

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

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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 adopted³—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

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 Textbook⁸: 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),

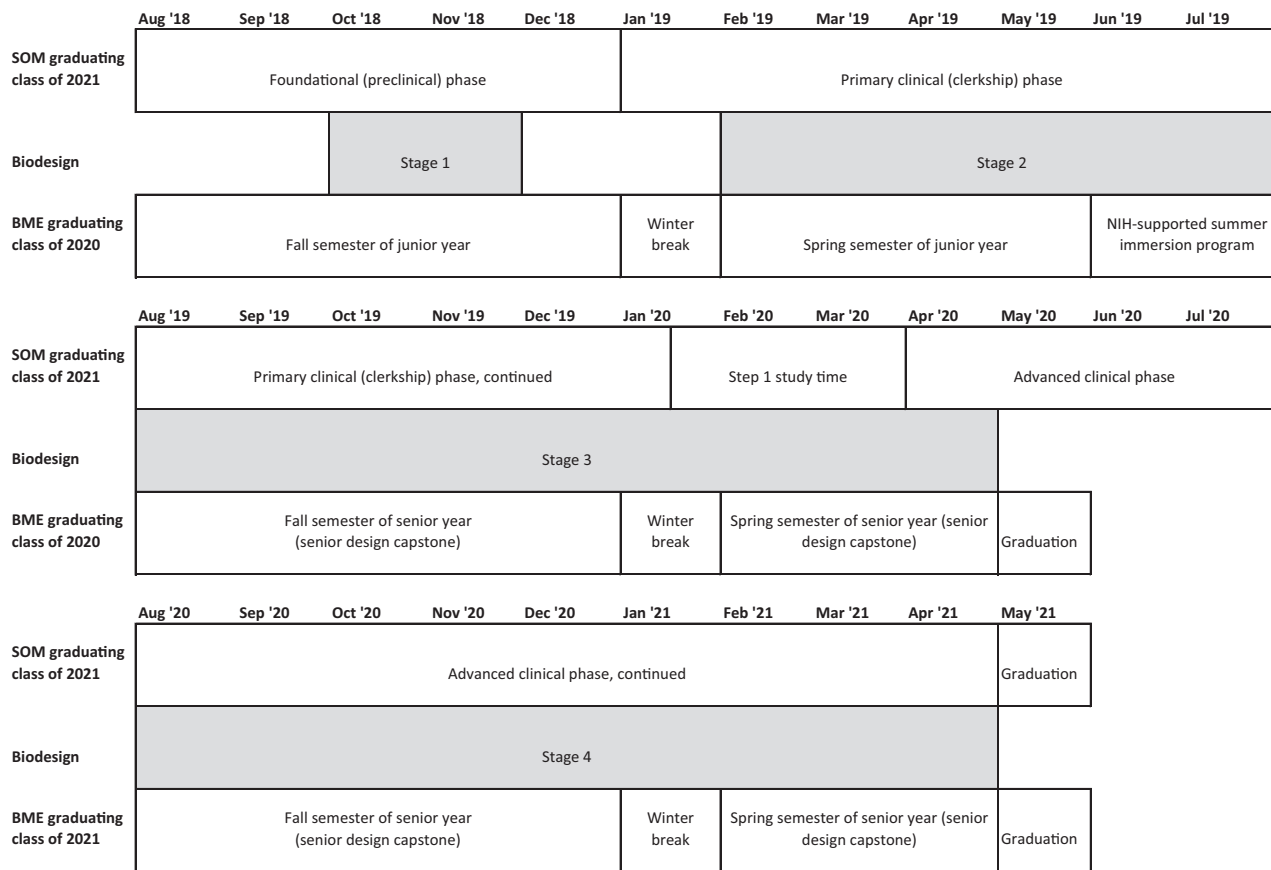


Chart 1 Visual timeline representing the relationship of the longitudinal interdisciplinary elective in biodesign with the curricular schedules of the medical students and undergraduate biomedical engineering students. Abbreviations: SOM, School of Medicine; BME, undergraduate biomedical engineering.

