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Major Article

A microbiological study to investigate the carriage and transmission-potential of *Clostridium difficile* spores on single-use and reusable sharps containers

Terry Grimmond FASM, BAgrSc, GrDpAdEd&Tr [a,*], Anu Neelakanta MD, MPH [b], Barbara Miller MSN, BSN, CPSO, CHSP [c], Asif Saiyed MT (AMT), BS, BA, MBA, CIC [d], Pam Gill MHA(c), BSN, BBA, RN, CIC, CRNI [e], Jennifer Cadnum BS [f], Russell Olmsted MPH, CIC, FAPIC [g], Curtis Donskey MD [h,i], Kimberly Pate MSN, RN, ACCNS-AG, PCCN [j], Katherine Miller BS [k]

[a] *Grimmond & Associates, Hamilton, New Zealand*
[b] *Department of Infectious Diseases, Carolinas Medical Center, Charlotte, NC*
[c] *Environmental Health and Safety Department, Carolinas Health System, Charlotte, NC*
[d] *Infection Control, Sinai Health System, Chicago, IL*
[e] *Infection Prevention, Iredell Health System, Statesville, NC*
[f] *Research Services, Louis Stokes Cleveland Veterans Affairs Medical Center, Cleveland, OH*
[g] *Infection Prevention & Control, Trinity Health Unified Clinical Organization, Livonia, MI*
[h] *Infection Control Department, Louis Stokes Cleveland Veterans Affairs Medical Center, Cleveland, OH*
[i] *Louis Stokes Cleveland Veterans Affairs Medical Center, Cleveland, OH*
[j] *Surgical-Trauma Division, Carolinas Medical Center, Charlotte, NC*
[k] *Levine Cancer Institute, Carolinas HealthCare System, Charlotte, NC*

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Background: A 2015 study matching use of disposable and reusable sharps containers (DSCs, RSCs) with *Clostridium difficile* infection (CDI) incidence found a decreased incidence with DSCs. We conducted microbiologic samplings and examined the literature and disease-transmission principles to evaluate the scientific feasibility of such an association.

Methods: (i) 197 RSCs were sampled for *C. difficile* at processing facilities; (ii) RSCs were challenged with high *C. difficile* densities to evaluate efficacy of automated decontamination; and (iii) 50 RSCs and 50 DSCs were sampled in CDI patient rooms in 7 hospitals. Results were coupled with epidemiologic studies, clinical requirements, and chain-of-infection principles, and tests of evidence of disease transmission were applied.

Results: *C. difficile* spores were found on 9 of 197 (4.6%) RSCs prior to processing. Processing completely removed *C. difficile*. In CDI patient rooms, 4 of 50 RSCs (8.0%) and 8 of 50 DSCs (16.0%) had sub-infective counts of *C. difficile* ($P = .27$). DSCs were in permanent wall cabinets; RSCs were removed and decontaminated frequently.

Conclusion: With *C. difficile* bioburden being sub-infective on both DSCs and RSCs, sharps containers being no-touch, and glove removal required after sharps disposal, we found 2 links in the chain of infection to be broken and 5 of 7 tests of evidence to be unmet. We conclude that sharps containers pose no risk of *C. difficile* transmission.

* Address correspondence to Terry Grimmond, FASM, BAgrSc, GrDpAdEd&Tr, Grimmond & Associates, 930 River Rd Queenwood, Hamilton, 3210, New Zealand.
E-mail address: terry@terrygrimmond.com (T. Grimmond).

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In 2011, *Clostridium difficile* was responsible for 453,000 healthcare-associated infections (HAIs) and 29,000 deaths in U.S. hospitals.[1] Despite an 8% decrease in incidence by 2014,[2] it is the most commonly reported pathogen causing HAIs.[3]

C. difficile is spread by the fecal-oral route, and any surface, device, or material contaminated with feces containing *C. difficile* vegetative cells or endospores may serve as a reservoir for this pathogen.[4] Hospitalized, noncolonized patients may acquire *C. difficile* directly from other patients with *C. difficile* infections (CDIs) or indirectly from the environment or from contaminated hands of healthcare personnel.[5] Surfaces in the patient room environment serve as a reservoir for 2%–10% of CDI cases,[6-9] and frequently touched surfaces close to the patient's bed are more likely the source of *C. difficile* contamination.[10-13]

Sharps containers are an "environmental surface" and may be a disposable (single-use) sharps container (DSC) or a reusable sharps container (RSC). In the United States, they have close to an equal market share. In patient rooms, they are commonly wall-mounted 1.5–3 m from the patient's bed. Although attention has been drawn to the microbial bioburden of poorly cleaned, reusable, regulated medical waste bins[14] and RSCs,[15] neither DSCs nor RSCs have been scientifically shown to be a fomite. With specific reference to CDI, neither DSCs nor RSCs have been mentioned as a "touched item" in *C. difficile* environmental surveys,[10-13,16] nor as a potential fomite in *C. difficile* evidence-based prevention guidelines.[6,17,18]

However, in 2015, Porgorzelska-Maziarz obtained hospital-wide CDI rates via Medicare Provider Analysis and Review data, ascertained and linked RSC or DSC usage via a telephone questionnaire of participating hospitals, and found a significantly lower rate of CDI in hospitals using DSCs over those using RSCs (incidence risk ratio [IRR] = 0.846, $P = .001$).[19] Dikon questioned the scientific credibility of the survey,[20] and Porgorzelska-Maziarz in reply confirmed the soundness of the methodology[21] but did not propose a scientific explanation as to how sharps containers might act as a fomite and recommended further studies involving direct culturing of sharps containers.

