34th Annual International Conference of the IEEE EMBS
San Diego, California USA, 28 August - 1 September, 2012

Achieving Appropriate Design for Developing World Heath Care: The Case of a Low-Cost Autoclave for Primary Health Clinics*

Hallie S. Cho, Gregory D. Tao, Amos Winter

Abstract—**In developing world health clinics, incidence of surgical site infection is 2 to 10 times higher than in developed world hospitals. This paper identifies lack of availability of appropriately designed, low-cost autoclaves in developing world health clinics as a major contributing factor to the dramatic gap in surgical site infection rates. The paper describes the process of developing a low-cost autoclave that addresses the unique challenges faced by developing world primary health clinics and discusses how appropriateness of design was determined. The resulting pressure cooker-based autoclave design was fabricated and tested against the CDC specifications. Twelve partnering clinics in Nepal trialed these autoclaves from July until December 2012.**

I. Introduction

Surgical Site Infections (SSIs) are infections that occur after surgery in the part of the body where the operation took place. Serious SSIs involve deep tissue layers and organs and put patients at a greater health risk. SSIs occur at a significantly higher rate in developing countries (5-20%) than in developed countries (2-3%)[1]. The WHO sites inadequate equipment, lack of basic infection control knowledge and implementation, and unsafe procedures as sources that elevate the risk of SSI[2].

Many SSIs can be prevented by practicing sterile technique and providing proper postoperative care. In developing world hospitals, frequent failures of autoclaving equipment and lack of repair parts, cost of replacement parts, and slowness of repair services pose significant obstacles to practicing sterile technique. Studies of post surgical infection in Tanzania by Fehr et al and Erikson et al have shown that contaminated instruments were responsible for introducing pathogens into the deep tissue layers during surgeries: SSIs in deep tissue layers and organ space accounted for 62% and 79% of observed SSIs[3,4]. Main cause of contamination in surgical instruments was strongly linked to the failure of current autoclave systems.

Even within the developing world context, resource-poor clinics in rural areas fare far worse than hospitals in urban settings. The WHO estimates that the incidence of SSI to be even greater (30%) in rural, resource-constrained health clinics of the developing world[2]. These primary health clinics in rural areas on average have 3 beds, usually do not have a doctor on staff, and do not have a reliable source of electricity (or clean water in some settings). Depending on availability of resources in terms of equipment, power, and trained staff, these clinics employ one of the methods described in Table 1 to clean their instruments.

There are commercially available autoclaves differentiated by complexity of features at various price points ranging from 100 USD to 100,000+ USD. However, vast majority of commercially available autoclaves require electricity. Given this information, we knew that an appropriate autoclave for the developing world primary health clinics needed to be able to run on power sources other than electricity. Our autoclave can be heated with any heat source: electricity, gas, wood fire, solar power, etc. Additionally, we were intrigued by the existence of low cost options that were not being put to use and set out to explore what made these designs inappropriate for this market in order to achieve a more appropriate design for our autoclave.

This paper presents our design process and results with comments on challenges of determining what is "appropriate" and how appropriate designs are powerful tools to drive changes in usage and behavior.

II. Methods

A. Identifying Users and Their Needs

Prior to developing the alpha prototype, the team broadly identified the target market as developing world hospitals and health clinics. Based upon prior experience† in medical device development, product development for the developing world, the team determined that the alpha prototype must address the following needs: 1) meet the CDC recommended[5] sterility assurance level (SAL) of 10^{-6}, 2) able to run on any energy source, 3) easy to use as well as easy to learn and teach how to use, 4) replacement parts and repair services need to be accessible and supplied at low cost, and 5) can be manufactured at low cost.

During the first field trial in June 2011, the team was able to visit 17 clinics of varying size and geographic location in Nepal and India. Average patient volume, different types of care provided, number of staff and their education level, types of disinfection or sterilization equipment available, and availability of electricity or other energy sources were noted. Doctors, nurses, nurse's assistants or technicians were

*Research supported by MIT IDEAS Global Challenge, MIT Public Service Center, and MIT International Development Initiative.

H. S. Cho is with Massachusetts Institute of Technology, Cambridge, MA 02139 USA (phone: 617-807-0652; e-mail: hscho@mit.edu).

G. D. Tao is with Massachusetts Institute of Technology, Cambridge,

H. S. Cho is with Massachusetts Institute of Technology, Cambridge, MA 02139 USA (phone: 617-807-0652; e-mail: hscho@mit.edu).

G. D. Tao is with Massachusetts Institute of Technology, Cambridge, MA 02139 USA (e-mail: gtao@mit.edu).

† Team members had not conducted user surveys in country specifically for the autoclave at this point. They were basing the requirements on existing knowledge of conditions in rural clinics and the user demographic from previous projects as well as knowledge of peers with extensive field experience.

