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Integrated Business and Engineering Educational Experience for Medical Students in the Development of Pediatric Medical Devices

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ABSTRACT

BACKGROUND: There are few opportunities in undergraduate medical education that provide formal training in engineering and scientific innovation. Institutions have sought to address student-specific career goals through combined degree programs such as the Medical Scientist Training Program and MD/MBA. However, only a small percentage of medical students pursue these additional degrees. Partnerships between medical schools and Medical Technology (MedTech) accelerators may create unique opportunities for medical students to gain real-world experience with scientific innovation and entrepreneurship.

METHODS: An internship program was developed by the Keck Translational Biotechnology Association and the West Coast Consortium for Technology & Innovation in Pediatrics (CTIP), a Food and Drug Administration-funded pediatric medical device accelerator. Students and companies applied to participate and were paired based on students' interests and experience, and project plans were developed together. An initial orientation provided an overview of the program structure and expectations. Students and mentors met biweekly to address questions or concerns surrounding the progress of their projects. Students gave final project presentations and completed program evaluations. Data from 3 iterations of the program are reported.

RESULTS: Student program satisfaction was measured across 5 domains. Students felt that working with CTIP was valuable to their education (mean score = 3.7 of 5.0) and encouraged them to pursue future careers in MedTech (mean score = 4.0 of 5.0). Students provided a few suggestions to improve the program, including more structure, clear expectations around time commitment and deliverables, and stipends for students. Participation in the program grew over time.

CONCLUSIONS: The initial iterations of the internship program were well received by students. Several opportunities for improvement were noted. The program grew over time. Partnerships with accelerator programs at medical schools and academic medical centers may provide key real-world opportunities for students to learn about MedTech.

KEYWORDS: medical technology, healthcare entrepreneurship, healthcare innovation, medical student education, applied learning, career exploration

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JJL and JL contributed equally to this work.

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Introduction

The advancement of modern medicine requires physicians to stay informed about evolving technologies, including recent innovations in medical devices, personalized medicine, and digital health.[1–6] Physicians and medical trainees may aspire to become innovators themselves, yet often lack the training to do so.[1,7,8] Strategies aimed at addressing this need in undergraduate medical education remain limited.[9–11] Combined degree programs such as the Medical Scientist Training Program and MD/MBA are offered by a majority of schools.[12] However, only a small proportion of medical students pursue these degrees.[13] A minority of medical schools have developed programs dedicated to innovation and entrepreneurship, but these programs are limited to a small number of students, despite many being interested.[10,14] In a survey conducted by Scott et al, 73% of medical students were interested in innovation being incorporated into the core curriculum, and 81% preferred being exposed to these topics particularly in

medical school rather than at later stages of training.[8] A 2022 review identified 103 information and technology programs available to medical students, 46 of which were student-led clubs.[15] The high proportion of student-led initiatives demonstrates the need for undergraduate medical education to include training in medical innovation.

Until 2019, our institution met this need for several years with the Health Technology Engineering at the University of Southern California (HTE@USC) program, run jointly by the medical and engineering schools. Modeled after the Stanford Biodesign fellowship,[2,16] the program connected engineering graduate students with medical students, provided coursework in biodesign and entrepreneurship, and offered mentors who guided project development. Several projects led to MedTech startups. In 2020, after the program ended, a group of medical students founded the Keck Translational Biotechnology Association (Keck TBA), a student interest group aiming to provide medical students with opportunities in medical technology (MedTech) and innovation. Keck TBA contacted The West Coast Consortium for Technology & Innovation in Pediatrics (CTIP), a Food and Drug Administration-funded pediatric medical device accelerator centered originally at Children's Hospital Los Angeles (CHLA), to explore opportunities for collaboration. Together, Keck TBA and CTIP developed a program where students could work with startups in the CTIP portfolio. The goal of the program was for students to gain real-world experience in scientific innovation and entrepreneurship. Since then, our program has gone through 3 iterations at the time of data compilation. Here we present our approach to the development and implementation of our program and lessons learned.

