In the event of a severe influenza pandemic, 700,000 U.S. residents would be at risk of dying simply because of a shortage of ventilators to keep people alive and breathing when their respiratory systems fail. In developing countries, the situation could be far worse. Because ventilators can cost up to $40,000, clinics in these countries find it impractical to purchase enough of these life-saving devices for daily patient care and hospitals find it nearly impossible to stockpile them for emergencies.

This is the kind of problem that fellows in Stanford University’s Biodesign program have been tackling for the past decade. Biodesign brings together graduate students from the medical, engineering and business fields to create innovative products that fill unmet medical needs and ultimately improve patient health. Biodesign fellows are funded in part by the Stanford Center for Clinical and Translational Education and Research (known as Spectrum), which is supported by NCRR through its Clinical and Translational Science Awards (CTSA) program.

“Biodesign specializes in ‘inventorship’ — a new skill that can be refined and honed,” said Spectrum director Harry Greenberg. “At its heart, Biodesign is a program that teaches people to be inventors, and this effort has been immensely successful.”

**BREATHING NEW LIFE INTO OLD TECHNOLOGY**

When Matt Callaghan and a team of Biodesign fellows learned of the need for an affordable ventilator, they took matters into their own hands and invented one. Callaghan was a surgical resident taking part in pandemic planning at his hospital when he recognized that a more economical, more efficient ventilator could potentially save hundreds of thousands of lives.

The unique training program at Biodesign, with its systematic approach to invention and design, was the ideal place to bring such a product to life. Biodesign’s method moves product development through three critical steps: need identification, concept development and business planning. Biodesign fellows first spend time in clinical observation and study of a biomedical need.

“The innovation process starts purely with a detailed understanding of an important clinical need,” said Paul Yock, Biodesign director, leader of the Spectrum innovations and pilot units and co-lead of its core resources. “We say that a well-characterized need is the DNA of a good invention. This emphasis on finding and characterizing clinical needs up front is one of the most important differences between our training process and most research programs.”

Biodesign fellows design and build prototype devices with the potential to fill the identified medical gap. Callaghan’s prototype ventilator, called OneBreath, is less expensive than existing devices and easier for novice users to operate. It also is portable and effective, two crucial features for use in emergency pandemic situations, in rural areas and in the terrains of resource-poor countries. Until now, all of these features had not been found together in one device.

Manufacturing costs for OneBreath are estimated at $800 per unit, and the device features technology that emphasizes efficiency. Most ventilators use expensive air flow sensors and complex motorized equipment, but OneBreath can be constructed with just 12 parts instead of hundreds.

It uses a basic pressure sensor, like those found in blood-pressure meters, to measure air pressure and volume in a patient’s airway as a compressor forces air into the chest. Specially designed software interprets the data and directs the ventilator to supply air through a valve system. If a patient starts to breathe on his own again, the device supplies less air, which enables the patient to gradually recover and to fully breathe independently of the ventilator.

Callaghan discovered through field research in India and China that factors other than price must be considered when designing a ventilator for use in developing countries. “You can’t just de-feature existing medical equipment and sell a stripped-down version to each country. Patients are sick there like they are here, but conditions and resources are all different,” he said.
For example, in developing countries, ventilators often need to be carried into rural areas, and hospitals generally do not have staff trained to use the equipment. OneBreath was built for easy use, with a simple interface and instructions printed on the back. It can run on a 12-volt battery for up to 12 hours in case of a power outage, and because it is smaller than a toolbox, it can easily be carried long distances. These same characteristics also make OneBreath useful in large-scale disasters in more developed countries, such as the U.S.

Now a postdoctoral fellow at Biodesign, Callaghan is working with his team through final testing as OneBreath moves toward commercial release. With direct funding from the Stanford Coulter Translational Research Partners program, the Biodesign team is collaborating with business students to ensure that OneBreath will have the greatest impact when it makes the transition from the drawing board to the marketplace.

Yock has witnessed the success of the program’s multidisciplinary, team-based approach as innovative projects like OneBreath move from mere idea to manufactured product. “These projects simply would not have come into existence without the close interplay of engineers, physicians and business experts who together can help navigate the complex and difficult process of technology transfer in the biomedical field,” he said.

“CTSAs are designed to enable these types of connections,” said Anthony Hayward, director of NCRR’s Division of Clinical Research Resources, which oversees the CTSA program.

WALKING INTO NEW TERRITORY

Another Biodesign project team, led by Thomas Andriacchi, also has developed an important new medical device after responding to a request to design a low-cost prosthetic knee. High-end titanium knee joints can cost from $10,000 to $100,000. This cost is far beyond the reach of most of the world’s 20 million amputees. Four out of five amputees live in the developing world, and many of them are coping with the impact of war and diseases like diabetes. Looking for a way to help these patients, the Jaipur Organization, a nonprofit group based in India, asked Biodesign to create a low-cost prosthetic knee.

Andriacchi presented the idea as a project for mechanical engineering students in his Medical Device Design class and selected five students to compose the JaipurKnee design team. With additional funding from Jaipur Organization supporter Armand Neukermans, the design team developed, built and then tested a prototype prosthetic knee in just 20 weeks. The result was the JaipurKnee, a $20 prosthetic limb designed specifically for amputees in resource-poor countries, with a target market of India’s 1.65 million above-knee amputees.

Existing lower cost models were built on a single axis joint, like a door hinge, which often buckled under the weight of its wearer and were unstable when used on uneven terrain. The JaipurKnee has a self-lubricating joint for greater flexibility and is easier for patients to use because it is designed to mimic the natural motion of the human gait.

“The students were highly motivated, and the number of hours they put in far exceeded the credit hours they received,” said Andriacchi. In fact, two students from Andriacchi’s design group, Joel Sadler and Eric Thorsell, continued to push the JaipurKnee into manufacturing after the course ended. The students have since formed a company called re:motion designs, with the goal of scaling up production of the JaipurKnee in India. So far, they have distributed more than 2,000 knees to amputees. While the company is ramping up knee production in India, it is also adapting the design for use in other parts of the world.

Ari Chaney, Biodesign’s executive director for technical translation and program manager for the Spectrum innovations and pilots unit, credits CTSA support with enabling innovative projects like the JaipurKnee and OneBreath to successfully move from concept to application. “NCRR and Spectrum funding enables promising projects to prove their concepts while still in the academic setting,” said Chaney. “That’s valuable because it’s often difficult to successfully navigate from research to commercial success. Proving that the technology works with steps such as prototyping, detailed design and clinical testing enables these projects to attract support and external funding,” he added.

FORGING NEW COLLABORATIONS

The success of projects like OneBreath and the JaipurKnee has helped launch the Stanford Global Health Consortium for Innovation, Design, Evaluation and Action (C-IDEA), a new initiative of Stanford University that will integrate the efforts of four of Stanford’s global health programs. C-IDEA is funded by the American Recovery and Reinvestment Act through an NIH Director’s award.

“We will focus on innovative design of diagnostics, drugs and devices for global health that are scalable, have high impact, and can be implemented and commercialized,” said Michele Barry, Stanford’s senior associate dean for global health.

The efforts of Biodesign will continue to spur innovations for global health that otherwise might not exist.

—TRISHA COMSTI