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Major article

Efficacy of commercially available wipes for disinfection of pulse oximeter sensors

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Noncritical device

Background: This study examined the effectiveness of commercially available disinfecting wipes and cosmetic wipes in disinfecting pulse oximeter sensors contaminated with pathogenic bacterial surrogates.
Methods: Surrogates of potential biological warfare agents and bacterial pathogens associated with hospital-acquired infections (HAIs) were spotted on test surfaces, with and without an artificial test soil (sebum), allowed to dry, and then cleaned with different commercially available cleaning and disinfecting wipes or sterile gauze soaked in water, bleach (diluted 1:10), or 70% isopropanol. The percentage of microbial survival and an analytical estimation of remaining test soil on devices were determined.
Results: Wipes containing sodium hypochlorite as the active ingredient and gauze soaked in bleach (1:10) were the most effective in removing both vegetative bacteria and spores. In the presence of selective disinfectants, sebum had a protective effect on vegetative bacteria, but not on spores.
Conclusions: The presence of sebum reduces the cleaning efficiency of some commercially available wipes for some select microbes. Various commercial wipes performed significantly better than the designated cleaning agent (70% isopropanol) in disinfecting the oximetry sensor. Cosmetic wipes were not more effective than the disinfecting wipes in removing sebum.

Hospital-acquired infections (HAIs), or nosocomial infections, continue to cause significant morbidity and mortality in patients receiving treatment in health care settings.[1-3] These infections are often caused by breaches of infection control practices and procedures, such as unclean and nonsterile environmental surfaces. Several risk factors increase the likelihood of contracting HAIs. Common causes include the use of improperly processed reusable medical devices (RMDs) and contamination of the health care environment, followed by transmission between patients and health care workers.[4,5] Numerous studies have shown that hospital surfaces and frequently used medical equipment become contaminated by various pathogenic and nonpathogenic organisms.[6-9]

Contamination of RMDs and medical equipment may occur in many ways. First, microbes are readily transmitted between patients from improper cleaning and disinfection or sterilization. Second, a bioterrorism attack could result in contamination of RMD surfaces.[10] These biological agents could then be inadvertently transmitted to and by health care workers, which would have the potential to pose a severe health threat. Third, nosocomial infection can be transmitted by direct contact with devices and equipment or by physical transfer between a susceptible host and an infected or colonized patient. Finally, a natural environmental disaster in a highly populated area with limited infrastructure also may be a source of transmission. Consequently, the regular practice of appropriate infection control procedures to prevent nosocomial infection is essential.[11]

RMDs undergo "reprocessing," involving a multistep process for cleaning and disinfection or sterilization. Inadequate reprocessing between patients can result in the retention of blood, tissue, and

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other biological debris (soil) on medical devices.[12] The ultimate goal of reprocessing is to make the medical device safe and effective for further use. Cleaning is the first important step in reprocessing; inadequate cleaning leads to less effective disinfection or sterilization.[13] Choosing a method of disinfection or sterilization is based largely on the Spaulding classification scheme, which divides instruments and items for patient care into 3 broad categories: critical (in contact with sterile tissue, thus requiring sterilization), semicritical (in contact with mucus membrane, thus requiring high-level disinfection), and noncritical (in contact with intact skin, with low-level disinfection recommended).[14] However, implementation of this scheme raises concerns in some scenarios where reprocessing might involve complex, heat-sensitive medical equipment or processing of a semicritical instrument that would be used in conjunction with a critical instrument that contacts sterile body tissue.[15]

Reusable pulse oximeter probes are classified as noncritical devices and thus require only low-level disinfection between patients as long as the probe is placed on intact skin and does not become soiled with blood or any other body fluid. Oximetry sensors are frequently used on skin that can be dry and cracked, which may increase the likelihood of transmission of microorganisms onto the device. Improperly applied sensors also might lead to skin breakdown, especially in neonatal intensive care units and burn units, where patients have poor skin integrity.[16] Ischemic pressure necrosis may result if the probe is placed too tightly on the patient. Prolonged placement of a pulse oximeter probe, which can occur in patients in the intensive care unit, may lead to physical injury as well.[17] In such cases, soiled noncritical items need to be cleaned and disinfected with intermediate or high-level disinfectants before reuse.[15]

The primary objective of the present study was to determine the efficacy of microbial removal/killing using a variety of commercially available wipes to clean and disinfect a common RMD surface (pulse oximeter), after contamination with surrogates of pathogenic bacteria, such as methicillin-resistant *Staphylococcus aureus* and *Clostridium difficile* spores. Surrogates of *Yersinia pestis*, *Burkholderia mallei/pseudomallei*, and spores of *Bacillus anthracis* were also used in this study, because these microorganisms are on the Centers for Disease Control and Prevention's list of potential biological warfare agents.

