

GLOBAL HEALTH

Innovation Insight Series



A mother and child in the ICU of a government hospital in Benin City, Nigeria

Photo: Ben Cline

BRILLIANCE I: From Prototype to Product Company

D-REV, STANFORD, CALIFORNIA

ESTABLISHED 2007

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THE PROBLEM/SOLUTION SPACE

Globally, 60 percent of all newborns experience infant jaundice each year.¹ Jaundice manifests as a yellowish appearance to the skin and sclerae (the whites of the eyes) caused by hyperbilirubinemia, or excess levels of the chemical bilirubin in the bloodstream. Bilirubin accumulates if a baby's liver cannot remove it from the blood fast enough due to immature liver function or other underlying conditions.

In most infants, jaundice resolves naturally; but for approximately 12 percent of babies, the condition requires treatment.² In the U.S. and other first world nations, infant jaundice is routinely treated with phototherapy—shining blue light of a specific wavelength

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and intensity on the baby's skin for two to three days. The blue light causes chemical reactions within the bilirubin molecules that enable the body to excrete bilirubin harmlessly into the urine and stool.

Without medical intervention, however, jaundice can result in learning disabilities, brain damage, deafness, and even death. Every year in South Asia and Africa, more than 5.7 million newborns with jaundice do not receive the simple treatment they need due to the lack of effective phototherapy solutions in these low-resource settings.³ Newborn jaundice and complications caused by the condition account for an estimated 6-10 percent of neonatal mortality worldwide.⁴

ABOUT D-REV AND THE BRILLIANCE PROJECT

When team members at D-Rev—a U.S. nonprofit technology company with the mission to improve the health and incomes of people living on less than \$4 per day⁵—became interested in the problem of infant jaundice, they initiated a detailed assessment of the phototherapy landscapes in India and Nigeria. From that work, D-Rev confirmed that

jaundice was a challenge in rural areas, where equipment to treat the condition was virtually nonexistent. But the team discovered that the situation was also problematic in urban hospitals and clinics in those countries. In these settings, phototherapy equipment was typically available, but a full 90 percent of the devices evaluated by D-Rev (in collaboration with the Stanford School of Medicine) were ineffective.^{6,7} The vast majority of solutions designed for these low-resource settings failed to meet international quality standards and offered suboptimal performance. Some healthcare providers even relied on homemade solutions that were not only unproductive but dangerous to the infants that they were intended to treat. Another factor that rendered phototherapy solutions ineffective in these settings was the cost to operate and maintain them. In D-Rev's re-

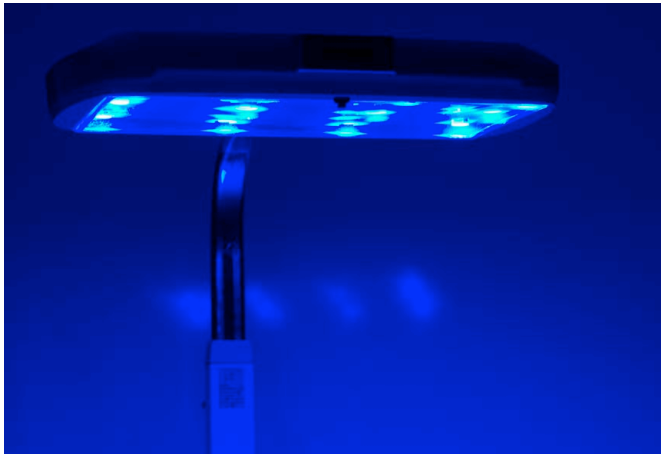


Photo: D-Rev

D-Rev's prototype device featured a high-intensity LED light source that consumed less power and cost less to maintain

search, one out of three devices had at least one bulb missing or burned out, for instance, with many healthcare providers unable to reliably procure or afford replacements.⁸

To address these challenges, the D-Rev team created a prototype for a jaundice treatment product that they called Brilliance. The new phototherapy solution used a high-intensity LED light source that consumed less power than devices with compact fluorescent bulbs (the current standard) and lasted significantly longer. Early test results also revealed that the technology had the potential to perform on-par with or better than state-of-the-art phototherapy equipment.

