Implications of a Novel Fast, Portable Treatment for Neonatal Jaundice

Little Sparrows Technologies
Big ideas for little babies

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Introduction

Much of the innovation in medicine comes when doctors, during their regular duties, spot opportunities to deliver treatments more effectively and in the process transform care and cut costs. Little Sparrows Technologies founder Dr. Donna Brezinski, a Harvard-trained neonatal specialist, noticed that jaundice treatment in newborns led to additional days in the hospital, interfered with maternal-newborn bonding, and ultimately cost more money than was necessary.

The treatment for jaundice was fairly straightforward and most of the babies were otherwise healthy. Did treatment need to occur in the hospital? Could the process be faster? And did it have to be so expensive?

The risks of elevated bilirubin

If left untreated, high levels bilirubin can cause permanent neurologic damage to newborns resulting in such conditions as cerebral palsy, deafness and vision impairment.

The Effects of Jaundice

10% of newborns require intervention to prevent brain injury risk from jaundice

Neonatal jaundice affects three out of five newborns in their first weeks of life. The condition arises from abnormally high blood levels of bilirubin, a waste compound produced when the liver breaks down old red blood cells. Jaundice causes a yellow discoloration of the skin and eyes and typically subsides within a few days for most newborns.

Although elevated bilirubin levels are normal in the first week of life, in roughly 10% of newborns the level rises high enough to require medical intervention. Left untreated, high bilirubin levels can lead to permanent brain damage, cerebral palsy, deafness, impaired vision, and even death.

Fortunately, there is a safe and surprisingly simple treatment: blue light. A specific wavelength of blue light, at a sufficiently high intensity, breaks down the bilirubin in the infant's skin into harmless water-soluble waste that is easily eliminated by the body. Each year in the US approximately 400,000 infants will require phototherapy to treat high bilirubin levels.

Readmissions Separate Mother and Baby, Lead to High Costs

Neonatal jaundice typically occurs in the first week of life and about half of affected infants are already home from the hospital when they are diagnosed. This results in as many as 200,000 readmissions for jaundice annually. Neonatal jaundice is one of the top causes of readmissions in newborns in the US, responsible for more than 1/3 of all rehospitalizations in the first month of life.

Jaundice readmissions can cost up $10,000 per hospital stay, representing an estimated $1.5 to $2 billion in healthcare costs each year. Moreover, readmission separates the mother from her newborn at a crucial time and can disrupt both bonding and breast-feeding.

Treatment

Blue light phototherapy is first-line treatment

The American Academy of Pediatrics (AAP) recommends high-intensity phototherapy as the first-line treatment for neonatal jaundice. This requires as much of the infant's skin as possible tone exposed to intense blue light until bilirubin returns to a safe level.

This process most often occurs in an incubator in a neonatal intensive care unit (NICU). The incubator setup and the intense light used in phototherapy can be a disconcerting sight for new parents, and extended hospital stays are stressful for both parents and newborns.

Smaller, portable phototherapy devices, which are meant to allow at-home treatment, are not nearly as effective as the NICU devices. For this reason, the AAP says that these devices are not suitable for treating babies with complicated or more advanced cases of jaundice.

A New Treatment Option

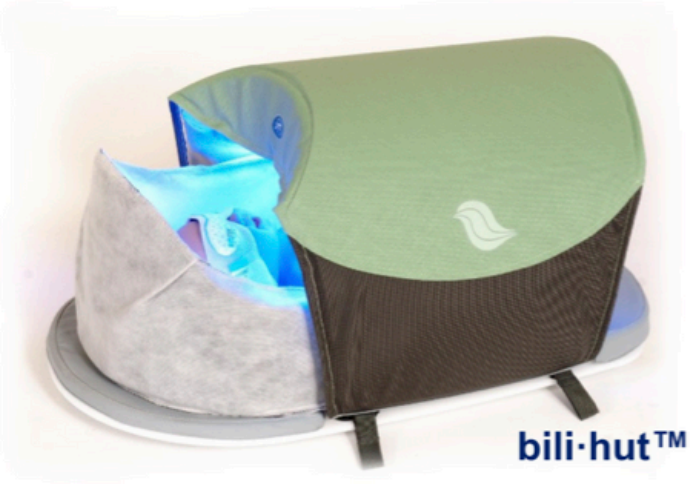
This is where Dr. Brezinski noticed a gap in the market for phototherapy devices. There was a clear need for a highly effective, portable treatment that could prevent an expensive NICU admission and didn't separate a mother from her newborn. Ideally, such a device would also be scalable for global use, providing an effective jaundice treatment accessible even in remote areas.

