INNOVATION

Teaching Biomedical Technology Innovation as a Discipline

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Recently, universities in the United States and abroad have developed dedicated educational programs in life science technology innovation. Here, we discuss the two major streams of educational theory and practice that have informed these programs: design thinking and entrepreneurship education. We make the case that the process of innovation for new medical technologies (medtech) is different from that for biopharmaceuticals and outline the challenges and opportunities associated with developing a discipline of medtech innovation.

THE INNOVATION MANDATE

We appear to have reached a political consensus that innovation is the key to "winning the future" (*1*). This focus raises a central question for educators: What is the role of our schools and universities in producing innovative thinkers and doers? Both in America and abroad, universities are experimenting with new programs and courses to teach innovation. Within the life sciences, there is particularly strong traction in the area of biomedical technology innovation, in which a number of interesting new training initiatives are being developed and deployed. In this Commentary, we trace the evolution of these new initiatives toward what we see as an emerging academic discipline.

TEACHING INNOVATION IN CONTEXT

For purposes of this discussion, we define innovation as "inventiveness put to use" (*2*)—that is, discoveries that lead to technologies or services that are taken up in the marketplace. Over the past 20 years, two major streams of educational theory and practice have come together to help motivate programs that teach innovation.

The first is "design thinking" (*3*, *4*). The basic premise is that there is a repeatable process for creating innovative solutions that is based on a clear understanding of how people experience needs. The approach has been most highly developed in the area of product design. Led by high-profile initiatives at Massachusetts Institute of Technology (MIT), Stanford University, and elsewhere, design education programs have been initiated in many universities over the past two decades. In general, these programs have grown up in engineering schools (sometimes in collaboration with art or architecture departments). There is a central emphasis on project-based learning to teach the fundamentals of the opportunity→idea→prototype→test cycle. Typically, these courses are also structured around teams, with a focus on mixing different skill sets in the team composition.

The second major stream is entrepreneurship education (*5*, *6*). The premise is that students from any discipline can benefit from an introduction to the skills and problem-solving approaches used by entrepreneurs. Substantial funding from organizations such as the Kauffman Foundation and the National Collegiate Innovators and Inventors Alliance (NCIIA) has fueled the growth of programs that teach entrepreneurship. These programs often employ experts from outside of the university, tapping adjunct faculty from the business world to teach courses and mentor students. In general, the emphasis in entrepreneurship classes is on skills and knowledge that are used further downstream in the innovation path from those taught in design classes. Design teaching starts with a need and ends with an idea for a product or service; entrepreneurship classes start with a product or service and teach the tools necessary to commercialize these ideas.

FUELING BIOMEDICAL INNOVATION

With these two major educational trends providing nourishment, innovation-training programs in the area of medical devices and diagnostics (medtech) are flourishing. The design methodology of needs finding and inventing lends itself well to medtech innovation projects; medical device development in particular fits beautifully into the brainstorming and rapid-prototyping cycle that is at the heart of a classic design approach. Medtech innovation cries out for interdisciplinary team building, mixing physicians, engineers, and business trainees. In fact, team-based training programs in biomedical device design have provided low-hanging fruit for universities that are striving to develop genuine collaborations across departments and professional schools.

From the standpoint of teaching entrepreneurship, medtech represents an interesting and manageable sector to analyze. There is a healthy entrepreneurial ecosystem in medtech that has, until just recently, been dominated by U.S. enterprises. The system consists of a relatively large number of venture-backed start-up companies with one major path to a financially successful "exit" in mind: ultimate acquisition by a small group of big, multinational companies.

The fusion of these two favorable environmental factors has spurred the launch of training programs in biomedical technology innovation that integrate design thinking and commercialization into a cohesive process. The ad hoc Biomedical Engineering Innovation Design and Entrepreneurship Alliance (BME-IDEA) has a membership of over 100 university programs in North America, most of which have been created in the last decade (*7*).

This rapid growth has also been fueled by substantial financial and strategic incentives. Beginning in 1989, the Whitaker foundation deployed more than $700 million in North America in helping to spawn some 50 new departments of biomedical engineering with a focus on developing technologies for health (*8*). Importantly, the Accreditation Board for Engineering and Technology requires substantial design experience for accreditation of undergraduate engineering programs, so that many of these newly created departments have found it productive to create training programs in biomedical technology design.

