

Medical Device Design Education: Identifying Problems Through Observation and Hands-On Training

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Key words

design education; observational learning; experiential learning; hands-on training; medical simulations; need finding

Abstract

Experiential learning, which may include hands-on learning paired with observation and reflection, has been applied in several industries; however, the impact of experiential learning in design education is not well known. We investigated how the type of simulation-based learning could affect the acquisition of knowledge and the ability to synthesize that understanding into insights for medical design innovation. One workshop included observational learning and the other experiential learning with hands-on training. Each course included 14-16 multidisciplinary undergraduate and graduate students. During both workshops, we measured student comprehension of two procedures— infant resuscitation and management of maternal hemorrhage. We focused on the first two phases of design thinking: “Understanding” and “Defining the Problems”. Although the course focused on “medical device design”, we encouraged students to look beyond the tool to imagine how their design change could impact the entire system. We did not find a significant difference between the scores given to students in the two courses by industry experts. Although the quality of the ideas and execution were similar between both workshops, the instructors noticed that the integration of hands-on training into the second workshop created a higher level of excitement in the class. The methodology and the approach adopted may be relevant to many design problems. In order to better understand the impact of observational learning versus hands-on training, both workshops could be expanded into full quarter classes that allow students to expand their design thinking skills to prototype and test their ideas in the real world.

Introduction

Experiential learning, which may include hands-on training paired with observation and reflection, has been utilized in other disciplines such as business, psychology, military and aeronautics (Crawley, Brodeur, & Soderholm, 2008; Gosen & Washbush, 2004; Seaman, Brown, & Quay, 2017; *The Handbook of Experiential Learning and Management Education*, 2007). However, the impact of experiential learning in design education is not well known. In this study, we sought to understand how observational learning versus experiential learning may impact a design student's comprehension of a medical procedure as well as their capacity for need-finding and innovation. During two different workshops, we purposefully contrasted observational learning with experiential learning that included hands-on training. Observational learning is defined as learning by observing others. Conversely, experiential learning is "the process of making meaning from direct experience, namely learning through reflection on doing," (Felicia, 2011, p. 1003)

Experiential learning can occur in the field or in a simulated environment. Some university programs allow design students observational learning experiences through field immersion. For example, Georgia Institute of Technology has partnered with Emory University School of Medicine to offer design students the opportunity to learn through immersion at the hospital (Ackerman & Schaar, 2016). However, they did not include a hands-on training component. Beyond auditory and visual learning, hands-on training offers design students a kinesthetic experience. The ways people receive information may be divided into three categories, sometimes referred to as modalities: visual—sights, pictures, diagrams, symbols; auditory— sounds, words; kinesthetic—taste, touch, and smell. An extensive body of research has established that most people learn effectively with one of the three modalities and tend to miss or ignore information presented in either of the other two (Felder & Silverma, 1988). In this study, we explored the impact of experiential learning through simulation on design education.

Simulation learning fits well within the design-thinking paradigm ("An Introduction to Design Thinking Process Guide,"): empathize (through immersion), define (the needs or problems), ideate (rainstorm), prototype (iterative low resolution style) and test with users (repeat). Two experimental medical device design workshops were co-taught by a lecturer from the Hasso Plattner Institute of Design and clinicians from two children's hospitals. Both workshops aimed to inform the Safety Learning Lab for Maternal and Neonatal Care and the d. School teaching community the differences in problem comprehension and solution development when students did observational learning versus observational learning and hands-on training. Our hypothesis was that used in the context of design education, hands-on training with medical simulations may lead to more effective and safe product or system development by helping designers develop a deeper understanding of what clinicians have to do step-by-step to achieve a desired outcome. Although this research was conducted in a medical

context for the purpose of designing safer and more effective medical devices, the methodology and the approach adopted may be relevant to many design problems.

Objectives and Research Questions:

In this study, we investigated how the type of simulation-based learning (observational learnings versus hands-on training) could affect the acquisition of knowledge and the ability to synthesize that understanding into insights that can contribute to medical design innovation. At the d. School, our healthcare design classes purposely avoid giving interdisciplinary students information regarding aspects of a procedure that need attention, instead relying on the student's ability to identify needs through their unique academic lens. Our study posed the following two questions:

1) Which mode of learning led to deeper insights and the identification of latent needs?

Often, these needs aren't so easy to find. Moreover, when we can find out a reasonable set of needs, we often have difficulty translating them into appropriate solutions to both find important needs and develop them into compelling solutions. It's necessary to move beyond what we can tangibly sense into more abstract realms of concepts, frameworks and ideas.

2) How did the mode of learning affect the quality of the solution ideas?

The term "quality" refers to "kind" rather than "high quality" or "poor quality".

Conceptual Background:

Needfinding is the act of discovering people's explicit and implicit needs so that you can create appropriate solutions. Looking for needs rather than specific solutions keeps all possible solutions open for consideration and avoids prematurely limiting possibilities. In our workshops we asked students to first state needs independently of ways those needs might be served (Patnaik, 2016).

