# GLOBAL HEALTH

## Innovation Insight Series

Photo courtesy of AdaptAir

*One of the first young patients who received bubble CPAP using AdaptAir*

# ADAPTAIR: Developing and Commercializing an Accessory Versus a Stand-Alone Product

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## THE PROBLEM/SOLUTION SPACE

Acute respiratory infections are one of the leading causes of death worldwide among children under the age of five.[1] In the developing world, respiratory distress syndrome (RDS) is a particularly significant contributor to the mortality of pre-term neonates.[2] Infants with RDS are unable to adequately expand their lungs and take in air due to a deficiency of pulmonary surfactant, which is needed to reduce the surface tension of pulmonary alveoli. Additional causes of respiratory failure in babies and young children include other birth-related complications and infections, including pneumonia which kills an estimated 1.2 million children under the age of five every year—more than malaria, tuberculosis, and AIDS combined.[3]

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In developed nations, infants and children with respiratory infections are routinely treated with mechanical ventilators (among other interventions), but this technology is too expensive for widespread use in resource-constrained settings. Bubble CPAP (continuous positive airway pressure) is one alternate approach that can be made available at roughly 15 percent of the cost of the most economical commercial ventilators.[4] Bubble CPAP devices deliver humidified air with a high oxygen concentration to the nose through a pressurized breathing circuit and nasal prongs to enable more effective oxygenation of pulmonary alveoli. Although it is not widely accepted as the standard of care for children with pneumonia and other respiratory infections, this approach has been used successfully for over 35 years in certain areas. It has the potential to be more accessible to low-resource healthcare delivery providers than ventilators due to its affordability. Unfortunately, awareness of this approach is not widespread and caregivers in these environments typically administer high-flow oxygen to patients without bubble CPAP.

Photo courtesy of AdaptAir

*The AdaptAir device*

## ABOUT ADAPTAIR

In 2011, Alejandro Palandjoglou, David Janka, Elizabeth Zambricki, and Neil Mehta enrolled in the Stanford University course Entrepreneurial Design for Extreme Affordability, which provides students with project-based opportunities to design solutions to address specific needs of the world's poor. Early in the course, Palandjoglou and his teammates needed to select a project to work on with a partner organization. They were particularly moved by the presentation made by a representative from icddr,b, an international health research organization located in Bangladesh, concerning the toll of pediatric respiratory infections on childhood mortality. Accordingly, they signed on to help develop improvements to the many bubble CPAP systems being used at the icddr,b hospitals.

Shortly thereafter, Janka traveled to an icddr,b hospital in Dhaka, Bangladesh to perform first-hand needs finding on the team's behalf. In the intensive care unit (ICU), he observed doctors and nurses examining the water bottles at the end of the CPAP systems, which were used to help generate pressurized airflow. If they did not see bubbles in a water bottle, caregivers would bend down, putting their ear next to the patient's face, to try to listen for a leak between the nasal interface and the baby's nose. In wealthy nations, providers have access to customized nasal interfaces of multiple sizes to secure a tight seal. In the developing world, more often than not, providers must depend on nasal cannula of a single size use on their pediatric patients, making an effective seal unlikely.

Janka spent significant time with Dr. Md Jobayer Chisti, head of the ICU in Dhaka. If Dr. Chisti discovered a leak, he would simply press on the child's nose to create a tighter fit with the nasal cannula, after which the water in the bottle attached to the CPAP system would immediately begin bubbling. Unfortunately, it was impractical for Dr. Chisti and his colleagues to ensure effective therapy in this way. Nurses and other caregivers used tape in attempts to tighten the seal between the nasal interface and the patient's nose, but these workaround solutions were inadequate and potentially dangerous (too much pressure could damage a child's nasal septum). Janka, Palandjoglou, Zambricki, and Mehta were struck by the apparent simplicity of what needed to be achieved to ad-

dress this widespread problem, and they dedicated themselves to creating a solution that would emulate "Chisti's fingers," reliably and affordably. Dr. Christi informed the team that if they could design a solution he would be willing to test it in a clinical trial. "This was the best motivation we could have had," recalled Palandjoglou, "the opportunity to create something meaningful to help these babies."[5]

