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Aseptic Stethoscope Barriers Prevent *C difficile* Transmission In Vitro

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Abstract

Objective: To evaluate whether *Clostridioides* (formerly *Clostridium*) *difficile*—contaminated stethoscope diaphragms remained aseptic by the placement of an aseptic diaphragm barrier.

Methods: On November 1, 2019, fresh cultures of *C difficile* were diluted to 10^7 colony-forming units (CFU)/mL and used to inoculate 16 stethoscope diaphragms; 8 had an aseptic diaphragm barrier applied and 8 served as nonbarrier controls. Contaminated stethoscopes were anaerobically incubated, then swabbed at 15 and 30 minutes, 2 and 4 hours, and 1, 2, 3, and 7 days after inoculation and subsequently plated onto blood, chocolate, and cycloserine-cefoxitin fructose agar. Plates were incubated for 48 hours and on November 9, 2019, the resulting colonies were manually counted. Statistical analyses (RStudio, version 1.0.153) used analysis of variance with post hoc Tukey honestly significant difference.

Results: Overall, mean colony count was 33 CFU on stethoscopes without barriers vs zero on those with barriers ($P \leq .05$). Growth was greatest at 48 hours, with colony counts as high as 160 CFU. The presence of the barrier resulted in no growth in 100% of stethoscope diaphragms for up to 1 week.

Conclusion: We found that stethoscope diaphragm barriers provide an aseptic patient contact point, thus reducing the potential for transmission of *C difficile* during the physical examination. In critical care environments, in which many hospitals use acoustically inferior disposable stethoscopes, the option of a disposable aseptic stethoscope barrier may allow high-quality auscultation while reducing the potential for pathogen transmission.

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Clostridioides (formerly *Clostridium*) *difficile* infection (CDI) is a major public health issue. *Clostridioides difficile* is an anaerobic gram-positive bacteria that can generate infection-causing spores that are highly resistant to heat and alcohol disinfectants. Infection commonly occurs following fecal-oral transmission of spores in patients taking systemic broad-spectrum antibiotics, which disrupt healthy gut flora and allow *C difficile* proliferation. Although guideline-compliant handwashing may limit *C difficile* transmission, alcohol-based hand rubs may be ineffective for removing spores from hands.[1] The persistence of *C difficile* spores in hospital environments has led to a high prevalence of CDI. In 2015, there were an estimated 450,000 US CDI cases, which resulted in 35,000 deaths.[2] Although overall rates of CDI have stabilized, rates of recurrent CDI, defined as greater than 1 recurrence after an initial CDI, have increased from 1.1 to 3.1 cases per 100,000 person-years from 2001 to 2012.[3] Because CDI and recurrent CDI are associated with severe adverse outcomes, novel strategies to prevent iatrogenic and nosocomial spread would be invaluable.

One potential source of iatrogenic CDI may be the stethoscope. An important interface during the patient examination, the stethoscope is used to examine most hospitalized patients. The Centers for Disease Control and Prevention guidelines define the stethoscope as a noncritical medical device (ie, in contact with intact skin but not bodily fluids) and recommend cleaning for longer than 1 minute after each patient interaction using an alcohol- or bleach-based disinfectant.[4] Unfortunately, recent studies demonstrate dismal rates of stethoscope hygiene compliance in

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the clinical setting, with observed cleaning rates occurring in less than 10% of patient encounters.[5-12]

Despite most providers understanding that the unsanitized stethoscope may be a microbial transmission vector,[13] poor stethoscope hygiene rates are persistent. When questioned, providers report barriers to hygiene performance that include the lack of time and poor access to disinfectants. Contributing to the potential of nosocomial infection, the recent literature questions the ability of common disinfectants to completely eliminate contaminating bacteria.[14] In 1 study, *Enterococcus faecium* was demonstrated to have an increasing tolerance to 70% isopropyl alcohol solutions,[15] which may result in its continued presence on the stethoscope even if it is cleaned per guideline recommendations. Coupled with the resistance of *C difficile* spores to alcohol-based disinfectants, this emerging evidence highlights the critical need for alternatives to alcohol- or bleach-based stethoscope cleaning processes.

Aseptic stethoscope barriers have been suggested as a more time-efficient and bacteriologically effective method to ensure a clean interface between the patient and the stethoscope diaphragm.[11] The purpose of this study was to evaluate the ability of a single-use aseptic barrier to prevent the transmission of *C difficile* from a stethoscope diaphragm.

This study was approved by the University of California, San Diego Administrative Panel on Human Subjects in Medical Research and was certified as category 4 exempt, which does not require informed consent.

