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DESIGN INSIGHT

Development of a breast pump part steriliser for the neonatal ICU

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SUMMARY

Our team prototyped a breast-pump part sterilising device for the NICU. The project stalled without further funding. We made three key mistakes while designing and prototyping our device:

1. We neglected the financial costs and incentives of hospitals and insurance companies.
2. We did not build a strong regulatory strategy.
3. We did not pre-emptively study relevant intellectual property.

Future designers must learn the legal hurdles and financial incentives and constraints early in the concept generation process so that these barriers do not ultimately block the project's path to clinical use.

Key Words

Neonatal infection; NICU; breast pump; design education

INTRODUCTION

Mothers of babies in the neonatal intensive care unit (NICU) pump breast milk 8–12 times per day to maintain a steady milk supply. After each pumping session, mothers wash the pump parts and often leave their parts to dry in plastic basins lined in paper towels near the communal sinks—environments prone to harbouring mildew and waterborne pathogens like *Pseudomonas aeruginosa*, a bacterium notable for NICU outbreaks that have claimed the lives of multiple neonates.[1] NICU infants have underdeveloped immune systems and face higher exposure to medical devices, antimicrobial drugs, and invasive interventions that render them more vulnerable to severe infections.[2]

In these high-risk patients, protecting them from further exposure to pathogens is crucial. To both improve the safety of the process and make it more convenient for parents, we set out to create a solution that would specifically fit the NICU environment.

SUMMARY

Our team extensively interviewed 14 NICU parents, nurses, and epidemiologists over video to explore the problem (Table 1). We favoured open-ended questions asked over a group video call. One team member led the interview as another team member jotted down notes and observations as the participant showed us their workspace and sink setup. We also washed breast pump parts ourselves to capture pain points firsthand. Our research expanded to explore methods of cleaning

equipment in other fields like the manufacturing, food processing, and textile industries. Afterwards, we studied products on the market to pinpoint their weaknesses and identify any unfilled niches based on themes we found in our analysis of common complaints, reviews, and ratings (<3 out of 5). Our research highlighted the drying step as the critical step to target. Drying was the most time-consuming step of the cleaning process, the most prone to pathogen contamination, and the step that current devices on the market fail to accomplish the most consistently.

Table 1: Video interview questions and insights

Questions	Insights
Engagement 1. What is your favourite company for breast pump accessories? 2. How often do you clean your breast pump parts? 3. How do you clean your parts and bottles, and what do you use to clean them? 4. What are your biggest grievances with the current process? 5. How have you tried to work around these problems?	Parents clean parts around the clock. Mothers and fathers might share the responsibility, and fathers are less familiar with the process. Biggest grievances: • ***Time consuming*** • So many parts and limited space to wash them • No safe place to store parts and let them dry • Getting milk out of every crevice, needing a brush • Disconnecting all the smaller parts and drying them • ***Drying parts***
Exploration 1. Which step is more important to you to in a product that cleans breast pump parts? — Washing/steaming them quickly — Washing/steaming them thoroughly — Easy to stack and unload parts — Drying them quickly — Drying them thoroughly — Other 2. What factor(s) is/are most important to you when picking a cleaning device? — I don't use one/I do it by hand — Affordability — Size — Recommended by my friend or nurse — Easy to use — Speed 3. How do you think the cleaning process should be improved?	Parents prioritized: • Drying them thoroughly ("The last machine I bought didn't dry them well and they were still damp.") • Easy to load and unload ("I hated using the microwave trays because I had to balance all the parts on the little racks and one time I dropped the tray and had to rewash them all.") • Brand familiarity and recommendations from peers Parents in the NICU wanted: • A bigger counter space dedicated for cleaning and drying • Tools to clean small parts • Soap • A "dishwasher" equivalent • Fewer parts and fewer steps
Exit 1. Is there anything else you'd like to say about why you use the current sanitation process you use? 2. Is there anything else you'd like to suggest about creating a better breast pump cleaning device?	A few companies capture a large portion of the market. Most commonly cited devices were by • Medela • Spectra • Ameda • Avent

We developed Cirrus, the first breast-pump part steriliser designed for hospital-grade pathogen control and high-volume use (Figure 1). It combines the steam sterilisation process and drying

process into one device, harnessing centrifugal force to reduce drying time from three hours to a mere 45 seconds. The parts rest in an enclosed inner basket elevated over a water tray so that the plastic pieces stay dry and protected until their next use. The separation of the upper basket chamber and the base motor allows each family to own a personal chamber and use the NICU's motor bases, facilitating high throughput, and complying with hospital cleaning protocol and safety regulations.

Figure 1: Cirrus, a hospital-grade device to clean breast pump parts

Note: Cirrus is a hospital-grade device that steams breast pump parts and dries them in one enclosed chamber. It consists of an upper basket chamber and a lower motorised base. Parents complete four steps: 1) load parts into the basket; 2) twist the lid onto the tray; 3) lock the upper chamber into the base; and 4) press the button to start an automatic steam-spin cycle.

