Learning the Language of Medical Device Innovation: A Longitudinal Interdisciplinary Elective for Medical Students

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Abstract

Problem
Physicians are playing a growing role as clinician–innovators. Academic physicians are well positioned to contribute to the medical device innovation process, yet few medical school curricula provide students opportunities to learn the conceptual framework for clinical needs finding, needs screening, concept generation and iterative prototyping, and intellectual property management. This framework supports innovation and encourages the development of valuable interdisciplinary communication skills and collaborative learning strategies.

Approach
Our university offers a novel 3-year-long medical student Longitudinal Interdisciplinary Elective in Biodesign (MSLIEB) that teaches medical device innovation in 4 stages: (1) seminars and small-group work, (2) shared clinical experiences for needs finding, (3) concept generation and product development by serving as consultants for biomedical engineering capstone projects, and (4) reflection and mentorship. The MSLIEB objectives are to: create a longitudinal interdisciplinary peer mentorship relationship between undergraduate biomedical engineering students and medical students, and encourage codevelopment of professional identities in relation to medical device innovation.

Outcomes
The MSLIEB enrolled 5 entering cohorts from 2017 to 2021 with a total of 37 medical student participants. The first full entering cohort of 12 medical students produced 8 mentored biomedical engineering capstone projects, 7 of which were based on clinical needs statements derived from earlier in the elective. Medical student participants have coauthored poster and oral presentations; contributed to projects that won WolfieTank, a university-wide competition modeled after the television show Shark Tank; and participated in the filing of provisional patents. Students reflecting on the course reported a change in their attitude towards existing medical problems, felt better-equipped to collaboratively design solutions for clinical needs, and considered a potential career path in device design.

Next Steps
The MSLIEB will be scaled up by recruiting additional faculty, broadening clinical opportunities to include the outpatient setting, and increasing medical student access to rapid prototyping equipment.

Problem

Academic physicians are well positioned to be significant collaborators in medical device innovation. The clinician–innovator is a logical concept based on the intersection of patient care, the firsthand familiarity with existing devices and resulting unmet needs in their specialty, and the strong emphasis on research and educational ventures that defines academic medicine.[1,2]

The COVID-19 pandemic highlighted the value of training future physicians in medical device innovation.[3] The limited availability of life-sustaining and protective equipment drove many clinicians to create temporary solutions, many of which were rapidly disseminated before any sort of iterative product testing or pragmatic validation.[3] Although their inventions were well intentioned, many had poor functionality, safety profiles, and ergonomics that were not observed until after they were widely adopted[3]—a demonstration of the MacGyver bias, or an individual's tendency to hold in high regard one's own personal improvised device despite lack of evidence for its efficacy.[4] In the future, involving trained clinician–innovators could allow such flaws to be identified, and potentially fixed, before the public sharing of novel devices.

Although formal immersive training programs in medical device innovation exist (e.g., the 10-month, full-time Stanford Biodesign Innovation fellowship; various multiyear master's degree programs at other universities), they usually require time away from medical school or clinical practice.[5,6] Longitudinal approaches have been proposed that encourage medical students to learn the process of innovation by incorporating innovative thinking into daily practice and building collaborative relationships with engineering peers.[1,6] Although graduating medical students are expected to possess such systems-level problem-solving skills, little consistency exists across medical

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school curricula for teaching the critical thinking and creativity needed for the medical device innovation process.[1,2,5,7] A 2016 survey of 158 allopathic medical schools found that only 13 offered such programs,[7] and public descriptions were available for only 2 of them.

This Innovation Report describes a 3-year-long innovation elective for medical students, called the Longitudinal Interdisciplinary Elective in Biodesign, that cultivates longitudinal collaboration with undergraduate biomedical engineering students.

Approach

Course objectives

The overall objectives of the medical student Longitudinal Interdisciplinary Elective in Biodesign (MSLIEB) are to (1) foster interdisciplinary peer mentoring as undergraduate biomedical engineering students (engineering students) and medical students concurrently progress through their respective educational trajectories, and (2) encourage codevelopment of professional identities during longitudinal exposure to the medical device innovation processes.

