Simulated-use testing of bedpan and urinal washer disinfectors: Evaluation of Clostridium difficile spore survival and cleaning efficacy

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Background: Reusable bedpans and urinals are frequently cleaned and decontaminated using washer-disinfectors (WDs) that may be located in the central processing department (CPD) or on the ward. The objective of this study was to determine how efficiently the WDs provided cleaning and to evaluate the ability of such WDs to kill Clostridium difficile spores.

Methods: The cleaning efficacy of 2 bedpan/urinal WDs (1 in the ward [ward-WD] and 1 in the CPD [CPD-WD]) were evaluated using simulated-use testing that included an ultraviolet-visible marker (UVM) that is readily removed when exposed to liquid. In addition, a proprietary test object surgical instrument (TOSI) device was used to assess the efficacy of the WDs. Artificial test soil (ATS) and C difficile spore removal and killing also were evaluated. The removal of \(10^6\) C difficile spores and subsequent killing of these spores was assessed using autoclaved stool and/or urine as the soil challenge.

Results: Reusable stainless steel bedpans, plastic bedpans, and plastic urinals were assessed. Triplicate testing done on 3 separate days using TOSI devices, UVM, ATS, and stool and urine soils indicated that the ward-WD did not demonstrate adequate cleaning. It was determined that installation errors accounted for the inadequate cleaning. But the ward-WD did not adequately inactivate C difficile spores even when the installation problems were corrected and the manufacturer-adjusted maximal thermal conditions were used. The CPD-WD was able not only to adequately clean the test devices of organic soil, but also to completely inactivate the 6 logs of C difficile spores placed in sealed ampules inside the WD.

Conclusion: The results of this study indicate that user testing of the efficacy of WDs is critical to ensure appropriate functionality. The currently accepted thermal decontamination parameters for all bedpan WDs (ie, 80°C for 1 minute) are not adequate to eliminate C difficile spores from bedpans. (Am J Infect Control 2008;36:5-11.)
of 2 types of WDs used in the reprocessing of bedpans and urinals, 1 designed for use on the ward (ward-WD) and 1 designed for use in the CPD (CPD-WD). We assessed the ward-WD against the CPD-WD (the device currently used for reprocessing bedpans and urinals) using a proprietary test object surgical instrument (TOSI) device, artificial test soil (ATS), as well as sterile feces and urine seeded with known concentrations of _C difficile_ spores.

**MATERIALS AND METHODS**

**Washer/disinfectors**

**CPD-WD.** The CPD-WD evaluated was a STERIS Reliance 444 single-chamber WD (STERIS Corp, Mentor, OH). The cleaning cycle used in the test was the "utensils" cycle, comprising a 2-minute prewash, a 2-minute wash at 66°C (150°F), a 15-second rinse with hot tap water, a 1-minute thermal rinse at 82°C (180°F), and a 10-second final rinse with treated (demineralized) water. This cleaning cycle was followed by a drying phase for 7 minutes at 116°C (240°F). This CPD-WD was designed for the reprocessing of many different medical devices, not just bedpans and urinals.

**Ward-WD.** This WD was designed specifically for location on wards to wash bedpans and urinals of various shapes and sizes. It was located in a tertiary care health care facility on a ward that had not yet opened. The device was set to the "standard" cycle for bedpans and to the "urinal" cycle for urinals, in accordance with the manufacturer’s recommendation. The cycle parameters included a 14-second cold water wash, followed by a 15-second warm water wash, and finally a 16-second warm water wash. The standard disinfection temperature was 80°C (176°F) for 60 seconds. The cycle used no detergent and had 2 cold water washes followed by 3 warm water washes. In addition, a custom-set (manufacturer-adjusted) cycle was evaluated that used detergent, 4 cold water rinses, 4 warm water rinses, and a disinfection temperature of 85°C (185°F) for 300 seconds. This WD is ISO-registered and licensed for sale in Canada, but no data are available for cleaning validation.

**TOSI device.** The TOSI testing device (Pereg GmbH, Waldkraiburg, Germany) consists of a stainless steel strip with red-colored soil dried on one surface. The devices used in this study were tested with and without the clear plastic cover. Exposing the strip to water during the wash cycle will remove the red material to some degree. A completely clean strip indicates a properly functioning WD.

**Bedpans and urinals.** All of the bedpans and urinals evaluated were reusable. The inoculation sites for the various bedpans and urinals are listed in Table 1.

