Use of containment pans and lids for autoclaving caustic solutions

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As a means of decontaminating instruments possibly exposed to Creutzfeldt-Jakob disease, the World Health Organization has recommended immersion and autoclaving in sodium hydroxide. However, this recommendation has raised concerns of possible damage to autoclaves, and hazards to operators as a result of the caustic vapors. A series of experiments has been conducted that demonstrate that there are containment pan-and-lid combinations in which instruments can be autoclaved in sodium hydroxide without risk to the autoclave or the operator. (Am J Infect Control 2003;31:257-60.)

The transmissible spongiform encephalopathies comprise a group of diseases that include Creutzfeldt-Jakob disease in human beings, bovine spongiform encephalopathy (mad cow disease) in cattle, and scrapie in sheep.[1] The infectious agents (prions) found in these diseases are very difficult to destroy. They are not completely inactivated by conventional sterilization methods such as steam autoclaving, even at increased temperatures, or by ethylene oxide gas.[2-6] Incubation time after infection may be a matter of years. Transmission of Creutzfeldt-Jakob disease in human beings and animals by contaminated instruments has been demonstrated, but the devices were not subjected to modern cleaning, disinfection, and sterilization methods.[7-9] In the absence of any scientific study demonstrating successful decontamination, there is a growing public health concern regarding the spread of the disease by potentially contaminated surgical or dental instruments subjected to standard hospital cleaning and sterilization protocols.

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The World Health Organization (WHO)[2] and the Centers for Disease Control and Prevention[3] recommend that before cleaning, terminal sterilization, and reuse, instruments should undergo one of several severe decontamination protocols if they have been used on patients with suspected or confirmed Creutzfeldt-Jakob disease. The most highly recommended protocol is to: "immerse (the instruments) in 1 N (3.9%) sodium hydroxide (NaOH) and heat in a gravity displacement autoclave at 121°C for 30 minutes, clean, rinse in water, and subject to routine sterilization."[2,3]

Autoclaving involves high pressure with steam to attain high temperatures. There is condensate formation during the cycle and hazardous substances such as NaOH condensate in the autoclave could cause corrosion. Some sterilizer manufacturers have stated that this will void their warranty. The objective of this study was to determine whether, with the appropriate containment pans and lids, it was possible to autoclave NaOH without high pH condensate contacting the autoclave.

METHODS

The initial objective of this investigation was to focus our attention on lid and pan designs. The classification scheme shown in Fig 1 was developed to help describe different designs that might contain the caustic vapors. Rather than attempt an exhaustive study of these 6 combinations, it was decided to test 2 combinations that showed promise of containing the caustic vapors. Both designs selected were made of polypropylene, which is known to be very resistant to autoclave temperatures and NaOH.

