Development of a Novel Consensus-Building Methodology to Design Valid Simulation-Based Medical Education-Supporting Technologies

by

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The above committee determined that the thesis is acceptable in form and content and that a satisfactory knowledge of the field covered by the thesis was demonstrated by the candidate during an oral examination. A signed copy of the Certificate of Approval is available from the School of Graduate and Postdoctoral Studies.

ABSTRACT

Industry 4.0 has introduced new combinations of technologies that have the potential to revolutionize the way in which medical education, more specifically healthcare simulation, is delivered. However, the integration of these technologies into healthcare simulation requires an interdisciplinary team to ensure that design meets the needs of medical community, from both a content and technical standpoint. The process to design simulation-supporting technologies needs to offer space for creativity due to the diverse perspectives that need to be involved while offering content validity in the final design to be deemed acceptable by the medical community. To address this, we have engineered a constraints-ideation-consensus approach based on the design-based research framework to design valid simulation-supporting technologies and have applied it to two tests cases to demonstrate how it could work, highlight strengths and weaknesses, and propose next steps.

Keywords: simulation-based medical education; consensus-building methodologies; industry 4.0; content validity

AUTHOR'S DECLARATION

I hereby declare that this thesis consists of original work of which I have authored. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

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MITHUSA SIVANATHAN

STATEMENT OF CONTRIBUTIONS

Part of the work described in Chapter 5 are presented as the following publications and has been kept it in the same format as it was when published:

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I performed the majority of the synthesis, testing of membrane materials, and writing of the manuscript.

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LIST OF ABBREVIATIONS AND SYMBOLS

CIC	constraints-ideation-consensus approach
DBR	design-based research framework
MRC	Medical Research Council framework
SBME	simulation-based medical education

Chapter 1. Introduction

1.1 Problem Statement

Industry 4.0 is a trend that uses and combines technologies in unique ways to increase production and efficiency in the manufacturing landscape (Ahsan & Siddique, 2022). The pillars which support this revolution include autonomous robots, big data analytics, augmented and virtual reality, additive manufacturing, the cloud, cyber security, internet of things, horizontal and vertical system integration, and simulation (Ibrahim et al., 2020). This paradigm shift has also cascaded over to many other fields, including the healthcare sector (Popov et al., 2022). Specifically, this sector's ultimate goal has been to increase access to better quality of care (Torralba & Katz, 2020) and so in an attempt to address this, the development of the industrial movement has been applied to medical education and training (Pandian et al., 2022). A key part of medical education and training is simulation which is an activity that attempts to replicate clinical scenarios artificially which allows trainees to develop clinical skills through deliberate practice, repetitive and focused training that does not compromise patient safety (Al-Elq, 2010). Because of the many new capabilities and modes of delivery offered by the advent of new technologies as a result of Industry 4.0, simulation-based medical education (SBME) has been significantly enhanced in the last few decades and is expected to continue to propel forward (Abdullah Mahdy et al., 2020; Herrera-Aliaga & Estrada, 2022).

While Industry 4.0 presents opportunities to create new ways in which SBME can be configured, SBME that use these technologies also need to show evidence of validity as expected by the healthcare research community before they are integrated into

educational programs. This is important because healthcare professionals who receive SBME are expected to apply what they have learned to their practice which will directly impacts quality of patient care (Howlett et al., 2014; Yauger et al., 2020). In the traditional sense, where the concepts of validity were developed through the lens of assessment tools, validity refers to how well a tool measures what it is intended to measure (Messick, 1989). Recently, this concept have been reimagined in the area of simulation innovation in light of the technology development. Specifically, for SBME-supporting technologies, validity is the degree to which they accurately achieve their intended training purpose (Gallagher et al., 2003). Typically, the tests of validity happen after the SBME-supporting technologies are built and deployed in an educational setting (Hollensteiner et al., 2018). However, validity needs to be considered during the development of SBME-supporting technologies so that evidence can be gathered to support the movement into practice more readily (Grimshaw et al., 2012). In this thesis, we propose to employ a different approach where tests of validity of the SBME-supporting technologies made using Industry 4.0 tools are built into the design process. This will be achieved by building a hybrid methodology stimulating ideation with consensus-building methods that provide validity.

Chapter 2. Theoretical Underpinnings

Hybrid methodologies are very common in the educational and clinical settings so our attempt to do this through our research presented in this thesis is not novel. For instance, Currant and colleagues (2012) created an effectiveness-implementation hybrid design to speed up translation of findings into clinical practice, create effective strategies for implementation, and provide more useful information for decision makers. Another example is an integrated approach engineered by Dubrowski and Morin (2018) for evaluating pain programs which involves merging outcome- and process-based models with models of clinical performance assessment to get a better understanding of how the program functions. To generate valid SBME-supporting technologies in today's technologically advancing society, a robust, scientific methodology suited for this dynamic environment that offers clear, detailed instructions and evidence of content validity is needed as it is currently lacking (Eppich & Reedy, 2022). What is unique in this day and age is that because different kinds of technologies are being combined in various ways for a wide spectrum of applications (Javaid et al., 2020; Marr, 2022), a team comprising of experts from disciplines in which the application touches (e.g., computer science, medicine, education, etc) must be involved in the development process to bring about an effective solution (Krause-Jüttler et al., 2022; Parti & Szigeti, 2021). The disciplines within this team should not work in a multidisciplinary fashion, this is, independently designing the simulation-supporting technology, drawing from their discipline's own knowledge and methodologies, and contributing their research to the overall project in a siloed manner (i.e., similar to how a relay race works). Instead, a team that encompasses various background should work in an interdisciplinary way whereby

all disciplines contribute their ideas to the project but in the process they learn from and about the other disciplines (i.e., similar to how a soccer game works) (Healy et al., 2022). This interdisciplinary process will allow teams to integrate their knowledge better and adapt their methods from different disciplines, creating a synergy of synthesis of knowledge and methodological approaches that facilitates the development of SBME. In sum, SBME is one of those applications that require an interdisciplinary team.

In order to build a valid SBME-supporting technology, these teams need to include input from researchers, clinical experts, computer scientists, and learners. Each of these groups employ different research frameworks and methodologies. For example, education and computer science researchers use typologies that generate creative and novel solutions such as design-based research (DBR). This framework consists of the following phases: 1) developing the instructional tool that is based on a learning theory, 2) testing the instructional tool in a classroom setting to gather feedback, 3) evaluating the instructional tool by using evidence of student learning, and 4) reflecting on the value of the outcomes provided by the instructional tool and the design of the instructional tool that led to the outcomes (e.g., theory, specific features, etc) (Scott et al., 2020). Although the outcomes of the programs that use DBR are highly innovative and creative, they may lack robust tests of validity that the medical sciences, including SBME, require. This is because tests for validity and reliability, that generate acceptable evidence for the medical system, are not built into DBR.

On the contrary, medical professionals often employ frameworks that generate clear evidence such as the medical research council framework (MRC). The MRC framework provides guidance to researchers on the process for developing and evaluating

interventions that contain several interacting components. It has four phases: 1) development - identifying evidence, theory, and processes and outcomes, 2) feasibility and piloting - testing procedures, estimating recruitment, and retention, 3) evaluation - assessing effectiveness, understanding changes, and assessing cost-effectiveness, and 4) implementation - disseminating findings, surveillance of performance of the intervention in the real world, and long-term follow up (Craig et al., 2008). Due to the very structured nature of the MRC, research conducted using this framework has little room for creativity.

Both the DBR and the MRC frameworks are similar in many ways as they both have phases that overlap in what they do. For instance, both frameworks start with designing or developing which will be the focus of this thesis. Neither the DBR or MRC framework provide any guidance on how to go about the designing or developing phase, therefore resulting in varying methods being followed for each case that undergoes these frameworks. In the modified version of the MRC framework made for SBME, Haji and colleagues (2014) articulated methods for the development phase. They break down this phase into two subphases, theory and evidence identification and intervention modeling. For the theory and evidence identification subphase, they argue that a needs assessment could support with understanding the gap that the research will address and a literature review could help with figuring out the relevant theories and concepts, the research questions, and hypothesis. For the intervention modeling subphase, they argue that the content, delivery and structure of the SBME being designed could be drafted using conceptual models and flowcharts, and research methods like focus group interviews, descriptive studies, key informant interviews, case studies and surveys (like Delphi)

could support the identification of active ingredients (i.e., mode of delivery, duration/location, instructional design, learner characteristics, etc) for the SBME being designed. For my thesis, we plan to combine methods in the design phase of DBR, such as creative problem-solving approaches, which stimulate ideation, with methods used in MRC that provide evidence about outcomes of consensus-building methods to satisfy the needs of developers and end point users in the context of SBME. Specifically, we have identified design thinking and Delphi method to support the generation and refinement ideas, and have analyzed both methodologies to see what elements of those could be useful for the purposes of creating valid SBME-supporting technologies.

2.1 Design Thinking

Design thinking is a design methodology that came about in the 1980s and its concepts were primarily used in the business, engineering, and architecture fields before they became more widely used by others in the 2000s (IDEO Design Thinking, 2018). It is defined as a non-linear and iterative solution-based approach used by teams to solve complex problems that are ill-defined or unknown (What Is Design Thinking?, 2022). The process can be broken down into five phases: empathize, define, ideate, prototype, and test (Figure 1). In the empathize phase, time is spent understanding the human needs involved and engaging and observing with people on an emotional and psychological level through interviews. The second phase is called define and this is where designers work with people to frame the problem in a human-centric way until they end up with a clear problem statement. Once a good understanding of the problem is achieved, creativity is unleashed and as many solutions as possible are brainstormed without judgement in the ideate phase. At the end of the ideate phase, the ideas are then classified

as either valid, absurd, or promising to help with selecting ideas that can move forward to the subsequent phases. Prototype is the fourth phase, which is about turning the solutions into tangible prototypes, scaled-down versions of the final product, to tease out any constraints and flaws. The solutions at this stage may be accepted, rejected or revised depending on how the prototypes fare. After the prototypes have been built, it undergoes the test phase. This phase may ultimately lead the designers to take the prototype back to previous phases in order to integrate any feedback and new insights garnered (What Exactly Is Design Thinking? (Updated Guide for 2022), 2021). The empathize and define phases can be classified as preparation, which leads to intuition (also known as ideation), and then the solutions undergo validation by the prototyping and testing phases (Figure 2).

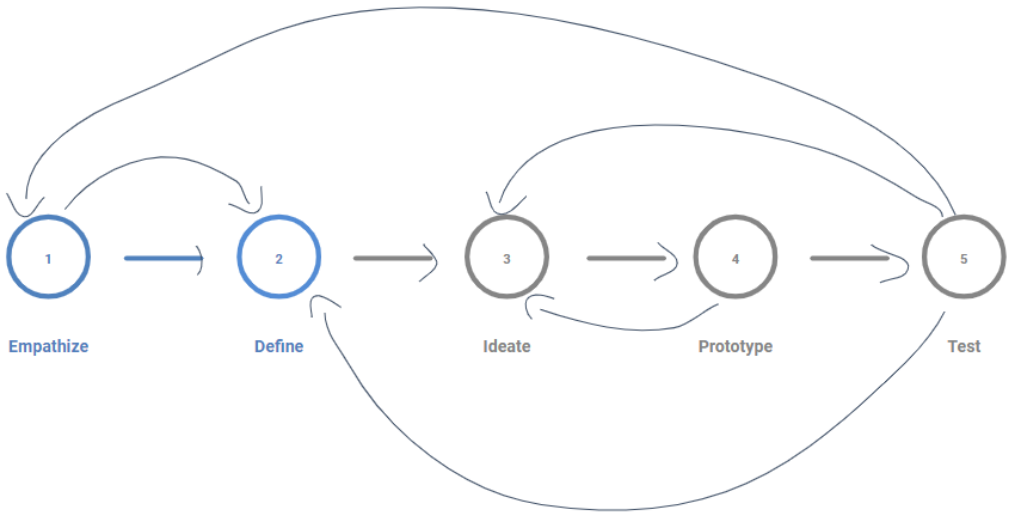

Figure 1: Design thinking process. (A. Quevedo, personal communication, April 22, 2022)

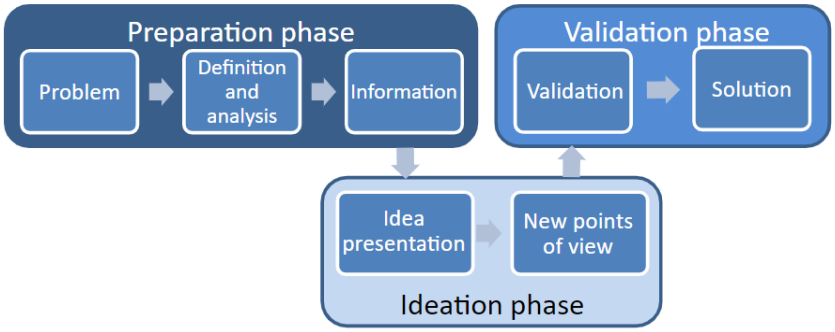

Figure 2: Preparation, ideation, and validation groupings of design thinking phases (A. Quevedo, personal communication, April 22, 2022)

Although design thinking is a single, efficient way to end up with actionable results relatively quickly (Storey, 2020), it does not generate the same quality of evidence of content validity that SBMEs, governed by the medical research community, requires. Medical research is ranked according to their rigor, strength, and precision of results obtained using specific research methods relative to the hypothesis regarding the efficacy of the tested intervention (Burns et al., 2011). The ranking scheme is referred to a pyramid called the evidence hierarchy which depicts the level of content validity of research methods, with increasing content validity from the bottom to the top of the pyramid (NHMRC, 2013). Content validity is measured is by gathering knowledge from experts in the field on how the relevant construct in the given context is (Andreatta & Gruppen, 2009).

In design thinking, validation occurs in 1) the prototype phase where ideas are made into tactile representations of the solution and provided to the designing team internally for feedback, and 2) the test phase where the prototypes are tested by end point

users for feedback before the finalization of the solution (Design Thinking 101, 2016). These phases do not address validity in a fashion that medical researchers accept as described earlier. We propose that during the prototype and testing phases in design thinking where ideas are synthesized into a solution, it is important to gather feedback from content experts to achieve content validity in the solution that would satisfy the medical sciences field. To address this, we propose that these two phases of the design thinking be substituted with a well-established method that can offer content validity to the solution, and this will be a Delphi method (Figure 3).

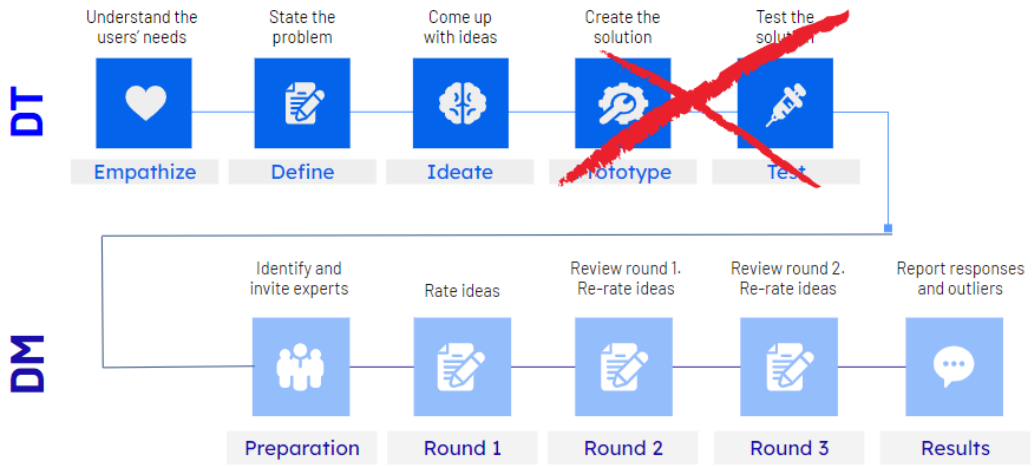

Figure 3: Design thinking and Delphi method

Abbreviations: DM= Delphi method; DT=design thinking

2.2 Delphi Method

The Delphi method was initially created for business forecasting using an interactive discussion among an expert panel, presuming that group decisions are more useful than individual ones (Nasa et al., 2021). Today, it is defined as a structured group

communication process that seeks to gather information and achieve consensus from a panel of experts using iterative survey questionnaires (Dalkey, 1969). This approach is commonly used in medical research because it provides enough content validity to be considered on par with meta-analyses, intervention studies and correlation studies ("Acute Pain Management: Operative or Medical Procedures and Trauma, Part 2. Agency for Health Care Policy and Research," 2020; Jorm, 2015). The way in which it works is through 'rounds' where experts are asked their opinion on a specific topic. The questions in each round are structured based on the results of the previous round (Barrett & Heale, 2020). Experts are also provided results from the previous rounds to allow for reflection on the anonymous viewpoints of other experts which may trigger them to reposition their answer in subsequent rounds (Keeney et al., 2006). Finally, to assess movement between rounds as a gauge of both stability and convergence of expert opinions, mean and standard deviation are used as quantitative evidence (Greatorex & Dexter, 2022). This kind of evidence is what provides validity favored by the healthcare system.

Chapter 3. General Research Methods

In this chapter, we will present the general hybrid methodology or approach taken and in Chapter 5 of the thesis, we will describe how it has been applied in two different studies. To recap, the proposal is to follow a unique approach that uses a combination of elements from design thinking in which its outputs will funnel into Delphi method to be narrowed down by experts into a single validated SBME-supporting technology design. However, prior to the design thinking portion of the process, a number of constraints must be identified and articulated to the participating stakeholders to guide the direction of the two methods. Once this is established up front, the methods will ensue. Next we will use design thinking to generate ideas within the proposed constraints; however the last two phases, prototype and test, will be replaced by a Delphi method.

That is, the Delphi method will be used as an iterative process to offer content validity to the ideas generated from the design thinking process, specifically the output of the ideate phase. Specifically, the ideas from the design thinking will serve as the initial parameters for the process (Martino, 1983) and will be posed as questions for the first round in the Delphi method that will ask experts to provide their input regarding the value of including the ideas as a part of the final solution. The predefined questions render this technique as a modified Delphi methodology as with the standard methodology, experts are asked open-ended questions to gather specific information on a topic (Custer et al., 1999). To summarize, the proposed approach to design SBME-supporting technologies is to first consider constraints, then to come up with ideas using design thinking and finally, to leverage the consensus on a single idea of experts on the topic of interest. Collectively,

this novel hybrid approach will be referred to as the constraints-ideation-consensus (CIC) approach (Figure 4).

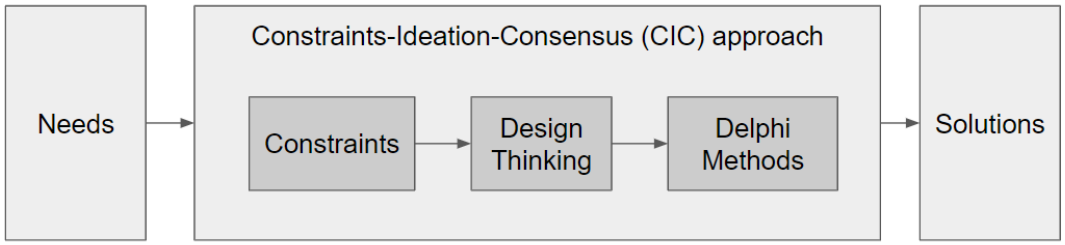

Figure 4: CIC Approach

The CIC method aims at the development of content for valid and reliable SBME-supporting technologies. As is, it is part of a larger programmatic research framework rooted in educational sciences called DBR. As described in the introduction section, the DBR framework aims to develop solutions to real life problems by engaging in iterative design phases and cycles to generate new knowledge and to improve educational practices or instructional tools (like SBME-supporting technologies) (Reeves, 2005). The DBR framework conceptualization we are interested in consists of four phases: design, test, evaluate, and reflect (Figure 5).

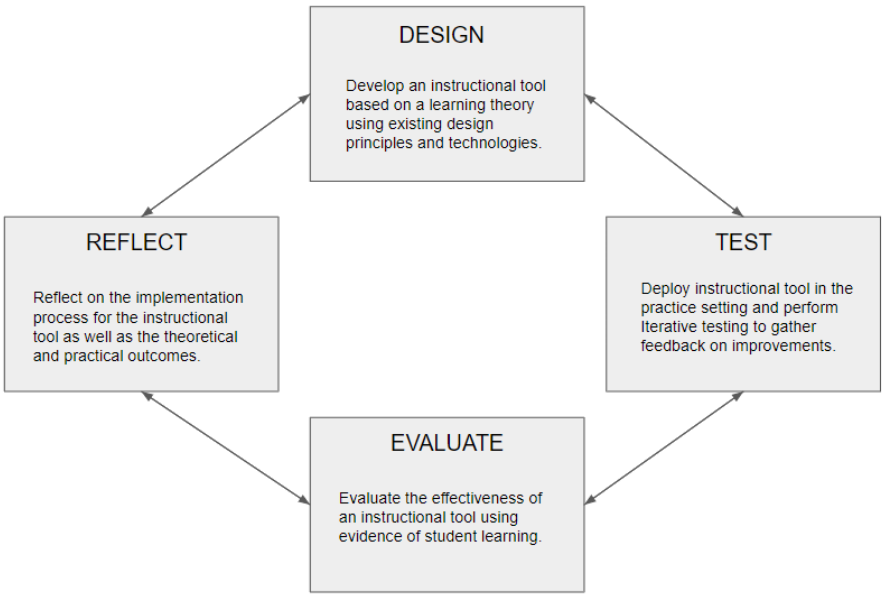

Figure 5: DBR framework

This thesis is situated in the design phase which involves developing instructional tools that address a problem but embody an underlying learning theory. The instructional tool is expected to produce experiences or materials that can be used to see if learning objectives have been met. The test phase involves testing the instructional tool by putting them in the classroom setting to see how they would perform in the real-life setting. The evaluate phase involves evaluating the effectiveness of the instructional tool using evidence of learning. The reflect phase involves a retrospective analysis of the instructional tool: 1) how did the theory support the research for the instructional tool?, 2) did the instructional tool support learning?, and 3) what are the features in the instructional tool that supported the learning (Scott et al., 2020)?

