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DESIGN OF A LOW-COST AUTOCLAVE FOR DEVELOPING WORLD HEALTH CLINICS

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ABSTRACT

Incidence of surgical site infection is 2-5 times higher in developing nations as compared to developed nations. A low-cost, easy to use autoclave was designed to address the unique technical, behavioral, and market challenges present in rural, health posts of the developing world. A thorough stakeholder analysis was performed very early in the design process to address non-technical needs for sustained user adoption as well as manufacturability and scalability. Twelve partnering clinics in Nepal trialed these autoclaves from July until December 2012. Usage statistics and follow-up observations highlight important factors for successful adoption. These findings were used to improve the autoclave design. The goal of this paper is to detail a case study and methodology to incorporate multiple stakeholder needs into the early design process.

Keywords: autoclave, surgical site infection, sterilization

INTRODUCTION

The incidence of surgical-site infections (SSIs) ranges from 5-20% in developing world hospitals, dramatically higher than the SSI incidence of 2-3% in US and European hospitals¹. The World Health Organization (WHO) estimates that the incidence of SSI is even greater in rural, resource-constrained clinics of the developing world, nearing 30% in some settings². These infections place an acute economic burden on poor patients who must repeat or prolong their hospital stay and absorb not only the living and travel expenses but also lost income from not being able to work during their trip and stay.

The way in which reusable instruments are cleaned between invasive procedures is of particular importance to the risk of SSI. The WHO states that inadequate equipment, lack of

basic infection control knowledge and implementation, and unsafe procedures elevate the risk of SSI². Studies of post-surgical infection in Tanzania conducted by Fehr et. al. and Erikson et. al. suggest that contaminated instruments were responsible for introducing pathogens into the deep tissue layers during surgical intervention, with a failure of their current autoclave system throughout the study cited as a root cause. These studies found that SSIs in deep tissue layers and in organ space represented 62% and 79% of observed SSIs^{3,4} as compared to 4% in comparable studies in Bolivia⁵ that had a functional autoclave.

Many cleaning methods exist with varying degrees of efficacy (Table 1). Decontamination is appropriate for hospital surfaces. High-level disinfection kills 95% of microbes but fails to kill endospores that cause tetanus and gas gangrene because the strains are particularly robust to heat and chemical exposure. Currently, it is the best alternative and commonly used in rural health posts (RHPs) where sterilization equipment is unavailable. Sterilization eliminates 100% of microbes, which is required for invasive surgical instruments. It is achieved by a multitude of methods, the simplest of which is steam autoclaving.

Table 1 | Effectiveness of microbe elimination by procedure.

METHOD	EFFECTIVENESS (eliminate microorganisms)	END POINT
Cleaning (water and soap)	Up to 50-80%	Until visibly clean
Decontamination (0.5% chlorine soln.)	Kills HBV, HIV, and most microorganisms	10 minutes
High Level Disinfection	Up to 95% (many endospores survive)	Boiling, steaming, or chemicals for 20 minutes
Sterilization	100%	High-pressure steam, dry heat, or chemical for recommended time

The risk of SSI in Nepal, the site of field trials, is 7.3% in urban hospitals⁷ and undoubtedly higher in RHPs where infection control is much worse and SSI incidence is poorly documented. Nepal was selected due to the high risk of SSI as well as contextual knowledge provided by Nepalese students at MIT with connections to the healthcare industry. Nepali hospitals perform major surgical procedures and are equipped with steam autoclaves and knowledgeable personnel to operate them. The Nepali doctors are trained in these hospitals and are aware of the importance of sterilization. However, they rarely visit RHPs, and the vast majority of nurses left in charge have never been exposed to an autoclave. RHP staff perform minor surgical procedures – deliveries, wound cleaning, and suturing – but, due to a lack of financial resources and trained staff, fail to use autoclaves, elevating the risk of SSI in their patients. According to the WHO, there are 2-3,000 government-run RHPs in Nepal⁸ and 20-30,000⁹ in India, our primary target markets.

