Is It Time for A Universal Sporicidal Disinfectant? Current Science and New Technology

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There is a plethora of scientific literature demonstrating that healthcare-associated pathogens frequently contaminate both porous and non-porous surfaces in the healthcare environment. The interconnection among environmental contamination, hands of healthcare workers and patients and reusable patient care equipment contributes to the colonization and/or infection of patients with these organisms. Many studies have associated environmental contamination with the transmission of methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Enterococcus* spp. (VRE), *Clostridiodes difficile*, and norovirus.[1] Recently, *Candida auris*, an emerging multidrug-resistant pathogen, has been linked to dissemination from contaminated surfaces.[2]

A unique microbiologic factor that can facilitate surface environment-mediated transmission for *C. difficile*, norovirus and *Candida auris* is the relative resistance to disinfectants used on environmental surfaces.[1] The environmental cleaning disinfectants for these organisms require or highly recommend a sporicidal claim. Historically, sodium hypochlorite (bleach) has been the most commonly used agent. In recent years, peracetic acid/hydrogen peroxide-based disinfectants became available. However, issues with odor, material compatibility, stability, and application methods have been cited for these products. This whitepaper will introduce a novel non-bleach, hydrogen peroxide sporicidal agent with a superior compatibility profile to bleach as an alternative disinfectant for environmental cleaning to prevent transmission of healthcare-associated pathogens.

Multiple outbreaks associated with *C. difficile*, norovirus and *Candida auris* occur in healthcare settings and are associated with widespread environmental contamination.[1,2] Although the epidemiology of *Candida auris* is still being elucidated, prolonged survival in the environment, likely associated with patient skin colonization and asymptomatic carriers, has been identified as a contributing factor to the establishment of endemicity and outbreaks.[2] *C. difficile* and norovirus have well-established epidemiology and these organisms have a number of microbiologic characteristics that promote environmental transmission to include: prolonged survival on surfaces, low inoculating dose, frequent environmental contamination, and relative resistance to germicides.[1] Despite the scrutiny that environmental cleanliness has received to prevent these outbreaks, suboptimal cleaning practices during daily and terminal cleaning are common. An evaluation of terminal room cleaning in 23 acute care hospitals using a fluorescent marker monitoring technique found only 49% of surfaces to be thoroughly cleaned.[3] Even with standardized training, variation in room cleaning practices has been observed among environmental services (ES) staff.[4] An examination of the relationship between the amount of time spent by an ES worker cleaning a hospital room and the thoroughness of surface removal of a fluorescent marker did not reveal a correlation.[5] Han and colleagues reviewed 4 systematic reviews and 76 primary studies of environmental cleaning and found that most studies do not report the thoroughness of cleaning or adherence to the manufacturers' recommendations for proper use of their products. They concluded that different cleaning methods need to be studied for comparative effectiveness.[6]

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As much of the recent attention has been on *C. difficile* transmission and environmental hygiene in healthcare settings, this paper will focus on this organism as an illustrative example for consideration of a universal sporicidal disinfectant. This attention is warranted as *C. difficile* is the most common cause of hospital-acquired infectious diarrhea and reduction of this infection is one of the national priorities for the elimination of HAIs (https://health.gov/hcq/prevent-hai-steering.asp). Significant increases in prevalence of infection within an academic medical center have been reported and a 2015 point-prevalence survey of healthcare-associated infections in U.S. hospitals identified *C. difficile* as one of the most common pathogens.[7,8] Considerable morbidity and mortality is associated with infection and treatment costs range from $8,911 to $30,049 for primary infections.[9] Asymptomatic *C. difficile* colonization can be seen in 10-25% of hospitalized patients.[10] A review of current science regarding the reservoirs of *C. difficile* in the hospital environment, identified deficiencies in the cleaning of colonized and infected patient rooms, the advantages and disadvantages of currently available sporicidal germicides, and the evolution of a non-bleach, hydrogen peroxide, sporicidal agent will be discussed.