ONE CHALLENGE: FROM PROTOTYPE TO PRODUCT COMPANY

Energized by its technical solution, the D-Rev team was eager to press forward. However, they faced challenges as they planned to transition from a team with a prototype to a company with a market-ready product. First, they needed to raise additional funds for

product development. Unfortunately, jaundice was not a top priority for many funders. According to Krista Donaldson, D-Rev's CEO, "The global health community really makes decisions about its priorities based on academically rigorous, published data. This can be difficult to get in developing countries, but especially for a condition like jaundice. With so many babies born at home, an infant might have the condition but the mother never takes him in for treatment. And the child may seemingly recover but end up with a learning disability or cerebral palsy even though no one ever knows it's linked to jaundice. So it's hard to know the full attribution of the disease."⁹

For the funders who did recognize jaundice as a priority, the field was crowded with opportunities to support emerging technologies. "There are multiple phototherapy devices in the social space. And I think it's because people have the inaccurate perception that it's a fairly easy device to design," Donaldson noted. In reality, the effectiveness of different technologies varied significantly, and funders did not always have the depth of technical expertise needed to identify the best solutions.

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Finally, D-Rev had observed that many funders were enthusiastic about underwriting early-stage concept design and prototyping, but less eager to back the more painstaking, time-consuming, and tedious work involved in product development and preparing a solution for manufacturing and commercialization. "People love prototyping and the really cool 'silver bullet' science and technology that goes into solving a problem. But at the end of the day, we need to find people who are also willing to support good old-fashioned engineering. That's not the sexy part to fund," Donaldson explained. "You can deliver a prototype and a really nice story in about a year," added Jayanth Chakravarthy, product manager for Brilliance. "But to make a real product, you need to invest two years at least. It's a lot of work and there's no immediate gratification. You have to wait for it."

In addition to these funding hurdles, Donaldson, Chakravarthy, and the rest of the team needed to figure out how they would get the product to market. Among other issues, they had to define a preliminary customer for the device, ensure the product met the unique needs of this audience, and craft a business model for manufacturing, selling, and distributing the product that would be realistic and sustainable in the long run.

THE SOLUTION: DEVELOPING A HOLISTIC PRODUCT STRATEGY

At this point, D-Rev mapped out a holistic product strategy. The team would use this plan as a roadmap to bring Brilliance to market.

To address its funding needs, the organization decided to focus on a series of unrestricted grants from smaller, more agile foundations rather than pursue contributions from major foundations. These smaller funders were able to make funding decisions more quickly, and were often more flexible in terms of how their grants could be used. Funding from larger funders frequently was restricted in such a way that it could limit D-Rev's ability to respond to unexpected challenges and opportunities when getting the product to market. D-Rev also discovered that smaller funders were more open to supporting innovative approaches to addressing global health needs, while larger organizations tended to limit themselves to more traditional models for international development, which was not a good fit for Brilliance.

In terms of the market, D-Rev determined that the team would initially focus where they perceived the need to be most urgent—providing a phototherapy solution to district-level and larger hospitals in India with neonatal intensive care units (NICUs). These hospitals, which might be in rural or urban environments, treated a relatively high volume of infants each year due to births at their own facilities, as well as the jaundiced babies who were referred to them by other healthcare providers in their surrounding areas. By targeting these providers, D-Rev believed it would address a significant need and have the greatest possible impact on the problem.

Additional research with physicians at approximately 40 target hospitals revealed that these doctors needed a phototherapy device that would allow them to address multiple conditions simultaneously. For example, a jaundiced pre-term baby might also be on a ventilator. “The physicians are dealing with complex health conditions in a stressful environment, so they need a solution that’s durable, versatile, and fits well with other medical devices,” Donaldson said. “Babies outside the NICU don’t need a lot of other treatment, so these providers can use a much simpler, smaller device that just addresses the problem of jaundice.” This observation had a significant impact on the final design for the initial Brilliance product.

Physicians in district hospitals also clearly communicated to D-Rev that quality was a top priority. “They told us time and time again that they didn’t want a new, silver bullet technology. What they want is technology that meets the same safety and effectiveness standards that we have for the phototherapy devices we use in Western hospitals, at a price they can afford,” Donaldson said. Accordingly, D-Rev committed itself to developing a product for low-resource settings that would meet American Academy

of Pediatrics recommendations—the gold standards for phototherapy devices. In addition, the team was determined to make the product available at a fraction of the \$3,000 price tag for state-of-the-art equipment.

