The Unmet Need and Idea

Our substance abuse epidemic is tragically impacting our newborns and disproportionately poor families. Called neonatal abstinence syndrome or NAS - it is the fastest growing infant health problem of this decade. NAS patients suffer from tremors, low birth weight and struggle to eat, sleep and relax. From '04 to '13 the rate of NICU admissions for NAS quadrupled and this year an estimated 50,000 NAS infants will be treated at a cost of more than $3 billion.

On the front lines, neonatal nurses are overburdened caring for these infants and administrators are struggling to find the resources to provide quality care with mostly capitated payments. Almost every State is tracking the incidence of NAS and looking for solutions to improve care and reduce costs. Meanwhile, much of the Federal Government spending on the opioid epidemic is for adult prevention and recovery with medication-assisted treatment (MAT).

Conversely, recommendations from HHS agencies and the GAO prioritize non-pharmacological treatments for NAS infants. Unfortunately, the most cited non-pharmacological treatments (swaddling, frequent feedings and skin to skin contact) all require significant human resources. To illustrate, Boston Medical Center utilizes 150 volunteers working in 2 hours shifts to cuddle and console their NAS patients. Because, not every facility or home to a NAS infant has readily available volunteers, what is needed is a clinically proven, non-pharmacological product used during withdrawal and post-withdrawal that consoles NAS infants to help them eat and sleep.

To address their need, hospitals use consumer baby products with mechanical motors to swing, sway and vibrate NAS infants. And while the soothing effects of vestibular and vibro-tactile stimulation on infants has been studied for decades, very few studies have been completed on NAS infants. More importantly, there is little evidence to suggest that consumer companies are developing or evaluating the effect of their stimulation on NAS or even healthy infants.

Our innovation is the integration of a clinically proven, stochastic, vibrating sleeping surface into a baby box to be used in the hospital and provided at discharge for caregiver use at home.

The gentle, stochastic vibration from the baby box stimulates nerves and as the brain processes the signals, pacemaker neurons enhance the rhythmicity of the lungs and heart increasing relaxation and improving cardiorespiratory function in NAS infants. The precise, random displacement of the sleep surface is controlled by 2 micro-processors and proprietary firmware.

There have been 4 studies on our stochastic vibro-tactile stimulation or SVS. The most recent is an independent study on NAS infants, published in PLOS One, which reported a 35% improvement in relaxation along with statistically significant improvement in respiratory rate and cardiac intervals. The technology is covered by an issued patent with another 4 submitted.

Made popular in Finland starting in 1938, the baby box has provided an affordable, safe sleep environment for millions of infants. More recently, baby boxes have been distributed free or charge in six (6) States and in several communities throughout the United States. On November 30th, our baby box with its SVS sleeping surface was recognized as the “Next-Gen Baby Box” by Johnson & Johnson, Janssen Pharmaceutical, and the Innovation agencies of Finland. We believe it to be the only non-pharmacological product proven clinically to console NAS infants and improve their cardiorespiratory function. We expect our innovation to reduce length of stay, morphine used for treatment and after discharge makes it easier for caregivers to console and improve sleep for everyone at home.

Team

My name in John Konsin and on the morning of November 4, 2016 my wife and I found our son lying on his bathroom floor overdosed on Heroin. Luckily, he survived and since then I've come to understand how difficult life can be for a recovering addict and family. However, I can't imagine how much more difficult it would be for a recovering addict with a newborn exposed to drugs.

Previously, I spent 35 years working in the Life Science Industry. Most of my time was spent in demanding roles with five (5) large, multi-national medical product and diagnostic companies. About a month after the overdose, the principals at Harvard's Wyss Institute asked me to recommend how to commercialize SVS technology. I recommended a focus on helping drug exposed infants. Several months later I created Prapela to help our kids and their caregivers.

