Curing with innovation

INTER ACTION

one in an occasional series of articles about multidisciplinary teaching and research

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Todd Brinton
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COLLAGE BY anna COBB / MADE WITH PHOTOS BY l.A.CICERO, MiCHAEL WaDE, aRMy.MIl AND IMaGES BY PaTRICk J. lYnCH; MEDICAL ILLUSTRATOR; C. CaRl JaFFE; CaRDIOLoGIST
In October 2003, when Stanford’s Clark Center opened as the home of the Bio-X initiative, it was hailed as emblematic of the university’s commitment to multidisciplinary research and teaching. As the initiative began taking shape, research groups at Clark coalesced around various themes. Engineers and physicians who were focused on medical devices adopted the name “Biodesign.” Today, their group is a nationally recognized leader in the training of young medical technology innovators.

The training program has two principal components: a two-year fellowship program and a two-quarter Biodesign Innovation course taught by professors from medicine, engineering and business, with an all-star multidisciplinary line-up of guest teachers.

“Biodesign’s objective is to teach medical-technical innovation,” said Todd Brinton, one of the course’s founders. My goal, as a former fellow and now one of the faculty members leading the course, is to teach the 50,000-square-foot view of medical technology innovation. As a physician, you can’t know everything you haven’t taken a step back to see all the pieces, get different viewpoints, learn to collaborate.

The fellows

There are eight biodesign fellows this year’s cohort includes residents from general medicine and neurosurgery, engineers with industry experience, an MD/PhD student and a law graduate. All have multifaceted backgrounds including engineering, computer science, healthcare and business development.

They arrived last summer and immediately got a boost for five weeks. There, they heard lectures (as many as six a day) on whatever the year’s focus is—this year it is gastrointestinal surgery—as well as on collateral fields essential to developing medical technology: finance, law, patenting, mechanics, policy, etc. Before their first day, the co-directors went on a business marathon, noting Kevin Chao, MD, a neurosurgery resident at Stanford and one of the eight fellows. “Early on, it’s easy to identify everyone’s weaknesses.” He remembered, for example, that one of the fellows with no medical background mis-spelled all the medical terms.

“Biodesign is a process; the only realities are the patients,” said fellow Greg Magee, MD, whose medical group director Paul Yock, a cardiologist and inventor, told the class early on, “The most important question you have to frame a needs statement was, ‘Who do I identify a need? What is a good need?’ Yock told the class.

“The most important question is, how do I identify a need? What is a good need?” Yock told the class.

“The only realities are the patients,” said fellow Greg Magee, MD, whose medical group director Paul Yock, a cardiologist and entrepreneur and former Biodesign fellow. “All successful organizations in the valley have multidisciplinary approaches. My goal, as a former fellow and now one of the faculty members leading the course, is to teach the 50,000-square-foot view of medical technology innovation. As a physician, you can’t know everything you haven’t taken a step back to see all the pieces, get different viewpoints, learn to collaborate.

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They arrived last summer and immediately got a boost from the fellows who were impressed with the Bay Area in general, and Stanford in particular, is a good place to learn how to acquire the skills and knowledge Yock referred to. Former students, venture capital executives, inventors, physicians and lawyers explained to the students what they could expect as they take a need, develop a product and implement a business plan.

Greg Lambrecht, for example, president and chief executive officer of Intrinsic Therapeutics (in Walnut Creek, Calif.), who has a long record of product development and invention, visited the class early in winter, and his advice about formulating needs statements set the tone.

Try to push your well-trained mind to solve problems into the background,” he said. “Enter the mindset of observation. And remember, everything can change. Feel free to imagine everything. The only realities are the patient, their problem and the outcome.”

Choosing a project

“The degree to which students had absorbed the lessons on how to frame a needs statement was put to the test in late January at the poster show. The 24 needs from the fellows had been divvied up among the students, who had to decide if they were worth pursu-
later by visitor Mark Deem, an inventor with more than 150 patents who is a partner at The Foundry, a medical technology incubator in Menlo Park.

"VCs are more interested in the team than in the business opportunity," he said, referring to venture capital investors along Sand Hill Road. "A good team can alter and save a bad business opportunity. A bad team can take a good opportunity and tank it."

And, he cautioned the class, "don’t fall in love with your idea unless it’s really, really good. It must fulfill a need, it must work for doctors, it must work within the healthcare system."

"Patients," he added, "don’t need cool technology."

Concept development

By spring quarter the class had moved on to concept selection and development strategy, and they were ready to hear about such daunting prospects as what Deem called “doing the Sand Hill crawl.”