To address this need, Dr. Brezinski founded Little Sparrows Technologies, which aims to transform neonatal jaundice treatment with **bili·hut™**, an award-winning, FDA-cleared phototherapy device providing hospital-intensity phototherapy at the mother's side. The device is simple to use, collapsible for easy transport, and energy-efficient enough to be capable of operating on battery power.

Innovative Design

Breakthrough curved light design treats more skin surface area

The bili·hut features a unique, flexible, LED-illuminated canopy that is curved to form an arc of light enveloping the baby and delivering high-intensity phototherapy treatment to 50% more of the infant's skin than leading hospital devices. In addition, the semi-enclosed design reduces heat loss, eliminating the need for an incubator during treatment for most babies.



This design also prevents light from leaking into the room, a bonus for nurses and parents who are sensitive to blue light exposure which can cause headaches and interfere with sleep.
Weighing less than 9 lbs with a compact footprint, bili·hut is easy to set up next to the mother whether in her postpartum room or at home.

bili·hut phototherapy surrounds the baby in a cocoon of healing light that treats 50% more skin area than competing hospital devices

Real-World Results

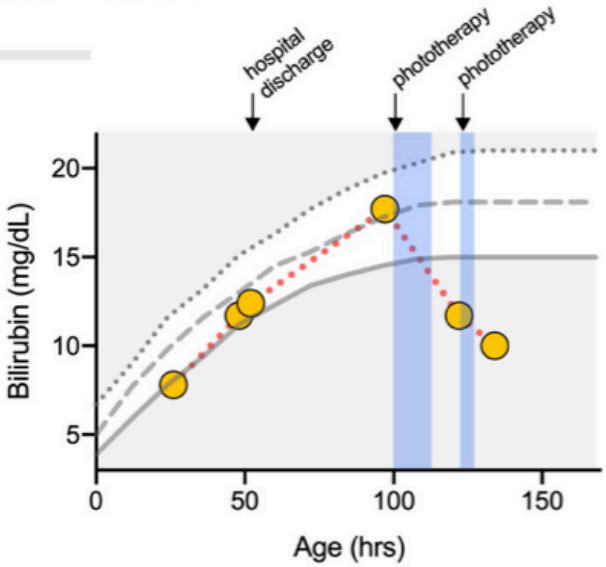
High Efficacy in a Small Package

With its breakthrough design, bili·hut is the first device to enable ultraportable, full-body LED phototherapy treatment. The first series of results using bili·hut in home treatment of jaundice show treatment times often less than 24 hours, two times faster than the reported inpatient treatment time of Natus neoBLUE®, the current NICU-based market leader, and more than four times faster than GE BiliSoft™, the current leader in the portable market. Field-testing of bili·hut prototypes in resourced-challenged areas of Africa and South America has also reliably shown high efficacy, with most inpatient treatments completed in 1 to 2 days, compared to 4 or more days with other devices. This has proven to be very helpful in reducing the burden on healthcare workers in hospitals that have been overwhelmed during the coronavirus pandemic.

Infant receiving bili·hut phototherapy home treatment at parents' bedside. (Photo used with permission.)