The hypothesis of our study was that the statistical association found by Porgorzelska-Maziarz is an artifact and that sharps containers (irrespective of type) may have a low spore burden but no fomite potential. We adopted a multifaceted epidemiologic, microbiologic, chain-of-infection, and test-of-evidence approach to determine if a relationship between CDI and sharps containers is scientifically feasible.

METHODS

The microbiologic aspect consisted of 3 stages and was approved by the institutional review boards at participating hospitals. An RSC company (Daniels Health, Chicago, Illinois) was approached and permission was obtained to sample recently received full RSCs before processing at their factories (Stage 1) and to conduct the challenge experiments (Stage 2). Six multi-hospital systems using RSCs and/or DSCs were contacted by the authors and invited to participate in Stage 3. An equal total number of beds was sought for RSC and DSC hospitals.

Stage 1 – Do RSCs carry *C. difficile* upon arrival at processing facilities?

One hundred ninety-seven, full, used, 22-liter RSCs (Sharpsmarts, Daniels Health) received at 4 geographically unique processing facilities (Sturtevant, Wisconsin; Walton, Kentucky; Westland, Michigan; and Fresno, California) were randomly chosen on arrival from client hospitals. Prior to processing, the RSCs were swabbed for presence of *C. difficile* by the same microbiologist at each processing facility. BD BBL Culture Swab Collection and Transport Systems (BD, Franklin Lakes, New Jersey) were used. Each sterile package contained 2 swabs co-joined by a cap and a sealed tube with transport medium in its base.

Using a thumb-forefinger rolling action, a dual swab-set moistened in sterile water was briskly rubbed in 2 opposing directions over the entire front surface and lid (approximately 700 cm^2 in total), inserted into labelled transport medium, and couriered to a *C. difficile* reference laboratory at VA Medical Center, Cleveland, Ohio. At the lab, each swab was cultured for broth enrichment into a tube of *C. difficile* Brucella broth with thioglycolic acid and L-cystine (CDBB-TC) (qualitative growth) and incubated aerobically at 37^0C for 72 hours.[22] CDBB-TC was chosen because of its superior sensitivity and specificity over standard *C. difficile* growth media[22]. *C. difficile* was confirmed by morphologic analysis and Microgen latex agglutination (Microgen Bioproducts, Surrey, United Kingdom). Culture results for this stage were recorded as positive/negative. Quantitation of *C. difficile* spores (via direct plate culture) was not conducted in Stage 1. Isolates were tested for toxin production by subculturing the isolate into 1 mL of Brucella broth, incubating anaerobically for 3 days (to accumulate toxin), then conducting a toxin assay on the broth using a commercial kit (Alere Inc, Waltham, Massachusetts). The sterile water used at each factory and an unopened swab were submitted for culture as negative controls. The results of Stage 1 were used to calculate sample sizes for Stage 3.[23]

Stage 2 – Does the decontamination process remove *C. difficile* spores from RSCs?

The proprietary decontamination process of the RSCs in this study comprised 6 wash stages: 2 cold water flushes, 2 hot water washes at 55^0C (the first with detergent), a scald rinse with water at 85^0C, an air-knife drying stage, and a final stage where a fine film of a proprietary formulation was applied to all internal surfaces to decrease adherence of organic matter and soil during the next client's use. This process has been repeatedly validated by independent laboratories to achieve a 6-log reduction of vegetative pathogens and a 4-log reduction of spores. Our experience in patient room surface-sampling indicated that the density and frequency of *C. difficile* spores on RSCs would be low given that they are no-touch[20] and are distant from the patient.[24,25] A statistical power calculation indicated that with low density and frequency, several hundred RSCs would need to be microbiologically sampled after processing. Instead, we elected to increase the test severity by challenging the process's ability to remove high-density challenges of *C. difficile* spores applied to RSCs. Our reference laboratory standardly conducts *C. difficile* surface challenges in 2x triplicate tests (6 surfaces); however, we increased this number to 10 RSCs. The challenge suspension of nontoxigenic spores (in sterile water) was supplied by the *C. difficile* reference laboratory and was designed to apply *C. difficile* spores to RSCs at 2 densities: a high density at approximately 1000–10,000-fold higher than counts we standardly find on low-touch CDI patient room surfaces; and a medium density of 1/100 dilution of the high-density suspension.

Using a sterile transfer pipette, 1 drop (approximately 0.2 ml) of high-density suspension was applied in a precise area to the right side of the counterbalanced tray on 4 clean RSCs, and a second drop (positive control) was placed on the left side. The medium-density suspension (test and control drops) were applied in the same manner in a defined area on the front of 6 clean RSCs. Once dry, a 10x10-cm area encompassing the control drop was swabbed in 2 opposing directions with a sterile moistened dual-swab, and the labeled swab was placed in its sterile transport media tube. The 10 RSCs were subjected to the factory's automated decontamination process ("Washsmart"), according to the factory's standard protocol.