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The Surgery Innovation & Entrepreneurship Development Program (SIEDP): An experiential learning program for surgery faculty to ideate and implement innovations in healthcare

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Abstract

OBJECTIVE—Surgeons are continually engaged in the incorporation of new technologies in their practice. In the operating room and beyond, they combine technical skill with creative problem solving to improve tools and techniques for patient care, making them natural innovators. However, despite their innovative tendencies, education on entrepreneurship and commercialization is severely lacking. Moreover, with increasing pressure to meet productivity metrics, their availability to learn the complexities of commercialization is limited. To address these challenges, we designed the Surgery Innovation and Entrepreneurship Development Program (SIEDP) with the objective to advance faculty innovations, develop new departmental innovation

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initiatives, and improve faculty education in the area of innovation, entrepreneurship, and commercialization.

DESIGN—The SIEDP is a first-of-its-kind experiential learning program specifically designed for busy clinical and research faculty in a major academic surgery department. Participants ideated and formed teams around healthcare innovations as they progressed through a 9-month curriculum of expert guest lectures and interactive workshops. A post-program evaluation and outcome tracking method was used to evaluate attainment of educational objectives and project development milestones.

SETTING—The Department of Surgery, University of Michigan Medical School, Ann Arbor, Michigan.

PARTICIPANTS—Eleven surgery faculty of varying academic rank and surgical sub-specialties.

RESULTS—The program generated two faculty start-up companies, one departmental commercial product, three patent disclosures, and three innovations that received additional funding. All participants in the program reported a significant increase in their understanding of innovation and entrepreneurship and that participation was a worthwhile faculty development activity.

CONCLUSION—Despite the various challenges and time constraints of surgical practices, programs like SIEDP can educate surgeons and other academicians on innovation, entrepreneurship, and commercialization and add value to the academic mission of providing excellent education, research, and clinical care.

Keywords

Innovation; Commercialization; Entrepreneurship; Faculty Development

COMPETENCIES

Patient Care; Interpersonal and Communication Skills; Systems-Based Practice

INTRODUCTION

Healthcare is currently experiencing great uncertainty at many levels. Academic medical centers, in particular, face increasing pressure in attempting to compete with non-academic health providers while fulfilling their tripartite missions of clinical care, research, and education. This uncertainty, combined with limitations of federal research funding, adds additional pressure to provide a continual source of innovative ideas for health care impact.

Surgeons are frequently engaged in the incorporation of new technologies in their practice. In the operating room and beyond, they combine technical skill with creative problem solving to improve tools and techniques for patient care, making them natural innovators. Surgeons are also keenly aware of how healthcare delivery and patient workflow can affect outcomes and overall costs. While surgical training and faculty development have evolved, one area that remains a challenge is the education on how to navigate innovation, commercialization, and entrepreneurship more effectively. Even surgeons who have had a

lifetime of clinical training and experience may lack the necessary tools, skills, and network to successfully take an innovation from an idea to an actual product or service that can impact patient care. Moreover, with increasing pressure to meet productivity metrics, their ability and bandwidth to learn the complexities of commercialization is severely limited.

To address these challenges, we describe the development and implementation of a first-of-its-kind program in innovation and entrepreneurship, specifically designed for clinical and research faculty in an academic surgery department. The Surgery Innovation and Entrepreneurship Development Program (SIEDP), a collaborative program between the University of Michigan Medical School's (UMMS) Fast Forward Medical Innovation (FFMI) program and the Department of Surgery, is an educational program combined with mentorship for faculty in the area of innovation and entrepreneurship, designed to develop and advance surgical innovations toward commercialization.

METHODS

Program Strategy

Program planning for SIEDP was led by an Administrative Director from FFMI and the Associate Chair for Innovation and Entrepreneurship within the UM Department of Surgery. Approximately three months of planning were required to receive approval for implementation, hire a Lead Instructor, develop the curriculum, and select the faculty participants. Participants were selected based on their interest in innovation or previous experience with commercialization as demonstrated by activities within the department or through interactions with FFMI. The targeted approach to selecting faculty ensured the correct participant to instructor ratio so projects could receive adequate coaching and mentorship. Several of the participants were already working on individual projects that had some preliminary commercial viability; however, dedicating the time and seeking expert advice was challenging. Those without personal innovation projects with commercial viability had an interest in developing innovative strategies to enhance the department's mission to excel in its tripartite mission. The incentive for faculty to participate was the opportunity to accelerate any personal innovation with dedicated time to work on the project under the direct mentorship and guidance of an experienced Lead Instructor and the FFMI commercialization team, as well as the ability to create and develop new departmental innovation strategies as an educational experience within the program. The incentive for the department to structure the program was to offer the educational experience as an investment in faculty and provide a mechanism for innovative ideas to be implemented within the department or commercialized as products. The overall goal was to provide dual opportunities for participants to advance their personal idea, as well as learn specific innovation concepts by forming teams around a department project.

