Solving a big problem, among some of the littlest patients

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Credit: AI-generated image (disclaimer)

Each year in the U.S. some 200,000 babies, struggling to survive their early days in a neonatal intensive care unit (NICU), require umbilical cord catheters to take food and medicine. While these tiny tubes serve as a lifeline, they can also be a conduit for harmful bacteria to enter the bloodstream. The resulting infection, which affects roughly one in five

babies with an umbilical cord catheter, means a longer and more expensive hospital stay and a significantly increased risk of developmental delays, or even death.

It's the kind of challenge that industry sometimes balks at. It's critically important to the families, but the relatively small number of patients affected makes it hard for companies and hospitals to invest the extraordinary amount of time and resources required to find a solution. But a team of graduate students in the Stanford Biodesign Innovation course saw things differently. They recognized that these infections were largely preventable, and by leveraging Biodesign faculty expertise, university research funding and a group of dedicated Stanford students, they found a way to bring a technology forward that could improve the odds for these critically ill babies.

The course brings together graduate students in engineering, medicine and business to address real-world healthcare problems, and gives them the opportunity to do what universities can do best: Take on complex, high-risk challenges by marshaling resources from across an entire institution.

To start, the team, which consisted of bioengineering student Eric Chehab, medical students Carl Dambkowski and Brian Matesic, business students Jon Fritz and Julie Papanek, and Stanford-India Biodesign fellow Siddartha Joshi, dug into the research. They quickly learned that, unlike the pre-packaged, sterile devices that protect and support central venous catheters in older patients, which lie flat against the skin, umbilical cord catheters rise perpendicularly from the body and require NICU nurses to construct a support using bandages and tape. With this in mind, the team set out to develop a device that would reduce the likelihood of infection by better supporting and protecting the umbilical line.

Design challenges included keeping the insertion site open to permit the natural desiccation of the stump, and accommodating the unique morphology of an umbilical catheter. By the end of the course, they had developed an initial prototype: a small, semi-rigid, open dome that could be secured against the baby's skin.

Though this early concept was promising, it seemed unlikely it would ever reach patients. With the class over, most of the original student team moved on to other academic priorities. Even more daunting, the market for the device was too small to attract traditional venture capital funding to advance the project.

However, the need resonated with the team's advisor, James Wall, MD, a pediatric surgeon and assistant director of the Stanford Biodesign Innovation Fellowship. Wall decided to try using the resources inside Stanford University to develop the project as a technology with "high impact but not necessarily a large market value." He brought in Ross Venook, assistant director of engineering for Stanford Biodesign and a lecturer in bioengineering, and the two expanded the team and began to actively guide the project forward.

With support from the MedScholars research program and a Coulter Foundation Translational Research grant, the team developed a series of prototypes, performed biologic testing to measure protection from bacterial contamination and did mechanical testing to assess the performance of the design. "The fundamental need was to reduce infection rates, but it would take a long time and lot of money to run the studies we'd need to prove this to the FDA when seeking regulatory clearance," said Wall. "A more stable catheter is less likely to get infected, so we focused on that."

Added Venook, "Specifically, we sought to prevent pistoning—the vertical movement of the line that can introduce contamination into the

vessel. We also wanted to isolate the site to prevent the migration of bacteria from elsewhere on the skin or from caregivers."

The deep resources at Stanford helped the team progress. "We started our laboratory research with goat umbilical cords," said Wall. "Then, taking advantage of the fact that the engineering buildings are right near the hospital, we were able to get human umbilical cords from the obstetrics department."

Once the team had positive bacterial and mechanical test results, they turned their focus to the user. "Our goal was to offer the NICU nurses value by replacing the 'arts and crafts' approach of building a support with an easier-to-use, standardized solution, while hopefully reducing the most significant causes of infection," said Venook.

To better understand the unique needs of the NICU nurses and the neonates they care for, the team spent time at Lucile Packard Children's Hospital, traveled to conferences and sought input from other partner institutions, including the Children's Hospital of Los Angeles and UCSF-Benioff Children's Hospital, among others.

By this point Chehab had completed his Ph.D. in bioengineering and re-engaged full time with the new venture as its CEO. The meetings, he said, generated important insights that the team translated into product features, such as making one side of the device red and the other blue to make it easy to distinguish an arterial line from a venous line. They also attracted Stanford and external funding.

"It took more than five years and the efforts of a lot of dedicated people to make this solution viable," said Wall. "It is an incredibly important unmet need—literally saving premature babies. By utilizing a full range of university resources, including students, facilities and internal grants, we were able to develop the device to the point that it could attract

funding—which would never have happened using traditional methods—and it is now on a path to reaching patients within the next year."

Provided by Stanford University