Families and nurses expressed enthusiasm for our device, and it garnered gracious funding from the Babyhood Lab incubator. Unfortunately, we failed to secure funding for further development. We applied to a number of local pitch competitions and targeted our applications to grants from paediatric and maternal health-centric foundations. Our concept was met with interest but also valid concerns, which we describe in the "Lessons Learned" section. Because the markets for the NICU and paediatric devices is much smaller than the markets for adult medical devices, we did not approach venture capital groups. As we received feedback throughout the fundraising journey, we understood the reservations surrounding our lack of broader strategy and haphazard prototyping process, so we ultimately chose not to pursue crowdfunding. The project stalled and did not reach the users we had hoped.

LESSONS LEARNED

We share three key pitfalls so that future designers can anticipate and learn from them:

1. *We did not consider the financial argument for hospital and insurance stakeholders.*

The current standard of care for breast pump parts is a disposable, microwavable plastic bag with a limited number of reuses. This method is drastically cheaper than our solution and easier to

restock and maintain. The true financial benefit to the hospital in terms of prevented neonatal bloodstream infections was unclear and difficult to establish. Though we referenced the option to seek partnerships with insurance companies, we did not establish a compelling insurance reimbursement model for the device either.

2. *We did not build a strong regulatory strategy.*

We pitched Cirrus as a class II medical device. However, we did not know how to navigate the regulatory process. We should have approached the US Food and Drug Administration (FDA) in a pre-submission meeting to learn what category to register our device, the testing we would need for approval, and any upfront concerns we could address. We did not know how to identify an appropriate predicate device. Evidence of earlier FDA engagement would have helped support the feasibility of actually bringing our device into clinical use.

3. *We did not pre-emptively study relevant intellectual property.*

Ultimately, we found a foreign patent for a device deemed too similar to ours. Although its centrifugation was at a different speed, for a different purpose and setting, these claims were no grounds for a new idea. We should have learned patentability upfront and performed due diligence earlier to make sure our device could be protected from market competition.

Together these three factors revealed that the device was built on a shaky financial foundation that investors understandably hesitated to finance further.

Medical schools around the country have implemented design curricula to nurture physician problem-solvers. These tracks teach design thinking—a user-centred, needs-based model to solve challenges in the healthcare space.[3] However, to train students in design thinking without an equally strong foundation in the healthcare business landscape is akin to sending innovators down a fruitless path, wasting time and resources pursuing financially unviable projects that the industry has no incentive to adopt.

The goal is to not only change health care for the better, but to produce lasting, sustainable change. While many promising projects emerge from design programs and incubators each year, only a rare few ever make it into clinical practice. To improve each project's long-term viability in the market, design curricula must introduce the FDA regulatory framework early, as well as basic reimbursement models for the main classes of medical interventions and equipment. The curriculum should include principles of basic market analysis and an overview of intellectual property rules. Only with the larger healthcare ecosystem in mind can designers, researchers, and clinicians start to build the more sustainable and cost-effective tools medicine truly needs.

Launching sustainable change requires screening the idea's regulatory and financial feasibility before any prototype building even begins.[4] Yock et al. provide a comprehensive process map of a medical technology's path to development and market.[4] Had our team scrutinised our regulatory requirements and business model beforehand, we would have realised earlier on how complex our path to market would have been and how our costs were not worth the poorly

defined clinical benefits we claimed. Future designers must respect how imperative it is to consider the legal and market landscapes of their projects, and educators need to incorporate this information into their lessons for any projects to make a real impact.

DESIGN INSIGHT

This paper presents excellent insight and critical advice when approaching the development of any new medical device, product, or technology. A problem was clearly identified in relation to breast pumps and the team sought to address this through structured design and product development activities. The team approached the design problem and produced an interesting outcome that solved the identified problem.

The oversights identified in this process and subsequently reflected upon in this paper are key lessons that are valuable to anyone involved in the development of a MedTech product. The lessons learned from the approaches undertaken are not only valuable to the MedTech sector, but also to personnel involved within product development and commercialisation in general. The challenges that design teams experienced with not only the design, but the funding and commercialisation of a product present several key hurdles that design teams and businesses experience on a regular basis.

The authors recognise the value of Design Thinking and the research/design activities involved to support product development, including the appropriate teaching of students on this approach. However, the value and use of multidisciplinary design teams cannot be overstated as receiving feedback from experts in relation to the regulatory approval pathway, the classification of a medical device/technology, awareness of prior art and intellectual property, amongst others, can help validate/invalidate product development decisions. The authors rightfully identify that in the future designers must think beyond the user and healthcare providers' requirements. Designers and healthcare providers must fully understand the value proposition of a new product as well as the health economic benefit and the product landscape in relation to intellectual property, otherwise the chances of success are unlikely.

Future design teams can learn from the insights collated within this article in order to increase the likelihood of navigating the product development pathway for a medical device, product, or technology. Although the design team was unsuccessful in its journey to commercialise its device, the insights gathered can help designers and healthcare providers with future decision-making.

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