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Learning from Failure: A Case Study of Human Driven Risk Assessment in Medical Simulator Design

RACHEL BARTUSKA
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Reviewed and approved* by the following:

Scarlett Miller
Professor of Industrial Engineering
Thesis Supervisor

Andris Freivalds
Professor of Industrial Engineering
Honors Adviser

* Electronic approvals are on file.

ABSTRACT

Failure Modes and Effects Analysis (FMEA) is a qualitative and quantitative approach to measuring and analyzing risk that compiles and ranks failure modes, their effects, and their corrective actions. Though widely used, traditional FMEA has been criticized for the lack of a scientific basis behind the Risk Priority Number calculation. To combat this, researchers have argued that Multiple Criteria Decision-Making methods, such as Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS), should be used to rank failure modes instead. TOPSIS, as with other MCDM methods, more rigorously ranks items based on a set of numerical scores. As such, the current paper was developed to present a case study that applies FMEA and TOPSIS to a Central Venous Catheterization (CVC) training simulator called the Dynamic Haptic Robotic Trainer (DHRT). FMEA was needed because while a beta prototype exists for research purposes, there are several failure modes that prevent this system from wide-spread deployment. Our results provide insight into how FMEA can be used to identify a system's highest priority failure modes and maximize improvement recommendations. Expert interviews were used to compile DHRT process steps and all possible failure modes that might occur during each step. The expert responses were consolidated to create one list of steps and one list of unique failure modes, each with a set of numerical scores. The expert-generated scores were also inputted into TOPSIS to prioritize the top 15 failure modes. Top ranking failure modes were the focus of recommendations for future work on the DHRT, particularly in the realm of usability.

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Chapter 1

Introduction

Failure Modes and Effects Analysis (FMEA) is a preventative risk assessment method for documenting and ranking all possible failure modes of a product or process. In FMEA, each failure mode is described in words and scored in several categories (Silva et al, 2014; Ribas et al, 2021; Wu & Wu, 2021). By multiplying the scores together, each failure mode is given a Risk Priority Number (RPN) and ranked from the highest RPN to the lowest (Silva et al, 2014). FMEA has been applied in the chemical (Rezaee et al, 2020), manufacturing (Godina et al, 2021), information technology (Silva et al, 2014), and energy fields (Ribas et al, 2021). Despite widespread use, FMEA has been criticized and subsequently modified over time, with no standard modified method (Carnero, 2020; Wu & Wu, 2021). One criticism is that the RPN has little mathematical meaning because category scores are discrete ordinal measurements, which are not meaningful when multiplied (Carnero, 2020; Wu & Wu, 2021). This limitation can be overcome by using a different ranking system, such as the Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS). The present case study will demonstrate the use of FMEA and TOPSIS for ranking failure modes on the Dynamic Haptic Robotic Trainer (DHRT).

The DHRT was created as a mixed reality Central Venous Catheterization (CVC) simulation training tool. CVC is a complex medical procedure that requires a catheter to be inserted into the body for critical medical delivery (Graham et al, 2007). CVC has a complication rate of about 15%, making it a strong candidate for simulation training (Taylor & Palagiri, 2007). To help the user complete CVC insertion, the DHRT has an ultrasound, needle, and graphical

user interface (Gonzalez-Vargas, 2020). In contrast to static manikin-based simulators, the DHRT utilizes robotic haptic feedback and a personalized learning interface to provide a stand-alone trainer for CVC (Gonzalez-Vargas et al, 2020). Importantly, the DHRT allows residents to experience the haptics (and subsequent visualizations) of different patient anatomies that provide a more realistic transfer of skill to a clinical environment (Pepley et al, 2016b). There are 17 different patient case profiles available for the user to read about and attempt to perform CVC insertion on. (Gonzalez-Vargas et al, 2020). After moving through a patient case, the graphical user interface will display a summary of feedback based on user performance (Gonzalez-Vargas et al, 2020). While the DHRT has been validated to work as well as manikin training that requires a stand-in expert trainer to provide feedback, there are opportunities to increase the usability and effectiveness for various aspects of the system (Chen et al, 2020). The main objective of this paper is to further bring the utility of FMEA into the Human Factors discipline by drawing on a case study of the DHRT trainer to demonstrate how FMEA and TOPSIS can be used to recommend usability improvements to a medical simulator. The remainder of this paper highlights the methodology, results, and impact on the Human Factors field.

Research Objectives

The main purposes of this study were to categorize the steps of using the DHRT, identify associated failure modes, and recommend system improvements. Specifically, the goals for this thesis were: 1) to determine the extent to which experts agreed upon the DHRT use process; 2) to determine whether FMEA could be used on the DHRT to categorize and document failure modes; and 3) to determine whether TOPSIS could be used in place of the traditional RPN

calculation to prioritize failure modes. For the first goal, it was hypothesized that experts would largely agree on the use process and that their understandings could be compiled into one set of processes. For the second goal, it was hypothesized that FMEA could be used to systematically compile failure modes. For the third goal, it was hypothesized that TOPSIS could be used in place of the traditional RPN calculation to more rigorously identify which failure modes were the most urgent.

As such, the study was designed to explore these hypotheses through the following research questions:

RQ1: How do experts understand the DHRT use process? To generate failure mode categories, DHRT experts were asked how they would divide the use of the DHRT into steps. Expert understandings were compared and combined into final categories. The main objective of this question is to create a framework of steps for DHRT use to incorporate into the FMEA and, eventually, standard operating procedures.

RQ2: What are the possible DHRT failure modes, and what corrective actions are recommended? FMEA was conducted to evaluate all possible failure modes at each process step. Expert responses were compared to compile all unique failure modes and corrective actions. The main objective of this question is to add to the documentation of the system and create a list of failure modes for prioritization.

RQ3: Which failure modes are the highest priority? TOPSIS was used to directly prioritize failure modes based on FMEA scores. Higher priority failure modes will be the focus of the recommendations and implementation of this analysis. The main objective of this question is to provide a list of the most pressing risks to experts.

Thesis Overview

This thesis demonstrates the ability of FMEA and TOPSIS to prioritize future project work on the DHRT and builds on expert understandings of the use process for the DHRT. Chapter 2 reviews the relevant literature on FMEA, CVC, and the DHRT. Chapter 3 describes the methodology, including descriptions of the participants and FMEA interview procedures. Chapter 4 describes and demonstrates the analysis performed, including data cleaning, consolidation, and TOPSIS rankings using FMEA interview responses. Chapter 5 overviews the results for each research question, while Chapter 6 discusses the results. Chapter 7 gives recommendations to build on the thesis work, and Chapter 8 concludes the paper.