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 WolfeTank 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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Supplemental Digital Appendix 1

Detailed Lesson Plans for the Medical Student Longitudinal Interdisciplinary Elective in Biodesign

Stage 1: Setting the Stage with a Shared Language

Objective: Medical students will develop their understanding of medical device innovation by participating in content discussions followed by progressive interdisciplinary small group projects designed to stimulate the medical students' synthesis of the presented concepts.

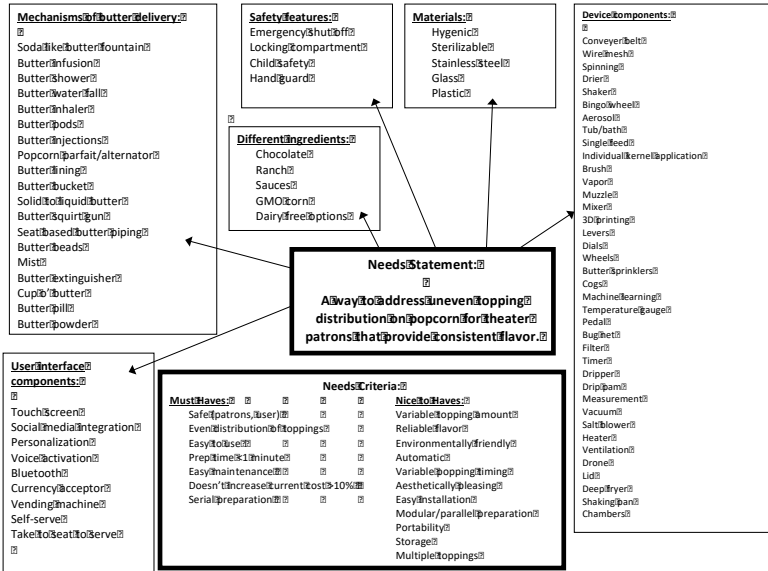
Textbook: Biodesign: The Process of Innovating Medical Technologies, Edition 2, by Yock, Zenios, Makower, Brinton, and Kumar. ISBN-13:9781107087354.

Lesson Title: Session 1- Teambuilding	Date:	Time: 2 hours
Objective: Provide an opportunity for the medical students and undergraduate biomedical engineering students to meet each other and participate in team building activities.		
Lesson Summary: i. Faculty introductions ii. Discuss structure of course, review syllabus iii. Student introductions (background, something unique/interesting) iv. Team building activity (communication, camaraderie, fun)		
Student Post-Class Activity: • None		

Lesson Title: Session 2- Needs Finding	Date:	Time: 2 hours
Objective: Medical students will be able to define the importance of needs finding as it relates to the evaluation of gaps in healthcare technology and provider workflow.		
Lesson Summary: <ol style="list-style-type: none">i. Topic discussion: Identify: Needs Finding<ol style="list-style-type: none">a. 1.1 Strategic Focusb. 1.2 Needs Explorationc. 1.3 Need Statement Developmentii. Workshop:<ol style="list-style-type: none">a. Presentation of the non-medical need, ex: it's frustrating when you go to the movie theater and there's only butter on the top layer of popcorniii. Wrap-Up:<ol style="list-style-type: none">a. View the need statement formula as a Mad Libb. Will brainstorm different components (problem, population, outcome) during the next session		
Student Post-Class Activity: <ul style="list-style-type: none">• Acclarent Case Study, p105-109• Write one narrow and one broad need statement		

Lesson Title: Session 3- Needs Screening	Date:	Time: 2 hours
Objective: Medical students will be able to define the importance of needs screening as it relates to the evaluation of gaps in healthcare technology and provider workflow.		
Lesson Summary: <ol style="list-style-type: none">i. Workshop:<ol style="list-style-type: none">a. Develop need statement (ex: A way to address uneven topping distribution on popcorn for theater patrons that provide consistent flavor.)ii. Topic discussion: Identify: Needs Screening<ol style="list-style-type: none">a. 2.1 Disease State Fundamentalsb. 2.2 Existing Solutionsc. 2.3 Stakeholder Analysisd. 2.4 Market Analysise. Needs Selectioniii. Wrap-Up:<ol style="list-style-type: none">f. Will brainstorm must have and nice to have criteria during the next session		
Student Post-Class Activity: <ul style="list-style-type: none">• Acclarent Case Study, p239-245• Create 5 must-have and 5 nice-to-have criteria		

