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These devices require careful monitoring, since PVC placement is not without risk in patients, especially patients who are immunologically challenged.

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This work has been presented in part at the XI International Conference on AIDS, Vancouver, British Columbia, Canada, July 7-12, 1996. Abstract 3181.

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Efficacy of a Washer-Pasteurizer for Disinfection of Respiratory-Care Equipment

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ABSTRACT

We evaluated the efficacy of a commercial washer-pasteurizer. Carriers were inoculated with 10^4 to 10^6 test organisms and pasteurized at 170°F for 30 minutes. Pasteurization eliminated all test organisms with the exception of *Bacillus subtilis* spores. Pasteurization appears efficacious for the disinfection of respiratory-care equipment and could result in a cost savings of approximately $30,000 per year (*Infect Control Hosp Epidemiol* 2000;21:333-336).

Contaminated respiratory-care equipment is a well-recognized source of nosocomial respiratory tract infections.[1] For this reason, it is recommended that respiratory-care equipment be sterilized or high-level disinfected between patients.[2,3] Failure to clean and disinfect ventilatory circuits properly between patients has led to outbreaks of *Pseudomonas aeruginosa*[4] and *Acinetobacter calcoaceticus*[5] infection.

Pasteurization is an alternative to high-level disinfection or sterilization that does not require the use of chemicals. The device to be disinfected is submerged for ≥30 minutes in water whose temperature remains ≥165°F. This study was undertaken to evaluate the efficacy of a pasteurization system to inactivate a variety of bacteria.

METHODS

Evaluation of Pasteurization Efficacy

Test organisms were clinical isolates obtained from the University of North Carolina (UNC) Hospitals' Microbiology Laboratory (*Klebsiella pneumoniae, Staphylococcus aureus,* and *Candida albicans),* the American Type Culture Collection (ATCC), Rockville, Maryland (*Mycobacterium terrae* ATCC 15755), or Difco Laboratories, Detroit, Michigan (*Bacillus subtilis).* Organisms, except *M terrae* and *B subtilis,* were grown on sheep blood agar and inoculated to trypticase soy broth and the turbidity adjusted to match the 0.5 McFarland standard. Surgical blades were aseptically placed in a sterile Petri dish and inoculated with 10 µL of this suspension in a biological safety cabinet. Porcelain penicylinders were allowed to sit in the inoculating suspension (1:10 dilution of 0.5 McFarland) for 10 to 15 minutes, then allowed to dry for 45 to 60 minutes at 37°C. To evaluate sporicidal activity, carriers were inoculated with 10 µL of the spore suspension, allowed to air dry overnight, and then stored for 7 days at room temperature before use.

For vegetative bacteria, carriers were quantitated in duplicate before use by placing the carrier in a test tube containing 10 mL of phosphate-buffered dilution water and vortexed for 1 minute. Serial 1:10 dilutions were made for each sample, with the last two dilutions of each set being plated in duplicate into trypticase soy agar with the pour-plate method. These plates were incubated at 37°C for 48 hours and assessed for growth. The spore carriers were quantitated by placing the carrier in a test tube containing 10 mL of sterile water and sterile glass beads. These tubes were sonically treated for 5 minutes, chilled in an ice-water bath for 2 minutes, vortex mixed for 2 minutes, and then chilled again in an ice-water bath for 2 minutes. After these steps were repeated two more times, the samples were heat shocked for 15 minutes at 100°C and then chilled in an ice-water bath. Serial dilutions (1:10×4) were made for each sample, with the last two dilutions of each set being plated in duplicate into trypticase soy broth with the pour-plate method. These plates were incubated at 37°C for 48 hours and assessed for growth.