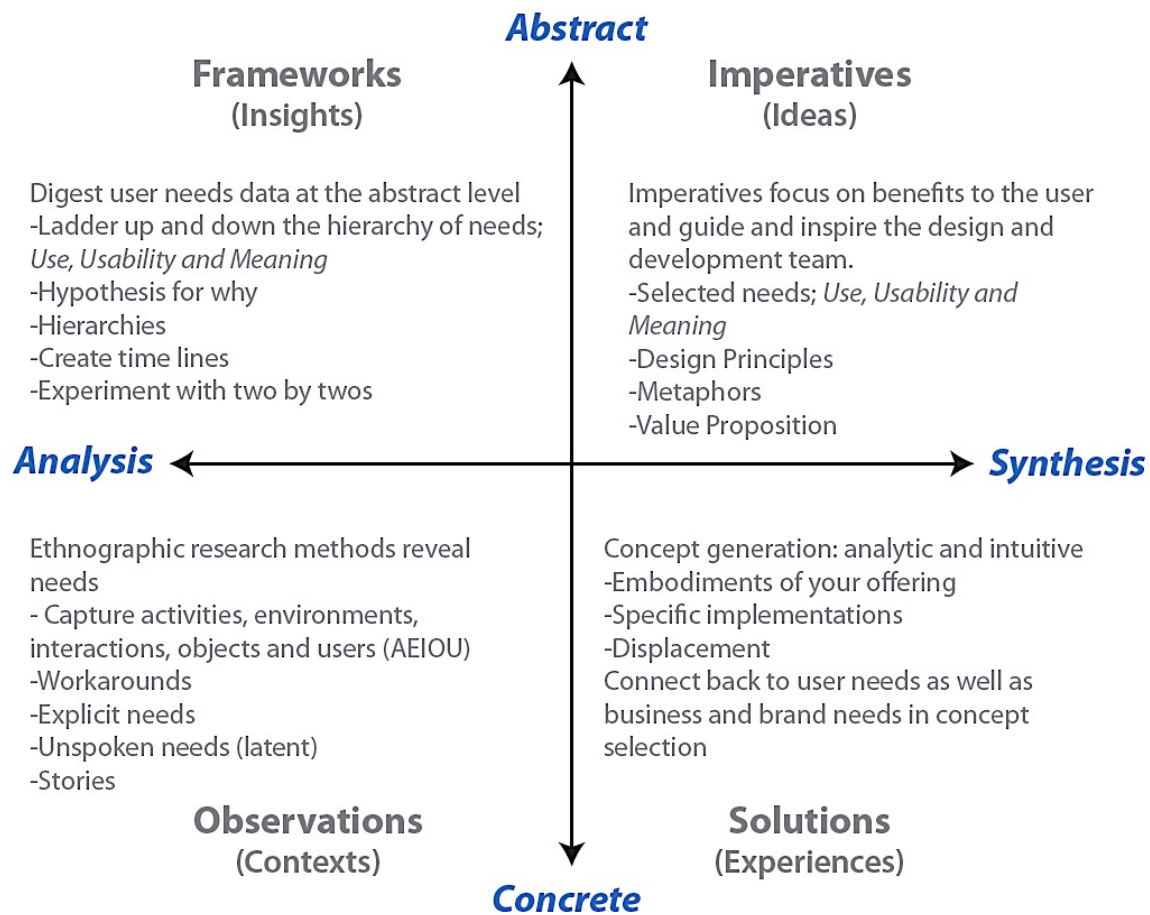


Figure 1. Experimental Learning Theory.

Figure 1 is a two by two diagram that organizes the design thinking process into four quadrants. Stanford’s d. School uses this model that connects two bodies of prior academic work--a design model first proposed by Charles Owen at the Illinois Institute of Design and David Kolb’s experimental learning theory. In our workshops we touched on each of the four quadrants, but focused on the “Observations” and “Frameworks” sections.

Researchers obtain the richest information on people’s needs by observing and interviewing users first-hand. The researchers can then directly see many small but important details about the user’s activities and the context in which they occur—details that wouldn’t be available outside that context. By directly observing users’ activities, need-finding avoids reliance on user’s’ memory, descriptive ability, or awareness of a need. In addition, the user’s environment facilitates communication between the researcher and the user by allowing them both to refer to and use objects in the environment during the discussion (Patnaik, 2016).

Once data are collected, the final stage of the need-finding process is to interpret the findings and categorize the needs through creating a hierarchy (synthesis). Information collected in the user's environment helps refine one's understanding and prepares the team for another iteration of research. Product development can then continue in parallel to the ongoing need-finding activity. Because need-finding is about studying people, as well as developing products, we frame interpretations in terms of what problems need to be solved to improve the user's situation (Patnaik, 2016).

The ability to discover important insights may suggest areas of innovation for designers, as well as new markets that await development. The result of practicing need-finding techniques can be applied to the recognition and refining of user workarounds, and inventing innovative new solutions that leap past incremental change (Patnaik, 2016).

At the d. School, experimental hands-on project courses give students practice in **eight abilities** via a wide range of tools, methods, projects, mindsets, behaviors, artifacts etc. (Carter, 2016). In our workshops we focused on the first three skills.

