Otto Clave: reducing post-surgical infection in developing countries

Team members:
- Greg Tao, Lead Engineer, MIT
- Hallie, Lead Business Strategist, MIT
- Andrew Bishara, Clinical Trials, Harvard Medical School

The Otto Clave is a low-cost autoclave with flexibility of use for developing countries. It has a specific set of instructions for users that makes sure that users without medical background can run the device. It can also be used with different sources of energy so that lack of resources is not a limitation of use. During a trip to Nepal, we learned the importance of designing a device that integrates with the needs of low resource settings. We found that small changes, like audio instructions in the language of the user can increase the likelihood that the device will be used regularly. We also proved that we could increase autoclave device usage in health posts in Nepal and hope to begin implementing more autoclaves in resource-poor settings with a proven SMS feedback system to monitor use. We hope to show that we can lower maternal mortality as well as other post-surgical infections with our autoclaves and our feedback system.

Developing countries bear approximately 99% of maternal deaths in the world and many of these deaths are directly or indirectly due to infection, which is exacerbated by unclean medical instruments used during delivery. Studies have shown that sepsis is responsible for up to 40% of these maternal deaths, and sepsis has also been shown to increase risk of hemorrhage, which is the leading cause of maternal mortality worldwide. Current recommendations by WHO World Alliance for Patient Safety state that using autoclaved instruments for cesarean sections and vaginal deliveries is absolutely necessary to prevent deadly infections by bacteria that make endospores. The need for improved sterilization is further evidenced by studies that have shown greater likelihood for mothers to contract infections in hospitals than delivering at home. Otto Clave addresses the needs of rural health clinics by using modular design and commoditized inputs to keep the cost low, with a cycle monitor to provide visual feedback and spoken instructions in local language to train first time users and guide users during regular use, and by being compatible with any heat source (electric, solar, gas, wood fire, etc.) powerful enough to boil water.

The OttoClave team will produce a batch of one hundred OttoClaves and test their impact on health and cost outcomes via a limited clinical trial over the coming year. The team proposes an automated electronic data collection system to monitor the use of our autoclaves in the field. In order to quantify the desired behavioral change, we will use the existing cellular networks to transmit usage data from our autoclave to a central server where researchers and field managers can access accumulated data for the entire autoclave fleet in real time. Availability of up-to-date and accurate usage information will improve tracking of broken or unused equipment. This approach to remotely monitoring prototypes has the ability to improve speed and quality of design iterations for development projects at any stage and makes our idea unique and relevant for future medical device development in the developing world.

During our visit to Nepal, 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. These hospitals typically had a 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.

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. We also hope to include everyone’s feedback through our SMS feedback system that we are currently implementing, which will allow all users to suggest changes to the device and to the way it fits in with workflow. In this way we will continue to include all users in our design of our autoclave.

By year 2, we expect sales of 250 units, and 10,350 and 158,390 units by years 5 and 10. We are being extremely conservative with our sales estimates in the early stages because we will be working exclusively with partnering organizations to develop a product into a kit and documenting evidence of cost effectiveness of our product on a firm’s development activities. After this development period focusing on making a product designed for the masses, general enough of a kit that even students can use to monitor usage of their projects. And during years 3 to 5, we expect to see tremendous growth in the product line and expansion of the company during years 5 to 10. The general impact of this product will be increased number of prototypes and final designs put forth by non-profit organizations focused on creating products for the developing world and increase in awareness of and education for providing solutions for developing world’s needs in form of innovative technology.

Greg Tao is the lead engineer for the Otto Clave project. He managed a team of 4 during the early development stages to manufacture fifteen alpha prototypes and five beta prototypes. He traveled with a team of 3 to Nepal and India during summer of 2011 and winter of 2012 where he field tested the prototypes. Greg holds a SB in mechanical engineering from MIT and has worked at leading firms in medical devices and consumer electronics industries.

Hallie has been studying the process of technology adoption in the developing world’s healthcare sector using Otto Clave as a case for her master’s thesis at MIT. As the lead business strategist, she has been focused on creating a sustainable business plan around Otto Clave. She spent winter of 2012 in Nepal and India interviewing manufacturers, suppliers, distributors, government purchasing officers, and hospital staff to analyze their purchasing decisions and to observe the communication along the supply chain. Hallie holds a SB in mechanical engineering and a SB in management science from MIT and has experiences in raising corporate venture capital, in conducting market research, and in product strategy. Upon graduation in June 2012, Hallie will be managing the Otto Clave project full time.

Andrew Bishara is leading the clinical trial design. He is a third year medical student at Harvard Medical School and has a SB in mechanical engineering from MIT. Andrew will be taking the upcoming year off from medical school to lead clinical trials in country. Andrew has been involved with projects in the medical technology sector in different stages. He has been on the development team, has led a development team, has been a project manager, and has been a cofounder for a start-up.