Lesson Title: Session 4- Concept Generation	Date:	Time: 2 hours
Objective: Medical students will be able to define the importance of concept generation as it relates to the evaluation of gaps in healthcare technology and provider workflow.		
Lesson Summary: <ol style="list-style-type: none">i. Workshop:<ol style="list-style-type: none">a. Select must-have and nice-to-have criteriaii. Topic discussion: Invent: Concept Generation<ol style="list-style-type: none">a. 3.1 Ideationb. 3.2 Initial Concept Selectioniii. Workshop:<ol style="list-style-type: none">a. Concept brainstorming (bring snacks (ex. popcorn) if possible)iv. Wrap-Up:<ol style="list-style-type: none">a. Reflect on brainstorming process		
Student Post-Class Activity: <ul style="list-style-type: none">• Acclarent Case Study, p280-281• Organize ideation brainstorm into a concept map		

Lesson Title: Session 5- Concept Screening	Date:	Time: 2 hours
<p>Objective: Medical students will be able to define the importance of concept screening as it relates to the evaluation of gaps in healthcare technology and provider workflow.</p>		
<p>Lesson Summary:</p> <p>v. Workshop:</p> <p>a. Assemble class concept map</p>  <p>vi. Topic discussion: Invent: Concept Generation</p> <ol style="list-style-type: none"> 4.1 Intellectual Property Basics 4.2 Regulatory Basics 4.3 Reimbursement Basics 4.4 Business Models 4.5 Concept Exploration and Testing 4.6 Final Concept Selection <p>vii. Workshop:</p> <ol style="list-style-type: none"> Break into 4 teams (each team with medical student and undergraduate biomedical engineering student representation) based on most popular initial concepts to create a product pitch for why their concept is the best <p>viii. Wrap-Up:</p> <ol style="list-style-type: none"> Sample product pitch from faculty member to serve as an example for what students can be thinking about over the next week in preparation for final class 		
<p>Student Post-Class Activity:</p> <ul style="list-style-type: none"> Acclarent Case Study, p449-454 Begin to formulate small group's product pitch 		

Lesson Title: Session 6- Product Pitch	Date:	Time: 2 hours
Objective: Medical students will showcase their ability to progress through needs finding, needs screening, concept generation, and concept screening and use their newly developed innovation language to communicate their team's proposed solution.		
Lesson Summary: i. Workshop: a. Time for small groups to create and rehearse their product pitch (60 minutes) which should include the need statement, how their solution meets the must-have and nice-to-have criteria, what their proposed solution is, what sets it apart from the competition, and why an investor should buy in. b. Students can whatever medium they would like to for the presentation (slides, easel paper) ii. Product Pitch: a. Small groups make their product pitch (5-10 min) to faculty and a guest judge b. Winning team receives small prize (ex. box of microwave popcorn) iii. Wrap Up: a. Reflection b. Reminders for Phase 2		
Student Post-Class Activity: • Acclarent Case Study, p686-698; 809-816		

Stage 2: Needs Finding and Needs Screening

Objective: Medical Students will demonstrate their understanding of the identification phase of medical device innovation by developing at least ten clinical need statements after a series of shared clinical experiences.

Description: In the second phase of the three-year long co-education experience, undergraduate biomedical engineering (BME) and medical students participate in shared clinical sessions and perform clinical need finding. BME students go through HIPAA and clinical environment expectation training, as well as medical clearance and N95 fit testing. Undergraduate BME students join the medical students for 4-hour blocks of shadow time, while the medical students are rotating through their clerkships. The days that the undergraduate BME students join the medical students are selected based on when the medical student is with a clinical preceptor who is part of the course faculty. After each shared clinical experience, students complete and submit a worksheet (total of at least 10 worksheets):

Once a month, students and faculty meet as a group to review and refine the submitted clinical need statements. At the end of the semester, the most viable options are screened and then selected to go on to become topics for Stage 3 Senior Design Capstone Projects.

Needs Statement Worksheet
(Medical Students are expected to complete worksheets 2 per month during Phase 2.)