1. **Navigate Ambiguity**

This is the ability to recognize and stew in the discomfort of not knowing, and then come up with tactics to emerge out of it when needed. Design is loaded with uncertainty. There are important skills to learn such as being present in the moment, re-framing problems, and finding patterns in information. (Carter, 2016)

2. **Learn from Others (People and Contexts)**

This ability includes the skills of empathizing with different people, testing new ideas with them and observing and noticing in different places and contexts. Recognizing the opportunity to, and then learning from others is something that happens throughout a design project, both with end users as well as other stakeholders and team members. There is a sensitivity to others that develops with this ability. (Carter, 2016)

3. **Synthesize Information**

This is the ability to make sense of information and find insight and opportunity within. Data comes from multiple places and has many different forms, both qualitative and quantitative. This ability requires skills in making frameworks, maps and [abductive thinking](#). This ability is co-dependent with navigating ambiguity. (Carter, 2016)

Methods

Course Description:

We designed two different workshops called “Medical Device Design: Identifying Problems Through Observation,” and “Medical Device Design: Identifying Problems Through Observation and Hands-On Training”. In this paper, we will refer to the first course as observational learning and the second as hands-on training. In this pilot study, 16 interdisciplinary students participated in the first workshop and 14 interdisciplinary students participated in the second workshop. Each workshop lasted two days. We provided our students with background clinical information on maternal hemorrhage and infant resuscitation in advance of the workshop. During the first workshop, students observed clinicians perform procedure simulations and then moved directly into synthesis and brainstorming possible solutions in teams of three (Figure 2). During the second workshop, another group of students followed a similar process, in addition they did hands-on training with neonatologists and OB/GYNs in the simulation lab (Figure 3).



Figure 2. Observational Learning: Students View Maternal Hemorrhage



Figure 3. Experiential Learning: Students Perform Infant Intubation

Due to the brevity of the course, we focused exclusively on the first two phases of design thinking: “Understanding” and “Defining the Problems”.

These workshops were mainly concerned with how we capture our research as designers. We discussed the importance of understanding the “story in,” or, what’s happening now, through focused *observation* (visual learning), *interviews* (auditory learning), and *hands-on training* (tactile learning) as tools for gaining empathy. Afterwards, we synthesized our research in small groups. “Use, Usability and Meaning” was employed as a framework to help students organize their research into a “story out,” or new vision. Where “Use” asks what is the tool or process being used for and “Usability” asks what are the shortcomings of the procedure, the tools or other aspects that could use improvement? We then asked the students to tell us the “Meaning” behind the particular use cases they found. In order to do this, they had to dig deeper into the motivations, culture, and barriers that might exist in the medical environment.

Rather than have students create a “Point of View” (POV) statement (*user + need + insight*), we asked students to state their insight “we were amazed to discover...”. Thereafter a solution space was framed by another statement “it would be game-changing if...” instead of the traditional “How Might We...” statement. A visual aid to describe the idea was then shared. Visual aids, or “prototypes” could be

We then measured the quality of needs identified and solutions presented through a Likert scale survey completed by a panel of industry experts in medicine and product design. Each expert was asked to evaluate each student project on a scale of 1 to 7, with “1” meaning strongly disagree and “7” meaning strongly agree”. The questions were:

1. You heard a memorable story that brings a person/group and their healthcare situation to life.
2. The “We were amazed to discover...” problem is believable and interesting.
3. There is an insight for the problem offered, one that makes sense and reveals unsatisfied or emerging needs.
4. There is an opportunity space (multiple solutions) or possible innovation suggested.

Summary statistics such as mean and standard deviation were calculated. Comparisons between groups were calculated using Student t-test.

Results

Each course consisted of 14-16 undergraduate and graduate students from engineering, design, medicine, business, law, humanities, education, and earth sciences.

The majority of codes fell into five key themes in both groups that students thought were most important both before and after the observational learning or hands-on training. The most prevalent themes were: 1) preparation 2) performance, and 3) communication. The remaining two were equipment design and a safe delivery environment. The comparative thematic data is shown in Figure 5. Analysis codes are shown in Table 1. The prevalence of each code is listed in descending order.