The course is divided into 4 stages (Chart 1), is graded on a pass/fail scale, and offers 4 weeks of elective credit. The medical student component is taught in tandem with 5 sequential college student courses spanning 4 traditional academic semesters (fall, spring) and 1 summer semester (Chart 1). Detailed descriptions of the lesson plans, textbook resources, writing prompts, and evaluation methods are available in Supplemental Digital Content 1 at http://links.lww.com/ACADMED/B268.

Location

The Renaissance School of Medicine at Stony Brook University is a public allopathic medical school, with a usual class size of 130 to 140 students, in Stony Brook, New York. The Department of Biomedical Engineering at Stony Brook University offers undergraduate and graduate engineering degrees accredited by the Accreditation Board for Engineering and Technology.

Participants

Up to 12 medical students are eligible to enroll in each entering cohort during the fall of their second year on a first-come, first-served basis after enrollment in the elective is announced to the class via email.

We initially intended to enroll undergraduate engineering students during their second year, so that the cohorts of medical and engineering students could spend 3 years together, but this was not possible due to the engineering students' course load. Instead, up to 12 undergraduate students majoring in biomedical engineering and beginning their third year join each entering medical student cohort for the first 2 of the 3 years that the medical students are in the program. We intentionally chose to include undergraduate engineering students for this program, rather than graduate engineering students, to consistently allow a multiyear overlap with the medical students.

The MSLIEB is led by 2 faculty members: a clinical assistant professor of emergency medicine who has formal education in biomedical engineering (L.M.M.) and a clinical associate professor of anesthesiology with extensive experience in the innovation and patent process, small business start-ups, and capital ventures (C.R.P.). The program also involves participation from additional engineering and clinical faculty who serve as guest speakers and project mentors.

Stage 1: Setting the stage with a shared language

Five 2-hour-long seminar sessions give the 2 student types (i.e., biomedical engineering undergraduate students and medical school students) a common foundation of shared terminology and a conceptual framework for medical device innovation. These sessions occur in the evenings after the standard college student and preclinical medical student lectures are over. Each of the first 4 sessions begins with a short lecture based on the Stanford Biodesign Textbook[8]: lecture 1 covers needs finding, "the process of making observations of opportunities for innovation"[9]; lecture 2 covers needs screening, "the process of organizing needs observations and filtering out those which will not be pursued"[9]; lecture 3 covers concept generation, "an iterative process of developing new solutions that potentially solve the given unmet need [via brainstorming and ideation]"[10]; and lecture 4 covers concept screening, "evaluating concepts based on several factors including intellectual property, regulatory pathway, reimbursement, business model, and technical feasibility."[10] After each of these short lectures, students work in small groups to apply the content to a need that is presented to them. A nonmedical need—such as the need to evenly distribute toppings on popcorn—is intentionally used to allow students to draw on common experiences; thus, students focus on the process and not on the medical jargon. For after-class reflection and concept reinforcement, students read the corresponding section of the case study in the Stanford Biodesign Textbook.[8] For the fifth session, the small groups prepare and present a product-pitch to their peers and a guest faculty member. This exercise facilitates learning how to communicate a solution verbally and visually, and it also encourages team building and camaraderie.

These 5 seminar sessions account for 5 weeks of a 15-week-long, 1-semester elective course for which the engineering students receive credit; other weeks involve sessions on computer-assisted drawing, 3D printing, and microcontroller programming. Medical students are invited to join these sessions if interested, although most of the session unfortunately conflict with their mandatory lectures and activities.

Stage 2: Needs finding and needs screening during shared clinical experiences

In this stage, medical students act as the primary center of information, learning how to translate and effectively communicate challenges, descriptions, and observations about their new clinical environments to the engineering students. The engineering students shadow the medical students for 4-hour blocks when the medical students are with an MSLIEB faculty member as part of their regular clerkship clinical activities. Through this shadowing, the students learn to translate and distill what stakeholders say they want into what they actually need. Students are encouraged to interact with a spectrum of stakeholders (e.g., housekeeping and clerical staff; nurses; nutritionists; phlebotomists; physical, occupational, and respiratory therapists),