Case Study

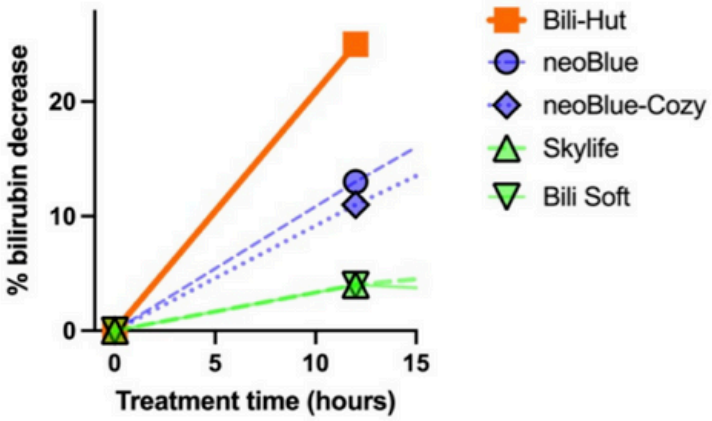
Preventing Neonatal Jaundice Readmission



Successful home treatment of a case of neonatal jaundice complicated by blood-type incompatibility. Baby A had blood-type incompatibility with the mother leading to rapid destruction of red blood cells and increase in bilirubin. Infants with this type of jaundice are most often treated in the NICU. The dotted red line (trend) and yellow circles (bilirubin level) denote the course of Baby A's bilirubin levels over time. The gray dotted, dashed, and solid lines define bilirubin level treatment thresholds for low-, medium- and high-neurotoxicity risk, respectively. (The presence of blood type incompatibility placed this patient in the medium risk category and treatment was started at 100 hours of age when the bilirubin level crossed this threshold.) The blue striped areas mark times when the infant received bili·hut phototherapy treatment. Despite the complication of blood type incompatibility, the bilirubin level dropped rapidly with home treatment of only about 16 hours duration. (The pediatrician caring for the baby opted for a second, short treatment to ensure levels did not trend up again.)

Comparison to Competing Technologies

Phototherapy with bili·hut helps newborns recover faster from jaundice



In this series of **9 bili·hut home jaundice treatments**, the percent bilirubin decrease over time for infants treated is compared to reported rates with inpatient treatment using neoBLUE® and neoBLUE® cozy (Natus), Skylife™ (NeoLight) and BiliSoft (GE) phototherapy devices. In contrast to home care with bili·hut, competitor device data is from hospital studies where infant placement and device use was performed by nurses. On average, home treatment with bili·hut was completed in 12 hours, while inpatient treatment with other devices required more than 24 hours.

Quality Improvement

Rethinking the phototherapy clinical pathway

The efficacy and ease of use of bili·hut™ create an opportunity to rethink jaundice treatment, both at home and in the hospital. Phototherapy treatment with bili·hut™ will enable infants to remain at home after they have been discharged and eliminate the need for readmission to the hospital. This will allow the infants to bond with their mothers and establish breast-feeding.

In addition, since the efficacy of bili·hut is greater than that of devices currently used in the NICU, the use of bili·hut in the hospital will eliminate the need to transfer infants to the NICU, allowing infants to remain at their mother's bedside in the postpartum room. Many jaundiced infants could complete treatment in less than one day, resulting in shorter hospital stays and lower costs.

Advantages for Payers, Providers, and Parents

Phototherapy treatment with bili·hut creates potential for significant savings by lowering cost of jaundice management throughout the care pathway including reductions in outpatient encounters, emergency room visits, lab testing and hospital readmissions. With these advantages in mind, third party payers can incentivize home treatment of jaundice, with substantial savings for them. For cases of jaundice diagnosed before the infant has been discharged from birth hospitalization, bili·hut also allows better allocation of healthcare personnel and frees valuable incubator space in NICUs for infants with more urgent conditions. For example, treating the baby next to the mother in the postpartum room reduces cost and improves hospital workflow by allowing the mother-baby pair to continue to be cared for by one nursing team, as opposed to separating them which would require two teams. In addition, since incubators can take as long as 90 minutes for a hospital worker to clean and sanitize between patients, such valuable personnel resources could be utilized elsewhere.