METHODS

This was an experimental study evaluating the effectiveness of a barrier to prevent the transmission of *C difficile* from a contaminated stethoscope diaphragm. Specimens of *C difficile* were obtained from ATCC, Inc. On November 1, 2019, two replicate clinical strains of *C difficile* were prepared. Fresh cultures of *C difficile* were diluted to 10^7 colony-forming units (CFU)/mL, and using Copan FLOQswabs (Copan Diagnostics Inc), were dipped into the vortexed diluted cultures. Inoculation of 16 stethoscope diaphragms was then performed (Figure 1). After the diaphragms were allowed to dry for 10 minutes, 8 stethoscopes had a barrier (Aseptiscope Inc) placed on the diaphragm, whereas the remaining 8 stethoscopes, serving as controls, had no barrier placed. The barrier was obtained from a hands-free dispenser system that provides a safe, medical-grade, impervious, aseptic, single-use disposable biocompatible tape that is acoustically invisible and leaves no residue on the stethoscope after removal. The stethoscopes were then placed in an anaerobic incubator and at the prespecified times of 15 and 30 minutes, 2 and 4 hours, and 1, 2, 3, and 7 days, the diaphragms of the control stethoscopes and the barriers of the interventional stethoscopes were swabbed with a clean swab, which was then placed into Eswab media (Becton-Dickinson). Subsequently, cultures were plated onto blood, chocolate, and cycloserine-cefoxitin fructose agar plates using the Copan WASP automated planting system (Copan Diagnostics Inc). These plates were incubated for 48 hours anaerobically using an Anoxomat Mark II System (Advanced Instruments Inc), and any resulting colonies were manually counted on November 9, 2019.

Statistical Analyses

Statistical analyses were performed using RStudio, version 1.0.153 (R Studio).

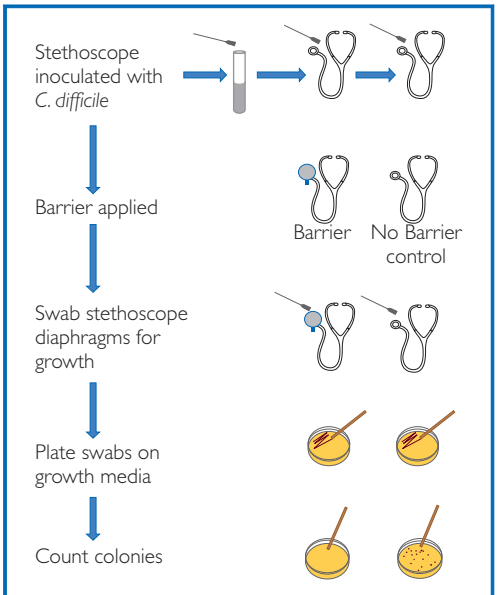

FIGURE 1. Flow chart. *C difficile* = *Clostridioides* (formerly *Clostridium*) *difficile*.

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Differences in colony counts between stethoscope diaphragms with and without barriers were determined using 1-tailed *t* tests. To compare colony counts from stethoscope diaphragms with barriers vs those without barriers, analysis of variance with post hoc Tukey honestly significant difference tests were used.

RESULTS

In this longitudinal assessment of *C difficile* growth on the stethoscope diaphragms without aseptic barriers, we reliably detected *C difficile* at all time points. Overall, the mean colony count was 33 CFU on the 8 stethoscopes without barriers (Figure 2). Growth rates were greatest at 48 hours, with colony counts as high as 160 CFU (Figure 3). Culturing the barrier surface of the *C difficile*–contaminated stethoscope diaphragm after incubation yielded no *C difficile* regardless of the time of exposure to *C difficile*. Colony counts were zero on all stethoscope diaphragms covered with barriers. The *C difficile* growth findings on stethoscope diaphragms without barriers were in stark contrast to those with barriers in respect to *C difficile* culture growth. The presence of the barrier resulted in no growth from 100% of stethoscope diaphragms for up to 1 week after contamination.

The difference in colony counts was evaluated using a 1-tailed *t* test. At each time point, there was a significant ($P \leq .05$) absence of *C difficile* growth on the stethoscope diaphragms with the barriers compared with growth on diaphragms without barriers. Although the stethoscope diaphragm is not be the only source of *C difficile* transmission, these results suggest that aseptic barriers will prevent transmission of *C difficile* bacteria from a contaminated stethoscope diaphragm to a patient.

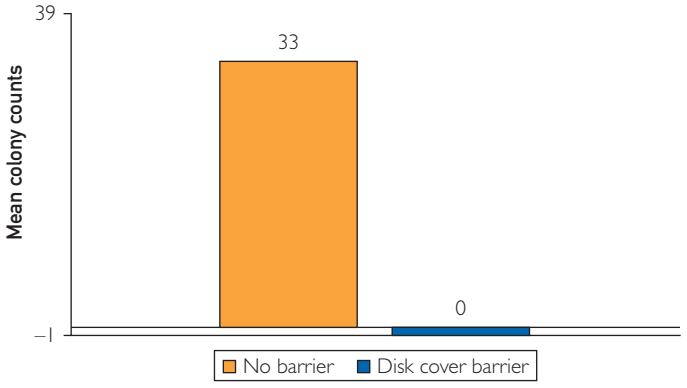

FIGURE 2. *Clostridioides* (formerly *Clostridium*) *difficile* (*C difficile*) cultures from stethoscope diaphragms with and without the disk covers.

