Neonatal TAPP (Thoracentesis, Abdominal Paracentesis, Pericardiocentesis) Trainer
Ethical Implications of Simulation-Based Medical Training Devices

A Thesis Prospectus
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By
Michael Pandula

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Technical Team Members: Ashley Houck and Grace Gawrylowicz

On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

ADVISORS

Prof. Dr. Gerard Fitzgerald, Department of Engineering and Society
Prof. Dr. Timothy Allen, Department of Biomedical Engineering
Dr. Jaclyn Wiggins, Department of Pediatrics (Neonatology)

Introduction

Over the past decade there have been several significant advancements in medical simulation technology that have changed the way clinical training is performed. My capstone project focuses on creating a neonatal manikin, a realistic model of a newborn infant, that will allow medical professionals to practice three different surgeries: thoracentesis, abdominal paracentesis, and pericardiocentesis. Performed on neonates, or newborn infants in their first month of life, these surgeries remove fluid buildup in the lungs, abdomen, and heart respectively. Neonatal surgery inherently presents several unique challenges. Due to the small size and fragility of neonates, these lifesaving surgeries are extremely difficult and require extreme precision. Neonatal procedures must be performed with the utmost care because even tiny mistakes can result in serious complications or even death. Currently, there is no existing training device which allows neonatal surgeons to practice these procedures without performing them on live neonates. The use of a life-like neonatal manikin, offers an opportunity for surgeons to gain hands-on practice with these procedures, gaining confidence in their abilities without risking the lives of the patients and would ultimately lead to improved patient care (Buck, 1991).

Though self-evidently helpful, this technology also presents a number of ethical concerns. For my ethical research I will focus on two interrelated ethical issues associated with the use of simulation-based medical training devices. The first issue of concern is that reliance on this technology may lead medical professionals to overestimate their competence in real life scenarios, thus impacting the actual patient care (Ziv et al., 2006). The unpredictable nature of operating on a live patient and the influence of human factors cannot be fully replicated by these simulators (Vincenzi, 2009). The second issue of concern is that these simulation training devices do not become a crutch at the exclusion of traditional training methods. There is an ethical responsibility that surgeons and medical professionals continue to access a variety of training methods. This problem can be analyzed within the SCOT lens to understand how different social groups may influence the development and adoption of simulation-based training devices, and thus revealing the ethical challenges that may arise. Taken together, these ethical and social considerations of such devices must be considered so that the public trust is not undermined, and they do not inadvertently hinder the quality of care being received.

The connection between my capstone project and STS research deals with the ethical responsibility to provide adequate medical training, while at the same time, addressing the limitations of simulation technology. As better tools continue to develop for medical training, we must also consider both the ethical and social ramifications to ensure that these devices continue to enhance rather than hinder patient safety.

Development of Neonatal Manikin for Surgical Simulation

For my capstone project, we will be developing a neonatal manikin designed to allow medical professionals to practice performing thoracentesis, abdominal paracentesis and pericardiocentesis neonates. These procedures are important for treating life-threatening conditions where fluid accumulates in the lungs, abdominal sac, or heart respectively. Thoracentesis is the removal of fluid from the pleural space around the lungs using a needle or a catheter. It is performed when a patient has pleural effusion, a condition where excess fluid builds up between the tissues surrounding the lungs and chest cavity. Abdominal paracentesis is the removal of fluid buildup from the abdominal cavity. Finally, Pericardiocentesis involves the removal of fluid from the pericardial sac, which surrounds the heart. All three of these conditions are life threatening especially to already at-risk neonates. Thus, it is important for surgeons to be well trained and respond quickly when they encounter these critical situations.

Although there are many types of neonatal manikins, none are designed to allow surgeons to practice performing these procedures. Currently neonatal surgeons practice by either shadowing real procedures, a process that does not yield the necessary hands-on experience, or they practice by draining medical balloons filled with saline, which also does not realistically simulate the complexities of actual surgery.