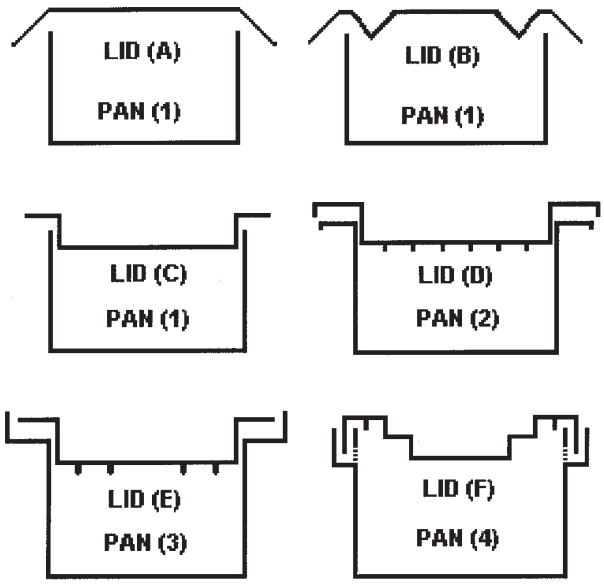

Fig 1. *Pan 1*, shown with 3 different lid designs, is simple with no unique features. *Lid A* is simple overhanging lid, much like aluminum foil stretched over pan. *Lid B* is overhanging lid with internal ridge, similar in concept to common kitchen saucepan with lip to contain steam and moisture. *Lid C* is shaped to drop down inside pan. *Pan 2* has flat, top flange designed to engage *lid D* when inserted in pan with outer overhanging lips, which fit snugly around flange. Sketch also shows points under lid that represent cross-supporting ridges acting as location for vapor to condense, much like classic cast-iron Dutch oven lid, which has drip points to insure uniform basting to contents. *Pans 3* and *4* are designed to confine lid within outer lip. *Pan 4* has added feature of gutter in which outer lip of lid sits. Gutter has slots (*broken lines*) that permit any condensate liquid to drip back into pan. *Lid F* is insert lid with extra molding that interdigitates with gutter and inner band to further insure that vapor condensate returns to pan.

Two approaches for examining the safety of decontaminating instruments in NaOH were taken. The first was to have a containment device in which we placed an open beaker with NaOH. The first approach required a pan deep enough to hold a beaker. The second was to fill the containment pan, itself, with NaOH.

For the first series we used pan 2 with lid D (Scienceware PP Instrument tray, Bel-Art Products, Pequannock, NJ). The pan dimensions were 16 × 28 cm with a depth of 11 cm. The pan had a 1.3 cm—wide flat rim, and the lid had a matching rim and 0.3-cm lip, which was inserted 1.2 cm below the top of the pan. We placed an open 30-mL beaker containing 10 mL of 1 N NaOH in this containment system. Any NaOH vaporized during autoclaving would condense on the lid, be of high pH, would cool, and drop into the bottom of the pan. Thus, the presence of condensate of high pH would indicate the potential for NaOH to be released into the autoclave if there were no containment lid. Before the autoclaving cycles, we placed pH paper on the top of the lid. The pH of the condensate on the bottom of the lid and the pH of the liquid in the pan itself were also measured.

Pan 4 and lid F (Nalgene instrument pipet sterilizing pan, Nalge Co, Rochester, NY) was used for the second series of experiments. According to the manufacturer, this system, "conforms to National Institutes of Health and federal register guidelines for biohazard and recombinant DNA research where disinfecting and subsequent autoclaving of pipets is required before cleaning or disposal," and meets the Occupational Safety and Health Administration standard 29CFR part 1910.1030 for use as protection against bloodborne pathogens. This pan was 12 × 43 cm × 5.5-cm deep and the lid was fully contained or inset 0.5 cm within the outer wall of the gutter. This pan was filled to a depth of about 2 cm with 1 L of 1 N NaOH. Several pieces of pH paper were placed on top of the lid before autoclaving.

For these studies we used a bench-top, gravity-feed, steam sterilizer (Harvey SterileMax, Barnstead Thermolyne, Dubuque, IA) that has a circular internal chamber about 30 cm in diameter and 47 cm deep. Although the WHO method calls for autoclaving at 121°C for 30 minutes, it was decided to use a worse case condition of 135°C for 1 hour, using the "liquids, slow exhaust" cycle. This higher temperature is recommended in some of the other WHO protocols. Before and after each run, pH paper strips were placed in several locations within the autoclave chamber and the pH of the condensate taken after pressure had returned to ambient and the temperature was low enough to open the door safely.

The water used for the generation of steam for this autoclave is from a self-contained water reservoir with a working volume of 6 L. To see if the fluid was getting contaminated by NaOH, the autoclave was run for 5 cycles, without water changing, with pan 4 and lid F filled with 1 L of NaOH. The pH of the

water was measured before and after each run with pH paper and a pH meter (Cole Palmer, Vernon Hills, Ill). Because the pH of the 1 N NaOH is 14 and the distilled water used is slightly acidic, any escape of the NaOH into the autoclave would result in an increase in pH in the reservoir.