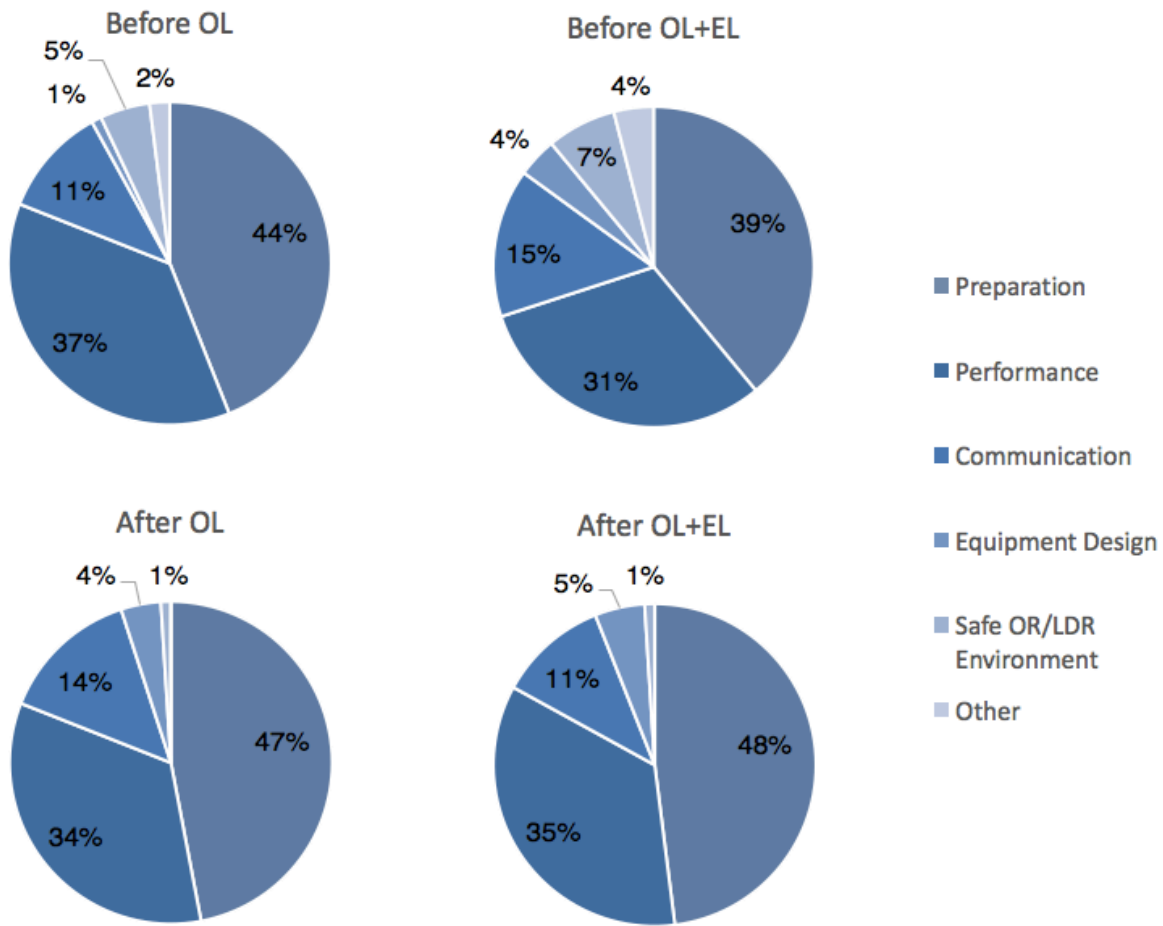


Figure 5. Thematic Comparison: What Students Thought Were Most Important Before and After Each Workshop

Table 1. Analysis Codes

1.	Preparation
1a.	Availability/Accessibility
	i.
	Tools
	ii.
	People
1b.	Relevant Knowledge
1c.	Experience

1d. Training

1f. Mental

1g. General Preparation

2. Performance

2a. Tools

2b. Timing

2c. Procedure

2d. Diagnosis/Assessment

2e. Follow-up

2f. Do No Harm

2g. Other Performance

3. Communication

3a. Medical Team Communication

3b. Communication with
Patient/Family

4. Equipment Design/ Efficacy

4a. Appropriate Device Size

4b. Ease of Use

4b. Equipment Material

5. Safe OR/DR Environment

5a. Sterile Environment

5b. No Obstacles

5c. Calm Environment

Under the theme “Preparation,” the most common code was “Availability of Equipment.” Other codes under this theme were “Relevant Knowledge” and “Experience and Training.” Examples noted by several students included the importance of having the right tools, access to blood, and the option to call for back-up staff. One student noted an important variable was “staff readiness (people, equipment, procedures in place), practiced, alert, proximity, equipment functioning and in a good position.” Another student reported that “anticipation of what might happen - tools preparation (access), skills access (mental prep)” as an important variable.

Under the theme “Performance,” the top three codes were “Tools,” “Timing” and “Diagnosis/Assessment.” We defined “Tools” as clinician’s ability to use the tools correctly. “Timing” was defined as completing a procedure efficiently. One student noted an important variable was “speed of decision making and actions taken.” We defined “Assessment” as identifying when the situation has escalated or changed. For example, one student noted an important variable was “having an RN that can recognize when to call for a pediatrician” and another student noted an important variable was “watching and knowing vitals and at what times to follow-through to next steps.”

The “Communication” theme was split into two codes: “Medical Team Communication” and “Patient/Clinician Communication.” We included visual and verbal cues as well as teamwork and coordination in this category. For communication between patients and clinicians, we defined this code as someone telling the mother and her support people what is going on and their options. Common variables reported by students included communication between the different types of providers (ie: neonatologists, nurses, techs). Some students mentioned allocating responsibility as a major variable (clear role assignments), and maintaining communication throughout the procedure.

The other themes we found were “Equipment Design and Efficacy” and a “Safe Labor and Delivery Environment”. These themes were not as common, but still mentioned by each group. “Equipment Design and Efficacy” included responses such as appropriate size of available devices, ease of instrument use, and appropriate materials for the equipment. For example, one student wrote on the importance of having “a new device that can accommodate babies specifically (keeping in mind their physiology) instead of a scaled down version of what we have for adults.” Another student noted the importance of “knowing how to quickly assemble tools or having easier to use tools.” Under the theme “Safe L&D Environment”, the most common student response was creating and maintaining a sterile environment. Other students noted that it is important that there are “no obstacles when moving close to the infant” and for clinicians to “maintain a calm atmosphere for parents during intubation.”