Chapter 4. Thesis Objectives

This research is situated in the design phase of DBR. The process underpinning the design phase consists of three steps: 1) to identify constraints consisting of the applicable learning theories and existing design principles (Reeves, 2007), 2) to identify or develop the research tools or methods using design thinking and Delphi method, and 3) to design the intervention content which is the simulation. To see if the idea of the CIC approach would be appropriate to move into testing, a feasibility study is required (Bowen et al., 2009). Feasibility studies are used to help researchers see if the proposed methodology, like the CIC approach, could be further shaped to be relevant and sustainable. In other words, it is an assessment to see if the proposed methodology is practical and viable for future implementation. It may also bring to light the changes to the research methods being employed and how they may occur. An example of a change could be due to the identification of possible issues that may arise from the proposed methodology (Bowen et al., 2009). Therefore, the focus of this thesis is to conduct a feasibility study of the CIC approach in the context of SBME-supporting technologies. The main research question, as a result, will be framed as what is the feasibility of the CIC approach to design technology/solutions to support the delivery of SBME in different contexts? The focus of the feasibility study will be acceptability, that is, how do the endpoint users react to this proposed methodology (Bowen et al., 2009). To understand the acceptability, two sub-questions supporting the main research question can be posed: 1) does the proposed methodology offer content validity that the medical community is looking for? and 2) does the medical community feel that this proposed methodology could be used in the future?

To answer the main research question and the subquestions, we used two test cases to undergo the design phase of the DBR using the CIC approach: test case 1 dealing with the acquisition of psychomotor skills, which is composed of cognitive and motor skills (Schmidt, R. A., & Lee, T., 2011), and test case 2 focusing on developing cognitive and affective skills. Test case 1 seeks to design anatomically-correct and affordable physical simulators to remotely train paramedics-in-training the intraosseous infusion (IO) access and infusion skill in the adult proximal tibia. Test case 2 seeks to design a virtual reality (VR) simulation to help nurses understand and mitigate moral distress due to workplace stressors. Designing SBME-supporting technologies for test case 1 and test case 2 using the CIC approach will provide evidence on 1) the content validity of the resulting SBME-supporting technology and 2) the perceptions of the CIC approach for future designing of SBME-supporting technology use by co-developers involved in the process. The hypothesis is that test case 1 and test case 2 using the CIC approach, as they go through the design phase of the DBR, will yield valid SBME-supporting technologies and the process will be rated as practical and sustainable by the co-developers of the SBME-supporting technologies.

Chapter 5. Test Cases

This chapter will describe the application of the CIC approach in the design phase of the DBR framework using two test cases. The test cases are presented as publications.

5.1 Test Case 1 – Development of Simple and Advanced Adult Proximal Tibia Simulators for a Decentralized Simulation-Based Education Model to Teach Paramedics-in-Training the Intraosseous Infusion Procedure

Abstract

Introduction: During the COVID-19 pandemic, public health had advised practicing social distancing which led to the temporary shutdown of simulation laboratories or centralized simulation-based education model, shared spaces that healthcare workers such as paramedics use to train on important hands-on clinical skills for the job. One such skill is intraosseous (IO) access and infusion, the delivery of fluids and medication through the marrow or medullary cavity of the bone which provides fast and direct entry into the central venous system. This skill is critical in emergencies when peripheral access is not immediately available. To continue the training of paramedics in life-saving skills like IO infusion in the post-pandemic era, a decentralized simulation-based education (De-SBE) model was proposed. The De-SBE relies on the availability of inexpensive and flexible simulators that can be used by learners outside of the simulation laboratory. However, to date, there is a paucity of simulation design methods that stimulate creativity and ideation, and at the same time, provide evidence of validity for these simulators. Our exploratory research aimed to test a novel approach that combines components of development-related constraints, ideation, and consensus (CIC) approach to develop and provide content validity for simulators to be used in a De-SBE model.

Materials and methods: The development of the IO simulators was constrained to follow a design-to-cost approach. First, a modified design thinking session was conducted with three informants from paramedicine and medicine to gather ideas for the

development of two IO simulators (simple and advanced). Next, to sort through, refine, and generate early evidence of the content validity of the simulators, the initial ideas were integrated into a two-round, modified Delphi process driven by seven informants from paramedicine and medicine. In addition, we surveyed the participants on how well they liked the CIC approach.

Results: The CIC approach generated a list of mandatory and optional features that could be added to the IO simulators. Specifically, six features (one mandatory and four optional) for the existing simple IO simulator and eight (three mandatories and five optional) for the advanced IO simulators were identified. Following a design-to-cost approach, the features classified as mandatory for the simple and advanced IO simulators were integrated into the final designs to maintain the feasibility of production for training purposes. The surveys with the participants showed that the CIC approach worked well in the group setting by allowing for various perspectives to be shared freely and ending with a list of features for IO simulator designs that could be used in the future. Some improvements to the approach included flagging for potential users to determine what works best concerning the mode of delivery (online or in person), and duration of the stages to allow for more idea generation.

Conclusion: The CIC approach led to the manufacturing of simple and advanced IO simulators that would suit a training plan catered to teach the IO access and infusion procedure decentrally to paramedics-in-training. Specifically, they have been designed in a manner that allows them to be made easily accessible to the trainees i.e., low costs and high mobility, and work cohesively with online learning management systems which further facilitates the use of a De-SBE model.

Keywords: pediatric emergency medicine, pediatrics, emergency medicine, additive manufacturing, three-dimensional printing, simulation-based medical education, intraosseous infusion, simulator, training, 3d-printing

5.1.1 Introduction

During the COVID-19 pandemic, to keep people safe from the infectious disease, public health entities advised social distancing [1]. Unfortunately, this practice led to unintended consequences in the training of healthcare workers [2]. For example, paramedics-in-training could no longer train in simulation laboratories, spaces where they congregated with educators to learn and teach essential psychomotor skills such as intraosseous (IO) access and infusion. Since simulation laboratories, referred to here as a centralized simulation-based education (Ce-SBE) model, were no longer appropriate during the COVID-19 pandemic, an alternative model, known as a decentralized simulation-based education (De-SBE) model, was needed to continue the training of healthcare workers. Decentralized simulation-based education refers to a model where learners can practice clinical, hands-on skills outside of the simulation lab such as in their own homes or other locations that allow for social distancing. The need for this model was specifically heightened during the COVID-19 pandemic as increasing numbers of hospitalized cases and fatalities due to the virus demanded support far greater than the number of trained healthcare workers available [3]. The development of a De-SBE model would potentially lead to uninterrupted training, reduced training costs, and offer students a unique opportunity to customize their learning according to their own needs and pace, which is called mastery-based learning [4].

In the post-pandemic era, the De-SBE model can help us optimize the Ce-SBE model to train paramedics-in-training (and other healthcare professionals). For example, current mastery-based simulation programs cannot be offered to students due to human (i.e., trainers) and equipment (i.e., simulators) resource constraints. It is believed that some of these potential benefits of the proposed De-SBE model would be retained in the post-pandemic landscape to complement the traditional ways of training [5].

The key elements of De-SBE are the availability of inexpensive and flexible simulators [2], instructions, motivation, and feedback for remote trainees [5]. The current report deals specifically with the methods underpinning the design of inexpensive and flexible simulators for De-SBE. The work is situated in the initial phases of the design-based research methodology [6]. Because the design of these simulators requires communication between designers, clinical educators, and simulation technologists the methodology underpinning the development must be accepted by all stakeholders. In particular, the designers favor methods, such as design thinking [7] that emphasize the generation of ideas and prototypes. On the contrary, clinical educators are mostly concerned with the content validity of the simulators (content validity is defined as the representation of currently available knowledge on a construct of interest [8]). Finally, simulation technologists are mostly concerned with the costs of simulation. Here, we propose a hybrid methodology that combines elements of crowdsourcing of ideas/solutions with a methodology that generates evidence of validity by leveraging consensus-building methods, and finally, puts financial constraints on the design process by using design-to-cost approaches.

Therefore, this technical report aims to describe this hybrid methodology exemplifying how it works in the context of the development of IO simulators for paramedic training and assess the acceptability of this hybrid method by participating groups of stakeholders.

5.1.2 Procedure

Based on the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2, Article 6.11, this work was qualified as a research tool and protocol development [14]. The local Research Ethics Board granted an exemption and issued approval (approval no.: 241-2122).

The simple and advanced IO models in the scope of this project were previously created by the development team and considered good educational tools requiring a few minor adjustments by clinicians and medical trainees [15,16]. Based on this feedback, to develop these existing IO simulators further yet appropriately for the De-SBE model, a process was required that could facilitate ideation while providing content validity. To fulfill this need, a modified design thinking process to generate ideas followed by a modified Delphi methodology to gather content validity of those ideas was conducted with a group of experts in the IO infusion and access skill to re-develop the IO simulators for the De-SBE model.

5.1.2.1 The Constraints-Ideation-Consensus (CIC) Approach

The CIC approach consists of three major methodological approaches. First, after the initial needs have been articulated, a set of constraints need to be put on the design process. Typically, these are related to design-to-cost and design-to-value. Design-to-cost

refers to the optimization of the total costs of a product through its design which in the context of simulation can be through sacrificing the realism as demonstrated by our development team through the creation of affordable take-home simulators [2]. Design-to-value, on the other hand, is making sure to deliver the best possible value to the endpoint user through the product without much regard for the costs [17].

Next, once these constraints have been identified, a design thinking process can be used in the ideation phase. Design thinking originates from engineering and business fields, and it is an iterative and non-linear process used to generate innovative solutions creatively and collaboratively with a team that could be multidisciplinary. It comprises five phases: empathizing, defining, ideating, prototyping, and designing [7]. However, in the context of healthcare professionals' education, all educational interventions need to be evidence-based. More specifically, when simulators are built, at a minimum they must show evidence of content validity to ensure that they can serve as educational tools [18]. One way to gather this evidence is by systematic documentation of content expert opinions about the validity of these simulators to serve educational purposes [19]. However, the design thinking process does not provide this type of evidence. Hence, we propose that only the first three phases (empathize, ideate, and define) of the design thinking process be used with a group of individuals, hereafter referred to as informants, to generate the ideas. Next, we propose to replace the last two phases, prototype, and test, with a Delphi method to harness the expert consensus in a fashion that is acceptable to clinical educators. Therefore, to further clarify and gather evidence regarding the content validity of the solutions, a Delphi methodology was used. Delphi methodology is a structured technique used to determine consensus among informants on a solution to a

complex problem. In this context, the Delphi methodology was modified as the informants were provided the solutions from the modified design thinking process for their input and to converge on, rather than starting with open-ended questions to solicit solutions [20]. Collectively, this hybrid approach to development will be referred to as the CIC approach (Figure 1).

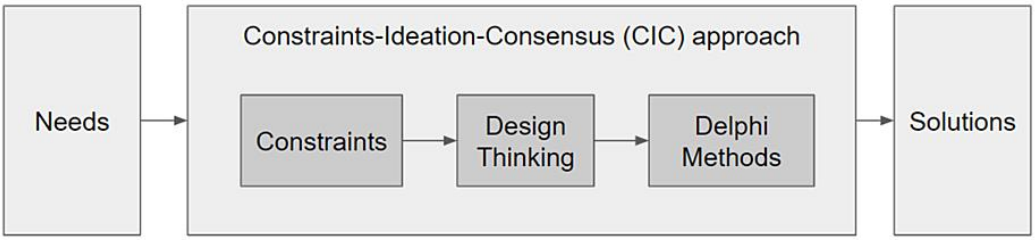

Figure 1: The CIC approach

CIC: Constraints-ideation-consensus

To test the CIC approach, we selected the development of two IO simulators. We assessed the products as well as surveyed participants who helped with the development to express their opinions about the acceptability of the CIC approach.

5.1.2.2 Participants

In total, seven participants (i.e., designers, practicing paramedics, and educators) took part in the development process. Three of the seven were involved in the modified design thinking process and all seven informants participated in the modified Delphi methodology. Six were paramedics of which three were from the Region of Durham Paramedic Services (Oshawa, Ontario, CA), one from Durham College (Oshawa, Ontario, CA), one from Lakeridge Health Hospital (Oshawa, Ontario, CA), one from the

University of Toronto (Toronto, Ontario, CA), and one from Sunnybrook Hospital (Oshawa, Ontario, CA). One was a medical doctor and was affiliated with Madrecor Hospital (Brazil), Memorial University of Newfoundland (Newfoundland, Ontario, CA), and Ontario Tech University (Oshawa, Ontario, CA). All seven had experience performing the IO access and infusion procedure in the proximal tibia in adult patients. Furthermore, the design process was facilitated by a designer and a simulation expert from Ontario Tech University.

5.1.2.3 Constraints

A design-to-cost approach served as a constraint for the development process to create affordable IO simulators under $15 for a simple version and $100 for an advanced version. Note that these are production costs and do not incorporate design-related costs.

5.1.2.4 Modified Design Thinking Process

The modified design thinking process ran as a two-hour video conference call through Google Meet (Google Inc., Mountain View, California, USA) and comprised two paramedics and one medical doctor. During the modified design thinking process, the informants were asked to 1) empathize with the designers and understand the need to improve the two IO simulators, 2) clearly define the problem, and 3) brainstorm ideas that would address the need and solve the problem. During the empathize phase, the informants were given the learning objectives of the IO simulators: the simple IO model is to be redesigned, if necessary, to teach the epitome of the IO skill, and the advanced IO model, would be updated to incorporate additional elements that would make the simple

IO model more challenging. All of the ideas during the modified design thinking process were captured on a Google Jamboard.

5.1.2.5 Modified Delphi Methodology and Analysis

The ideas that resulted from the modified design thinking session were carried over into a modified Delphi methodology to gather expert consensus on the ideas for improvements to be made to the simple and advanced IO simulators. Seven informants participated in the modified Delphi rounds. The activity was hosted in Google Forms and completed by the informants remotely over two weeks. In the first round, the informants were asked to rank the ideas from the modified design thinking process based on the importance of including the ideas in the final design of the simple and advanced IO simulators using a Likert scale of one to five, where one was considered very unimportant and five was considered very important. Ideas that received an average rating of 3.5 or above were considered important to include while ideas that received an average rating below 3.5 were considered unimportant to include in the final design of the simple and advanced IO simulators [21]. Variability in responses was examined using standard deviation (SD), and ideas that had an SD of 1 or greater were considered for the subsequent modified Delphi round as they indicated low levels of agreement amongst informants on the importance of including the idea in the final design of the simple and advanced IO simulators [21]. To help with the interpretation of the SD values, comments provided through open-field text boxes after every idea were also assessed. Based on this algorithm, ideas requiring further clarification from the informants due to lack of consensus were rephrased and reinstated in the second modified Delphi round. However, the majority of the ideas in the second modified Delphi round were structured as

multiple-choice questions, requesting informants to classify the ideas as “mandatory”, “optional/nice-to-have”, or “not required”. This approach was followed because most of the comments provided by informants in the first modified Delphi round naturally offered a similar classification of the ideas using terms such as “mandatory”, “optional/nice-to-have”, or “not required”. Therefore, this format was used to confirm the inclusion or exclusion of tangible ideas into the simple and advanced IO simulators. Abstract ideas that could not be physically represented in the simple and advanced IO simulators that needed revisiting in the second modified Delphi round followed the Likert scale layout used in the first modified Delphi round. The modified Delphi methodology was concluded in two rounds.

5.1.3 Results

5.1.3.1 Results of the modified design thinking process

During the modified design thinking process, 14 ideas from three informants were offered on how to improve the simple and advanced IO simulators. The ideas noted in the Google Jamboard from the modified design thinking process have been presented in Table 1. These 14 ideas were used as the starting point for the modified Delphi methodology.

Simple IO Simulator	Advanced IO Simulator
Provides resistance when performing the IO technique on it	Bends and laterally exposes the tibia (e.g., 360-degree swivel on the superior end so that we can also move the leg and position it on the table)
Simulates the bone marrow (e.g., in the hollow space of the bone, place a sponge and add liquid to it)	Made longer from the knee down
Demonstrates people of different weights (i.e., make simple IO models with varying skin thicknesses)	Has skin that is more realistic than the simple IO model (e.g., skin is textured with pores and hair, different skin colors, etc)
Demonstrates different scenarios/contraindications (e.g., simple IO models with bone fractures, skin infections, etc.)	Has resistance to flow coming either from a syringe or an IV bag (e.g., in the model, incorporate a Luer lock adaptor that you could hook IV tubing up to the back which could stay hidden inside of the model to fill it with red liquid, and then when the IO is established, there would be positive feedback and the ability to run fluids/push meds)
Includes a portion of the calf to help with landmarking (e.g., use a sponge to surround the top of the bone)	Has skin that could show infiltration (e.g., use a bladder pump to show how if you miss the bone during the IO procedure, the space under the skin would fill up with liquid and bubble up)
Made with different densities so that when you insert the needle, it goes in more easily or not? (e.g., make the bone softer for young people, make the bone thinner for 65+, etc.)	Is a full leg
	Shows the muscle/anatomic contours of the leg better than it does now (e.g., create a snug "sleeve" to serve as the skin to slide over the top of the muscle/bone structure of the model)
	Has a bigger patella than what we already have in our model (see the pictures/video above) and be made mobile (e.g., all the other bones in the model are fixed while the patella is made separately to fit in and could give way when you feel for it to help with landmarking).

Table 1: Ideas generated from the modified design thinking process with three informants

IO: Intraosseous, IV: Intravenous

5.1.3.2 Results of the modified Delphi methodology

In round one of the modified Delphi methodology, seven informants were sent a survey with the 14 ideas created in the modified design thinking process in the form of questions to rank their importance to include in the simple and advanced IO simulators using Likert scales (Table 2). For each of the ideas, informants were provided an option to add comments, questions, and/or suggestions through free-text fields. In round one of the modified Delphi methodology, all seven informants responded.

No.	Question
Simple IO Model	
1	How important is it that the simple IO model: Provides resistance when performing the IO technique on it?
3	How important is it that the simple IO model: Simulates the bone marrow? (e.g., in the hollow space of the bone, place a sponge and add liquid to it)
5	How important is it that the simple IO model: Is designed to demonstrate people of different weights (i.e., make simple IO models with varying skin thicknesses)?
7	How important is it that the simple IO model: Is designed to demonstrate different scenarios/contraindications? (e.g., simple IO models with bone fractures, skin infections, etc)
9	How important is it that the simple IO model: Includes a portion of the calf to help with landmarking? (e.g., use a sponge to surround the top of the bone)
11	How important is it that the simple IO model: Is made with different densities so that when you insert the needle, it goes in more easily or not? (e.g., make the bone softer for young people, make the bone thinner for 65+, etc)
13	Please provide any OVERALL comments/suggestions/questions for the simple IO model
Advanced IO Model	
14	How important is it that the advanced IO model: Is able to bend and laterally expose the tibia? (e.g., 360-degree swivel on the superior end so that we can also move the leg and position it on the table)
16	How important is it that the advanced IO model: Is made longer from the knee down?
18	How important is it that the advanced IO model: Has skin that is more realistic than the simple IO model? (e.g., skin is textured with pores and hair, different skin colors, etc)
20	How important is it that the advanced IO model: Has resistance to flow coming either from a syringe or an IV bag? (e.g., in the model, incorporate a Luer lock

	adaptor that you could hook IV tubing up to the back which could stay hidden inside of the model to fill it with red liquid, and then when the IO is established, there would be positive feedback and the ability to run fluids/push meds)
22	How important is it that the advanced IO model: Has skin that could show infiltration? (e.g., use a bladder pump to show how if you miss the bone during the IO procedure, the space under the skin would fill up with liquid and bubble up)
24	How important is it that the advanced IO model: Is a full leg?
26	How important is it that the advanced IO model: Shows the muscle/anatomic contours of the leg better than it does now? (e.g., create a snug "sleeve" to serve as the skin to slide over the top of the muscle/bone structure of the model)
28	How important is it that the advanced IO model: Has a bigger patella than what we already have in our model (see the pictures/video above) and be made mobile? (e.g., all the other bones in the model are fixed while the patella is made separately to fit in and could give way when you feel for it to help with landmarking).
30	Please provide any OVERALL comments/suggestions/questions for the advanced IO model.

Table 2: Modified Delphi round one survey questions

IO: Intraosseous, IV: Intravenous

The averages and SDs of these 14 questions along with their comments are provided in Table 3. Two out of 14 questions i.e., questions 14 and 22, reached unanimity (SD of 0.76 and 0.9) amongst the informants. Specifically, they agreed that it is important to update the advanced IO simulator so that it 1) is able to bend and laterally expose the tibia (i.e., have a 360-degree swivel on the superior end so that the leg can be moved and positioned on a flat surface), and 2) has skin that could show infiltration (e.g., use a bladder pump to show how if the bone is missed during the IO procedure, the space under the skin would fill up with liquid and bubble up). Therefore, these questions were deemed resolved for modified Delphi round one, noted as features to include in the updates to the simple IO simulator, and were not revisited for modified Delphi round two. The rest of the questions in the modified Delphi round one scored below the threshold and had high variabilities. Using the commentaries of the informants in the free-text field, these

questions either needed revising for further clarification in round two due to mixed opinions or were discarded as the overall notion of the comments suggested that the feature presented in the question was unimportant to include in the updates of the simple IO simulator (Table 3).

Question #	Average	SD	Comments
			Simple IO Model
			The IO model must provide strength to simulate real anatomical parts.
			The leg is movable during the procedure and the thigh must rotate externally for proper landmarking and insertion. With the piece being fixed the paramedic will have to adjust their angle to ensure they are inserting on a 90 degree angle.
			There has to be transitional resistance - as the needle goes through the skin, then at the bone, then as the needle is advanced through the bone and finally a loss of resistance when the needle enters the bone matrix to indicate correct placement.
			Very important - this is possibly the most important part of this trainer as the point is to realistically simulate the skill.
			tactile feel for performing the skill is important for learning
1	4.43	1.13	I do not think that the simple model requires skin. I feel it is important to understand bone anatomy on its own. The advanced model should incorporate skin, muscle, subcutaneous tissues.
			Bone marrow is very important. When inserting a needle into a long bone, the contents within the bone marrow must be aspirated and visualized for the procedure to be considered successful.
			I think this provides excellent feedback and is a reminder you may need to hook a pressure infuser up to be able to run fluids rapidly to work against the added pressure.
3	3.71	1.5	This is where the model starts to change. The simple IO model is a good tool for the initiation of the IO. The addition of a sponge/fluid etc is nice for the advanced use of the tool in providing fluid or medication administration. It is not required for the initiation.

