Sterilization Equipment

Technology Opportunity Assessment

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Summary

All health care facilities should have access to sterilization equipment to reduce disease transmission, including during emergency obstetric procedures. While the World Health Organization (WHO) recommends using autoclaves (technologically advanced sterilizing equipment) at the district hospital level, there are various innovations for sterilization that could be useful in low-resource settings.

Statement of Need

Around 15% of all pregnant women develop a potentially life-threatening complication that calls for skilled care from a facility that provides emergency obstetric care (EmOC).1 Skilled care is needed to provide basic EmOC services defined as parenteral administration of antibiotics, uterotonics, and anticonvulsants; manual removal of the placenta and retained products; assisted vaginal delivery; basic neonatal resuscitation; and the ability to perform these services at community health centers (basic facilities).2 Additional skills are needed to provide comprehensive EmOC services, defined by the additional signal functions of cesarean delivery and blood transfusion to address certain complications such as obstructed labor, severe hemorrhage, and complications from abortion. WHO recommends four basic EmOC facilities and at least one comprehensive EmOC facility per every 500,000 population. Facilities with comprehensive EmOC services must be equipped with anesthetic machines, monitors, respirators and oxygen supply, sterilizing equipment, and other equipment suitable for the level of service.3 A recent analysis of 24 national or near-national needs assessments showed that all but two countries met the minimum acceptable level of one comprehensive EmOC facility per 500,000 population, and in countries with high maternal mortality ratios the number of basic facilities was insufficient.4 Lack of basic facilities and the need for more comprehensive facilities contributes to the inability to meet the fifth United Nations Millennium Development Goal, to reduce maternal mortality.5 Constraints are numerous and are often due to lack of equipment, inadequate equipment maintenance, poor training, and insufficient infrastructure. There is a need for EmOC technologies that are reliable, cost-effective, and easy to implement in both basic and comprehensive facilities.

All health care facilities should have access to recommended basic infection-prevention processes to reduce disease transmission from soiled instruments and other reusable items. The steps for processing are decontamination, cleaning, and either sterilization or high-level disinfection (HLD).5,6 Sterilization is the safest and most effective method for the final processing of instruments, ensuring that instruments are free of all microorganisms including bacterial endospores. WHO recommends autoclaving (steam sterilization at 121°C for 30 minutes) for sterilization at the district hospital7 in preference to other...
sterilization technologies (including dry heat, chemical, gas, plasma, etc.). In peripheral health centers, sterilization equipment may either be unavailable or unsuitable because of price, size, or power requirements. In these cases, HLD has been the only acceptable alternative. Although the HLD process destroys all microorganisms (including vegetative bacteria, tuberculosis, yeasts, and viruses) except some bacterial endospores, experts now recommend that autoclave technology be made available down to peripheral health centers.³

Unreliable or nonexistent power sources, high prices for electricity and/or fuel for generators, and high prices for autoclaves or other sterilization equipment have made implementing these recommendations extremely difficult. As a result, even in areas where surgeries are already performed, one-fifth of the patients suffer from postoperative infection due to, among other causes, the use of improperly sterilized equipment.³ In addition, use of dirty instruments may transmit serious incurable diseases including HIV and hepatitis B and C and other health care-associated illnesses. Serious morbidity and possibly mortality from contaminated instruments could be prevented if reliable sterilization equipment were made available at all points of care. There is consequently a clear need for sterilization equipment that is robust, affordable, reliable, simple to use, and able to tolerate fluctuations in power or operate on alternate power sources.

Technology Solutions Landscape

Where electricity is a problem, high-pressure steam (autoclave) is the oldest and most widely used economical, practical, effective, and reliable method of sterilization in health care facilities. Ideally, the autoclave should be able to withstand harsh environmental conditions, be reliable, cost less than US$500, be simple to use, have a lifespan of at least five years with minimum servicing costs, and have a short cycle length.† The autoclave must be able to obtain the minimum temperature requirements and hold the temperature for the minimum time to achieve microorganism kill. Pressure within the vessel needs to be regulated at 15 pounds per square inch (psi) (103 kPa) to shift the boiling point of water from 100°C to 121°C, the temperature at which microorganisms are inactivated. Hold times will vary depending on wrapped or unwrapped loads. Minimum process parameters are⁹:

- Unwrapped items: 121°C / 15 psi / 20 minutes.
- Wrapped items: 121°C / 15 psi / 30 minutes.