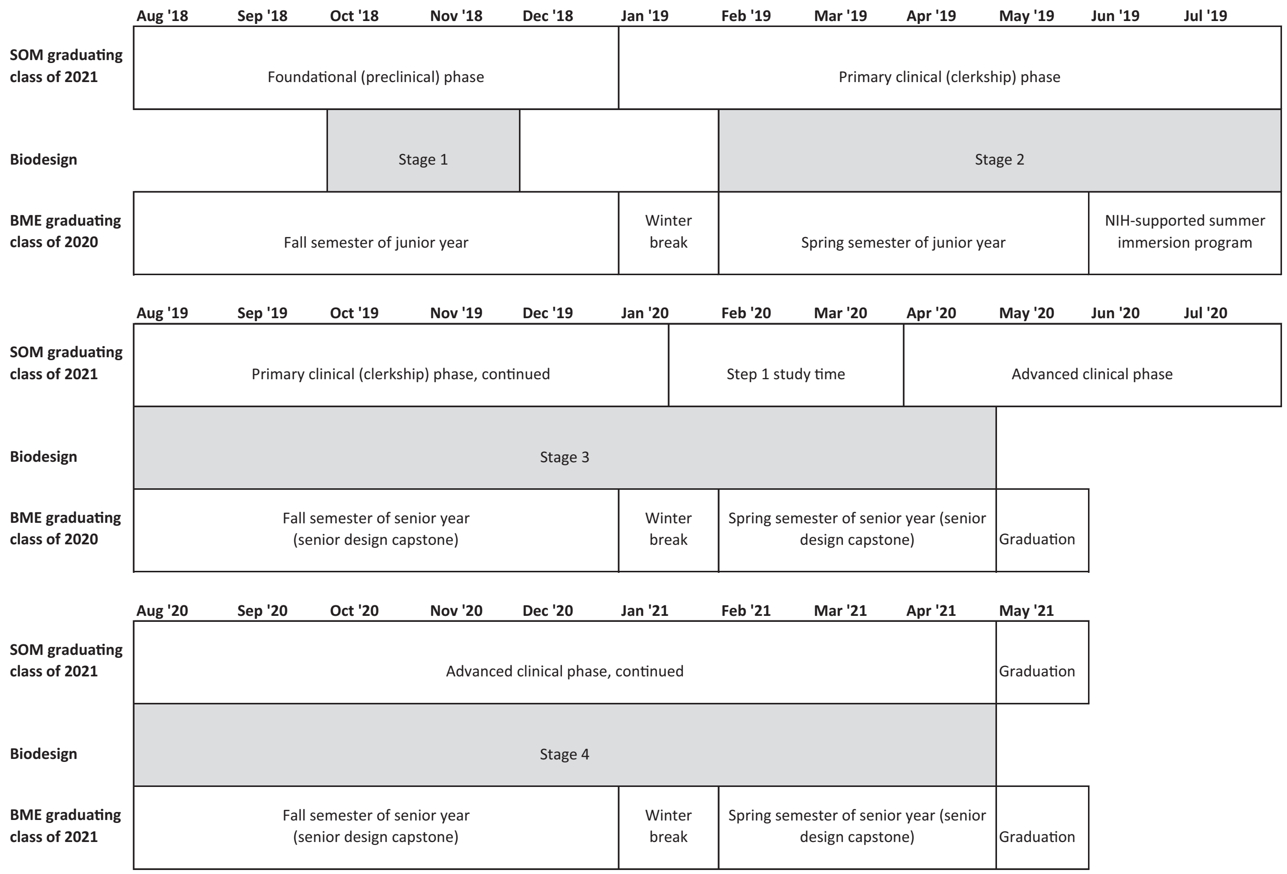

Chart 1 Visual timeline representing the relationship of the longitudinal interdisciplinary elective in biodesign with the curricular schedules of the medical students and undergraduate biomedical engineering students. Abbreviations: SOM, School of Medicine; BME, undergraduate biomedical engineering.

not just physicians. Ideally, engineering students would be with a medical student for every shadow experience, thus encouraging initial near-peer inquiry about "why" and "how" things happen. However, this is operationally impossible given medical student clerkship timeline changes and multiple clinical campuses. As such, for some shifts, only a medical student or an engineering student is with an MSLIEB faculty member.