They also heard from biomedical alumni who have founded medical technology firms. Darin Buxbaum, chief executive officer of HourGlass Technologies, described how he and his colleagues developed a non-surgical technique to combat morbid obesity.

"VCs told us we were crazy; they said there’s a graveyard of companies that tried to develop devices for obesity," he said. "But a little luck and a lot of hard work paid off."

But finance is a real hurdle, Buxbaum and everyone else admitted, and venture capital is not the only good source that students should consider. "This fall, everyone was running to VCs to get money before it ran out," Buxbaum said in April. "It was like gridlock with VCs. It’s still like that."

"There’s a saying now, flat is the new up. This can be very important when getting second-round funding. People are getting less than before, and the terms are being changed to favor investors."

By this time, the class was down to eight needs, and teams were busy trying to figure out the best concept for each one. The needs concerned sigmoid diverticulitis, pancreatitis, sleep apnea, chronic back pain, vascularized tumors, deep vein thrombosis, partial small bowel obstruction and preventing fall-induced injuries in the elderly. Most teams comprised students from various fields, each with their own strengths.

Another round of presentations took place in early April, similar to the early poster presentations but this time more focused and with the benefit of two months of research. Among them was one describing ways to prevent elderly people from falling.

Team members (a product designer from India, a medical student with a biophysics degree, a bioRobotics doctoral student and a business student) explained that their earlier approaches had been heavy on the technology and light on the environment. So they went back to nursing homes and, simply, observed. They saw a lot. For example, old people hoist themselves up from a sitting position by using their walker, a recipe for falling, and often have impaired depth perception, which makes it easy to trip. Using what they saw, the students came up with a better proposal.

"I love the fact that you went to nursing homes," said Yock at the presentation. "That makes my heart happy." His only criticism was that the proposal seemed a bit complicated. "Think of the simplest thing you can do to mitigate the transfer problem," he suggested, referring to the way in which a walker could assist rather than hinder elderly people from getting up.

"The great thing here is that you guys truly understand the need," Magee told the group. "You went back and figured it out. This is one of the best things I’ve seen."

Getting paid

Meanwhile, Magee and his seven colleagues were...
still working on their own projects. By mid-spring, each team of four fellows had three concepts, each with its own business, technical and medical challenges.

Reimbursement from Medicare was turning out to be especially important. The government assigns reimbursement codes to devices that determine how much money is paid. So being classified correctly is essential, but not easy. “The best thing is to have a unique code, but that’s expensive and lengthy,” Palmer said. “We need immediate reimbursement, so we’re trying to come up with a creative way of defining our technology.”

Ten months after he got here, Magee said, “I’ve learned that you really need to hire smart consultants. It’s very political, and these people have been dealing with government for a long time. They can negotiate. It’s very political, and these people have been dealing with government for a long time. They can negotiate.

“The fellows’ six projects concerned hemorrhoids, fecal incontinence, bedsores, gall bladder ailments, congestive heart failure and laparoscopic tools. Their final presentation was scheduled for June 9. After that, the non-surgical fellows will leave Stanford, the surgeons will remain for another year and they’ll all do what they can to move the projects forward.

“Formers” told all of them that this experience gave them new skills that made them more valuable, that led them to take on new responsibilities, because they had more depth and breadth than before,” Magee said. As a physician, it gives you a greater appreciation of how hard it is to invent things. If I’m shown a bunch of data and I don’t quite believe it, I say, do it over again. Now I have more appreciation of how much work and money is involved in that.”

Money, as it happens, is essential. Financial modeling is, basically, "what you’re going to do and how much money you need to do it," Zenios told the class. "Every strategy, whether it’s intellectual property or reimbursement or clinical, requires a financial component, and this should be done early, not late."

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“You have to sell the idea.”

And in that process, maybe one becomes a better physician. An engineer or businessperson who can’t tell a catheter from a stent might be able to do something for medicine. Both Magee and Chao commented on recent medical cases where it turned out that what everyone assumed was true in fact wasn’t. Mammmograms, blood sugar levels, PSA tests and the like are all coming under renewed scrutiny.

“We need to think about our own protocols,” Chao said. “We think things are written in stone, but then you start reading articles and you find that they’re all controversial but that the whole world bases medical procedures on some pretty arbitrary decisions. I’m more open now to challenging medical protocols.”

“Once you’re in medicine, you have blinders on, you have no vision of anything else,” Magee said. “So any time you can be exposed to new things, you get a better perspective.

“You spend your life trying to help people, and that makes us risk averse. We might not want to change. We often feel good about what we do, we don’t want to change. But there are many things we do that should be changed.”

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