Chapter 2

Literature Review

Failure Modes and Effects Analysis (FMEA)

Failure Modes and Effects Analysis (FMEA) is a widely used, adaptable risk assessment method. It is a qualitative and quantitative approach to compiling previous, predicted, or hypothetical failure modes for a design or process (Wu & Wu, 2021). Each failure mode's effects, causes, and corrective actions are documented (Ribas et al, 2021). Each failure mode also receives numerical category scores: usually a severity (S), occurrence (O), and detection (D) score (Silva et al, 2014). The severity score indicates how catastrophic a failure would be if it occurred, the occurrence score indicates how often the failure occurs, and the detection score indicates how likely the failure would be known (Silva et al, 2014). The scores are combined into a Risk Priority Number (RPN), where a higher RPN indicates a higher priority (Silva et al, 2014). Thus, FMEA rankings can be used to generate focused recommendations for system improvement to avoid risks before a failure occurs (Silva et al, 2014; Godina et al, 2021). Alternate approaches to FMEA include Fault Tree Analysis (FTA) and Hazard and Operability Assessment (HAZOP) (Joshi & Joshi, 2014). FTA is useful for visually following causal relationships to reach a deeper cause, while HAZOP uses guide words to assess risk (Joshi & Joshi, 2014). FMEA was chosen instead because it is more exhaustive for cataloguing failure modes and includes a ranking system.

While proven to be beneficial, traditional FMEA has limitations which result in widespread use of modified or extended FMEA (Carnero, 2020; Wu & Wu, 2021; Zadeh, 2008).

The following paragraphs detail limitations of FMEA which can be overcome via modification or extension.

Regardless of what field FMEA is used in, traditional (and most modified) analyses use three categories: severity (S), occurrence (O), and detection (D). However, the traditional categories ignore many potentially important aspects of a failure mode, particularly economic qualities (Carnero, 2020; Wu & Wu, 2021). Failure costs can become an additional multiplier, as well as project-specific metrics, such as an environmental impact measure of a manufacturing project (Lo et al, 2020). One study by Vazdani et al replaces the detection criterion with one for the extent of pollution after a failure mode occurs (2017). No categories outside of the traditional S, O, and D were identified as relevant for the present case study.

For each chosen categorical measure, traditional FMEA uses a 10- or 11-point scale; for example, a severity ranking from 0 (not at all severe) to 10 (catastrophic). Because FMEA is generally conducted as an interview, some studies model the category using a 5- or 7-point Likert scale (Vazdani et al, 2017; Li & Zu, 2020; Qin et al, 2020; Bhattacharjee et al 2020; Shirouyehzad et al, 2010; Wu & Wu, 2021). These studies may choose a 5-point scale because using more than 6 points is generally not recommended when constructing a Likert scale (Nemoto & Belgar, 2014). The present case study employs a 5-point scale for the same rationale.

One widely criticized area of traditional FMEA is the RPN calculation, which is the product of the categorical scores (S x O x D) (Carnero, 2020; Wu & Wu, 2021; Zadeh, 2008). Many criticisms are not widely addressed in the literature, such as: noncontinuous nature of RPN; oversensitivity of RPN to changes in S, O, or D; nonstandard conversion between each category score's meaning and its assignment on a scale from 1 to 10; and lack of solid evidence for why multiplying category scores measures risk priority in the first place (Carnero, 2020; Wu

& Wu, 2021). Those issues that are addressed in literature tend to use one or more of the following modifications: weighting methods; fuzzy logic or an alternative; or an extended FMEA method.

Since the formula for RPN weighs all categories equally, some studies have elected to incorporate a weighting method (Wu & Wu, 2021). If, for example, an analysis is focused on improving those failures which occur the most often, even if the failure is not very severe and is easily detectable, a weighting method may be appropriate. Simultaneously, a weighting mechanism can increase the number of unique RPNs (Carnero, 2020; Wu & Wu, 2021). Because traditional calculation is based on multiplying a limited number of integers, it is possible to generate many identical RPNs, even when the combination of category scores is unique. Weighting methods include Ordered Weighting Average (OWA), Analytic Hierarchy Process (AHP), and others (Wu & Wu, 2021; Li et al, 2021). The present case study considered all categories to be equally important, and thus a weighting method was not applied.

Due to the subjective nature of collecting expert opinions on each category, some studies elect to conduct a fuzzy FMEA or use an alternative to fuzzy logic to calculate RPN. Fuzzy logic provides a framework for making precise calculations on data that is ambiguous, approximated, or subjective in some way (Zadeh, 2008). For instance, two experts could each give a severity score of 8 and 9 on a failure mode, but they actually agree that the subjective severity of the failure mode is the same. In FMEA, fuzzy logic can be used to account for the probability that this instance occurs. Fuzzy logic has a few alternatives. One alternative to fuzzy logic is the use of an ambiguity measure, such as the Ambiguity Measure Weighted Risk Priority Number (AMWRPN) (Tang et al, 2018). AMWRPN incorporates an exponential weighting mechanism to compensate for subjectivity and prioritize the categories that are most important (Tang et al,

2018). Another fuzzy logic alternative is to use a utility priority number, which incorporates the nature of a potential solution in addition to its failure mode (Chen, 2007). Fuzzy logic is used more often than the alternatives in literature, especially in the chemical industry (Rezaee et al, 2020).

Whether fuzzy logic is employed in a FMEA or not, some studies use an extended FMEA, usually by incorporating a more sophisticated ranking system. Multiple Criteria Decision Making (MCDM) is one category of methods used to increase the numeric meaning associated with the RPN (Wu & Wu, 2021). Since the traditional category scores are a ranking from 1 to 10–using the discrete ordinal scale–simply multiplying them together yields a product with little meaning (Wu & Wu, 2021). Thus, one of several MCDM methods that incorporate weighting and ranking can be employed to assist in failure mode prioritization. Specifically, Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS) is an MCDM method that can be used to balance the categorical scores in FMEA to produce a ranked list (Kushwaha et al, 2020). The present case study uses TOPSIS to directly rank failure modes.