* Required

1. Name *

2. Clinical Specialty *

3. Providers spoken with (select all that apply) *

Check all that apply:

Attending physician
 Resident physician
 MD student
 Physician's assistant
 RN (nurse)
 Biotech representative
 NP (nurse practitioner)
 Tech
 Pharmacist
 EMT
 Cleaning staff
 Scribe
 Patient

Other: _____

Needs identified
A way to address (problem) in (population) that (outcome)

4. Need 1 *

5. Need 2 *

6. Need 3 *

Stage 3: Peer Consulting

Objective: Medical students will demonstrate their understanding of the invent and implement phases of medical device innovation by acting as a peer clinical consultant for the Senior Design Capstone Projects.

Description: At this point in their training, medical students are finishing their clerkship experiences and beginning to participate in advanced electives. During this stage, undergraduate BME and medical students will work together on a multidisciplinary scholarly activity, culminating in a business plan and prototype (Senior Design Capstone Projects). In the beginning of the year, medical students and BME undergraduate students form teams of 4-6 students based on interest in a clinical need statement derived during Stage 2. As the undergraduate BME students progress through BME 440 and 441 (Senior Design Project) and learn about market analysis, stakeholder analysis, quality function deployment analysis, intellectual property, FDA regulations, and business models, the medical students join in for team meetings and act as peer consultants, with the end expectation of presenting their prototype and business plan as a university-wide research day. Each group is mentored by at least two faculty members, one clinical faculty member and one engineering faculty member. Medical students are expected to meet with the Senior Design Capstone Project teams at least 3 times per semester, which includes in-person or via Skype/etc. Summaries of these meetings are entered into a Google form by each student, which helps in determining inventorship status, confirming meaningful medical student group participation, and serving as a memory aid when writing the end-of-course reflection paper. Course faculty regularly meet with medical students to ensure that the experience is progressing in a productive manner. Throughout this process, medical students have the opportunity to learn 3D CAD printing and the rapid prototyping process.

BME Senior Design Peer Consulting

* Required

1. Medical Student Name *

2. Date of Meeting *

Example: January 7, 2019

3. 3-4 sentence summary of what was discussed *

Stage 4: Graduated Responsibility in Peer Consulting

Initial Intended Objective: Medical students will refine their personal and professional understanding of medical device innovation by participating in discussions during which current clinical innovators share their own stories, thereby encouraging the students to ponder how their own future clinical practice may foster opportunities for innovation.

Additional Objective: Medical students will demonstrate understanding of the concepts of biodesign and medical ingenuity by way of producing a business plan and prototype of their biomedical innovation and acting as the senior medical student.

Description: At this point in their training, medical students are completing advanced electives, sub-internships, and interviewing for residency programs. In the fourth stage, medical students now act as the senior medical student on the Senior Design Capstone Project teams, mentoring junior medical students as well as the undergraduate biomedical engineering students as a peer consultant. As the senior medical student, they are the only members of the team to have completed the entire Senior Design Capstone Project process before, which affords them the unique opportunity for both near-peer mentoring of the junior medical student, but also provide feedback and clinical insights to the undergraduate biomedical engineering students. They serve as the primary point of contact for clinical questions; in the event they are unable to answer the question, it then goes to the team's clinical faculty mentor. As in Stage 3, medical students are expected to meet with their Senior Design Capstone Project teams at least 3 times per semester, which includes in-person or via Skype/etc. Summaries of these meetings continue to be entered into a Google form. Course faculty regularly meet with medical students to ensure that the experience is progressing in a productive manner.

The initial plan for this stage was for medical students to participate in 4 seminar sessions over the span of their final year of medical school during which they would listen to and interact with practicing clinicians as they describe their own experiences going through the medical device innovation process, as they now have their own first-hand experience from Stage 3 to draw from. Stage 4 coincided with the peak of the COVID-19 pandemic, and due to daily staffing reassignments and expanded clinical responsibilities, clinical faculty were unable to commit to participating in these seminar sessions. We anticipate integrating these sessions into the Stage 4 described above as an additional element of reflection and application of the biodesign process to their future clinical practice.