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

interviewed and were invited to discuss various problems faced by the clinic or them as individuals. We also observed how surgical instruments were cleaned at these facilities.

Then, we presented the clinic with our autoclave, demonstrated how to use it, and asked if they would be willing to use our autoclave. All the clinics agreed to participate were asked to keep a usage log and to fill out a weekly survey that will be collected monthly by a volunteer.

Each participating clinic was incentivized to fill out the paperwork with the promise of receiving new and improved autoclave during the second trial in winter 2011 for compliant clinics.

During the second field trial, the actual user of the autoclave was interviewed. The team made a conscious effort to interview these users away from their peers and supervisors and invited them to openly discuss what they liked and disliked about using the autoclave. A list of important product attributes was extracted from these conversations. At the end of the interview, users were asked to rank this list from most important to least important.

B. Design of the Autoclave

Based on our preliminary user needs identification exercise, we determined the product architecture, as shown in Fig. 1. Using a commercially available pressure cooker and modular attachments, we addressed the need for low cost of manufacturing and the need for ease of repair and low cost of repair parts. We decided to use a commercially available pressure cookers because: 1) they are widely available in most developing countries, 2) they can be heated by any energy source, 3) they are able to achieve 203kPa – and 121^{O}C – at any elevation by adding the appropriate number of small washers onto the dead weight that regulates the gauge pressure inside the cooker, 4) manufacturers have already validated their safety.

The sensor module measures the pressure inside the pressure vessel and relays this information to the cycle monitor. We agreed upon a modular design because this allows us to be compatible any manufacturer's pressure cooker. If the sensor were to fail, replacement part can be delivered via postal service or a messenger and the repair is as simple as unscrewing the broken module and screwing on the replacement module, see Fig 2.

A unique cycle monitor, as shown in Fig 3, was developed to address the need for a product that was not only easy to use repeatedly but also easy to teach how to use. The cycle monitor is powered by rechargeable batteries—can last up to 4 trials on a single charge—and continuously measures the internal pressure of the pressure cooker. The cycle monitor allows the user to track the progress of a trial and alerts the user when an action is required. Second version of the cycle monitor came with a voice feature that instructs the user in their native language how to use the autoclave and handle instruments afterwards to ensure sterility. The cycle monitor is vital to ensuring proper use over time. All components were designed to accommodate materials and processes used by small to medium size manufacturers in India.