FMEA, both traditional and modified, has been applied across many fields, but this review focuses on medical FMEA. In the medical field, FMEA has been used to successfully compile medication safety failures (Anjalee, 2021), healthcare waste segregation failures (Carnero, 2020), and other hospital ward failures (Dastjerdi et al, 2017; Warm et al, 2021). FMEA has specifically been used to assess invasive bedside procedures and central venous catheterization (CVC) (Warm et al, 2021; Duncan et al, 2010). Importantly, several studies have indicated that implementing FMEA-driven changes to a medical system led to failures occurring less often and being more detectable when they did occur (Anjalee, 2021).

A primary motivation for analyzing the risk of medical procedures is to improve training programs which in turn prevent human errors (Dastjerdi et al, 2017; Warm et al, 2021; Duncan et al, 2010). For example, a mixed-method approach to assess invasive bedside procedures cited several failures related to standardization of training in its FMEA (Warm et al, 2021). Specifically, medical training simulation could benefit from FMEA. While FMEA has been applied to Human Factors (Village et al, 2011), healthcare, and in situ simulations (Davis et al, 2008), there is not much existing literature on FMEA as a tool for assessing medical simulators, such as the Dynamic Haptic Robotic Trainer (DHRT).

Central Venous Catheterization (CVC)

Central Venous Catheterization (CVC) is performed over 5 million times per year in the United States (Taylor & Palagiri, 2007). CVC is used under circumstances where a central vein is the only or best option for administering lifesaving drugs to a patient, who may be in intensive care (Taylor & Palagiri, 2007). There are 3 possible points of entry for the central line; it can be inserted into the jugular vein or subclavian vein in the neck, or the femoral vein in the leg (Graham et al, 2007). The chosen vein for the procedure varies based on the ability to access the vein without passing through scar tissue or other obstacles (Graham et al, 2007). The risk of complications, which may be lower at the subclavian and internal jugular sites, is sometimes used as criteria for vein selection (Graham et al, 2007; Askegard-Giesmann et al, 2009). To access the chosen vein, ultrasound guidance is commonly used to find the point of entry (Graham et al, 2007). Once the point of entry is found, the needle can be inserted with aspiration to check for venous access by drawing flash up into the syringe (Graham et al, 2007). Once venous access

is established, the syringe can be disconnected from the needle and a guidance wire can be threaded through the needle (Graham et al, 2007). The guide wire will enter the vein and is ultimately used to guide a catheter into place for the dispensation of medication (Graham et al, 2007).

There are a high variety of complications that can arise, at any step in the procedure, ranging in severity and possibly leading to death of the patient (Taylor & Palagiri, 2007; Graham et al, 2007; McGee & Gould, 2003). CVC complications arise in about 15% of patients and can be mechanical, catheter-related, or thrombotic (Taylor & Palagiri, 2007; Kuminsky, 2007; McGee & Gould, 2003; Graham et al, 2007; Mathrani et al, 2003). They can occur at the insertion site, during insertion or threading, while administering medication, or during extraction (Kuminsky, 2007; McGee & Gould, 2003; Graham et al, 2007). Complications are more likely to occur in patients with morbid obesity, scarring or healing wounds at the insertion site, deformity, or a history of insertion failures or surgery at the insertion site (Taylor & Palagiri, 2007; Mathrani et al, 2003). Complications are more likely to occur when the practitioner is less experienced, the catheter used is too large, or, pertinently, a higher number of unsuccessful insertions have already occurred (Kusminsky, 2007).

FMEA has been applied to CVC specifically (Duncan et al, 2010). CVC failure modes deemed the most pertinent included: non-comprehensive or inaccurate training information, not using an ultrasound, or not having adequate supplies, such as those used to create sterile barriers (Duncan et al, 2010). These failure modes could lead to retained guidewires, bloodstream infection, or an insertion failure (Duncan et al, 2010). Following the recommendations generated from these FMEA, simulation-based training could be a preventative measure (Duncan et al, 2010; Warm et al, 2021). Simulation-based training for CVC is shown to improve learner

performance, learner attitudes, and patient outcomes, further supporting its use as a failure-prevention method (Soffler et al, 2018).

Dynamic Haptic Robot Trainer (DHRT)

Traditional resident training for CVC involves completing the insertion on manikins. While it is considered the standard for resident education, manikin training simulates the procedure on only a single patient anatomy (Pepley et al, 2016a). It is unlikely that a resident would be able to practice CVC insertion on a patient with challenging anatomy before encountering it in real life if manikin trainers are all they have access to. Further, even the most sophisticated manikins do not provide sufficient feedback for the learner, which must be compensated for with human supervision during training (Yovanoff et al, 2018). Thus, a novel device for mixed reality-driven surgical training was developed to simulate CVC for medical residents (Pepley et al, 2016b). The Dynamic Haptic Robotic Trainer (DHRT) has a haptic robotic arm and position tracking system to simulate the experience of using a syringe and ultrasound probe (Pepley et al, 2016b). The haptic robotic arm features force feedback which varies based on the arm's position and the patient scenario (Pepley et al, 2016b). This feature is what enables the DHRT to simulate different patient cases, which showcase different patient anatomies (Pepley et al, 2016b). The ability to simulate varied anatomy is a major factor separating the DHRT from manikin training (Gonzalez-Vargas et al, 2020). During initial testing, residents successfully learned to use the DHRT (Pepley et al, 2016b).

The initial design of the DHRT draws from studying learning curves, motion analysis, and stochastic event detection. By identifying the key aspects of successful CVC insertion

through assessment of learning curves, a focus on the economy of motion and hand-eye coordination could be considered during design (Kim et al, 2014b). A study in motion analysis evaluating CVC in terms of hand-eye coordination concluded that CVC experts were able to multitask more effectively than non-experts and that their motions were smoother and more direct than non-experts (Kim et al, 2014a). The force profiles for the needle insertion were also established in the earlier stages of development of the DHRT. By modeling the relationships between the force of needle insertion into different tissues, a simulation of needle insertion would hopefully be truer to life (Kim et al, 2015).

After the DHRT was introduced in 2016, it underwent a variety of evaluations and improvements. One initial study done on third-year residents supported that either manikin training, training on the DHRT, or mixed training with both methods could support the improvement of skills and confidence (Yovanoff et al, 2016). Yovanoff et al concluded that after training, robotic and mixed methods may have equal or higher self-efficacy than manikin training, particularly for preparing residents for variety in patient anatomy (2016). Another study tested the effectiveness of the DHRT with 12 medical students who had no CVC experience (Pepley et al, 2016a). The DHRT effectively varied the difficulty of insertion and resulted in a 4.2% increase in successful first insertions for the students over time (Pepley et al, 2016a).