The Nepali government distributed pressure cookers for use as autoclaves in the early 1990s, but the pressure cookers were removed during the civil war (1996-2006) because of their use as bomb-making material. New infection control workshops train RHP staff on the importance of hand washing and autoclaving among other measures. During our first trip to Nepal in the summer of 2011, the team visited twenty different pre-screened healthcare facilities including many RHPs. The RHP staff that we interviewed who had attended these workshops had a poor understanding of what an autoclave was and certainly did not use them in their RHPs. Instead, RHP staff preferred and used boilers because they required less time and attention.

Herein we investigate the potential for product-driven behavioral change, using the autoclave as a case study, where previous training-based efforts have failed. Since impact at scale is a typical objective of development work and profit margins are typically low necessitating economies of scale, mass manufacturing and related business considerations should be introduced very early in the design process to better position products for scale up. The thorough stakeholder analysis conducted herein presents a case that can inform appropriate design education where manufacturing capabilities and market forces are critical but stakeholders are difficult to access.

PRIOR ART

The first autoclave, designed by Chamberland in 1879¹⁰, looked strikingly similar to modern day pressure cookers. Since then, the autoclave has become an essential tool for hospitals, with vendors offering autoclaves that vary widely in size and sophistication. Autoclaves designed for developed world markets have many features that maximize safety and automation and cost anywhere from \$3,000 to \$100,000+ USD depending on size and automation¹¹. Less expensive autoclave designs popular in developing world markets lack progress monitoring features, focus more on robustness, and cost anywhere from \$250 to \$5,000 USD depending on size¹².

Small autoclaves designed for small healthcare facilities of the developing world come in a variety of sizes from 4L to 60L¹² and are robust. Unfortunately, most of the small autoclave designs require electricity, which is often unavailable in RHPs. Additionally, these autoclaves are often prohibitively expensive compared to electric boilers, which are only \$10-20 USD. Even when an autoclave is present in a health post, appropriate use poses a significant challenge as instructions are not included, and the autoclaves are not intuitive for unskilled and often illiterate nurses' assistants.

In lieu of an autoclave, the low cost of consumables (water and heat) and ease of use make boiling the most widespread disinfection measure in Nepali RHPs. Bathing surgical equipment in a chemical solution (i.e. chlorhexidine or glutaraldehyde solutions) is sometimes used to disinfect latex examination gloves and is used by mobile surgical camps due to its portability and electricity independence. These measures, however, are still clinically inferior and elevate the risk of SSI. The prevalence of these practices was observed in all partnering RHPs during the authors' first trip to Nepal in the summer of 2011.

Clinicians and researchers from around the world have developed many different autoclaves to address poor autoclave usage by focusing on either manufacturing or energy source. Oyawale and Olaoye¹³ developed a low-cost autoclave in Nigeria from locally available materials and manufacturing skills of the researchers. While the product is well designed for low-cost and local manufacturability, it operates on electricity where many developing world environments have frequent power outages, and there are significant safety concerns around quality control of a locally welded pressure vessel. Other groups are focusing on ways to heat the pressure vessel¹⁴ or retrofit current autoclaves to make them portable for surgical camps.¹⁵ However, there is a significant opportunity to improve appropriate autoclave use by creating an autoclave that is low cost enough to fit a RHP's budget and simple enough for untrained nurses' assistants to learn and use.

MEDICAL DEVICE REQUIREMENTS

Sterilization destroys all microorganisms on a surface to prevent disease transmission via that object. Many different methods can be employed to sterilize medical instruments including steam or dry heat, chemicals, and radiation. High temperature steam heating, achieved by boiling water at high pressure, can be achieved using a household pressure cooker, ubiquitous even in remote regions of the developing world.

The CDC recommends that invasive surgical instruments achieve a sterility assurance level (SAL) of 10^{-6} or conditions where the probability of a spore surviving is one in one million¹⁶. To achieve a SAL of 10^{-6} using steam sterilization, the CDC minimum exposure period for linen-wrapped instruments is 30 minutes while maintaining 121°C and 203kPa absolute pressure¹⁷. As the exposure temperature decreases, the time required to reach a SAL of 10^{-6} increases exponentially. Iterative boiling over multiple days is the only way to kill these spores and achieve the SAL of 10^{-6} . This helps explain the

inferior cleaning capabilities of boiling instruments at 100°C, and the need for a pressure vessel for high temperature boiling.