We did not find a significant difference between the scores given to students in the observational learning versus hands-on training course by industry experts ($p=0.44$). Comparative and summary statistics are shown in Table 2.

Question #	OL		OL+EL		Comparison	
	Mean	SD	Mean	SD	t-statistic	p-value
1	5.8	1.1	5.9	1.1	0.29	0.77
2	6.0	0.7	6.1	0.8	0.58	0.57
3	6.5	0.4	6.0	0.5	1.82	0.08
4	6.5	1.4	5.9	0.8	0.87	0.38
Overall	6.1	0.8	6.0	0.8	0.78	0.44

Table 2. Summary and Comparative Statistics. SD=standard deviation

Student Examples

An example of systems innovation in the OL+EL workshop was a group that developed “The TACO Truck”. “TACO” was an acronym for: “Training Advanced Critical Care Operation”. In this project, students imagined a mobile unit for offering smaller hospitals without simulation facilities the opportunity to practice critical care skills in L&D and the neonatal intensive care unit (Figure 6[HCL6]).

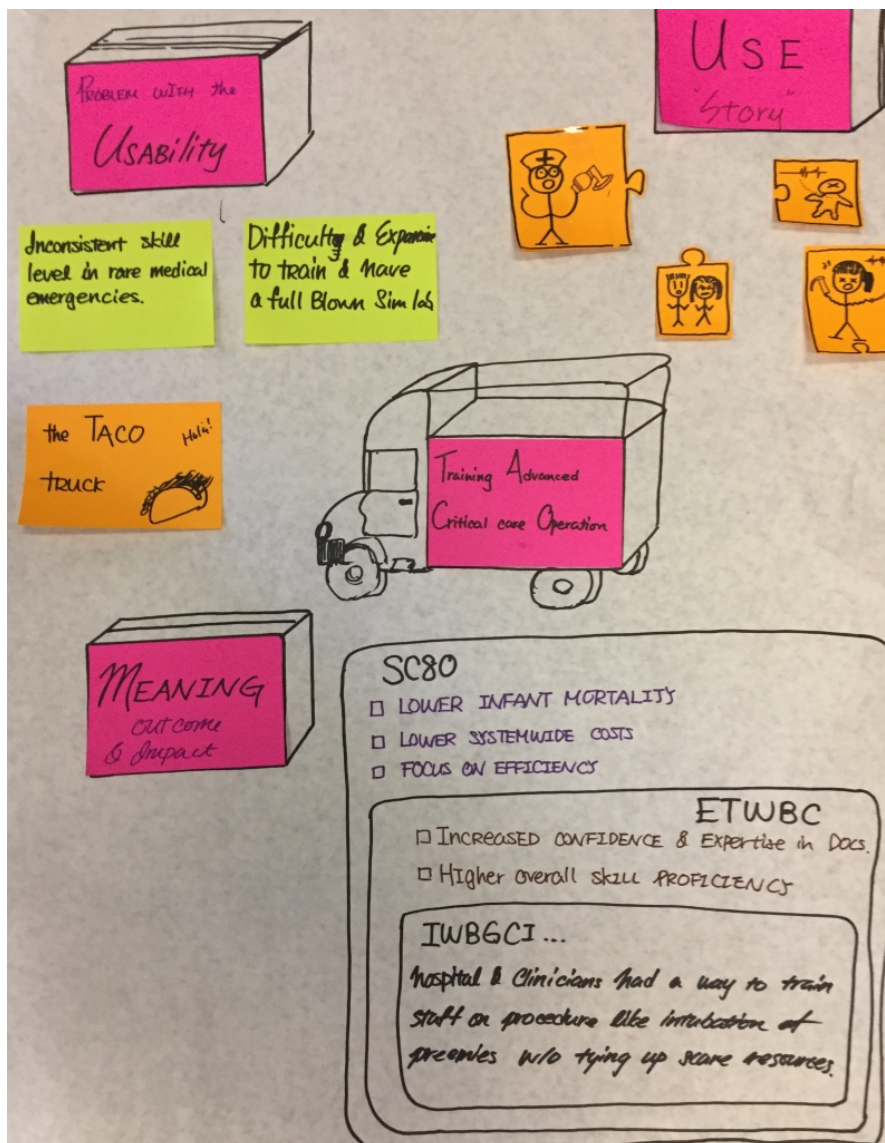


Figure 6. Student Example: Training Advanced Critical Care Operation (TACO) Truck

In contrast, a group in the observational learning workshop focused on the difficulties of infant intubation. They noticed that the clinicians had a difficult time seeing down into the laryngoscope in order to place the breathing tube correctly in a newborn. Even though there are three sizes of laryngoscope depending on the size of the baby one is intubating, the opening is small, so tube placement errors frequently occur (Figure 7). According to an attending neonatologist at Lucile Packard Children's Hospital, and also a co-instructor, 40-60% of intubations actually require a reintubation due to errors in placing the tube. "Intubation is a high-pressure situation, the heart rate is low, they are effectively are not circulating blood and are close to death." With stress level in mind, the group told a new product design story "story out" using an existing laryngoscope and paper model that represented

a camera that connects to the device. The camera would allow a neonatologist to clearly see both the trachea (airway) and esophagus clearly while intubating a baby. This camera could also be used more generally for pediatric or adult intubation. The story expanded with the potential for integrating sensors that could give haptic or visual feedback (on the camera) if the tube was placed at the wrong angle, or distance (Figure 8). Although later the group realized that cameras which attach to such devices already exist, the addition of haptic or visual feedback was unique.