			Less important, but when developing the muscle memory of the skill it would be ideal. This is often a failure point when performing the skill in real life (Forgetting to flush the IO after needle insertion) so the more realistic the better.
			Would be a bonus to have marrow you could draw back but I don't think as important as other aspects
			Many of my successful IO placements have not had positive results for aspiration of marrow.
			In my experience, the patient's weight does not affect the procedure at all.
			This will allow proper needle selection
			Not really significant to me
			This is less important in my opinion, but the more variety the better. Especially if you can realistically recreate the feeling of proper landmarking.
5	2.57	1.27	This would be a nice added bonus for training and for determining size of needle to use, but not essential
			This would be interesting to expand the content taught and learned.
			I think that is unnecessary
			Less important in my opinion. We must discuss these verbally.
7	2.14	1.07	I dont feel this is an important consideration
			Palpable bony areas are much more important
			Creates more realism
			The landmarking starts from the tibial tuberosity, not the calf. It depends on what the model is being created for? If it's just an IO initiation tool, then no, if it is more a part of a full simulation and patient care, then maybe.
			The more realistic and complete the model, the better.
9	2.71	1.38	My first thought with the picture is to extend it to be longer. I think this is important for landmarking and as well for more realistic training
			This is very important and helps to demonstrate that different ages should be treated in different ways and with different strengths.
11	3.14	1.46	I think different sizes would be better, and more focus on how the pediatric/neonatal bone feels like, recreating the density of that bone. Neonates are the most difficult to landmark, small bones and lots of adipose.

			Bone density will not change that much. The bigger value would be in alternate sizes of IO to emulate infant, child, adolescent and adult.
			Similar to the "different weight" option - nice, but not a need to have
			Would be a nice added feature as well.
			Realism is key to success in simulation and learning, as well as being able to reuse the same product. A removable insert would be ideal as we have up to 350 medics passing through CE, that's 350 pokes.
13	N/A	N/A	My main question about the simple vs advanced IO model is that it would be good to know how you see these two different models being used and what the goal is for each model. The most important thing I think from a training perspective is feel and ensuring that the feel is as realistic as possible. The other stuff is an added bonus if possible to incorporate.
Advanced IO Model			
			I believe the most interesting thing is the flexion of the thigh and not the rotation.
			Being able to actually manipulate the joint would be nice
14	4.29	0.76	This seems like a key design feature to this advanced model.
			I think this would be a waste of time to build and also a waste of material and money. The area around the patella is more than enough to train.
			maybe nice in a full simulation and advanced IO training, but not required for IO initiation only.
			Same as above - if making an advanced model, it should be as realistic and whole as possible.
16	3.86	1.07	Or insert into a hollowed out leg portion on full leg or mannequin.
			This is cool, and it brings more realism.
			Less important, but would certainly be nice if not too expensive to reproduce.
18	2.86	1.35	I don't think this stuff is necessary but one comment is that the skin should be realistic in that there is generally very thin skin over the tibial area where landmarking occurs so making it anatomically realistic is important
			Resistance must come from the outside to the inside (saline bag) and not from inside the bone.
20	3.71	1.11	Same as the simple IO model response. It depends on what the tool is being used for.

			I think this would be a good feature
			probably not important but would be a nice feature
			This would demonstrate a kind of iatrogenics and it would be very interesting if the simulator could simulate this as well.
			Not sure.
			Again a great feature, but not necessary. As an example, you could design the bone to show that it was correctly placed, and the lack of feedback there would show that it is in the incorrect spot.
22	4.14	0.9	I was thinking about this in the simple model - but would make sense that this is a part of the advanced model if it is realistic and reasonable to do
			I believe this would be a waste of time and money.
			The more complete the model the better
			Not necessary
24	3	1.15	Or inserted into a full leg.
			Bone palpation is much more important. But OK.
26	3.57	1.4	For an advanced model - the more realistic, the better
			Having a big or small patella doesn't matter. But it must be palpable enough so that the anatomical area can be recognized by the doctor's hand.
			Patella does not play a role in the landmarking or procedure
28	3.29	1.5	For an advanced model - the more realistic, the better
30	N/A	N/A	Would be good to add in additional features to the advanced model. I think feeling for infiltrate in the calf area and some resistance to pushing fluids would be important clinical applications.

Table 3: Modified Delphi round 1 average, standard deviations, and comments

SD: Standard deviation, IO: Intraosseous, N/A: Not applicable, CE: Centralized education

Through the comments, some informants strived to determine the appropriate learning objectives of both the simple and advanced IO simulators and offered suggestions. One such idea was that “the simple IO model would be a good tool for the

initiation of the IO while the advanced model would be a good tool in providing fluid administration". Informants agreed that the "loss of resistance" is appropriate to learn from the simple IO simulator as a first step, and then "the aspiration of bone marrow" could be looked at secondarily, possibly in the advanced IO simulator as the next step. The inclusion of the different weights of individuals through varying skin thickness, bone densities according to age, and contradictions (e.g., bone fractures, skin infections, etc.) in the simple IO simulator, and for the advanced IO simulator, the addition of hair, textured skin, and skin colors as well as making the contours of the leg more visible was generally perceived to be insignificant to the procedure but noted to augment the realism. When asked about the lengthening of either the simple IO simulator or the advanced IO simulator beyond the knee to help with landmarking (i.e., either a portion of the calf or a full leg), the informants, again, mentioned that this would also contribute to the realism, but emphasized that the tibial tuberosity is where the landmarking starts and making that region of the simulator palpable would be more important. Finally, for the advanced IO simulator, the average of 3.71 for question 20 indicated that informants agreed that including the resistance to flow coming from either a syringe or IV bag would be a necessary feature to have. However, an SD of 1.11 and the comments for this question suggested heterogeneity in opinions, warranting revising and reexamination of the question in modified Delphi round two. In summary, based on the ratings, distribution of ratings, and comments on the questions in modified Delphi round one, many of the questions needed to be adjusted in order to clarify the updates required to be made to both the simple and advanced IO simulators to increase their effectiveness in teaching the IO access and infusion procedure.

In round two of the modified Delphi methodology, the same seven informants who participated in modified Delphi round one were sent a survey with a combination of new and revised questions based on the results from modified Delphi round one (Table 4). The modified Delphi round two questions were structured in two different ways. New questions concerning the learning objectives of the simple and advanced IO simulators asked informants to rate their importance using a Likert scale similar to the modified Delphi round one. These new questions were made specifically to obtain consensus on the learning objectives from all the informants as the majority of the informants did not partake in the modified design thinking process to weigh in. As a result, during round one, most of the informants made comments about the learning objectives, not in response to any particular question, suggesting that the learning objectives needed clarification. Based on the thematic analysis conducted on the modified Delphi round one results, some of the comments classified the possible ideas to include as updates to the simple and advanced IO simulators as either "mandatory", "optional/nice to have", or "not required". To confirm what features to include in the simple and advanced IO simulators, all informants were asked to classify the ideas as "mandatory", "optional/nice to have", or "not required" through a multiple-choice format in round two. Similar to the modified Delphi round one survey, informants were provided an option to add comments, questions, or suggestions through free-text fields in the modified Delphi round two. In round two of the modified Delphi methodology, all seven informants responded.

No.	Question
Learning Objectives	
1	The simple IO model should focus on teaching the initiation of the IO (i.e., drilling into bone and feeling loss of resistance once the needle enters the bone matrix).
3	The advanced IO model should focus on teaching the aspiration of bone marrow and the administration of fluid.
Simple IO Model	
6	Make the simple IO model with a pronounced tibial tuberosity to facilitate landmarking (more palpable) and to add to the realism
8	Make the simple IO model in different bone sizes to emulate infant, child, adolescent, and adult scenarios
Advanced IO Model	
11	Make the advanced IO model with a pronounced tibial tuberosity to facilitate landmarking (more palpable) and to add to the realism
13	Make the advanced IO model longer from knee down to show full patient care and to add to the realism, but how far? (e.g., to extend to the ankle, including the calf muscles it will increase the price of the model by $200-300)
15	Make the advanced IO model with different skin thicknesses to test for proper needle selection
17	Make the advanced IO model with different bone sizes to emulate infant, child, adolescent, and adult scenarios
19	Make the advanced IO model with skin that has pores, hair, and different skin tones/colors to add to the realism
21	Make the advanced IO model include resistance to flow from an IV bag or syringe to add to the realism
23	Make the advanced IO model with skin that could infiltrate to show that the IO procedure was done incorrectly
25	Make the advanced IO model show muscle/anatomic contours of the leg better to add to the realism

Table 4: Modified Delphi round 2 survey questions

IO: Intraosseous, IV: Intravenous

Two questions, questions 1 and 3, in the modified Delphi round two focused on clarifying the learning objectives of the simple and advanced IO simulators (Table 5). Informants agreed that the simple IO simulator should focus on teaching the initiation of the IO (i.e., drilling into bone and feeling loss of resistance once the needle enters the bone matrix) (average of 4.29, SD of 0.95). For the advanced IO simulator, informants

overall rated the learning objective of being able to aspirate the bone marrow and administer fluids as important (average of 3.71). However, there was some degree of variability (SD of 1.11) which was reflected in the comments. Informants mostly suggested that the focus of the advanced IO simulator should not be the aspiration of the bone marrow as it is no longer necessary in the procedure but the administration of fluids, particularly honing in on the resistance to flow feature during administration. These comments were used to modify the focus of the advanced IO simulator accordingly. Overall, gauging the learning objectives of the simple and advanced IO simulators through the modified Delphi round two survey, helped with guiding the selection of the features to include in the updates to the simple and advanced IO simulators.

Question #	**Average**	**SD**	**Comments**
Learning Objectives			
1	4.29	0.95	Just drilling through the bone without having any content to aspire to in my opinion would train the student just to handle the Gundriver.
			Oddly enough when we teach the skill, we listen and feel for a pop, like it's breaking through this pressure gradient
			Landmarking placement is an essential practice that we would include in even the most simple teaching of the skill.
			I think value in training is from completing the skill. important pieces would be landmarking, initiation, and hooking up iv post-initiation. I gave neutral as I was not sure if you were thinking all of this or just drilling the bone itself. I find less value in drilling the bone if you cannot hook up the IO after - once you have drilled it a few times the usefulness becomes less
3	3.71	1.11	"And the accurate identification of landmarks is proper. Placement. "
			This is one of the biggest strengths of a good IO simulator.
			We no longer aspirate marrow for confirmation but definitely for fluid administration especially delivery of fluid under pressure (pressure infuser attached to the bag that pushes through the resistance we typically face

			The advanced IO shouldn't necessarily "focus" on the aspiration aspect of the skill. It should be all encompassing.
			This model would be great for aspiration, administration, as well as interstitial recognition.
Question #	**"Mandatory Optional/Nice to have Not required" (number of votes)**		**Comments**
Simple IO Model			
6	Mandatory (6/7)		This helps to identify the proper location.
			Would make as anatomically correct as possible - not over exaggerated but correct anatomy
8	Mandatory (3/7) Optional/Nice to have (4/7)		It helps to have experiences with other types of patients with different ages.
			The silicone will play a huge role when simulating neonate/infant IO Models as the bone to fat ratio is very different than an adult
			Ideally an adult and an infant would be ideal.
			Would be a nice additional feature
Advanced IO Model			
11	Mandatory (6/7) Not required (1/7)		Different bone shapes and skin types make situations challenging for the user.
			Again, this helps to identify the proper place to insert the needle.
13	Optional/Nice to have (5/7) Not required (2/7)		Suggest to have 1 full leg model that you can rotate/bend the knee. Interchangeable less expensive models can be inserted and removed as needed.
			I see no reason for this.
			I think it would provide more realism but not necessary
			Could you have both options ultimately? There are arguments on both sides including cost, portability but also realistically.
			To the knee would be more than enough.
			I guess it depends on the goals of the model. If you want the most realistic model, where you can assess for infiltrate etc. you would require this - which I guess unfortunately would come with a cost. otherwise I would say if you are

		not interested in that degree of realism and you were more concerned about initiation and using the IO I think you could get away with having enough space that someone could place their other hand below (similar to how you would in real life for stabilization) so I guess in that case 6" below proper landmarking area?
15	Mandatory (3/7) Optional/Nice to have (3/7) Not required (1/7)	There is really only one needle size for infants/children and one needle size for adults. This is independent of skin thickness which is generally not very variable except in the very obese settings
		The skin over the appropriate needle puncture site is thin. In my opinion this is not mandatory.
		This is more clear when talking about neonate and infants
		would be a nice added feature
17	Mandatory (3/7) Optional/Nice to have (4/7)	Being realistic is important and this is for more than the insertion but also rendering treatment and having an appropriately sized bone will add to realism.
		Different models help to understand different scenarios.
		Would be a nice added training feature.
19	Optional/Nice to have (5/7) Not required (2/7)	In my opinion this does not add much to the purpose of teaching how to perform this procedure.
		Not sure this adds a ton. it looks neat but in terms of being able to use the model I am not sure it is as helpful. if it was free it would be a great feature, assuming it costs money I would say that the trade off may not be worth it.
21	Mandatory (5/7) Optional/Nice to have (1/7) Not required (1/7)	Definitely beneficial
		In my opinion, it's not mandatory but it would be nice to have this.
		Not sure this adds much in terms of usefulness for the skill
23	Mandatory (2/7) Optional/Nice to have (5/7)	As long as there is a way to clean the model after use and remove the infiltrated solution as that is what degrades models most quickly and is also a source of mold growth. Unless the skin is "sealed" to the bone, a missed IO will produce infiltration. The concern would be where the bone is used in more than 1 IO initiation and therefore there are multiple holes in the bone that then leak - i self sealing membrane inside the bone matrix would help prevent that.
		This could prove to be very difficult.

		This iatrogenesis happens and is not uncommon. It would be interesting to demonstrate what it looks like and discuss how to avoid it.
		Only if it does not overly complicate the device.
		I think this would be a great feature - something that is currently missing is how to prepare people for this adverse event.
25	Mandatory (1/7) Optional/Nice to have (6/7)	It may be simply the picture but the advanced IO with skin does not look realistic in the picture. Realism and the ability to properly landmark is crucial.
		This helps to better identify the needle insertion site
		Probably within a certain degree this would add to the realism although most of the muscle etc. is not really involved in any area you start the IO - so not sure it is necessary. If there is a way to have different tissue thickness in different areas that correlate to muscle mass etc. it doesn't matter as much if it is anatomically correct that would allow people to look/feel for the area without tissue.

Table 5: Modified Delphi round 2 average, standard deviation, and comments

SD: Standard deviation, IO: Intraosseous

With regards to the features to include in the updates to the simple and advanced IO simulators, the features that showed high distribution in the ratings during modified Delphi round one, were classified as “mandatory”, “optional/nice to have”, or “not required” by informants in the modified Delphi round two (Table 5). For the simple and advanced IO simulators, most informants ranked having pronounced tibial tuberosity to facilitate landmarking and to add to the realism as a mandatory feature. Another feature that was voted as mandatory by the majority of informants was the demonstration of the resistance to flow from a syringe or an IV bag in the advanced IO simulator. Bone sizes, length of the tibia, skin thicknesses, skin details (i.e., hair, pores, color, texture), muscle contours, and the demonstration of infiltration were all considered “optional/nice to have”

features in the simple and advanced IO simulators as they would all add to the realism according to the comments. Using these results from modified Delphi round two, the research team decided to select the features that were chosen as mandatory to include in the simple and advanced IO simulators in order to follow a design-to-cost approach and concluded the modified Delphi methodology.

A summary of the modified design thinking process and the modified Delphi methodology is shown in Table 6. The final output of the modified Delphi round two generated a list of features that would be either mandatory or optional to include in the final designs of the simple and advanced IO simulators. Based on the comments provided by the informants throughout the process, a feature is classified as optional if it adds to the realism of the simulator whereas a feature is classified as mandatory if it adds to the learning objectives of the IO access and infusion procedure. For the simple and advanced IO simulators, the features that were considered mandatory were selected in order to follow a design-to-cost approach. The design-to-cost approach focuses on reducing development costs by sacrificing part of the realism of the model to make the simulator more accessible for learners [17]. A design-to-cost approach was followed in this development of simple and advanced IO simulators to maintain the feasibility of production for training purposes.

Design Thinking Results	Delphi Round 1 Results	Delphi Round 2 Results
Simple IO Simulator	Include?	Mandatory?
Provides resistance when performing the IO technique on it	X	X
Simulates the bone marrow (e.g., in the hollow space of the bone, place a sponge and add liquid to it)	X	
Demonstrates people of different weights (i.e., make simple IO models with varying skin thicknesses)		
Demonstrates different scenarios/contraindications (e.g., simple IO models with bone fractures, skin infections, etc.)	X	
Includes a portion of the calf to help with landmarking (e.g., use a sponge to surround the top of the bone)	X	
Made with different densities so that when you insert the needle, it goes in more easily or not? (e.g., make the bone softer for young people, make the bone thinner for 65+, etc.)	X	
Advanced IO Simulator	Include?	Mandatory?
Bends and laterally exposes the tibia (e.g., 360-degree swivel on the superior end so that we can also move the leg and position it on the table)	X	X
Made longer from the knee down	X	
Has skin that is more realistic than the simple IO model (e.g., skin is textured with pores and hair, different skin colors, etc.)	X	
Has resistance to flow coming either from a syringe or an IV bag (e.g., in the model, incorporate a Luer lock adaptor that you could hook IV tubing up to the back side which could stay hidden inside of the model to fill it with red liquid, and then when the IO is established, there would be positive feedback and the ability to run fluids/push meds)	X	X
Has skin that could show infiltration (e.g., use a bladder pump to show how if you miss the bone during the IO procedure, the space under the skin would fill up with liquid and bubble up)	X	
Is a full leg		
Shows the muscle/anatomic contours of the leg better than it does now (e.g., create a snug “sleeve” to serve as the skin to slide over the top of the muscle/bone structure of the model)	X	
Has a bigger patella than what we already have in our model (see the pictures/video above) and be made mobile (e.g., all the other bones in the model are fixed while the patella is made separately to fit in and could give way when you feel for it to help with landmarking).	X	X

Table 6: Features of the simple and advanced IO simulators from the modified design thinking process that were selected in each round of the modified Delphi methodology

IO: Intraosseous, IV: Intravenous

5.1.3.3 Design of the simple and advanced IO simulator

After the modified Delphi round two, the design ideas for the simple and advanced IO simulators were then relayed to and discussed with the development team, a group of three graduate students from maxSIMhealth, a research laboratory at Ontario Tech University, experienced in 3D digital design and printing and additive manufacturing techniques, in order to determine feasibility from a manufacturing standpoint.

5.1.3.3.1 Architecture of the Simple and Advanced IO Simulator

The simple IO simulator was developed using Fusion360™ (Autodesk Inc., San Rafael, CA, USA), based on the digital assets from a previous project [22]. The digital design was sliced using Ultimaker Cura (Ultimaker B.V., Utrecht, Netherlands), and the parameters were set so that there was a 3 mm wall thickness to better simulate resistance to the drill, and a 30% infill using the line pattern to simulate bone marrow within the tibia. The sliced design was printed using white Ecotough™ polylactic acid (PLA) filament material (Mississauga, Ontario) on an Ultimaker S5 3D printer (Ultimaker B.V., Utrecht, Netherlands). In addition to the bone, a clamp and slide were designed using Fusion360™ so that the bones could friction-fit onto the slide, and be secured onto the stand, as shown in Figure 2. Both parts were also printed using PLA filament material on an Ultimaker S5 3D printer.

Figure 2: Simple IO simulator on a stand

IO: Intraosseous

The design process for the advanced IO simulator started based on specific features and adaptations discussed with the informants during the modified design thinking process and modified Delphi methodology to create a more realistic prototype that could fulfill the requirements in a real-life scenario. The proportions and shape of the leg were based on a human leg that was 3D scanned using an Artec Space Spider 3D scanner (Artec3D, Santa Clara, CA, USA) and then customized to 75% of its original size to create a more manageable prototype. The 3D scanned leg was scanned so that the leg is bent at the knee, as requested by the informants. The 3D scanned leg was modified in Solidworks (CAD MicroSolutions Inc ©, Etobicoke, Ontario, CA) to contain a cut in the top part of the leg that goes from the knee to the middle of the shin to create a small box where the bones can slide in, as shown in Figure 3. This leg was 3D printed using skin-tone PLA filament on an Ultimaker S5 3D printer. The bone insert consisted of the

patella and the top portion of the tibia. This design was based on available digital assets and was modified using Autodesk Meshmixer (Autodesk Inc., San Rafael, CA, USA) so that a small platform was added underneath to make the bones more stable at the moment of use, as shown in Figure 4. The design for the leg and the bone insert together is shown in Figure 5. The modified designs for the bone were printed using the same 3D slicing parameters as the simple IO bone (3 mm wall thickness and a 30% infill) using white PLA filament on an Ultimaker S5 3D printer. The 3D-printed leg and bone are shown in Figure 6. To simulate a fat layer, a sheet of foam was cut and placed into the empty spaces within the leg surrounding the bone, as shown in Figure 7. To create a skin layer that would wrap around the leg and bone, a rectangular mold was designed in Solidworks, and 3D printed using PLA filament using an Ultimaker S5 3D printer. Ecoflex 00-20 FAST silicone (Smooth-On, Macungie, PA, USA) and Silc-Pig™ coloring skin tone pigments (Smooth-On, Macungie, PA, USA) were combined, poured into the 3D printed mold, set to cure for approximately 75 minutes, and removed to create the skin. Velcro inserts were created along the edges of the silicone skin layer to ensure the skin can be secured tightly around the leg, bone, and foam as shown in Figure 8. Finally, a 3D-printed stand was designed using Solidworks and 3D printed using PLA filament on an Ultimaker S5 3D printer. This stand holds the entire advanced IO simulator so it remains in an upright position, but can still give users the freedom to move if needed (Figure 9).

