

The Medical Device Sandbox: A Creative Learning Experience for BME Students and Medical Learners

Dr. Rachael Schmedlen, University of Michigan

Rachael Schmedlen is a Lecturer IV in the Biomedical Engineering Department at the University of Michigan. She holds a Bachelor of Science degree in Chemical Engineering from the University of Michigan and a Ph.D. in Bioengineering from Rice University. Over the past ten years, Dr. Schmedlen has played a critical role in evolving the U-M biomedical engineering undergraduate curriculum, particularly the BME Design Program. Passionate about expanding engaged, active-learning experiences and clinical immersion opportunities for students that improve their ability to execute the design process, Dr. Schmedlen has developed an undergraduate capstone design course, biomedical engineering laboratory, and clinical observation and needs finding course. In addition to teaching an introduction to biomedical engineering course for first-year students, she also serves as an advisor for undeclared engineering undergraduates.

Dr. Stephanie Marie Kusano, University of Michigan

Stephanie Kusano is an assessment and evaluation postdoctoral research associate at the Center for Research on Learning and Teaching at University of Michigan. She has a Ph.D. in Engineering Education, M.S. in Biomedical Engineering, and B.S. in Mechanical Engineering, all from Virginia Tech. Her research interests include engaged learning and high impact practices, assessment, and design education. Her teaching experience has primarily been with first-year engineering.

Dr. John Gosbee, University of Michigan

Physician with human factors engineering background who works with academia, industry, and regulatory bodies to design safer medical devices and systems. Previously with NASA contractors, Michigan State University, and Dept. of Veterans Affairs Patient Safety Center. Now both industry consultant and teacher at University of Michigan Medical School and Department of Biomedical Engineering. Published widely in medical and engineering press, and invited speaker internationally. Received medical device achievement award in 2003 from Association for the Advancement of Medical Instrumentation (AAMI).

Ms. Jennifer Chen Lee, University of Michigan

Jennifer Lee is a third-year student pursuing biomedical engineering student at the University of Michigan. She is currently a research assistant at the Laboratory of Innovation in Global Health Technology. Her research interests include areas of global health technologies and engineering design. She is also currently a facilitator for the Medical Device Sandbox at University of Michigan and a member of Tau Beta Pi.

Prof. Jan P Stegemann, University of Michigan

Jan Stegemann is a Professor in the Department of Biomedical Engineering at the University of Michigan in Ann Arbor. He received BS and MS degrees in Chemical Engineering from the University of Toronto. Prior to earning his PhD in Biomedical Engineering from the Georgia Institute of Technology, Dr. Stegemann worked for five years at Boston-based W.R. Grace & Co. (later called Circe Biomedical), where his research focused on cell-based bioartificial organs. Dr. Stegemann's current research focuses on the use of extracellular environments to control cell function and the development of engineered tissues. He is also an active educator in the BME Design Program at the University of Michigan, with a focus on graduate-level medical product design and development.

The Medical Device Sandbox: A Creative Learning Experience for BME Students and Medical Learners

Introduction

We have developed a Medical Device Sandbox (MDS) to promote interprofessional collaboration and learning between biomedical engineering (BME) students and medical learners that is critical to the design, development, use, and commercialization of safe and effective medical equipment. Currently, interprofessional learning opportunities among medical trainees and BME students are informal and ad hoc. Medical students and residents occasionally seek engineering expertise about device safety and design. BME students occasionally use simulation facilities at the medical school with little guidance or continuity. All these learners seek a better blend of realism and clinical expertise.

The Medical Device Sandbox provides a structured environment and mechanism to bring these groups of learners together, to help them understand “what is” and “what could be” in regards to medical devices in hospital, clinic, and homecare settings. It consists of a simulated clinical space equipped with medical devices and accessories used in these settings. During scheduled sessions facilitated through expert instruction, interprofessional teams of BMEs (undergraduates and/or graduates in design courses) and medical learners are presented with a realistic patient safety scenario involving the use of a medical device, asked to identify problems associated with use, and brainstorm solutions on-the-spot. The key learning objectives of the MDS are given as follows.

BME students and medical learners will:

1. Report an enhanced understanding of the clinical perspective and more positive attitudes toward interprofessional teams.
2. Better identify possible use errors and design flaws that can be corrected to improve device safety and functionality.
3. Effectively design low-fidelity prototype devices that address use errors and fit into current hospital/clinic settings.
4. Demonstrate enhanced creative process and ability to innovate solutions to medical device design.

