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INNOVATION AND AGILE PROJECT MANAGEMENT METHODS FOR NEONATAL MEDICAL DEVICE DEVELOPMENT AND DEPLOYMENT: *AN ENGINEERING-NEONATOLOGIST-BUSINESS COLLABORATION CASE STUDY ON NON-ELECTRIC INSTANT INFANT WARMING BLANKET INCUBATORS*

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Figure 1. The Infant Warming Incubator Blanket (IncuBlanket) and Warming Pack (InstaWarmer)

BACKGROUND AND AIMS

The Warmilu engineering team learned that immediate thermal care, including kangaroo mother care and plastic bags/wraps, could reduce neonatal morbidity and mortality. But existing thermal care solutions were not always accessible; mothers could be receiving postpartum care, incubators could be overcrowded, broken, or lacking electricity, and plastic bags/wraps might not be in stock. The design and development process included 50 interviews over the course of 1-3 years to identify current challenges and best practices for thermal management. With design input, including on-site field observations and digital conference calls, with senior practicing neonatologists, medical device regulatory experts, government health officials, nurses, and midwives, the Warmilu team used lean startup methodology (LSM) to accelerate development. These methods led to expansion in a single year from 3 hospitals in 3 countries (2017) into 28 hospitals based in 9 resource-scarce countries (2018) and led this engineering-physician-business collaboration to create a new low-risk neonatal warming medical device in 8 years from concept to market with a budget totaling <$350,000. The team then conducted pilot clinical trial testing. The purpose of the study is to test initial validity and feasibility of the new warming mattress in a small cohort of preterm, low birth weight infants in a resource scarce setting.

METHODS

LSM is a framework for customer development first developed by Steve Blank (*The Four Steps to the Epiphany: Successful Strategies for Products that Win (2005, 5th edition 2013*). The LSM process is meant to reduce time for product development and assess whether a product, service, or software will meet an unmet need in the marketplace and sustainably scale the product and business model. Eric Ries developed the terminology for the LSM loop called Build-Measure-Learn which defined the Ideas→Build→Prototype→Develop Test and Measurement Methods→Collect Data→Learn. The LSM and framework was applied to engineering with clinician feedback (**Figure 2**) during medical device development. LSM helped reduce development time leading to a prototype medical device that was ready to test in a pilot clinical trial for safety and effectiveness. The purpose of this study was to keep preterm and low birth weight infants warm, improve infant outcomes, and determine safety and efficacy of the heat source and blanket (**Figure 1**). This pilot clinical trial took place in a neonatal intensive care unit based out of KIMS Hospital in Bangalore India and was conducted on 20 low birth weight and preterm infants without any morbidity. Informed consent of parents and/or caregivers was required. The study and its protocol was approved by the KIMS Hospitals Institutional Ethics Committee (institute's committee on human research on Nov 12, 2012). All the users (nurses and doctors) were given detailed training about the product and instructions to use the same. This controlled study was conducted under the supervision of doctors and nurses. The infants were kept in the infant warming blankets and their temperatures monitored at 15 minutes interval for the first hour and then half hourly.

METHODS (CONT)

During the time infants were in the warming blanket, no other external heat source was used. The end point of the study occurred when the temperature of the baby was equal to or below 36.5 degrees Celsius or 180 minutes, whichever occurred earlier. Any adverse events such as hypothermia or hyperthermia were monitored, documented and appropriate actions taken. Local reactions if any due to the texture and quality of the parts of the devise coming in contact with the baby's skin were also closely monitored. The pilot study also studied the process of activating the blanket for usage ease and usability. The results were analyzed to gauge the performance of the infant warming blanket.

RESULTS

LSM uses agile learning cycle testing to validate business hypotheses; this framework was applied to engineering with clinician feedback. This allowed the Warmilu team to 1) build rapidly, completing preliminary prototypes and prototype iterations in 2 weeks (reduced from 6-8 months); 2) conduct design validation benchtop testing quickly and 3) loop in neonatologists, nurses, midwives, and medical device distributors/regulators for meaningful early design feedback. BMC documentation improved design innovation and testing accountability, leading to more rapid clinical trial testing and design history file development for faster regulatory clearance. The LSM build-measure-learn cycle spurred hypothesis driven development, better organizing internal and external stakeholder project management. These methods reduced common financial and time restrictions for medical device innovation in resource limited settings.