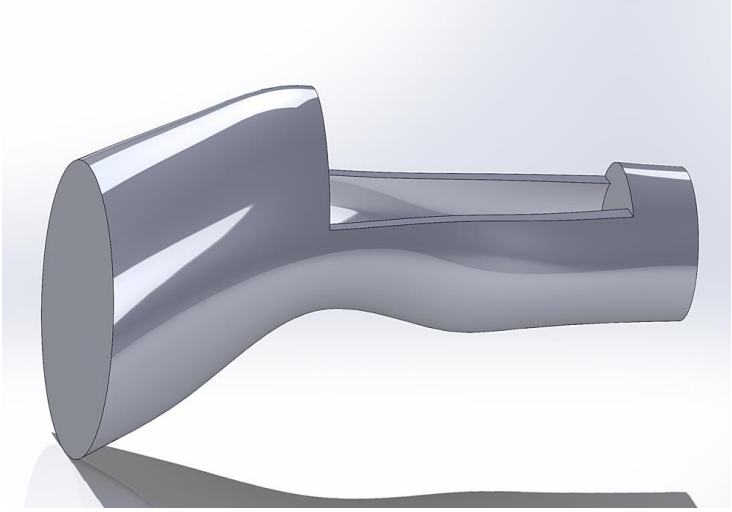

Figure 3: Solidworks rendering of advanced IO simulator with a cut in the top part of the leg that goes from the knee to the middle of the shin to create a small box where the bones can slide in

IO: Intraosseous

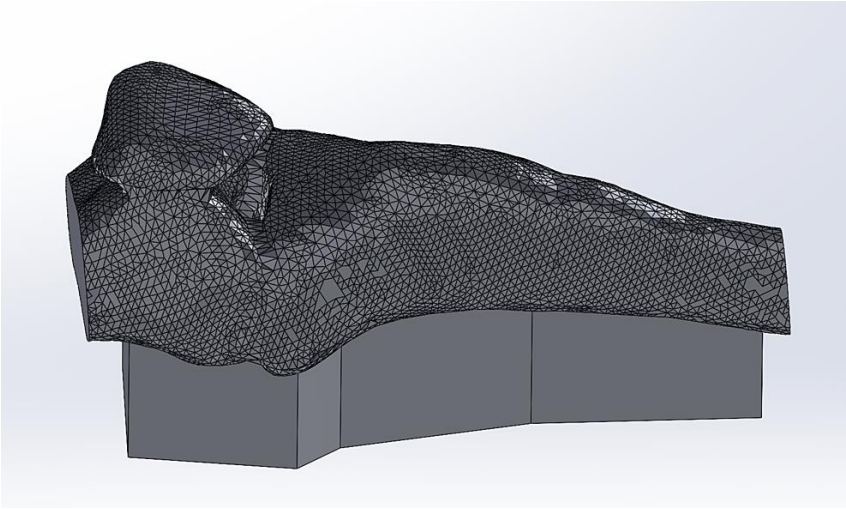

Figure 4: Solidworks rendering of advanced IO simulator modified with a small platform underneath to make the bones more stable at the moment of use

IO: Intraosseous

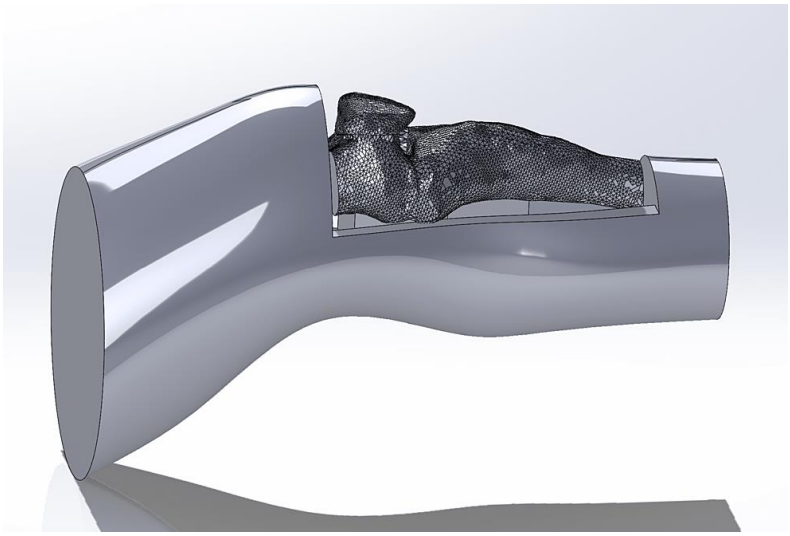

Figure 5: Solidworks rendering of advanced IO simulator showing the leg and the bone insert together

IO: Intraosseous

Figure 6: 3D-printed advanced IO simulator

IO: Intraosseous

Figure 7: 3D-printed advanced IO simulator with foam as fat

IO: Intraosseous

Figure 8: Silicone skin attachment for the 3D-printed advanced IO simulator

IO: Intraosseous

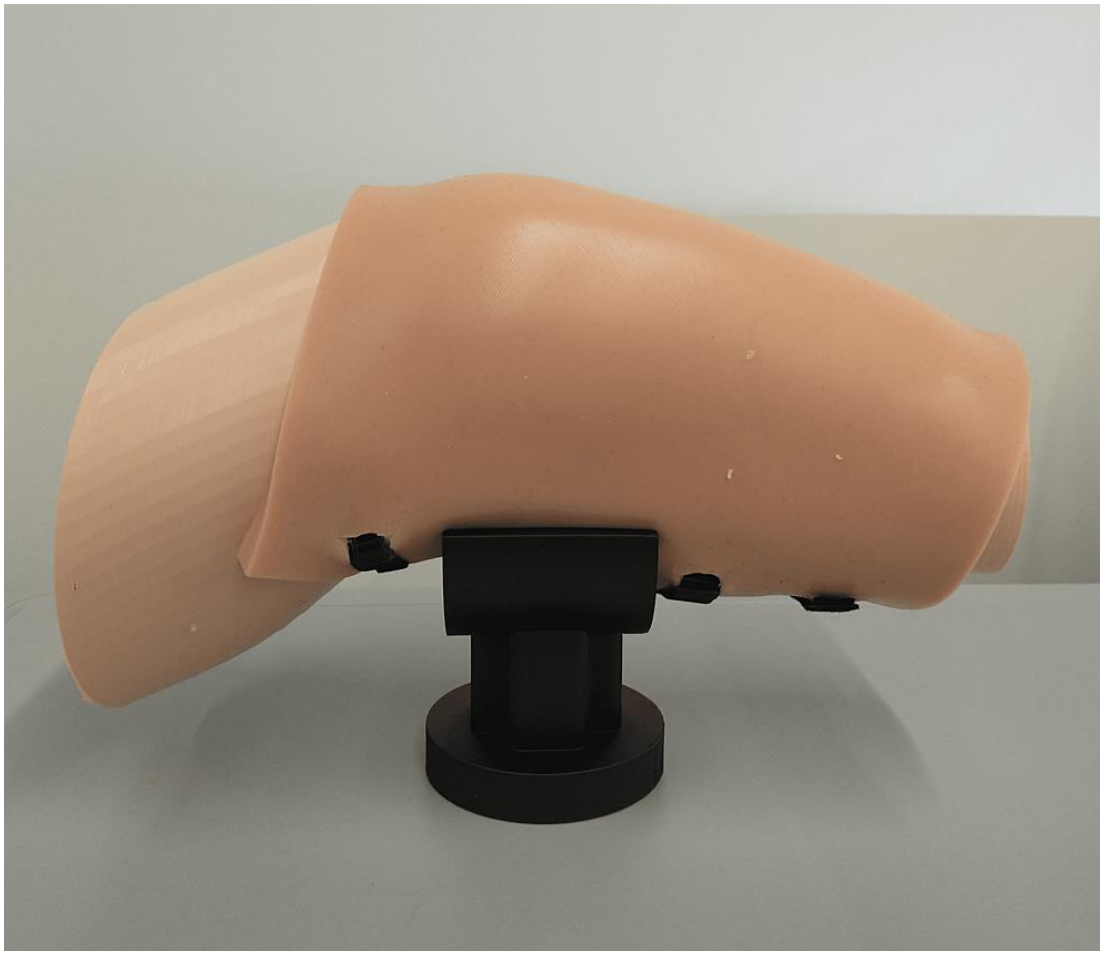

Figure 9: 3D-printed advanced IO simulator with silicone skin attachment on a 3D-printed stand

IO: Intraosseous

5.1.3.4 Costs

Table 7 illustrates the breakdown of all costs associated with the manufacturing of simple and advanced IO simulators. All cost estimates are in Canadian dollars (CAD), including local taxes based on the manufacturing cost of a single simulator.

Material	Simple IO Model	Cost of Simple IO Model (CAD)	Advanced IO Model	Cost of Advanced IO Model (CAD)
PLA	280 g*	12.66	667 g**	30.15
Ecoflex™ 00-20 FAST	0	N/A	400 g	22.30
Foam	N/A	N/A	432cm^{2***}	1.31
Velcro	N/A	N/A	4 pieces	0.13
TOTAL COST		**12.66**		**53.89******

Table 7: Cost breakdown of the materials needed to produce the simple and advanced IO simulators

*Includes bone, clamp, and slide.

**259g leg + 230g bone insert + 178g (skin mold)

***includes 3 pieces of foam that are 18cm x 8cm=144cm2

**** bone insert (for replacement) is $10.40 from this total (including tax)

IO: Intraosseous, CAD: Canadian dollar, PLA: Polylactic acid, N/A: Not applicable

5.1.3.5 Strengths, weaknesses, opportunities, and threats (SWOT) analysis survey results

Three of the seven participants who took part in both the modified design thinking process and the modified Delphi study were sent a Google Form survey in the form of a SWOT analysis to provide feedback on the CIC approach [23]. Two participants completed the survey which equates to a 67% response rate. For the strengths of the process, participants stated that the instructions were clear, felt that all ideas could be

considered, and the environment was made welcoming and comfortable to share thoughts. Participants also appreciated hearing and viewing the ideas of others, especially those from different scopes of practice (i.e., paramedicine vs medicine), which allowed them to gain insights and build on ideas. With regards to weaknesses, participants indicated that more participants during the design thinking session would have potentially led to further discussion and capturing more ideas. Another area for improvement mentioned was for the design thinking session, where the time for idea generation could have been pushed longer to attempt to force as much volume of ideas as possible so that further content could be included in during the Delphi process. In terms of threats, participants pointed out that technical difficulties using technology to facilitate the process could restrict individuals from fully participating as seen with one of the participants during the design thinking when their microphone stopped working on Google Meet. Lastly, participants highlighted that conducting this process face-to-face with all participants, for the design thinking process as well as after each round of Delphi, could be considered an opportunity as it could allow for further exchange of ideas through group discussions. In sum, this SWOT analysis offered participants' evaluations of the CIC approach and offered suggestions on where the process could be further improved for future use.

After the survey, an informal interview was conducted with the respondents of the SWOT analysis to pinpoint the feedback for the new approach. The main suggestion that surfaced was that the approach could be used to generate many ideas that could be used in the future. Specifically, during the CIC approach, it was observed that, in addition to providing the details of the elements that were required to construct the simple and

advanced IO simulators, the process also led to a list of features that can be employed to change the difficulty of the simple and advanced IO simulators. The features that could achieve this are as follows: 1) demonstrates people of different weights (i.e., make simple IO models with varying skin thicknesses); 2) demonstrates different scenarios/contraindications (e.g., simple IO models with bone fractures, skin infections, etc.); 3) has skin that could show infiltration (e.g., use a bladder pump to show how if you miss the bone during the IO procedure, the space under the skin would fill up with liquid and bubble up); 4) made with different densities so that when you insert the needle it goes in more easily or not (e.g., make the bone softer for young people, make the bone thinner for 65+, etc.).

Features like these are important as modular and customizable simulators can be used as a flexible and adaptive means to challenge learners as they progress through the acquisition of skills. Specifically, the difficulty of the IO skill can be increased by changing the design of the simple and/or advanced IO simulator such as incorporating those features described above. This in turn will lead to the deterioration of immediate practice performance but will lead to improved long-term performance [24].

For instance, changes in the thickness of the adipose tissue of the simple or advanced IO simulator can allow the trainee to assess the appropriate IO needle set according to the size and weight of the patient. Another example is to create the bone in the simple or advanced IO simulator in varying sizes and densities so that the trainee can learn how patients of different ages should be treated (i.e., the bone is smaller and softer for younger patients and larger and thinner for older patients and may require less pressure during IO access and infusion compared to adult patients). Different

contraindications or scenarios demonstrated in the simple or advanced IO simulator, like tibial fractures and skin infiltrations would challenge the trainee to identify and undertake measures to alleviate and prevent further harm to the patient during the IO access and infusion [25]. By adding these features to the simple and/or advanced IO simulator, the trainee can be exposed to various situations that can increase the complexity of the IO access and infusion procedure, supporting their learning journey.

5.1.4 Discussion

This original article aimed to describe the development of simple and advanced IO simulators that may be used in the future to enhance the effectiveness of a De-SBE model to teach paramedics-in-training the IO access and infusion skill from any remote location. To accomplish this goal, we designed a unique expert informant crowdsourcing mechanism that consists of a combination of modified design thinking and Delphi methodologies: the CIC approach.

This approach starts with the articulation of needs and design constraints. In particular, we suggest at minimum to focus on the design-to-cost vs design-to-value approaches. The described test case of development of the simple and advanced IO simulators required a design-to-cost approach. Next, in the ideation phase, we used a design thinking methodology. The advantage of employing design thinking for the development of a simulator is that it generates ideas in a creative and collaborative way. It also fostered a unique collaboration between a university and community healthcare professionals in designing educational tools to advance the care provided by current and future professionals. However, the process lacks the rigor expected by the healthcare simulation community in refining the most important elements that need to be

incorporated into the final design. This is often referred to as gathering evidence to support the construct validity of the simulator [19]. Therefore, we substituted the final phases of the design thinking, which narrows down the ideas to a few executable ones, with a Delphi methodology. This method is widely accepted in the simulation community as a tool that provides content validity evidence [20].

The use of online tools such as Google Meets and Google Jamboards to facilitate the design thinking process and Google Forms to execute the Delphi study allowed the informants to share their ideas for the design of the simple and advanced IO simulators remotely and instantaneously, contributing to the speed of data collection. The disadvantage to using Google Meets is that it posed technological problems (i.e., Internet connectivity and hardware issues related to audio), and limits individuals from contributing their ideas. The disadvantage to Google Jamboards and Google Forms to collect data on the design of the simple and advanced IO simulators is that information provided by informants can be difficult to interpret and may require follow up whereas, in person, ambiguities could be resolved more readily. Despite these shortcomings, overall, the modified design thinking and modified Delphi methodologies successfully delivered useful information from informants on the design of the IO simulators we aimed to present in this original article. To improve the overall study using these online tools, informants from other geographical areas could be identified and invited to participate in an effort to gather more diverse perspectives and attempt to draw a more generalizable inference.

Based on the data gathered, we have constructed an affordable advanced IO simulator compared to commercially available trainers. For instance, the Sawbones®

(Seattle, USA) Intraosseous Access Injection Trainer is $414 USD [26] while the production costs associated with our simple IO simulator is $12.66 CAD and our advanced IO simulator is $53.89 CAD. In addition, the tibial replacement piece for the Sawbones® trainer is $35.50 USD [27] while the 3D-printing one for our advanced IO simulator is $10.40 CAD. Evidently, the manufacturing of both our simple and advanced IO simulators can be made at a fraction of the costs compared to commercially available trainers. The developmental costs, which include designer time, initial purchases like the 3D printer and its associated consumables (i.e., electricity, parts, maintenance, etc.), have not been added to the production costs, as they have already been covered through research and development funding not applicable to this work.

The stakeholders who tested the CIC approach provided comments about the pros and cons. In general, the features that favor this approach are grouped around the collaborative nature, the clarity of instructions pertaining to the process, and the ability to generate ideas for future use. These features were noted to facilitate the overall design process well with a group of experts. However, they also provided considerations for future CIC approach undertakings, which centered around the use of technology and timing. It was mentioned that although technology allows stakeholders to participate from any remote location, it takes away from rich discussions that could take place in a face-to-face setting. Secondly, the duration of the ideation phase could be given more time to allow for a maximum number of ideas. If these parameters of the CIC approach are adjusted according to the composition of the team involved and the context and construct of the problem in scope, it could result in a better output.

Finally, following a design-to-cost approach, the development team selected the mandatory features that resulted from the hybrid modified design thinking-Delphi process which allowed us to manufacture the advanced IO simulator at a cost that is a tenth of an average commercially available simulator. The cost was taken into account from the beginning of the design process, with the goal to minimize expenses by surrendering some realism while incorporating features classified as mandatory to include in the final design that would add educational value [28]. At this price tag, these IO simulators are valid, customizable, multifunctional, and inexpensive and as such may be potentially used in the De-SBE model.

5.1.5 Conclusions

In conclusion, the CIC approach was useful for the purpose of designing a simple and advanced IO simulator that would suit a training plan catered to teach the IO access and infusion procedure decentrally to paramedics-in-training. Specifically, they have been designed in a manner that allows them to be made easily accessible to the trainees i.e., at low costs and high mobility, and work cohesively with online LMSs, which further facilitates the use of a De-SBE model. However, before implementing the De-SBE model within curricula, the development team will test the IO simulators in the DE-SBE model, following the design-based research framework, a process for developing solutions to real-life problems by engaging in iterative design phases and cycles to generate new knowledge and to improve educational practices.

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5.2 Test Case 2 – Development of Content for a Virtual Reality Simulation to Understand and Mitigate Moral Distress in Healthcare Workers

Abstract

Background: In high-stakes situations, healthcare workers are prone to suffer moral injury, the psychological, social, and spiritual impact of events involving betrayal or transgression of one's own deeply held moral beliefs and values. As a result, this may negatively impact their capacity to provide adequate levels of care to patients. There is a lack of educational resources catered to help healthcare workers navigate ethical situations in clinical settings that may lead to or worsen moral distress. The aim of this report is to describe the methodology of development and resulting outcomes in the form of an educational resource that includes a virtual reality (VR) simulation to help healthcare workers understand and mitigate moral distress as a result of internal and external constraints at their workplaces.

Methodology: A study using a method outlining a set of constraint parameters, followed by ideation utilizing design thinking (DT), and concluding with a consensus-building exercise using Delphi methodology (DM) with a group of 13 experts in healthcare simulation, VR, psychiatry, psychology, and nursing. The constraints parameters included technology use (VR), use of experiential learning theory, and duration of the intervention (15 minutes). A DT process was performed to generate and expand on ideas on the scenario and intervention of a possible VR simulation which were funneled into a three-round DM to define the foundations of the VR simulation. Average, standard deviations, and free-text comments in the DM were used to assess the inclusion of the

produced requirements. Finally, a focus group interview was conducted with the same experts to draft the VR simulation.

Results: Within the specified constraints, the DT process produced 33 ideas for the VR simulation scenario and intervention that served as a starting point to short-list the requirements in Round 1. In Rounds 1 to 2, 25 items were removed, needed revising, and/or were retained for the subsequent rounds, which resulted in eight items at the end of Round 2. Round 2 also required specialists to provide descriptions of potential scenarios and interventions, in which five were submitted. In Round 3, experts rated the descriptions as somewhat candidate to use in the final VR simulation, and the open feedback in this round proposed combining the elements from each of the descriptions. Using this data, a prototype of the VR simulation was developed by the project team together with VR designers.

Conclusions: This development demonstrated the feasibility of using the constraints-ideation-consensus approach to define the content of a possible VR simulation to serve as an educational resource for healthcare workers on how to understand and mitigate moral distress in the workplace. The methodology described in this development may be applied to the design of simulation training for other skills, thereby advancing healthcare training and the quality of care delivered to the greater society.

Keywords: mental health, psychiatry, psychology, educational resource, virtual reality, healthcare simulation, moral injury, moral distress, mobile app, covid-19

5.2.1 Introduction

Internal and external constraints in clinical settings have caused healthcare providers to transgress on deeply held moral values and commitments [1]. When this occurs, their moral foundation is threatened or violated which can lead to moral distress [2], negatively impacting their emotional and physical well-being [3,4], which, in turn, can diminish their capacity to provide adequate levels of care to patients [5].

To date, there is limited research on factors leading to and the treatment of moral distress in healthcare providers as the concept of moral distress is not diagnostically coded and remains ill-defined [6,7]. Gilligan (2014) suggested that healthcare providers who are chronically exposed to moral distress may suffer from subsequent moral injury, "a shattering of trust that compromise[s] our ability to love" [8]. Because moral injury and post-traumatic stress disorder (PTSD) have overlapping symptoms, treatments targeting PTSD symptomatology have been used to target moral injury. However, this has generally rendered them unresponsive [9]. Fortunately, healthcare providers' moral compass can be repaired by strengthening it through healthcare ethical education. Then, they may be ready to handle ethical challenges and the effects of moral distress which can lead to better patient outcomes [10-12]. Currently, there is a lack of sufficient educational resources to help healthcare providers navigate ethically challenging situations [13].

To address this gap, we propose to develop and test an educational resource that is rooted in Kolb's experiential learning theory and supported by a digital technology platform consisting of virtual reality (VR) simulation to understand and mitigate the effects of moral distress on healthcare workers. This original article aims to (a) describe the use of a novel, hybrid methodology, which sets design constraints and combines

elements of two consensus-building methodologies, a design thinking (DT) process and Delphi methodology (DM), with an interdisciplinary team to define and scope the parameters, needs, and requirements to develop content for the VR simulation, and (b) to describe the final outcome of this development.

5.2.2 Materials & Methods

As of March 20, 2021, the research ethics board at St. Michael's Hospital, Unity Health Toronto has approved the study, with the reference number UHTDTS25377.

5.2.2.1 Participants

The interdisciplinary team was a group of 13 individuals. The following disciplines were represented: five in psychiatry, three in psychology, three in nursing, one in game development, and one in healthcare simulation.

The project team consisted of eight individuals who prepared and facilitated the development process. There was one engineer, two computer scientists, one healthcare simulation specialist, one healthcare simulation researcher, two psychiatrists, and one health sciences graduate student.

5.2.2.2 Design constraints

There were three design constraints that were imposed on the development of the simulation, namely, learning theory, technology, and time. Kolb's experiential learning theory was selected as an educational framework to structure the educational resource. Kolb's experiential learning theory consists of the following four stages: concrete experience, reflection, conceptualization, and active experimentation. Following this

cycle, an individual learns effectively when they have had (1) exposure to a real-life event, (2) followed by observation and reflection on that experience. This then leads to (3) the formation of abstract concepts and generalizations, (4) which are then used to test a hypothesis by applying what they have learned in future situations, resulting in new experiences [14].

In this conception, as it is logistically and ethically unacceptable to expose healthcare providers to real-life events that evoke moral distress, VR will provide these experiential opportunities, hence, the selection of this technology. Specifically, concrete experiences will be provided to healthcare workers by immersing them in the VR simulation that will trigger moral distress. Reflection and conceptualization will be facilitated by an in-VR intervention made up of assessments, tests, and reflective exercises, which will be used to guide the learner to reflect on the experience, providing them with knowledge and skills related to dealing with moral distress in the future. The in-VR intervention will be based on a concept known as “psychological first aid” from “A guide to moral injury” [15]. This guide offers advice on how to implement preventative and early intervention structures to support healthcare providers before they are morally injured and outlines the support that needs to be provided at the organizational, team, and individual levels. Finally, active experimentation will be achieved by having the healthcare participant undergo the same VR simulation again so they can apply and test the newly learned concepts from the in-VR intervention (Figure 1).