The team’s ability to make Brilliance affordable would depend heavily on the business model it devised for manufacturing, sales, and distribution. “I feel like our space is littered with good intentions and great ideas that aren’t sustainable because so many people overlook the business model,” Donaldson commented. Toward this end, D-Rev evaluated its own competencies and concluded that the organization’s strengths were not in product manufacturing or after-sales services, and that it did not have the vast expertise and connections needed to establish a sales and distribution network in India. “We knew that we needed to license in this case,” said Donaldson. “We felt like that was the best model for economic sustainability and for having a huge impact.”

Choosing the right partner was essential, and D-Rev ultimately entered into an agreement with Phoenix Medical Systems, an Indian for-profit company with a well-established presence in the infant and maternal care field. Donaldson and team invested



Photo: D-Rev

D-Rev engineer Ben Cline, who started the Brilliance project, getting feedback on an early prototype from a neonatologist in New Delhi

substantial time in negotiating a novel licensing agreement that provides a reasonable revenue stream for both organizations, while encouraging Phoenix's sales representatives to target D-Rev's top priority customers for the device through a variable incentive structure. In addition, Chakravarthy and his engineers dedicated significant time and resources to making sure the device could be manufactured at an affordable cost, and that checks and balances were in place to guarantee that defined quality standards were met.

Together, D-Rev and Phoenix were able to produce a market-ready product that consumes half the power of existing phototherapy units, with LED bulbs that last 16 to 25 times longer than compact fluorescent alternatives. Brilliance is height-adjustable, with a tiltable head and locking wheels, and can be seamlessly integrated with other hospital equipment. It also meets American Academy of Pediatrics recommendations and UNICEF phototherapy specifications and has been shown in benchtop tests at Stanford to perform as well as (or better than) the most expensive equipment used in Western NICUs. "But I think the thing that really makes it different is the cost," said Donaldson. D-Rev and Phoenix agreed to cap the selling price of Brilliance based on the cost of goods sold to ensure affordability in emerging and undercapitalized markets.¹⁰ With this model, they hoped to make the device available for roughly \$400 per unit. Brilliance was scheduled to launch in mid-2012 and the partners had a goal to treat 2 million babies in India by 2016. ♦

NOTES

- 1 Jaundice, Centers for Disease Control and Prevention, <http://www.cdc.gov/breastfeeding/disease/jaundice.htm> (September 11, 2012).
- 2 "Brilliance: Need," D-Rev, <http://d-rev.org/projects/brilliance/need.html> (August 8, 2012).
- 3 B.K. Cline, et al., "Global Burden and Unmet Need for Hyperbilirubinemia Treatment," http://www.d-rev.org/assets/2011_PAS_Global_Unmet_Need_for_Phototherapy.pdf (September 11, 2012).
- 4 "Project Firefly," Design That Matters, <http://designthatmatters.org/portfolio/projects/firefly/> (June 14, 2012).
- 5 "About Us," D-Rev, <http://d-rev.org/about.html> (August 8, 2012).
- 6 B.K. Cline, R.E. Daly, K.M. Donaldson, et al, "Evaluation of Phototherapy Device Efficacy in Resource-Limited Nurseries," Pediatric Academic Societies. Abstract, poster 1496:535, 2010.
- 7 B. K. Cline, H. J. Vreman, K. Faber, H. Lou, K. M. Donaldson, E. Amuabunosi, V. K. Bhutani, B. Olusanya, T. Slusher, "Phototherapy Device Effectiveness: Performance Assessment in Nigeria," publication scheduled for 2013.
- 8 B.K. Cline, R.E. Daly, K.M. Donaldson, et al, op. cit.
- 9 All quotations are from interviews with Krista Donaldson and Jayanth Chakravarthy of D-Rev unless otherwise cited.
- 10 "Delivering Brilliance to Hospitals Across India—And the World," D-Rev, <http://www.d-rev.org/projects/brilliance/delivery.html> (August 9, 2012).