## ONE CHALLENGE: DEVELOPING AND COMMERCIALIZING AN ACCESSORY VERSUS A STAND-ALONE PRODUCT

Back at Stanford, the team began translating the information collected during needs finding into design requirements in parallel with brainstorming potential solutions. Early in this process, the team had an important insight. Despite the limitations of the existing bubble CPAP equipment used in many low-resource settings, most hospitals could not readily afford to replace these devices. The team determined that the simplest, least expensive solution they could design would be an adapter that enhances the performance of existing equipment. "We didn't want to change their whole setup," said Palandjoglou. "We didn't want to change their hose, their mask. So, we knew that we wanted to create an add-on solution."

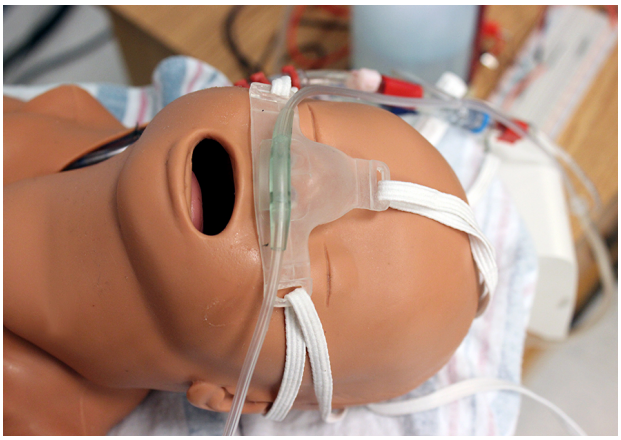

Photo courtesy of AdaptAir

*Testing the device in the simulation lab at CAPE*

Based on this direction, the team conceptualized dozens of approaches for tightening the seal between different-sized nasal cannulas and an infant's nose. They experimented with plaster and Play-Doh, using each other's noses as models, to create some of their first crude prototypes. From there, drawing on his background in industrial design, Palandjoglou took the lead in creating more sophisticated designs that leveraged low-cost materials. He collaborated with the Engineering School and used fused deposition modeling (FDM) to refine prototypes and then tested them at Stanford's Center for Advanced Pediatric Education (CAPE), a simulation center for pediatric care at the Lucille Packard Children's Hospital. After collaborating with nurses, respiratory therapists, and pediatric critical care physicians, Palandjoglou and his team finalized a prototype composed of silicone.

When they sent the add-on prototype to Dr. Chisti for his feedback, Palandjoglou recalled, "He was really happy about it. He shared it with his team and they said, 'Oh yeah, we understand it. We just plug that into the nasal cannulas we already have and it's really cheap.' We knew that we had something because they were asking, 'Okay, how much is it going to cost? And how soon can we get it?'"

Over the summer, Palandjoglou's team secured just enough grant funding to return to Dhaka to test its designs. Under Dr. Chisti's supervision, they were able to test the device, first on healthy infants and then on a small number of babies in the ICU. Through this field testing, they made significant enhancements to their innovation, ultimately designing a one-size-fits-all adapter with one end that fit the generic nasal prongs of available bubble CPAP machines and the other end that had flexible, tapered cones able to fit a wide range of pediatric nostril sizes to create a strong seal.

Despite an enthusiastic reception by physicians in Bangladesh and encouraging results from AdaptAir's early tests, the team encountered new barriers at this stage of the project. Janka, Zambricki, and Mehta had all accepted full-time jobs, leaving most of the responsibility for moving forward to Palandjoglou. He remained committed to AdaptAir, but was busy working on contract design projects to make ends meet. "Sometimes I can spend 50 hours per week on the project, and sometimes I can only spend five," he noted.