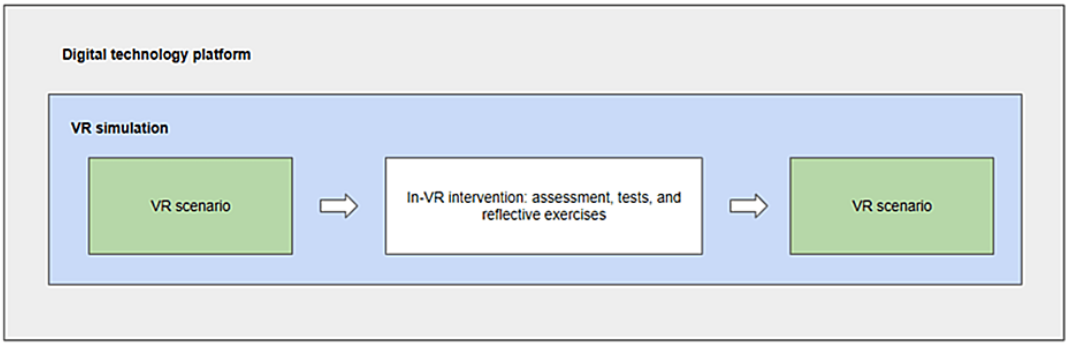

Figure 1: The educational resource consists of a digital technology platform which is made up of a VR simulation. The VR simulation is structured according to Kolb's experiential learning theory and takes the learner through a VR scenario, an in-VR intervention, and then the VR scenario again.

VR: virtual reality

This VR simulation is intended to be structured as a 10-minute scenario, a 10-minute in-VR intervention, and then the VR simulation again, totaling 30 minutes. The intent for this length is to provide enough content to participants, which includes the experience and teachings, during the VR simulation while keeping it short enough to encourage recruitment and capture emotional reactions from participants as they occur.

5.2.2.3 Hybrid design thinking and Delphi methodology

DT is an iterative and non-linear process that provides a solution-based approach to solving complex problems. It comprises the following five stages: (1) empathizing - understanding the human needs involved; (2) defining - re-framing and defining the problem in human-centric ways; (3) ideating - brainstorming as many ideas in ideation sessions; (4) prototyping - adopting a hands-on approach in prototyping; and (5) testing - developing a prototype/solution to the problem. It is useful in tackling complex problems

that are ill-defined or unknown and within a multidisciplinary team setting where the diversity of thinking accelerates the process [16].

For the educational resource, we chose to focus on only the first three stages of the DT process with an interdisciplinary team to generate a set of ideas that were discussed and classified based on their feasibility as promising and valid. These valid and promising ideas required content validity, a measure of how well the content of the VR simulation reflects real-life situations and learning needs [17]. To accomplish this, we skipped the last two stages of the DT process, namely, prototype and test, and instead, moved the valid and promising ideas into a three-round DM (Figure *2*). Due to the elimination of DT steps in the process, the DT in this original article will be considered modified.

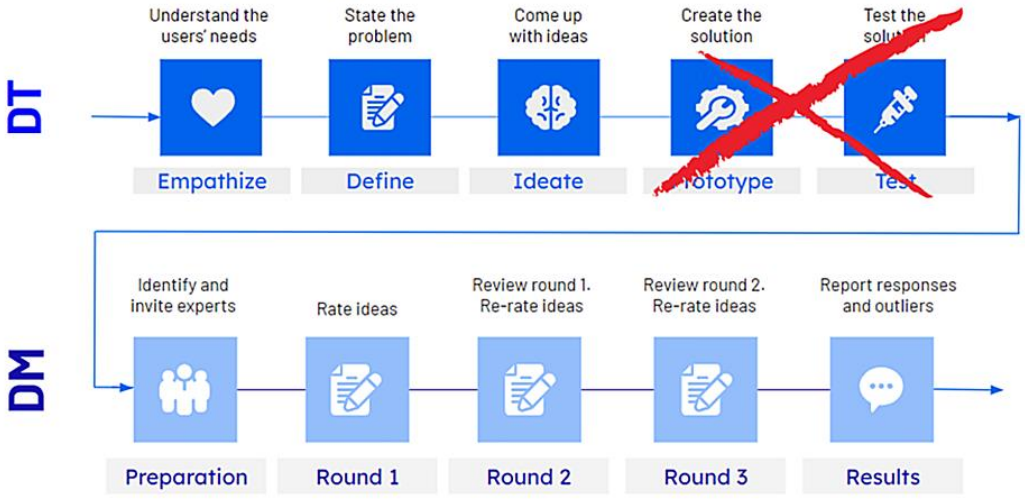

Figure 2: The DT-DM is a novel consensus-building methodology that is a combination of DT and DM elements. The first three phases of DT, empathize, define, and ideate, are involved to help generate and expand on ideas. Before prototyping and testing the ideas, the ideas need evidence of content validity to be accepted by the medical research community. To achieve this, the ideas are put through a DM in which the ideas are fine-tuned until an expert consensus is reached.

DT: design thinking; DM: Delphi methodology

The DM is a group communication process that seeks to gather information and achieve consensus from a panel of experts using iterative survey questionnaires [18]. It is widely used in medical education and has been applied in needs assessment processes [19], in identifying content for assessment instruments [20], and in research priorities in medical education [21].

The first survey questionnaire for the DM was formulated by the project team by taking all valid and promising ideas from the modified DT and structuring each of them into a question that asked to rank their importance. Because these questions were pre-defined by the DT in the DM which is different from the conventional DM where the starting questions are open-ended, the DM will be referred to as modified [22]. The same interdisciplinary team that took part in the DT was given three rounds of the DM survey questionnaires to gather their insights on the topic and come to an agreement on the criteria for the content of the VR simulation.

5.2.2.4 Focus group interview

The output from Round 3 of the DM was then used to draft the content in the form of a script for the VR simulation scenario and a slide deck for the in-VR intervention. The script and slide deck drafts were shared via Google Docs and Google Slides, respectively, with the 13 participants for their feedback for a week. The comments for both the script and slide deck drafts were integrated accordingly. These preliminary drafts were then discussed during a one-hour Zoom meeting focus group interview with the same 13 participants to address any outstanding comments. The revised script and slide deck drafts were then provided to two VR designers to create a prototype of the VR

simulation. The first VR simulation prototype was created in two weeks, and a video recording of the prototype was then given to the participants for their feedback.

5.2.2.5 Constraints-ideation-consensus approach

In summary, the process of creating content for the VR simulation underwent the following steps: (1) the identification of constraints, (2) the generation of ideas through DT, (3) a DM using the DT ideas for expert consensus, and (4) a focus group interview to clarify the outcome of the DM. This sequence of tools will be referred to as the constraints-ideation-consensus (CIC) approach (Figure 3). Participants who took part in the CIC approach were sent a Google Form survey in the form of a SWOT analysis to provide feedback on the methodology which inquires about the strengths, weaknesses, opportunities, and threats of the process [23].

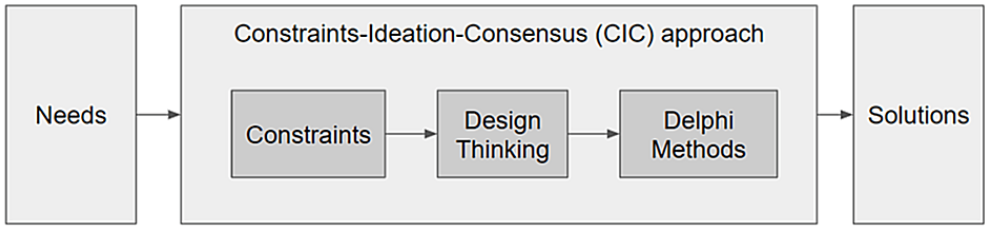

Figure 3: The constraints-ideation-consensus approach.

5.2.2.6 Protocol

5.2.2.6.1 Modified Design Thinking

The modified DT process took place over a two-hour Zoom meeting with 13 participants. To ensure ideas for content were gathered for all parts of the VR simulation according to Kolb's experiential learning theory, the VR scenario and the in-VR intervention, participants were then assigned to one of the three areas, namely, scenario,

intervention, and assessments, through the use of breakout rooms in Zoom. For each breakout room, a facilitator guided the participants through the first three stages of the modified DT process and recorded all ideas for each stage on a Google Jamboard. After the modified DT process, the ideas were summarized and integrated into the modified DM.

5.2.2.6.2 Modified Delphi Methodology

Afterward, a modified DM was conducted with the same 13 participants who took part in the modified DT process. The modified DM took the form of a survey questionnaire hosted in Google Forms and was sent electronically to the 13 participants to complete via email within one week per round. The survey questionnaires were based on the ideas generated from the modified DT process. In each round, participants were asked to rate items to include in the content of the VR simulation on a Likert scale of one to five, one being very unimportant and five being very important [24]. For each item, participants were provided the opportunity to provide comments through a free-text field. After each round, the results were statistically analyzed using mean and standard deviation (SD). Items with a mean of 3.5 or greater and demonstrated low variability (i.e., SD less than 1) were considered important by the majority of participants. These items were noted as elements to include in the final content of the VR simulation and were not revisited in the subsequent rounds of the modified DM. Items that had a mean lower than 3.5 and demonstrated low variability (i.e., SD less than 1) were considered unimportant by the majority of participants. These items were noted as elements to not include in the final content of the VR simulation and were not revisited in the subsequent rounds of the DM. Items that displayed high variability (i.e., SD equal to 1 or greater) suggested a lack

of consensus among participants on the inclusion of the element in the final content of the VR simulation [24]. To gain clarity on these particular items along with any of their comments in the associated free-text fields, after the relevant modified DM round was concluded, a one-hour Zoom meeting was conducted with the participants. Then, these items were revisited in the subsequent rounds of the modified DM through the survey questionnaires until an agreement on the inclusion of the items among the participants was achieved. The modified DM process garnered consensus among the participants by the third round and this took approximately three weeks to complete, given one week per round.

5.2.3 Results

5.2.3.1 Modified design thinking

During the modified DT process, 13 participants generated 33 valid and promising ideas for the content of the VR simulation (Table 1). The ideas served as the items for the survey questionnaires for the modified DM Round 1 and free-text fields were included to gather any comments, questions, and suggestions on the overall VR simulation (Table 2).

VR Simulation Scenario Ideas
Virtual actors doing self-harm
Virtual actors being dehydrated
Have virtual actors lacking sleep
Have a moral debate between virtual actors (scripted) and the participant observes the interaction
Have virtual actors experiencing misplaced anger
Have the participant observing interactions between virtual actors

Have virtual actors being exposed to a demonstration of bad leadership
Have virtual actors making mistakes unintentionally/intentionally
Offer a team experience
Require that the participant goes through a decision-making tree
Make the participant aware that they are in a moral dilemma
Have virtual actors feeling unsafe
Require the participant to make time-sensitive decisions
Have virtual actors experiencing frustration
Have virtual actors feeling betrayed
Offer an individual experience
Have the participant actively interacting with virtual actors
Have virtual actors feeling the effects of staffing issues
Include evocative storytelling
Trigger emotional responses in the participant
Prompt reflection in the participant
Shows something has happened and the participant goes through the experience
Elicit genuine reactions from the participant which drives their responses to the intervention
in-VR Simulation Intervention Ideas
Have the participant identify the values in conflict
Have a moral debate between virtual actors and the participant (scripted)
Have various pathways that can help the participants navigate the scenario
Teach the participant about moral distress
Require the participant to experience moral distress
in-VR Simulation Assessment Ideas
Use participant biometric data (e.g., physiological markers of stress levels) gathered during the VR simulation to request participants to share reflections on the experience and suggest tools provided during the "intervention" that would help deal them this situation in the future
Require the participant to complete "perceptual scales" (e.g., anxiety scales/stress index) such as pop-up in-scenario quizzes (provide results concurrently) based on standardized instruments
Require the participant to complete "reflective" short writing tasks (asks participant to provide summary as terminal feedback) based on standardized instruments

Require to participant to complete matching “logic” games based on standardized instruments
Include in-scenario metrics of performance that would provide feedback (concurrent) about logic/reasoning or correctness (if applicable)

Table 1: List of 33 valid and promising ideas generated from the modified DT process

Questions #	**Modified DM Round 1 Question**
1	How important is it that the VR scenario is developed to: Have virtual actors doing self-harm?
2	How important is it that the VR scenario is developed to: Have virtual actors being dehydrated?
3	How important is it that the VR assessments are developed to: Require to participant to complete matching “logic” games based on standardized instruments?
4	How important is it that the VR assessments are developed to: Include in-scenario metrics of performance that would provide feedback (concurrent) about logic/reasoning or correctness (if applicable)?
5	How important is it that the VR scenario is developed to: Have virtual actors lacking sleep?
6	How important is it that the intervention is developed to: Have a moral debate between virtual actors (scripted) and the participant observes the interaction?
7	How important is it that the VR assessments are developed to: Require the participant to complete “reflective” short writing tasks (asks participant to provide summary as terminal feedback) based on standardized instruments?
8	How important is it that the VR scenario is developed to: Have virtual actors experiencing misplaced anger?
9	How important is it that the intervention is developed to: Have the participant identify the values in conflict?
10	How important is it that the intervention is developed to: Have a moral debate between virtual actors and the participant (scripted)?
11	How important is it that the VR scenario is developed to: Have the participant observing interactions between virtual actors?
12	How important is it that the VR scenario is developed to: Have virtual actors being exposed to a demonstration of bad leadership?
13	How important is it that the intervention is developed to: Have various pathways that can help the participants navigate the scenario?

14	How important is it that the intervention is developed to: Teach the participant about moral distress? This was the emphasis in Phase 1, see video above.
15	How important is it that the intervention is developed to: Require the participant to experience moral distress?
16	How important is it that the VR assessments are developed to: Require the participant to complete “perceptual scales” (e.g., anxiety scales/stress index) such as pop-up in-scenario quizzes (provide results concurrently) based on standardized instruments?
17	How important is it that the VR scenario is developed to: Have virtual actors making mistakes unintentionally/intentionally?
18	How important is it that the VR scenario is developed to: Offer a team experience?
19	How important is it that the VR scenario is developed to: Require that the participant goes through a decision-making tree?
20	How important is it that the intervention is developed to: Make the participant aware that they are in a moral dilemma?
21	How important is it that the VR scenario is developed to: Have virtual actors feeling unsafe?
22	How important is it that the intervention is developed to: Require the participant to make time-sensitive decisions?
23	How important is it that the VR scenario is developed to: Have virtual actors experiencing frustration?
24	How important is it that the VR scenario is developed to: Have virtual actors feeling betrayed?
25	How important is it that the VR scenario is developed to: Offer an individual experience?
26	How important is it that the VR scenario is developed to: Have the participant actively interacting with virtual actors?
27	How important is it that the VR scenario is developed to: Have virtual actors feeling the effects of staffing issues?
28	How important is it that the VR scenario is developed to: Include evocative storytelling?
29	How important is it that the VR scenario is developed to: Trigger emotional responses in the participant?
30	How important is it that the VR assessments are developed to: Use participant biometric data (e.g., physiological markers of stress levels) gathered during the VR simulation to request participants to share reflections on the experience and suggest tools provided during the “intervention” that would help deal them this situation in the future?

31	How important is it that the VR scenario is developed to: Prompt reflection in the participant?
32	How important is it that the VR scenario is developed to: Shows something has happened and the participant goes through the experience?
33	How important is it that the VR scenario is developed to: Elicit genuine reactions from the participant which drives their responses to the intervention?
34	Please provide an optimal setting for this scenario (e.g., ICU, ER, Long-term care, outpatient). It would be beneficial to have a scenario which any nursing professional could relate to as a specialized scenario (e.g., ICU) will exclude nursing professionals working in other settings and not allow for recruitment of 100 participants over 6 months.
35	Please provide any comments/suggestions/questions for the OVERALL development of the VR assessments.
36	Please provide any comments/suggestions/questions for the OVERALL development of the VR intervention.
37	Please provide any comments/suggestions/questions for the OVERALL development of the VR scenario.
38	Please provide any comments/suggestions/questions for the OVERALL development of the VR simulation.

Table 2: List of questions for modified DM Round 1

5.2.3.2 Modified Delphi methodology

In Round 1 of the modified DM, all 13 participants rated the importance of the inclusion of the 33 items from the modified DT process in a survey questionnaire. Statistical analysis and review of free-text field commentaries provided in Round 1 led to nine items being removed, 12 items being retained, and 12 items requiring further clarification from the participants (Table *3*). After Round 1 ended, a Zoom meeting with the participants resulted in the 12 items merging into eight items requiring revisiting in Round 2 (Table *4*).

Question #	AVG	SD	Decision for DM Round 1	Comments
				Way too low a baserate.
				There should be harm, but not likely self-harm
				Typically a very rare event in a real scenario
				Too extreme.
1	2.08	1.00	Remove	Stopping self harm likely not a dilemma for a nurse
				Dehydrated? Excess alcohol consumption?
2	2.33	0.78	Remove	In a war zone maybe not here
				What is this and what is the aim?
3	2.75	1.06	Remove*	Logic? This sounds like the early days of bioethics when it was believed that ethical theory would make our ethical problems go away. Logic can be good for dilemmas but not so much for moral distress.
				What is this and what is the aim?
				Again, reasoning isn't the problem otherwise all the years of ethics education in nursing would have reduced moral distress.
				Development of models that would assist in predicting and responding to risks associated with “moral injury” during the next Phase of the pandemic or in the future, including, but not limited to development of critical models of disease prevention and psychological, neurological, and endocrine intervention models for responding to risks.
4	3.00	1.13	Remove*	Must balance this to make sure we aren't interfering with process
				It might help the scenario, but isn't necessary
				Sleep is important obviously but not central to moral distress.
5	3.08	1.16	Remove*	Sleep loss, maladptive coping and adverse outcomes is important

				What is a moral debate and what would that achieve?
				This is a good way to get at the concept of moral distress
				This is a core requirement for decision making so important to include this
				It would be good if perhaps someone were taking a position that is unethical.
6	3.17	1.34	Remove*	Post-funeral reflection with a peer ("root-cause analysis") could be considered, what was the nurse going through (emotions & thoughts) and decision making framework debate either internal or external is important
				Too clunky.
				Would be nice, but not necessary
				I think we will get more out of them by asking them to speak as opposed to write.
				Could this be the debrief?
7	3.17	1.27	Remove*	Want to avoid burden but a qualitative way to see if we hit the mark
				This all depends if we are trying to evoke other directed MI or self directed MI.
				Why misplaced? When is anger misplaced?
				This may well trigger HCP, we'll have to be able to manage this
				Anger isn't always part of moral distress
				This is possible in a natural scenario so good to include that component
				It's hard to know where to place anger when you don't have much power. Where would it be properly placed? Political action maybe...
				Anger turned inwards!-maladaptive behavior by the nurse-poor team/organizational response
8	3.25	1.14	Revisit for Round 2	Anger good not sure we can determine misplaced
9	3.42	1.51		The types of conflicts we may expose them to may not be productive

			Revisit for Round 2	The values might not be conflict--because again that's more of a dilemma. It is important for participants to be able to express what values/beliefs etc are being compromised. It's important in any scenario that participants be able to express themselves using ordinary language. The 'values' can be identified if necessary by someone doing the data analysis.
				Values in conflict and maladaptive responses
				Don't get it
				Helps with engagement
				Great to have the first person focus--but the scripted element limits what is possible.
				Post-funeral reflection with a peer ("root-cause analysis") could be considered, what was the nurse going through (emotions & thoughts) and decision making framework
10	3.50	1.24	Remove*	Debate with internal actors can accentuate it
				I think it is more important that the participant is active in the interactions more than observing.
11	3.50	1.17	Remove*	A conversation among virtual actors (as was done for Phase 1 in the ICU) could model impaired dynamics at the team/organizational levels
				Disagree, this implies that moral distress / injury is caused by bad leadership in healthcare
				Not a demonstration but a story of the same.
				Most of the time, this is also a key cause of moral distress
				This could be a realistic component, but I don't think essential.
				Betrayal at all 3 levels, might want to consider personal/family impact
12	3.50	1.38	Revisit for Round 2	Poor or lack of leadership may help increase distress
				To reduce complexity we should minimize branching
13	3.58	1.24	Revisit for Round 2	Yes, this wold help with future real-life scenarios that participants may encounter

				If possible that would be great because it was a criticism by participants of the scenario from Phase 1.
				Didactic and reflective
				Ideal but challenging. it supports the idea that in "moral dilemmas" there may not be a right answer
				It is important to educate the user. At the same time this should not bias the experience of the participant.
				It's important that they can label the experience. I would think that many would be already be familiar with the concept.
				Recognition of distress in general & moral distress in particular
14	3.58	0.79	Keep	I think that depends on the purpose of the study ...we can understand distress without this
				I assume that it is that they experience moral distress during the initial phase, with the intent being that the intervention is designed to mitigate the moral distress.
				Requiring is too strong a term. We have to assume that the challenge left them with something and that something is what is being addressed in some way in the intervention
				This is also an important requirement of this project
				This likely not important if the participant can reflect on 'real' moral distress they have experienced in their practice.
15	3.67	1.67	Revisit for Round 2	Participant is coming into the 10 minute intervention with hopefully "moral distress", the intervention should help reduce it
				Like a moral stressor at work and then they rate symptoms as a result? I would go with the residue of the challenge and last month symptoms.
				Will there be too many moving parts?
16	3.67	1.15	Revisit for Round 2	Empirical research methods and proposals for measuring stress-related physiological response (e.g., inflammation) that will characterize the effects of population-level

				prolonged stress exposure on brain structure and function and on patterns of physiological response
				Helpful to see what we elicit
				This all depends if we are trying to evoke other directed MI or self directed MI.
				Have someone share their story of mistakes and the impact. Better yet, have a nurse tell a story of being overworked, having bad leaderships and supports, poor self-care, having patients and family members acting out their anger, and then at some point taking their anger out at patients and doing something they are ashamed of.
				It should involve involving the participant also making mistakes, either intentionally or unintentionally
				If mistake means doing something unethical then yes it is important. If a mistake is not present, then a problematic policy must be in the background--like limited staffing, discharging pts too early, etc.
				Making mistakes at individual/team/organizational levels--participants recognising this
17	3.67	1.23	Revisit for Round 2	If the scenario is witness and transgression and decide to report
				I don't have a strong opinion either way.
				Not every moral distress scenario needs to involve a team, but it usually does.
				Team dynamics might add an additional layer of complexity and might "mask" individual characteristics and trends.
				The team aspect is essential because the relative power of nurses in the hospital hierarchy, along with its constraints, generally is at the center of moral distress experience. The team should include administrators.
18	3.67	1.30	Revisit for Round 2	I feel moral dilemmas are quite personal and individual experiences
19	3.67	1.37	Revisit for Round 2	I think we should 86 this idea of helping people make better decisions. In morally complex and horrible situations there is no right way to respond that would make the experience not impactful and it is not the decision per se that is harmful but the situation

				and context. It is important to understand that moral injury is not only about doing harm to others, that is personally transgressing, it is most commonly about bearing witness to injustice and bad acts or impossible moral stressors, or being the direct victim of others bad behaviors.
				I believe it would be important to immerse participants in a decision-making situation in morally challenging contexts; however, another possible idea is to have them watching a discussion about a ethical dilemma or witnessing an unethical situation
				Decision making is important for intervention, and the real-time aspect is a key component,
				There must be something that constrains the participant from acting on their decisions.
				A decision tree might allow for breakdown of decisions at individual/team/organizational levels, asking stress-related questions at each point of the decision tree and promote reflective learning. the tree may be part of the education ....
				Not in real time. The question should be: "What about the virtual experience resonates with you and how does it make you feel? And, how common is this experience and does it interfere in the quality of your life and your functioning at work, home, and in terms of leisure?" Etc.
				A key goal is to make participants aware of being in a moral dilemma
				Again--moral dilemmas are distinct. They are about having 2 options that are equal but only one can be acted on so that the person doesn't know what to do. Moral distress is more about knowing what to do but not being able to act.
				Coming out of a funeral in mourning would hopefully put the participant in a "stressful but reflective state"
20	3.75	1.48	Revisit for Round 2	That should be the training. Likely a bridge too far for everyone
				This would speak to the high stakes situation.
21	3.75	0.62	Keep	unsafe settings with poor organizational oversight