PRODUCT DESIGN

Adoption and sustained usage are central goals of our autoclave project, but scalability is also fundamental to maximizing impact. Inputs from many stakeholders other than the end user – buyers, manufacturers, and repairmen - were important to consider early in the design process, as their interests often conflict but all greatly influence the probability of scaling success. For example, government buyers typically disregard usability features as superfluous whereas end users consider these features indispensable. Also, manufacturers tend to add extra features to increase their profit margins, but the buyer will purchase the lowest cost item. Therefore, an easy to use, low-cost, mass-manufacturable, and profitable product design was pursued to fulfill each of the stakeholders' unique interests and incentives (Fig. 1).

Design for User

Nepalese students at MIT were able to utilize their personal networks to identify and screen interested clinics in Nepal. Partnering clinics were consulted to understand the clinical environment and competing devices. We learned that instruments were autoclaved in hospitals but boiled in RHPs, even though pressure cookers, a tool fit for autoclaving, were in use in nearby kitchens. Our Nepali advisors had no idea that a pressure cooker could be used as an autoclave, and we realized that people had a hard time making the mental leap because of product perception. The advisors also warned that autoclaving, taking approximately 1 hour, was far less convenient than boiling for 15 minutes, the prevailing substitute. The team concluded that a comprehensive solution to improve product perception and maximize convenience was necessary.

We designed our product architecture (Fig. 1) around the existing autoclave infrastructure – a pressure cooker and any local heating source used for cooking. These components take advantage of embedded knowledge of pressure cooker operation in context of cooking and utilize existing supply chains for fuel, heating units, and pressure cookers.

The cycle monitor and pressure sensor were added to improve product perception, convenience, and adherence to the correct autoclave protocol. The Nepali advisors said staff in the developing world typically follow ritualistic protocols that are often ineffective. The pressure sensor (Fig. 1, inset A) monitors the internal conditions of the pressure cooker and relays that information to the cycle monitor (Fig. 1, inset B), which guides the user through the correct protocol every cycle. Users receive feedback on successful or failed cycles every time the device is used via backlit success and fail graphics. The cycle monitor also makes the process convenient by only alerting users for their attention when it is required. The electronic cycle monitor was designed to look and feel like a professional medical product to clearly delineate the system from pressure cookers for cooking.