Methods

Program creation

The partnership between CTIP and Keck TBA was initially formed in December 2020. Planning for the launch of the pilot program took place over 2 months. Each year, the opportunity to work with CTIP companies was publicized to medical students with digital flyers, a booth at the student club fair, a lunch seminar, and email messages to the member list of the Keck TBA (Table 1). A form was sent to students to gauge interest and collect information on skill sets, fields of interest, and desired time commitment, as well as short biographies. In parallel, CTIP companies were offered the opportunity to work with medical students. Companies were asked to describe themselves and to identify one or more projects or areas that students could work on. These descriptions were provided to interested students, who on their application forms ranked their 3 top companies to work with and indicated whether they wanted to collaborate with other students. Students on the leadership board of Keck TBA worked with CTIP faculty advisors to match students to compatible companies based on student interests. Companies and students worked together to design internship projects which were carried out through the spring semester, culminating in a capstone presentation.

Program overview

The process of recruiting new students and matching them to companies took place in the fall and winter. The program itself was 4 months in duration each spring (Figure 1). Students and company mentors met biweekly to discuss the progress of their project. Students were also invited to participate in an educational webinar about medical devices. At the end of the program, students prepared capstone presentations describing their projects and experiences. The capstone presentation event was held virtually and attended by several members of the MedTech community and CTIP stakeholders. New student leader cohorts were recruited every fall to continue

Table 1. Student demographics.

CHARACTERISTICS	OVERALL (N)	COHORT 1	COHORT 2	COHORT 3
Graduation year				
2024	8	7	1	0
2025	9	0	9	0
2026	19	0	0	19
Ethnicity				
East Asian	12	3	1	8
South Asian	8	1	4	3
MENA	4	0	1	3
African American	1	0	1	0
Southeast Asian	3	0	1	2
None apply	9	3	1	5
Gender/sexual orientation				
Female	18	3	6	9
Male	18	4	4	10
LGBTQ+	1	0	0	1
How did you hear about the program?				
Keck TBA***	33	4	10	19
Classmate	6	3	1	2
CTIP website	2	0	1	1

Demographic characteristics of participating students from all 3 cycles of the Keck TBA CTIP program from 2020 to 2023.
***Keck TBA email list, lunch seminar, or booth at student club fair.
Abbreviations: MENA, Middle Eastern and North African; LGBTQ+, lesbian, gay, bisexual, transgender, intersex, queer, etc; TBA, Translational Biotechnology Association.

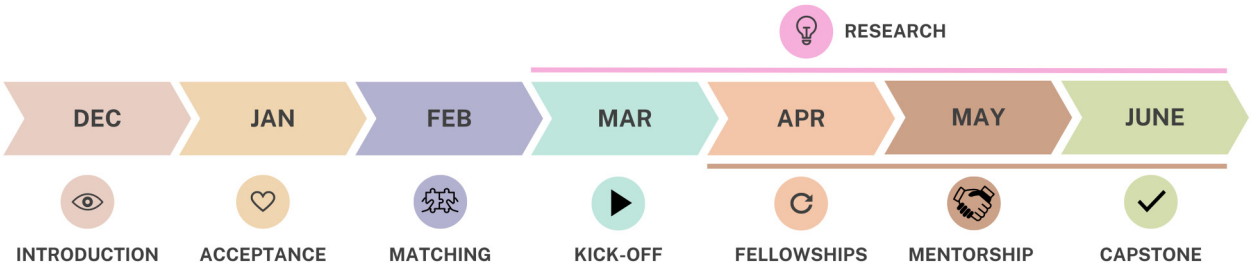

Figure 1. Program timeline. CTIP-Keck TBA MedTech internship program timeline and key milestones.

running the program and maintain structure while implementing annual feedback. The program structure was designed with guidance from a core faculty member on the CTIP team.

Data collection, program evaluation, and data analysis

This was a quantitative and descriptive study using surveys. Surveys were administered to students who participated in the first 3 iterations of the program at the Keck School of Medicine of USC from 2020 to 2023. Applicant demographics were collected at the time of the initial application, and company information was collected from the CTIP database. Learner satisfaction with the program was evaluated through a survey completed 1 week after the program. We developed 7 total Likert-scale and open-ended questions to explore students' motivations, overall experiences, career impact, and suggestions for improvement.

1. What drew you to this program?
2. On a scale of 1 to 5, how was your overall experience with the CTIP-Keck TBA internship program?
3. On a scale of 1 to 5, did this program add value to your education?
4. On a scale of 1 to 5, are you excited to continue your project?
5. On a scale of 1 to 5, how much has this experience encouraged you to pursue a future career in MedTech?
6. On a scale of 1 to 5, how much has your experience encouraged you to pursue other opportunities working in the MedTech field, paid or unpaid?
7. What can be done to improve this program?