Course Wrap-Up and Final Evaluations:

During Stages 3 and 4, medical students are expected to be contributing authors to poster presentations given each spring at the University. In addition to learning how to create and present a poster, it affords the opportunity to grow their resume for residency applications. Many groups also choose to submit their posters to local and regional engineering competitions. In addition to scientific presentations, medical students have the opportunity to enter WolfieTank, a university-wide competition modeled after the popular TV show in which groups make product pitches (idea, research, business plan) in the hopes of obtaining a cash prize to fund the patent process. Furthermore, medical students have the opportunity to be listed as inventors on provisional patents, depending upon the success of the overall group as well as their individual contributions.

Besides the proof generated by these activities of the students' synthesis and direct, hands-on application of the concepts of medical device innovation, medical students are asked to write a 5 page (size 12 font, double spaced) reflection paper at the end of the elective, which may include sketches, pictures, and 3D CAD renderings. Suggested prompts include:

- What you thought the medical design device innovation/biodesign was before starting the elective
- How successful were the different phases in achieving its objectives; what can be improved for future iterations
- How did COVID impact your expectations and experiences in the elective
- How would you characterize the interaction with the Senior Design Capstone Project teams? How did this change from Stage 3 to Stage 4?
- Have you been able to apply (or at least ponder) the medical device innovation process as medical student?
- Has learning about the medical device innovation process influenced your decision of specialty or where you're applying to for residency?
- If you could add 1-2 things to the elective, what would they be?
- Are there any networking or professional development opportunities that would be beneficial to further refine within the elective?

Finally, students are expected to complete an anonymous course evaluation through the school of medicine.

Supplemental Digital Appendix 2

Firsthand Accounts of the Longitudinal Biodesign Experience

As part of their end-of-course reflection papers, medical students were asked to ponder their overall experiences within the elective. Students were invited to write about their journey through the elective, their experience as it related to the pandemic, and any constructive feedback for future iterations of the elective. They were also encouraged to include pictures, drawings, or 3D CAD renderings of their work. Specific prompts they were provided included:

- What you thought the medical design device innovation/biodesign was before starting the elective
- How successful were the different phases in achieving its objectives; what can be improved for future iterations
- How did COVID impact your expectations and experiences in the elective
- How would you characterize the interaction with the Senior Design Capstone Project teams? How did this change from Stage 3 to Stage 4?
- Have you been able to apply (or at least ponder) the medical device innovation process as medical student?
- Has learning about the medical device innovation process influenced your decision of specialty or where you're applying to for residency?
- If you could add 1-2 things to the elective, what would they be?
- Are there any networking or professional development opportunities that would be beneficial to further refine within the elective?

The following excerpts were selected from the reflection papers by the authors to highlight the overall sentiments relating to their experiences. Excerpts that described unique, personal observations, were initially selected by a faculty member (LMM). As authors on the paper, the twelve medical students who wrote the reflection papers as part of the course, had the opportunity to edit the excerpts as needed to ensure their intended meaning and context were conveyed. Excerpts were then grouped according to overarching themes which appear in bolded font.

Rekindled a former interest in device development

“I really looked forward to the biodesign projects... In fact, I had fond memories of serving on the other side, as an undergraduate senior in mechanical engineering.”

“This course reminded me of my passions I had as an engineering student, and encouraged me to be a more critical thinker, like I was during college. Although I am ecstatic to be in medical school and pursuing my interests, I think my critical thinking and problem-solving skills have diminished greatly. I went from working on a team designing complex, efficient solutions to cramming all this medical information and learning to pick the best multiple-choice answer... With the experience and knowledge I have acquired from this elective, I feel better equipped to address areas of needs I will come across and attempt to find an efficient solution instead of just accepting things as they are.”

“I thought the [MSLIEB] was a perfect opportunity for me to pursue my engineering interests during medical school. I was especially drawn by the fact that the course was longitudinal over the duration of 3 years and allowed biomedical engineering students to interact with medical students. As an undergraduate student, I would have found this opportunity to interact with medical students invaluable. I was ecstatic to participate in this course that highlighted the advantages of Stony Brook University because the undergraduate campus and medical campus are so interconnected.”