Role of the contaminated environment in the transmission of *C. difficile*

C. difficile, is an anaerobic, gram-positive, spore-forming, toxin-producing bacillus, transmitted by the fecal-oral route. The potential mechanisms of *C. difficile* transfer include: 1) direct transfer from a colonized or infected patient to the environment, such as by a commode chair, and contact by another patient with inoculation into the mouth or the colon or self-inoculation by touching a contaminated fomite and then introducing into the mouth; 2) direct transfer by the hands to a non-colonized or non-infected patient; and 3) indirect transfer from a healthcare worker contact with the contaminated environment and transfer to a

non-colonized or non-infected patient.[1] Environmental contamination has been found to be highest prior to treatment and has been shown to be strongly correlated with the frequency of positive hand cultures from healthcare workers.[11] *C. difficile* spores can persist in the environment for up to 5 months and have been isolated from various high-touch surfaces in the patient zone, surfaces in the bathroom and the floors of rooms previously occupied by a colonized or infected patient.[10] It has been reported that *C. difficile* was cultured from 49% and 29% of rooms occupied by symptomatic patients and asymptomatic carriers, respectively.[12] A multi-center prospective microbiological survey of multidrug-resistant organism (MDRO) contact precaution rooms, undertaken to determine the typical microbial bioburden of MDROs on high-touch surfaces after routine or terminal cleaning, identified that *C. difficile* was the predominately recovered organism from terminally cleaned rooms and that 50% of the *C. difficile* isolates were recovered from non-*C. difficile* rooms.[13] Biswas and colleagues[14] assessed environmental contamination in rooms of patients with CDI (PCR+, EIA toxin+) and *C. difficile* excretors (PCR+, EIA toxin -) and recovered the organism in 49% and 34% of the rooms, respectively. Although there was significantly higher contamination in the rooms of infected patients, the finding of a third of the rooms of the excretors with contamination represents an important reservoir for transmission of *C. difficile* to future room occupants if a sporicidal disinfectant is not used.[14] Shaughnessy and colleagues[15] found that of patients who acquired *C. difficile* infection (CDI) after admission, 4.6% had a prior occupant without CDI, whereas 11.0% had a prior occupant with CDI (P = .002). In a recent review of *C. difficile* colonization, Crobach and colleagues[16] highlight that patients colonized on hospital admission play a role in healthcare-associated transmission of *C. difficile* and have an associated risk of progression to CDI and that the extent of environmental contamination in patient rooms depends on the *C. difficile* status of the patient: <8% of culture-negative patient rooms, 8-30% in rooms of patients with asymptomatic colonization, and 9-50% in rooms with CDI patients. In a quasi-experimental study that included 7599 patients over 15 months, screening and isolation of asymptomatic *C. difficile* carriers was followed by a significant progressive decrease in hospital-associated CDI incidence.[17]

The frequency and level of contamination of rooms from both symptomatic and asymptomatic patients with *C. difficile* highlights the inadequacy of current daily and terminal cleaning processes and the prolonged survivability of the spores. Sitzlar and colleagues[18] demonstrated that significant reduction of *C. difficile* contamination can be achieved with a dedicated daily disinfection team and a terminal cleaning process with supervisory assessment of CDI rooms. During the baseline period, 67% of CDI rooms had positive cultures after disinfection with hypochlorite. After the intervention, the prevalence of positive cultures was reduced by 89% (P = .006). In an investigation of *C. difficile* contamination in non-CDI rooms after post-discharge cleaning with a quaternary ammonium disinfectant was changed to the use of a bleach spray, the frequency of *C. difficile* recovery was significantly reduced from 24% to 5%. These authors concluded that routine use of a sporicidal disinfectant in all post-discharge rooms could potentially result in reduction of *C. difficile* transmission from environmental surfaces.[19]

Disinfection Products and Methods

Sodium Hypochlorite

As previously mentioned, *C. difficile* is not susceptible to commonly used disinfectants (e.g. quaternary ammonium compounds and phenolics); therefore, current guidelines recommend the use of a chlorine-containing cleaning agent or other sporicidal agent, particularly in hyper-endemic or outbreak settings.[20] The Association for Professionals in Infection Control and Epidemiology recommends mixing of a 1:10 dilution of hypochlorite or use of an Environmental Protection Agency (EPA)-registered hypochlorite wipe with an equivalent dilution.[21] Rutala and coworkers[22] demonstrated that wiping with non-sporicidal agents (which may be a practice for reusable equipment used on CDI patients or daily cleaning of CDI patient rooms) resulted in >2.9 $\log_{10}$ reduction in *C. difficile* spores but the use of a non-sporicidal wipe that becomes contaminated with *C. difficile* spores would allow the spread of spores to other surfaces and areas. Wiping with a sporicidal agent eliminated >3.9 $\log_{10}$ reduction in *C. difficile* spores and was recommended as an integral part of a *C. difficile* control plan. Spraying of a sporicidal agent without wiping is not recommended due to prolonged drying times and lack of dirt and debris removal. Cadnum and colleagues[23] performed an in vitro study to examine the potential for transfer of *C. difficile* spores by quaternary ammonium-impregnated wipes and by hypochlorite wipes used for longer than the recommended duration. They found efficient transfer of spores from contaminated to clean surfaces by the non-sporicidal wipes and the potential for transfer of spores from hypochlorite wipes used inappropriately.