				In health safety (health) is often the issue
				Again here - it's not clear if the intervention require times-sensitive decisions, but rather the VR scenario incorporates time-sensitive decisions, as this will maximize the degree to which it mimics a scenario where moral distress is possible.
				Requiring is too strong a term. We have to assume that the challenge left them with something and that something is what is being addressed in some way in the intervention
				Time-sensitive decisions induce stress and are commonplace in healthcare setting
				Yes, they should make poor decisions in the moment
				Time is of essence in all these
				It needs to be time-sensitive enough to be realistic, but again the distress isn't so much about the decision as the inability to act on ones judgments/decisions.
				Decision-making errors can be points for course correction
22	3.83	1.11	Revisit for Round 2	I can’t see it being possible in 10 minutes without the pressure
				This all depends if we are trying to evoke other directed MI or self directed MI.
				Frustration isn't necessarily a situation caused my a moral mistake
				This is possible in a natural scenario so good to include that component
				The participant needs to experience frustration in response to a constraint. All the actors do not need to be frustrated, however.
				Frustration with maladaptive behavior at all levels
23	4.00	0.74	Keep	I think frustration towards participant may add to urgency and anxiety
				This is the key feeling in moral distress
				It could be that nurses feel betrayed by the system.
				Betrayal at all 3 levels, might want to consider personal/family impact
24	4.08	1.24	Revisit for Round 2	Yes they should react strongly regardless of decision participant makes

				It is unrealistic that a healthcare professional would be working alone
				Moral distress usually involves more than just the person experiencing it. Someone else may have caused it.
				Better than team dynamics as individual characteristics and trends may not be "masked".
				If the scenario is individualized it will be more realistic, but it will be more difficult to make conclusions across participants.
				Individual is the focal point for reflection and bringing about change. Interaction with group and organizational levels is important but it is individuals who are participating/reflecting and not groups/organizations.
25	4.08	1.24	Revisit for Round 2	I feel they are highly personalized and individual (almost lonely)
				If someone is telling their story, maybe the thing could pause and the nurse could respond out loud. That could be good.
				This could help with engagement in the scenario
				Interaction can bring more realism
26	4.17	0.72	Keep	Interpersonal tension would be great
				This is probably one of the main issues facing frontline HCW, and definitely need to be embedded in the VR scenario design process
				Yes--this is a constant even if it is the background.
				Staffing issues could happen at anytime including COVID
27	4.17	0.83	Keep	May be an issue if that creates pressure re decision
				I think to maximize a response, the situation needs to be immersive and evocative
				I think the best challenge experience is to hear a very real and very compelling story of various moral harms and their impact.
28	4.17	0.94	Keep	Storytelling might divert the user from the actual medical event

				A generalizable scenario with an adverse event (e.g., death by suicide), having adverse events to both patient and nurse and how things are handled on an individual/team/organizational level might allow for evocative story telling.
				The scenario needs to be able to evoke strong emotions - in fact, I would go so far as to exclude participants from analysis of the effect of the intervention if they do not exhibit some degree of distress during the initial scenario
				This is ideal but we have to find a way to be impactful when the scene is not very evocative. Many nurses will need to imagine these challenges and think about the future rather than having the capacity to be triggered because of personal moral stress.
				I think this is where personalized aspects of the participant could be recorded and analyzed to provide specific parameters.
				Important for objective and subjective data capture
29	4.25	0.87	Keep	I would not call the sense or urgency and angst emotional
				This is hard to pull of because you would need a benchmark for sufficient arousal to warrant concern. I think it easier to simply ask folks the thoughts and feelings that come to mind as a result of the challenge and go from there. It would be important to correlate active and passive data for searching for potential physiological markers of stress / moral dilemma
				"Diagnostic criteria reflecting the cluster of features and symptoms of “moral injury” that may be linked to but separate from PTSD that can be used to accurately identify those affected Empirical research methods and proposals for measuring stress-related physiological response (e.g., inflammation) that will characterize the effects of population-level prolonged stress exposure on brain structure and function and on patterns of physiological response
				Biometric data captured in the VR setting should match the real-life ones.
30	4.33	0.78	Keep	We are using distress as a surrogate to internal angst so best we can do this

				This will support learning and potentially lead to a bigger response
				Reflection could happen after the scenario is experienced
				I think the reflection could be helpful for learning.
				This is the purpose of the scenario + intervention (Compound intervention/Kolb's model)
31	4.58	0.79	Keep	I feel time pressure and urgency is key
				Situation needs to be something high stakes (e.g., life and death decision), trigger distress, have a moral component
				Situation needs to involve a difficult moral dilemma or moral decision that the nurse needs to make or observes someone else making
				It seems you are trying to replicate the idea of a moral dilemma and a nurse choosing a strategy as if the challenge should pertain to decision-making rather than an immersive experience that brings up moral emotions and personal experiences or worries about these things happening, which can then lead to a self-assessment and framing of the lasting impact of these experiences as moral harm moral stress and leaning about ways of managing and mitigating these very human and very understandable responses.
				"Adverse outcomes as a result of individual/team/organizational decision making with repercussions at the three levels. The adverse event could include death of patient (including by suicide) with wrongful implication of the team/nurse and adverse outcomes to the nurse (could range from loss of job, reputation, maladaptive coping including addictions/drug use, or at the extreme stress/PTSD/depression/suicide, etc), scenario could end at the funeral with participant exiting with PTSD.
				Diagnostic criteria reflecting the cluster of features and symptoms of "moral injury" that may be linked to but separate from PTSD that can be used to accurately identify those affected;"
32	4.58	1.16	Keep*	better that participant is engaged as opposed to observer in my opinion
33	4.67	0.65	Keep	Plan for the lowest common denominator which may be minimal real time emotional reaction.

				This is would be a key component of the interventional strategy and any associated physiological and emotive responses and parameters
				Yes, but to be ethical the genuine reaction must be a small dose
				May be pertinent to get participants to name the "thought" or "emotion." However, given that the scenario is only 10 mins, this would have to be laid out as choices and not open ended
				Reaction maybe internal distress but a decision or reaction/action is a must
34	N/A	N/A	N/A	Inpatient ward Community care ICU ER LTC Any unit General medicine
				Again, I think the assessment should be based on theory - if the goal of the intervention is to reduce moral distress - then this is what should be the focus. The question then becomes how to measure moral distress - biometric markers could potentially be used to measure correlates of hypothesized moral emotions such as guilt, shame, and anger [I'm thinking simple things like arousal, though this one is non-specific]. Since we know very little about peri-situational reactions to moral distress, it is difficult to firmly provide hypotheses about what might be happening - but if I was to hazard a guess I would think we'd want to focus on self-reported emotional response; beliefs about the situation and the decision and potentially about causality of the decision etc. [I have a took we've used to look at reactions to potentially morally injurious events that I am happy to share]
35	N/A	N/A	N/A	I would administer a mood scale like the Positive and Negative Affect Scale referenced to the reaction to the challenge and at some point have them fill out the MIOS with respect to their own worst and most currently distressing potentially morally injurious nursing experience and based on that score provide feedback and suggestions.

				Make use of qualitative approaches as much as possible.
				"The psychological trauma associated with moral injuries can lead to insomnia, depression, physical and psychological pain, and maladaptive behaviours, including isolation from friends and family, self-medication with alcohol and drugs, etc. While these symptoms are often ascribed to operational stress injuries, notably, Post-Traumatic Stress Disorder (PTSD), moral injuries produce “scars” that are not well captured by these current conceptualizations
				Means to identify events and circumstances that have the potential to cause “moral injury,” and to measure its severity, in First Responders and primary healthcare workers;
				Does the data collected through app/wearables (pre-participation) determine stress levels at VR participation--after VR participation
				What subjective data collection and subjective-objective correlation is needed for model development? What baseline data can be collected while keeping REB constraints (e.g. mental health data-personal health information of nursing professionals)"
				Overall I think the intervention should be grounded in theory about potential ways to mitigate, reduce or prevent moral distress.
				Goals: to increase awareness of moral dilemmas; and to increase moral resilience, if possible
				The purpose of this challenge is to stimulate empirical research on “moral injury/distress” among healthcare workers and First Responders. It is hoped results will also act as a proxy for understanding the ways military personnel are likely to respond when faced with similar morally injurious circumstances during combat, peacekeeping operations or when responding to a future pandemic.
				"Evidence-based methods for the prevention of moral injuries and/or treatment therapies"
				Consider didactic 10 minute version versus an interactive 10 minute version with a therapist. Didactive will cover more material but does not need to be a VR intervention.
36	N/A	N/A	N/A	Pre-reading before the scenario but his could bias responses as some may read/not read/assimilate.

				I think that the most important part of the scenario is to decide if it's self or other directed moral situation, and to set the situation up such that the participant either observes or has to make a high stakes moral decision. To evoke moral distress, I also think it's important that it's highly interactive, to promote emersion in the situation, and to maximize the likelihood of the participant responding emotionally.
				"GUILT & SHAME, ANXIEY, DISTRESS AND BURNOUT ARE KEY.
				While the risk of “moral injury” is typically associated with warfare and conflict, evidence from the front-line of the COVID-19 pandemic suggests that healthcare workers and First Responders are also suffering extreme psychological, cognitive, and emotional responses, including guilt and shame. This state of anxiety and distress is often described as burnout. However, the cluster of features and symptoms of moral injury is not adequately captured by interventions and treatments associated with burnout
				QUICK DECISION MAKING (TIME/RESOURCE CONSTRAINTS)-->REAL-TIME INSIGHT FOR DECISION MAKING-->CUTTING EDGE PREVENTION MODELS & TREATMENT STRATEGIES TO PROVIDE FOR LONG-TERM MENTAL HEALTH
				Canadian Armed Forces members operate in extremely difficult and dangerous operational contexts and situations, in which they routinely face complex moral and ethical dilemmas. All military members are trained to make quick moral-ethical decisions, at times, with only limited information. Still, some operational experiences can be profoundly distressing. These experiences can give rise to feelings of guilt and shame, which can be morally injurious and result in long-lasting mental health challenges and impairment if left unresolved.
37	N/A	N/A	N/A	time pressure, tragic moral dilemma
				In general I think all three components are key, and all three components should be driven by a theoretical model of moral distress/moral injury development and prevention.
38	N/A	N/A	N/A	I believe the VR scenario should be as realistic as possible and evoke a common situation nursing professionals must face, so participants can emotionally resonate with the virtual avatars and easily recall past experiences of moral dilemmas

				VR instrumentation comfort level is a key element as many may not have experience with headsets so ease of device usage should be factored in to avoid any device related bias of interaction/bias during the actual VR experiment
				"SUMMARIZING KEY TASKS FROM THE DND CALL" The goal is to understand the circumstances and events that can give rise to “moral injury/distress,” diagnostic criteria, prevention models, and treatment strategies (e.g., psychological, neurological and endocrine interventions for prolonged stress-related response treatment).
				Evocative scenario with ""truly"" adverse outcomes to the patient & participant in scenario-->stress/moral distress-->DSM-based symptoms-particularly PTSD & differentiation from moral distress-->identifying factors/correlation between virtual & real life correlation of stress response-->measuring stress-related responses-development of predictive models--> reflective methods for prevention/treatment"

Table 3: List of modified DM Round 1 items/sketches, free-text field comments, means, and SDs

* Item originally “Revisit for Round 2” based on statistical analysis, however, was reclassified based on comments/end-of-round meeting discussions.

SD: standard deviation; ICU: intensive care unit; MI: moral injury; DM: Delphi methodology; COVID-19: coronavirus disease 2019; PTSD: post-traumatic stress disorder

Questions #	Question
1	How important is it that the VR scenario is developed to: Have participants experiencing anger?
2	How important is it that the VR scenario is developed to: Have the participants identify their values in potential conflict/difficult citation portrayed in the scenario?
3	How important is it that the VR scenario is developed to: Have the participants been exposed to a betrayal at a team level?
4	How important is it that the VR scenario is developed to: Have the participants navigate the scenario using a decision-making tree under a time crunch?
5	How important is it that the VR assessments are developed to: Require the participant, in real time during the scenario, to complete "perceptual scales" (e.g., anxiety scales/stress index) such as pop-up in-scenario quizzes (provide results concurrently) based on standardized instruments? (please refer to the videos from DND1 for samples)
6	How important is it that the VR scenario is developed to: Have participants making mistakes unintentionally/intentionally?
7	How important is it that the VR scenario is developed to: Focus on the individual participant but the scenario is embedded within a team setting?
8	How important is it that the intervention is developed to: Explicitly make the participant aware that they are experiencing moral distress?
9	Please provide us with a sketch of a potential scenario and intervention that include as many of features as possible.

Table 4: List of questions for modified DM Round 2.

VR: virtual reality; DM: Delphi methodology

In Round 2 of the modified DM, 10 out of 13 participants rated the importance of the inclusion of the eight items from Round 1 in a survey questionnaire and provided sketches of potential VR simulation scenarios and in-VR interventions using free-text fields. As a result of the statistical analysis and review of the free-text field commentaries provided, four items were removed and four items were retained. Five VR simulation scenarios and in-VR intervention sketches were provided (Table 5). After Round 2 ended, a Zoom meeting with the participants resulted in retaining the decision to rank the VR simulation scenarios and in-VR intervention sketches in Round 3.

Question	AVG	SD	Decision for Modified DM Round 2	Comments
				More than anger, with moral distress, it is usually shame and guilt.
				Anger is one possible emotion but I don't think it is absolutely essential.
				Participants need to experience and identify the emotion such as anger
				Anger or frustration is good if we hope to create an element of "betrayal" but not all events will cause anger
1	3.44	0.73	Remove	Anger is a moral emotion that arises from exposure to others' transgressive and betraying behaviors. It is half the moral injury puzzle. Shame is the moral emotion that arises from one's own transgressive behaviors. So, it depends on the focus of the challenge task.
				If they can name their values, it may be helpful in coping with the conflict
				There likely are value conflicts embedded in any moral distress situation involving nurses, but not all participants will be able to articulate them because they are inherent in social structures that devalue care work and those who provide it. It's impossible to fully understand moral distress without an analytical lens that can capture power.
				Naming the emotion and reflecting on underlying causes is important
2	3.67	1.22	Keep*	they may not see it during the initial VR exposure but eventually this is important
				Despite some thought on the topic, it is often the leadership that betrays what the team is able to do, causing distress.
				I have mixed thoughts about this one. The betrayal is often at the level of the institution as opposed to the team.
				Participants need to experience and identify the emotion (e.g. betrayal) and reflect on underlying causes including at the team level.
3	3.56	0.88	Keep	again possible depending on if the scenario is meant to evoke a "anger" rather than guilt/shame ...one scenario is unlikely to evoke all 3

				If we are going for betrayal and no personal transgressive behaviors, this seems ecologically important for nurses and something that would hit home.
				Immediate action without being able to think it through can lead to moral distress and situations causing it.
				Will be limited by the time we have to create the VR scenario
				Depends on the scenario.
				Time crunch (scarcity of time/resources for decision making) is key. However, this could be portrayed in the scenario, the decision-tree approach could be better used for the participant to identify the emotion and causes at individual/team/organizational levels. A 10 minute scenario will not be enough time to have a participant go through a detailed decision-tree with various branch points AND also stop and reflect on the emotion/cause. A feasible alternative is to get the participant to reflect on what the person in the scenario was experiencing as the scenario plays out.
				i feel this is a good way of increasing some stress/distress with
4	3.44	1.13	Keep*	I don't like this contingency. This assumes that we want to create a challenge task that requires decision-making as if the enterprise will help them make right decisions under stress. Moral injury is what happens when people are betrayed by their own behaviors or those of others and these things are not strategies or choice points but non-conscious and non-deliberate and non-deliberative.
				Is this the best way to collect the data? If we're embedding these into the VR it would reduce the amount of time they can actively participate in the scenario. Something to consider.
				It's a good idea but it might be necessary to pull out items that measure emotion as opposed to mood.
				See comment above. There maybe elements of the perceived stress scale or even participants stopping to name the emotion/cause at different time points.
				this may interfere with process perhaps reflection afterwards will capture
5	3.33	1.50	Remove*	This will provide an informed design of labeling for signal/scene analysis

				I would not do this because it gets in the way of being present to the challenge task. Ask afterwards. Why is real time assessment needed?
				It depends on what is meant by a 'mistake.' A more likely scenario would include someone misusing their power in a way that does not ultimately serve a patient's good.
				See comment above- the person in the scenario makes decisions under a time/resource crunch which lead to negative outcomes. The participant then reflects on the experience of the person in the scenario.
				best is "no right answer" .ie perception of wrong
6	3.11	1.54	Remove*	I don't think this is the way to go.
				Emergent situations, or situations likely to cause moral distress are usually handled by a team.
				I think to be realistic for nursing, a team context is important.
				The person in the scenario makes decisions under a time/resource crunch with individual/team/organizational aspects which lead to adverse outcomes at the individual/team/organizational levels. The participant then reflects on the experience of the person in the scenario.
7	4.33	0.50	Keep	i think MI is an individual process that can occur in an individual or group setting
				Not necessarily immediately, but if they do not recognize their distress as moral, perhaps some prompt might be in place to help them.
				In the long run I think is beneficial for participants so that they can label it when they experience again. The best intervention is to support participants in being assertive and making organizational change.
				The person in the scenario should clearly experience stress in general and moral distress in particular. The participant puts himself/herself in the shoes of the person in the scenario and reflects on the process.
8	3.11	1.17	Remove*	I am not sure it will be explicit...they will feel distress but may not see it is as values in conflict

				Not in real time. Do something immersive so that the person can be present to it and then ask them afterwards what is coming up for them right now.
				1- Perhaps a nurse caring for many more patients than they normally do without back up. Admins gets involved and tells them they just have to do the best they can and no help is forthcoming. The nurse night take shortcuts to try to keep up, then makes a serious med error and a patient is harmed - necessitating movement to a higher level of care, or a patient dies. Perhaps while all this is going on the nurse intentionally ignores a call bell for help when a patient falls. The nurse gets blamed by admin for both mistakes.
				2- "A nurse who works in long term care/home care etc. shows up to their shift and is told they are working short and have an increased assignment as a result. At some point there is a lack of resources (PPE, or meds or equipment due to supply chain issues) At some point they have a patient who is declining (medically) and one who is very emotionally distraught- RN has to choose who to care for. At some point they are given an important task (e.g. sterile dressing change) that requires 2 people- they don't have the second person, so either can't do the task, or it's done not to best practices At some point they have a colleague who confides in them they don't have the energy to do their job, and/or isn't doing their full roles/responsibilities because they are so burnt out. OR colleague goes on a rant (unprofessionally) about another patient because they are burnt out. Consider lumping multiple triggers for moral distress together to maximize effect."
9	N/A	N/A	N/A	3- "10 minute scenario outline Participant becomes the ""nurse in the scenario"" with other avatars at individual/team/organizational levels. First 5 minutes- Early discharge from inpatient unit (or emergency unit) due to time/resource crunch-patient death in the ICU with difficult family/team discussion. Stop at few timepoints to get participants to reflect on being the nurse in the scenario. Second 5 minutes- Consequences to the nurse at individual/team/organizational level, nurse has negative outcomes (?burnout) and job loss. Stop at few timepoints to get participants to reflect on being the nurse in the scenario."

				4- I am not sure I have one in mind. above is a bit confused. if we want anger and "institutional betrayal" then an urgent need, decision made but not enough supply (ie blame the organization for failing)
				5- Nurse working on a busy inpatient unit, they are short staffed this shift and the nurse is also training a newly hired new graduate nurse during this shift. The nurse is unable to meet his / her patient's needs (eg. cannot respond to emergency situation in timely manner) or has to reallocate resources / make decisions under a time crunch or nurse makes a mistake or witnesses another nurse / team member make a mistake with poor patient outcome (eg. administers wrong dose of narcotic and patient experiences respiratory arrest / death). The nurse knows the right thing to do but cannot do it because of the system / environment. Nurse is angry, feels betrayed by the organization and the system, feels guilty that the new graduate nurses are being introduced into the profession this way. Both patient well being and professional well being are impacted.
				6- "First 5 minutes: Frontline HCW discussion in LTC with patient's family with complex/morally challenging decisions under time pressure at individual/team/organizational level leading to patient death (anger, betrayal, loss, etc). Second 5 minutes: Copying of frontline HCW with depression and ending in self-injury. INTERVENTION: 10 minutes: Instructional in a conversational context"
				7- As many as what features?
				8- "SCENARIO: Hospital is understaffed and nurse must make decisions about who on the team works in what area/unit that day, and is forced to place nurses who are untrained or unfamiliar in some areas/units. This scenario could be rigged such that a bad outcome occurs regardless of the decisions of the nurse, resulting in harm to a patient and/or administrative/disciplinary action against one if the nurse's team members due to the choices of the nurse. INTERVENTION: brief (~5 -10 min) didactic on moral distress and mindfulness, possibly also on power and control (e.g. we could pull talking points from Cognitive Processing Therapy for PTSD handouts). Then an ~10 minute mindfulness exercise emphasizing grounding and attentional control (e.g. similar to attention training), to help the nurse create

				the space to recognize their reaction and identify what they have the power to do in this context."