To determine whether biological soil could provide bacteria any protection against the cleaning process, an artificial soil (sebum) was used to mimic worst-case soiling conditions that might be present in a used pulse oximeter. Natural sebum, secreted by the sebaceous glands, is a key component of the skin surface.[18] Sebum is a complex mixture of naturally produced fats, oils, waxes, cholesterols, and other molecules. The composition, as well as rate of sebum production, vary widely among individuals. Increased sebum secretion has a direct correlation with bacterial skin infections. Moreover, sebum reportedly functions as a nutritional source in harboring certain skin microflora. Thus, varying amounts of sebum contamination are expected in reusable pulse oximeter sensors before cleaning. Synthetic sebum was used as a test soil to challenge the cleaning and disinfection process and evaluate whether a cleaning agent can provide adequate disinfection in the presence of some reasonable amount of organic matter.

MATERIALS AND METHODS

Bacteria used

Yersinia pseudotuberculosis American Type Culture Collection (ATCC) 6902 (surrogate for *Y pestis*), *Burkholderia thailandensis* ATCC 700388 (surrogate for *B mallei/pseudomallei*), and *S aureus* ATCC 6538 (surrogate for methicillin-resistant *S aureus*) were used in this study.

Spore culture

Bacillus atrophaeus spores (surrogate for *B anthracis* spores) were purchased from Steris Life Sciences (Mentor, OH; NRRL-B4418) as a suspension of bacterial spores in an aqueous solution. The spore suspensions were manufactured to meet the ISO 11138-1 standard (as per the manufacturer), with varying populations ranging in age between embryonic day 3 and 9, and the recommended storage temperature was 2-8° C. *Clostridium sporogenes* spores (surrogate for *C difficile* spores) purchased as spore suspensions from Mesa Labs (Butler, NJ) served as the stock spore culture.

Media and cultivation

B atrophaeus spores and *S aureus* were cultivated in tryptic soy (TS) broth and TS agar, *B thailandensis* was cultivated in nutrient broth and nutrient agar, *Y pseudotuberculosis* was cultivated in brain heart infusion broth and agar, and *C sporogenes* spores were cultivated in blood agar. Liquid cultures were incubated overnight at 37° C and 250 rpm in an incubator shaker (Southwest Sciences, Santa Fe, NM), except that for *B thailandensis*, which was incubated at 30° C in accordance with ATCC instructions. After inoculation, the agar plates were incubated overnight at 37° C. The next day, colonies were counted, and CFU/mL was determined. For *C sporogenes*, the blood agar plates were incubated in an anaerobic jar with gas packs at 37° C for 24-48 hours.

Device description

The test pieces were reusable SP-Ox handheld pulse oximetry units (Schiller America, Doral, FL) and adult reusable SpO_2 finger sensors (S400A-160114; Solaris, Milwuakee, WI). The sensor pads, with which patient fingers are in direct contact, served as the test surface.

Inoculation and soiling

For testing of microbial removal/killing efficiency, the 3 vegetative bacteria and 2 types of spores were each inoculated on the test area of the pulse oximeter sensor. Log-phase liquid cultures of the bacteria were centrifuged (model 5417C; Eppendorf, Hamburg, Germany) at 8000 $\times$ *g* for 10 min and suspended in sterile PBS (Life Technologies) to the desired cell concentration. The spores were inoculated at a final concentration of 10^6 CFU/mL; the vegetative bacteria, at 10^8 CFU/mL. Because spores are comparatively more resistant to disinfection and more difficult to destroy, a higher concentration of vegetative bacteria was used to simulate consistent test conditions. A 10-μL drop of the suspended culture was applied on the inner designated test area of the pulse oximeter sensor and allowed to dry on the device for 1 hr at room temperature.

The chemically defined artificial test soil used in this study was sebum (A9 synthetic sebum; Scientific Services S/D, Sparrowbush, NY).[19] Because the test soil was solid at room temperature, an aliquot of the sebum was diluted (1:1) in glycerol (Sigma-Aldrich, St Louis, MO) and incubated in a water bath at 40° C to keep it in solution. In accordance with the manufacturer's instructions, the remaining sebum in the bottle was purged with nitrogen gas and stored at room temperature. Microorganisms were suspended (same concentration of bacteria and spores as used previously) in the serum-glycerol mixture and similarly inoculated on the test surface. The addition of the test soil provided a worst-case