Helping Newborns And Their Parents Breathe Easier

Rice University

Each year, millions of babies are born with an urgent struggle: breathing. It's particularly common for premature babies who don't have fully developed lungs, and one solution that can save lives is a machine called a bubble CPAP (which stands for "continuous positive airway pressure").

Originally developed more than 40 years ago, it's widely available throughout hospitals in developed nations. That's not the case in most developing countries, where the World Health Organization estimates that almost 800,000 neonatal deaths occur each year due to acute respiratory infections. A typical bubble CPAP machine can cost more than $6,000 dollars, placing it out of reach for low-resource facilities. That's changing, thanks to a low-cost bubble CPAP machine called Pumani (which means "breathe easy" in Chichewa, the national language of Malawi).

> *Initially developed at Rice University, this affordable, durable, and easy-to-use device has*

> *already proven it can dramatically improve infant survival rates.*

The idea behind Pumani emerged from Rice 360° Institute for Global Health Technologies — a program where Rice faculty and students develop low-cost health technology to address the needs of developing nations. As part of that program, students, and their advisors collaborate extensively with Queen Elizabeth Hospital in Malawi. As co-founder and director of Rice 360, Rebecca Richards-Kortum, Ph.D. visits the hospital three times a year and sees the resource challenges first-hand. "In the neonatal ward, you might find 60 or 70 babies with only two nurses to take care of them. And it's not uncommon to see up to four babies sharing a single bed," says Richards-Kortum, who is also Malcolm Gillis University Professor.

When Rice 360 participants asked clinicians to identify gaps in their ability to deliver care, the main request was the development of a robust, affordable bubble CPAP system. An air tube extends from the baby's nostrils to a column of water in the machine — the air flow in the system creates water bubbles, and the machine helps increase lung pressure and keeps airways open for lungs that haven't fully developed yet.

In 2009, a team of senior Rice undergraduate students began working on the problem, with initial funding from the Howard Hughes Medical Institute, the U.S. Agency for International Development (USAID), and the National Collegiate Inventors and Innovators Alliance (now called VentureWell). "We looked at the main components of a CPAP which provide pressure and flow — and tried to determine the best way to provide those in a low-cost, durable way," says Jocelyn Brown, who was part of that student team. After considering several off-the-shelf pumps and fans, the team discovered that aquarium pumps would work well for their prototype, which took about nine months to complete.

"I was still an undergraduate student, and I really had very little idea of what is actually required to bring a medical device to market," says Brown. "In my mind, it didn't seem like a possibility at the time." That changed after she went to Rwanda with other Rice students to meet with doctors in major hospitals and demonstrate the prototype. Then something unexpected happened: One of the hospital administrators tried to buy the prototype from the team. "It was very encouraging in a certain way, but also really evident to me that there was such a desperate need for equipment like this," she says. "That experience really showed me that there was huge potential for the device."

To help refine how the device would be designed and manufactured for a reasonable price, Rice University enlisted the services of 3rd Stone Design, a product design and development company. The San Rafael, Calif.-based firm had worked with the Rice 360 program on two previous projects. "Every now and then, students come up with something that isn't just a good student project, but is potentially a good product," says Robert Miros, founder of 3rd Stone Design.

Although he calls the students' use of the aquarium pump "a stroke of genius," the Pumani design changes included a different pump to maximize product durability. "We found that with aquarium pumps, sourcing might be problem to get the adequate amount consistent to our required specifications." The current pump is one that's commonly used in fountains "to keep them from getting slimy," says Miros. Data shows those pumps can run continuously for nine years, while the aquarium pumps might only last for a few years.

For a high-volume production unit, most companies invest in expensive tooling to make injection-molded parts, says Miros. Instead, 3rd Stone Design focuses on lower-cost tooling production methods. That includes sheet metal — which

makes the product heavier, but also more durable. “With higher-tech stuff, [the manufacturers] know it isn’t going to last forever, so they design that way. We’re designing something that will last five to 10 years in the field,” he says.

In 2013, Miros hoped that Rice would find a commercialization partner to license and produce the Pumani long-term — but he wasn’t keenly interested in that role. “There are global distribution challenges, and it costs a fair amount to develop it, and there are regulatory reviews and other additional overhead. Honestly, I was not certain it was a good fit for us."

He reached a turning point later that year, after visiting Queen Elizabeth Hospital and other clinics in Malawi. “There’s an extreme disparity between what you see there and what you might see in a U.S. hospital,” he says. "What they showed me was, with the Pumani hooked up, these babies are breathing and they're going to make it— without it, the chances are not as good. That really changed my attitude,” he says. “I decided we should figure out a way to do it. And it's worth any added headache and financial cost, because it really is going to have this tremendous impact."

The university’s Office of Technology Transfer (OTT) had discussions with several potential licensees before talks began in earnest with Miros’ firm in October 2013. "The licensing process was a bit different than most, in that we were working with a company that was aiming to produce and sell products in developing markets. The licensing structure and royalties were negotiated to facilitate entry into these low resourced markets,” says Andy Castillo, Licensing Associate, Biological Division at the Office of Technology Transfer.

By the end of May 2014, the device was exclusively licensed by Rice to Hadleigh Health Technologies, LLC., a subsidiary of 3rd Stone Design. “This is something that, frankly, is never going to make a tremendous amount of money,” says Miros. “The OTT was flexible and willing to consider variations on what is probably the standard formula for licensing,” he says. “And they were also able to realize that we are a smaller entity, and they were willing to hear me out on what was reasonable from our perspective, in terms of assurances and payments."

Hadleigh Health Technologies, LLC., also has assistance from one of the device’s creators: Jocelyn Brown, who works as product manager at the firm. "She spent two years living in Malawi, and I saw she was best person to have here as product manager, to help expand its presence in the world,” says Miros.

One study has already demonstrated Pumani's life-saving potential. Under a seed grant from USAID’s Saving Lives at Birth program, a clinical trial conducted at the Queen Elizabeth Hospital in Malawi showed that the device improved the survival rate of newborns with severe respiratory illness, from 44 percent to 71 percent. For babies with low birth weight and sepsis, survival rates more than tripled after treatment with the device. The United Nations has also taken note of Pumani. In September 2013, it named the device as one of 10 “Breakthrough Innovations That Can Save Women and Children Now.”

With funding from USAID, Pumani bCPAPs are now being placed in all government hospitals in Malawi, and units are also being distributed in hospitals in 12 other African countries, along with Pakistan, Indonesia, Haiti, and Cambodia. Hadleigh Health has received interest from more than 100 hospitals worldwide, as well as NGOs like UNICEF and Doctors Without Borders, says Miros. The units sell for no more than $800, and may even have potential customers in developed countries, he says. Although the initial market of Pumani will amount to hundreds of devices, Miros says that ultimately, it could encompass tens of thousands of devices — maybe even hundreds of thousands. His firm may

be able to support distribution to several countries, but Miros knows the need for a device like Pumani covers a wider territory. “To get to 100 countries, we may need to partner with a larger company.” he says.

It's not unusual for undergraduates to have good ideas about how to change the world, says Yousif Shamoo, Vice Provost for Research at Rice’s Office of Research. Fortunately, Pumani has moved far beyond the "good idea” stage. "A lot of times, good ideas don't go anywhere because there's not a network, or a framework, to bring them to market,” he says. "The role that tech transfer has is to give them the opportunity and the ability to get the technology out there."

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