The team would try demonstration projects with sample infant warming blankets and packs, leading to the collection of data helping to demonstrate blanket safety as well as feedback for future product development. This openness in the collaboration with engineers, physicians, nurses, medical device distributors, NGOs, government organizations, Ministries of Health, and Warmilu led to the development of partnerships within shorter timeframes (4 months – 8 months). We tested 20 preterm and low birthweight infants who were stable prior to study in NICU and were receiving feedings in the incubator or under a radiant warmer. The average age was 35.25 weeks and average weight 1.75kg. The selected participants did not have additional morbidities, except being preterm and/or low birth weight in these infants. Upon placement into the Warmilu blanket, each infant's temperature started at 36.5°C-37.5°C. These infants were constantly temperature monitored, every 15 minutes for the first hour, and every 30 minutes for the next 2 hours, and their temperature profiles as seen in **Figure 3**. No hypothermia or hyperthermia was noted in any of the infants during the 180 minutes. The infants' body temperatures can be regulated with this particular infant warming blanket for at least 3 hours at 40.1°C. One infant was unable to complete last temperature measurement due to reaching 36.5°C mark at 150 minutes.

RESULTS (CONT)

In terms of usability testing and ease of use, the nurses indicated a few key suggestions that informed the product development and build process. First, the nurses stated that the metal disc activator was not easy to find. This would cause the nurses to take longer than 3 seconds to activate the disc. There is also the need to create ports in the infant warming blanket to record vital signs and thread IV lines. The ease of cleaning was not tested partly because instructions were not provided for cleaning and also because the ease of cleaning was not clear. This pilot clinical trials feedback was part of the LSM Build-Measure-Learn loop, leading the team to update the production tooling design for the warming pack to capture the disc. The team also updated the blanket patterns to create ports and openings to record vital signs such as blood draws for measuring blood sugar and IV line openings.

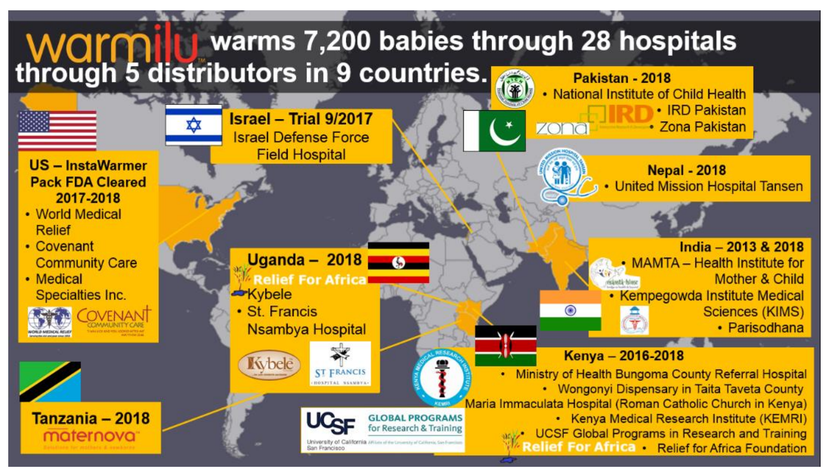

Figure 4. Hospitals served by the infant warming blanket and pack.

CONCLUSION

LSM and the Build-Measure-Learn loops played integral roles in the infant warming medical device development process. LSM led to reduced product development or product improvement lead times for the organization as a whole, taking a 5 years long concept to market timeline for the first medical device prototype with clinical trials and regulatory clearance to a turnaround time from idea to usable prototype in 6-8 months on average. The fastest turnaround time for a general nonmedical prototype became 2 weeks. The team applied this LSM method to generating awareness and deployment and partnership building of the infant warming blankets. The team was subsequently able to expand from 3 hospitals using IncuBlankets in 3 countries (2017) to 28 hospitals based in 9 resource-scarce countries (2018) as shown in **Figure 4**. The study demonstrated feasibility and validity of the product to maintain the infant's body temperature between 36.5°C-37.5°C.