To generate department innovation projects, participants brainstormed during an ideation session at the onset of the program to develop ideas and innovations in the areas of clinical care, education, and research. After forming teams around the projects, the curriculum facilitated individual working sessions for teams to apply concepts to their department innovation project, as well as any personal innovation with commercial potential. Furthermore, under the guidance of a Lead Instructor with expertise in innovation,

biomedical technology development, and entrepreneurship, the curriculum successfully balanced the portfolio of department innovation projects and personal innovations with commercial potential by offering the coaching and oversight to develop a comprehensive business case for both. In addition, the guest lectures from various University of Michigan (UM) schools, colleges and units, including UMMS, Engineering, Law, Information, Office of Tech Transfer, Food and Drug Administration (FDA) regulatory leadership, private industry contacts, and venture capital partners, created perspectives and exposure to strategies that faculty participants can use throughout their careers to creatively address patient needs via a rigorous and methodical innovation and commercialization process.

Program Objectives and Structure

The 9-month program consisted of monthly sessions scheduled on Fridays from 9 am to 2 pm during regularly scheduled and protected faculty development time within the Department of Surgery. For each session, participants convened to hear expert presenters, workshop department innovation and commercialization concepts in teams, and present findings to the group for feedback. The agenda topics were designed to be sequential and culminating in the formulation of a compelling business case for each innovation by the final session. Table 1 provides an overview of the program objectives and the 9-session progression of agenda topics.

Ideation and Team Formation (Sessions 1–2)

The first session began with a discussion on trends in medical innovation to initiate ideas, followed by a 3-hour ideation session. To begin the ideation, focus areas aligned with the department's mission were provided, including ways to improve clinical care, education, and research. Participants generated a master list of over sixty "big ideas" across each focus area. The master list was then prioritized and reduced to a list of ten ideas, based on overall interest from the program participants. The first session concluded with an example of a professional business pitch to illustrate the difference from a research presentation and provide an example of a program outcome for each team. The pitch was delivered by the former Chief Operating Officer and Vice President of Research and Development of a life science startup company that has successfully raised more than \$96 million.¹

Between the first and second session of the program, the ten ideas generated during the ideation session were presented to all surgery faculty (n = 140) at a mandatory department retreat for a rank order vote based on interest in implementation; commercial viability was not considered. The vote was administered using the Qualtrics™ online survey tool and received an approximate 30% response rate (n = 40). Table 2 contains the results of the vote for department innovation projects selected to progress through the program, as well as the commercially viable innovation projects enrolled with individual participants. As a result of this dual approach to innovation (department innovation and commercially viable), each remaining session of the program, combined with personal coaching from the Lead Instructor, was designed to meet the needs of both types of projects, resulting in concepts that were applicable to the implementation of department innovation projects and development of personal faculty innovations with commercial potential.

Participants formed teams around the four department innovation projects during the second session. Following team formation, a lecture was delivered on the importance of a clearly defined value proposition, described as a statement identifying the problem or opportunity being addressed, the proposed solution, the critical stakeholders or customers, and the benefit the solution provides. Participants used a stakeholder mapping exercise to identify end users, influencers, recommenders, decision-makers, payers, and saboteurs for the solution. As part of the LEAN Startup Methodology, a scientific approach to successful business ventures and a technique deployed throughout SIEDP, this activity is helpful to identify customers for the follow-up activity of conducting interviews to gather insight (customer discovery).^{2,3} Information collected during these interviews is critical to the development of a validated business case or rationale for implementation or commercialization of a project.

Commercialization Concepts and Business Case Development (Sessions 3–7)

Sessions 3–7 were designed to provide hands-on workshops about core commercialization concepts to be applied to both the personal innovation projects with commercial potential and the department innovation projects. Each session offered an opportunity for teams to present progress on the development of their business case in the form of a presentation or pitch. To begin session three, a case study featuring EXUBERA® (insulin human [rDNA origin]) Inhalation Powder, which was removed from the United States market in 2007, was presented to underscore the importance of a clearly defined value proposition.⁴ Most importantly, the case study was presented to identify the challenges and likelihood of failure if the technology's core value proposition is not validated through customer discovery interviews. Following the case study, instruction was provided on conducting quality interviews by introducing techniques and demonstrating during role-play exercises. The session concluded with an opportunity for each project team to present their stakeholder map for feedback.