Inspired student doctors to look for opportunities to innovate

“If my engineering background and this bio-design elective have taught me anything it is that opportunities to innovate are all around us in the everyday interactions and challenges we face. I have learned to look at problems through an engineering lens and ask myself whether a design or system is the way it is because it is the best version of itself, or if it is the way it is because no one has ever questioned it before. The opportunities to innovate are out there—you just have to look.”

“In a way, I think this experience has helped me approach my medical career differently. A lot of medicine is protocolized and algorithm based. What is fascinating is that many people enter medicine for the exact opposite: the ability to creatively think, diagnose, treat and by utilizing expertise in an area. Then, we enter medical school and residency and there are order sets for everything, checklists of notes, and a lot of automatic processes. This course has helped me to realize and develop a sense of inquisitiveness and a desire for ingenuity so that when we come across the patient that does not fit the algorithm, we can pivot and rely on our medical skills, knowledge, and broad understanding of medicine to not get trapped in a particular diagnosis but explore the unusual disease or presentation.”

“Being challenged to actively identify problems within each field during our clerkships really enriched our clinical experiences. It forced us to take a more pragmatic approach to our interactions with patients and care providers, and think about simple or complex issues that still remain un-addressed.”

“During the clinical year it was fascinating to approach each day with a mindset of identifying any inefficiencies or problems in the workflow, writing them down, and then actually thinking of real-world solutions to address those issues.”

“While I am not sure how much I will be able to participate in biodesign related endeavors during residency, I do know that I will be taking the ‘solver’ attitude with me wherever I end up in my career. I believe that this will not only have a positive impact on my work, but also on my mental health. Being able to think about issues as problems with solution will allow me to have a creative outlet as well as see things with a more positive outlook.”

“I remember being almost dismayed at first when we were told that our first order of business would be to brainstorm a means to make popcorn... However, I didn’t realize at the time that such a low stakes, low pressure design idea was just what we needed in order to get into the frame of mind necessary for the elective... No one really thinks about how popcorn should be revamped—it’s delicious and simple enough to make. However, it seems to me now that the reason popcorn was chosen is specifically because of how mundane and simple it is. We don’t necessarily need to tackle the biggest and most obvious issues with our eventual device ideas, we need to look at how everything in the health care system works and see what could be improved or done more efficiently. Doing this simple exercise helped me to gain perspective on the elective, and also remains one of my fondest learning experiences during medical school. Naturally, things got a bit more difficult once clerkships and clinical responsibilities began to pile up. Thankfully, our task while on clerkships was simple, at least on paper—look out for any areas that you or your colleagues (attendings, residents, nurses, custodial staff) felt could use some improvement. I remember struggling greatly at first and feeling almost overwhelmed because everywhere I looked there was a device that already addressed a problem that I had noticed. However, thinking back to the popcorn exercise helped me to settle in and recognize some more simple issues that could be addressed. Months passed and I found that noticing issues became easier with practice.”

Trained student doctors to communicate and collaborate effectively across disciplines

“My main takeaway was that it is incredibly important to have good communication.”

“I thought it was fascinating to see the process of turning a very broad concept into a specific solution that I could actually hold in my hand. The BME students were warm, inviting, and engaged during our meetings and I believe I learned as much from them as they did from me. I think that the best part of our interaction was the afternoon we were able to spend together testing their prototype and giving feedback on their progress.”

“Inherent to this course was unique mentoring. It promoted multidisciplinary collaboration. Specifically, when students sought out specific needs to be addressed, they not only consulted attending physicians, but also resident physicians, physician assistants, registered nurses, nurse practitioners, physical therapists, scrub techs, and respiratory therapists. This is what makes the biodesign process so incredible – the fact that in order to truly be successful, you need to cultivate the minds and expertise from various specialties and backgrounds. This process has taught us to value the unique perspectives of various individuals, and reap the benefits of such diversity in solution development.”

“The metamorphosis of knowledge during medical school is so gradual, you may not quite realize exactly how much your understanding has grown or unique your perspective has become until you’re acting as the clinical consultant for a bio-design team explaining the pathophysiology of a concussion as if it were a trivial matter. There were numerous instances where I was able to act as a bridge for my design team and provide clinical context or even interpret research articles littered with medical jargon and biostatistics.”

