Curing with innovation

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

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INTERACTION

COLLABORATED BY ANNA COBB / MADE WITH PHOTOS BY L.A.CICERO, MICHAEWADDE, 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 yearlong fellows program and a two-quarter Biodesign Innovation course taught by professors from medicine, engineering and business, with an all-star multidisciplinary line-up of guests and speakers.

“Biodesign’s objective is to teach medical-technical innovation,” said Todd Brinton, one of the course’s teachers and now one of the faculty members leading the course. “All successful organizations in the valley have multidisciplinary approaches. My goal is to make of Biodesign as a formal program 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 have to take 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 comprises residents from general medicine and neurosurgery, engineers with industry experience, an MD/PhD student and a law graduate. All have different backgrounds including engineering, computer science, healthcare and business development.

They arrived last summer and immediately got a brief crash course for five weeks. There, they heard lectures (as many as six a day) on whatever the week’s focus is — this year it is gastrointestinal medicine — as well as on collateral fields essential to developing medical technology: finance, law, patenting, mechanics, policy, etc.

During a class session titled “disparate backgrounds and strengths,” noted Kevin Chao, MD, a neurosurgery fellow at Stanford and one of the eight fellows. “Early on, it’s easy to identify everyone’s weakness.” He remembered, for example, that one of the fellows with no medical background mis-spelled all the medical terms. “But it was refreshing,” he said, “because she challenged our strongly inherited beliefs. Doctors have a strong aversion to risk.

After that immersion, they launch into a second one, this time at the hospital. Divided into two teams, for two months they observe and take notes about every medical encounter. They search for needs they think could be usefully addressed by new techniques or devices. Amazingly, each team collects some 300 needs, and the fellows spend the last portion of fall quarter culling the wheat from the chaff, checking journal articles, re-interviewing the players, discussing among themselves what makes sense and what doesn’t.

“Don’t you know if they’re good or bad till you know the market and the medicine?” said fellow Erika Palmer, PhD, an engineer with expertise in spinal degeneration. “So you need lots in order to get a few good ones.” Each team keeps four needs for themselves, and the fellows give a total of 24 others to the class, which starts in January.

One of the key lessons of the program is how to define a true need. A problem is not the same as a need, and it is essential to never state a need in terms of a supposed solution.

One of the fellows, Stanford inventor, surgeon, medical faculty member and local vintner Thomas Fogarty is quoted in the class reader as saying, “Innovation tends to go out and ask people what they want rather than observe what they need. When you talk to physicians, as well as others involved in the delivery of care, you’ve got to learn the difference between what they say, what they want, what they’ll pay for and what they actually do.

So the process entails a lot of looking and thinking, which is harder than it sounds.

“We’d write down any and all observations,” said fellow Greg Magee, MD, whose medical school thesis was based on fieldwork in Bolivia.

They might be stupid, but there might be a pearl.

“You have to keep solutions out of the need,” said Palmer, echoing advice from the “design thinking” experts at the Engineering School’s design program.

“Innovation is a process, not a brilliant hiccup,” program director Paul Yock, a cardiologist and inventor, told the class early on. “The most important question is ‘Do I identify a need? What is a good need?’

The class
For the class, identifying needs and developing products to address them follows a process similar to the arduous (but fun) one experienced by the fellows. All graduate students, they hail from electrical, chemical, bio and mechanical engineering; management science; genetics; biology; medicine; and business. Most have an assortment of degrees and work experience from related fields.

“You are the future leaders of biomedical technology innovation,” announced Yock on the first day of class. “We are not here so that you can start a company. But we do want you to acquire the skills and knowledge to be able to do that someday.”

The course’s third instructor, Stefanos Zenios, gave students a valuable lesson the very first day: Zenios, a professor at the Graduate School of Business (with a courtesy appointment in bioengineering) and an expert in health delivery systems, presented students with a quick pair of medical problems and had them write down two questions. He then called on them and asked whom they would consult to get answers to their questions.

Turns out a business student had different questions and seeks different advice than an engineering or medical student.

It became clear as winter and spring progressed that 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 Woodland Hills, 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 desire 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 patients, 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 biodesign 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 one 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 codes to devices that determine how much money is involved in that.”

