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CADTH

A newsletter on new and emerging health care technologies in Canada

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New Disinfection Technologies to Reduce Health Care-Associated Infections

Health care-associated infections (HAIs), which are caused by microorganisms such as bacteria, viruses, fungi, and parasites, put patients at risk for serious illness and death.[1] Patients can acquire HAIs while receiving health care in any setting, including hospitals, long-term care facilities, community clinics, or at home.[2,3] The microorganisms that cause these infections can be found on or inside the patient, or they can come from external sources, such as health care providers' hands or clothing, medical instruments, or a contaminated environment.[4]

More than 200,000 Canadians acquire an HAI each year, and an estimated 8,000 of them die as a result.[2] These infections generate significant and potentially avoidable health care costs due to longer hospital stays, more diagnostic tests, isolation precautions, and additional treatments.[3,5-7]

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FEEDBACK

Have you heard of a new health technology you think will have an impact on health care in Canada?

Please let us know!

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

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Many Canadian acute care facilities do not meet cleanliness standards for infection prevention and control, and most hospitals report that they do not have enough housekeeping staff to provide optimal levels of cleaning.[8,9] A shortage of hospital beds and the pressure to move patients into available beds as quickly as possible are other obstacles to thorough cleaning.[10]

Even after cleaning (i.e., removing surface dirt and debris) and disinfection (i.e., killing bacteria and other microorganisms), some microorganisms may remain, allowing surfaces to quickly become re-contaminated.[10-13] High-touch surfaces are particularly prone to contamination — for example, door handles, bed rails, call buttons, and bathrooms in patient rooms, and patient monitoring equipment, computer keyboards, and the operating room bed in operating rooms.[10,12-14] Microorganisms that become suspended in the air during times of activity in the room, such as when bed linens or wound dressings are changed, also subsequently settle on surfaces.[14,15]

ANTIMICROBIAL-RESISTANT ORGANISMS

Antimicrobial drugs (such as antibiotics) are used to treat many HAIs; however, antimicrobial resistance is an increasing problem.[2] Antimicrobial resistance occurs when microorganisms adapt and the drugs used to prevent or treat the infections are no longer effective. Over-use and inappropriate use of antibiotics contribute to the problem.[16]

Antimicrobial stewardship involves system-wide interventions that encourage best practices in the use of antimicrobials (e.g., appropriate dosage, administration, choice of drug, and duration of therapy)[3,16] These measures will help to ensure these drugs continue to be effective against infections in the future.[3,16] Infection prevention and control initiatives contribute to antimicrobial stewardship. Improvements such as enhanced terminal room disinfection, hand hygiene, and cleaning practices — even in facilities where compliance with standards is already high — can further reduce rates of HAIs and the need for antibiotics.[2,3,16-21]

Clostridium difficile is the most common antibiotic-resistant bacterium responsible for outbreaks in Canadian health care facilities.[15] Some people are colonized with C. *difficile* but have no or only mild symptoms, while in others the bacterium causes severe life-threatening diarrhea.[2,6] In hospitals, C. *difficile* spreads mainly through hand contact or contact with contaminated surfaces.[22,23]

C. *difficile* spores (dormant forms of the bacteria) are more resistant to light, heat, and chemical disinfection, including common cleaning solutions, than the growing, vegetative forms of the bacteria.[6,17,22,24] The spores can survive for months or years on surfaces and can persist in patient rooms even after terminal cleaning (i.e., cleaning and disinfection after a patient is discharged).[6,22]

Other common antibiotic-resistant bacteria in Canadian hospitals include methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant *enterococci*.[2,15] In addition to these common antimicrobial-resistant bacteria, there are other bacteria, viruses, and fungal pathogens causing HAIs that can survive on surfaces that have not been adequately disinfected.[25]

WHO MIGHT BENEFIT?