<table>
<thead>
<tr>
<th>Device</th>
<th>Test soil</th>
<th>Site inoculated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plastic bedpan</td>
<td>ATS</td>
<td>• Inside bedpan on bottom surface</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Inside bedpan under front lip</td>
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<tr>
<td>Stainless</td>
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<td></td>
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<tr>
<td>steel bedpan</td>
<td>ATS</td>
<td>• Outside bedpan on seat surface</td>
</tr>
<tr>
<td></td>
<td>UVM</td>
<td>• Inside bedpan on bottom surface</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Inside bedpan under front lip</td>
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<tr>
<td></td>
<td>Sterile</td>
<td>• Outside bedpan on underside surface</td>
</tr>
<tr>
<td>feces</td>
<td>UVM</td>
<td>• Inside bedpan on bottom surface</td>
</tr>
<tr>
<td></td>
<td>Plastic</td>
<td>• Inside bedpan on bottom surface</td>
</tr>
<tr>
<td>urinal</td>
<td></td>
<td>• Inside bedpan under the seat side lip</td>
</tr>
<tr>
<td>Sterile urine</td>
<td></td>
<td>• Inside bedpan under the seat side lip</td>
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</tbody>
</table>

**Test soils**

**ATS.** For simulated-use testing, we used ATS, which mimics the worst-case organic load expected for flexible endoscopes exposed to the human gastrointestinal tract. This soil has been studied extensively for evaluating the cleaning of medical devices.\(^1\)\(^6\) The same lot of ATS was used for all of the experiments performed in this study. The ATS was stored at 4°C until use and was used within the 1-month expiration period.

ATS was inoculated onto the internal and external surfaces of the devices to be tested. Bedpan inoculation involved placing a 50-μL drop of ATS into the center of the square and using the edge of the sterile tip to spread out the soil within the boundaries of a 2-cm² area. For urinals, 10 mL of ATS was inoculated along the inner flat side (ie, opposite the handle). The soil was swirled around the bottom and along the entire length of the inner side. Once inoculated, the devices were allowed to dry at room temperature for 1 hour before processing in the WD.

After processing in the WD, the inoculated area was harvested using a sterile swab moistened in sterile reverse-osmosis water that was thoroughly rubbed over the entire inoculated area. Each test represented a separate inoculated area. The swab used to "harvest" any residual soil was then placed into a tube containing either 1 mL of Bradford reagent (which turns blue in the presence of protein) or 1 mL of tetramethylbenzidine (TMB) reagent (which turns green in the presence of blood). The swabs were immersed in the test reagent for 20 minutes at room temperature for the Bradford reagent and for 30 minutes at room temperature for the TMB reagent and then the absorbance was measured at 595 nm for protein or 650 nm for blood. The higher the absorbance value for the Bradford or TMB reagent,
the more protein or hemoglobin is present. Negative (not soiled and not cleaned) and positive controls (soiled but not cleaned) were included for all experiments. All tests were performed in triplicate on 3 separate days.

**Ultraviolet-visible marker.** Ultraviolet-visible marker (UVM) lotion (GlitterBug; Brevis Corp, Salt Lake City, UT) is visible under UV light and is used to monitor compliance with handwashing. It is nontoxic and readily removable by washing with water. This lotion was applied to ~2-cm² surface areas using a sterile swab inside and outside the test devices and allowed to dry for 1 hour. The inoculated devices were then exposed to the wash cycle to evaluate the efficacy of removal of the UVM. After processing in the WD, the inoculated sites on the devices were harvested using a sterile swab. This swab was rubbed over the area inoculated. This swab was then evaluated by exposing it to UV light in a dark room. The presence of any detectable fluorescence indicated inadequate cleaning. The amount of fluorescence detected was scored as 3+ (100% fluorescence), 2+ (66% fluorescence), 1+ (33% fluorescence), 0.5+ (10% fluorescence), or 0 (no fluorescence). Negative (not soiled, not cleaned) and positive (soiled but not cleaned) controls were included in all experiments.