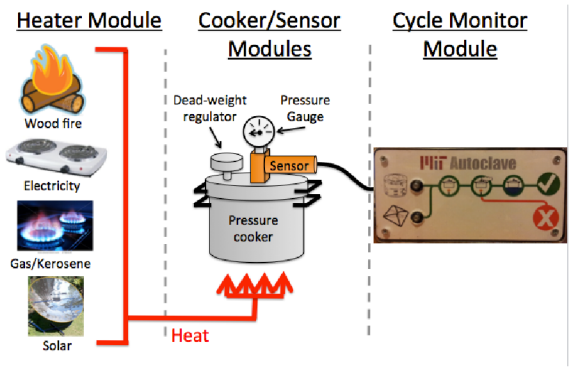

Figure 1. Product Architecture

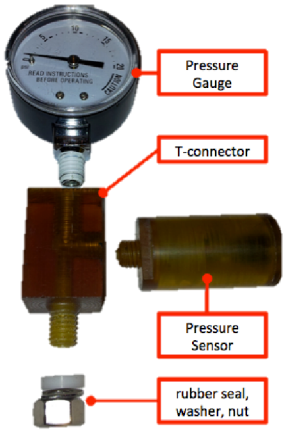

Figure 2. Modular Sensor Attachment

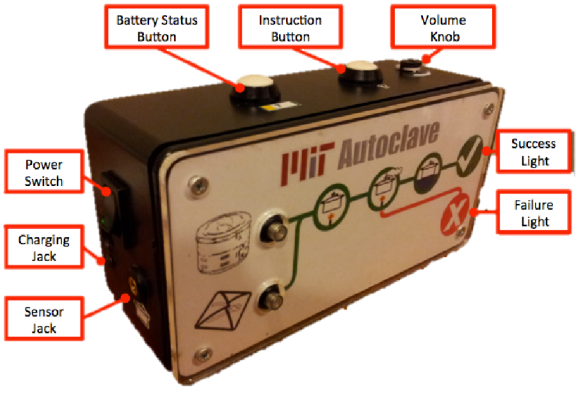

Figure 3. Cycle Monitor

C. *Mechanical and Biological Testing*

Each final autoclave unit was extensively tested using both mechanical and biological methods before they were tested during one of our field trials. The pressure and temperature was recorded throughout the cycle for each autoclave to ensure that 121^{O}C and 203kPa absolute pressure was maintained for 30 minutes to meet CDC requirements, see Fig. 4. When the temperature or the pressure falls beneath the threshold, the cycle monitor would alert the user to restart because conditions for success have not been met. The autoclave and cycle monitor system is in open loop and the user must complete an action to close the loop. Two 3M Attest biological indicators (3M-1262), an industry standard for testing steam autoclave efficacy, were placed in each autoclave with one wrapped in an instrument pack and the other unwrapped. These vials were incubated after the cycle at 56^{O}C for 48 hours in an incubator (3M-116). If the autoclave failed to reach the required SAL of 10^{-6}, living spores within the vial would multiply during incubation turning the colorimetric media yellow; however, the media remains purple in the absence of living spores, which indicates a successful autoclave cycle. All biological indicators autoclaved by our autoclave remained purple after incubation.

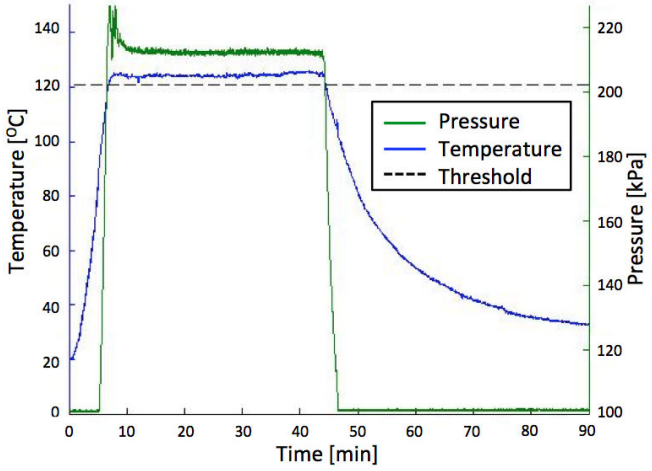

Figure 4. Pressure and Temperature Profile during Autoclave Cycle

D. *Field Trials*

All field trials were conducted in Nepal and India primarily because we had team members that were from these regions, spoke the language fluently, were knowledgeable of cultural norms, and had personal connections to a number of clinics and government officials.

III. RESULTS

A. *First Field Trial*

The team traveled to Nepal and with 15 alpha prototypes and visited 17 clinics from June 2011 to August 2011. All of the doctors we interviewed were trained in hospitals equipped with an autoclave and understood the importance of practicing sterile technique and were aware that inadequate sterilization of instruments in rural clinics was an important issue.

During this visit, we realized that our actual target market was not all hospitals and health clinics in developing countries but more specifically primary health clinics in remote areas. Hospitals in urban areas were well staffed with doctors, nurses, technicians, equipment, and source of electricity (back up generators for frequent power outages). These hospitals typically had a much larger volume of patients and had a large autoclave that was regularly used and could not be replaced by our autoclave that was smaller. Private clinics in urban areas were most similar to family doctors offices in the US and seldom performed invasive procedures.

We found the best fit in primary health clinics or health posts and district-level hospitals in remote areas. These heath posts and hospitals continued to use our autoclave mainly to sterilize instruments used during deliveries and family planning surgeries. The fact that the nurses and assistants continued to use our autoclave in the presence of an easier and faster substitute—boiling the instruments for 20 minutes—confirmed our belief that coupled with proper training, appropriate designs can change behavior. Fig. 5 summarizes our findings on how different health sectors received our autoclave. Based on these findings, we determined our target market.

After our initial visit to each of the clinics, we made a follow up visit after a month to see how compliant they were in following up with paper work and to observe whether or not the autoclave was being used properly, if at all. We were extremely disappointed to find that most urban facilities were not using the autoclave. One of the problems was that our autoclave was simply not a good fit for the bigger hospitals and clinics and we took the autoclaves out of these places and found a new clinic in our target market to place them.

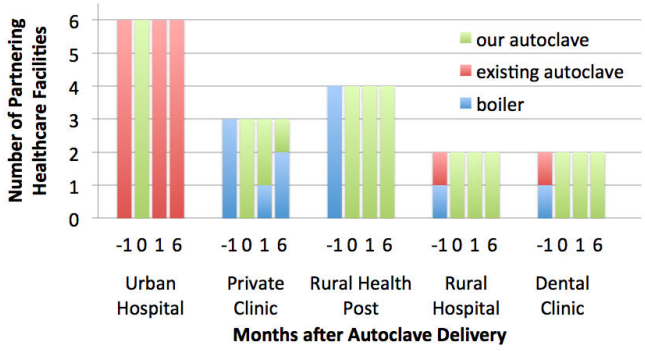

Figure 5. Comparison of usage of boilers, existing autoclaves, and our autoclaves over time in different sectors: (-1) indicates before delivery, (0) during delivery, (1) one month post delivery, and (6) six months post delivery.