DISCUSSION

We tested the ability of aseptic barriers to prevent an unwashed *C difficile*–contaminated stethoscope diaphragm from serving as an iatrogenic vector between patients. Our results suggest that a stethoscope diaphragm that is contaminated with *C difficile* is rendered aseptic by the placement of a bacteriologically impervious barrier. Although we focused on *C difficile* as the primary agent, prior work supports the concept that an impervious barrier is efficacious in preventing the stethoscope diaphragm from becoming an infectious vector. In one study by Vasudevan et al,[11] aseptic barriers placed on the stethoscope diaphragm that had been contaminated with anaerobes, antibiotic-resistant bacteria, yeasts, and infected samples that included saliva, stool, urine, and sputum were persistently sterile for up to 24 hours. Further, studies evaluating stethoscope diaphragms contaminated with vancomycin-resistant *Enterococcus* (VRE), methicillin-resistant *Staphylococcus aureus*; extended-spectrum β-lactamase–producing *Escherichia coli*; and multidrug resistant *Pseudomonas aeruginosa, Staphylococcus epidermidis*, *Bacteroides* species, and *Candida albicans* have demonstrated the same results.[11] Considering these prior studies, as well as the findings from our investigation, it is clear that a cover placed over the stethoscope diaphragm can provide an aseptic point of patient contact.

As hospitals have recognized the importance of stethoscope hygiene for infection prevention practice,[16] many institutions have attempted to provide alternatives to the contaminated stethoscope. Unfortunately, this has not elicited effective results. Education seems to have a poor effect in changing health care provider stethoscope cleaning behavior. One investigation provided stethoscope hygiene visual reminders and alcohol swab–containing baskets on the hospital wards. They reported stethoscope hygiene rates no higher than 59%.[17] Another

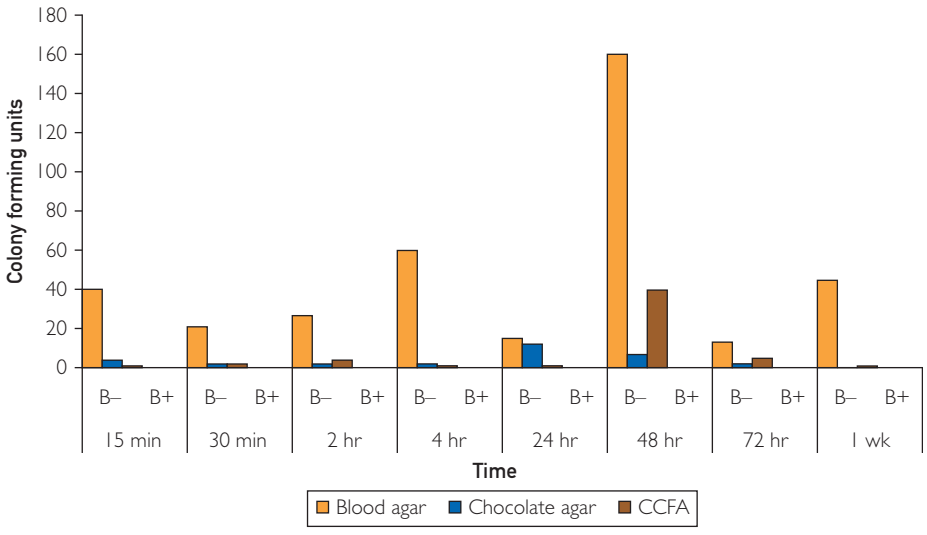

FIGURE 3. Culture results of stethoscope diaphragms protected with (B+) and without (B−) an aseptic barrier. CCFA = cycloserine-cefoxitin fructose agar.

intervention implementing a similar protocol with the addition of providing informational lectures to the medical staff observed absolutely no compliance (0%) either before or after the intervention.[18] It seems well documented that education has limited effectiveness at improving stethoscope hygiene, a result that suggests that alternative interventions are necessary to prevent a stethoscope vector from contaminating patients.