Figure 7. Examples of Existing Intubation Equipment

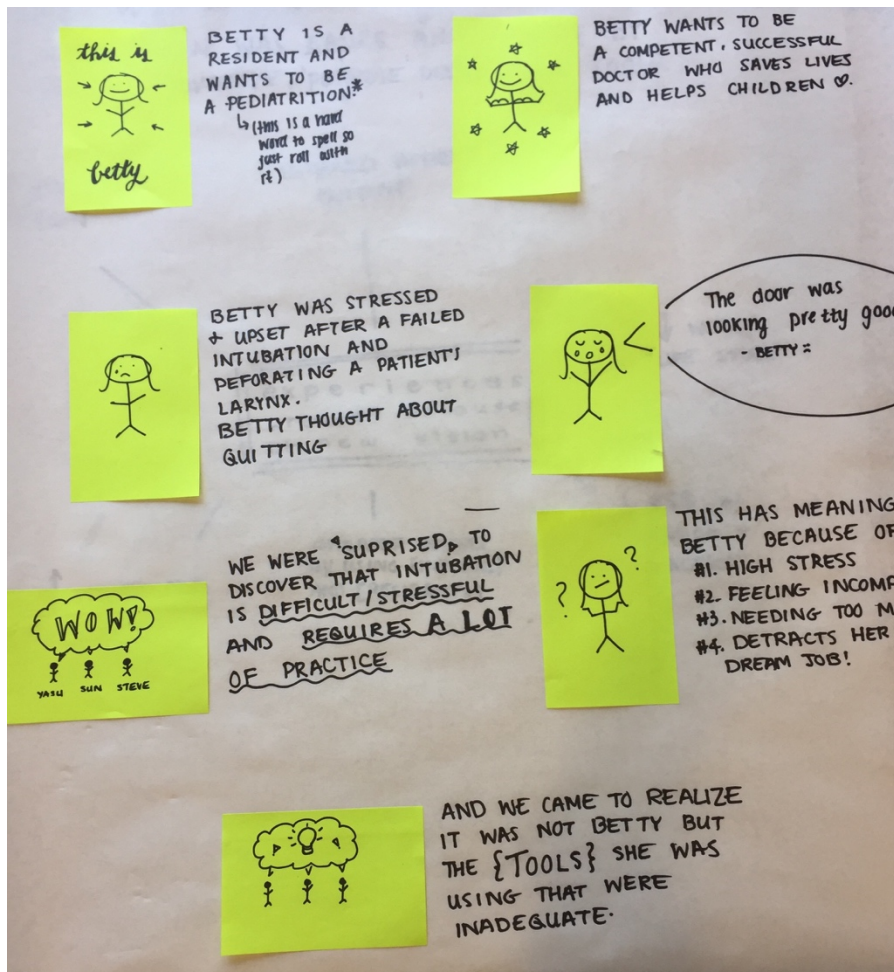


Figure 8. Student Example: Infant Intubation Camera

When a student group in the OL+EL class observed OB nurses using the Bakri Balloon[®], they noticed the grimace on the nurse's face after pumping the water into the uterine balloon for several minutes. After experiencing performing the procedure themselves, they learned that the pump system is extremely uncomfortable to use, and set out to design a new handle on the pump in order to improve ergonomic issues associated with this device (Figure 9; Figure 10). The EL strongly influenced the project they wanted to explore.