There was also an issue with the perception of donated goods. Staff at these clinics did not expect to actually see us again and were genuinely—at times pleasantly—surprised by our follow up visit. But this incident helped us build

closer relationships with these clinics because we were able to build trust and communicate to them we were developing a product to directly answer their needs.

Another problem we found when we asked the staff to show us how they use the autoclave was that people were not comfortable letting us know when they did not understand something during the training. We realized the need for a "teacher" who would always be there to instruct the user when a user was confused. This realization was the basis for the redesign of the cycle monitor to include voice instructions that would speak to the user in their native language.

B. Second Field Trial

The team made a second visit to Nepal and India from January 2012 to February 2012 with 4 beta prototypes (beta prototype features voice instruction). We revisited our partnering clinics and interviewed clinic staff who were in charge of operating the autoclave.

During this interview, the users were also asked to rank the product attributes they talked about as mentioned previously in the methods section. All the interviewed users ranked either safety or autonomy as the most important attribute. We realized that our users continued to use our product because the cycle monitor's alarm system and pressure cooker's built in safety features gave them sufficient assurance to let the autoclave run by itself. These health posts are usually understaffed, and the users appreciated that they could tend other duties while the autoclave was running. Even the clinics that had been using an autoclave had completely switched over to using our autoclave because of the cycle monitor and its ability to operate during frequent, long-term power shortages. Currently available autoclaves require electricity and only come with a pressure gauge so that a user must stand over the autoclave throughout the cycle continually tracking the pressure level and time.

The new version of the autoclave with voice instruction was enthusiastically received. There are very few electronic devices other than radio and television that speak in Nepali. For the next field trial, we are interested in observing whether or not the new voice instruction feature promoted continued usage in comparison to the older version without the voice instructions. The newer version also comes with a feature that tracks usage internally so we will be able to observe the differences in self reported usage log.

IV. DISCUSSION

During our field trials and interviews with users, doctors, government officials in charge of procurement, distributors and manufacturers, we learned that different needs of each of the stakeholders need to be considered to achieve appropriate design. Manufacturers often cater solely to the needs of the government because neither are in communication with the end users. Products that come out of this collaboration do a great job of addressing a developing countries' government's need for large quantity of products at low cost. But this approach does not ensure that users will actually adopt the product and use it to bring out the social impact the product was designed to achieve. On the other hand, products that come out of an academic setting focus on the user-centered product design approach and do a great job of addressing user needs but often have trouble gaining government support or scaling up manufacturing.

We strongly feel that there is a need for a whole systems approach when it comes to designing products for the developing world. The developer needs to identify early on in the design process who the stakeholders are and what their needs are in order to achieve appropriate design.

ACKNOWLEDGMENT

We would like to thank our Nepal community team, Shambhu Koirala, Pramod Kandel, and Aswin Poudel for all their help on the field;our field advisor Dr. Kiran Awasthi for all his encouragement and for connecting us to numerous clinics and government officials. This project would not have launched without the generous support of MIT IDEAS Global Challenge, MIT Public Service Center, and MIT International Development Initiative. We would also like to acknowledge the following individuals for all their support: Laura Sampath, Kate Mytty, Alison Hynd, Shawna MacDonald, Lars Hasselblad Torres, Prof. J. Kim Vandiver, Prof. Maria Yang, Prof. Dan Frey, and Prof. Amos Winter.

REFERENCES

[1] B. Allegranzi, S. Bagheri Nejad, et al. "Burden of endemic health-care-associated infection in developing countries: systematic review and meta-analysis." *The Lancet*, vol. 377, 2011, pp. 228-241.

[2] "Health Care-associated Infections More Common in Developing Countries." WHO. int. WHO, 10 Dec. 2011. Web. 14 Oct. 2011.

[3] J. Fehr, C. Hatz, I. Soka, et al. "Risk factors for surgical site infection in a Tanzanian district hospital: a challenge for the traditional national nosocomial infections surveillance system index." *Infect Control Hosp Epidemiol* vol. 27, 2006, pp.1401–04.

[4] H.M Eriksen, S. Chugulu, S. Kondo, E. Lingaas, "Surgical-site infections at Kilimanjaro Christian Medical Center." *J Hosp Infect vol. 55, 2*003, pp.14-20.

[5] W.A. Rutala, D.J. Weber, "Guidelines for Disinfection and Sterilization in Healthcare Facilities." Centers for Disease Control 2008, pp.58.

[6] L. Tietjen, D. Bossemeyer, N. McIntosh, "Infection Prevention: Guidelines for Healthcare Facilities with Limited Resources." JHPIEGO Corp., 2003.