Inclusion criteria were current medical students enrolled at the Keck School of Medicine of USC and companies in the CTIP portfolio who expressed interest in participating in the program. Demographic data from all students who expressed initial interest in participating in the program were analyzed. Data from the final program evaluation survey excluded students who ultimately did not complete the program despite initially expressing interest. The data were analyzed, and plots were generated with Seaborn (Version 0.13.0) and Pandas (Version 2.1.3).

The DoCTRINE Guidelines (Defined Criteria To Report Innovations in Education) were followed.[17] The completed checklist of the guidelines is included as a Supplemental file.

Regulatory statement

This project was deemed exempt by the Children's Hospital Los Angeles Institutional Review Board (IRB# CHLA-21-00278).

Results

Over 3 years, 36 students applied, and 34 of 36 (94.4%) were eventually matched with companies (Table 1 for student demographics). Of the students who started projects, 26 of 34 (76.5%) reached the final project showcase stage. Students reported a variety of reasons for leaving the program early, including time constraints and not being aligned on the outcome (eg, research paper vs presentation). Participating students came from various undergraduate backgrounds including biomedical engineering, anthropology, chemistry, electrical engineering, and computer science. The students had experience in areas including 3-dimensional printing, educational technology, medical device design, and health education and advocacy. A few had worked at early-stage startups such as GoodRx and Epic Systems. Characteristics of participating CTIP companies are listed in Table 2.

Student experience and satisfaction

Based on qualitative feedback, the top 3 reasons students decided to pursue projects with CTIP were general curiosity, interest in medical devices, and interest in entrepreneurship. One student commented that the program should continue and showed great potential. Throughout the program, students felt that working with CTIP was valuable to their education (mean score = 3.7 of 5.0) and encouraged them to pursue careers in MedTech (mean score = 4.0 of 5.0) (Figure 2). Students expressed that working with CTIP companies encouraged them to continue pursuing opportunities in the field of MedTech (mean score = 3.4 of 5.0). There was an uptrend in the number of students and companies participating in the program, which doubled over 3 years (Figure 3).

Table 2. Company demographics.

COMPANY	YEARS PARTICIPATED	NUMBER OF STUDENTS	CLINICAL FOCUS	DEVICE STAGE	ANTICIPATED DEVICE CLASS	ANTICIPATED REGULATORY PATHWAY	NUMBER OF TEAM MEMBERS	FUNDRAISING STAGE
A	2020-2021	1	Obstetrics & gynecology	Advanced prototype	Class 2	510(k) exempt	3 to 10	Grants, institutional support, philanthropy
B	2020-2021	2	Pediatric surgery	Commercial use	Class 2	De novo	3 to 10	Series B
C	2020-2021; 2022-2023	3; 1	Orthopedics	Commercial use	Class 1	510(k) exempt	More than 10	Series A
D	2021-2022	3	Cardiothoracic	Preclinical	Class 3	PMA	3 to 10	Seed
E	2021-2022	1	Maxillofacial surgery	Advanced prototype	Class 2	510(k)	3 to 10	Seed
F	2021-2022	1	Surgery Radiology Education	Preclinical	Class 2	510(k)	3 to 10	Pre-seed
G	2021-2022	1	Neonatology	Advanced prototype	Class 2	510(k)	3 to 10	Grants, institutional support, philanthropy
H	2022-2023	6	Neurosurgery	Clinical	Class 2	De novo	3 to 10	Series A
I	2022-2023	2	Neonatology	Commercial Use	Class 2	De novo	More than 10	No funding
J	2022-2023	1	Infectious disease	Advanced prototype	Class 2	510(k)	3 to 10	Seed
K	2022-2023	1	Radiology	Advanced prototype	Class 2	510(k)	3 to 10	Grants, institutional support, philanthropy
L	2022-2023	1	Pediatric cardiology	Clinical	Class 3	PMA	3 to 10	Series B

Characteristics of participating CTIP companies from all 3 cycles of the CTIP-Keck TBA program from 2020 to 2023, including number of students who worked with each company in each year.
Abbreviations: CTIP, Consortium for Technology & Innovation in Pediatrics; PMA, Premarket approval; TBA, Translational Biotechnology Association.