**Efficacy of WDs in removing and/or killing C difficile spores.** The test organism used was a patient-derived strain of *C difficile* (strain 765 from clinical stocks at the Microbiology Laboratory, St. Boniface General Hospital). Spores were prepared by inoculating a 48-hour culture of the organism on blood agar plates and incubating these under anaerobic conditions for 7 to 14 days. The surface growth was harvested and suspended in sterile reverse-osmosis water and assessed using malachite green stain to ensure that spore formation had occurred. If adequate spore formation was identified, then the spore concentration was determined by pelleting the spores by centrifugation and then alcohol-shocking the pellet by incubating it in 95% alcohol for 20 minutes at room temperature, followed by determining the viable count using the spread plate method on *C difficile* moxalactam norfloxacin (CDMN) agar (Oxoid Ltd, Nepean, ON, Canada). The spore preparation was stored at 4°C until use.

The test soils used for these studies consisted of stool and urine. The stool was a clinical sample obtained from the diagnostic laboratory that was negative for *C difficile* toxin. The stool was autoclaved and subsequently inoculated onto CDMA, blood agar, chocolate agar, and fastidious anaerobe broth (FAB) to confirm its sterility. The urine was a clinical sample obtained from the diagnostic laboratory known to be culture-negative (ie, no organisms were detected using standard microbiology methods when 0.001 mL of urine was inoculated onto blood agar medium). The urine was also autoclaved and subsequently inoculated onto blood agar, MacConkey agar (split-plate) and FAB to confirm that it was sterile. The *C difficile* spores were mixed with the sterile urine or sterile stool to provide a final concentration of about 1 × 10⁷ cfu/mL. The devices to be evaluated were inoculated as described previously and allowed to dry at room temperature overnight before testing. In addition, 0.2 mL of the fecal suspension containing *C difficile* spores was placed in a cryovial and sealed. The closed cryovial containing the *C difficile* spores was placed in the WD along with the devices to evaluate the effect of heat of the cycle on spore killing (ie, to assess the heat effect of the cycle independent of the wash-off effect of the cycle).

Once the devices were removed from the WD, a single Rodac plate containing CDMN agar was pressed flat onto the circular marked area that had been inoculated and was held there for 5 seconds. The plates were incubated anaerobically in an anaerobic chamber containing palladium catalyst and a gas mixture comprising 5% H₂, 10% CO₂, and 85% N₂. The colony counts of *C difficile* were determined after 48 hours of incubation. Only colonies that had appropriate colony morphology and Gram's stain were counted.

In addition, the suspension in the cryovials was serially diluted, and viable counts were determined using the spread-plate method on CDMN agar. The inoculated CDMN agar was incubated anaerobically; after 48 hours of incubation, colony counts were determined as described previously.

**RESULTS**

**TOSI testing**

The TOSI device was positioned in the ward-WD and the CPD-WD. Original and repeat testing indicated that the ward-WD did not completely remove the soil, whereas CPD-WD did completely remove the soil. These tests were performed with and without the protective plastic cover on the TOSI device, and similar results were obtained in both cases. Additional testing was performed by placing the TOSI device inside a bedpan and a urinal. Again, the results indicated incomplete removal of soil by the ward-WD.

To evaluate the difficulty of soil removal, several TOSI devices without the plastic protective cover were held under running warm (45°C) tap water. Within ~2 minutes, 99% of the visible soil was removed, indicating that removing the soil from this device is not a difficult challenge.

**Testing of ATS-soiled devices for residual protein and hemoglobin (blood) postcleaning**

The 2 types of bedpans and the urinal were inoculated with ATS as described in Materials and Methods,
and the soiled devices were processed through the ward-WD and CPD-WD. The results of testing for residual organic material (protein and hemoglobin [blood]) are shown in Figure 1.

UVM removal

The stainless steel and plastic bedpans and plastic urinals were inoculated with UVM as described in Materials and Methods. Figure 2A shows how the fluorescence on swabs used to sample the devices was visualized using UV light. This swab collection method was necessary because some sites could not be readily illuminated directly with UV light. The efficacy of the 2 WDs in removing this water-soluble mark is summarized in Figure 2B.

C difficile spore removal

The stainless steel and plastic bedpans and plastic urinal were soiled with feces (bedpans) or urine (urinal) containing C difficile spores. After the complete cleaning and decontamination cycle, the inoculated areas
were directly sampled using Rodac plates pressed onto the surface. For the purposes of graphing, the Rodac plates that had too many colonies to count were scored as having 100 cfu per plate. All testing was performed in triplicate (on 3 separate days); the results, presented in Figure 3, are the average viable counts. For the sake of graphing, plates with colonies that were too numerous to count were graphed as having 100 cfu/plate.