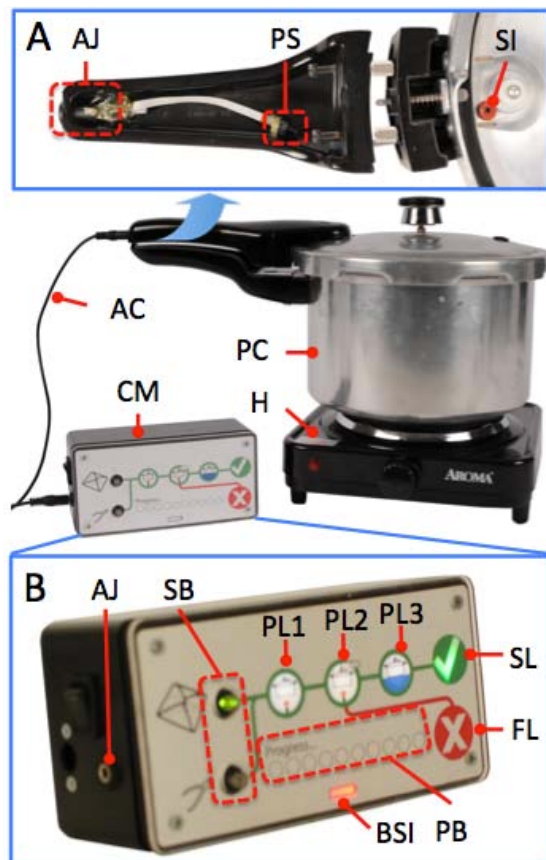


Figure 1 | The autoclave product architecture includes a heating element, pressure cooker, pressure sensor, and cycle monitor. The sensor and cycle monitor increase the convenience of the autoclaving process as compared to other autoclave designs. **Inset A** | The pressure sensor is integrated into a tube. **Inset B** | The cycle monitor reads the internal pressure from the sensor and relays information to the user via backlit graphics and a speaker. The user selects whether instruments are wrapped in liners or not using the select buttons. The user is then guided through the autoclave process via the phase lights and progress bar. Finally, cycle success or failure is indicated by the check and X lights.

Labels: AJ-audio jack, PS-pressure sensor, SI-sensor inlet | AC-audio cable, CM-cycle monitor, PC-pressure cooker, H-heater | SB-select buttons, PL1/2/3-heating/steam/cooling phase lights, BSI-battery status indicator, PB-progress bar, SL-success light, FL-fail light

We also recognized a need for training on the clinical value of autoclaving versus boiling to drive initial adoption. Additionally, sterile technique protocols were designed for the nurse's assistants to keep instruments clean after autoclaving. Finally, small washers were added to the dead-weight pressure regulator to account for decreases in ambient pressure from high elevations, ensuring that 203kPa – and 121°C needed for sterilization would still be achieved.

Design for Buyer

The Director General of logistics in the Nepali Ministry of Health is in charge of all medical equipment and pharmaceutical procurement for all government-run hospitals and RHPs, controlling funds for all large purchases over ~\$30 USD. These purchases are made for bundled equipment, so a full solution including the pressure cooker and the monitor is required. His buying decisions are based primarily on cost, perceived robustness, warranty, and repair services. There are no regular channels of communication between this minister and the RHPs, which de-emphasizes the importance of usability in his purchasing decision. He recommends a market price less than \$250 USD, a product lifetime of at least five years, and a warranty period of one year or more. His inputs are especially important because the autoclave adoption at the national level is needed to generate demand at a high enough volume to reach economies of scale.

Design for Manufacture

Incorporation of a commoditized input, pressure cooker, and eliminating integration of the heating source accelerated prototyping, drove down costs, and removed dependence on the inconsistent electric grid. Pressure cookers and heaters, such as gas stoves and open fires, have established supply chains making them widely available in the developing world. The cycle monitor and pressure sensor module utilize electronics that can easily be mass-manufactured and enclosure materials and designs that are injection mold-able. A small patient monitor manufacturer in India agreed to partner with us to mass-manufacture the electronic systems and their enclosures. This early partnership allowed us to make more informed design for manufacture decisions on later iterations.

Design for Repair

Commoditized pressure cooker and heater inputs also simplify sourcing repair parts. The monitor and sensor apparatus were designed so that mobile phone repair shops would be able to fix most minor electronic failures, but if local repair is impossible the small components are easy to ship back to the manufacturer. More complex repairs require electric and mechanical skills as well as the appropriate tools and spare parts. This combination of skills and hardware can only be found in specialized traveling repairmen or workers at a central refurbishing facility where broken parts are shipped. Traveling repairmen typically service their employer's high margin medical devices (i.e. ultrasounds, x-rays); however, they often refuse to visit rural locations because of rough travel conditions and low compensation. A central refurbishing facility would be able to attract the skills and required materials and is the most appropriate and viable repair structure for the autoclave.

MECHANICAL AND BIOLOGICAL TESTING

Initial testing was performed to ensure the boiling point increased with pressure and that the appropriate temperature and pressure could be maintained for 30 minutes at different pressures. These tests were carried out using thermocouples¹⁸

spread throughout the inside of the pressure cooker and a pressure sensor connected to internal cooker conditions via a PTFE tube. The results in Fig. 2 show that pressure and temperature are linked once boiling is achieved and that conditions exceed the 121°C and 202kPa threshold required by the CDC standards for sterilization.