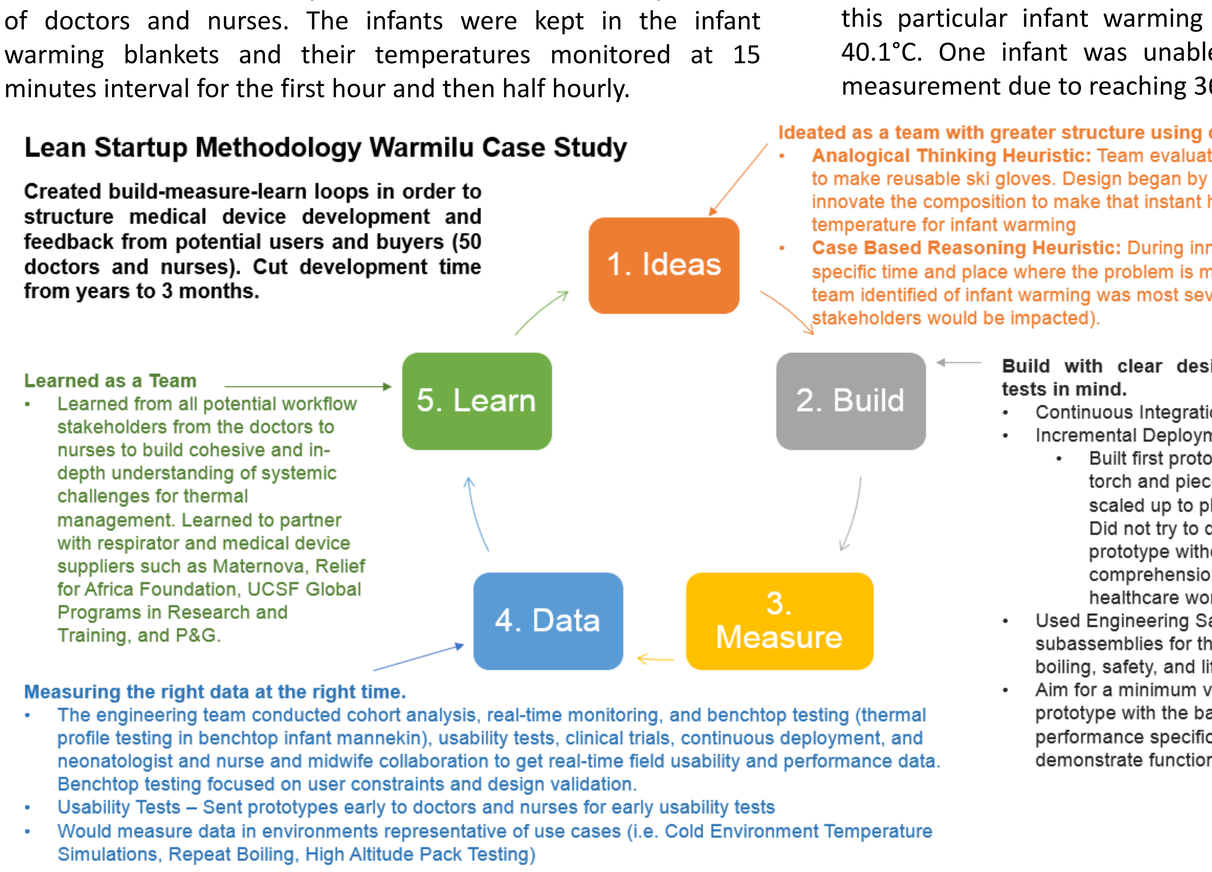

Figure 2. The ways our innovation team applied the LSM and Build-Measure-Learn loop.

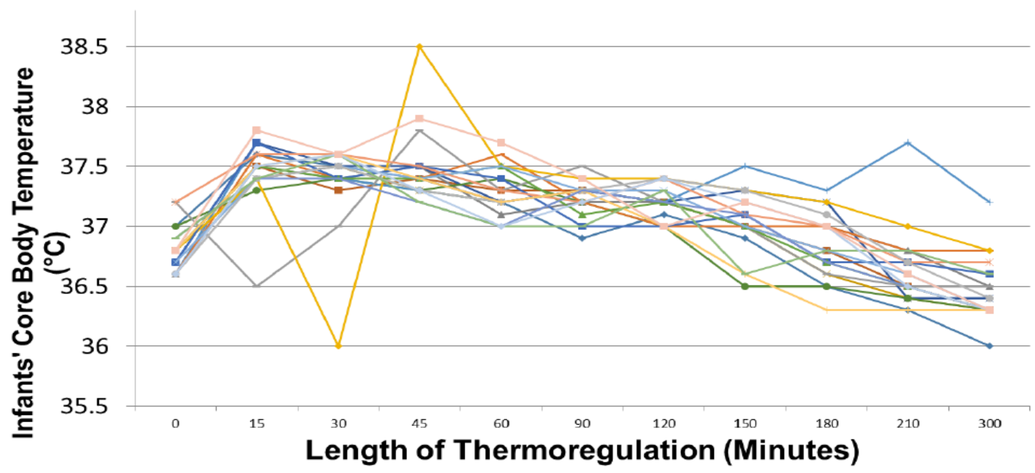

Figure 3. Thermoregulation clinical trials summary of infant core temperature vs. time profile.

Ethical Review Board: Not Required