“One of the big challenges I faced with interpreting and explaining medical research papers was making sure to avoid too much medical jargon and setting aside assumptions about the team’s understanding of the basic science or anatomy involved.

Communication is a key element for success in the medical field. Not only do you need to be fluent in medical terminology to hold meaningful conversations with your colleagues, you also have to know how to explain the same topics in much more colloquial terms for the average person. I initially found it easy to explain medical topics at a basic level when I started medical school, but as time went on and the complexity of my understanding evolved, I began to forget which words or concepts were common knowledge. So, while discussing medical topics with the biodesign team, I found it helpful to check in with their understanding of the topic first before moving on to an explanation. Also, letting them know in advance that it was okay to ask questions helped make the environment more comfortable for each team member and ensured that everyone left the conversation with a better understanding of the topic at hand.”

“During medical education very little time is spent focusing on teamwork and non-medical problem solving. The initial popcorn challenge alone had a great impact on my medical education as I noticed myself using many of the deductive reasoning skills I use in medicine on developing the popcorn maker design.”

Broadened perspectives on potential future career paths

“This course was a tremendous experience for me that I would recommend for anyone wishing to learn more about the design process and take on a consulting role early in their medical careers. The experience and knowledge I gained throughout it were unique compared to what most medical students are offered – from teamwork to engineering design processes.”

“The process with which we worked through problems during the biodesign elective will remain one of the most important things I learned during medical school. Working closely with a multidisciplinary team in order to solve complex problems is a perfect representation of what my career in medicine will be like. Moreover, I believe that I would like to become involved in hospital administration in the future, as high quality care is something that I am highly interested in. The idea of reducing a noticed issue to the exact cause and then working on ways to address it will likely be a big part of my career as well, as it is a necessary skill for root cause analysis.”

“Aside from learning about the design process, interactions during this course demonstrated that physicians are capable of engaging in this type of work without necessarily requiring advanced degrees in engineering or business.”

“This elective helped me determine what residency I wanted to attend. When I began medical school, I knew that I wanted to do Emergency Medicine or Orthopedic Surgery. Throughout this elective most of the problems we have focused on have involved Emergency Medicine or Anesthesiology. Realizing how much space there is for engineering design in Emergency Medicine helped me make the final decision to pursue

Emergency Medicine. Furthermore, the amount of teamwork involved in this class is similar to the teamwork needed in the Emergency Department, which also influenced my decision to find a career in Emergency Medicine.”

“Teaching is a vital part of medical practice so the experience teaching medicine to undergraduate students will pay off later in my career.”

Stood out as a refreshing change from traditional medical curricula

“A lot of my interviewers were very intrigued by this class—we talked at length about this during many interviews! It was really exciting to mention how we were able to take what we noticed on a day-to-day basis and translate that into clinically meaningful and actionable projects.”

“There is so much value to be gained from speaking to different stakeholders and getting their opinions and perspectives, in addition to working with the undergraduate students—we can learn so much for each other! This is the only elective I know of that is longitudinal, and taking this class definitely added an extra element to my residency application.”

“I was very pleased at the number of other students in my class who were interested in biodesign. We had great discussions about the biodesign concepts and it was nice having such a large group to come up with fun and interesting problem statements.”

“The pre-clinical portion of the course was an entertaining and informative introduction to the process of design and a ‘solver’ mentality. I thoroughly enjoyed the exercises during lectures, and it was very interesting to see how differently the BME students approached problems than I did.”

“A surprising result of all of this is how much it influenced my application for residency in the sense that I was able to connect with many of my interviewers along the way about the impact this elective had on me. When I brought up about the newfound hobby of 3D printing and how great it is for students to prototype ideas and was especially of great use during the pandemic, my interviewer was also using these concepts of the biodesign process during the pandemic. He was able to show me a piece that he had designed for the ventilators at his hospital so that one ventilator machine could be split up to provide for multiple patients simultaneously due to the high capacity of COVID patients. I thought it was very interesting how I can see the use of biodesign concepts in response to a pressing need for treatment of critically ill patients in such a constrained environment.”