To further evaluate the effect of the heat on killing *C. difficile* without the liquid wash-off effect, cryovials containing the same stool soil seeded with *C. difficile* spores were placed in the WDs for the entire washing and drying cycle. The contents were subsequently evaluated for residual viable organisms; the data represent the average of 3 replicate experiments done on 3 separate days. For the sake of graphing, plates with colonies that were too numerous to count were graphed as having 100 cfu/plate.

**Fig 3.** Residual viable *C. difficile* spores on bedpans or urinals postwashing and disinfection. Spores of *C. difficile* were suspended in sterile feces (for bedpan testing) or sterile urine (for urinal testing) to a final concentration of $1.1 \times 10^7$ cfu/mL (ie, $5 \times 10^5$ cfu/site inoculated). Plastic bedpans (plastic-BP), stainless steel bedpans (SS-BP), and urinals were inoculated and dried as specified in Materials and Methods. Rodac plates were used to sample the inoculated surfaces. The data represent the average of 3 replicate experiments done on 3 separate days.

The manufacturer then made additional adjustments, including increasing thermal disinfection to 85°C (185°F) for 300 seconds (5 minutes), installing a detergent dispenser, and changing the wash program from 2 cold rinses followed by 5 warm rinses to 4 cold rinses followed by 4 warm rinses. Repeat testing for the plastic bedpan with stool and *C. difficile* spores resulted in the bedpans being visibly clean but still having >100 colonies/site when tested by Rodac plates.

To further assess why *C. difficile* spores survived the heat decontamination cycle provided by the ward-WD but not the CPD-WD, additional testing with stool containing *C. difficile* spores in sealed vials was performed. The viable count results indicated that the spore count in the vial was 6.41 log$_{10}$ cfu/mL, and after exposure to the ward-WD (with revised cycle parameters), the count was 6.07 log$_{10}$ cfu/mL. To determine the role of drying (at 116°C for 7 minutes) on spore viability, vials of stool containing *C. difficile* spores were evaluated after exposure to only the thermal decontamination cycle (ie, no drying cycle) of the CPD-WD. The inoculum of spores was 6.16 log$_{10}$ cfu/mL in feces, and after the wash cycle only, the viable count was 4.59 log$_{10}$ cfu/mL. It should be noted that the CPD-WD also has a hot water rinse at 82°C (180°F) for 1.25 minutes as well as a 66°C (150°F) hot water rinse for 2 minutes before the thermal decontamination cycle. The ward-WD does not have these hot water rinses.

Because there were surviving *C. difficile* spores in the ward-WD, we further evaluated whether there could be “cross-contamination” between bedpans. We did this...
by processing one bedpan that had been inoculated with spores in fecal material, followed by an uninoculated bedpan, then testing the uninoculated bedpan using Rodac plates to determine whether it had acquired any spores. We detected no spores on the bedpans evaluated in this manner (data not shown).

**DISCUSSION**

Although the ISO has developed guidance documents for WDs and others have evaluated flexible endoscope WDs and medical devices, this is one of the first published studies to compare the efficacy of bedpan and urinal cleaning efficacy of a ward-WD and a CPD-WD. The data demonstrate that for all of the tests undertaken, the ward-WD (as it was originally installed) did not provide the equivalent level of cleaning (ie, removal of ATS, feces, urine, or UVM) or decontamination (ie, killing of *C difficile* spores) as shown by the CPD-WD. Correction of improper installation improved the ward-WD cleaning function, but despite maximal possible adjustment to temperature/time parameters, the ward-WD was not able to provide *C difficile* spore killing equivalent to that achieved by the CPD-WD (Fig 4). Review of other manufacturer’s ward-WD cycles indicated that thermal decontamination at 80°C for 1 minute was commonly used. Furthermore, these conditions are endorsed by ISO 15883 for bedpan reprocessing.