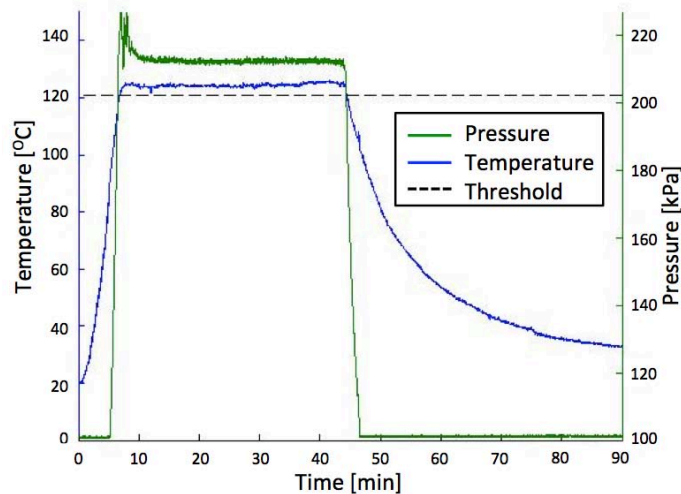


Figure 2 | Pressure and temperature from autoclave validation testing show values above 121°C and 203kPa for >30min, the required exposure conditions outlined by the CDC sterilization specifications¹⁴.

Twenty final autoclave units were extensively tested using both mechanical and biological methods before release into the field. The pressure was recorded throughout the cycle for each of the autoclaves to ensure that the appropriate pressure was maintained for 30 minutes. Two 3M Attest biological indicators (3M-1262)¹⁹, an industry standard for testing steam autoclave efficacy, were placed in each autoclave with one wrapped in an instrument pack and the other place anywhere outside the pack. These vials were incubated after one autoclave cycle at 56°C for 48 hours in an incubator (3M-116). If the autoclave failed to reach the appropriate SAL, living spores within the vial multiply when incubated, turning the colorimetric media yellow; however, the media remains purple in the absence of living spores, which indicates a successful autoclave cycle. All autoclave cycles yielded successful, purple biological indicators after incubation meaning a sterile environment (SAL of 10⁻⁶) was achieved.

FIELD TESTING

Over the summer of 2011, fifteen autoclaves were delivered to Nepali healthcare facilities that had given verbal commitment to use the autoclave. These facilities included RHPs (outpatient), small private clinics (outpatient), dental clinics, as well as urban and rural hospitals (>40 beds, inpatient). A variety of facilities were visited to help identify the best-fit facility demographics in order to tailor future iterations to their unique needs. Follow-up interviews were conducted one-month after delivery. We returned to Nepal during a second trip in the winter of 2011 to conduct another

follow-up interview six months after delivery and get feedback on our second iteration of the autoclave. The following describes the findings from interviews and observations pertaining to the first autoclave design.

In user interviews during autoclave delivery, we discovered that nurses' assistants or technicians usually have no formal training and are usually trained on site by the nurses. They were less aware of sterile technique than the nurses and were hesitant to speak to us whatsoever for fear of their superiors' disapproval. This necessitated segregation of the operator from superior clinic staff during some training and especially during later follow-up interviews.

Upon conclusion of device delivery, users were given usage survey forms to fill out periodically and a contact number of a local volunteer who would visit to collect paperwork and conduct maintenance. Usage data were collected for the six-month period following autoclave delivery. At one and six months post-delivery, sustained use and operator understanding were evaluated through a teach-back where users were asked to teach us their autoclave operation protocol. Co-design principles were also employed at one and six months to critique the design and learn what features the users liked and disliked as well as how the autoclave caused any shift in their daily duties. Cumulative results for sustained adoption are presented in Figure 3.