Much of the further work related to the DHRT centers around improving the needle. A force and depth measuring syringe was developed to increase the data collected by the robot arm from the syringe (Pepley et al, 2017a). The force-measuring syringe was tested in a cadaver experiment and the force profile generated from the test was implemented into the DHRT system (Pepley et al, 2018). This implementation was particularly useful because the needle force profiles may make surgeons more cognizant of differences in patient anatomy (Pepely et al,

2018). Additionally, an incremental needle insertion system for force and position sensing was developed to increase the accuracy of measurement (Brown et al, 2020). In addition to further device improvements surrounding the needle insertion, the DHRT also had implemented probe improvements to simulate vessel deformation in real time (Pepey et al, 2019). By analyzing video footage of a nerve block in a cadaver, the deformation could be characterized and implemented in the system (Pepley et al, 2019).

Another crucial element of the DHRT is its user interface. The monitor displays on screen instruction, patient case details, ultrasound imagery, and scoring based on resident performance (Gonzalez-Vargas et al, 2020). By basing the user interface design on feedback that trainees were receiving during manikin training, the DHRT could include common mistakes or points experts believed were important (Yovanoff et al, 2017). To further validate the interface, expert interviews were conducted (Gonzalez-Vargas et al, 2020). While experts agreed with perceptions of patient case difficulty conveyed in the DHRT user interface, the scoring system could better reflect the difficulty of the scenario being simulated (Gonzalez-Vargas et al, 2020). These studies would help shape future interface design and redesign.

The DHRT has been shown to be an effective learning tool in evaluations. One study aiming to evaluate and validate its effectiveness indicated that the patient scenarios with smaller vessels had increased difficulty (Pepley et al, 2017b). In another study where residents trained on both the DHRT and a manikin, either training environment showed an improvement in self-efficacy (Yovanoff, 2018). While DHRT users reported more confidence in using tactical feedback, manikin users reported more confidence in finding the center of the vein (Yovanoff, 2018). Manikin users reported higher self-confidence overall, while DHRT users reported more self-made errors and were better able to predict their performance scores (Yovanoff, 2018). A

larger evaluation with 52 participants split the group into 2 groups of 26 and had each group train on either the DHRT or using a manikin (Chen et al, 2019). After completing pre- and post-training tests on manikins, both groups showed improvement overall with no training group differences (Chen et al, 2019). Another case study compared novice and expert performance on the DHRT, finding that the system was able to identify significant differences between the two groups (Chen et al, 2019). In a clinical environment, it was once again found that there were no significant differences between DHRT trainees and manikin trainees (Chen et al, 2020). With the completion of FMEA on the DHRT, opportunities to make the DHRT more effective by improving its usability will arise.

Chapter 3

Methodology

The purpose of this thesis is to demonstrate the use of FMEA and TOPSIS to categorize, compile, and prioritize failure modes of the DHRT. Interviews were conducted to gather process and failure mode data. Qualitative data was used to create a consolidated step-by-step process of using the DHRT and a list of unique failure modes. Failure modes were categorized into the steps it would take to use the system for ease of analysis and to build on DHRT internal documentation. Quantitative data—the FMEA category scores—were inputted into TOPSIS to rank failure modes.

Participants

Five experts who were involved in the design and testing of the DHRT system were gathered to conduct the FMEA. Specifically, the participants had had between 2 and 8 years of experience designing, using, and improving the DHRT. Of the two most experienced experts, one focused on understanding how doctors learn and applying that knowledge to create a user-friendly simulator while the other studied the mechanical workings of needle insertion and skin-force profiles and developed a working haptic simulator. Another expert is currently validating the DHRT system's efficacy in a clinical environment while the final two experts design components of the user interface, physical system, and software.

Procedure

To answer the research questions, the process shown in Figure 1 was used. Expert data was collected via structured interviews based on the steps of a traditional FMEA (Ribas et al, 2021). At the beginning of each interview, the expert reported on the steps that a user would take to use the system. For instance, one expert walked through the process of turning on the system, calibrating it, opening the simulation, and moving through a case. Once each expert had demonstrated their understanding of the process and defined their steps, they gave information about failure modes that might occur in each of the steps which they reported. For example, one expert identified that "not using tools appropriately" while moving through a case could result in a "poorly trained resident." Another expert identifying failures in the same step reported that the needle breaking would mean that the resident "can't train or would delay training." On average, 22 (s.d. 8.99) failure modes were identified by experts.

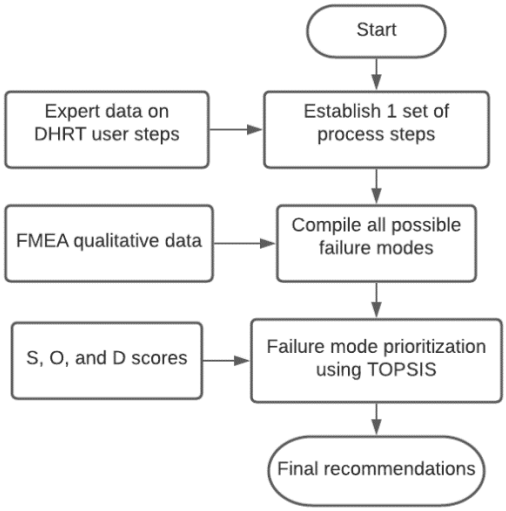

Figure 1. Procedure Flow Chart

Once a failure mode was identified, the experts were asked to rate it in several categories. While this FMEA used the traditional severity, occurrence, and detection categories, linguistic variables based on a 5-point Likert scale were used, as shown in Table 1.