By the time the Whitaker Foundation came to its sunset in 2006, the Wallace B. Coulter Foundation (*9*) had begun to supply major new funding for technology translation in biomedical engineering in the form of its Early Career and Translational Research Programs. The Coulter Foundation has recently endowed five U.S. universities

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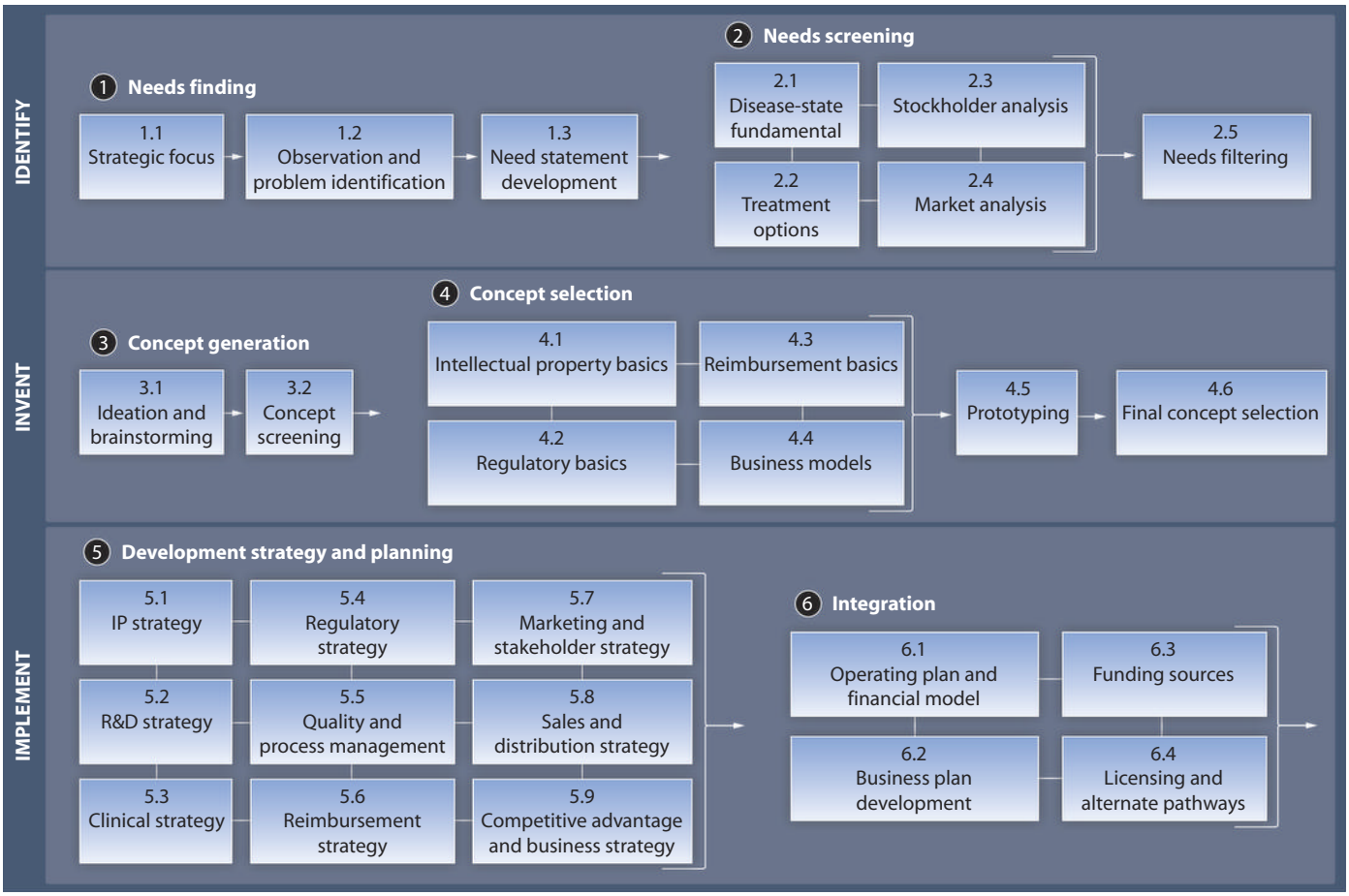

Fig. 1. Design within reach. Map of the "biodesign" process for medical technology innovation that shows the progression through three major phases (identify, invent, and implement). The individual boxes are content areas that form a basis for assessing core competencies. [IP, intellectual property; R&D, research and development]

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with funding to follow a disciplined process of project selection and monitoring for early-stage technology innovation in biomedical engineering.