Conducting a risk analysis as a strategy for project planning was the focus for session four. A template was introduced to capture the planning strategy and begin the formation of a successful business presentation. The session concluded with a panel discussion on intellectual property strategies for different product categories (e.g., therapeutics, diagnostics, devices, and mobile applications or software) and an interactive debate with professionals on the advantages and disadvantages of licensing versus startup pathways to commercialization.

Product development planning, slightly modified to meet the needs of both types of projects in the program, opened session five. Additionally, the session offered each project the opportunity to conduct customer discovery interviews with critical stakeholders. The in-class interviews were offered to ensure that each project team conducted a minimum number of interviews and provide a learning opportunity for those not conducting the interview to observe and critique the technique of the interviewer. To conclude the session, the Chair of the Department of Biomedical Engineering at UMMS and the UM College of Engineering (dual department) presented opportunities and resources for clinicians and biomedical researchers to collaborate with engineering colleagues.

Several guest experts from across UM delivered education on project development and additional resources as part of session six. A professor from the UM Ross School of Business delivered a healthcare economics primer, underscoring the data needed for a successful life science venture. The Director of the Michigan Investigator Assistance Program from the Michigan Institute for Clinical and Health Research, UM's National Institutes of Health (NIH) funded Center for Translation Science Award, delivered a comprehensive look at the Investigational New Drug/Investigational Device Exemption application process and clinical trial management resources.

Session seven focused on commercialization business case development and was structured to give the program participants a perspective on potential industry partners and an update on recent regulatory changes at the FDA. To begin the session, the Vice President of Global Technology Assessment and Health Policy and the Director of Regulatory Affairs from Cook Medical joined the Medical Director of Surgical Innovations from Medtronic to discuss the oftentimes-competing factors facing corporations with respect to biomedical innovations. Immediately following, the Associate Director for Technology and Innovation from the FDA's Center for Devices and Radiological Health, provided a lecture on device regulation in the United States, including challenges related to the accelerated lifecycles for health information technology and digital innovations.

The Final Presentation (Sessions 8–9)

Session eight was dedicated to presentation development, delivery, and refinement. Each project team was provided the opportunity to present their initial presentation to the class and Lead Instructor for constructive feedback. The working session prepared the group for the following session, a pitch presentation to a panel of expert judges, including university leadership, venture investors, and the entire Department of Surgery in a grand rounds forum.

Session nine was formatted as a competition, similar to the hit television show Shark Tank®, that featured a combination of six commercially viable innovations and department innovation projects. The six projects were selected based on quality of presentation during the previous session and viability for department implementation. Table 2 lists all of the experiential learning projects, including the six selected projects to compete in the competition.

Executives from UM and the local entrepreneurial community were invited to serve as judges for the competition, including the Director of Strategic Development at Michigan Medicine and a Managing Director for a life science venture capital firm. The judges were instructed to score each presentation by allocating 10 points across the six teams, and written feedback on a scorecard. The project team receiving the highest number of points was declared the overall winner. In addition to scoring from the judges, faculty in the audience were able to score each presentation using an electronic audience response system. The audience vote was used as a tiebreaker and a method for awarding a project team as the "Audience Favorite".

Program Expenses

Actual expenses for the UMMS Department of Surgery to fund the program were approximately \$60,000. The two largest expenses were the hiring of an Administrative Director and a Lead Instructor to design and implement the curriculum. At a rate of \$30,000 (0.3 FTE), the Administrative Director led all program planning, the recruitment and hiring of the Lead Instructor, invitation of guest lecturers, coordination of each session, and overall program delivery. The Lead Instructor, a serial entrepreneur and successful Chief Executive Officer of several life science startups, was hired at a rate of \$20,000 (\$200 per hour) to assist with the program planning, provide curriculum content, and coach participants and their projects outside the scheduled dates of the program. The remaining expenses included \$8,500 to provide 3 meals per session for all attendees, instructors and invited guests, \$1,000 in instructional materials, and \$500 in honoraria. Loss of productivity costs to the Department of Surgery were not factored into the total expense budget, as the program was offered during regularly scheduled faculty development time.