New Revenue Streams for Outpatient Providers

Pediatricians can treat jaundice with a bili·hut device that is owned or leased by the practice, with positive impact on earnings. They will retain care of their jaundiced patients, realizing that revenue instead of transferring to a hospitalist. Further financial benefits may accrue to practices that are part of a value-based system when they meet utilization benchmarks, with savings from reduced hospitalizations reverting to the practices.

Home healthcare agencies will benefit by adding jaundice phototherapy to their other service offerings. The NICU-level efficacy of bili·hut phototherapy will drive outpatient jaundice home care referrals. Rapid treatment with bili·hut allows for faster turnover of devices, translating to a reduction in capital equipment cost since fewer units will be needed to meet demand.

bili·hut creates potential for significant cost savings across the board...

About Little Sparrows Technologies

Founded in 2013 by two Harvard Medical School-affiliated doctors, Donna Brezinski MD and Gary Gilbert MD, Little Sparrows Technologies offers an innovative approach for the treatment of neonatal jaundice. In addition to the bili·hut™, the company offers additional products for the treatment of jaundice including the bili·ruler™ jaundice screening device.

Awards and Recognition

Little Sparrows Technologies has been recognized with numerous awards and distinctions. The company received a 2018 Patents for Humanity Award from the US Patent and Trademark Office. The World Health Organization has included bili·hut in its Compendium of Medical Devices for Global Health.

Little Sparrows Technologies was the recipient of a 2014 Saving Lives at Birth grant from the United States Agency for International Development (USAID) and the Bill & Melinda Gates Foundation, as well as Phase I and Phase II SBIR grants from the National Institute of Health. The company was also a 2013 global finalist in the MassChallenge Accelerator program.

For more information about Little Sparrows Technologies and bili·hut phototherapy please visit www.littlesparrowstech.com or email us at info@littlesparrowstech.com

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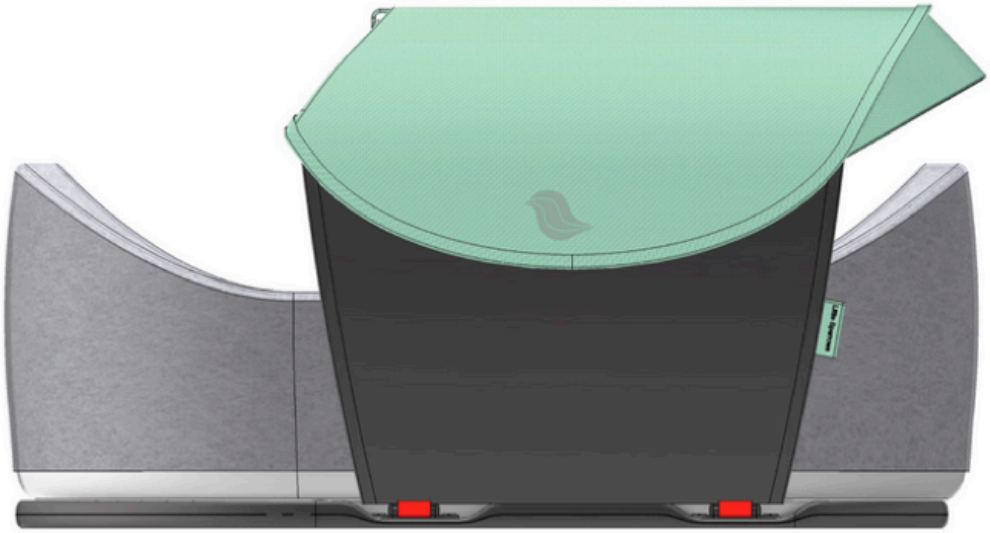

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