During the same 10- to 15-year period, several universities developed model interdisciplinary programs in medtech innovation. Perhaps the best known of these is Boston's CIMIT (Center for Integration of Medicine and Innovative Technology), which brings together engineers, scientists, and physicians from Boston-area universities and hospitals. The program helps to catalyze the commercialization of medical technologies by providing seed grants and guidance in intellectual property, technology transfer, and business strategy (*10*). The Alfred Mann Institutes at the University of Southern California and, more recently, Purdue University also provide seed funding for carefully screened technology innovations. A third initiative, the Biodesign Program at Stanford, focuses primarily on training and education at the doctoral and postdoctoral levels. The program has developed a specific curriculum in medtech innovation that integrates design thinking and commercialization processes and targets them to the medtech sector (*11*). A number of other programs have been initiated in the United States and internationally over the past few years and generally involve some combination of training and seed funding.

MEDTECH VERSUS PHARMA

One mistake universities make when developing training programs in life sciences innovation is the tendency to lump biopharmaceutical discovery (small-molecule drugs and biologics) together with medical device innovation. Although there are considerable overlaps in these two domains, it is important to realize that the training processes have some fundamental differences. The distinction stems from the fact that the industry itself is segmented along these lines. Much has been made of the blending of device and drug technologies, but for the most part, medtech and biopharma companies still function in distinct business domains. The U.S. Food and Drug Administration (FDA), for example, has separate centers and regulatory processes for medtech and biopharma products. And the timelines, investment requirements, and development strategies differ substantially for medtech versus biopharmaceuticals inventions.

Within the university, too, medtech and biopharma projects draw on different types of students and faculty members. Medtech interfaces most closely with clinical departments such as medicine, surgery, and pediatrics—those physicians and trainees who are "in the trenches," directly observing patient needs and the effects of medical technologies. With respect to engineering expertise, medtech tends to attract mechanical, electrical, and, of course, biomedical engineers. Biopharma most closely relates to the basic

medical sciences (pharmacology, molecular biology, and genetics) and to computer science and chemical engineering. Here, too, there are substantial overlaps and synergies between domains; but the overriding observation is that the centers of mass of medtech and biopharma within the university are in different places and generally involve distinctly trained people.

The innovation processes for medtech and biopharma also differ in fundamental ways. Medtech innovation often starts purely with a clinical need. In the Biodesign program at Stanford, the basic mantra is that "a well-characterized need is the DNA of a good invention." The fellows in this program spend 5 months identifying and characterizing clinical needs before taking the first steps toward inventing a solution. In contrast, in biotech and pharma the birth of a new biologic or chemical drug is generally driven by a scientific breakthrough. Through a process of opportunity assessment, the therapeutic agent is mapped to potential clinical needs, and then preclinical and clinical experiments are performed to identify the most promising of these opportunities.

WHAT AND HOW TO TEACH

The Stanford Biodesign program provides a map of the needs-driven medtech innovation process (Fig. 1). This approach conceptualizes the innovation sequence in three major stages: identification (of needs), invention, and implementation.

Of these three stages, by far the most critical is identifying the need (known in design teaching as "opportunity assessment"). The first phase of needs identification, needs finding, is a creative, open-minded process of collecting a large number of clinical needs by direct observation of the day-to-day delivery of health care from the perspectives of multiple stakeholders (patients, families, physicians, nurses, staff, and payers). In this phase, it is important not to serve judgment on how important or promising each individual need may be. The didactic point here is to demonstrate that finding a need is relatively easy; in fact, the Stanford Biodesign program asks its fellows to come up with a list of at least 200 needs before proceeding to the next step of needs screening.

In the needs screening process, the domain specificity of medtech begins to assert itself, and the real work of developing a deep understanding of the need begins. Here, the large list of possible needs is filtered according to a number of different parameters, including current understanding of the pathophysiology of a disease, the existing and emerging treatment options, the potential market for a new technology, and the various stakeholder interests. The innovator is looking for a key insight within these areas—something no one has seen clearly before—that opens up the potential for a new solution. These insights can come from a variety of sources: a new understanding of pathophysiology that stems from emerging clinical science, such as an observed response to a new therapy; recognizing an example of inefficient, costly, or difficult workflow; or simply paying attention to the patient experience itself. For example, from the early days of angioplasty, patients complained that the most difficult and painful part of the experience was the pressure hold on the wound after the catheter was removed. It took 15 years for scientists to recognize that this was an important clinical need; once appreciated, researchers quickly showed that this need could be addressed with new devices designed to actively close the entry site in the blood vessel.