The main goal of this project is to create a life-like, reusable neonatal manikin that mimics the anatomy of a neonate, allowing surgeons to gain hands-on practice in performing these clinical procedures without risking harm to live patients. The manikin will feature several key characteristics: it will be ultrasound-compatible, anatomically accurate, and fluid refillable. The focus on ultrasound compatibility is especially important, because while performing these surgeries, surgeons use ultrasound to help guide the needle or catheters placement in real time. By using ultrasound capable materials, clinicians will be able to more realistically practice the procedural and imaging aspects of the surgeries. Most importantly, the manikin must be biologically accurate with regard to neonatal anatomy so as to allow clinicians to simulate the procedure with extreme accuracy. The 3D printed exterior must be designed to mimic the dimensions of a neonate. Similarly, inside the abdomen, the 3D printed abdominal structures, lungs, and heart must also be designed to mimic that of a neonate. In between these abdominal structures, using the same ultrasound compatible material as we used for the skin, we will create the peritoneal cavity, a pleural cavity, and a pericardium into which physicians can inject saline. These cavities must be refillable, allowing for repeated use.

Finally, as part of the development process, we also plan to work closely with the neonatal surgeons throughout the project. We plan on teaching them how to use the manikin and will incorporate their feedback in the iterative design process. Such collaboration will help ensure that the manikin accomplishes its goal of being a valuable training tool.

Ethical Implications of Using Simulation-Based Medical Training Devices

Despite these obvious technological benefits, simulation based medical training devices also pose ethical concerns that must be considered when these devices become adopted. My STS research explores the ethical implications of relying on such simulation-based devices in medical training. In particular, I will be answering the following question: What are the ethical implications of using simulation-based medical training devices, and how do they affect the quality of medical training and care?

In order to analyze this problem, I will collect evidence from literature concerning the ethical considerations of medical training (Jacobs & James, 2019). I will also analyze case studies where these technologies have been adopted, as well as interviews from healthcare care professionals to understand their personal perspectives on the role of simulation in training (Gisondi et al., 2004). Additionally, I will analyze case studies from the defense and aviation industries as they offer insights into how high-stakes training and simulation practices are managed (Cheng et al., 2016; Finley et al., 2000). I will analyze the similarities and lessons that can be applied to medical training. I will discuss the potential that the use of these devices can create over confidence amongst healthcare professionals, to the detriment of the quality of care given (Ziv et al., 2006). I will also explore the ethical considerations of these devices using the application of the Social Construction of Technology (SCOT) framework.

The first ethical concern I will be analyzing is the potential of simulation-based training devices creating a false sense of confidence in those who use them to train. While these devices can simulate the physical conditions, they cannot recreate the emotional aspect of real-life clinical settings (Vincenzi, 2009). By training solely using these devices, medical professionals may create a false sense of security, which could lead them to believe they are fully prepared for real-world clinical challenges when in fact they may not be. This can be a problem because this can result in clinicians being unable to properly carry out the procedures, putting the patient's safety at risk.

Research supports this claim, documenting how certain training devices, while enhancing the technical proficiency of the clinicians, do not fully prepare the clinicians emotionally for real-life medical care (Ziv et al., 2006). Medical Professionals may underestimate the emotional difference between performing a procedure on a simulation versus on a live patient. It is important to ensure that the clinicians are aware of and understand the limitations of these simulations. In military and aviation contexts, simulations are used to replicate high-pressure situations, however they often fail to capture the emotional intensity and stress seen during the real-life missions or flights (Best, 2013; Garrett-Rempel, 2019). Similarly, in medical training, while simulation-based learning can replicate clinical procedures, it cannot fully prepare clinicians for the emotional challenges involved. Thus, these simulation-based devices should be used in conjunction with the shadowing of real-life procedures, where clinicians observe and learn by watching experienced professionals perform the same procedures on actual patients to produce a more complete training experience (Riley, 2016).

In order to maintain public trust in medical care, it is extremely crucial to communicate that the role of simulation-based devices are training aids, rather than replacements for real-world clinical experience. Medical professionals must understand and be transparent about their limitations and take steps to ensure they are also prepared for the emotional side of live procedures (Jacobs & James, 2019).

While analyzing the ethical implications of simulation-based medical training devices it is also useful to apply the Social Construction of Technology (SCOT) framework. The SCOT method emphasizes that technology is not developed in isolation but rather is shaped and defined by many different, social, cultural, and political factors. It is important to view how different social groups influence the design and adoption of simulation based medical training devices to better understand the ethical considerations that may arise in their deployment. Examples of different social groups associated with these devices are healthcare professionals, educators, policymakers, and the patients themselves. For healthcare professionals and medical educators, the devices are seen as tools to improve training and reduce risks associated with training on patients. On the other hand, policymakers and the hospital management might view them as costly and have concerns if they are of use in preparing clinicians for real world medical challenges. The patients themselves might have a different perspective, viewing these simulation-based devices through the lens of trust and quality of care. As seen in the SCOT diagram in Appendix 1, each of these groups play a role in shaping how these devices are used, thus highlighting the importance of addressing the ethical concerns.

