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CONSIDERATIONS FOR HCWM SYSTEM DESIGN IN AFRICAN HOSPITALS FOR USAID ASHA PROGRAMS

AUTOCLAVES

Overview

Autoclaves are devices used for wet thermal sterilization and disinfection processes of medical waste. They are widely used in hospitals and medical facilities to sterilize both reusable medical equipment and waste materials prior to disposal. Autoclaves are available in a variety of sizes and capacities, in gravity-fed, pre-vacuum, and pulse models. Wet thermal, or steam-based, disinfection is an efficient and environmentally sound process, in which contaminated materials are exposed to temperatures high enough to achieve sterilization, but low enough to avoid emitting pollutants into the atmosphere, a key advantage of autoclaving over other waste management methods.

Autoclaves vs. Incinerators

Wet thermal disinfection systems are widely used by hospitals in the developed world, but are still relatively new to many developing countries, where incineration remains more common and, in some cases, more appropriate.

Improper incineration of hospital waste is associated with a variety of environmental and public health threats. It is linked to the release of heavy metals, acid gases, and particulates, into the air and ultimately, into bodies of water. If the ash isn't disposed of properly, it, too, poses a threat to air quality and water supply (Stringer, R., etl al). Accordingly, reducing incineration of toxin-emitting plastics represents a significant opportunity to eliminate some of the most long-lived anthropogenic pollutants, of particular interest for the many developing countries that have signed the Stockholm Convention on Persistent Organic Pollutants (Stringer, R., et al).

Autoclaves are becoming increasingly popular because the wet thermal sterilization process reduces the risk of toxic emissions associated with improper incineration. However, in some cases, incineration is preferable to autoclaving for reasons of scale, capital and operating costs, and local availability of skilled technicians (Agenda for Environment and Responsible Development).

Advantages of Autoclaves for Health Facilities in Limited-Resource Contexts

- Simple and effective technology, when operated correctly. Easy to understand for hospital staff and the general community.
- Relatively low capital and operations costs.
- Variability of models allows for selection of appropriate autoclave for each facility's unique needs.
- Autoclaves are well known in the developed world, and have a demonstrated track record of reliability (Health Care Without Harm).

Autoclave Technology

An autoclave consists of a metal chamber enveloped in a steam jacket, and connected to a steam generator and an electric supply. Some models also require additional utility connections (World Health Organization).

Air must be removed from the chamber in order to ensure that the waste has adequate exposure to heat.

In gravity displacement models, air is removed by introducing steam, forcing the air downward into an outlet. Pre-vacuum autoclaves require less heat exposure time for disinfection because vacuuming air out maximizes efficiency. Autoclaves must be monitored continuously for effectiveness, using either indicator strips (Health Care Without Harm).

How Autoclaves Work: Step by Step
In order to ensure optimal disinfection and to eliminate risk of environmental contamination, any hospital waste management system must emphasize effective segregation of waste streams. Waste to be autoclaved should be collected in appropriate autoclavable bags to prevent contact with the container. The autoclave operator then takes the following steps:

1. Preheating by introducing steam into outer jacket.
2. Loading waste containers/bags into the autoclave. Closing and sealing of door.
3. Evacuation of air from chamber by gravity displacement or pre-vacuuming.
4. Introduction of steam into chamber, to reach and maintain necessary temperature for required sterilization time.
5. Venting of steam from chamber to reduce pressure and temperature.
6. Cooling and unloading of waste; evaluation of indicator strips to determine whether disinfection has been achieved.
7. Mechanical treatment of sterilized waste (e.g. shredding, compacting) may be carried out either before or after disinfection, depending on the system selected. Mechanical processes may be necessary to reduce the volume of the waste, and/or to render it unrecognizable (Stringer, R., et al)

General temperature-time guidelines are published in engineering manuals and elsewhere, but it is critical that an engineer or skilled technician conduct comprehensive testing at each facility to determine the optimal standards for the specific composition of waste unique to each hospital, prior to use of the machinery.

