EDUCATION

Mastering Translational Medicine: Interdisciplinary Education for a New Generation

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Graduate-level education in translational medicine will require more than just scientific research.

Affordable and accessible health care is essential for a successful and productive society, yet the cost of therapy can prevent this goal from being realized. Providing universal access to affordable high-quality health care requires not only advances in science, technology, policy, and clinical services but also more effective translation of technological innovations.

To cross the gap from lab bench to patient bedside, innovators must deal with issues related to product development, technology management, market positioning, cost/reimbursement, and regulation. Thus, specialized graduate education that teaches skills needed to negotiate the entire translational medicine continuum is invaluable for training the next generation of scientists, physicians, and managers; these colleagues can then work together at interdisciplinary interfaces in order to more effectively bridge the gap between bench and bedside. In this Focus, we discuss the essential components of such training using the joint "Master of Translational Medicine" (MTM) program of the University of California, Berkeley (UC Berkeley), and the University of California, San Francisco (UCSF), as an example.

UNIQUE SKILL SET

The metrics of success for traditional advanced training in the biomedical sciences and engineering are usually publications and patents rather than products, but an advance at the bench that suggests a bedside improvement must be translated into a product if it is to have an impact on human health. The translation process typically relies on funding sources quite different from those that drive scientific research and requires a different set of skills to meet the business, management, design, regulatory, and clinical challenges. Training in these skills is typically not offered or emphasized by traditional advanced degree programs (*1*, *2*).

For example, a physician-researcher with an intimate understanding of a clinical need may turn to a specialist engineer for their design experience, whereas an engineer with a novel medical sensor may require a regulatory expert to guide her through the U.S. Food and Drug Administration's (FDA's) 510(k) process. A Ph.D. or M.S. graduate may be qualified to lead R&D activities on the basis of their research experiences but is rarely qualified to contribute to other aspects of the translational process, such as regulatory issues, cost analysis, or clinical trials.

Graduates of MBA programs may have the business acumen to manage general operational and financial issues faced when bringing new technologies to market, but they may have little understanding of the product profile, FDA regulatory pathways, specific marketing requirements, or complications of health care insurance and reimbursement. Translational medicine needs an educational program designed to train leaders to work effectively in this complex space. A new generation of medical innovators must be taught to recognize, accept, and then effectively navigate the major challenges in translational medicine. Our experience as graduate educators has allowed us to compare new educational opportunities in translational medicine with those of traditional research-focused programs.

STUDENT COHORTS

Translational medicine education at the postgraduate level could be either a Master's program or an alternative training program for professionals, such as a Certificate or Advanced Education program for clinicians or business executives. The participants of such a program should be encouraged to come from a variety of backgrounds—engineering, physical sciences, law, business, pharmacy, and medicine—and may come from industry, from clinical training or practice, or directly from undergraduate education. It is with this melting pot of disciplines, experiences, and occupations that a program can be successful in cross-training translational experts.

In 2010, with the generous support of the Grove Foundation, UC Berkeley and UCSF initiated a 1-year joint MTM program (http://bioeng.berkeley.edu/mtm). Applicants often have an undergraduate degree in biomedical engineering, but many come from related educational backgrounds, including other engineering disciplines, biological sciences, pharmacy, and medicine. In general, applicants to the program share a common interest in medical technologies and, more specifically, in learning how to transform new medical innovations into practical clinical solutions. Although the MTM program is intended to serve as a terminal degree for those students interested in an industry career, it can also provide supplemental translational training for those on the path to another advanced specialty (M.D., Ph.D., or MBA). Depending on the specific career goals of each student, the MTM program is intended to train experts who can operate in a variety of translational settings, including labs, clinics, and corporations.

Because one of the primary goals of the MTM program is to fast-track students for success in medical technology–focused industries, the program specifically targets early-career applicants. Many MTM applicants have just completed their undergraduate training, whereas others may have a few years of industry experience. A minority (typically 5 to 15%) of the applicants already hold advanced degrees and are often skilled medical researchers or clinicians who are looking to supplement their professional or clinical skills with new training in the fundamentals of translation. This diversity in the student population is crucial to a field that hinges on contributions from a broad spectrum of players: scientists who make new discoveries, engineers who design and build new technological solutions, business executives who navigate issues of finance and marketing, regulatory agents who monitor and enforce the rules, and clinicians who use these newly approved medical technologies in their practices. The goal of the MTM program is not to focus on a particular subset of these players but rather to offer a comprehensive view of translational medicine in order to accelerate

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and amplify the skills of those best poised to have an impact on medical innovation.

CURRICULUM COMPONENTS

Although translational medicine is clearly multifaceted, we believe that successful training in this discipline requires an understanding of three main subject areas: biomedical technology, clinical issues, and leadership and technology management (Fig. 1A). Although every translational training program will be specific to its sponsoring institution, most programs likely will share some of the fundamental features described in this section.

The "biomedical technology" component focuses on technological solutions to unmet clinical needs. Although there are portions of the translational process that can be accomplished without a scientific or engineering background, we believe that a fundamental understanding of the technology is paramount to successful translation. Before any medical innovation can help a patient in need, the technology must be well designed and well constructed. Without a sound technological solution as a starting point, the remaining steps in the translational pathway are meaningless. The technology training can be customized to the needs and interests of students from different backgrounds.