Figure 9. Students Using Bakri Balloon

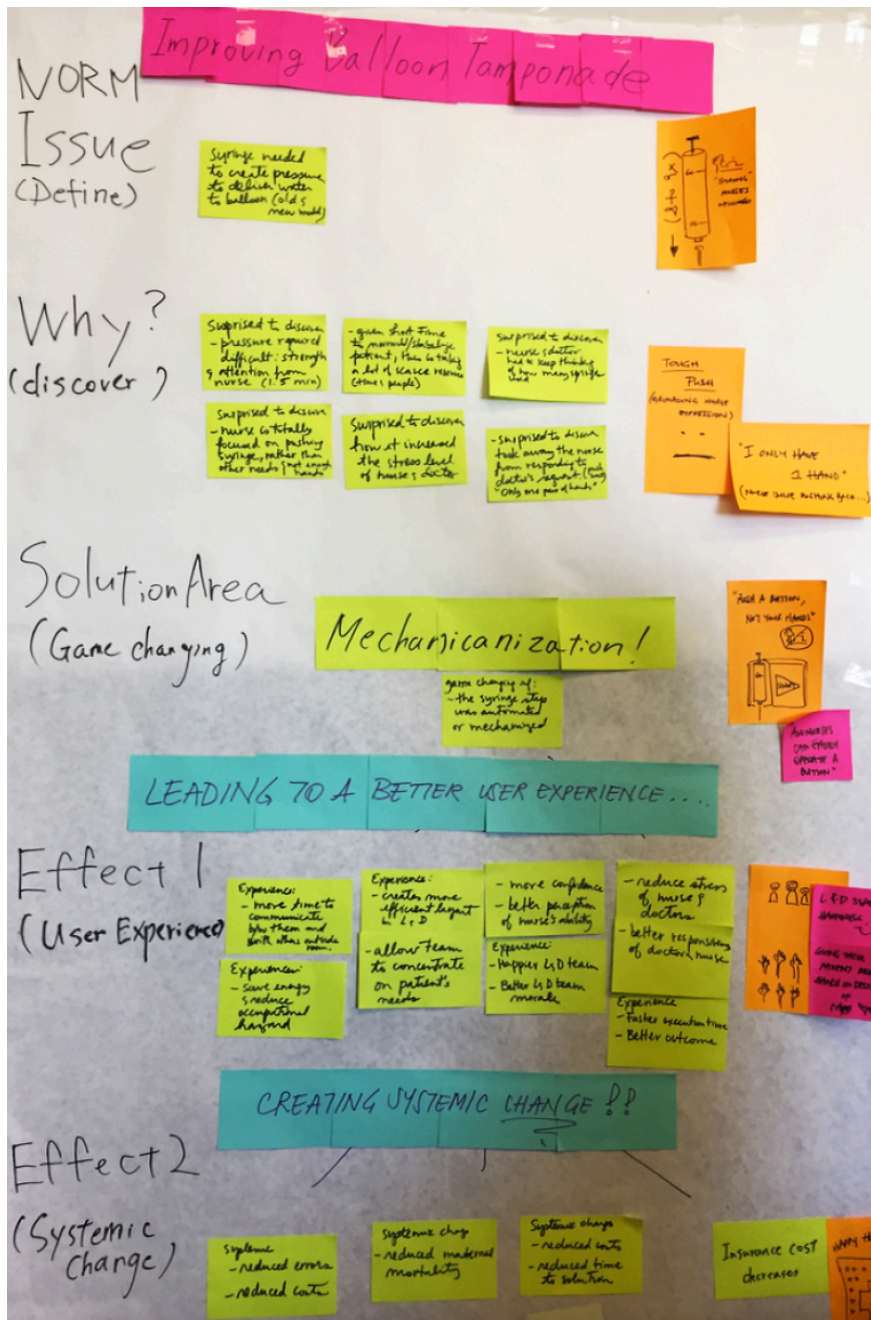


Figure 10. Student Example: Improving Ergonomics of the Bakri Balloon

Blood accessibility during maternal hemorrhage was addressed by a student group in the observational learning workshop. After observing the entire scene during the simulation, they created a list of all the barriers that could potentially delay getting blood to the patient (Figure 11). By creating a timeline of what they saw during the hemorrhage simulation, they were able to tell a new story:

- Suggested points during care when new protocols might be implemented to initiate faster communication between the OR/LDR and the blood bank in the hospital.
- Recommended shorter distances between blood bank and the L&D unit.
- Imagined new tools for quantifying blood loss.



Figure 11. Student Example: Blood Accessibility During Maternal Hemorrhage

Discussion

While innovation may improve a specific procedure or work-flow, the effects may radiate out to the greater system. We asked students in both workshops to share their perceptions of how improving standard practice would not only affect the end user, but how it might impact the entire healthcare system.

Recognition of emotional drivers may lead to faster adoption of new products, systems or services. During our clinician interviews students asked, “What may be the emotional consequences of bad design?” Physicians indicated that blaming others for bad outcomes, self-consciousness, and feeling incompetent could be triggered by poorly designed equipment. Besides looking for fundamental engineering and human factors issues in existing equipment, designers need to probe how these products are perceived by clinicians. “Work-arounds,” (home-made solutions) are a good indicator that a device or system is subpar, or that something needed simply does not exist.

Observational learning represents a learning method that places observation in the forefront of the learning process, with a key benefit seeming to derive to observational learning from heavy cognitive demands placed on people when directly experiencing a task, as opposed to lighter demands placed on observers (Many & Sims, 1981; Nathan & Kooor-Misra, 2002). Observational learning affords design students or a professional designer the ability to simultaneously see how current medical devices are

being used as well as observe peripheral activities. This includes the use of other devices in tandem, workflow of clinicians and communication. Being able to see “the big picture” may allow the designer to understand various challenges at once thereby leading to a holistic approach to design.

Other studies that compare observational learning and hands on training suggest that complex simulations need to be supported with information regarding the aspects on which students should focus. At the d. School, we deliberately do not give students direction regarding where they should put their focus (Stegmann, Pilz, Siebeck, & Fischer, 2012). Our students were simply provided with background clinical information on maternal hemorrhage and infant resuscitation. The entire point of interdisciplinary human-centered design classes is for students to uncover needs that they see through the lens of their own unique backgrounds.