Table 1. Linguistic Variables for Categorical Scoring

SEVERITY (S)	*OCCURRENCE (O)*	*DETECTION (D)*	*SCORE*
None	Almost never	Almost certain	1
Slight	Less than half of the time	High	2
Moderate	About half of the time	Medium	3
Significant	More than half of the time	Slight	4
Very Significant	Almost every time	Almost impossible	5

The FMEA interviews were structured and included open-ended questions, which were tailored to the DHRT. The full list of questions is shown in Table 2. Considering that the system trains medical residents who will later perform CVC on patients, both the short- and long-term potential effects of each failure mode were discussed. This resulted in a two-part question: what is the potential effect of this failure during CVC training, and what is the potential effect during a real CVC procedure after training? Interviewees were also asked about previous actions to mitigate the failure mode in two parts: has anyone tried to prevent this failure mode, and has anyone tried to make it easier to detect this failure? If the expert indicated that previous actions have been taken, then they would be asked to provide details. Finally, the experts were asked about corrective actions that should be taken to address the failure mode. The previous and corrective actions were explored in detail due to the lack of existing documentation.

Table 2. Structured Interview Questions

	QUESTION	*ANSWER FORMAT*
POTENTIAL FAILURE MODE	What could fail during this step?	Open-ended
POTENTIAL EFFECTS	What is the potential (short term) effect on the medical resident if the failure occurs?	Open-ended
	Are there potential cascading effects for a patient if their doctor learned using this system if the failure occurs?	Open-ended
SEVERITY	How severe is it if this failure occurs?	Multiple choice
POTENTIAL CAUSES	Why would the failure mode occur, or in what circumstances would it happen?	Open-ended
OCCURRENCE	How often does the failure mode occur?	Multiple choice
PREVIOUS ACTION	Is there anything currently in place to prevent this failure mode from occurring?	Open-ended
	Is there anything in place to detect this failure mode, should it occur?	Open-ended
DETECTION	If this failure mode occurs, what is the likelihood of detection?	Multiple choice
CORRECTIVE ACTION	Do you recommend any action to prevent, deescalate, or detect this failure mode?	Open-ended

Chapter 4

Analysis

Once interviews were conducted, data analysis began. The current chapter details: 1) how expert understandings of using the DHRT were consolidated into a single process; 2) how failure mode data was cleaned and consolidated, including how non-unique responses were dealt with; and 3) how TOPSIS was used to rank failure modes based on quantitative interview data. Each of the three parts of the analysis will produce results for each of the three research questions.

Immediately after data collection, expert understandings of the process steps were compared. Some experts cited fewer steps overall, possibly because they only focused on steps for which they wanted to cite a failure mode. This discrepancy in responses was potentially due to the different specialty areas between experts. The final set of steps, consolidated for research question 1, included all steps so long as at least one expert cited it. Additionally, some experts separated steps into more categories than others. For example, some had answered “calibrating the system” while others had answered “calibrating the ultrasound” and then “calibrating the needle” to refer to the same set of actions. The larger set of steps (i.e., “calibrating the system”) was used to sort failure modes across experts. By combining the expert responses, an overall process of using the system was constructed.

After establishing process steps, a single list of failure modes was compiled for research question 2. Some experts identified the same failure mode within the same step, so these non-unique failure modes were combined by averaging the S, O, and D scores and preserving all qualitative data. For example, two experts cited that if the ultrasound is not working properly that either the “image does not appear” or the user will see a “black ultrasound screen.” While the

descriptions were not verbatim, it was determined that the two failure modes were the same and could be combined. S, O, and D scores from unique (or combined) failure modes were used for TOPSIS prioritization, which was used to answer the last research question. Given a list of options, TOPSIS is an MCDM ranking method based on each option's distance from the best option on the list (Zhang et al, 2019). To demonstrate the calculations from this thesis, 5 of the 78 failure modes are used as an example.

For TOPSIS, Categorical scores were input into a decision matrix, $A = (a_{ij})_{m\times n}$ such that each row contains the category scores for one failure mode:

$$\begin{aligned} A = \{&5, 3, 4;\\ &5, 3, 3;\\ &4, 3.5, 2.75;\\ &4, 3, 3;\\ &\cdots\\ &3, 3, 1\} \end{aligned} \tag{1}$$

The matrix is then normalized into matrix $B = (b_{ij})_{m\times n}$:

$$b_{ij} = {a_{ij}}\Big/{\sum_{i=1}^{m}(a_{ij})^2}, i = 1, 2, \dots, m; j = 1, 2, \dots, n \tag{2}$$

$$\begin{aligned} B = \{&0.134, 0.109, 0.285;\\ &0.134, 0.109, 0.214;\\ &0.107, 0.127, 0.196;\\ &0.107, 0.109, 0.214;\\ &\cdots\\ &0.081, 0.109, 0.071\} \end{aligned} \tag{3}$$

Each category is also assigned a weight, $W = w_j$, where W contains the weights of the severity, occurrence, and detection, respectively. All weights in this thesis were equal to $^1/_3$ because the three categories were of equal importance. The weighted normalized decision matrix, $C = (c_{ij})_{m\times n}$, can then be constructed.

$$c_{ij} = w_j b_{ij}, i = 1, 2, \dots, m; j = 1, 2, \dots, n \tag{4}$$

$$C = \{\ 0.045, 0.036, 0.095;\ 0.045, 0.036, 0.071;\ 0.036, 0.042, 0.065;\ 0.036, 0.036, 0.071;\ \ldots\ 0.027, 0.036, 0.024\} \quad (5)$$

The weighted normalized decision matrix is used to determine the positive and negative ideal solutions (PIS and NIS), $C+$ and $C-$:

$$C+= \{(max_i\ c_{ij} \mid j \epsilon J), (min_i\ c_{ij} \mid j \epsilon J *)\} \quad (6)$$

$$C-= \{(min_i\ c_{ij} \mid j \epsilon J), (max_i\ c_{ij} \mid j \epsilon J *)\} \quad (7)$$

where J=$\{\ j$ associated with the benefit attribute$\}$ and $J*$=$\{\ j$ associated with the cost attribute$\}$. Row 1 of matrix C was considered the NIS and the final row was considered the PIS as a higher score in any category indicated a worse failure. Each row in the weighted normalized decision matrix can be compared by its distance from the PIS and NIS, d_i^+ and d_i^-:

$$d_i^+ = \sqrt{\sum_{j=1}^{n}(c_{ij} - c_j^+)^2}, i = 1, 2, \ldots, m \quad (8)$$

$$d_i^+ = \{0; 0.024; 0.032; 0.025; \ldots 0.074\} \quad (9)$$

$$d_i^- = \sqrt{\sum_{j=1}^{n}(c_{ij} - c_j^-)^2}, i = 1, 2, \ldots, m \quad (10)$$

$$d_i^- = \{0.074; 0.051; 0.043; 0.048; \ldots 0\} \quad (11)$$

where c_j^+ and c_j^- are the j^{th} score for the positive and negative ideal solutions. The ranking criteria is generated from the distances:

$$f_i = {}^{d_i^-}\!/_{(d_i^- + d_i^+)}, i = 1, 2, \ldots, m \quad (12)$$

$$f_i = \{0; 0.319; 0.424; 0.344; \ldots 1\} \quad (13)$$

The result of TOPSIS is the list of alternatives, ranked from the lowest distance ratio f_i to the highest. The top-ranking failure modes are shown in the results for research question 3.