The pasteurizer used in these experiments was a Steri-Vers Washer Plus (model 540-2; ClearMedical,

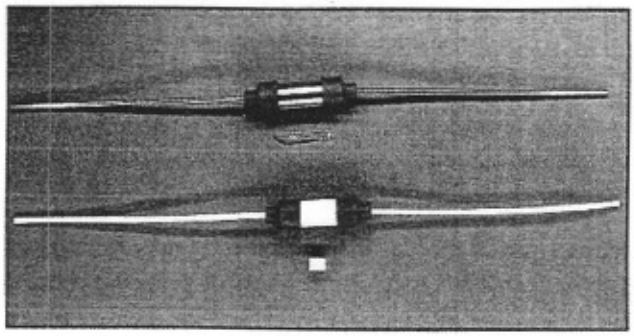


FIGURE. Top: 40-cm–long and 3-mm–diameter stainless steel lumen test unit with stainless steel surgical-blade carrier. Once inoculated, the blade is aseptically placed in the removable center portion by unsealing the hard rubber septums connecting the stainless steel tubing. Bottom: 40-cm–long and 3-mm–diameter plastic lumen test unit with porcelain cylinder carrier. Once inoculated, the carrier is aseptically placed in the removable center portion by unsealing the hard rubber septums connecting the plastic tubing.

Bellevue, WA). This device was leased by UNC Hospitals.

The microbicidal activity of the pasteurization process was assessed by aseptically placing inoculated carriers into 40-cm–long lumen test units ([LTUs] Figure). Two types of LTUs were used. First, a stainless steel LTU with a removable 5-cm centerpiece (1.2-cm diameter) of stainless steel sealed to the narrower steel tubing by hard rubber septums. Second, a plastic LTU with a removable 5-cm centerpiece (1.2-cm diameter) of nalgene plastic sealed to the narrow plastic tubing by hard rubber septums. The lumen of both LTUs was 3-mm.

Two types of carriers were used: number 10 Bard-Parker stainless steel surgical blades (Becton-Dickinson Acute Care, Franklin Lakes, NJ) were used in conjunction with the stainless steel LTUs, and porcelain cylinders were used with the plastic LTUs. The LTUs were then placed within the pasteurizer as recommended in the operating manual. Three or four LTUs were placed within each of the three layer dividers (total 10 LTUs) that fit into a stainless steel basket, the soap provided by the manufacturer was added, and the pasteurization cycle initiated. The temperature was monitored at each cycle, and the average temperature was 170.40°F (range, 166°-173°F). The mean disinfection cycle time was 30.45 minutes, and the total mean processing time was 81.82 miutes.

After completion of the pasteurization cycle, the carriers inoculated with *S aureus, C albicans, K pneumoniae,* or *B subtilis* were aseptically removed and placed in tubes containing trypticase soy broth. The tubes were incubated at 37°C for 7 days. *M terrae* was placed in 7H9 broth and incubated for 7 days at 37°C with CO_2. Positive culture results were confirmed as representing the test organism using API 20E and API 50CH as appropriate (bioMérieux Vitek, Inc, Hazelwood, MO).

Estimation of Cost Savings

Cost estimates were based on the cost of the pasteurization equipment, straight-line depreciated over 10 years. The cost of pasteurization per cycle was estimated at $2.94 (equipment costs) plus $0.84 for soap. It was assumed that incorporation of pasteurization would not result in a change in labor, water, or utility expenses. Costs of the alternative sterilization method, ethylene oxide (ETO), were determined to be $103.76 ($97, ETO; $1.20, soap; $5.56, alcohol) per sterilization cycle based on actual costs of providing this service at UNC Hospitals. The totals reflect three cycles of pasteurization per day to accommodate the equipment and a single cycle of ETO per day (90% of available space used for respiratory-care equipment).

TABLE
RESULTS OF PASTEURIZATION OF EXPERIMENTALLY CONTAMINATED CARRIERS

Organism	Microbial Load Per Carrier (CFU)	Metal Lumen Test Unit With Metal Carrier	Plastic Lumen Test Unit With Porcelain Carrier
Bacillus subtilis	8.5×10^5	30/30*	Not tested
	1.1×10^1	20/20	Not tested
Klebsiella pneumoniae	1.2×10^3	0/60	Not tested
	9.1×10^5	Not tested	0/10
	5.7×10^7	Not tested	0/20
Staphylococcus aureus	1.8×10^6	0/30	Not tested
Candida albicans	1.3×10^5	Not tested	0/10
	1.5×10^8	Not tested	0/40
Mycobacterium terrae	1.3×10^6	Not tested	0/30

Abbreviation: CFU, colony-forming unit.
* Number of positive carriers per number of replicates tested (see text).