This paper presents findings from our pilot study of the MDS, which focused on data collected for the first learning objective and anecdotal evidence for the second and third objectives. Based on this data, we will refine the MDS sessions and our assessment methods to conduct a more complete and rigorous evaluation of the latter three objectives.

Methods

Medical Device Sandbox Sessions

During the Fall 2015 semester, eight sessions of the MDS were conducted with 29 engineering students (14 undergraduates, 15 graduate BME students) and 20 medical learners (16 second-year medical students, 4 medical residents). The 14 undergraduate students included 2 first-year students, (1 BME, 1 undecided), 3 second-year students (2 BMEs, 1 ME), 1 third-year BME student, 8 fourth-year students (7 BMEs, 1 ME), and 1 fifth-year ME student. The two-hour

sessions took place in a simulated exam room at the medical school's Center for Experiential Learning and Assessment. Due to logistical difficulties coordinating sessions around both medical learner and BME schedules, a cohort of medical learners enrolled in a patient safety elective were identified to participate as part of the elective requirement. BMEs were then recruited through design courses and a global health engineering extracurricular group to volunteer for sessions that coincided with the medical learners' availability. Because this is a pilot study, the diversity of education levels of BME students still allowed for an initial assessment of patient safety and human factors learning, interactions between BMEs and medical learners, and ways to improve future offerings of the MDS.

Each MDS session was attended by four to five engineering students, four to eight medical learners and a faculty member who facilitated the activities: simulated use of common medical devices, discussion of confusion and use errors associated with the design, and brainstorming and/or prototyping of redesign to address the errors. Six different simulated use scenarios (listed below) were developed for the MDS based on similar medical learner patient safety training modules previously reported.^[1, 2]

MDS Device Exercises

1. Automated external defibrillator in layperson setting
2. Exam table in clinic
3. Pulse oximeter in EMT-Paramedic bag
4. Epinephrine autoinjector in layperson setting
5. Medication organizer in home setting
6. Resuscitation guidebook/tools in intensive care setting

Each session focused on use errors associated with two of the above six devices. Following the hands-on use simulation, BMEs and medical learners were divided into mixed groups of three to four to brainstorm novel solutions that address the use errors using low fidelity prototyping materials. The sessions concluded with the small groups coming together to share their ideas and discuss take-away lessons. Figure 1 shows students working during one of the Medical Device Sandbox sessions.



Figure 1. Engineering students and medical learners collaborating during a Medical Device Sandbox session.

Qualitative Assessment of MDS Student Experiences

A qualitative approach, supported with descriptive statistics, was used to assess the MDS student experience. Specifically, the assessment included a retrospective survey and focus groups with students. The retrospective survey questions were informed by the Interprofessional Socialization and Valuing Scale (ISVS). ISVS has been validated for evaluating the beliefs, behaviors, and attitudes of students during interprofessional and collaborative practice in health care settings.^[3] A retrospective pre-test (i.e., a single survey administered at the end of the experience) was used because this method has been shown to be a valid measure of perceived changes in attitudes, behaviors, or skills.^[4] Respondents typically overestimate skills on pre-tests, often resulting in conflicting pre-post tests. Conversely, respondents are more accurately able to gauge perceived change when responding to retrospective surveys.^[4, 5] The survey questions focused on capturing students' attitudes towards interdisciplinary teams and the clinical perspective, as well as students' perceived ability to better identify possible use errors and design flaws that can be corrected to improve device safety and functionality. The survey also allowed for open-ended responses, to allow students to further explain their responses or to share additional comments about their MDS experience.

In addition to the student survey, focus groups were conducted with 11 of the participating students. Focus group data was particularly important for this pilot study, as it allowed the researchers to identify affordances or barriers that might have been unintentional or unanticipated, therefore informing future assessment approaches for the larger study. The MDS session facilitator conducted 3 focus groups with 8 participating students immediately following the MDS experience, and an external evaluator conducted one focus group with three participating students at the end of the academic term. Focus group questions asked students to reflect on their experience in MDS sessions, as well as how MDS has changed their mindset and approach to medical device design.

Results

Survey Findings

As previously stated in the methods section, this pilot study employed a retrospective pre-test approach. Therefore, results are presented as *perceived changes* in attitudes and abilities, rather than as a comparison of a pre- and post-response. The survey was administered to the 25 participating engineering students via Qualtrics, with a 75% response rate (18/25). Survey respondents were made up of 12 (63%) engineering undergraduate students, and 6 (32%) engineering masters students. As shown in Figure 2 below, the MDS experience was the first time nearly half (47.4%) of participating students had ever worked with medical professionals. This was the first interdisciplinary collaborative experience for about 10% of participating engineering students.