Opportunities for improvement

Students suggested several ideas for improvement, which included receiving a stipend, having the opportunity to write a research paper, having clear expectations on time commitment and scope, and having more frequent check-ins and feedback during the program. Some students also requested additional structured educational opportunities (eg, lectures) that would provide more insight into the medical device field.

Discussion

To our knowledge, this is one of the few student-led initiatives in the country providing medical students with experiential learning opportunities in healthcare innovation.[18] The need for healthcare innovation and the desire of physicians and trainees to become innovators represents an ever-growing need for training in healthcare entrepreneurship,[1,8,19] yet the topic remains underprioritized in undergraduate medical education. Creating and continuing to build the CTIP-Keck TBA MedTech internship program has been our way of addressing this need at our institution.

A small but growing number of medical schools have invested resources into developing medical innovation and engineering programs. According to a 2021 review of American and Canadian allopathic medical schools, 15.2% of schools provided the option to participate in innovation and entrepreneurship programs.[20] Among these curricular programs, however, only a few offered students hands-on experiences in MedTech.[8,10] One pilot program at the University of Louisville School of Medicine, led by Gupta et al[21] in 2023, showed early success with improved self-comfort levels among medical students in applying the Biodesign process to their practice. At Stony Brook University, a team of academic physicians created a 3-year-long Longitudinal

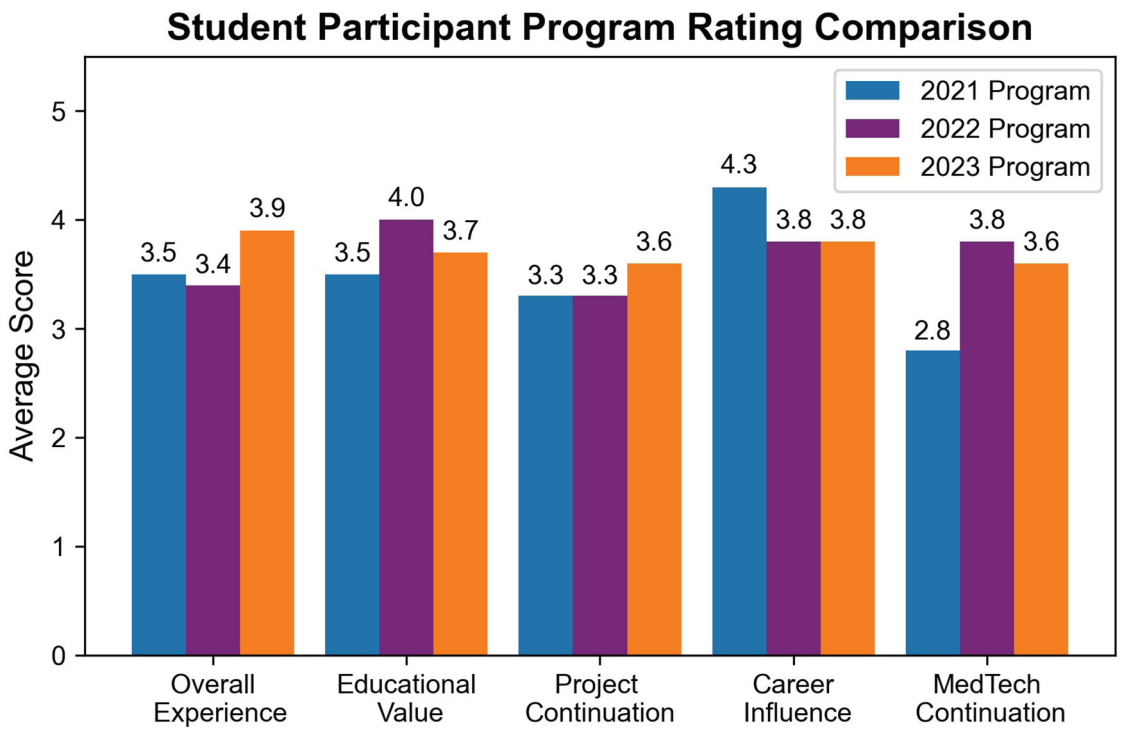

Figure 2. Student survey. Average scores across 5 quantitative domains collected from program evaluations by participating students.