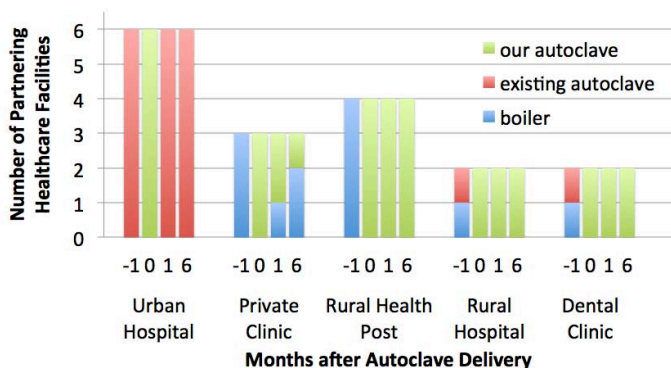


Figure 3 | Autoclave use was measured at each partnering clinic before delivery (-1), during delivery (0), and one (1) and six (6) months post-delivery. All autoclaves were successfully adopted in rural hospitals, RHPs, and dental clinics where our equipment was the primary autoclave and staff were highly motivated. In most private clinics and all urban hospitals, autoclave use was suspended due to low surgical patient volume and inconvenience, respectively.

We found that some participating clinics were not diligent about paperwork and in one case, it was clear that the data were false. Inaccuracies of self-reporting affected the data; however, observed trends still show interesting trends. The following trends were first identified in these data and confirm during the second visit: discontinued use was highly correlated with device failure (typically easy to repair) and users were very confident about their ability to operate the device properly.

Summary of Learning from Field Testing:

Healthcare Facility Fit

- Identification of target facility demographic is critical to know who and what setting to design for.
- RHP nurses and nurse's assistants have a poor understanding of the difference between steam autoclaving and boiling.
- The autoclave was used extensively in government-run RHPs and rural hospitals.
- The autoclave was donated but not used in urban hospitals and private clinics.

Data Collection

- Users have a hard time thinking abstractly and creatively during design reviews and evaluations of non-functional prototypes.
- Users are not accustomed to filling out paperwork and many have difficulty reliably self-reporting information due to inconvenience and/or poor literacy.
- Staff power structure and cultural norms prohibits assistants from speaking their mind freely

Autoclave Usage

- Users were very confident about their ability to operate the device properly after the six-month trial.
- Increased safety and autonomy to do other tasks during the autoclave cycle were the most important benefits to our users.
- Users typically accept device failures and stop using the equipment rather than seeking repairs.
- The first version, equipped with only a buzzer, was difficult for users to understand, especially in infrequent events such as cycle failure.

REDESIGN

Before returning for a second trip in the winter of 2011, the pressure sensor module and cycle monitor were redesigned - based on the aforementioned findings - with a heavy focus on training and minimizing user interpretation. The second design (Fig. 4) features voice instructions. The voice prompts, in combination with the backlit graphics, tell the user the following: how to set up the autoclave properly, the progress and instructions for each stage, battery status, and how to care for the instruments at the end of the cycle. These voice prompts seek to emulate how a doctor would train assistants in person. In Nepal, the only electronics that talk in Nepali were the television and the radio, and doctors and staff were very excited about the new talking cycle monitor during our second trip. We also noted during our first visit that some of the clinics were located in loud settings or the room where the autoclave is located is far from where the user normally conducts his or her duties, in which case the alarms were not loud enough to actually give the user freedom to tend to other tasks. The second design comes with an auxiliary audio output that can connect to external speakers.

