UVA}) \) were interviewed immediately after encountering the simulation. These participants volunteered many informative comments: 25 stated that they were impressed by the realism of the virtual patient and scenario; 27 stated that the simulation was an “impressive and unique experience” that would benefit students; 55 were excited about educational opportunities for the simulation; 20 stated that they found the system sufficiently interesting and engaging to allow them to suspend disbelief; 37 empathized with Robin, the virtual patient. Many indicated that they wanted feedback about their performance; 24 wanted immediate feedback about which answer was optimal and why. Overall, participants were impressed with the realism of Robin’s portrayal of emotions and most felt engaged in the scenario.

Evaluation of the MPathic-VR System to Demonstrate the Assessment Value of the MPathic-VR Prototype Simulation

Although beyond the scope of funding from the SBIR I grant, we took advantage of an opportunity to collect preliminary evidence of validity of the MPathic-VR prototype for the purpose of assessing advanced communication skills. Specifically, we investigated the use of MPathic-VR to assess performance-based competence for a specific communication task of breaking bad news. A quasi-experiment was designed to test whether MPathic-VR could detect pre-post change in communication skills among medical residents at the University of Wisconsin who attended a 3-hour in-person seminar on breaking bad news. To account for pre-test sensitization, one group \( (n = 12) \) completed the virtual human simulation only after the seminar, and a second group \( (n = 15) \) completed the simulation before and after the seminar. Post-test scores of both groups were not statistically significantly different based on an independent samples t-test \( t(19) = -.91, p > .05 \), indicating that both groups had comparable performance. Furthermore, the second groups’ mean post-test scores of 8.1 \( (SE = 0.69) \) was statistically significantly improved over the mean pre-test scores of 12.7 \( (SE = 1.24) \), \( t(14) = 3.41, p = .002 \), based on a paired-samples t-test. These results provided validity evidence that MPathic-VR was able to reliably detect changes in performance-based competence, as expected from attending the seminar.

Phase I - Substantive Findings and Implications

To summarize, there were several major findings from Phase I: (a) The project required a highly diverse, multi-disciplinary team with representation from private industry and academics. The success of Phase I demonstration project and prototype demonstrated the investigators’ ability to successfully build collaboration among the highly diverse contributors to this ambitious endeavor; (b) The vast majority of research participants envisioned the MPathic-VR prototype as having the potential to contribute significantly to medical education; (c) The
The prototype was capable of engaging users and eliciting empathic responses from them. They cared about the virtual human patient, became involved in her story and her distress, and wanted to do their best for her; (d) The team successfully and subtly embedded evidence-based pedagogy into the interactive narrative, and developed an assessment rubric that could reliably detect changes in performance-based competence; (e) Lessons learned from participant interviews were used to develop an expanded pedagogy, assessment, and feedback elements included in the Phase II application; (f) The qualitative and quantitative data collection procedures and instruments worked, and the team developed the expertise to manage the large volume of quantitative and qualitative data that would be used to demonstrate the MPathic-VR Phase II educational program’s effect on enhancing cancer-related communication skills and professional performance; and (g) When we conducted Phase I, Aim 1, there was scant research regarding what level of character realism would promote empathy, and certainly nothing about the development of empathy among physicians. A critical finding for this project turned out that a stylized character rather than a highly realistic character was most effective.

Implications of Aim 3 Findings for Phase II

The MPathic-VR team successfully created a proof of concept that engaged users in authentic, high-stakes conversations with virtual human characters, and had the potential to teach users how to manage those interactions in a successful manner. The virtual human’s capacity to express emotions in a nuanced and believable way created an empathic connection with learners. The simple user interface using voice recognition to simulate a human-to-human discussion further increased a learner’s immersion. The proof of concept was crucial to the development of a more feature-complete Stage 2.