RESULTS

Microbial Inactivation

Pasteurization eliminated all vegetative bacteria whether placed in plastic or metal LTUs (Table). Pasteurization was completely effective in eliminating *C albicans* and the highly resistant bacterium, *M terrae. B subtilis,* a spore-forming bacteria, was not completely eradicated from any carrier during 50 replicate tests at two concentrations.

Cost Savings

Based on these figures, the yearly cost of pasteurization is estimated to be $4,139 compared with a yearly cost of ETO of $34,085. Thus, pasteurization at our hospital will result in a yearly savings of $29,946.

DISCUSSION

Nosocomial pneumonia represents an important hazard for hospitalized patients, especially persons requiring mechanical ventilation. The incidence of ventilator-associated pneumonia has ranged from 11 to 54 per 100 patients, depending on the population, and the crude

mortality is in the range of 20% to 40%.[1,6] Contaminated respiratory-care equipment represents an important potential cause of nosocomial pneumonia. For this reason, the Centers for Disease Control and Prevention recommends high-level disinfection or sterilization for semicritical equipment or devices that come into direct or indirect contact with mucous membranes of the lower respiratory tract.[2]

Pasteurization is not a sterilization process; its purpose is to destroy all pathogenic vegetative microorganisms, but it may not destroy bacterial spores. The term *high-level disinfection,* a process that eliminates all microorganisms except high numbers of bacterial spores, is most commonly applied to chemical germicides, but data suggest that pasteurization may achieve similar microbial inactivation. The time-temperature relation for hot-water pasteurization is generally 70°C (158°F) for 30 minutes. This temperature is well under the temperature that would cause deleterious effects on plastic materials such as respiratory-therapy equipment. Pasteurization of respiratory therapy[7] and anesthesia[8] equipment is a recognized alternative to chemical disinfection. After pasteurization, the equipment is wet and is dried in hot-air drying cabinets prior to storage.

Our test system is a very stringent test of disinfection efficacy. The test carriers are inoculated with high numbers of test organisms and placed into the center of long narrow-lumened test units. Our system relies on passive rather than active flow to achieve contact between the test organism and the disinfecting solution (in this case, hot water). Further, a positive culture will result from a failure to eliminate all test organisms. In addition to testing metal tubing, we also tested plastic tubing in the belief that it would represent a more stringent test for a process that relies on heat for inactivation, because plastic would transfer heat less efficiently to the interior of the tubing.

Our data demonstrated complete elimination of high numbers of vegetative bacteria (*S aureus, K pneumoniae),* fungi (*C albicans),* and mycobacteria (*M terrae). S aureus* and *K pneumoniae* were chosen as test organisms because they are among the top four pathogens associated with nosocomial pneumonia.[9] *C albicans* was chosen since *Candida* species are the most common fungal causes of nosocomial infection. *M terrae* is increasingly used as a surrogate for *M tuberculosis* to test the efficacy of disinfectants.[10] Spores were not eliminated by the pasteurization process; however, spore-forming bacteria have only rarely been described as a risk factor for infection caused by contaminated respiratory therapy equipment.[11] Pasteurization was also demonstrated to be effective by Jette and Lambert, who used two hot-water washer-disinfectors and showed inactivation of *A calcoaceticus, P aeruginosa,* and bacterjophage Felix 01.[8] Other investigators have also demonstrated the efficacy of pasteurization.[12] However, Gurevich and associates[7] reported a disinfection failure rate of 83% when using a machine-assisted pasteurization process. These investigators experimentally contaminated 40-in–long tubing with ~10^7 *P aeruginosa* or *A calcoaceticus.* The reason for the disparity between our results and that of Gurevich and colleagues is unclear, although we note that that their tubing was approximately 2.5 times the length of our LTUs. It is likely that air bubbles or other incomplete water flow led to a failure of contact between the hot water and their test organisms.

Pasteurization was able to eliminate high numbers of a variety of bacteria, including mycobacteria, placed into the center of narrow-lumened test units. It is likely that this process would be even more effective with wider-bore tubing, presuming there is hot-water exposure of all surfaces. Although pasteurization did not eliminate *B subtilis,* only a single outbreak of *Bacillus cereus* infections has been described due to the failure of pasteurized respiratory-care equipment.[11] If additional outbreaks are reported, we may need to reassess this equipment.

In summary, we believe pasteurization is a safe, effective, and cost-effective method for disinfecting respiratory-care equipment.

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