Jim Niemi, co-founder of Prapela, is the product innovator behind SVS. Working with Dr. David Paydarfar, respected Neurologist and Chair of Neurology at the Dell Medical School, UT Austin, Jim spent 7 years developing this breakthrough in vibration for infant health. Jim received his Bachelor of Science in Bioengineering from Boston University and an MS in Engineering from Brown University. For the past ten years of his life he has focused on the application of stochastic resonance technology to help babies breathe, senior citizens keep their balance and help the disabled improve proprioception and recovery.

Together, we can't slow the opioid epidemic. But, we believe, by further developing our core competency in the application of SVS to infant health, we can help improve care and reduce the costs of caring for drug-exposed infants. It's our focus and it's what excites us every day.

Our Approach

Our product is a baby box including a sleeping surface inserted inside the bottom of the box with an attached power cord with integrated controls which extends outside the box. The box ships flat and pops up to be 27" long, 16.5" wide and 10.5" high. The box is constructed of either corrugated cardboard or polypropylene that can be sterilized. Both box constructions can hold and transport a 75-pound object. The sealed platform inserted inside the bottom of the box contains an actuator which vibrates and uses extremely low power. A foam sleeping pad covered with both a waterproof liner and a natural cotton fitted sheet sits on top of the platform. A small hole in the box below the sealed platform accommodates the pass through for the plug-in power cord. The vibration is turned on for a 3 hour on/off cycle by depressing a button - much like a heating pad switch. Set up takes about a minute and with one setting the product is easy to learn and use.

While treating NAS infants during withdrawal our baby box would be used as the primary bassinet both in the nursery as well as in-room with mother. Whenever caregivers are unable to hold or cuddle a NAS infant, the patient would be placed in the baby box and the switch turned on to activate the SVS platform. After discharge from the hospital, the baby box would be used at home as the primary sleeping environment for both daytime naps and evening sleep. Again, whenever a caregiver at home is unable to console an infant by touch, swaddling, skin to skin contact or rocking, the baby would be placed in the box and the switch turned on to help console the infant. A second touch of the button will shut off the vibration cycle. To start the cycle again, the caregiver touches the same button. A dim LED on the control switch will confirm the vibration is active. When the LED light is off, so is the vibration.

The first prototype SVS units were designed for limited hospital investigational use for apnea of prematurity. Although successfully used in a pilot NAS cohort, revisions are necessary to support additional NAS clinical studies as well as commercialization. As a next step, we will complete our planned design integrating SVS into a baby box. The SVS baby box design will reduce the cost of goods for product launch, manufacturing scale-up, and distribution far beyond the device used in investigational studies. In addition, we will complete the required safety testing for product introduction. Finally, we will build the required number of units to support an outcomes study.

Previous published SVS clinical studies have demonstrated reduced irritability and improved cardiorespiratory function to the NAS infant. While motivating, this single exposure study design did not capture metrics associated with outcomes and cost of care. Using the manufactured devices, in collaboration with a leading clinical group delivering care in a high-risk area, we will use the devices in a pilot cohort of NAS newborns for the duration of their hospital, as well as for the first month at home. We will demonstrate the value of the technology in reducing the length of stay, morphine use, readmission rate, and caregiver/infant bonding. In addition to improved outcomes, we aim to demonstrate significant reductions in cost of care.

For commercialization, we have already identified and started the product development process with our US based contract manufacturing partners and we will bill and ship from a central site in New England. Our unique, foldable box will be made by an established box manufacturer located in Maine. A polypropylene version, suitable for sterilization, will be made by a respected supplier in California. Our electronics package will be assembled and tested by an electronic manufacturing services company in operation for almost 40 years. We will be proud to say our product will be made in America.

Priced at approximately $150 each, we will position the product to help reduce stay, reduce morphine use and improve care after discharge. For hospitals that prefer not to provide the product at discharge, the same product will be available online at our eCommerce website at $150 with two-day delivery.