Interdisciplinary Elective in Biodesign (MSLIEB) including seminars, shared clinical experiences, concept generation, and mentorship. Two of the medical students ended up being oral presenters at a regional engineering design competition and 4 were finalists for a university-wide funding competition.[22] In the CTIP-Keck TBA MedTech internship program, working with early-stage companies provides a novel opportunity for medical students to actively engage in healthcare innovation. Our model allows students to explore their interest in health technology with hands-on experience at an early stage, which can encourage and prepare them to continue in the field.

A few areas of improvement in our program have been identified. In the first 3 rounds of implementation, we erred on the side of a less formal structure to observe how the projects would evolve organically. However, based on student feedback, the program would benefit from more structure, particularly with setting clear expectations for time commitment and the types of deliverables students are responsible for (though this could vary with each company). More meetings and lectures could be held. Another limitation is the lack of institutional and financial support. As a student-led program, it is currently not formally integrated into the curriculum and requires time invested outside the classroom. There is also no budget to support a paid internship. Of note, however, one team was able to leverage their project to qualify for institutional research scholarships during the summer between the first and second year of medical school.

From an evaluation standpoint, we have relatively few students to report on as only 3 cycles of the program have been assessed. Our sample size was limited by the number of students who were interested in participating in the internship program. A power analysis was not performed because our Likert-scale items were not designed with the aim of determining whether an effect size was significant. Given the overall success and innovative nature of the program, we felt it would be beneficial to attempt to disseminate our program at this stage. Additionally, no formal, validated instruments were used to assess student satisfaction or knowledge gained. Though we could not find standardized tools specifically designed to assess the experiences and knowledge of medical students working in the MedTech space, it may be possible to identify and adapt more generic learner assessments in the future, or to develop our own learning objectives. This would be important to assess in trainees from the medical student to the fellow level because of the low level of confidence in topics such as medical device development and drug development.[1] Further evaluation of the program in the future could also include quantifying deliverables such as presentations, publications, and patents, as well as assessing impact on residency applications for students who have completed the match process in order to evaluate career impact.

Challenges to our program's sustainability include accommodating students' time constraints, recruiting companies, and ensuring compatible interests and expectations between students and companies. In addition, since part of the program was piloted during the COVID-19 pandemic, interactions were limited to Zoom, which may not be as effective for the progress of collaborative research work compared to