RESULTS

The condensate on the internal (underside) surfaces of both types of lids had a pH of 14, indicating that caustic fumes were created during autoclaving. There was condensate with a pH of 14 on the bottom of pan 2 with the open beaker indicating that the beaker contents were released inside the pan. There was no pH change in the condensate on the top (outer) surface of either type of lid.

The pH of the distilled water in the autoclave reservoir was 5.5 before the first cycle. No change in pH occurred in the reservoir water after each of the 5 cycles with pan 4 and lid F filled with 1 L of NaOH. No pH change was detected at any site inside the autoclave in the 5 sterilization cycles as indicated by pH paper placed into the autoclave before the run and by pH paper placed at the end of the run. Thus, pan and beaker contents were contained by these 2 lid and pan combinations.

None of the pans and lids showed any signs of damage as a result of the NaOH. Stainless steel pans and lids have been tested, but showed signs of corrosive attack after only limited exposure. In a subsequent communication, the effects of the WHO decontamination protocols on the instruments, themselves, will be discussed.

DISCUSSION

The first series of tests with the type pan 2, 2-D lid D containment demonstrated that autoclaving a beaker containing a small amount of NaOH resulted in condensation of caustic vapors inside the containment vessel. The pH on condensation on the bottom of the pan, and on the underside of the lid was 14. However, there was no pH change in the condensate on the top (outside) of the lid or on the internal surfaces of the autoclave. This study indicates that if the containment vessel had not been used, caustic vapors would have come in contact with portions of the autoclave.

In the second series, pan 4 was filled with a large volume of NaOH. Although it was only to a depth of 2 cm, the fluid level came close to the lid as a result of the slope of the autoclave chamber. This presented a large volume of NaOH compared with the 6-L volume of the autoclave water reservoir. It also presented a large surface area of the liquid (12×43 cm) compared with the dimensions of the autoclave chamber (30×47 cm). Even after 5 cycles of 1 hour at 135°C, there was no measurable change in pH of the condensate on the top of the F lid and in the chamber, or in the water reservoir.

These studies have demonstrated that even at the extreme conditions of 1 hour at 135°C, compared with the WHO recommendations of 30 minutes at 121°C, it is possible, with appropriate containment pans and lids, to prevent escape of NaOH vapors that might cause damage to the autoclave. These studies have not included measurement of actual temperatures of the liquids, which is an inherent problem with gravity-feed, bench-top systems. It should be pointed out that these WHO recommendations are only for instrument decontamination. After this process, routine cleaning and sterilization with validated methods is required.

Both the pans and the autoclave used in these studies were small compared with those used in clinical or commercial settings. By comparison, a standard clinical autoclave may have a 51- × 76-cm opening and be 127 cm deep ($2 \times 3 \times 5$ ft), which is a volume 15 times that of the table-top system. As such, larger loads could be used in such units. More importantly, clinical autoclaves often have a preset prevacuum cycle program that contains several pulses between high-pressure steam and vacuum. These can not be used with liquids such as NaOH, because the hot liquids will boil during the vacuum phase. The use of a gravity-feed cycle, in which the pressure and temperature are slowly increased, held for a preset time, and then slowly decreased ("liquids, slow cool") is essential for preventing boiling.

These results do not imply that these are the only pan-and-lid combinations that would work, or that they will work in all situations. We would anticipate that lid A would drip outside of the pan, and lid B would drip back into the pan. It is incumbent on the decontamination facility to validate the method used. Autoclaves present various hazards that are magnified when caustic substances are used. All standard precautions must be followed: use the slow exhaust (liquid cycle); allow the chamber and contents to return to ambient temperature and pressure before opening the door; insure the liquid

is cool before handling; and take care in removing the instruments. Disposal of the NaOH should be done according to institutional guidelines.

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