Palandjoglou and his teammates, who continued contributing to the effort as they could, considered establishing a company to further develop and commercialize AdaptAir. However, the challenge of raising funds for an accessory device that would be priced at just a few dollars per unit was daunting. Manufacturing was not a problem, as the device was composed of a single material and one simple process: injection molding. The issue was the cost of developing the infrastructure needed to sell and distribute the device, and the sales volume needed to recoup that investment. Moreover, because bubble CPAP still was not considered the standard of care for pneumonia and other respiratory infections in many locations, clinical trials would be needed to prove its effectiveness as a safe and efficacious alternative to mechanical ventilation. Investors worried that without more widespread acceptance, the AdaptAir device would not achieve market penetration. Dr. Chisti was actively conducting a study on bubble CPAP, but because it was already underway he could not change the protocol to incorporate AdaptAir (such a change would invalidate the results collected to date). He intended to run another a trial using AdaptAir, but he would not be able to initiate it until after the current study concluded in late 2013. Palandjoglou was negotiating with other hospitals to conduct clinical trials and had an agreement in place to initiate a study with a hospital in Malawi (comparing bubble CPAP treatment in patients with and without AdaptAir). But he needed to raise funding to support that study.

Photo courtesy of AdaptAir

*Dr. David Janka, Dr. Md Jobayer Chisti, and Alejandro Palandjoglou*

Licensing seemed like a more feasible alternative for getting AdaptAir to market, so Palandjoglou began investigating potential licensors in parallel with these other activities. "I met with a representative from one global medical equipment manufacturer and he was really excited. I gave him a sample and he took it to his team [in India]. I had a phone meeting with the bigger team and they said they were really interested in selling the device along with their CPAP machines. The thing is, they want me to give them the market-ready device with their packaging and they'll take care of the sales. I would have to take the product through clinical testing and regulatory approvals, which is time consuming and expensive to do." Palandjoglou proposed turning over the technology to the manufacturer in its current state of development, but the team implied that it would likely get lost inside such a large organization with competing priorities. "And it would be easier if I took it forward and sold it to them when it was ready to go," he added.

## THE SOLUTION: PATIENT PERSEVERANCE IN IDENTIFYING A LISCENSING PARTNER

As of early 2013, Palandjoglou and the AdaptAir team had not yet devised a concrete solution to their challenge. "I think what we're struggling with is how to achieve the goal of licensing the product the fastest," Palandjoglou said. "With AdaptAir, we wanted to keep the design really simple. Our concept was so strong that doctors and nurses were captivated from the start. They loved that this was an add-on device, which made their current set-up as effective as one that you'd find in a well-resourced hospital in a developed country." Reflecting on the innovation process, he added, "When we were designing AdaptAir we thought about the option of creating a stand-alone product that replaced the nasal cannula completely, but that idea was left aside because it would increase the parts and cost. The team also focused on immediate impact and that is where AdaptAir offers a major benefit. Having this small adapter that plugs into the prongs of a nasal cannula is so easy and intuitive, and it produces results instantly. But having a simple medical device doesn't mean the road for bringing it to market will be easy."

*They loved that this was an add-on device, which made their current set-up as effective as one that you'd find in a well-resourced hospital in a developed country.*

At the same time that he pursued licensing options, Palandjoglou continued to refine his design and move it closer to the market as time and financing allowed. For instance, team members understood that they would need CE Mark certification to commercialize the device in their target markets, so they were investigating what resources would be needed to achieve that milestone. In addition, he reported, "I'm talking with other physicians about testing the device, mainly in observational studies." Palandjoglou was optimistic that these efforts would get him one step closer to identifying a partner to take AdaptAir to market.

### NOTES

1 Global Disease Burden, World Health Organization, 2004, http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_part2.pdf (February 5, 2013).

2 Neonatal Mortality from Respiratory Distress Syndrome: Lessons for Low Resource Countries," Pediatrics, May 2, 2011, http://pediatrics.aappublications.org/content/127/6/1139.full.pdf (February 5, 2013).

3 "Pneumonia Fact Sheet," World Health Organization, November 2012, http://www.who.int/mediacentre/factsheets/fs331/en/ (February 6, 2013).

4 "Continuous Positive Airway Pressure," MANDATE: Maternal and Neonatal Directed Assessment of Technology, http://mnhtech.org/technology/technology-briefs/continuous-positive-airway-pressure/ (February 5, 2013).

5 All quotations are from an interview with Alejandro Palandjoglou conducted by the authors, unless otherwise cited.

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