The advantages to the use of sodium hypochlorite are a wide antimicrobial spectrum, including sporicidal efficacy, inexpensive in dilutable form, relatively stable, fast-acting and non-flammable. Disadvantages include corrosive to metals which can lead to costly equipment damage, production of a salt residue, discoloration and staining of fabrics, efficacy impacted by organic matter, and an unpleasant odor that is irritating at high concentrations.[24] Additionally, the instructions for use of some bleach wipes states that pre-cleaning is required "in advance of disinfecting *C. difficile* spores."[25]

Peroxygens – Hydrogen Peroxide (H2O2) and Peracetic Acid (PAA)

In the last several years, improved hydrogen peroxide-based technology was introduced into healthcare for disinfection of noncritical devices and environmental surfaces as an alternative to bleach. Hydrogen peroxide is one of the oldest biocides and is commercially available in a variety of concentrations. The peroxygens decompose to safe by-products - H_2O_2 into water and oxygen and PAA into acetic acid and oxygen (ultimately water, oxygen and carbon dioxide) – and are classified as environmentally friendly with the lowest toxicity rating from the EPA.[26,27] The initial introduction to the market was an improved hydrogen peroxide (IHP) product, which was not sporicidal. The in vitro efficacy of 2 IHP products was tested against standard HP products and a quaternary ammonium compound using three epidemiologically important pathogens and were found to be significantly superior to all standard HP products and similar or superior to the quaternary ammonium product.[27] Boyce evaluated a IHP wipe used to disinfect 10 high-touch surfaces in 72 patient rooms and found 75% of the sites yielded no growth after cleaning.[28] These products have become competitive with the quaternary ammonium compounds for environmental cleaning in healthcare settings. The advantages to IHP products include a wide antimicrobial spectrum, excluding sporicidal activity at low concentrations, fast efficacy

(30 seconds-1 minute), the lowest EPA toxicity level, are eco-friendly, non-stainable, non-flammable and have good surface compatibility. These products are more expensive than the quaternary ammonium and quaternary ammonium plus alcohol disinfectants.[29]

In 2014, a novel peracetic acid/hydrogen peroxide-based (PAA/H_2O_2) sporicidal was released to the market. An in vitro study confirmed the synergistic interaction of PAA and H_2O_2 against bacterial spores and found that the sporicidal activity of the combination was largely due to PAA with H_2O_2 enhancing PAA penetration through compromising the spore coat.[30] Deshpande and colleagues[31] evaluated and found the PAA/HP product to be as effective as a 1:10 dilution of bleach for in vitro killing of *C. difficile* spores, MRSA and VRE at 3 minutes. The effectiveness of PAA/H_2O_2 against the pathogens was not altered by the presence of organic matter, in contrast to bleach where a significant reduction in sporicidal (e.g., *C. difficile* spores) and bactericidal (e.g., MRSA) activity was observed at 3 minutes ($P < .01$ for each comparison). The researchers also conducted an in vivo assessment of the effectiveness of PAA/ H_2O_2 in CDI and MRSA isolation rooms for bedrails, bedside tables and floors. A 1:10 dilution of bleach was used as the comparator for the bedrails and bedside tables and a quaternary ammonium compound as the comparator for the floors, as bleach was not used on floors due to concern for corrosive damage. Both PAA/H_2O_2 and bleach significantly eliminated CD and MRSA contamination on the bedrails and bedside tables. PAA/H_2O_2 significantly reduced the recovery of CD and MRSA from the floors. The authors noted that PAA/H_2O_2 did not cause damage to tile or laminate flooring with 30-day repeated applications or leave residue on surfaces after drying. The vinegar odor did not result in ES or healthcare worker complaints.[31]