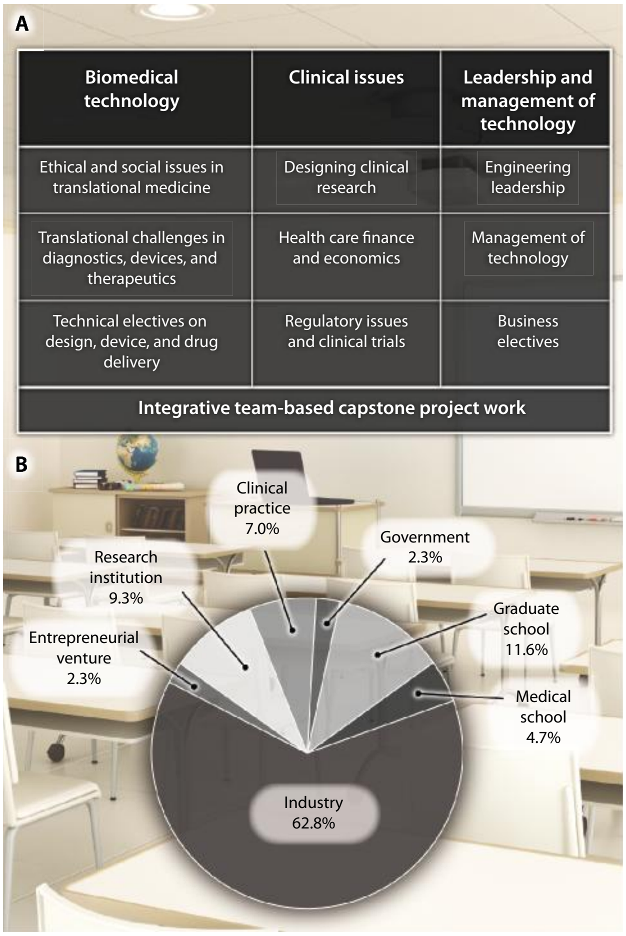

Fig. 1. Training for tomorrow. (**A**) MTM curriculum. Coursework is divided across three main subject areas, and general topics are listed under each subject area (see for details: http://bioeng.berkeley.edu/mtm/program). (**B**) Activities of MTM alumni. Representative data collected from 43 graduates of the MTM program as of November 2013. "Graduate school" represents enrollment in either a Ph.D. or M.S. program; "Medical school" represents enrollment in a M.D. degree program; "Industry" represents employment in an established company; "Entrepreneurial venture" represents employment in a start-up company; "Research institution" represents employment in a nonindustry research setting (university or national laboratory); "Clinical practice" represents employment as a practicing clinician or in a post-M.D. training program (residency or a clinical fellowship); and "Government" represents employment in a nonresearch setting within a government institution.

The "clinical issues" component is crucial for training students to recognize unmet clinical needs and for helping them to understand the additional factors involved when dealing with health care organizations and human subjects, such as FDA regulations, health care finance, reimbursement, and the design of clinical trials. These issues distinctly separate the field of translational medicine from parallel industries dealing with nonmedical technologies. No matter how groundbreaking the technology is, a new medical product is likely to fail if it is not developed with a full consideration of the clinical and regulatory issues involved.

Yet, even good technologies that adhere to the regulatory policies can be prone to failure in the marketplace because of a lack of leadership or business savvy. The "leadership" component of the MTM curriculum fills this educational gap and is essential for successful product development. By training students to analyze new medical technologies from a business as well as a technological perspective, their chances for successful translation are enhanced. Identifying ways to reduce risk and learning to treat failures as opportunities for improvement are also essential parts of this educational component.

We believe that these three educational components are most effective when brought to bear in integrative team-based capstone projects in which students collaborate in real-world settings on newly developing technologies. In the MTM program, project proposals are submitted from a variety of prospective project leaders, including faculty members, clinical researchers, and industry partners. Each project addresses an unmet clinical need with a novel medical technology that is beyond the initial discovery phase (some proof-of-concept has been demonstrated). Each project is discrete, the project leaders work with the program faculty to define the project goals for the year, and all projects aim toward the same long-term goal: to create a new medical innovation and translate it into clinical use.

Students in past cohorts have used their training to work on project deliverables, such as completing a market assessment, devising a regulatory strategy, filing new intellectual property, designing and implementing preclinical trials, or verification and validation testing of a device. By integrating the project work with the required courses in the curriculum, students experience firsthand how various components of the translational process affect the development of a new medical product.

RELATED PROGRAMS

There are several educational programs offered by other U.S. institutions that are similar in spirit to the MTM program. These programs are either professional Master's programs or Master of Science/Engineering programs and focus on technology innovation, design, and product development. For example, Georgia Institute of Technology offers a professional "Master of Biomedical Innovation and Development" degree (https://bioid.gatech.edu), UC San Diego offers a "Master of Advanced Study in Medical Device Engineering" (http://maseng.ucsd.edu/mde), and Johns Hopkins offers a "Master of Science in Bioengineering Innovation and

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Design" (http://eng.jhu.edu/wse/cbid/page/cbid_graduate).