Multiple test soils, including ATS, UVM, TOSI devices, and autoclaved feces and urine, were evaluated, and the same conclusions were reached. ATS has been used to evaluate cleaning of various medical devices and is a relevant soil for simulated-use testing to determine how well organic material is removed from the devices processed through the washers. This soil is not overly difficult to remove, so although the residuals from Figure 1 appear to be low for the ward-WD, these should have been equivalent to the negative control if adequate washing had been achieved (as was observed for the CPD-WD). The presence of UVM after the wash cycle further confirms the inadequacy of washing by the ward-WD (Fig 2B). These 2 experimental approaches clearly document that cleaning was inadequate for the ward-WD. This lack of efficient cleaning after the original installation appeared to have been due (at least in part) to the sprayer arm problems identified by the technical specialist sent by the manufacturer to address our concerns with the device.

The disinfection capability of the 2 WDs was evaluated using *C difficile* spores as the microbial indicator. This is a relevant indicator, because the bedpans from patients who either carry *C difficile* or are ill with this organism would be processed through such WDs. It is critical to ensure that no spores remain after the cycle, to prevent staff exposure and ensure that the bedpans are not a source for nosocomial transmission of *C difficile* between patients. Figures 3 and 4 indicate that the ward-WD did not provide decontamination of *C difficile* spores to a level that would ensure that the bedpans were safe to handle and safe to use on a patient. This insufficient decontamination appears to be due to too-low thermal conditions for the ward-WD at its standard settings. In contrast, the success of the CPD-WD appears to result from a cumulative effect of the hot water rinses, thermal decontamination, and drying cycle. This raises infection control concerns regarding the use of such ward-WDs for bedpans, in which high levels of *C difficile* spores are commonly encountered because CDAD is a common nosocomial infection in hospitalized patients.

Although the ATS, feces, urine, and *C difficile* spore testing used in this study are beyond the capability of routine onsite user testing, UVM and the TOSI device can be used onsite to evaluate the cleaning efficacy of WDs. This evaluation demonstrates that user assessment of WDs is important to ensure adequate performance even for new equipment; for example, the use of these tests at our site helped identify problems that were ultimately determined to be installation errors. Furthermore, our data demonstrate that the maximum temperature of 85°C (185°F) in the ward-WD was inadequate to eliminate *C difficile* spores effectively. (Note that the manufacturer does not claim that the ward-WD can eliminate *C difficile* spores.) The cleaning provided by the ward-WD was not sufficient to remove the spores from the surface of the plastic bedpans. This is not a unique problem to this specific type of ward-WD; we are not aware of other ward-WDs that have decontamination cycles differing from that used in this study. This is an important issue that should be taken into consideration for the thermal conditions for bedpan washers recommended by national and international guidance documents. The *A*<sub>o</sub> value for reprocessing of bedpans currently recommended by ISO guidance document 15883 (ie, *A*<sub>o</sub> = 60) is insufficient from an infection control perspective to ensure reliable elimination of *C difficile* spores. Although ISO 15883 recommends that the setting be approved by infection control in the context of the type of pathogens expected, it is apparent that the existing ward-WDs may not be able to provide adequate conditions for killing *C difficile* spores, because they cannot achieve the necessary thermal killing conditions. Testing of ward-WDs from 2 different manufacturers produced similar findings (data not shown).

Zuhlsdorf et al has documented that decreasing the reprocessing temperatures for endoscope WDs can allow significantly more bacterial survival. Furthermore, they reported that evaluation of cleaning efficacy in
various endoscope WDs indicated variability. As more attention is focused on testing the cleaning efficacy of WDs, it is becoming apparent that users need to incorporate this type of testing as part of their ongoing quality assurance program. Although hospitals have traditionally monitored temperature and cycle parameters to verify adequate functioning of WDs it is also useful to monitor the cleaning efficacy of these units. This is a valuable parameter to evaluate, because it provides a cost-effective means of reducing the risk of improperly cleaned and decontaminated bedpans and urinals, which may pose a risk for nosocomial infection transmission. This also reflects the recommendations by Ransjo et al., although they used microbial markers (Enterococcus faecalis and Bacillus subtilis spores) to monitor cleaning and disinfecting. For users in health care settings, methods that require bacterial culture are often too difficult to implement.

In conclusion, our data support the value of users evaluating the cleaning efficacy of WDs used in their facility by either UVM or TOSI testing. WDs that do not provide adequate cleaning as determined by these tests should be taken out of service until they are fixed or replaced. Furthermore, the data demonstrate that thermal settings achieved by currently available ward-WDs cannot effectively kill C difficile spores. This has significant infection control implications that should be taken into consideration by international and national bodies when drafting guidelines for washers used to reprocess bedpans.

References