A central feature of the needs-filtering process—in fact, the key enabler of success—comes from the exercise of comparing needs one with another. This approach effectively prevents the innovator from short-circuiting the needs-identification process. A considerable amount of research is required to define and analyze the parameters of the information matrix for a given clinical need in order to determine whether it is worth the time, effort, and investment to pursue a solution. Having to select the best need from a larger list provides a disciplined approach that avoids the most dangerous reflex of inexperienced inventors: the tendency to latch onto an interesting problem and invent a solution quickly, without the diligence needed to assess the relative importance of a need and the mandatory characteristics of a successful solution.

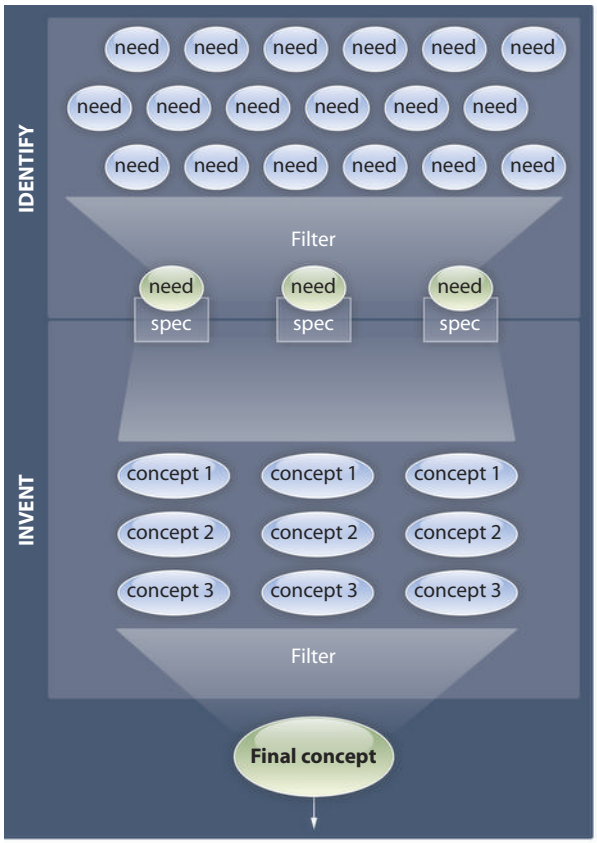

Fig. 2. According to need. Shown is a conceptual approach to the concept-generation process. The input to the "Identify" stage of the process is multiple clinical needs, which are filtered down to those few needs with the most promising characteristics. These needs are fully researched, generating a needs specification (spec) that details the characteristics of an ideal solution. In the "Invention" stage, multiple concepts are generated for each need. Then, a second filtering process selects the strongest concept (the one that best fits its need specification) to move forward into development.

The second major step in the process, invention, follows design-thinking methodology for ideation. Team-based brainstorming draws on expertise from both engineering and medicine. The teams generate multiple possible solutions for each need. Once a large number of concepts are generated, a filtering process begins in which the multiple concepts are compared and a small number of frontrunners are selected to take forward into further prototyping and testing. The overall form of the needs identification and invention stages is similar—first, generating multiple possibilities; then, filtering down to the best of the group (Fig. 2).

The third stage of the process, implementation, brings to bear an explicit consideration of

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commercialization potential. Here, the final concepts go through an early development process in which there are assessments of intellectual property viability, engineering feasibility, preclinical and clinical testing design, understanding of likely regulatory and reimbursement pathways, planning for sales and distribution, development of financial models and funding strategies, and consideration of alternative commercialization plans. This part of the training requires real-world expertise in the various domains, ideally from innovators who have experienced the development of medical technologies for the marketplace.

WHO SHOULD BE TAUGHT?

The discussion around what segment of a student population should be candidates for a training experience in medtech innovation is part of a larger debate on the role of applied versus basic research and education in the university. As a starting point, we would argue that students in engineering, medicine, and business who are headed for careers in medtech development would benefit substantially by training in a domain-specific process of innovation. Because many of these graduates will wind up in industry careers, it is logical to ask whether, for these students at least, the appropriate locus for innovation training is the companies themselves. There are, in fact, a number of companies that have developed training programs in medtech innovation. Of course, these programs have the benefit of the deep commercial experience and financial resources of the companies.