Other programs provide comprehensive curricula on health technology management and commercialization. For example, Case Western Reserve University offers a "Master of Science in Biomedical Engineering" degree with a concentration in Translational Health Technology (http://engineering.case.edu/Translational-Health-Technology); Marquette and the Medical College of Wisconsin offer a "Master of Science in Healthcare Technologies Management" (www.marquette.edu/engineering/hctm); Rensselaer Polytechnic Institute offers biomedical engineering electives in its "Master of Science in Technology Commercialization and Entrepreneurship" program (http://lallyschool.rpi.edu/academics/ms_tce.html).

Master's-level programs in translational medicine may currently be the most abundant option, but non-Master's training programs are emerging. For example, Tulane has a Ph.D. program in "Bioinnovation" that focuses on biosciences and entrepreneurship (https://tulane.edu/bioinnovation-IGERT). In 2005, the Howard Hughes Medical Institute (HMMI) launched its "Med into Grad" initiative, which has awarded $26 million in grant funding to help graduate students better interface with clinicians and find translational opportunities (www.hhmi.org/programs/med-into-grad-initiative). There are also several entrepreneurship fellowship programs that bring together clinicians, engineers, and business professionals, during or after their professional training, to develop products to meet clinical needs, such as the "Biodesign Innovation Fellowship" at Stanford (*3*) and the "Center for Device Development Fellowship" at Northwestern (http://cd2.northwestern.edu).These programs are typically 1 year in length and are often intended for students who already hold an advanced degree.

The need for skilled professionals who can bring new medical technologies to the clinics quickly and efficiently is clearly increasing, and the educational system is responding with greater options for training in translational medicine. Although these programs have developed largely independently of each other, their fundamental missions are similar: educate new leaders to excel in the field of medical technology translation so that they can transform the face of health care.

METRICS

As educational opportunities in translational medicine continue to expand as discussed above, the true impact of these programs will be felt when graduates apply their new training in the field. From our experience with the MTM program, we have seen alumni (n = 46 to date) move on to a variety of postgraduation opportunities (Fig. 1B). For most students, this type of education serves as a terminal training program that will help graduates excel in the biotech or medtech industries.

Some graduates of these programs may choose to apply their new skills in a more clinical or academic setting, for example by using their new training as a supplemental tool in their careers. Other graduates may opt to pursue further academic training, such as a Ph.D., to become an expert in a particular technological area. These graduates will not only be able to discover and invent the medical innovations of the future but also have the translational skills to deliver these innovations to the people who need them.

In the MTM program, international students have become an increasingly important part of the cohort (growing from 7% in 2010 to 18% in 2013), and many are from emerging economic leaders, such as China and India. There are tremendous opportunities for well-trained international scientists and managers who understand how to interface with and navigate the U.S. regulatory and technological landscape. From just a few years of tracking our alumni, it is clear that educational programs focused on translational medicine can be extremely effective at placing young leaders in professional positions in which they can have a direct impact on the development of new medical technologies, both domestically and abroad.

Master's-level education in translational medicine is designed to accelerate the conversion of research findings into clinical treatments and provides interdisciplinary training in engineering, clinical science, regulatory issues, and business management. We believe that the multidisciplinary curriculum, the integrative team-based capstone projects, and the partnership with industry and medical centers are essential for the success of an educational program in translational medicine. Although several new educational programs are attempting to improve the bench-to-bedside process in this way, it is still too early to fully evaluate the broad impacts of these initiatives. We are encouraged by the steady demand from prospective applicants (64 applications in 2013) and by the early-stage successes of former students. For example, Gauss Surgical, Inc., is a company that originated from a MTM project. The team was a finalist in the USAID/Gates Saving Lives at Birth 2011 Grand Challenge and received two Forge Incubator grants from the Business Association of Stanford Entrepreneurial Students (BASES). The company currently holds two 510(k) FDA clearances for its Pixel App. Intelligent Obstetrics, cofounded by a MTM alumnus, won the competition at Berkeley's Center for Entrepreneurship and Technology Venture Lab and was one of the first start-ups to join Berkeley's Skydeck incubator. At NanoNerve, Inc., several teams of MTM students have contributed to preclinical experiments and the successful SBIR Phase II project.

Long-term data tracking from alumni, clinicians, and industry professionals will be crucial to determining the deeper benefits of this type of translational training. Although the exact metrics of success, which are different from translational research (*4*), have not been well defined, we believe that the quality of training and the number of graduates who go on to have careers primarily in medtech and biotech can be early indicators of a program's educational contribution to the field of translational medicine. Larger-scale and longer-term considerations of alumni career trajectory, salary, intellectual property development, and involvement in products that secure FDA approval will allow for more detailed analysis of the impact over time. Thorough evaluation of the societal benefits of such programs may require deeper examination of the medical technologies translated by program alumni, including health economics analyses, to determine how the graduates of these programs are making meaningful contributions to human health.

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Editor's Summary