Following each shared clinical experience, students submit clinical needs statements and a description of the stakeholders interviewed. Students and faculty regroup monthly to discuss and screen the submitted need statements. These sessions occur in the evenings after they have concluded their usual daily courses.

The engineering students receive elective credit for this stage as part of an independent research project requiring a 5-page paper to be submitted at the end of the semester. Furthermore, they are responsible for obtaining medical clearance, occupational safety, and health information privacy training, and they are N95-fit tested before beginning the shared clinical experiences.

Stage 3: Concept generation, concept screening, iterative prototyping, market analysis, and business plan development

As the engineering students begin their final year, the medical students choose a Senior Design Capstone Project Team and act as their peer clinical consultant. The Senior Design Capstone Project is the pinnacle experience within undergraduate biomedical engineering education. Assisted by clinical and engineering mentors, engineering students take a vetted clinical need from idea through to product while performing iterative prototyping, conducting a market analysis, and developing a business plan. As such, the engineering students now drive the transfer of knowledge, translating these different components and technicalities for their medical student colleagues. The medical students join the monthly team meetings to act as peer consultants, offering the engineering students their developing clinical acumen and their insights as they progress through clerkship and subinternship experiences. This affords the medical students the opportunity to learn how to actively listen to ideas and articulate constructive feedback. These team meetings are scheduled around the medical students' clerkship and advanced elective obligations.

Stage 4: Mentorship with graduated responsibilities

The plan for this stage was for medical students to participate in several interactive seminar sessions led by current clinician–innovators who would share their unique paths to innovation. This would reinforce the shared learning concepts of Stage 1, although by now the medical students would have their own clinical and engineering experiences to add context to the discussions.

This intended plan was greatly impacted by the onset of the COVID-19 pandemic. Because of the constantly changing work schedules of clinicians, it was impossible to reliably schedule these seminar sessions in spring 2020 (during the third year of the elective of the cohort that started in 2019). Thus, in their final year of medical school, they essentially repeated Stage 3 with a cohort of Stage 3 medical students and engineering students who were a year behind them in the program. As the only ones to have gone through the Senior Design Capstone Project process before, they functioned as the senior consultants on the teams. This allowed them to act similar to senior residents when mentoring junior colleagues. For consistency and continuity, these medical students participated in the monthly team meetings described in Stage 3, which were scheduled around the medical student subinternship and residency interview obligations. Because of feedback from students, this approach was adopted for future cohorts, with the intent of adding seminar sessions with current clinician–innovators when possible.

Outcomes

As of spring 2022, the MSLIEB had enrolled 5 entering cohorts, with a total of 37 medical students participating. Starting years of the program for these cohorts were 2017, 2018, 2019, 2020, and 2021, with all cohorts starting in the fall. The 12 medical students representing the first full entering cohort for the MSLIEB graduated from medical school in May 2021. During this cohort's Stage 4, 7 of the 8 senior design projects derived from clinical needs observed during Stage 2. Table 1 describes results from the standard school of medicine course evaluation by this cohort. Supplemental Digital Content 2 at http://links.lww.com/ACADMED/B268 offers qualitative course feedback from these students (IRB2021-00438) from their end-of-course reflection papers. Overall, as described in Supplemental Digital Content 2 at http://links.lww.com/ACADMED/B268, the medical students reported that participating in the program resulted in a change in their attitude towards existing medical problems; they also felt better-equipped to collaboratively design solutions for clinical needs, and many considered a potential career path in device design.

Participation in the MSLIEB also offered the medical students valuable professional experiences. All of them appeared as coauthors on institutional poster presentations. In addition, 2 of the medical students were also coauthors on an oral presentation at a regional engineering design competition, and 4 were finalists for WolfieTank 2021, a university-wide competition modeled after the popular TV show, Shark Tank. Finally, many of these medical students were involved in discussions about intellectual property and the filing of provisional patents.