Chapter 5

Results

A total of 78 unique and 23 non-unique failure modes were identified based on the analysis. The remainder of this section is structured according to our research questions and describes results of the analysis from the previous chapter.

RQ1: How do experts agree on the DHRT use process?

Our first research question was about how experts understand the system's process. To analyze this, we compared the steps identified at the beginning of the interviews. Table 3 shows the full expert responses and the resulting consolidation of steps.

Table 3. Expert Step Responses

EXPERT 1 HF ENGR	*EXPERT 2 HF ENGR*	*EXPERT 3 HF ENGR*	*EXPERT 4 ROBOTICS ENGR*	*EXPERT 5 ROBOTICS ENGR*	*COMBINED STEPS*	
Plug in and turn on	Turn on DHRT	Turn on system	Turn on system	Turn on robot	**1**	**Turn on system**
Log in to system						
Calibrate robot	Probe calibration	Calibrate probe	Calibration	System calibration	**2**	**Calibrate system**
	Needle calibration	Calibrate needle				
Run program			Start main program	Open software	**3**	**Open Simulation**
Calibrate ultrasound					**4**	**Calibrate simulation, if needed**
Calibrate needle						
Log in to program	Create new profile	Log in		Log in	**5**	**Log into program or create new profile**
Tutorial	Instructional video	Instructional video	User goes through training case	Watch tutorial	**6**	**Watch instructional video**
		See patient profile		Read patient profile	**7**	**Read case profile**
		Click start		Start simulation	**8**	**Start case**
Move through trial	Pick up probe and locate vessels	See vein with ultrasound		Finding the vessels	**9**	**Move through case**
	Take needle, locate on ultrasound screen	Take out needle and see how to insert		Center vessel on screen, center needle		
	Needle insertion until aspiration	Insert needle		Insert needle with aspiration		
	Place probe in blue section	Put probe in blue section		Put probe in blue section		
Understanding feedback	Receive summary of performance	Feedback screen		Feedback screen	**10**	**Receive summary of feedback**
Proficiency testing					**11**	**Go through proficiency test case, if applicable**
Logging out	Tap 'Next Case'	Click 'Next Case'			**12**	**Tap 'Next Case' or log out**

The following list describes each of the steps in the consolidated version:

1. *Turn on system.* All cords and components of the system must be plugged in correctly and then powered on.
2. *Calibrate system.* Initial robot calibration must be completed so that the probe and needle are accurate, and the system can verify that everything is working.
3. *Open simulation.* Blender, the program on which the simulation runs, must be powered on.

4. *Calibrate simulation, if needed.* Secondary calibration within the simulation may be necessary for needle and probe accuracy.
5. *Log into program or create a new profile.* To track progress, users must sign into their current account or create a new one with a unique login.
6. *Watch instructional video.* To understand how to move through a case, the user must watch a tutorial.
7. *Read case profile.* Before attempting insertion, the user learns about their patient and is given a case profile with hints about what kind of anatomy the patient may have.
8. *Start case.* When they are finished reading, the user may press a button to start their insertion attempt.
9. *Move through case.* The user uses the probe to find the vessels, aims with the needle, and inserts the needle into the vessel with aspiration. To end the trial, they must hold the needle still and place the probe outside of the simulation area.
10. *Receive summary of feedback.* The user reads their overall score with detailed feedback based on their performance on the previous case.
11. *Go through proficiency test case, if applicable.* Additional steps are required for users seeking accreditation for their training.
12. *Tap 'Next Case' or log out.* The user has the option to complete a case with a different patient profile or exit the simulation.

Overall, the hypothesis was confirmed it was determined that the experts agreed to the extent that consolidated steps could be formed and used in future documentation for the DHRT. The consolidated list of steps will be used to classify the results of research question 3.

RQ2: What are the possible DHRT failure modes and what corrective actions are recommended?

Our next research question was to compile all possible failure modes for the system. To analyze this, we collected data from expert FMEA interviews and combined non-unique failures as per the analysis chapter. A total of 78 unique failure modes were found across all process steps. Step 9, moving through the case, had the most failure modes with 19. For clarity, moving through the case is the process of using the ultrasound and needle to complete insertion for a given patient profile. System calibration had the next highest number of failure modes, 13, while logging in or creating a new profile had the third most failure modes, with 11. More examples of failure modes are included in the next section and in the discussion. Overall, our hypothesis that FMEA could be used to successfully document and compile all possible failure modes of the DHRT was confirmed.

RQ3: Which failure modes are the highest priority?

Our last research question was to assess which failure modes were the highest priority. To analyze this, we inputted the S, O, and D scores of all 78 failure modes into TOPSIS, as opposed to relying on the traditional RPN calculation. The top ranking 15 failure modes are shown in Table 4. The failure modes are ordered by what process step they would occur in, based on the step list created for RQ1. The Rank is based on TOPSIS calculations, where a lower ranking indicates a lower distance ratio compared to other failure modes. Corrective actions for the failure modes are also shown because their rankings indicate that doing something to prevent, deescalate, or detect that failure mode is highly recommended.