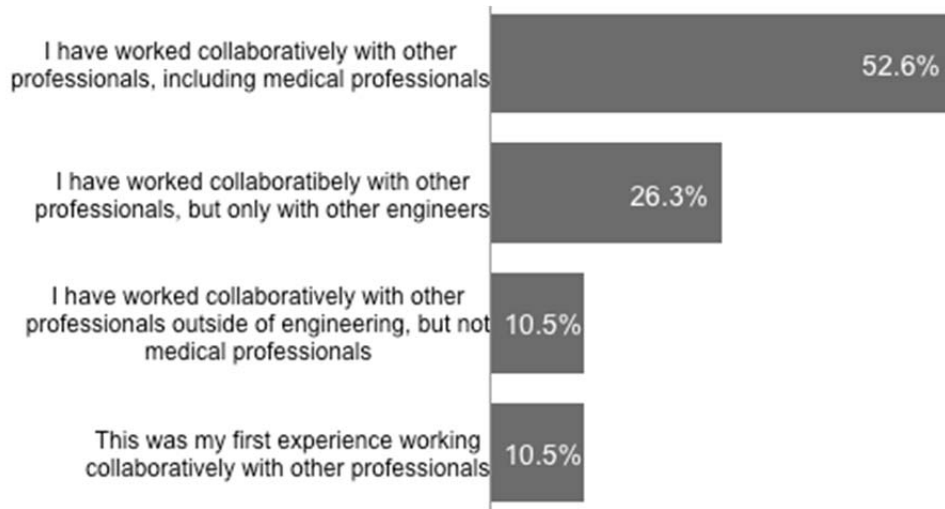


Figure 2. Experience on interdisciplinary teams of participating engineering students.

Table 1 shows the descriptive statistics of students' attitudes and abilities towards interdisciplinary collaborative work after participating in the Medical Device Sandbox, as well as their perceived changes in their attitudes and abilities. When asked about their expectations of medical professionals when collaborating on medical device design projects, 94% of students indicated that they believe they now have realistic expectations. Students then indicated that their expectations of medical professionals became slightly more realistic because of the experience in MDS (mean score: 3.41/5.0). 81% of students indicated that they now see themselves as preferring to work in interdisciplinary settings, and that this preference has increased as a result of their MDS experience (mean score: 3.94/5.0). 100% of students indicated that they now see the value of contributions medical professionals can make on medical device design projects, and that they perceived an increase in how they value medical professionals contributions due to their MDS experience (mean score: 3.94/5.0). Elaborating on their survey responses, one student says:

“In addition to changing my expectations of a working relationship with a medical professional, the Medical Device Sandbox made key components in the design process much more apparent. As an engineer, I should know better than to latch on to ideas/solutions right from the beginning. Understanding the problem is more important and produces even better ideas and solutions moving forward.”

Lastly, 94% of students indicated that they are now able to actively listen to medical professionals when collaborating on medical device design projects, and that this ability to listen improved because of their MDS experience (mean score: 3.88/5.0). One student elaborates:

“Through the design workshops, it's interesting to hear their perspectives on how they want to improve. With my engineering background, I can understand some of the pitfalls they're making in the design process. But also I like hearing them think without any limitations that my previous engineering design experience prevents me.”

Table 1. Descriptive statistics of students' responses regarding abilities and attitudes towards collaborative interdisciplinary work after participating in the Medical Device Sandbox.

	Disagree	Neutral	Agree	Perceived Change (Average out of 5)	Min	Max
Realistic expectations of medical professionals	0.00%	6.25%	93.75%	3.41	2	4
Preference working in interdisciplinary settings	0.00%	11.76%	88.24%	3.94	3	5
Perceived value of medical professionals' contributions	0.00%	0.00%	100.00%	3.94	3	5
Ability to listen to other's contributions	0.00%	6.25%	93.75%	3.88	3	5

Figure 3 shows students' perceived gains in their ability to recognize user errors in the operation of medical devices, their understanding of patient safety issues, and their ability to design usability tests for medical device prototypes. When asked if they believed the MDS experience increased their ability to recognize user errors during operation of medical devices, 87% of students indicated that they agreed. 87% of students also agreed that they believe they have a better understanding of patient safety issues in the design of medical devices. Lastly, 87% of students agreed that they have an increased ability to design usability tests for medical device prototypes. A few students elaborated on these responses:

“Through this exercise I have been inclined to be critical towards any medical device rather than assuming it to be error free.”