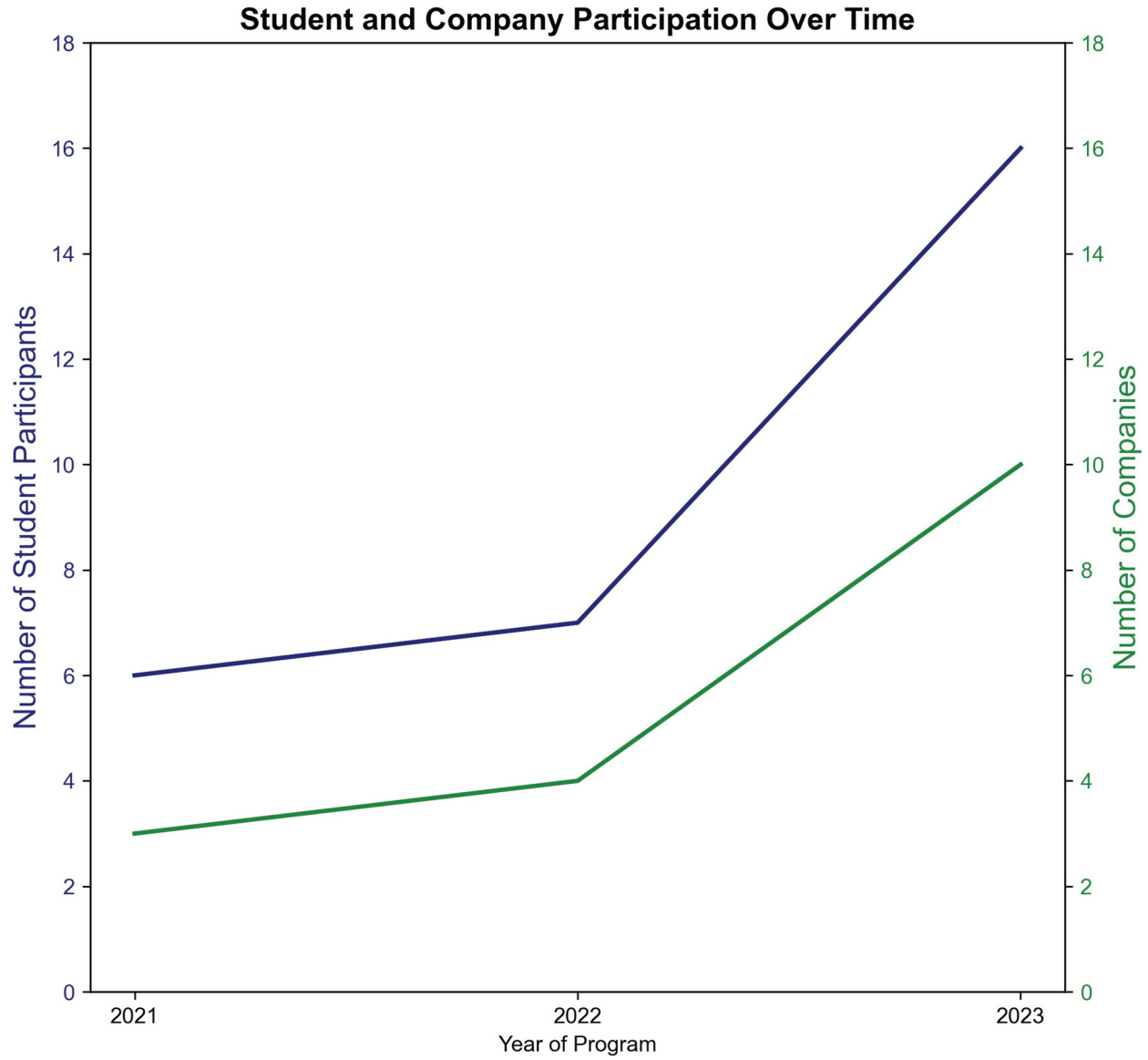

Figure 3. Student and company participation from 2021 to 2023. Student participation was measured based on the number of students who matched with companies.

in-person environments. This limitation may have contributed to students' lower desire to continue projects (Figure 2). Nevertheless, student interest and participation has grown over time (Figure 3).

Moving forward, we aim to use the feedback collected to improve, formalize, and scale the program. We are pursuing funding opportunities to provide stipends to students. We are also working with advisors of our school's impending curriculum renewal to discuss the possible integration of our program with a fourth-year elective on health technology and innovation. Another possibility for curriculum integration is encouraging students to use their CTIP projects to fulfill the institutional requirement to conduct a research project, as some students did submit abstracts and manuscripts based on their projects with companies. Both companies and students have expressed interest in creating more structure around the program, which we intend to implement in future cycles by offering didactics and meetings with the Keck TBA and CTIP teams more frequently. We also intend to develop and assess achievement of learning objectives to design a formalized curriculum.

Conclusions

The CTIP-Keck TBA MedTech internship program was well received by students and shows future promise. The program was a valuable educational opportunity and positively impacted students' future interest in medical technology. Interest and participation in the program grew over time. Several opportunities for improvement were noted, including more formal structure, didactics, and student stipends.

Partnerships with accelerator programs at medical schools and academic medical centers may provide key hands-on opportunities for students to learn about healthcare innovation when there are few other opportunities at the undergraduate medical education level to do so.

Acknowledgments

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Consent to participate

Students and companies gave verbal consent for participation in surveys.

Consent for publication

Students and companies gave verbal consent for publication of survey data. Student and company data has been anonymized.

Ethical considerations

This project was deemed exempt by the Children's Hospital Los Angeles Institutional Review Board (IRB# CHLA-21-00278).

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Supplemental material

Supplemental material for this paper is available online.