Table 5: List of modified DM Round 2 items, free-text field comments, means, and SDs.

* Item originally “Revisit for Round 3” based on statistical analysis, however, was reclassified based on comments/end-of-round meeting discussions.

SD: standard deviation; ICU: intensive care unit; MI: moral injury; DM: Delphi methodology; COVID-19: coronavirus disease 2019; PTSD: post-traumatic stress disorder

In Round 3 of the modified DM, nine out of 13 participants ranked the five VR simulation scenarios and in-VR intervention sketches provided in Round 2 on a Likert scale of one to five, one being the most likely candidate and five being the least likely candidate. To assist with the ranking, participants were presented with the 16 items that were retained from the previous DM rounds as elements to be integrated into the content of the final VR simulation (Table *6*).

The scenario would:
Educate the participant about stress in general and moral distress in particular, and have them be able to label the experience
Have participants actively interacting with virtual actors
Have participants exposed to betrayal and reflect on underlying causes at a team level
Have participants reflecting on their reactions to the scenario in relation to their values/beliefs
Educate the participant about stress/moral distress and be able to help the participant label the experience
Have the participant navigate a time-constrained scenario using a decision-making tree
Include evocative and immersive storytelling
Trigger genuine, emotional responses in the participant (small doses)
Show that something high stakes had happened with a moral component
Focus on the individual participant but be embedded within a team setting
The virtual actors, due to the scenario, would:
Feel unsafe to speak
Experience frustration and display maladaptive behaviour
Feel the effects of staffing issues
The intervention:
Is didactic on recognizing at individual/team/organizational levels stress→moral distress→values in conflict
Includes some interactive component related to the scenario for active learning
The assessments would:

Use participant biometric data (e.g., physiological markers of stress levels) gathered during the VR simulation for pre-post intervention stress and moral distress comparison.
Get participants to feel/think/reflect on the experience at different time points in the scenario→intervention→repeated scenario and examine the pre-post effects of the intervention.

Table 6: List of items retained from modified DM Rounds 1 and 2.

VR: virtual reality; DM: Delphi methodology

All five VR simulation scenarios and in-VR intervention sketches were rated as somewhat candidates to use as the content for the final VR simulation (Table 7). After Round 3 ended, a Zoom meeting with the participants suggested combining some of the elements from each of the five VR simulation scenarios and in-VR intervention sketches to create the content for the final VR simulation. The general content of the VR simulation and in-VR intervention was decided to be the following: in the VR simulation, the participant is a novice nurse and due to staffing shortages, needs to choose between attending to two patients who are in critical, near-death conditions. As a result, one patient who is not cared for dies, and the participant is then reassured by a colleague which is delivered in the format of an intervention on ways to mitigate moral distress. This was converted into a VR simulation script for the scenario and an in-VR slide deck as the didactic intervention and a focus group interview to review these materials took place afterward.

Scenario Stem #	Ranking	SD	Scenario Suggestions	Intervention Suggestions
			This seems more tailored for an admin or middle manager. If we want to get to "boots on the ground" nurse distress this scenario is unlikely to do that, especially if the participant is not in admin.	I like the ideas for the intervention provided in this stem
			No suggestions	"Intervention suggestions are excellent and could be incorporated into the 10 minute set up as things which could be done in addition to reflection to lower stress- mindfulness, attentional control, psychological first aids. These could 20 second exercises within the otherwise didactic intervention"
			A nurse making decisions about allocating other nurses sounds like a "charge nurse" role. This may not be relatable for as many participants as not all nurses take on the charge nurse role.	I can't comment, not an expert in moral distress
			I like this scenario because it is realistic / relatable regarding the difficult and morally conflicting task of making staffing re-allocation decisions (redeployment) which occurred during several waves of the pandemic. I would suggest the nurse in the scenario is the charge nurse (or nurse manager). The bedside nurse does not typically make these decisions though a bedside nurse participant would be able to relate as they may have been redeployed themselves, or may know colleagues who were redeployed.	I have no suggestions for the presented intervention.
5	2.22	1.2	Scenario would need expansion.	

			It would be very difficult for a group of non-RNs to rig the system in a realistic way enough to get to the error. It could unintentionally lead the RN to think "well I would never do that" and we wouldn't get the response we are looking for.	
			This is a well-articulated scenario! Hope other scenarios especially #3 and #4 can provide this level of specificity	
			Good ..forced to do something that compromises the value of supervisor send only those prepared. Also harm to patient	
			Have the some of the nurses complain about being assigned to unfamiliar areas/units, and have the participant pull rank and force them to work any way.	
4	2.44	1.33	I think this is a good scenario, and introduces moral distress. This is a scenario that is played out in a big way recently. It needs more specifics - such as what is the emergency situation, what are the decisions that need to be made, etc.	I would echo here the answer for scenario #1
			Vague. Least favourite option for this reason	This is not my area of expertise so I will not comment on ideas for an intervention
			"Perhaps combine this with some of the ideas in scenario 1: med error and/or fall. Adding a student nurse is an interesting idea. I wonder if/how that contributes to the moral distress? Is it a value-add?"	The 10 minute intervention could be didactic on individual/team/organizational aspects with some non-didactic material tailored to the scenario. The most the intervention could achieve in the immediate term is to get people to reflect on their values/thoughts/perspectives/emotions

			I like this scenario for the less overt examples of mistakes and for acknowledging the current and ongoing context of learners (new graduate nurses, nursing students) in the environment and how that can play a part regarding the emotions triggered - I wrote this scenario so I am not sure if I was supposed to rank it	I can't comment, not an expert in moral distress
			Some pertinent elements but may need to be made more "challenging"	basically aware that they are in a difficult situation and what values are in conflict and a possible process to make these decisions . forced to prioritize
			Like #2 very realistic. It is also very distressing as relatively recently an RN in the US made a medication error that they were held liable for, so it's on the top of folks' radar and may trigger more of a response than otherwise.	Explain how the participant could reach out for support about the organization 'betrayal', and how to guide the new graduate nurses.
			The factors that constrain the nurse to perform their obligations could be made specific.	
			good overall lots in 10 minutes	
			Have the new graduate nurse ask questions and provide comments, like 'shouldn't we report that?' when they notice that the other nurse/team member made a mistake.	
2	2.77	1.2	This scenario is messy because it contains things that might cause distress, but not necessarily moral distress. I would axe this one. Long-term care is a huge issue and should be addressed, but if we are focusing on moral distress, this one does not do the job.	This is not my area of expertise so I will not comment on ideas for an intervention

			no suggestions - I like the idea of multiple triggers to maximize effect; but could introduce unwanted/uncontrolled variability	The 10 minute intervention could be didactic on individual/team/organizational aspects with some non-didactic material tailored to the scenario. The most the intervention could achieve in the immediate term is to get people to reflect on their values/thoughts/perspectives/emotions
			I wonder how distressing weighing medical vs. emotional needs would be? I suspect most nurses would be somewhat accustomed to prioritizing medical needs.	I can't comment, not an expert in moral distress
			"I like this scenario for the realistic patients (medically unstable and emotionally distraught) and realistic nursing interventions and environment. This may not be applicable to a broad group of nursing participants due to the environment (long term care / home care) but is still relevant / relatable. As note, there are Registered Nurses (RNs) and Registered Practical Nurses (RPNs) at Unity Health Toronto, so please state ""nurse"" instead of ""RN"" in the scenarios - to be inclusive and representative of both types of nurse participants "	Explain to the participants that they have done all they could within their capabilities, and how to properly communicate/deal with a colleague that is making unprofessional remarks.
			Perhaps 1 & 2 could combined, the scenario may not be challenging enough.	
			This is very realistic as many HCP rely on their colleagues to support them emotionally. It would also be fairly straight forward to design.	

			This is an interesting scenario and appears to be a "busy one" and the main challenge would be to succinctly communicate this within the available time	
			Reasonable to make a difficult choice. this is more classic ie there is no right choice and either choice will lead to a negative outcome	
			At the end of the scenario, show what happened to the other patient that didn't receive service/care. Maybe show that a family member came to complain about that.	
			This scenario contains many of the elements of moral distress and betrayal. However, it does need an intervention to assist the nurse in dealing with feelings. The problem is that everyone will react differently - some are more resilient already than others, but having a participant correctly label these feelings would tailor an intervention to assist them in sorting out the feelings and effectively dealing with them. There really is no "one size fits all" intervention. Betrayal of trust can have long term effects that a short 5 minute intervention cannot manage.	We need to pick one intervention that has evidence behind it to use to determine its efficacy
			I think the concept and stress of working short staffed is very realistic and relatable across most areas of healthcare/nursing right now.	Walk through ethical decision making; exploration of all the factors that contribute to event
1	3.11	1.53	This is not realistic regarding the "blame" component of this scenario. It is not that overt in a real situation, and in my experience it is usually	This is not my area of expertise so I will not comment on ideas for an intervention

			self-inflicted blame, vs. being blamed by "admins" (who are the "admins"?) Also, the leadership and teams in real situations are supportive to offer help or reallocate resources so help can be available	
			There could be "added" stress with individual/team/organizational impact (practice review, audits, supervised practice, reporting to the professional organization etc). At different time points, participant's perceptions could be gauged as done in Phase 1.	The 10 minute intervention could be didactic on individual/team/organizational aspects with some non-didactic material tailored to the scenario. The most the intervention could achieve in the immediate term is to get people to reflect on their values/thoughts/perspectives/emotions
			This scenario feels very similar to stem # 2 and the latter already have more of the components we are looking for. Suggest stem #2	I can't comment, not an expert in moral distress
			The intensity of the scenario could be increased by assuming the patient has died rather than escalating to a higher level of care. Also, the situation regarding patient falls could be expanded by providing a resultant serious medical condition as an example after the fall.	just ensure people are aware of the values in conflict ie leadership should be supportive and help me do my job to the best of my anilities
			Good although it appear are setting the scenario up as an "institutional betrayal" rather than a direct struggle with values ..ie my leadership has put me in an impossible situation	Present the support mechanisms that the nurse can rely on if it is under pressure by the admin.
			Nurse is sick but is forced to go to work because it doesn't have paid sick days or is forced by the admin, and a patient ends up getting sick.	
3	3.77	1.2	ED and ICU are completely different, though they do impact each other, this one also is not realistic	This is not my area of expertise so I will not comment on ideas for an intervention

			with too much in here. The ED nurse would not be dealing with family in the ICU.	
			I think this stem is less clear than options 1 & 2.	The 10 minute intervention could be didactic on individual/team/organizational aspects with some non-didactic material tailored to the scenario. The most the intervention could achieve in the immediate term is to get people to reflect on their values/thoughts/perspectives/emotions
			Is it realistic for the negative outcomes (burnout, job loss) to be so obvious and immediate after only one event?	I can't comment, not an expert in moral distress
			Scenario outline looks good, needs more color & drama!	as above basically aware that they are in a difficult situation and what values are in conflict and a possible process to make these decisions
			This would be challenging as it would have almost infinite branching.	Explain how the participant could get support.
			The aspect of job loss should be clarified as whether it is a resignation due to burnout or layoff	
			unclear if nurse is passive witness. i think better if engaged	
			Make it feel as if the patient death was blamed on the participant (maybe during the family discussion).	

Table 7: List of modified DM Round 3 sketches, free-text field comments, means, and SDs

SD: standard deviation; DM: Delphi methodology; ICU: intensive care unit; ED: emergency department

5.2.3.3 Feedback from the focus group interview

The feedback provided after the focus group interview led to seven additional rounds of iterations to both the VR simulation script and slide deck via email. Main changes to the VR simulation script included (1) removing the racialized components (i.e., racialized names and accents) to avoid possibly reinforcing stereotypes, (2) making the narration and speech of the virtual characters more natural and realistic (e.g., instead of "what kind of professional are you?!," the text was changed to "what's wrong with you?!"), and (3) incorporating rage in the decision tree options for participants to pick when prompted (Table 8). Concerning the major updates to the in-VR intervention slide deck, they involved: (1) removing transitional or introductory slides that led from one topic into the next to run the intervention within the time constraints of the VR simulation (i.e., within 10 minutes), and (2) rephrasing the symptoms of moral distress and strategies to mitigate moral distress to better convey the learnings to the end user (Table 9). The VR simulation prototype was also improved to (1) include more facial and verbal expressions in the virtual characters to provoke emotional reactions in end users, (2) add natural body movements to the virtual characters (previously, the animation was set to idle so virtual characters were looking down and swayed side to side) to increase realism, and (3) have a professional voice actor narrate. All of these changes were made with the intent to align with the objectives of the educational resource to understand and mitigate moral distress in healthcare workers (Video 1).

Version	Updates
1	N/A
2	Added MIOS and IPQ scales
3	Changed Patient #2's surname to avoid stereotypes; Changed Patient #2's diagnosis from eclampsia to stroke; Skin tone as a randomized feature; Removed patient accents; Renamed RPN to "nursing colleague"; Removed nursing colleague's reference to feeling burnt out; Added more decision trees (DTs); Removed reference to Patient 1 being an important person and receiving preferential treatment; Added outgoing nurse performing the Transfer of accountability; Added Code Blue being called by the ward admin; Changed Patient #2's husband to be less punitive and more empathetic; Specified in the script indications of actions and narration
4	Added answers with rage to the DTs; Remove Patient #2's husband accusing the staff of thinking Patient #2 is hysterical
5	Added tutorial to the VR scenario; Updated actions and narration. Some actions were changed to be narrated passages; Updated MIOS questions; Added details of the location for each passage; Removed the threat of the ward admin to report to the hospital director
6	Added more narrated elements. Additional actions were replaced by narration; improved clarity of description of actions; Changed narrator referring to the participant from "participant" to "you"; Added a new character (doctor) to show support and empathy to the participant and the end of the story; Added in the tutorial a reference to unburdening to be done by a virtual avatar
7	Changed skin tones from randomized to preset; Removed other demographics features apart from gender and skin tone; Removed from tutorial a reference to unburdening to be done by a virtual avatar; Minor updates to a few dialogues to sound more natural

Table 8: Feedback provided from the focus group interview on the VR simulation script.

VR: virtual reality

Version	Updates
1	N/A
2	Decreased size from 40 to 29 slides; Added reference to COVID-19 in the problem statement of MD in healthcare; Added content about stress, moral distress (MD), and the difference between both; Removed content about moral emotion, the difference between MD and moral injury (MI); Removed slide about takeaways from the intervention; Added content about physiological, emotional and cognitive responses to stress; Removed content related to MI; Removed MD related to COVID-19 restrictions and measures; Added more interventions to mitigate MD: breathing exercises; Removed recommendations and rationale for a nurse leader to be a support team member; Slight aesthetic improvements
3	Decreased slide count to 18; Reduced content related to interventions at the individual, team, and organizational levels; Removed all specific interventions to mitigate MD
4	Removed problem statement; Added a slide with a summary of the intervention slide set; Reduced content on stress (physiological, cognitive, and emotional responses) and MD; Added more interventions to mitigate MD: grounding techniques (diaphragmatic breathing, 5-4-3-2-1 technique, self-compassion); Added links to YouTube videos as examples of each intervention
5	Changed slide format to script; Further shortened content
6	Improved accuracy of the content on MD in healthcare, symptoms of MD, strategies to mitigate MD, and specific interventions to mitigate MD
7	Changed format back to slide set and (slide count:15); General decrease in content (which was reorganized across the slides); Removed the summary slide added in the previous version; Removed slide about moral stressors; Removed YouTube links; Added a new intervention: unburdening; Style improvements (added avatars while considering diversity; added smooth slide transitions)
8	Changed format to video; Reduced content on symptoms of MD; Removed the 5-4-3-2-1 grounding technique; Improved content on the unburdening intervention; Slight improvements to style and text accuracy

Table 9: Feedback provided from the focus group interview on the in-VR intervention slide deck.

VR: virtual reality

Video 1: Video recording of the first VR simulation prototype that resulted from the CIC approach (https://youtu.be/bDPcxjFRIbc).

VR: virtual reality; CIC: constraints-ideation-consensus

5.2.3.4 SWOT analysis on the constraints-ideation-consensus approach

Participants who took part in the CIC approach were sent a Google Form survey in the form of a SWOT analysis to provide feedback on the methodology. The SWOT analysis is a technique for identifying and analyzing internal and external opportunities and threats [23].

In terms of strengths, participants stated that the approach was an excellent way to capitalize on and integrate expert knowledge of a wide range of areas of expertise relatively efficiently. They felt that it organized thought processes well and that it offered an equitable way of choosing key content areas for the development of the VR simulation. Lastly, they noted that it gave them an opportunity for everyone to speak out their ideas and suggestions that otherwise would not be feasible in large and hierarchical group discussions.

With regards to weakness, participants mentioned that it was challenging for them to commit and follow through all stages of the process as it spanned for around two months. During this time participants were required to attend a two-hour DT session, answer three rounds of DM survey questionnaires, and attend focus group interviews after each round. They felt that this process was time-consuming and long, and they were not sure if they were present or engaged throughout. Particularly for the DM rounds, there were concerns with how the responses from individuals were weighted. As there were people from various backgrounds, those with no background in moral injuries, such as simulation experts, had their opinion count equally as those with a background in moral injuries, such as psychologists and nurses, which could have led to watering down the responses of the different experts input provided through the DM. Another pain point of the CIC approach was that participants felt that sometimes it resulted in content not grounded in theory. For example, the rationale for the interventions was somewhat post hoc - they seemed to be chosen primarily because they were a good fit for the study design not because of any theoretical connection with target processes. Participants also thought that the large size of the group may have slowed down the efficiency of the process.

The opportunities that the CIC approach yielded for participants was that it was able to offer fresh perspectives and more clarity on moral distress. The virtual setting used meant a wide range of experts from multiple locations could regularly interact and collaborate. Finally, the CIC approach allowed for the project to be constrained by an initial methodology and understanding of assessing and mitigating moral injury in healthcare workers which guided the brainstorming and discussions on the topic.

The threats that were imposed on the CIC approach included participants' limited availability to meet, low engagement, and not being able to follow through the steps as planned. Also, while online interactions allowed geographically distant participants to join, they lacked the same effectiveness as physical meetings where ideation and paper prototyping can be jointly done. Tight timelines of the project which did not allow for enough information shared far enough in advance were also noted to have a negative impact on the process by participants. Overall, through this SWOT analysis survey, participants provided valuable insights into the novel CIC approach.

5.2.4 Discussion

This original article tested a novel CIC approach to describe the generation of parameters, needs, and requirements for the development of content for a VR simulation as a part of an educational resource to understand and mitigate the effects of moral distress on healthcare workers. To accomplish this, we utilized a unique expert-informant crowdsourcing method which consisted of a combination of constraints settings, DT and DM, followed by a focus group interview. The advantage of having employed DT for the development of content for the VR simulation is that it generated and expanded ideas in a creative and collaborative way [16]. However, this process alone lacks the rigor expected by the healthcare simulation community as the ideas lack evidence of content validity [25]. Therefore, we skip the final two phases of the DT to narrow down the ideas to a few executable ones using expert consensus through a DM before we prototyped and tested the VR simulation. The DM is widely accepted in the medical simulation community as a tool that provides content validity evidence [24]. The output of the DM was used to draft a scenario and intervention to embed into the VR simulation. An initial VR simulation

prototype was created based on this output. To ensure that the VR simulation accurately conveyed the outputs, a focus group interview with the participants was conducted online.

With regard to the CIC approach, there were benefits relating to its execution and output. Starting the process by breaking down the problem into scenarios, interventions, and assessments for the VR simulation ensured that all aspects of the educational resource were being thought of and addressed by the participants. The way in which the CIC approach guided the participants in understanding what the needs for the content for the VR simulation are, garnering more clarity in every phase, was helpful. It prepared the participants to be able to offer suggestions on possible "stems" for VR simulation in the final phase of the CIC approach. This resulted in five possible stems which provided a base for the content for the VR simulation script and slide deck, fast-tracking the creation of a preliminary draft to feed into the VR simulation development process. The CIC approach also posed some challenges. For instance, during the DM, although a specific statistical algorithm was established to classify the items as "remove," "keep," or "revisit," many of the comments did not correspond to this statistical algorithm. Specifically, many items were initially labeled as needing revision or clarification in the subsequent rounds of DM based on the algorithm. However, a closer look at the free-text fields linked to the items revealed various ideas were to be classified as either "remove" or "keep." As a result, the analysis of the DM at the end of every round was difficult to conduct because both the statistics and the free-text comments needed to be examined. What alleviated some ambiguity around the interpretation of end-of-round DM results

were the group meetings that occurred after each DM round where further discussion on these particular topics ensued.

The SWOT analysis completed by the participants also highlighted valuable insights into the CIC approach. Overall, participants felt that the process facilitated the discussion between various disciplines well, encouraged all viewpoints, and organized and refined the ideas in a logical and structured manner. The virtual platform enabled many individuals from various backgrounds situated across North America to participate. Mainly, it was the nature of DT and DM embedded within the CIC approach that allowed for the large group to work cohesively together [16,26]. A weakness and threat that was shared by the participants on the process was that it was long and over time they felt they became disengaged, thus not being able to contribute as much as they would have liked to. The online setting in which this process took place is mentioned in the literature to have this effect on participants due to the isolation and disconnection between them and the other participants [27]. What may have also led to mental withdrawal in participants could have been the widely contrasting opinions offered by the interdisciplinary group. To elaborate, the perspectives provided during the rounds for participants to review and rate as a part of the subsequent round may have become unmanageable and outside of the scope and interest of certain experts (e.g., details on moral distress provided by psychologists; however, computer scientists as one of the experts participating in the Delphi are expected to weigh in [28]. As considerations for future CIC approach use, the DT and post-DM rounds could be done as a group meeting in person in which all stakeholders could be seen physically (i.e., non-verbal communication) and viewpoints could be better articulated organically. To improve the exchange of ideas and knowledge

between the different participating experts in the CIC approach, specific points that need input from a particular area (e.g., nursing) could be called to comment instead of having all expertise involved in the CIC approach expend their energy in trying to talk on items that they may not have knowledge on (e.g., simulationists being asked to address VR technical questions). The combination of a face-to-face setup along with being selective on how to use the participating stakeholder's knowledge could allow for improved collaboration and outcomes from the CIC approach.

The use of online tools such as Zoom and Google Jamboards to facilitate the DT process and Google Forms to execute the DM allowed for the participants to share their ideas for the design of the VR simulation remotely and instantaneously, contributing to the speed of data collection [29,30]. The downside to Zoom is that it can pose technological problems (i.e., Internet connectivity and hardware issues related to audio) that can limit individuals from contributing their ideas. The disadvantage to Google Jamboards and Google Forms to collect data on the content for the VR simulation is that information provided by participants can be difficult to interpret and may require follow-up whereas in-person this could be resolved more readily. Despite these shortcomings, overall, the CIC approach was successful in delivering useful information from participants on the content for the VR simulation we aimed to present in this original article.