“I never learned how modeling can improve the design process.”

“Through one of the activities, I realized that usability testing is very important, especially when medical professionals must do things very quickly.”

“I really enjoyed the hands-on approach and can better see the importance of having hands-on usability tests for my current and future projects.”

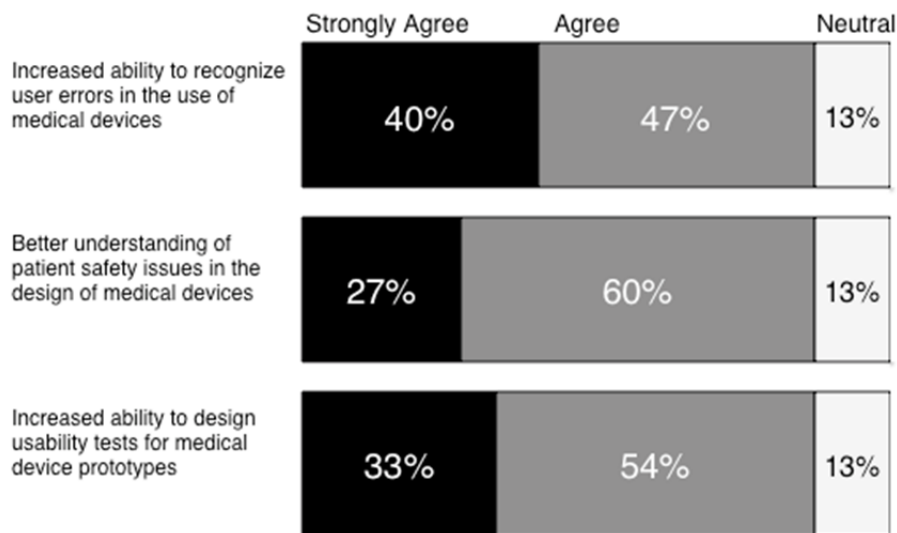


Figure 3. Students' perceived gains in ability and understanding of medical device design factors. Note that no students disagreed or strongly disagreed with the statements.

Focus Group Findings

One of the big takeaways from the focus groups is that the MDS provided a unique and eye opening learning experience for the engineering students, one that appears to be filling an educational gap. Students reported experiencing a change in their mindset, particularly their perspectives of medical professionals. This was indicated in the survey findings, but was further elaborated on during focus groups with students:

“I hadn’t really worked with too many doctors before, and the few that I had spoken with were very experienced surgeons. They’re brilliant, but extremely stubborn... it’s very difficult to change their way of thinking. I was interning at a medical device company and that was what was more concerning, was trying to get them to agree, or we would show them statistics and they would say ‘I don’t think so’. Working with doctors, or future doctors, they haven’t yet been locked down in their way of thinking. They still had their non-engineering mind providing ideas, but they were open to other ideas. That was really refreshing. Not all doctors think they’re the smartest ones in the room. It changed my perspective of doctors.”

Similarly, students also provided further insight on their changed perspectives in the open-ended portions of the survey:

“At first I thought I was going to be the one with ideas, and they would be telling how viable those ideas were, but it was the opposite. They had great ideas and I found out I have a lot to learn about the medical device field.”

“... second year med students were much more creative than the fourth year students. I think the same happens with engineers. Maybe we become too worried about finding the “correct” solution as we get older. Perhaps these workshops could be a way of preserving that creativity and warding off that fear of being wrong.”

“Prior to the medical device sandbox, I viewed only a select population of medical professionals as those who would like to innovate and that take the time to start the innovation process. I was not aware that there is so much interest in innovation, but that it was not obvious where medical professionals should go to pursue innovation.”

The Medical Device Sandbox sessions also influenced students’ approach to future design challenges. This was particularly the case with respect to the role of human factors in design.

“If you want to be a design engineer, the user experience is something that is not emphasized enough until your upper level courses. You almost have to have a first round of design practice to understand why the user experience is so important... talking with as many professionals as possible and doing a deep dive of a needs assessment rather than just reading the literature, so really taking the time to talk with professionals, with people who are in the field, you really have to get that full view, and not take short cuts with that process.”

MDS helped students better understand the importance of collecting as much information as possible before designing a solution to a challenge, including human factors issues. Students also came away with a better understanding of the role that other perspectives (i.e., of the users and other professionals) play when considering design solution.