Table 4. Priority Failure Modes

STEP	*FAILURE MODE*	*CORRECTIVE ACTION*	*RANK*	*TYPE*
2	Skipping system calibration	Call system calibration within simulation software	12	Mechanical
2	System calibration is finicky or difficult to use	Improve mechanical components, reorder how components power on, make calibration faster	8	Mechanical
2	Unsuccessful system calibration	Create standard operating procedures	11	Usability
4	Cannot find needle in simulation calibration	Indication of needle location other than image, add error message	13	Mechanical or usability
4	Unsuccessful simulation calibration	Verification that calibration is successful	1	Usability
5	Two identical login codes	-	3	Software
5	User information is not saved	-	4	Software
7	Needle bounces during a case	Reprogram software	5	Software
7	Needle pops during a case	Reprogram software	6	Software
7	User nicks artery when inserting needle	Provide more detailed feedback during trial	2	Usability
7	User does not know when they have accessed the vessel	Provide more detailed feedback during trial	14	Usability
7	Aspirator fails	-	7	Mechanical
7	User does not recognize aspiration	Improve user interface during trial	9	Usability
7	User does not keep needle still when ending trial	Improve feedback screen, improve tutorial	10	Usability
10	User does not understand feedback or scoring	Improve user interface, reformulate scoring equations	15	Usability

The priority failure modes by step and failure type are shown graphically in Figure 2. For ease of analysis, priority failure modes were subjectively categorized into relevant failure types. Three major failure types were found: usability failures, mechanical failures, and software failures. A usability failure included user interface issues or points of user confusion; mechanical failures included malfunction of a physical component; and software failures included issues which require a software change. For example, a usability issue found was that the user does not understand feedback or scoring, and its corrective action included improving the user interface or reformulating scoring equations. One mechanical issue cited was the aspirator, a needle component, fails. A software issue was that two users could potentially be given identical login

codes. Failure modes were classified as a usability, mechanical, or software failure based on the nature of the failure mode, its potential causes, and its corrective actions.

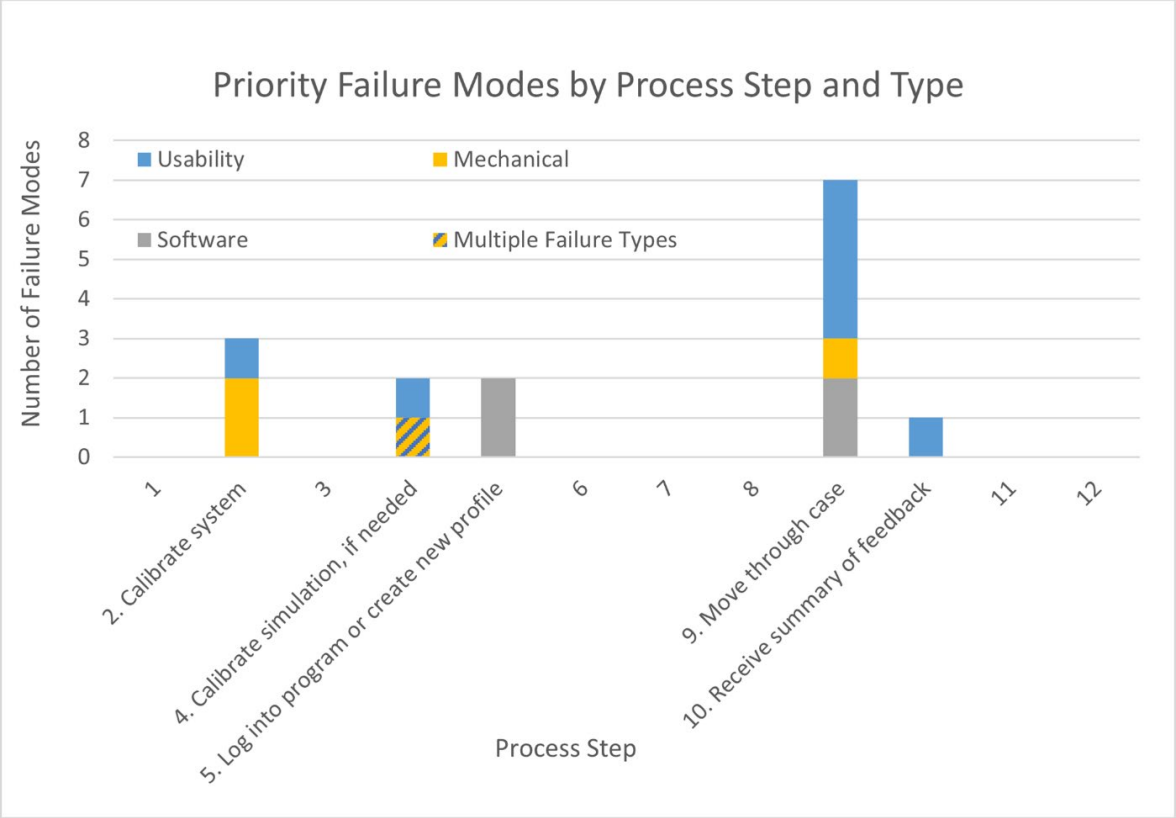

Figure 2. Priority Failure Modes by Process Step and Failure Type

Chapter 6

Discussion

The main goal of this thesis was to recommend corrective actions based on a FMEA for the DHRT. The main results are as follows:

- Experts agreed on the process of using the DHRT enough to help create a consolidated list of 12 steps.
- FMEA was successfully employed to document and compile DHRT failure modes.
- Across all steps and failure types, there are 78 unique failure modes.
- TOPSIS was successfully used in place of the traditional RPN calculation to prioritize failure modes.
- The top 20% of TOPSIS ranked failure modes can be used as focused recommendations for future project work.
- Many of the priority failure modes reveal opportunities to improve the DHRT's usability.

The results are discussed further in the following paragraphs:

When considering use of the DHRT, individual experts gave between 4 and 13 steps during interviews. Some experts separated different parts of calibration, such as needle calibration and probe calibration. Other experts did not, so these steps were combined into one step for calibrating the system. Several experts defined steps for the user to follow as they move through a case, but these were also combined to cleanly group failure modes together. Individual expert responses, especially those that refer to moving through a case, should be considered in future work.

Generation of standard operating procedures and other internal documentation are one use of the compiled steps and individual responses.

From the 15 prioritized failure modes, 7 were usability failures, with one failure classified as both usability and mechanical. There were 3 additional mechanical failures and 4 software failures. Just as step 9, moving through the case, had the highest number of failure modes, it had the highest number of prioritized failure modes, 7. Thus, step 9 provided a large opportunity to improve system usability, followed by step 2 with 3 priority failure modes, steps 4 and 5 with 2 priority failure modes, and step 10 with 1 priority failure mode.

Using the TOPSIS rankings as a guide, the first failure mode to be addressed should be the potential for an unsuccessful simulation calibration. Its corrective action is adding a verification for whether calibration has been accomplished correctly. The second highest priority is the user nicking the artery when inserting a needle, resulting in a failed case. The corrective action is providing more detailed feedback to the user when they attempt insertion. This corrective action has the potential for an especially large impact due to the number of other priority failure modes (user does not know when they have accessed the vessel, user does not recognize aspiration) which have a similar corrective action. The 3rd and 4th ranking failure modes both deal with the potential for login issues (two identical login codes, user information is not saved). No corrective actions were cited for either of these failures; thus, further investigation or a root cause analysis may be necessary to address these failure modes.