Evaluating the Program

Eleven faculty members from various subspecialties and academic ranks participated in SIEDP. Table 3 contains a complete overview of the specialties, dual appointments, and academic ranks represented across the eleven participants (some multiple appointments). At the conclusion of the program, an online evaluation was delivered to all participants using the Qualtrics™ survey tool. Respondents were asked to indicate on a scale of 1–5 (strongly disagree, disagree, neither agree nor disagree, agree, strongly agree) their willingness to agree or disagree with a variety of statements to measure attainment of objectives and identify areas of improvement.

RESULTS

Evaluation Results

Based on the provided scale (1–5), 100% of respondents strongly agreed or agreed that the program helped them advance an individual innovation with commercial potential or a department innovation project. Moreover, 100% of respondents strongly agreed or agreed that the program was worth the time and effort, was a good faculty development activity, and would recommend the program to a colleague. Amongst busy clinicians, this is a strong vote in favor of the format of this type of program and its relevance to the faculty participants. A summary of the evaluation results can be found in table 4 with verbatim responses that were helpful to determine how to improve the program in the future, including specific recommendations on enrollment from other departments.

Program Outcomes

The program was successful in educating faculty in an experiential learning format and providing a mechanism for projects to be advanced on a commercialization pathway or implemented within the department. The ideation session conducted during the program resulted in four department innovation projects. At the conclusion of the program, three of those projects: (1) Departmental Contract Research Organization (CRO), (2) Department-

based Research Concierge, and the (3) Priority Patient Programs were funded and implemented. The CRO project is already generating revenue through industry contracts. In addition to the department innovation projects, three of the personal innovation projects with commercial viability have received additional funding and resources through programs such as the Michigan Translational Research and Commercialization for Life Sciences Innovation Hub, UM Ross School of Business Venture Accelerator, and the NIH's National Heart, Lung, and Blood Institute Center for Accelerated Innovations. The program was also instrumental in the filing of three patents and the startup of two companies. The return on investment for providing such a program can be evaluated in a number of ways, including financial, the impact on faculty careers, and fulfillment of the department mission. With an initial investment of \$60,000, the projects in the SIEDP have received more than \$1 million of follow-on funding through internal and external sources. Furthermore, with faculty moving their ideas into startup companies and engaging more fully with industry partners, the level of funding is likely to increase.

DISCUSSION

The SIEDP was a first-of-its-kind partnership at the UMMS between FFMI and a clinical department. With the consistent participation of eleven faculty members, including senior level faculty and the chair of the department, the program clearly addressed an unmet need. An additional benefit is the change in culture produced as a result of the program. The faculty development structure, combined with the support from the department chair, has changed the traditional view of innovation and commercialization as a secondary pursuit by faculty to a natural and expected academic behavior. By establishing such a program with FFMI, the Department of Surgery has been on the forefront of this culture change at UMMS, something that has quickly spread to other clinical and basic science departments since the conclusion of the program.

FFMI was developed and launched in 2014 to nurture this culture of innovation, commercialization, and entrepreneurship within UMMS by offering resources and programs such as SIEDP. Part of the newly expanded FFMI mission is to integrate innovation and entrepreneurship programming to realize the greatest economies of scale within UMMS, across the entire UM campus, and State of Michigan. For example, FFMI co-developed and supports a new UMMS Pathway of Excellence program for medical students on innovation and entrepreneurship. Future iterations of SIEDP and similar programs will offer the opportunity to engage and integrate medical students into faculty-led projects, leading to improved recruitment opportunities for students in the field of surgery.

Conclusion

Despite the time constrained environment of academic surgery, opportunities exist to provide faculty the tools to take their creative thoughts from a loosely defined idea to a compelling case for additional investment. Providing a specialty-specific educational program for innovation, commercialization, and entrepreneurship has allowed the Department of Surgery to effectively move innovative ideas forward. The acquired skills for faculty will become increasingly useful as academic medical centers continue to face challenges in funding

support while providing optimal patient care. It is clear that providing such resources and educational opportunities can add value to the development of new technologies, as well as advance individual department missions. As a result of this successful pilot program within the Department of Surgery, FFMI intends to offer a follow-up program in 2018 to a broader audience of faculty, trainees, and students from a variety of UM colleges, schools, and units, with the goal of attracting participation from multiple departments and a greater number of participants.