“I had previously thought that medical professionals were more focused on treating patients and determining issues with current methods, however, I now realize they are a fundamental part of designing as well and are needed throughout the whole process (rather than just at the beginning).”

Summarizing the focus group findings, engineering students noticed a change in their perspective of medical professionals and their roles in contributing to medical device design work. Students noticed a shift in their attitudes towards doctors, valuing medical professionals' perspective more after having an opportunity to conduct collaborative work with medical professionals in the Medical Device Sandbox. This shift in attitude was particularly valuable when students were faced with human factors considerations involved in the design of medical devices. Not only did students more greatly value medical professionals' perspectives and role, students also learned to place greater value on considering and fully understanding human factors issues that are relevant to their design challenges. These preliminary focus group findings point to the potential of the Medical Device Sandbox to provide an opportunity for engineering students to practice and further their understanding of collaborative interdisciplinary work, as well as to improve their overall approach towards engineering design challenges.

Discussion

The findings of this pilot study indicate that students view MDS sessions as positive learning experiences that provide a unique opportunity to collaborate on interdisciplinary teams on medical device design challenges. MDS follows recommendations found in the literature for fostering interdisciplinary collaborations by engaging multiple epistemologies and “promoting the cognitive flexibility of students and preemptively preparing them for some of the roadblocks generally attributed to a narrow engineering point of view focused on technical details at the expense of societal impacts.”^[6, p.133] For nearly half of participating engineering students, this was their first time collaborating on an interdisciplinary team. Even for the students who had prior interdisciplinary team experiences, many described MDS as being a more positive experience due to the open-mindedness of the participating medical students and residents. This experience helped change initial perceptions of medical professionals that the engineering students had, making them more likely to choose to participate on interdisciplinary teams for future design challenges.

In addition to positively influencing students' attitudes towards interdisciplinary collaboration, MDS also changed students' perceptions on the value of human factors when working on design challenges. After participating in MDS sessions, students had a better understanding and appreciation for why human factors are an important element of the design process. For example, as one student explained during a focus group, he initially believed that the design solution only needed to be informed by prior research and academic literature. However, after he realized how much new information he was able to gather just from speaking and working with the medical students and residents, he understood that any design solution that does not involve a human factors analysis will likely not be an ideal solution. Although only a pilot study, this study begins to indicate that MDS is a promising approach to developing students' understanding of human factors in medical device design.^[7]

Conclusion

This was a pilot study for a larger study that will more rigorously assess students' learning outcomes, specifically gains in engineering students' and medical learners' creative processes, and their abilities to effectively design low-fidelity prototype devices that address use errors. That said, these preliminary data on students' perceptions and experiences indicate that MDS is a promising educational program, as well as inform future evaluations of learning outcomes. Next

steps will include true pre-post student surveys, evaluations of students' creative process using the AAC&U VALUE rubric on creativity, and a comparative analysis of students' interdisciplinary attitudes by comparing students and medical learners who participate in MDS versus students and medical professionals who have not participated in MDS.

Works Cited

1. Hall L, Scott S, Cox K, Gosbee JW, et al. Effectiveness of patient safety training in equipping medical students to recognize safety hazards and propose robust interventions. *Quality & Safety in Health Care*. 2010;19:3-8.
2. Gosbee JW, Anderson T. Human factors engineering design demonstrations can enlighten your RCA team. *Quality & Safety in Health Care*. 2003; 12: 119-121.
3. King, G., Shaw, L., Orchard, C. A., & Miller, S. (2010). The interdisciplinary socialization and valuing scale: A tool for evaluating the shift toward collaborative care approaches in health care settings. *Work*, 35(1), 77-85.
4. Finney, H. C. (1981). Improving the reliability of retrospective survey measures results of a longitudinal field survey. *Evaluation Review*, 5(2), 207-229.
5. Wright, M. C., & Howard, J. E. (2015). Assessment for Improvement: Two Models for Assessing a Large Quantitative Reasoning Requirement. *Numeracy*, 8(1), 6.
6. Borrego, M., & Newswander, L. K. (2008). Characteristics of Successful Cross-disciplinary Engineering Education Collaborations. *Journal of Engineering Education*, 97(2), 123-134.
7. Zoltowski, C. B., Oakes, W. C., & Cardella, M. E. (2012). Students' Ways of Experiencing Human-Centered Design. *Journal of Engineering Education*, 101(1), 28-59.