Communication training tool. From Phase I data gathering and analysis, we developed a special method for scripting physician-patient communication about cancer that established a standard for more extensive scripting. Among those who engaged in the simulation, 58.8% (n = 87) agreed that the encounter felt like a clinical visit. Phase I created an emotionally evocative virtual cancer patient, a realistic hospital environment, and a user-friendly interface. Medical students, medical educators, breaking bad news experts, and clinicians overwhelmingly supported this approach as a template for future characters (e.g., family members, friends, co-workers) and program development. For example, more than 97% agreed that Robin’s speech and non-speech sounded authentic. Also, 96% believed that Robin’s emotional responses were authentic, 95% believed that her facial expressions were authentic, and 90% believed that Robin looked and behaved like a genuine patient. In addition, 93% believed that the emergency room environment of the prototype appeared authentic and 95% believed that the software for interacting with Robin was intuitive to use.

Phase II - Multisite, Single-Blinded Mixed Methods Research Design

During Phase II, the MPathic-VR team received SBIR Phase II funding to expand the prototype by building two new scenarios, and by incorporating more advanced capability relative to computer simulation with virtual humans as Part I, and then tested the new intervention in an RCT as Part II (Figure 1).

The overall conceptual model of Phase II as proposed in the grant can be seen in Figure 8. The figure shows that the MPathic-VR system captures learner performance data from a plurality of inputs, including a microphone, a webcam, and a Kinect for Windows version II. The MPathic-VR system utilizes these data in combination with other information that is programmed into the system to determine the real-time responses of the virtual human. Learner data also drive an After-Action Review component, in which the learner can see himself or herself interacting with the virtual human and receives individualized feedback based on what the learner did well, or what could be done better. Implied but not explicitly shown is the fact that the learner can repeat the interaction, and the interaction will change according to what the learner does differently. This conceptual model was not followed exactly in the final design process, but it was used in the grant application and provides an overall view of the concept. As illustrated in Figure 8, the VR simulation experience involves engagement of a learning with programming designed to detect non-verbal behavior using voice recognition, incorporate feedback from the users behavior into the response of the virtual human, and deliver an after action review in parallel screens so that the user can see her performance, and the response evoked in the virtual human. The system orchestrates the interaction using a learning scenario database, scoring rubric and input from the interaction real time. For the after action review, user communication behaviors are interpreted and incorporated into teaching that grounded in the evidence-based learning objectives woven into each interaction.
Phase II - Mixed Methods Research Procedures

The detailed procedures of the two-stage mixed methods Phase II project as submitted in the grant are illustrated in Figure 9. This contains the specific aims, the procedures uses, the analytic strategy, and the expected outcomes. Because Aims 1-4 all related to the preparation for the trial, we have referred to these as Part I, and Aim 5 as Part II. These procedures are explained in detail below.
Phase II, Part I: Expand the Phase I “Breaking Bad News” (BBN) design into a more comprehensive training experience. In Phase II, Part I, we expanded the Phase I “Breaking Bad News” design into a more comprehensive training experience to address additional ACGME core competencies. This included two new, thematically linked scenarios that addressed inter-professional and intercultural communication competencies. The modules that were developed featured (a) a family conference that taught cultural sensitivity and empathic communication, and (b) an interaction with an oncology ward nurse that taught professionalism and interpersonal communication skill. Learning objectives were drawn from established communication protocols, such as SPIKES (Baile et al., 2000), CRASH (Rust et al., 2006), and TeamSTEPPS (Agency for Healthcare Research & Quality, 2010, n.d.). Conversational exchanges between the learners and virtual humans also contained learning objectives directed at specific verbal and nonverbal communication skills, known to support the development of rapport. The scripts for the new interactions involved written qualitative feedback on the scripts from cultural content experts including a lay Salvadoran woman and her husband, a Latino physician and an advocate.
for lesbian, gay, bisexual, and transsexual (LGBT) persons, and several oncology nurses.

Phase II, Aim 2: Develop a character animation-authoring framework for rapid creation of highly expressive virtual human characters. We developed an enhanced means of performance capture and transfer onto uniquely rigged, highly expressive virtual human characters that were created in a virtual environment based on a multi-platform game development tool. A new authoring framework was added that enhanced collaboration between animators and behavioral psychologists, and simplified the process of fine-tuning virtual human performance.