Lastly, a limitation that this original article presents is that although there is very little research on factors on and ways to mitigate moral distress, the in-VR intervention was based on "A guide to moral injury." This was one of the few resources that were known to psychologists and psychiatrists on the team to provide some guidance on moral

distress for the development of the educational resource and so, as a starting point, the decision was made to build upon this aid.

5.2.5 Conclusions

The CIC approach demonstrates feasibility in leading to the identification of parameters, needs, and requirements for the development of an expert-validated VR simulation early prototype that, with testing, could be used as an educational resource for healthcare workers to understand and mitigate moral distress. The methodology also proved to be flexible by morphing ideas into questions about the content of the VR simulation that were able to collect critical, stakeholder-approved, elements for an educational resource. The applicability of this process for other healthcare simulations seems promising based on our findings; however, it requires further testing by the research community to fully explore its potential.

5.2.6 References

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Chapter 6. Results

The main research question that we aimed to address in this thesis is what is the feasibility of the CIC approach to design SBME-supporting technologies? This question was further broken down into two sub questions: 1) does the proposed methodology offer content validity that the medical community is looking for? and 2) does the medical community feel that this proposed methodology could be used in the future? To answer these questions, we have put two test cases through the CIC approach to generate SBME-supporting technology designs: 1) test case 1: to design anatomically-correct and affordable physical simulators that could teach paramedics-in-training the IO skills remotely and 2) test case 2: to design a VR simulation that could teach nurses about moral distress and ways on how to mitigate it. The research conducted through these test cases underwent the design phase of the DBR framework. The design phase entails 1) identifying an appropriate learning theory to underpin the instructional tools as well as existing design principles to guide the development of the research tools, 2) developing/identifying the research tools/methods using design thinking and Delphi methodology, and 3) designing the instructional content for SBME-supporting technology. Prior to the research, it was hypothesized that after the SBME-supporting technology designs are made through the CIC approach, the process would have resulted in SBME-supporting technology designs that hold content validity as it would have been provided through the Delphi, a well-established consensus-building methodology that uses expert knowledge, and 2) the stakeholders involved in the CIC approach would be interested in using the process to design SBME-supporting technologies since it offers content validity, structure that can guide their thinking, and creativity all at once. Each of

these aims in the design phase were achieved by testing the test case through the CIC approach in the design phase of the DBR and in the end, two SBME-supporting technology designs were generated.

6.1 Test Case 1 Results

For test case 1, the CIC approach helped to design simple and advanced IO simulators that would complement a decentralized SBME to train paramedic-in-training, i.e., work in conjunction with an online training module to train paramedics-in-training in the skill instead of in a shared simulation laboratory setting. First, the constraints – learning theories and design principles – were decided upon. Mastery-based learning theory and optimal challenge point framework were identified as the learning theories to underpin the design of the instructional tool, the physical simulators. Mastery-based learning theory describes trainees being able to practice according to their own needs and pace to reach a predefined skills proficiency level (McCarthy et al., 2020). This theory was deemed suitable for the development of the simulators because in the decentralized SBME environment, students would be left to their own devices to train and therefore would be inclined to spend time in areas of the skill that they feel are lacking in an attempt to perform better. Optimal challenge point framework describes trainees being challenged according to their skill level which will ultimately lead to better long term performance (Guadagnoli & Lee, 2004). This theory was also deemed suitable for the development of the simulators because the intent was to create simulators that would appropriately challenge the paramedic-in-training who can show up as two types of learner – either junior (i.e., having no knowledge in the skill) or senior (i.e., having some knowledge in the skill). The design principle was identified to be a design-to-cost

approach in order to achieve cost-effective simulators. Next, the research tools/methods, being the design thinking and Delphi methodology, was identified and structured in a way to design the simulators.

The ideation and consensus phases occurred with six paramedics and one medical doctor as participants who provided content validity for the final design of the simulators. The design thinking went through the first three phases, empathize, define, and ideate, to generate six ideas to improve the simple IO simulator ideas and eight ideas to improve the advanced IO simulator. For the simple IO simulator, ideas included: provides resistance when drilling, simulates bone marrow, demonstrates different weights, demonstrates different scenarios/contraindications, includes a portion of the calf, and is made with different densities. For the advanced IO simulator, ideas included: bends and laterally exposes the tibia, made longer from the knee down, has more realistic skin than simple IO, provides resistance to flow, make skin show infiltrations, is made into a full leg, shows anatomic contours of the leg better, and make patella bigger. Next the ideas were moved into a Delphi methodology, where after two rounds, participants classified the features as either mandatory or optional. Specifically, they categorized the ideas as one mandatory and five optional updates for the existing simple IO simulator and three mandatory and five optional updates for the advanced IO simulator. In the end, following the design-to-cost design principle as the constraint, the mandatory features were incorporated in the final designs. Specifically, the simple IO simulator was manufactured to have a more pronounced tibial tuberosity and the advanced IO simulator was manufactured to bend laterally to expose the tibia, have a bigger tibia, and provide resistance to flow. Following the CIC approach, a simple IO simulator under the budget

of $15 and an advanced IO simulator under the budget of $100 was made and the experts ideas on how to make them anatomically-correct was achieved.

With regards to comments on the overall CIC approach through a SWOT analysis, it was highlighted that the process allowed diverse perspectives from different scopes of practices (i.e., medicine vs paramedicine) to be heard without a fear of misjudgment. An area for improvement for the logistics would be to consider allocating more time for the design thinking portion of the ideation part of the CIC so that a greater volume of ideas could be collected and funneled through the validation process, leading to simulators that could better meet the learning objectives delineated during the Delphi rounds by the experts (i.e., simple IO simulators would teach the access portion of the skill while the advanced IO simulators would teach the infusion portion of the skill). Lastly, with regards to future use of the CIC approach, it was noted that the process could yield additional features that could be implemented for future models such those optional features seen in this particular test case that were not used. In sum, with a few adjustments to the CIC approach, participants deemed it was a useful process to produce physical simulators to teach and advance paramedic-in-training IO access and infusion skill.

6.2 Test Case 2 Results

For test case 2, the CIC approach helped to design a simulation that would help nurses understand and mitigate moral distress due to workplace stressors. First, the constraints – learning theories and design principles – were decided upon. Kolb's experiential learning theory was identified as the learning theory to underpin the design of the instructional tool, the simulation. Kolb's experiential learning theory allows for

trainees to 1) be exposed to real life events, 2) observe and reflect on that experience, 3) form abstract concepts and generalizations, and 4) test a hypothesis by applying what they have learnt in future situations, resulting in new experiences (Kolb, 1984). This theory was deemed suitable for the development of the simulation as the structure coincides well with the objective of the simulation which was to have nurses experience a morally distressing situation, learn from the experience, and apply their learnings and this coincides well. Next, the research tools/methods, being the CIC approach, was identified to design the simulation. The design principle was identified to be the choice of technology, virtual reality (VR) and time, as in how long the instructional tool could be for the intended users. VR was selected as a constraint so that it could provide trainees the experience of moral distress without putting them in real-life situations which would be unethical. Time was selected as a constraint, specifically to have the instructional tool no longer than 20 minutes as this was deemed appropriate for endpoint users who are busy nurses who do not have time to take part in traditional interventions such as cognitive behavioural therapy which extend for many sessions (Cognitive Behavioural Therapy, 2022; Digital Interventions to Reduce Moral Distress among Frontline Health Care Providers: A Feasibility Trial, 2015). Next, the research tools/methods, being the design thinking and Delphi methodology, was identified and structured in a way to design the simulation.

The ideation and consensus phases occurred with five psychiatrists, three psychologists, three nurses, one game developer, and one healthcare simulationist as participants who provided content validity for the final design of the VR simulation. The design thinking went through the first three phases, empathize, define, and ideate, to

generate 33 ideas to come up with the content for the scenario and intervention embedded within the VR simulation. The general themes of these ideas revolved around having the virtual actors act negatively (e.g., making mistakes, lack of sleep, angry), having the virtual actors being exposed to something negative (e.g., bad leadership, staffing issues), creating a moral conversation between participants and virtual actors, teaching the participant about moral distress, and gathering the participant data through biometrics at various checkpoint of the simulation and assessments of feelings and knowledge on moral distress during and after the simulation. Next the ideas were moved into a Delphi methodology, where after three rounds, participants collectively whittled down the ideas to 16 items and put them together to create potential stems for scenarios and interventions for the simulation. The 16 items mainly concern having the scenario show something of high stakes with a moral component, trigger an emotional response in participants and have them reflect, and educate the participant about moral distress and teach them how to recognize the intervention. The stem was sketched out to have the participant as a novice nurse who needs to choose between attending to patient #1 who needs CPR or patient #2 who has a stroke due to staffing shortages. As a result, patient #2 who is not cared for dies and the participant is then reassured by a colleague which is the format of a didactic intervention on ways to mitigate moral distress. This stem provided the project team a set of parameters for the team to work with, but not a storyline which is needed to create the design of the VR simulation.

Based on this unanticipated outcome, the project team decided to conduct a focus group using this stem to ask participants to offer more body to the stem. This tactic is called being responsive to emergent outcomes (Haji et al., 2013). The outcome of the

focus group interview was a script for the scenario and a set of slides as the didactic intervention for the VR simulation which went through several iterations of edits by the research team. These were then provided to a VR design team who converted these into VR format. With the VR platform and the timing constraint in mind, a 20-minute VR simulation prototype that content experts believe could elicit and teach moral distress was created using the CIC approach.

Chapter 7. Discussion

7.1 General Observations and Thoughts

With regards to comments on the overall CIC approach through a SWOT analysis, it was agreed among the participants that the process allowed for an equitable and organized means to integrate options from various content areas such as computer science, psychology, and nursing to name a few. Although all voices felt and were heard, there were some concerns about how the responses were being weighted because not all of the participants who responded were well-versed in the subject to be able to comment appropriately, which could lead to the watering down of responses. Contrary to test case 1, an area for improvement for the logistics would be to consider shortening the length CIC approach as they felt that the two hours over a Zoom call for the design thinking, the Delphi rounds spanning over four weeks, and a final focus group interview a week later for an hour again over Zoom took up too much of their time and thus felt disengaged in the process overtime. Finally, the focus group interviews not only in between rounds but also at the end of the CIC approach allowed clarification was considered a valuable in that it allowed for outputs at every stage in the process to garner more clarity, which was much needed for the topic of moral distress, an area that has limited knowledge. This allowed for the VR designer to translate the scenario and intervention requirements into a prototype for a simulation for nurses to understand and mitigate moral distress.

7.2 Limitations

We have identified some limitations with the work we have done in my thesis. These touch on areas such as the amount and quality of endpoint user feedback received, the amount and types of test cases, research pertaining the frameworks and methods, and the effectiveness of the CIC approach. These limitations serve to highlight areas of improvement that could be implemented to extend the research conducted for my thesis.

Firstly, for test case 1, there were a limited number of endpoint users who experienced the entire CIC approach. In particular, the design thinking only involved two paramedics and one medical doctor and later, those individuals along with four other paramedics participated in the Delphi. So, we were only able to request the two paramedics and one medical doctor who took part in both the design thinking and Delphi for their thoughts on the full process. Even then, only two of those three individuals offered their feedback. For continued testing of the CIC approach, it would be ideal to recruit more endpoint users who can take part in entire duration of the methodology so that multiple perspectives could be analyzed.

Relating to the feedback given by the endpoint users in general on the CIC approach, it was done through a SWOT analysis. There were two notable issues with its delivery and its composition that we feel could have better executed looking back. The SWOT analysis was sent to the endpoint users who took part in the whole CIC approach via email in the Google Form format, but three months after the activity had ended. Because of this delay, we think that the responses could have been subjected to recall bias. In addition to this, a few participants who did respond did not provide feedback on the CIC approach but on the final products that came out of the CIC approach, which was

not the intent of the SWOT analysis. We also noticed we were not able to gather feedback from all the endpoint users despite sending all participants the SWOT analysis. These points could have also been as a result of endpoint users not being able to remember the CIC approach to provide feedback. Finally, the SWOT analysis only asked about the strengths, weaknesses, opportunities and strength of the CIC approach. One of the sub research questions of this thesis was whether or not the medical community would suggest this process be used in the future. Using the SWOT analysis responses (particularly responses from medical professionals), we inferred what the answer to this question could be as we did not explicitly ask this question in the SWOT analysis. As next steps, the SWOT analysis could be deployed immediately after having the endpoint users go through it and also include the question seeking their thoughts on future use of the CIC approach to better address this.

Given the short one-year duration of my Master's program, we were only able to apply the CIC approach to two test cases. Test case 1 was a part of larger study where the IO simulators developed through the CIC approach would become elements of a De-SBE model to train paramedics remotely. Test case 2 was also a part of another larger study where the content of the VR simulation developed through the CIC approach would become a part of an intervention for nurses to understand and mitigate moral distress due to workplace stressors. All activities pertaining to test case 1 and test case 2 in relation to this thesis occurred simultaneously. The preparation leading to put test case 1 and test case 2 through the CIC approach took approximately five months and the execution of the CIC approach with endpoint users spanned one month. Using the outputs of the CIC approach (i.e., list of criteria for the development of test case 1 and test case 2), the

development of the tangible products for test case 1 and test case 2 (i.e., the IO simulators and the VR simulation) happened within two months. Now that all of this groundwork has been done to develop the preliminary structure for the CIC approach and to apply the idea to two test cases, others simulation projects planned could also go through the CIC approach which could provide more data to the medical and simulation community on whether or not this approach has potential to be useful to endpoint users and should be further developed. Other simulation test cases could experiment with different variables including different contexts, industry 4.0 technologies and learning objectives, to name a few.

The CIC approach described in this thesis composes of design thinking and Delphi as research methods that make up the majority of its structure and decided to be situated in the design phase of the DBR framework. The design thinking and Delphi methodology were selected because they were considered well-known by the professions in the teams that we were working with in both test case 1 and test case 2. In the specific groups we collaborating with, the DBR framework was recognised by the education and computer sciences and the MRC framework was regularly used by the medical sciences, however, the decision was made to work with the DBR framework. Since there has been simulation work had been done in the past following the MRC framework, the MRC framework had already been adapted for simulation development, and no research in simulation using the DBR framework had previously been done, the simulation researchers on the team felt that exploring the DBR framework through these test cases would offer something new to the research community in addition to the novel CIC approach. Although the rationale behind selecting these research methods and framework were based on what was familiar

to the teams involved in test case 1 and test case 2, research could have been done on what research methods and frameworks would be best suited for the interdisciplinary team. A scan in the literature on what research methods and frameworks exist and their advantages and disadvantages could be completed. Then, the endpoint users could be presented with this information and could also be involved in the selection or development of research methods and frameworks that could best work for them to work as an interdisciplinary team to build simulations using industry 4.0 technology.

Finally, in my thesis, we have successfully collected the initial perceptions on the feasibility of the CIC approach with the endpoint users who utilized it to develop simulations for test case 1 and test case 2. The results of test case 1 and test case 2 having gone through the design phase of the DBR are merely prototypes of simulations. Other than the fact that gathering and using expert input to design simulations in test case 1 and test case 2 provides content validity, other forms validity need to be checked to truly make the case that the simulations resulting from the CIC approach were valid. For instance, we do not know based on our research if the prototype simulations as a result of this work does what it is set out to do which is referred construct validity. Specifically, we are unsure if 1) the IO simulators developed as a part of test case 1 can teach paramedics how to perform the IO skill on their own and accurately and 2) the VR simulation developed as a part of test case 2 can teach nurses about moral distress and way in which they can mitigate it if they come across any triggering workplace stressors. So, to gather evidence of this kind of validity, the test cases could move through the rest of the phases of the DBR in order to seek out the efficacy of the simulations: were the

simulations designed as a part of the CIC approach able to achieve their intended training purposes?

7.3 Future Directions

Future directions of the CIC approach would entail adding some components to its current structure which we believe would result in simulation designs that are more representative of the endpoint users needs. To begin, the CIC approach in my thesis is positioned as only involving endpoint users of the methodology, the content experts (i.e., computer sciences, education, and medical sciences professionals). However, since the simulation is being designed to teach learners as the endpoint users of the simulation, it would be beneficial to invite them to take part in the CIC approach. This way, they may be able to have a say in what they would like the simulation to teach them and be a part of designing their own learning journeys. Perspective from the students on what would best facilitate their learning would greatly shape the development of simulations through the CIC approach.

Relating to the inclusion of specific groups during the development of simulation using the CIC approach, prior to starting this process, the identification of stakeholders could be delineated as a step in the process as an improvement. Although the CIC approach we outlined in my thesis did have this step, for test case 1 and test case 2, this identification of stakeholder step was done as a brainstorming session before the CIC approach where the research team drew from their former research network to identify pertinent expertise. Adding this step at the beginning of the CIC approach would provide guidance to potential endpoint users of the tool and increase the likelihood of bringing most of the relevant stakeholders to the table at the beginning. If during the CIC

approach, any part of it warrants additional expertise input, it would be good to suggest as a part of the CIC approach guidance that a reassessment of the stakeholders involved in the process could occur. This would ensure that all points of clarification are addressed and lead to a robust simulation design in the end.

In addition to the selection of stakeholders at the beginning of the CIC approach, there could also be a step where appropriate research methods are chosen. For the CIC approach we presented in my thesis, in the ideation phase we picked design thinking and in the consensus phase we used Delphi. The selection of these research methods for the CIC approach for test case 1 and test case 2 were based on what research methods were familiar to the group of experts that were invited to participate. According to the SWOT analysis for both test case 1 and test case 2, the research methods employed worked well to capture the key informants knowledge and opinions on specific subject matters for the development of simulations. What we are suggesting is to explore a variety of research methods, with regards to their strengths and weaknesses, and even engage stakeholders in the selection of the research methods, to figure out the best research method(s) suited for the team and how to make the method(s) work for the project goals before starting the CIC approach. Aside from design thinking for the ideation phase in the CIC approach, it is possible to look into using research methods like think aloud protocols, focus group interviews, descriptive studies, and case studies. Examples of research methods other than Delphi for the consensus phase in the CIC approach can include nominal group techniques, RAND/UCLA appropriateness method, and again, focus group interviews. The identification of research methods for the CIC approach can possibly improve the

collaboration of the interdisciplinary team by identifying and using methods that would meet the different disciplines needs.

As described earlier, the future directions for the CIC approach would be to have steps for the selection of stakeholders and research methods prior to the constraints phase of the CIC approach. This selection calls for an in-depth analysis of the tools (i.e., stakeholders and research methods) that will be used to implement the process (i.e., CIC approach) and the development of design principles (i.e., constraints). This activity fits the description of the reflect phase of the DBR framework and precedes the design phase in which we situate the CIC approach. The DBR framework currently starts with the design phase but we propose that the activities of the reflect phase occur prior to the design phase. We suggest that the DBR framework, for the purposes of interdisciplinary simualtion design, starts with the reflection phase, whereby conscious conversations about the goals, the solutions, the resources (i.e., stakeholders), and the research methods that will be used to accomplish these goals should occur to set up a clear project blueprint to offer some direction of the execution of the project. Once the project goes through the rest of the phases, the design phase which entails the CIC approach, the test phase, and the evaluate phase, the project should return to the reflect phase so as to understand what worked well and not so well with the initial project plan and the changes made along the way.

Finally, after testing the reactions of the participants of the CIC approach for test case 2, it appears that adding a focus group component would be a good way to tie up the loose ends before moving on. This addition of the focus group interview would not be considered an opinion but rather an evidence-based decision on the final outcomes of the

stage or process since it would still be using a group of expert's knowledge. In light of the usefulness perceived by the participants of this additional component added to the original CIC approach, a consideration for next steps for the CIC approach would be to offer guidance to endpoint users that the CIC approach has room for flexibility to accommodate other methods, like focus group interviews. As we have shown through these two test cases, the CIC approach could not be used in an identical way for both the development of the physical simulator (three-dimensionally printed) and the VR simulation, two different simulation modalities brought about by the Industry 4.0 technologies. So to accommodate the needs each test case design may require through the CIC approach, be it due to differences in technology platforms as exemplified here or other differences (e.g., objectives, domains of learning, etc), making the CIC approach flexible will allow endpoint users to add, modify, and/or remove research tools/methods to the process which could best help them develop their designs. This versatility should be tested by trying the CIC approach with different test cases (e.g., different simulation modalities) and how the research tools/methods could change with each test case should be recorded and mapped out in terms of strengths and weaknesses. For example, designing of virtual gaming simulations could go through the CIC approach by using think-aloud protocols instead of design thinking in the ideation phase (Wahab et al., 2022). We propose this fluid nature of the CIC approach could be labeled instead as a CIC+ approach where the "plus" means that the CIC approach is more of a guide with regards to the way and order in which the research tools/methods in the approach are used rather than a prescriptive approach to encourage full potential in the design process.

Chapter 8. Conclusion

Both the outcomes of test case 1 and test case 2 demonstrated the feasibility and acceptability of the CIC approach. Having this process embedded into the design phase of the DBR would provide those interested in following the DBR framework to develop SBME-supporting technologies 1) clear instructions on how to conduct the design phase and 2) content validity and reliability. This is especially important in the medical research community, in which the field of health simulation fits under, as they require evidence-generating processes to formulate solutions that can have a positive influence on patient care, directly or indirectly. To gain more trust in this CIC approach, research investigating the nature of the CIC approach is required using more test cases. It would be ideal to include simulators that offer various levels of complexities (i.e., anywhere in the spectrum from simple to advanced) and a range of modalities (i.e., augmented reality, simulated patients, computer-based training, etc). Another extension of this research that could be explored are other types of validity such as construct, concurrent, and predictive, for example. By testing out these different kinds of validities, the design and appropriateness of the CIC approach could be better supported by the medical research community and offer confidence to endpoint users in the resulting products from the process. We speculate based on the test cases that underwent the CIC approach, the CIC approach should be more of a guide to allow flexibility in the research tools/methods being used to encourage maximum design potential. Finally, to understand the effectiveness of SBME-supporting technologies made using the CIC approach in the design phase of the DBR and how well this particular approach fits into the overall DBR framework, after the use of the CIC approach to attempt to create a SBME-supporting

technology, the research should continue to follow through on to the other subsequent phases in the DBR, such as test, evaluate, and reflect. This way, the SBME-supporting technology could be tested to see how well they work, adapted and re-tested to gather more data, and generate new theories and frameworks to conceptualize learning.

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