Note: It is essential that medical facilities avoid using a single autoclave for both reusable medical equipment and waste, to avoid contamination of equipment that will be reused. Models designed for waste are typically larger with a capacity for greater volumes of material to be disinfected (Health Care Without Harm).

Types of Waste that Can be Treated in an Autoclave

- Sharps, cultures, stocks
- Non-chemical lab waste
- “Soft waste,” including textiles
- Materials that have been in contact with anatomical fluids
- Human anatomical waste can be disinfected using autoclave technology, but this practice is limited, mostly due to ethical concerns

Types of Waste that Cannot be Treated in an Autoclave

- Chemical waste including semi-volatile and volatile organic compounds, and chemotherapy waste
- Large volumes of textile waste
- Large/bulky animal carcasses
- Any containers or other materials that slow heat transfer
- Lab waste including solvents, waste pharmaceuticals, and other chemicals.

General Guidelines for Safe Use of Autoclaves
The most important factor for safe and effective disinfection is a well-carried out waste segregation system, to prevent mixing of hazardous chemical waste with waste to be autoclaved. Hospital staff must be properly trained, and ongoing oversight is necessary to ensure adherence to best practices for waste

management for autoclaving. It is necessary to establish unique temperature-time parameters for each facility, as temperature and exposure time depend on variables such as the moisture content and composition of the waste, which vary from hospital to hospital (World Health Organization).

Risks
If waste is not adequately segregated, hazardous chemicals may contaminate waste to be autoclaved. Consequently, toxins may be released into the air and the treated waste, which ultimately pollutes the air, ground, and water around the landfill site where sterilized waste is permanently disposed of.

Training
Staff training should include an overview of wet thermal sterilization systems; occupational health and safety standards; proper operating procedures, especially safety and record-keeping; waste stream segregation and management; identification and resolution of problems; regular maintenance; and contingency plans.

Maintenance
Record-keeping is a critical component of autoclave maintenance; data on chemical and biological indicator tests, time-temperature standards, replacement of parts, and other activities should be regularly recorded and periodically evaluated. Staff should be trained in record-keeping and maintenance procedures, including the following considerations:

1. Autoclaves should annually be run empty with standard time-temperature settings, to allow for monitoring of time-temperature profiles and equipment performance from year to year.
2. In order to control air quality problems, there must be adequate air space around the autoclave, to allow for proper ventilation. .
3. Continuous testing with indicator strips is necessary in order to guarantee that every load achieves sterilization.
4. Factors associated with ineffective treatment of waste:
    - Improper operation of equipment
    - Improper handling of instruments and equipment (cleaning, storage, packaging)
    - Improper loading and overloading of chamber
    - Inadequate air circulation space between packages within autoclave
    - Improper temperature and/or exposure time

The following references provide additional technical information about autoclave safety, operation, and maintenance:
- http://www.asu.edu/uagc/EHS/documents/autoclave-sop.pdf
- http://www.stanford.edu/dept/EHS/prod/researchlab/bio/docs/Autoclave_Safety.pdf
- http://www.ehs.washington.edu/rbsbiosafe/autoclave.shtm
- http://www.cdc.gov/oralhealth/infectioncontrol/faq/sterilization_monitoring.htm

Occupational Safety and Health
Facilities that acquire and use autoclaves should be aware of all occupational health and safety risks, and establish procedures for the safe and effective operation of the equipment, as well as contingency plans for emergency management. Facilities should ensure that all staff members are provided with personal protective equipment (PPE) and hepatitis vaccinations.

Autoclave Limitations

Inappropriate for Medical Facilities of Limited Scale and Capacity
According to the World Health Organization, autoclave technology is not recommended for some rural facilities with limited resources. Although the technology is conceptually simple, it relies on technical precision in order to be effective. The WHO recommends autoclaves only for facilities that have access to

financial resources and trained technicians (World Health Organization).

Consequences of Improper Operation and Maintenance

- Inadequate ventilation may lead to odors and poor air quality.
- Improperly segregated waste streams may lead to hazardous chemical contamination of treated waste, releasing pollutants into the environment and possibly damaging the equipment.
- Improper operation of machinery may compromise effectiveness and fail to achieve disinfection.