Phase II, Aim 3: Develop capability to capture learners’ nonverbal behavior to create a natural, human-like interaction between virtual humans and learners. We developed the capability to capture learners’ nonverbal behavior and facial expression using a Kinect for Windows version II to create a bi-directional, multi-modal, real-time interaction between virtual humans and learners that improved the experience of the Phase I prototype. Because of constraints required by the Phase II budget and research protocol, nonverbal behavior and facial expression capture data were not utilized extensively in the Phase II application; however, it will be increasingly integrated into MPathic-VR program functionality to more profoundly influence real-time virtual human responses, and learner assessment/feedback.

Phase II, Aim 4: Implement automated methods to bookmark “teachable moments” occurring in each learner-virtual human interaction, and provide learners with summative feedback on their effective/ineffective communications. We implemented an After Action Review (AAR) segment that brings out teachable moments that occur in each learner-virtual human exchange. Using a split-screen display, learners saw themselves interacting with the virtual human, and received personalized feedback on their non-verbal communications, facial expressions and cognitive communication strategies. The object was to encourage reflection on knowledge and on action as learners watched the AAR, and reflection in action when learners repeated scenarios.

Phase II, Aim 5: Demonstrate the effectiveness of the MPathic-VR educational program in a randomized controlled mixed-methods trial. The purpose of Phase II, Aim 5 was to demonstrate the effectiveness of the MPathic-VR educational program in a two-armed, mixed methods trial with a control and an intervention arm at each of two medical schools. In actuality, we expanded the trial into three medical schools.

Method

The design involved a single-blinded, mixed methods, multisite randomized controlled trial (RCT). The setting was three medical schools: Eastern Virginia Medical School, UVM, and UVA Medical Schools. Of all eligible second-year medical students, 421 (87.5%) participated. For the intervention arm, students passed a communications quiz, then assumed the role of an intern in two scenarios, one on cultural issues in family decision making for a cancer patient, Robin (virtual human) and her Latina mother (virtual human), and one on interprofessional conflict resolution with an oncology nurse (virtual human). Scores were recorded for each try. In an AAR, students saw themselves interacting with the virtual humans, received individualized feedback on verbal and non-verbal communication. Then, they repeated the scenario. Students in the control group took an interprofessional computer-based learning communications module, then took and passed a communication quiz, and then took the attitudinal survey and short reflective essay.

A mixed methods analysis was conducted based on responses of both MPathic-VR and computer-based learning students who first responded to the same 12 items on an attitudinal survey using a 7-point Likert-format scale and, secondly, responded to a required short reflective essay written at the end of training by both groups. The assessment was focused on actual communication skills performance in a subsequent (within two weeks after training) realistic clinical scenario during an OSCE. All students completed the same OSCE scenario on interprofessional conflict resolution with a surgical assistant trainee (a standardized patient instructor) angry about losing her turn in the operating room. The standardized patient instructors were blinded and evaluated student performance via a 3-point grading system (13 items of 4 domains: openness/defensiveness, collaborative/competitive, nonverbal communication, and presence). Multivariate analysis of variance was used to compare outcomes.

Findings from the Mixed Methods Trial

The findings from the single-blinded mixed methods trial have been published previously in detail (Kron et al., 2017). Briefly, the study population comprised a MPathic-VR group (n = 210) and a control group (n = 211). There were no statistically significant demographic differences between participants in the two groups as a
function of age, gender, race, or ethnicity.

Our first hypothesis was that students randomized to the intervention group would improve between the first and second tries within both scenarios created for the trial, (i.e., the Intercultural Scenario and the Interprofessional Scenario). This hypothesis was confirmed because the scores of students in the MPathic-VR intervention group did improve between the first and second tries, both for the Intercultural scenario, $F(1, 207) = 166.14, p < .0001, \eta^2 = 0.45$, and for the Interprofessional Scenario $F(1, 207) = 104.64, p < .0001, \eta^2 = 0.36$.