Shorter cycle times can be achieved by increasing the temperature (and therefore the pressure) and are the basis for immediate use steam sterilization (IUSS) (flash sterilization). IUSS is employed only for items to be used immediately after sterilization, not for items to be stored for later use. The need, however, is for wrapped basic surgical kits that can be stored for later use. There are a number of commercially

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³ HLD can be achieved by boiling in water, steaming (moist heat), or soaking instruments in chemical disinfectants.
† Considerations that should be taken into account when choosing an autoclave include: (1) complexity of setting up and operating it, (2) average lifespan, cost of servicing maintenance, cost and need for replaceable parts, (3) energy source (electric or non-electric), (4) size and range of items that can be placed in the autoclave, (5) cycle length, and (6) purchase cost.
available autoclaves in various sizes and configurations; however most are electrically powered. Below is a list of promising technologies for facilities with erratic, limited, or no electric power supply.

Nonelectric “Pressure Cookers”

These autoclave devices are designed for placement over an external thermal source such as a coal or wood fire or over a more controlled source such as a propane flame or hotplate. The materials of construction are typically aluminum and/or stainless steel. Controls are manual and cycle times are determined and controlled by the end-user. Wisconsin Aluminum Foundry (Manitowoc, WI, USA) makes a line of non-electric steam sterilizers under the All-American Brand (models 1915X, 1925X, 1941). The models offer different capacities and range in price from US$319 to US$556.10 Multiple manufacturers in India (Life Steriware, Apothecaries Sundries Mfg. Co., Narang Medical)11,12,13 appear to offer a similar product, however prices are not shown. Instructions for using pressure cookers designed for food preparation for the purpose of sterilization are also available but tend to focus on immediate use of the instruments after the sterilizing cycle is complete. Although food preparation pressure cookers are relatively inexpensive, these devices are only suitable for steam sterilization if the correct settings are chosen. The likelihood of misuse is high and, therefore, these devices are not recommended.

Solar-Powered Autoclaves

Solar energy can be used to directly heat matter. Solar concentrators are reflecting shields, usually in the shape of a parabola, which take solar energy from a larger area and concentrate it into a smaller area. The concentrated radiated energy is converted to thermal energy. Autoclaves are being developed that follow this principle. Most of the projects are academic; however some of the projects have been tried in the field and at least one of the projects is in a pilot involving 1,200 units. The following is a list of the academic projects, a brief description of their technology, and the current stage of their development:

- **Solarclave.**14 The Solarclave concept began in 2008 when a group of students entered a business plan competition at the University of Dayton. The concept has since been transferred to Massachusetts Institute of Technology where Anna Young and a team from the D-Lab have developed the concept into working field units in Nicaragua. The latest design uses 90 pocket mirrors to concentrate the solar rays onto a pressure vessel that produces steam at a sufficient temperature to sterilize instruments in the vessel. The device can be manufactured in country with locally sourced materials.

- **Capteur Soleil.** A 2011 team of Rice University students have modified the classic Jean Boubour design to function as an autoclave. The design includes an array of curved mirrors that focus sunlight on a steel tube filled with water. The tube produces steam that in turn heats a custom-designed hotplate. The hotplate is made available to heat a standard non-electric “pressure cooker” (see above) or any other items requiring a thermal source. The device has not been tested in the field although a similar version used to heat food and water is being used in Haiti.15

- **Prometheus.**16 In 2003, a team from Sydney University developed an autoclave made from a set of long copper tubes encased in evacuated solar collector tubes. The solar collector tubes have an
optically sensitive surface that allows visible and UV radiation to pass into but not out of the tubes. The radiation is absorbed as heat. It is unknown what happened to the Promethus team and if their design has been advanced.

- **Solar Brucke.** In 2004, a team from Aillingen, Germany, and Solar Alternatives (India) installed a Scheffler reflector-based autoclave at Holy Family Hospital in Mandar, India. The 10-m² reflector heats a 230-kg iron block which functions as a once-through steam generator. The solar-powered steam generator is connected to a traditional electric boiler providing a hybrid design suitable for sunny and non-sunny days.

The one advantage the solar concentrator autoclaves have over pressure cooker autoclaves is the ability to harness the sun as a reliable power source. Of the four solar concentrator autoclaves identified, the Solarclave technology appears to be the most promising. The design uses simple, readily accessible components that result in a low-cost yet effective device and is being field tested in Nicaragua.

