

Virtual Mentor

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MEDICAL EDUCATION

A Patient-Centered, Ethical Approach to Medical Device Innovation

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Students, residents, and fellows are in the front lines of patient care, confronting countless unmet clinical needs daily. Usually these needs are recognized momentarily and forgotten quickly, with attention diverted to the next consult or procedure. Often the need is missed completely. Medical trainees are all too familiar with the 2 a.m. page about the confused elderly patient who fell on the way to the bathroom, screaming baby with challenging IV access, or conversation with a cancer patient when no further allopathic treatment options are warranted. Each is an opportunity to ask, “Can we do better?” Those in the trenches are best positioned to identify problems and develop solutions. The guidelines for developing needed solutions to these unmet needs that follow come from a program dedicated to that specific purpose.

Demystifying Medical Device Innovation

To those outside the industry, medical device innovation can be daunting—where does one even begin? The process is undoubtedly arduous and full of uncertainty, but Paul Yock, MD, director of Stanford’s Biodesign Program and inventor of many catheter-based technologies, believes it can be taught. The Biodesign Program, now in its 9th year, brings together students and postgraduates in medicine, engineering, law, and business to embark on a 1- to 2-year fellowship in medical device innovation. The focus is on early-stage device development, from need identification, to concept and prototype development, to completion of a business plan [1]. Along the way, the fellows learn about intellectual property, the regulatory pathway, reimbursement patterns, and market evaluation and apply this knowledge to their fledgling projects. Dr. Yock emphasizes that the program is about education—by understanding the process, an innovator can maximize his or her probability of success. But Dr. Yock will also note with a smile that a dozen or so companies have developed out of the Biodesign Program.

Challenging Conventional Wisdom

More than 50 years ago, when he was still a scrub technician at a Cincinnati hospital, Thomas Fogarty, MD, imagined using a tiny balloon at the end of a thin rubber tube to extract clots from the inside of blood vessels. His prototype was the cut fingertip of a size-5 surgical glove tied to a urethral catheter. Surgeons scoffed at his naivete. “Only one so uninformed and inexperienced would dare do such a thing” [2]. Conventional wisdom held that manipulating the inside of a vessel, much less scraping it with a balloon, was dangerous. Surgery was the only way, even if it required slicing up a major vessel, putting the patient through hours of general

anesthesia, and substantial risk of losing that limb. Undeterred, Dr. Fogarty—then just “Tom”—persisted. His invention became what is now known as the embolectomy balloon catheter, a device used in hundreds of thousands of cases a year and whose underlying technology is the cornerstone of endovascular therapy.

As physicians, our pledge to “first, do no harm” can put us at odds with our natural drive to explore new ways to improve the care we give our patients. A novel treatment, especially a device-based one, inherently carries new risk. The more novel the idea, the more risky it often is. The original problem or unmet clinical need must have the potential to bear a solution that justifies the risk of trying something new.

Challenging conventional wisdom in medicine is difficult, especially for those still in training who are struggling to master accepted practice, prognoses, and pathophysiology. This preoccupation with committing tradition to rote memory may deter the young trainee from questioning the status quo. It is precisely this category of innovator, however, who is unaware of what cannot be done and unhindered in recognizing the true clinical need, the root cause, current solutions, and potential better options.

Focusing on the Patient

Navigating the difficult process of medical device innovation while maintaining an unwavering moral clarity is an immense challenge and responsibility. Stanford Biodesign’s philosophy is that innovators must focus on the needs of the patient [1]. When confronted with competing interests, recognize that gray areas exist and that each innovator will be guided by his or her own ethical compass and unique set of values. Having a mentor, insightful colleague, or supportive innovation network can help assure that energy is devoted to areas that offer high potential for success and that the process maintains the highest ethical standards. As a concrete ethical framework [3, 4], we follow the four foundational principles of biomedical ethics established by the Belmont Report in 1979 [3,5]:

Beneficence. Aiming to do good for patients is the underlying motivation in solving any unmet clinical need.

Nonmaleficence. “First do no harm.” Most devices carry inherent risk, and the potential benefit must justify the potential risk.

Respect for autonomy. Respecting others’ rights to make their own, fully-informed choices demands that innovators be completely transparent with anyone who could be affected by the technology, informing them of potential risks, benefits, and alternatives. It also demands disclosing all conflicts of interest.

Justice. Justice requires commitment to deciding fairly among competing interests, sometimes through third-party arbitration, in resolving conflict. It also calls for reasonable, nonexploitative, and well-considered procedures to be administered fairly.

Confronting Ethical Challenges

Innovators may encounter ethical challenges at any phase of the innovation process. A common dilemma for physician-innovators is participation in early-stage evaluation and development of their own ideas and technology [7, 8]. In preresearch phases, the physician is on his or her own in framing an ethical procedure. Often a promising device has several suspected flaws that can only be tested and mended through more experience with its use in patients. At this stage, an institutional review board (IRB) becomes involved, but the need to strike clinical equipoise remains. Is there honest professional disagreement among clinicians about the preferred treatment? Do informed professionals have no preference between the standard and innovative treatments? If the device in question were a cell phone, the deliberation would be far less weighty. But because human lives are at stake, medical device entrepreneurs must be rigorously vigilant about the potential effects of their decisions.

Moving from Development to the Clinic

Only a small fraction of ventures are successful. With idea in hand, one must seriously vet the opportunity in terms of market, competitive landscape, and technology risk; bring together the right people; and raise sufficient capital from the right investors. “Sufficient” generally means “a lot of money,” more than what grants and donors can typically provide. Exactly how much depends on the nature of the venture. How technically complex or invasive is the technology? How many patients will need to be studied and for how long? What kind of business model drives revenue?

In most cases, getting a device to market is only the beginning. From there, the battle increases in intensity. How will the company drive adoption, secure reimbursement from payers, beat out its competitors, and continue innovating? Many medical device start-ups raise tens to hundreds of millions of dollars from investors. At later stages, most founders will have lost control of the company to investors. The innovator must recognize that investors are most interested in making a return on their investment—that is their fiduciary duty to their limited partners. The innovator must strike a balance between meeting the needs of patients and those of current or future investors. Often these duties are aligned, but conflicts of interest can arise.

Making an Impact

Medical device innovation is undoubtedly arduous, but physicians owe it to their patients and to the next generation of doctors to question the status quo continually. There are many ways to improve the lives of patients—innovating medical devices is one way that can affect many. Medical trainees and anyone who still practices with curiosity and wonder should recognize a clinical need when confronted by one, challenge conventional wisdom, be alert to new opportunities. If you think there is a better way, write your ideas down. At first, the idea may be criticized as heretical. That’s okay. It would not be revolutionary otherwise.

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