NAS is a concentrated market which makes it easy and affordable to reach. The highest incidence of NAS infants is concentrated in New England and Appalachia with approximately 200 centers (mostly Level III and Level IV NICUs) providing much of the treatment. Neonatologists and Neonatal Nurse Practitioners are the most active health care practitioners and regularly attend a few national organization meetings/conferences. Special meetings on NAS held by State agencies and professional medical organizations are well promoted and attended. Our plan is to cover the market with a small number of neonatal specialists and an informative and efficient e-commerce website.

Further, through social media we plan to educate the community on the benefits and affordability of our product, encouraging them to evaluate and purchase the product. The world's largest online nursing community, with over 650,000 members is so excited about our work that they have agreed to provide free on-line education and webinars to all its members on the Prapela SVS baby box. We will also be using a proprietary tool from a company in Cambridge Massachusetts that will allow us to recognize and directly contact NAS thought leaders and influencers on social media.

Our goal is that within 2 years after launch, we expect more than 50% of the drug-exposed newborns and their caregivers will use the product - improving their overall health and giving them a better chance at a lifetime of wellness

Verifying the Need

Since July 2017 we have been testing our product concept with neonatologists, neonatal nurse practitioners, community volunteers, parents, judges of pediatric device competitions and investors. While there is no substitute for asking the target audience to purchase a finished product, our interactions give strong indication that the Prapela SVS product for NAS infants is needed and will be purchased.

Neonatologists are rapidly shifting to the rooming-in approach to treat NAS infants. The basic concept is that both the NAS patient and mother will recover better together in a quiet room rather than separated and with baby in a busy, distracting NICU. The Prapela SVS concept complements the rooming in approach. It provides an affordable, safe sleep environment next to mother and consoles infants at times when mother is unable to hold or care her baby.

Neonatal nurses and volunteers are the predominant caregivers for NAS babies in hospitals. Many express their concerns using consumer baby products, especially ones where a newborn must sit up. They also recognize that the tools used in the hospital to console their patients will not be available after discharge. The idea of a clinically proven, affordable product is very appealing to this target customer group.

In the limited studies done with SVS on NAS infants a familiar ask of many caregivers at discharge has been "where can I buy it?" Separately, Prapela did a survey of over 100 parents to determine a price point that would entice most parents to purchase a product that consoles infants and improves cardiorespiratory function. Our survey results indicated that over 90% of parents would likely purchase the product if it were priced at $200 or less. Our target price is $150 per unit.

We have been fortunate to have been recognized in recent local, national and international pediatric device competitions. On 11/30/17 Prapela won the global Next-Gen Baby Box Challenge receiving $75,000 from Johnson & Johnson, Janssen Pharmaceuticals and the innovation agencies of Finland – Tekes & Sitra. The competition, held in Helsinki, included 135 entries from 17 different countries. On the national scene, Prapela won $25,000 at the FDA funded 5Th annual pediatric device innovation symposium (9/24/17) sponsored by Children's National hospital and locally in the Boston area we won the "best overall presentation" at Mass Medic's MedTECH showcase event (10/27/17).

In terms of investors, our recent recognition has prompted savvy investors to take a deeper look at Prapela, our product and our pricing. The takeaway thus far is that we are pricing the product too low. We disagree. Recognizing that lower income families are more susceptible to stress caused by irritable or inconsolable infants, we feel it is our privilege to bring the product to market at an affordable price – for everyone.

We have also been asked about insurance coverage which ultimately translates into coding, coverage and reimbursement for durable medical equipment or "DME". We are not interested. The pay and chase model of CMS reimbursement (payments come quickly and then are followed by audits, holdbacks and disruptions to cash flow) adds cost which would have to be gained back with a higher price. We believe, the value the product will bring to hospitals, physicians, caregivers and parents will be quickly recognized and accepted by our target customer.

At Prapela, we are confident about our potential to make a real change in the World and we're excited to have the opportunity to extend the legacy of the affordable baby box from a safe sleep environment to a product that improves the health of all infants and their caregivers. Thanks!