Considerations for Autoclaving Program Design/Implementation

Program Design

1. In order to be effective, any autoclaving system depends on good waste management practices.
2. Budgeting for an autoclave program should include both capital costs (such as shipping, import taxes, site preparation, installation, and testing), and operating costs (such as labor, utilities, supplies, maintenance, periodic monitoring for effectiveness).
3. Site preparation should provide for adequate circulation, storage, and washing areas, as well as adequate space for the autoclave and shredder. Some models require a source of steam, compressed air, and other utilities. Adequate ventilation is essential to ensure air quality and reduce odors.
4. Selection of mechanical treatment machinery (e.g., shredder, compactor) should be in accordance with specific needs of each facility. For example, where people and/or animals scavenge in landfills, sharps should be shredded. If disposal cost is based on weight, drying machinery may be a worthwhile investment.
5. A variety of tests should be run to establish the most efficient time-temperature combination for each facility's unique conditions. The established time-temperature standards should be greater than those identified during testing, to provide a margin of error.
6. The temperature within the chamber should be continuously monitored in various locations to detect thermal problems and inconsistencies.

Selecting a Model

1. Models with pre-vacuum cycles evacuate air more effectively.
2. Consistent heat penetration increases efficiency; loads should be packed with adequate air circulation space between the bags.
3. Different autoclave models have differing degrees of automation and ease of use. Occupational health and safety considerations, as well as availability of local skilled technicians/operators, should be taken into account when selecting a model.
4. Reliability of technology and manufacturer/supplier should be considered; how easily can parts be replaced or fixed? Is a given model compatible with parts from other manufacturers? Is the vendor trustworthy?

SUPPLIERS FOR AFRICA

Health Care Without Harm publishes a list of global suppliers of non-incineration waste disposal technology: http://noharm.org/lib/downloads/waste/For_Proper_Disposal.pdf

List of manufacturers and suppliers located in Africa:

1. http://optimascientific.co.za/laboratoryEquipmentAutoclaves.php#.Udjy9vnrySo (South Africa)
2. http://www.hospi.co.za/index.htm (South Africa)
3. http://www.selectech.co.za/ (South Africa)
4. www.compass.za.net, http://www.compass.za.net/contact-us/regional-offices (South Africa)

References

Agenda for Environment and Responsible Development. “Needs Assessment for Hospitals in African Countries in Relation to Infectious Waste Treatment: Demonstrating and Promoting Best Techniques and Practices for Reducing Health Care Waste to Avoid Environmental Releases of Dioxins and Mercury.” May, 2009. <http://gefmedwaste.org/downloads/Report:%20Needs%20Assessment%20for%20Hospitals%20in%20African%20Countries%20in%20Relation%20to%20Infectious%20Waste%20Treatment.pdf>

Arizona State University Standard Operating Procedure (SOP) for Autoclave Operation. <http://www.asu.edu/uagc/EHS/documents/autoclave-sop.pdf>

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Stanford University Autoclave Safety Fact Sheet. <http://www.stanford.edu/dept/EHS/prod/researchlab/bio/docs/Autoclave_Safety.pdf>

Stringer, R., Kiama, J., Emmanuel, J., Chenya, E., Katima, J.,& Magoma, F. “Non -Incineration Medi Waste Treatment Pilot Project at Bagamoyo District Hospital, Tanzania” September, 2010. <http://www.gefmedwaste.org/downloads/Non%E2%80%90Incineration%20Medical%C2%A0Waste%C2%A0Treatment%C2%A0Pilot%C2%A0Project%C2%A0at%C2%A0Bagamoyo%C2%A0District%C2%A0Hospital,%C2%A0Tanzania%C2%A0%20.pdf>

World Health Organization. “Treatment and Disposal Technologies for Health-Care Waste.” <http://www.who.int/water_sanitation_health/medicalwaste/077to112.pdf>