Our second hypothesis that students in the intervention arm exposed to MPathic-VR would perform better in a realistic clinical situation (the OSCE) than would students in the control arm exposed to a multimedia computer-based learning module was also confirmed. The OSCE evaluators rated the communication skills of MPathic-VR-trained students statistically significantly higher ($M = 0.806, SD = 0.201$) than they rated the computer-based learning students ($M = 0.752, SD = 0.198$). Additionally, a statistically significant difference was found between groups on nonverbal communication, $F(1, 414) = 13.70, p = .0002, \eta^2 = 0.0320$.

On the attitudinal survey, the mean ratings aggregated across 12 survey items were statistically significantly more positive for students with MPathic-VR experience than for students with computer-based learning experience. Students who trained with MPathic-VR valued the following elements: teaching nonverbal communication skills, providing immediate feedback, and preparing them for emotionally charged encounters ($p < .001$). For the mixed methods analysis, the attitudinal scores and associated qualitative findings from a reflective essay were organized into a joint display. This mixed methods analysis largely demonstrated concordance of the attitudinal scores and qualitative comments, for example, verbal communication scores were better for the intervention group than for the control group. Differences in quantitative attitudinal scores confirmed the qualitative analysis in all domains—for example, verbal communication, non-verbal communication, training was engaging, and effective for handling emotionally charged situations. Although attitudinal scores for improved clinical skills did not discriminate the two groups, the qualitative findings were more positive about their experience in the trial for the intervention group than for the control group.

**Discussion of Phase II Findings**

When we began pre-Phase I and Phase I research and development, in the field of computer simulation, there were only very general ideas about many of the components that would ultimately coalesce into MPathic-VR, but no signposts and no roadmaps to guide the MPathic-VR team with certainty regarding our desired destination. Consequently, the work that went into this project was groundbreaking for its time, just as the current iteration of MPathic-VR is groundbreaking today. In our main outcomes manuscript (Kron et al., 2017), the MPathic-VR team demonstrated that MPathic-VR’s computer-based virtual human simulation not only offers an effective method of training advanced communication skills, but we further demonstrated that the skills learned with MPathic-VR were resilient, and transferred into another realistic clinical situation. To the best of our knowledge, there are no comparable data supporting the use of any other simulation methods to develop advanced communication skills. We are hopeful that this work will trigger a paradigm shift in how advanced communication skills can be assessed and taught in healthcare and elsewhere. Providing an opportunity to remediate a serious previously intractable problem regarding the teaching of communication skills, these findings have potential for a tremendously positive impact on patient care not just in cancer communication, but across the healthcare continuum. Moreover, the detailed and precise data produced by the MPathic-VR system provide medical organizations with a novel opportunity to factor previously unmeasurable provider communication information into healthcare analytics that are designed to improve quality of care/patient outcomes across healthcare systems.

**Business Implications**

Based on these successful SBIR Phase I and II mixed methods projects, we demonstrated that MPathic-VR is a tabletop simulation method that can be distributed, is scalable, and allows for asynchronous use by staff who might be geographically distributed across many cities or states. The application collects detailed and precise data on the communication aptitude of healthcare providers, even in large, expansive organizations. This functionality offers such organizations a first-ever opportunity to factor previously unmeasurable provider communication information into healthcare quality analytics that are designed to improve patient experience and health outcomes. It also gives these organizations a tool that could be used to empower providers to measurably improve their communication skills. These and other useful features of the MPathic-VR application notwithstanding, it would not be possible to get market traction without the high-quality mixed methods research that
must, by necessity, be integral in the development of any similar effort.

Section IV: Implications for Innovation in the Field of Mixed Methods Research

Before our most recent work, there was no effective method of training communication. However, the MPathic-VR team developed the MPathic-VR technology platform, and demonstrated that MPathic-VR’s computer-based virtual human simulation offers an effective method of training advanced communication skills. We further showed that the skills learned with MPathic-VR transferred into another realistic clinical situation. To the best of our knowledge, there are no comparable data at the time of publication supporting the use of any other simulation methods to develop these advanced communication skills.