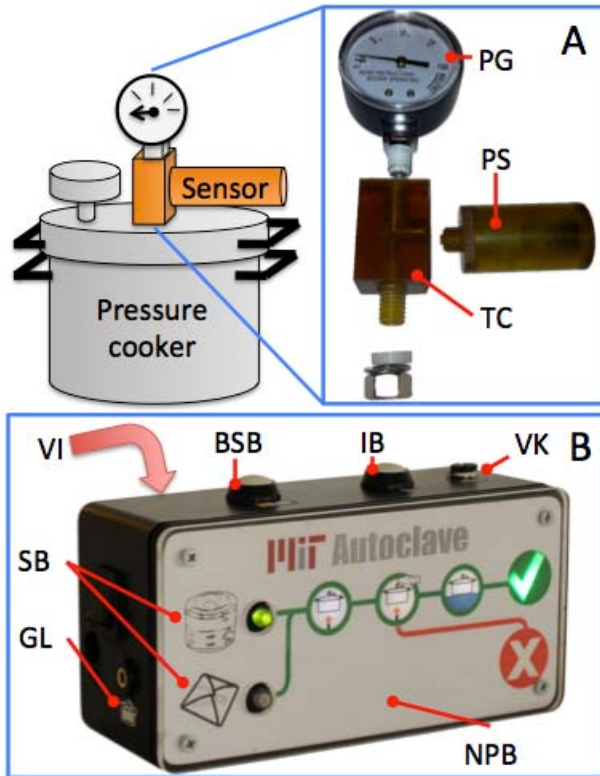


Figure 4 | A full redesign of the sensor module and iterative improvements to the cycle monitor make the second autoclave iteration more intuitive to use and easier to mass manufacture. **Inset A** | The new sensor module can be attached to any pressure cooker or autoclave via a multitude of T-connectors. The sensor component easily unscrews for easy assembly and replacement. **Inset B** | The new cycle monitor includes voice instructions (VI) and graphical tweaks to make the use more intuitive. The monitor also includes a full tutorial to standardize the teaching process and make expert instruction available in remote regions.

Labels: PG-pressure gauge, PS-pressure sensor, TC-T-connector | VI-voice instructions, SB-select button graphics, GL-graphic labels, BSB-battery status button, IB-instruction button, VK-volume knob, NPB-no progress bar

FUTURE WORK

Given the user feedback over the two staggered visits, we aim to further improve the autoclave's safety and autonomy features and design for manufacturability. We have partnered with an Indian industrial designer to explore new enclosure configurations to improve intuitive interaction design. Total physical redesign of the system will be conducted to address the potential safety issues with the wire that connects the sensor to the cycle monitor in the current design. Different alarms and speakers will be analyzed to ensure appropriate loudness and alertness. In addition to improved usability, we are working on a design that is scalable and cost-effective during production to attract buyers and increase manufacturer profitability.

CONCLUSIONS

A low-cost autoclave has been developed for RHPs in Nepal and the wider developing world to meet not only the technical requirements for sterilization, but also relevant social and business factors. The pressure cooker based design is grounded in sound autoclave theory; however, the design also addressed needs for ease of use to drive sustained adoption and mass manufacturability to increase potential for scale. The stakeholder-centric approach allows the early stage product to evolve with a user focus while being aware of the multitude of other diverse needs and their relative importance.

This approach represents a significant deviation from human-centered design that concentrates almost exclusively on the user. While the user is often the most important stakeholder, an isolated focus on the user alone neglects many other important stakeholder inputs and can lead to product evolution away from the needs of buyers, manufacturers, and distributors. This differentiation often requires back tracking if the design is later transitioned to manufacture as many of the design elements may conflict with system-level incorporation.

The introduction of a functional prototype on our first visit catalyzed discussions and reviews by users not well versed in the creative design process. The prototype, compared with abstract concepts and sketches, engaged those stakeholders more and elicited more realistic feedback from them. The prototype helped convey our purpose and extract latent needs through observation of actual use, which would be nearly impossible by abstract conversation alone. The wide distribution to a variety of partnering healthcare facilities allowed us to narrow our target clinic demographics and tailor future design iterations to address the unique needs of those market segments.

The product also helped engage other stakeholders, such as buyers and manufacturers, as the level of execution conveyed a significant commitment and competence on the part of the design team. The team was able to interview buyers, manufacturers, and distributors that supply government-run RHPs and rural hospitals. A thorough understanding of the procurement chain and the market player's individual incentives allowed us to better tailor the autoclave to their needs as well. Many university student teams approach these domestic gatekeepers with their next great development product or service, but almost always fail to deliver due to lapses in commitment or failure to anticipate market forces.

We recommend a more holistic approach to design education that recognizes the importance of the user, but not at the cost of excluding relevant market players and their incentives. At early stages there is typically a lack of access to these stakeholders, especially in the developing world. Given this limitation, design educators should emphasize the importance of developing a functional prototype suitable for long-term use that can be tested by local partners in the field. Although this approach may take more time and resources, it enables students and researchers to monitor real usage patterns and seriously engage other important partners.

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