Because the workshops were brief, students did not have time to master these skills, but were introduced to each skill. In most of the healthcare design classes that we teach, the full quarter format allows students to practice each of these skill sets in order to become more comfortable with the design process. In the past, substantial history and background of whatever subject we were studying: hospital birth, the history of the NICU, etc. would be offered to students. As we continue to teach healthcare design classes and workshops, class time dedicated to background and expert lecturers becomes less substantial. We have found that forcing students to jump right into a complex medical environment, with very little information keeps their perspective fresh, and retains the *naïveté* that is so important for reframing old problems. In this way, we create an environment that allows students to form their own conclusions before learning other people’s perceptions of a procedure, product or protocol.

Although the quality of the ideas and execution were similar between both the observational learning and hands-on training workshop groups, the instructors noticed that the integration of EL into the second workshop created a higher level of excitement in the class. Most of the students were not from a medical background, so the opportunity to be trained in medical procedures was fascinating and unique. The simulation environment is always impressive for outsiders and the opportunity to interact with attending doctors for both procedures was an unusual privilege. For other instructors teaching medical device design, we would recommend combining both observational learning and hands-on training into their curriculum.

Pilot studies represent a fundamental phase of the research process. The purpose of conducting a pilot study is to examine the feasibility of an approach that is intended to be used in a larger scale study. A pilot study is an initial first step in exploring a novel intervention or an innovative application of an intervention. Yet still, pilot studies carry inherent limitations. The brevity of these workshops may have influenced the outcome of the study, and finally a high level of curiosity and motivation among the student population probably led to above average outcomes in the workshops.

In order to understand the impact of observational learning and hands-on training at a deeper level, both workshops could be expanded into two different full quarter classes that follow the same model, but allow the students to expand their design thinking skills to prototype and test their ideas in the real world. By having the luxury to experience every phase of the design process with more rigor, the data we collect on two full-quarter classes would likely be more comprehensive and reveal differences that could not be measured during a two-day workshop.

The novel intervention for design students was to allow them to experience hands-on training, like medical students, but with a very different end goal in mind. Rather than a goal of mastering the procedure, our design student's goals were to understand the challenges associated with learning the medical tools abilities and limitations, and the clinician work-flow in order to not only see, *but feel* what kind of design solutions may improve a particular procedure—in this case maternal hemorrhage or infant intubation.

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References

- Ackerman, J., & Schaar, R. (2016). Clinical Observational Design Experience: A Large Design Oriented Clinical Immersion Course Based in Emergency Departments. *Open*, 1-10.
- An Introduction to Design Thinking Process Guide. In: Hasso Plattner Institute of Design.
- Carter, C. (2016). Let's stop talking about THE design process. Retrieved from <https://medium.com/stanford-d-school/lets-stop-talking-about-the-design-process-7446e52c13e8>
- Crawley, E. F., Brodeur, D. R., & Soderholm, D. H. (2008). The Education of Future Aeronautical Engineers: Conceiving, Designing, Implementing and Operating. *Journal of Science, Education and Technology*, 17, 138-151. [doi:10.1007/s10956-008-9088-4](https://doi.org/10.1007/s10956-008-9088-4)
- Felder, R. M., & Silverma, L. K. (1988). Learning and Teaching Styles in Engineering Education. *Engineering Education*, 78(7), 674-681. <http://192.100.77.68/ILS/info/LearningAndTeachingStyles.pdf>
- Felicia, P. (2011). *Handbook of Research on Improving Learning and Motivation through Educational Games: Multidisciplinary Approaches*: IGI Global.
- Foley, G., & Timonen, V. (2015). Using Grounded Theory Method to Capture and Analyze Health Care Experiences. *Health Serv Res*, 50(4), 1195-1210. [doi:10.1111/1475-6773.12275](https://doi.org/10.1111/1475-6773.12275)
- Gosen, J., & Washbush, J. (2004). A review of scholarship on assessing experiential learning effectiveness. *Simulation & Gaming*, 35(2), 270-293. [doi:10.1177/1046878104263544](https://doi.org/10.1177/1046878104263544)
- Many, C. C., & Sims, H. P. (1981). The Ethics of Behavioral Management. *Leadership & Organization Development Journal*, 2(4), 2-8. <https://doi.org/10.1108/eb053490>
- Nathan, M. L., & Kovoov-Misra, S. (2002). No Pain, Yet Gain: Vicarious Organizational Learning from Crises in an Inter-Organizational Field. *The Journal of Applied Behavioral Science*, 38(2), 245-266. <https://doi.org/10.1177/00286302038002006>
- Patnaik, D. (2016). Needfinding: The Why and How of Uncovering People's Needs
Retrieved from <http://www.jumpassociates.com/learning-posts/needfinding-uncovering-peoples-needs/>
- Seaman, J., Brown, M., & Quay, J. (2017). The Evolution of Experiential Learning Theory: Tracing Lines of Research in the JEE. *Journal of Experiential Education*, 40(4), NP1-NP21. [doi:10.1177/1053825916689268](https://doi.org/10.1177/1053825916689268)

Stegmann, K., Pilz, F., Siebeck, M., & Fischer, F. (2012). Vicarious learning during simulations: is it more effective than hands-on training? *Med Educ*, 46(10), 1001-1008. [doi:10.1111/j.1365-2923.2012.04344.x](https://doi.org/10.1111/j.1365-2923.2012.04344.x)

The Handbook of Experiential Learning and Management Education. (2007). (M. Reynold & R. Vince Eds.): OUP Oxford.