The unavailability of impregnated wipes requiring manual dilution of concentrated PAA/H_2O_2 disinfectants is a major disadvantage to their use. On-site dilution is required to address the instability and short shelf-life of these products. Boyce identified significant variations in the concentrations of a quaternary ammonium disinfectant delivered by automated dispensers: range <200 – 600 ppm.[32] Manual dilution by many different ES workers of PAA/H_2O_2 could potentially result in the same finding. In the case of one healthcare facility that noted an increase in CDI incidence after switching from bleach to a PAA/H_2O_2 product for daily and terminal cleaning of CDI patient rooms, the measured concentrations of PAA in the product (50-800 ppm) were significantly lower than the level on the label (1,500 ppm) when newly activated and in-use.[33] An investigation substantiated that multiple lot numbers of the product from this facility and another local hospital had low concentrations. The EPA was informed and following testing of product formulations that confirmed the product was not effective against *C. difficile* spores at the specified contact time of 5 minutes, therefore the product was ordered to be removed from the market. Wiemken and colleagues[34] addressed the concern of improper mixing and use of diluted disinfectant contained in a bucket. In this small evaluation of predominately ES workers who were randomized to use either hypochlorite from a bucket or ready-to-use (RTU) hypochlorite wipes for cleaning, the authors found that compliance (measured by residual fluorescent marker on designated surfaces) was significantly better with the RTU wipes. Additionally, time to completion of the cleaning assignment was significantly lower with the RTU wipes. They concluded that the ease of use of the RTU wipes promotes cleaning thoroughness and improves time efficiency for ES workers and nurses.

A New Non-Bleach, Hydrogen Peroxide Sporicidal

The evolution of hydrogen peroxide (HP) disinfectant technology has led to the development of a 4% HP formulation with 1 minute bactericidal, virucidal, tuberculocidal and fungicidal efficacy and 5 minute sporicidal efficacy. As a ready-to-use (RTU) spray (available in 2019) or impregnated wipe (to be available at a later date), this product can be utilized for routine and discharge cleaning of all patient rooms to promote product standardization and minimize confusion associated with the use of different disinfectants by ES and nursing staff. Using the five key criteria identified by Rutala and Weber[24] of the properties of an ideal disinfectant, the new 4% HP formulation is:

1. Broad spectrum- the product kills the most prevalent healthcare pathogens, including *C. difficile* and other organisms for whom the use of sporicidal agents is recommended e.g. norovirus.
2. Rapid efficacy – 1 minute kill time for all organisms except *C. difficile*, which has a 5 minute kill time.
3. Safe – EPA Level III toxicity rating as HP is eco-friendly. Personal protective equipment to be used as dictated for contact with blood or body fluids. Compatible with common healthcare surfaces, including stainless steel and coated fabrics, particularly polyurethane and vinyl coated fabrics.
4. Easy to use – One-step cleaning and disinfecting (*C. difficile* disinfection requires a pre-cleaning step) – which works in the presence of organic matter. Product odor found to be acceptable by user group. [Data on File: Usability Lab Report, Nov. 2018.]
5. Cost-effective – One product solution for disinfection.

Summary

Multiple outbreaks associated with methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Enterococcus spp.* (VRE), *C. difficile*, norovirus and *Candida auris* occur in healthcare settings and are associated with widespread environmental contamination. It is critical for infection prevention staff, in collaboration with ES, to be able to select a disinfectant that is effective against all of these epidemiologically important pathogens. The evidence of spore shedding by asymptomatic carriers of *C. difficile*, the risk of acquiring CDI from an inadequately cleaned room previously occupied by a CDI patient and the prolonged survival of *C. difficile* spores, provide support for the use of a universal sporicidal disinfectant. Product standardization facilitates compliance, simplifies the cleaning process for ES and nursing and is cost-effective. The availability of a hydrogen peroxide-based sporicidal, which is safe to use and compatible with healthcare surfaces, provides us with a one-product solution.

	Novel Sporicidal HP (4%)	Bleach	Non-sporicidal HP (IHP)	PAA/H_2O_2
Kills *C.difficile*	Yes	Yes	No	Yes
Kills epidemiologically important pathogens	Yes	Yes	Yes	Yes
Compatible with broad range of surfaces	Yes	No	Yes	Yes
Standardizes disinfection protocols	Yes	No	No	Yes
Easy to use	Yes	Yes	Yes	No
Safe	Yes	Formula Dependent	Yes	Formula Dependent

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The authors wish to express their sincere thanks for the review and comments provided for this white paper by William A. Rutala, PhD, MPH, CIC, Professor of Medicine at UNC School of Medicine and Director, Statewide Program for Infection Control and Epidemiology (SPICE) Division of Infectious Diseases, UNC School of Medicine, Chapel Hill, NC.

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