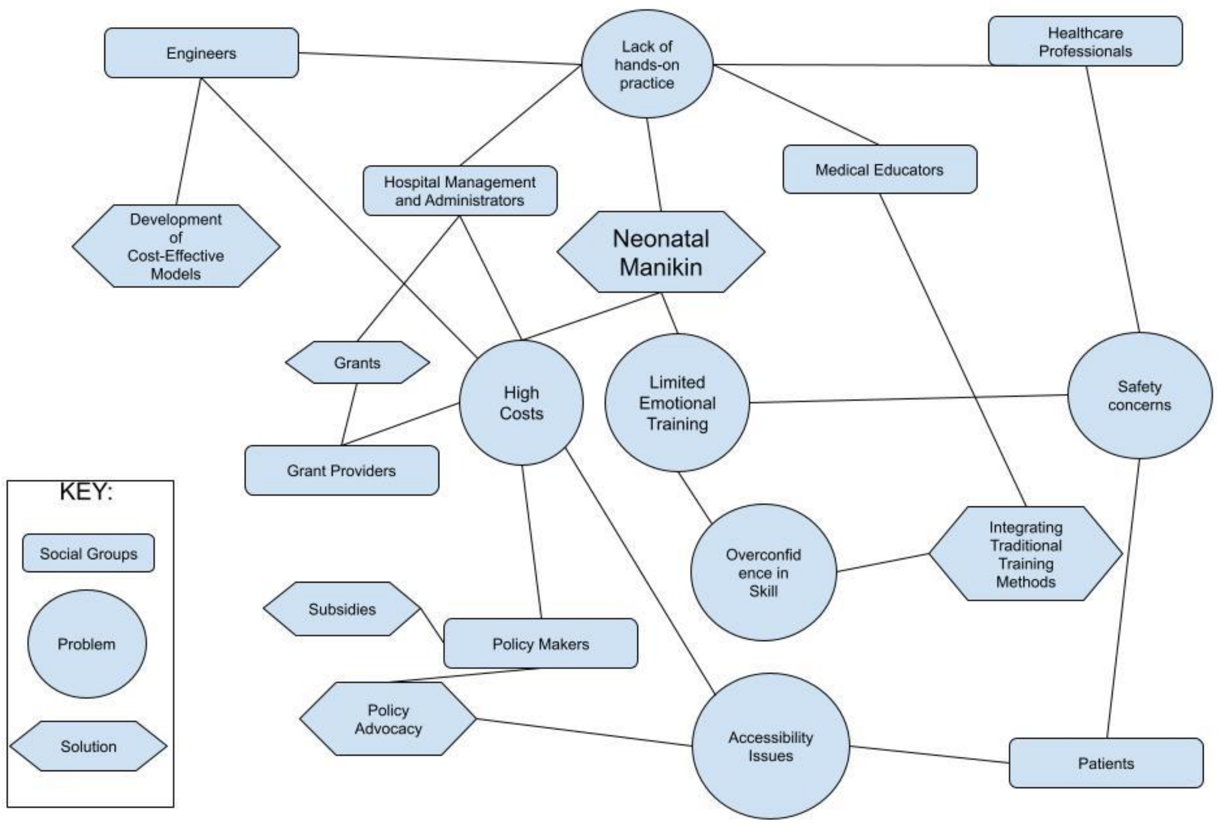
By interpreting this evidence, I will be able to evaluate the benefits of simulation technology as well as the ethical concerns that also arise. My analysis will deal with ways to mitigate the ethical risks as well as ensuring equitable access to the devices.

Conclusion

For my Capstone project, I plan on developing a neonatal manikin which will be used by clinicians to practice thoracentesis, abdominal paracentesis, and pericardiocentesis. This manikin will allow medical professionals to gain realistic hands-on experience without compromising patient safety. For my STS research I plan on exploring the ethical implications of using such simulation- based medical devices. I plan on collecting evidence from literature, case studies, and interviews with professionals to better understand the ethical implications of relying on such devices. Together, these deliverables will improve medical training as well as address the ethical implications that may arise due to this and similar technologies.

Appendix 1

SCOT Diagram - Neonatal Mankin



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