**Gap Analysis**

A survey of rural clinics in Nicaragua identified that only one in eight had an autoclave of some type. Why do so few rural clinics have autoclaves when simple non-electric pressure cooker devices have been commercially available for many years? Understanding the poor adoption and shortage of pressure cooker devices is critical to estimating the success of solar concentrator autoclaves. If the main deterrent is fuel supply needs for pressure cookers, then solar concentrators may succeed. If instead, the main deterrent is training, perceived high cost of pressure cookers, availability of pressure cookers, or some other reason unrelated to fuel source, then solar concentrator autoclaves may not address the true needs of the rural clinic.

The complexity of setting up and operating an autoclave varies with the type of autoclave and the quality control specifications. While most autoclaves are fairly simple to operate and maintain, providers will need some level of training in their use to ensure that items are being sterilized correctly. Facility staff will also need to be trained to correctly maintain the autoclave to ensure that the machine is being used in a way that can increase its lifespan. Where possible, mechanical, chemical, or biological indicators should be used to provide evidence that the sterilization cycle was successful. Health facilities must, therefore, have up-to-date guidelines and protocols, trained staff, and the requisite equipment and supplies for processing medical and surgical instruments, as well as designated areas and procedures for storing sterilized items.

From a technology standpoint, the Solarclave team is iterating their design each time they introduce the product in the intended use environment. The current design uses 90 pocket mirrors as a concentrator, locally supplied materials for the pressure vessel and reservoir, and a locally made stand. The product is intended for use at a rural clinic although larger-scale designs suitable for use at district-level hospitals
have been proposed. The units being used in Nicaragua have a five-hour cycle time. Shorter cycle times are preferred especially since the autoclave is only available for use during usable daylight hours. Additional development is still required to bring the Solarclave or a similar product to market at scale. The Solarclave design appears to be the most likely to succeed and represents the most promising technology solution for non-electric autoclave needs.

**Investment Opportunity**

Infection-prevention processes must be implemented and followed at all points of care, from community clinics up to tertiary-level hospitals. In facilities that have erratic, limited, or no electricity, equipment used to sterilize instruments and other reusable items should be designed with these variations taken into consideration.

**Community Clinic Opportunities (benchmark technology—HLD)**

The Solarclave pilot in Nicaragua will generate sufficient data to determine the technology readiness of the design. By partnering with a local cooperative to build the devices (Mujeres Solares de Totogalpa), the Solarclave team should be able to recommend if local manufacturing is the preferred supply chain model or if central manufacturing and distribution will yield better results (quality, consistency, availability of components, cost, etc.). The pilot should also yield data regarding training requirements, average daily capacity, durability, and workflow challenges. Investment opportunities for a community clinic system include:

- Conduct a survey to determine if community clinics are with/without autoclaves, and if pressure cooker autoclaves are appropriate to fill the needs.
- Organize a pilot study in another region (Africa, India).
- Collaborate with the Solarclave team to optimize the design.
- Analyze make vs. buy alternatives.
- Generate training materials suitable for regional variations.
- Generate workflow recommendations that include all steps for sterile item processing.
- Generate a marketing plan.

**District Hospital-Level Opportunities (benchmark technology—electric-powered autoclave)**

The Solarclave solar-powered autoclave team has focused on a design that is targeted at the rural community clinic level. District hospitals generate a greater volume of materials that need sterile processing than a single Solarclave unit can process in a single day. Options to increase capacity are to use multiple units or scale the design. A system at the larger scale may have unanticipated challenges that require design iterations. Therefore, it appears that investment opportunities for district-level hospital devices include:
• Conduct a survey to determine how a solar concentrator autoclave would be used in conjunctions with or as a substitute for the hospital’s electric autoclave. Understand if pressure cooker autoclaves are appropriate to fill the needs.
• Identify the optimal size unit to meet typical capacity requirements of the targeted facility.
• Complete a conceptual design and prototyping of the new design configuration.
• Optimize the design.
• Conduct pilot operation in multiple regions.
• Determine manufacturing plan and identify manufacturers or generate kit-building instructions.
• Give consideration to other steps in the decontamination, cleaning, and sterilization process including facility, workflow, handling, storage, record keeping, and quality control.
References