On the other hand, from the standpoint of the medtech innovation process itself, there are several important advantages and resources that universities offer. University programs are not blinkered by a need to enhance a product line; there is considerably more freedom to think beyond the bottom line and take risks in identifying needs and devising solutions. Universities have relatively easy access to faculty from multiple disciplines within a single organization (such as engineering, medicine, and business), and these different experts are aligned with respect to the central mission of teaching. Another benefit of the university environment is relatively unimpeded access to academic medical centers, which house clinical mentors who are committed to training and who have first-hand experience with medical needs as well as diverse patient populations. In the current climate of concern regarding overly cozy industry-hospital relationships, entry to medical centers by industry engineers has been markedly restricted. In addition, there is at least a theoretical argument that the best time to learn a disciplined innovation process is before entering a company position; that is to say, the situation is not different from learning the fundamental disciplines of, for example, mechanical engineering or pathophysiology.

Innovation training at the university level may also provide substantial benefit for students who are destined for faculty careers in engineering or medicine and who intend to invent and translate new medical technologies. Although there are faculty members at many universities who are experienced entrepreneurs, the ratio of these experts in technology translation to the number of faculty inventing biomedical technologies is not high—certainly not a majority. One effective way to change this ratio over time is to provide training and experience in innovation before the tenure clock begins.

FORWARD IN THE NEW ENVIRONMENT

For the past 50 years, the United States has enjoyed a dominant global position in the creation of new biomedical technologies, in large part because of a highly effective ecosystem of innovation. At present, there is great concern that the United States is losing its preeminence (*12*) at least in part as a result of the contraction of the venture capital market, the sluggishness and unpredictability of the FDA's device-approval process (*13*), and the looming uncertainty of health care reform. This increasingly difficult environment has important implications for the type of training that will help prepare students for future careers in medical technology. In the current climate, then, what key steps are needed to advance the educational agenda in the field of medtech innovation?

First and most important, educational institutions must make a commitment to the development of excellent training programs in biomedical technology innovation. One major challenge in this regard is the creation of an administrative home and structure for this type of hybrid program and the aligning of incentives among the various schools and departments required for support. CIMIT, Mann, and Stanford Biodesign are specially structured entities that combine engineering, medical, and business faculty and facilities with expedited access to hospitals and extensive external advisory capability. These are complex structures administratively and may be difficult to replicate—much less to finance. Another bottleneck is the finding and developing of faculty with genuine expertise in tech transfer. Project mentoring in technology development is highly time-intensive. Partly for this reason (and because real entrepreneurial expertise is thin at many universities), these roles are often "outsourced" to adjunct faculty members who may have relatively marginal status in their home departments. If technology innovation is to be an emerging focus, universities need a new generation of faculty experts who have direct experience as innovators. To this end, university leaders must commit to attracting such individuals and giving them the necessary resources (including a promotion pathway) to develop effective translational research, teaching, and mentoring programs.

Second, it is essential to clearly define the core competencies in biomedical technology innovation. It is not difficult to outline a body of information that must be mastered within the medtech domain; to a first approximation, this knowledge base comprises the material within the categories indicated in Fig. 1. Guidelines for training in medical device technology translation are being developed by a working group of the Public-Private Partnership Committee of the Clinical and Translational Science Awards (CTSA) Consortium (*14*). The development of criteria for assessment of the "soft" skills of innovation (including creativity and leadership ability) is, of course, a complex and nebulous enterprise (*12*, *15*) not confined to the field of innovation.

Lastly, it is important to point out that, in this rapidly changing environment, universities have a distinct opportunity to address some key challenges in medtech innovation. We have arrived at a historical inflection point at which the cost of new biomedical technology has become a major determinant of whether it will move forward into the clinical care realm. Navigating this environment will require a nuanced understanding of health economics and comparative effectiveness—areas of study that are being developed in close collaboration with university faculty members who specialize in health policy and economics. At the same time, expanding global markets provide important opportunities for value-based innovations that can reach large numbers of patients. Universities with international affiliations are in a strategic position to help

accelerate the development of affordable technologies for broad emerging markets.

The stakes in the new medtech innovation economy are high—for national and business interests, certainly, but more importantly for an aging global population that stands to benefit from the invention of high-quality, cost-effective health technologies. Recently, we have begun to see some productive experiments in training of the next generation of medtech innovators. These initiatives need to be evaluated fully and, no doubt, improved—but they point to the emergence of a new discipline in this sector of translational medicine.

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