Now I have more appreciation of how much work and data and I don’t quite believe it, I say, do it over again. “Risk aversion

As Yock said at the start, the objective is not to establish medical technology companies, though one or more usually grow out of each cohort. The point is to develop the sort of observational and conceptual skills that might make that possible. For that to happen, graduate students and fellows have to reconsider their assumptions.

“Doctors have a strong aversion to risk,” said Chao. “They say, you can’t do that! You might get sued.” “Engineers have an easier time with risk,” according to Palmer, “and that affects how we approach problems.”

“I had a medicinal approach to how I think about problems, a very exact approach,” Chao remembered. “But then [another fellow] said, ‘Just estimate! That number is good enough.’ In medicine and engineering you have to be more exact than in business. It was a leap of faith for me, and that was a good challenge.”

It is that combination of approaches that Biodesign aims at encouraging.

“There’s a lot of leadership here,” Magee said. “No one’s going to buy your idea just because you propose it. You have to sell the idea to the team.”

And in that process, maybe one becomes a better physician. An engineer or businessperson who can’t sell 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. Mammograms, 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.”

“One 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 should be changed.”

Stanford India Biodesign

Once the Biodesign Fellowship program was up and running, the founders turned their attention to India, a country with which Stanford has strong and lasting ties. Today, the second cohort of India fellows is finishing up the first half of their fellowship year. They’ll spend the next six months back in India, working at medical and technology schools.

“You can get into an entrepreneurial mode here, saying, how much money can I make?” said Christrine Kurilhara, associate director of Stanford India Biodesign. “But now, with the India program, there’s a new sensibility: How many people can I affect? Business needs to think differently about the poor, and there are ways of reaching them. This isn’t about charity; you can make inexpensive devices and sell a billion of them. Beyond that, it’s the right thing to do now.”

So the four fellows—physician Darshna Nayak, engineering professors Rahul Ri- beiro and Asokan Thondiyath and product designer Pulin Raje—have to keep one eye on what’s going on here and the other eye on how the knowledge and experience will play out at home.

“Our intention is to design for India,” said Raje. “What I learned about the U.S. Food and Drug Administration, which the Biodesign Innovation class spends a lot of time discussing, is helpful because India is in the midst of establishing itself to ensure safety and encourage innovation. We’re hoping to play a role in the development of Indian medical technology. Intellectual property is different here too, but we can think about it in an Indian scenario.”

The principal difference is that Indians pay for medical care out of pocket, and therefore it must be inexpensive.

“This is a hurdle for designers because the product may be as low cost as possible,” Raje said. “Here I can sell something for $100, but in India no one will buy it.”

“The needs are similar,” Chao pointed out, “but the solutions must be cost-effe-
tive.”

Raje, “You see things here and you say, that’s the same as in India. But can I take this product to India? No, it won’t work, it’s meant to be used here.”

The Indians are participating in the class teams, and they all remarked on the usefulness of combining medical, engineering and business professionals.

“We educate each other,” noted Ribeiro. The mix mimics the “vibrant ecosystem” of Silicon Valley, said the program’s executive director, Raj Doshi, and that mix does not yet exist in India.

“People are more spread out there, and it’s rare for them to come together. Now they work in silos,” he said. In order to combat that isolation, Stanford India Biodesign and its Indian partner institutions have set up a biodesign network to bring people together.

“If the Biodesign program had existed when I was in school, my life would have been easier,” said Doshi, laughing. Instead, he constructed the pieces himself: He earned degrees in chemical and biomechanical engineering and in medicine, all from Stanford (where he worked in Paul Yock’s lab), and from there launched a series of medical inventions. He has around 20 patents issued or pending.

In addition to taking the class and working on team projects, the four Indians are immersing themselves in Stanford’s emergency room, and a second project will emerge there, depending on which needs they observe. They are especially interested in targeting the “golden hour” just after the onset of an emergency, which is when lives can be saved. India does not yet have systematic ambulance, paramedic or 911 service, so whatever project they come up with will surely meet a need at home.

“With 1.2 billion people, four fellows isn’t enough!” joked Doshi, which is why Stanford India Biodesign also has an internship program in India, providing around 20 young scientists, physicians and engineers with a similar, albeit brief, opportunity.

“We spend long hours on Skype,” he said.