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Table 1

SIEDP Objectives and Session Agenda Topics

Program Objectives	
	<ul style="list-style-type: none"> Provide a consistent and unified innovation and commercialization education curriculum that could be applied to department faculty with research-based biomedical innovations, such as novel therapeutics, devices, diagnostics, and health information technology (IT) products.
	<ul style="list-style-type: none"> Develop innovative approaches to improve the clinical care, education, and research mission of the UM Department of Surgery.
	<ul style="list-style-type: none"> Foster an experiential learning environment focused on teamwork and interpersonal skill building.
	<ul style="list-style-type: none"> Provide protected time for clinical faculty to pursue the commercialization/implementation of their innovation under the guidance and mentorship of an experienced Lead Instructor.
SIEDP Agenda and Session-by-Session Progression	
Session 1	<ul style="list-style-type: none"> A Warm Up: Trends in Medical Innovation Developing Innovation Projects: A Facilitated Ideation Session The SIEDP Deliverable: A Professional Business Pitch
Session 2	<ul style="list-style-type: none"> Project Selection and Team Formation Value Proposition Design & Analysis The Innovation Landscape: Developing Stakeholder Maps
Session 3	<ul style="list-style-type: none"> Case Study: The Importance of a Value Proposition Customer Development (Discovery): The Best Approach for Quality Interviews Team Report-Out: Stakeholder Maps
Session 4	<ul style="list-style-type: none"> Risk as an Effective Planning Strategy Building Your Presentation: The Executive Summary Template Intellectual Property and Paths to Commercialization
Session 5	<ul style="list-style-type: none"> Product/Project Development Planning Conducting Customer Development (Discovery) Interviews Medical & Engineering Collaborations
Session 6	<ul style="list-style-type: none"> Healthcare Economics: Supporting Data for your Innovation Project The Investigational New Drug/Investigational Device Exemption (IND/IDE) Clinical Research Management & Additional Translational Research Resources
Session 7	<ul style="list-style-type: none"> Industry Engagement Changes at the Food and Drug Administration (FDA)
Session 8	<ul style="list-style-type: none"> Pitch Presentation Coaching
Session 9	<ul style="list-style-type: none"> Final Pitch Event for External Expert Feedback

Table 2

Experiential Learning Projects in SIEDP

Department Innovation Projects (Results of Ideation Session and Faculty Selection)	
•	Creation of a Departmental Contract Research Organization (CRO) to Enhance Industry Contracts and Laboratory Funding *
•	Priority Patient Programs to Optimize Clinical Patient Flow for Procedures *
•	A Department-based Research Concierge to Connect Faculty with Research Opportunities *
•	Establishing a Surgical Performance Index for Branding and Quality Reporting
Individual Research-based Innovations (Commercially Viable)	
•	Novel Anti-thrombotic Therapeutic *
•	Drug-device Combination to Accelerate Bone Fracture Healing *
•	Mobile App for Breast Cancer Patient Education *
•	Medical Education Evaluation Tool for Efficient Learner Feedback

* Project selected to present during final session competition

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Table 3

SIEDP Participant Representation by Surgical Specialty, Dual Appointment, and Academic Rank

Specialty/Subspecialty	Dual Appointment	Academic Rank
General Surgery	Pharmacology	Department Chair
Neurosurgery	Pathology	Distinguished Professor
Plastic Surgery	Biomedical Engineering	Professor
Thoracic Surgery	Internal Medicine	Associate Professor
Surgical Oncology	Nutritional Sciences	Assistant Professor
	Public Health	Research Professor

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Table 4

SIEDP Evaluation Results (n=5, 45% of participants)

	Strongly Agree/Agree	Neither Agree nor Disagree	Disagree/Strongly Disagree
<i>The program met my expectations</i>	100%		
<i>The program was worth the time and effort commitment</i>	100%		
<i>I would recommend the program to a colleague</i>	100%		
<i>The program was a good faculty development activity</i>	100%		
<i>The program helped me advance a personal or department improvement project</i>	100%		
What did you like best/least about the program?			
<i>“The program was a great primer into developing projects and pitches for investors and innovation.”</i>			
<i>“This program got me thinking about aspects of academic surgery that I didn’t before. It allowed me to take an innovation I created for the surgery clerkship and see its potential for much wider use both inside the U of M and outside. The program also provided concrete skills and resources to push my innovation forward.”</i>			
<i>“Best are the concrete discussions about commercialization, interacting with VCs etc.”</i>			
How can we improve the program?			
<i>“It would be improved by a bigger enrollment, achieved perhaps by combining more than one department.”</i>			
<i>“I think it would be awesome to have a wider diversity of fellow classmates in the program besides just other surgeons. If there were some business, engineering, health care policy, etc, students and faculty taking the program at the same time I think it would allow for new relationships across these disciplines and would result in some really innovative ideas.”</i>			

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