Next Steps

The most significant challenge when looking to scale up this innovative elective is recruiting resources to expand

Table 1

Unedited Responses to the Standard School of Medicine Course Evaluation From the Medical Student Cohort Who Graduated in 2021 and Completed the Voluntary Course Evaluation, n = 9

Question	Strongly disagree, n (%)	Disagree, n (%)	Indifferent, n (%)	Agree, n (%)	Strongly agree, n (%)
This course had clear learning objectives.	0 (0)	0 (0)	0 (0)	3 (33)	6 (67)
This course met its stated objectives.	0 (0)	0 (0)	0 (0)	3 (33)	6 (67)
The teaching methods were appropriate for the stated objectives.	0 (0)	0 (0)	0 (0)	3 (33)	6 (67)
The evaluation methods were clear.	0 (0)	0 (0)	0 (0)	3 (33)	6 (67)
The course content was relevant and of sufficient detail.	0 (0)	0 (0)	0 (0)	3 (33)	6 (67)
Adequate time was provided in this course to meet the learning objectives.	0 (0)	0 (0)	0 (0)	3 (33)	6 (67)
There was good integration of basic science and clinical correlates in this course.	0 (0)	0 (0)	0 (0)	3 (33)	6 (67)
The learning materials in this course were appropriate.	0 (0)	0 (0)	0 (0)	3 (33)	6 (67)
Overall, this course was well structured.	0 (0)	0 (0)	0 (0)	3 (33)	6 (67)
The learning environment conveyed the values of collaboration, respect, and integrity.	0 (0)	0 (0)	0 (0)	3 (33)	6 (67)
Overall I am very satisfied with this course.	0 (0)	0 (0)	0 (0)	1 (11)	8 (89)
I would recommend this elective to future students.	0 (0)	0 (0)	0 (0)	1 (11)	8 (89)

The best feature of this course was:

- "The longitudinal aspect, allowing us to develop ideas for biodesign over multiple years and phases of our medical education curriculum. Also, being able to work with multiple students, and faculty members."
- "I thought this course was excellent for students with an interest in biodesign and allowed the opportunity to conduct research and participate in intercollaborative projects and strengthen skills for future careers."
- "I was given a lot of autonomy while working with and advising the senior design students. Dr. Maloney was an amazing instructor and was very understanding and reasonable as we navigated the course during the pandemic. She also made sure to check in on us throughout the course to make sure we were okay."

The aspect of this course in most need of improvement was:

- "The alignment of medical students with undergraduate students so that as second-year students, we work with sophomore college students over the course of the 3 years and create a final project during the end of college/medical school career."
- "Meetings via Zoom should be recorded in the future for documentation purposes."

faculty and administrative bandwidth. We also would like to expand our clinical shadowing opportunities. Currently, shadowing only occurs in the hospital setting (e.g., Emergency Department, Operating Room, Labor and Delivery). Prehospital, ambulatory care, and additional inpatient settings are needed to ensure diverse experiences and allow more opportunities for the engineering students to shadow the medical students during the limited timeline of Stage 2.

Much as with iterative prototyping, each entering cohort into the MSLIEB brings new curricular variations. Based on our experiences with the early cohorts, we have modified the curriculum so that Stage 1 now includes a sixth session for team building and communication exercises. We also learned that clear expectations and documentation are needed for determining inventorship, as the distinction in intellectual property ownership becomes challenging when faculty, medical students, and engineering students collaborate on a shared project. To this effect, we have added a dedicated lecture from the university's intellectual property office to the beginning of Stage 3. In addition, we have modified the original proposed plan for Stage 4 as a result of adjustments we made during the COVID-19 pandemic; student feedback indicated that the overlap of third- and fourth-year medical students on each senior design team was a valuable experience.

Looking ahead, we hope to create a makerspace on the hospital campus to support collaborative innovation among the students and faculty. This space could provide rapid prototyping tools (3D printers, 3D scanners, electronics stations, sewing machines) and a readily available, dedicated physical space where students and clinical staff can put their shared language of medical device innovation to good use.

Overall, this elective offers medical students and the involved clinical faculty a creative outlet that embraces interdisciplinary collaboration and develops a shared language of medical device innovation. With these added tools in their toolbox, clinician–innovators are well poised to have a meaningful impact on the evolution of the devices used in modern-day medicine.

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Ethical approval: The inclusion of anonymous excerpts from reflection papers submitted by medical students at the end of the elective was reviewed by the Stony Brook University Institutional Review Board and deemed "not human subjects research" (08/12/2021, IRB2021-00438).

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