While many of the cited failure modes and corrective actions could potentially be found by using a different method, such as FTA or HAZOP, FMEA and TOPSIS provided a clear ranking of which failure modes are the most important to address first. Additionally, the exhaustive nature of FMEA will allow DHRT designers to expand their documentation.

Though FMEA and TOPSIS were used to find the failure modes that had the most urgency due to their ability to impact the system, not all of them were immediately solvable. Some failure modes did not have any sort of corrective action (meaning that the expert cited a failure mode but did not have a recommendation in mind), while other failure modes had corrective actions that would take up a considerable amount of time and/or resources. Not considering corrective actions during prioritization is a limitation of FMEA, which can be addressed using a utility priority number (Chen, 2007). Since the utility priority number was not used in this thesis, in addition to analyzing failure modes using FMEA and TOPSIS, 7 of the corrective actions were flagged as immediately actionable. A corrective action was flagged if it required a reasonable cost, low technical knowledge, and relatively little time. The corrective actions were converted into 7 detailed recommendations:

1. Rearrange the desktop screen on the DHRT by moving the main program icon from the top center of the screen to the actual center of the screen. The icon will still be found easily by the user but not accidentally tapped.
2. Use electrical tape to color code DHRT cords and where they plug into the machine so it is easier to set up.
3. Make a part list with all components, cords, and the color code established for number 2.
4. Make a packing list for any tools or other items needed when traveling with the DHRT.
5. Redesign packaging system for driving or flying with the DHRT, with efficiency and quality in mind.
6. Make a setup guide for the DHRT, with troubleshooting in mind.
7. Make standard operating procedures for using the DHRT, with troubleshooting in mind.

In pursuing these objectives, one of several existing DHRTs was used to pilot changes. The icon was moved out of the way, cords were color-coded, and a part list, packing list, and setup guide were created. Before implementing any changes, the setup process was explained to a person unfamiliar with the system. They completed the setup in 10 minutes and 24 seconds and completed taking apart the DHRT (the reverse steps of setting up) in 5 minutes and 58 seconds. After completing several of the objectives, setting up took 6 minutes and 9 seconds and taking the DHRT apart took 4 minutes and 1 second. Though these corrective actions were not considered a priority via FMEA and TOPSIS, the improvement made was justified because of the small amount of time and resources needed to implement impactful changes.

Chapter 7

Recommendations and Future Work

Future work for this project will include implementing corrective actions for the identified failure modes and leveraging qualitative interview data. Implementing the corrective actions, particularly those recommended by the TOPSIS analysis, provides great opportunity to improve the DHRT's usability. The corrective actions marked as immediately actionable provide additional opportunity to impact the system when time and resources are constrained. Once corrective actions have been implemented, their efficacy should be measured.

To further justify the use of TOPSIS instead of traditional RPN calculation, the data set could be used to compare the differences between the two methods. Since TOPSIS was already completed, the RPN could be calculated for each failure mode and then the rankings using each method could be compared.

The qualitative interview data can also be used in future work for the DHRT. Prior actions taken to mitigate failure could be useful for internal documentation. Some failure modes may be identified as candidates for root cause analysis due to vague or incomplete data on potential solutions. In the long term, corrective actions are meant to improve the overall efficacy of the DHRT. If the DHRT can more effectively teach residents to perform CVC, future complications may be avoided.

Chapter 8

Conclusions

The case study successfully demonstrated failure mode prioritization on the DHRT using FMEA and TOPSIS. To understand how experts believe the system should be used, interview responses were compiled into process steps, each of which had several failure modes. 78 unique failures were found and prioritized. About half of the top 15 failure modes were categorized as usability issues. While the results are beneficial to the designers of the system, making corrective actions to the DHRT has a large potential for long term impact on residents and their patients. Applying Human Factors analysis to the DHRT via FMEA is an important step in ensuring that medical personnel get the best possible CVC training.

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ACADEMIC VITA

EDUCATION

The Pennsylvania State University, *University Park, PA*
Bachelor of Science in Industrial Engineering
Minors in Information Sciences & Technology, Six Sigma
Schreyer Honors College
Anticipated Graduation: Spring 2022

GLOBAL EDUCATION

Engineering Abroad Scholar May 2019
Politecnico di Milano e SUPSI, *Como, Italy and Lugano, Switzerland*
- Studied technical presentations and Italian language and culture
- Attended engineering excursions throughout Northern Italy, Switzerland

EXPERIENCE

Quality Engineering Intern June - Aug 2021
Appian Corporation, *Remote Internship*
- Reviewed software developer changes to ensure quality
- Automated quality tests using OWL and Python
- Presented technical and non-technical topics to an audience of full-time employees

Undergraduate Research Assistant Jan 2020 - Present
Penn State University, *University Park, PA*
- Catalogued and assessed robot failure modes under the direction of Dr. Scarlett Miller, professor of Industrial Engineering
- Investigated automotive user interfaces under the direction of Dr. Syed Billah, assistant professor of IST
- Conducted nuclear forensics research under the direction of Dr. Marek Flaska, assistant professor of Nuclear Engineering
- Conducted human subject research to visualize and test accessibility aids under the direction of Dr. Mary Beth Rosson, professor of IST

Teaching Intern, Engineering Analytics Course Jan - May 2021
Penn State University, *University Park, PA*
- Lecture Industrial Engineering students on data management
- Assist students with programming, statistics, and analytical concepts

SOFTWARE

C++	MATLAB	Simio
Python	R	SolidWorks
Visual Basic	SQL	AMPL

LEADERSHIP & INVOLVEMENT

Undergraduate Research Ambassador, *Undergrad. Fellowships & Mentoring*
- Present resources and guidance to students wishing to pursue research
- Support new ambassador training

Sophomore Envoy, *Penn State Women in Engineering Program*
- Provided yearlong service to the Women in Engineering Program and prospective engineering students

HONORS & AWARDS

Marcus Scholarship, 2021
Steele Scholarship, 2018-19
Beier Scholarship, 2019-21
President's Freshmen Award, 2018