REFERENCES

1. Boms O, Shi Z, Mallipeddi N, et al. Integrating innovation as a core objective in medical training. *Nat Biotechnol*. 2022;40(3):434-437. doi: 10.1038/s41587-01253-x
2. Wall J, Wynne E, Krummel T. Biodesign process and culture to enable pediatric medical technology innovation. *Semin Pediatr Surg*. 2015;24(3):102-106. doi:10.1053/j.sempedsurg.2015.02.005
3. Rambukwella M, Balamurugan A, Klapholz H, Beninger P. The application of engineering principles and practices to medical education: preparing the next generation of physicians. *Med Sci Educ*. 2021;31(2):897-904. doi:10.1007/s40670-021-01217-x
4. Smith SW, Sfekas A. How much do physician-entrepreneurs contribute to new medical devices? *Med Care*. 2013;51(5):461-467. doi:10.1097/MLR.0b013e3182836d76
5. Wartman SA. The empirical challenge of 21st-century medical education. *Acad Med J Assoc Am Med Coll*. 2019;94(10):1412-1415. doi:10.1097/ACM.0000000000002866
6. Aungst TD, Patel R. Integrating digital health into the curriculum—considerations on the current landscape and future developments. *J Med Educ Curric Dev*. 2020;7(1):2382120519901275. doi:10.1177/2382120519901275
7. Battle C. Healthcare innovation absenteeism: the rise of physician entrepreneurs & medical startups. *Bus Adm Diss*. Published online May 6, 2022;160:1-122. doi:10.57709/28547929.
8. Scott KW, Trumbull D, Zaldivar J, et al. Bridging the gap between innovation and medical curricula. *MedEdPublish*. 2021;10(1):13-24. doi:10.15694/mep.2021.000013.1
9. Korczak JF, Chung DW, Rosemond E, et al. The National Cancer Institute R25 cancer education grants program: a workshop report. *J Cancer Educ*. 2017;32(1):3-10. doi:10.1007/s13187-016-1161-8
10. Niccum BA, Sarker A, Wolf SJ, Trowbridge MJ. Innovation and entrepreneurship programs in US medical education: a landscape review and thematic analysis. *Med Educ Online*. 2017;22(1):1360722. doi:10.1080/10872981.2017.1360722
11. Suryavanshi T, Lambert S, Lal S, Chin A, Chan TM. Entrepreneurship and innovation in health sciences education: a scoping review. *Med Sci Educ*. 2020;30(4):1797-1809. doi:10.1007/s40670-020-01050-8
12. Considering a combined degree: MD-PhD, MD-MBA, MD-MPH, MD-JD. Students & Residents. Accessed October 3, 2022. https://students-residents.aamc.org/applying-medical-school/considering-combined-degree-md-phd-md-mba-md-mph-md-jd
13. Chakraverty D, Jeffe DB, Tai RH. Transition experiences in MD–PhD programs. *CBE Life Sci Educ*. 2018;17(3):ar41. doi:10.1187/cbe.17-08-0187
14. Ahrari A, Sandhu P, Morra D, McClennan S, Freeland A. Creating a healthcare entrepreneurship teaching program for medical students. *J Reg Med Campuses*. 2021;4(1):7-14. doi:10.24926/jrmc.v4i1.3564
15. Wang JJ, Singh RK, Miselis HH, Stapleton SN. Technology literacy in undergraduate medical education: review and survey of the US medical school innovation and technology programs. *JMIR Med Educ*. 2022;8(1):e32183. doi:10.2196/32183
16. Brinton TJ, Kurihara CQ, Camarillo DB, et al. Outcomes from a postgraduate biomedical technology innovation training program: the first 12 years of Stanford biodesign. *Ann Biomed Eng*. 2013;41(9):1803-1810. doi:10.1007/s10439-013-0761-2
17. Blanco M, Prunuske J, DiCorcia M, Learman LA, Mutcheson B, Huang GC. The DoCTRINE guidelines: defined Criteria To Report INnovations in education. *Acad Med*. 2022;97(5):689-695. doi:10.1097/ACM.0000000000004634
18. Much to learn when med students leave classroom, enter boardroom. American Medical Association. Accessed October 2, 2022. https://www.ama-assn.org/medical-students/medical-school-life/much-learn-when-med-students-leave-classroom-enter-boardroom
19. Loscalzo J. Entrepreneurship in the medical academy: possibilities and challenges in commercialization of research discoveries. *Circulation*. 2007;115(12):1504-1507. doi:10.1161/CIRCULATIONAHA.107.694869
20. Arias J, Scott KW, Zaldivar JR, et al. Innovation-oriented medical school curricula: review of the literature. *Cureus*. 2021;13(10):e18498. doi:10.7759/cureus.18498
21. Gupta A, Tran D, Nguyen D, et al. Bluegrass biodesign: why an integrated biomedical engineering curriculum is crucial for medical education. *Cureus*. 2023;15(10):e47261. doi:10.7759/cureus.47261
22. Maloney LM, Hakimi M, Hays T, et al. Learning the language of medical device innovation: a longitudinal interdisciplinary elective for medical students. *Acad Med J Assoc Am Med Coll*. 2022;97(9):1341-1345. doi:10.1097/ACM.0000000000004723