This program of research further illustrates the use mixed methods trials in education research and specifically medical education research. This project further illustrates feasibility of collaboration across many different disciplines—in our case, between mixed methods researchers and experts in family medicine, oncology, behavioral psychology, virtual humans, human-computer interface, simulation, facial expression, instructional design communication science, computer science, standardized patient instruction education, screenwriting, acting, directing, producing, performance capture, and more—so that potentially transformative work could be accomplished. Although not necessarily a defining feature for mixed methods programs of research, multidisciplinary teamwork is certainly a highly common attribute.

This study illustrates mixed methods research funded through the SBIR I and SBIR II mechanisms of the National Institutes of Health. Although the SBIR is business-focused (SBIR, 2017), it requires that innovators provide not only a strong business model, but also compelling data sufficient to drive the adoption of new technologies in target markets. From a business perspective, this study shows that mixed methods research was valuable to develop a technological platform that could be used to develop a suite of products designed to assess, teach, and certify competency in breaking bad news or in any of a number of other professional areas where adept communication is key (e.g., providing informed consent, giving advanced directives, transitioning to comfort care, holding family conferences, demonstrating cultural sensitivity). In contrast to the Crabtree et al. (2011) program of research, which involved multiple funding sources, the SBIR Phase I and II program facilitated, this program of mixed methods research from a single mechanism, even though the Phase I and Phase II were funded by different NIH agencies, the National Cancer Institute for Phase I and the National Center for Advancing Translational Science for Phase II.

In Phase I, the mixed methods research methodological significance from the perspective of integration is the step of building (Fetters et al., 2013). The intense qualitative work conducted under Phase I, Aim 1 was critical for developing and building the prototype system. The script for the engaging pathway through the interactive computer simulation benefitted substantively from target user input. Moreover, key features of the virtual human development, both voice and appearance, all the way down to hair, were also greatly informed by the initial qualitative data from focus groups.

Once the prototype had been built, a mixed methods approach using numerous qualitative and quantitative assessments ensued. These procedures, just under the third aim alone, involved focus groups of medical students and education experts about emotional response. It also involved quantitative efficacy/feasibility testing of prototype. Qualitative interviews with target users (medical students as learners as well as faculty as instructors) further informed integration as building because qualitative data collected from them informed developments that were included in the Phase II SBIR grant application and product development. Finally, quantitative data collected as users explored the simulation were used to further understand the scoring rubric, and were employed for validation of the system’s utility for assessment.

Phase II - Mixed Methods Methodology Implications

Integration through the methodological procedures occurred in Phase II as building during Part I, and merging of data in Part II (Figure 1). The building process primarily occurred in Phase I, but also involved qualitative feedback on scripts in Phase II, Part I. As illustrated by the pre-simulation examination, the scoring from first to second try during the simulation, the attitudinal scores, the qualitative reflective essays, and the quantitative scoring during the OSCE, mean that mixed methods procedures were heavily utilized. The mixed methods integration procedure of merging (Fetters et al., 2013) is evident based on the qualitative after action reviews and attitudinal scores (Kron et al., 2017).
Conclusion

This multiphase project illustrates a sustained program of mixed methods research and may inform researchers working in a variety of fields. Relative to the field of education and medical education, this line of research illustrates the use of a mixed methods RCT. Moreover, the two mixed methods phases were conducted in support of research and development of a small business under a federal funding mechanism. Finally, the study illustrates the utility of using mixed methods when applied to virtual human engineering and computer simulation. At an even more macroscopic level, it illustrates how a two-phase mixed methods line of research can be used simultaneously across multiple fields and disciplines.

Author Note

On behalf of the full MPathic-VR team:


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Various aspects of this multiphase project have been presented in multiple academic venues:


Other disclosures: Frederick Kron serves as president and Michael Fetters has stock options in Medical Cyberworlds, Inc., the entity receiving SBIR II grant funds for this project—the University of Michigan Conflict of Interest Office considered potential for conflict of interest, and concluded that no formal management plan was required.

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