Strategies that are commonly used, especially for patients infected with multidrug-resistant organisms (MDROs), include the implementation of contact precautions, strict hand washing protocols, and the use of disposable gowns, gloves, and single-patient disposable stethoscopes to decrease the likelihood of transfer to other patients.[19] Although effective for infection control,[20] the single-patient disposable stethoscope allows only suboptimal auscultation due to poor audio quality,[21] potentially leading health care providers to abandon their use in favor of their own stethoscopes. This not only results in the potential contamination of the provider's stethoscope with an MDRO, but also creates the exact scenario that the disposable stethoscope was implemented to prevent; that is, facilitating the transfer of an MDRO to other hospitalized patients.[22]

A simple answer to the challenge of the contaminated stethoscope could be the requirement of stethoscope disinfection. Unfortunately, data regarding this strategy have not been reassuring. In a self-reported survey study of 1401 physicians, 76% believed stethoscope hygiene to be important but only 24% reported cleaning their stethoscope regularly.[13] Observational studies suggest that the reported rate is actually inflated. Jenkins et al[23] reported that in 352 stethoscope cleaning opportunities, physicians or students cleaned their stethoscope in only 16% of encounters (n=58). Even worse rates were reported by Boulee et al,[24] who noted that in 84 patient encounters, only 4% of attending physicians cleaned their stethoscopes in a guideline-compliant fashion. Ultimately, although health care professionals recognize the importance of stethoscope hygiene, it is rarely performed.

Finally, even when the stethoscope is disinfected, complete sterility may not result. Zachary et al[25] found that 31% of stethoscopes are contaminated with VRE and although washing with 70% alcohol decreases VRE contamination, an absolute 2% of

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stethoscopes remain VRE positive. Similarly, Parmar et al[26] cultured 100 health care worker's stethoscopes, finding that 90% are positive for some staphylococcus species, and after washing with 66% isopropyl alcohol, 28% remain culture positive. These studies suggest that even guideline-compliant stethoscope washing does not guarantee sterility.

The most concerning investigation of a stethoscope washing strategy is recent research published by Pidot et al.[15] They report that from 1997 to 2015, *E faecium* tolerance to 70% alcohol has increased 10-fold. This suggests that the Centers for Disease Control and Prevention recommendation that the stethoscope be cleaned for 1 minute with 70% alcohol swabs between patients may become ineffective in the future.

As we report, medical-grade aseptic barriers that do not affect the subjective quality of auscultation[27] can provide physical protection from microbes. Ideally, these single-use barriers are applied to the stethoscope diaphragm from a hands-free dispenser just before evaluating the patient, thus ensuring hygienic patient contact similar to that obtained by disposable gowns/gloves. The potential benefits of barriers include reduced transmission of pathogenic and antibiotic-resistant microbes, as well as the improved quality of auscultation by the use of the physician's clean personal stethoscope rather than that of the single-patient disposable stethoscopes.[21]

Alternatively, other stethoscope hygiene solutions have been described. One study evaluated the antimicrobial properties of a copper-alloy metal stethoscope, citing decreased levels of contamination. However, it did not mention the cost of implementing such a change.[28] Another investigated a stethoscope UV light case but reported incomplete decontamination.[29] An additional study investigated an antimicrobial stethoscope coating,[30] but such a coating could select for resistant microorganisms. Our study demonstrated the effectiveness of an aseptic diaphragm barrier without antimicrobial properties (Figure 3) to limit the formation and propagation of resistant pathogens. Because the barriers are disposable, are single-use, and work by providing a physical rather than antimicrobial barrier, they provide protection without the risk for resistant microorganisms. Although prior technologies have accomplished only a partial reduction in stethoscope contamination, our data support that diaphragm barriers are capable of remaining aseptic against pathogens.

This study has some limitations. This was a small in vitro evaluation of *C difficile* placed on stethoscope diaphragms and did not evaluate the potential for human-to-human infection. It is possible that in vivo evaluations could show different viability rates. However, our rates suggest that *C difficile* can survive on the unprotected stethoscope diaphragm, which should be of concern to both patients and practitioners. Furthermore, real-life studies could identify other relevant contact points for *C difficile* transmission, such as the examiner's hands and stethoscope tubing. Finally, costs were not examined in this evaluation. The relevant expense of disposable stethoscopes (eg, dollars) vs disposable barriers (eg, cents) could have important infection control decision-making attributes.

CONCLUSION

We found that stethoscope diaphragm barriers provide an aseptic patient contact point, thus reducing the potential for transmission of *C difficile* during the physical examination. In critical care environments, in which many hospitals use acoustically inferior disposable stethoscopes, the option of a disposable aseptic stethoscope barrier may allow high-quality auscultation while reducing the potential for pathogen transmission.

Abbreviations and Acronyms: **CCFA** = cycloserine-cefoxitin fructose agar; **CDI** = *Clostridioides* (formerly *Clostridium*) *difficile* infection; **CFU** = colony-forming unit; **MDRO** = multidrug resistant organism; **VRE** = vancomycin-resistant *Enterococcus*

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