Environmental disinfecting technologies are intended to reduce the risks that people in hospitals and other health care settings face from HAIs, and to reduce transmission of these infections to others.[13,24] Some individuals are particularly at risk from these infections, including infants, the elderly, people with multiple chronic health conditions, patients in burn units, patients undergoing surgery or in intensive care, and those with weakened immune systems, such as patients undergoing cancer treatments.[2,7,10,24,26]

CURRENT PRACTICE

Canadian environmental cleaning standards for infection prevention and control include routine terminal cleaning of rooms with detergents and chemical disinfectants.[3,10,13,24] The level of cleaning and disinfection required varies depending on the type of space and whether special precautions are needed.[10,13,27] Additional infection control protocols, such as hand hygiene, the use of personal protective equipment (gloves, masks, and gowns), and contact precautions, are also used to reduce the spread of HAIs.[3,10,13,27] Quality control processes should include routine monitoring — for example, by using a bioluminescent tracer to detect residual contamination — to confirm that adequate cleaning and disinfection has taken place.[10,13,24]

A recent systematic review noted that common standards for surface cleanliness are still needed: "There is no established benchmark for defining a surface as 'clean.' The real-world goal of environmental cleaning and disinfecting should be to reduce risk for pathogen transmission rather than establishing a continuously sterile surface."[28]

It is also difficult for studies evaluating environmental disinfection technologies to control for confounding factors — for example, compliance with hand hygiene and cleaning standards, and antibiotic use — and study results should be considered with this reality in mind.[22,28,29]

BEYOND MANUAL CLEANING AND DISINFECTION

In addition to regular cleaning and disinfection, the use of new non-manual technologies may help prevent the spread of HAIs, which could reduce the level of antibiotic drug use.[24] These automated systems and antimicrobial surfaces can provide episodic or continuous environmental decontamination.

Ideally, non-manual disinfection systems should meet the following criteria:

- they have a short operating, or cycle,

time (to minimize disruption in access to the room)

- they are highly effective in destroying surface pathogens that are likely to be found in that environment
- they offer a high ease of operation or full automation
- they require few safety restrictions (i.e., they are safe for staff use) and allow access to the room when needed
- they will have no adverse environmental impact and will not cause the degradation of hospital surfaces and equipment
- regulatory approvals are in place
- there is published evidence of their clinical impact.[24,30]

In addition, the ECRI Institute has outlined the following considerations for implementing these technologies:

- where the system will be used, and in how many rooms
- how often the disinfection system will be used
- which staff will operate the system, and what training they will need
- how the technology will affect the time required for room turnover
- how the technology fits with current cleaning and disinfection procedures or protocols.[31]

Five new environmental disinfection technologies to help prevent externally acquired HAIs are described in this issue of *Health Technology Update*. These technologies supplement (but do not replace) standard cleaning and disinfection procedures. As part of system-wide infection prevention interventions, they may further reduce patients' exposure to pathogens and, consequently, their risk for acquiring an HAI. Moreover, reducing HAIs may support antimicrobial stewardship by decreasing antibiotic use.

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Blue-Violet Light Disinfection for Hospital Rooms

Indigo-Clean (Kenall Manufacturing, Kenosha, WI) is a non-manual (or "no-touch") environmental disinfection technology that uses high–intensity narrow-spectrum (HINS) blue-violet visible light to destroy bacteria and other pathogens.[1] The technology, which was developed at the Robertson Trust Laboratory for Electronic Sterilisation Technologies (ROLEST) in Scotland, is intended to provide continuous air and surface decontamination of hospital spaces, including patient rooms, waiting rooms, bathrooms, and surgical suites.[2]

Image courtesy of Kenall Manufacturing

HOW IT WORKS

Indigo-Clean uses blended blue-violet and white light-emitting diodes (LEDs) to produce a visible HINS light with a wavelength of 405 nanometers, which is considered the peak antimicrobial wavelength.[1,3,4] The light reflects off walls and other surfaces and is absorbed by bacteria, whose light-sensitive porphyrin molecules become excited and, as a result, experience oxidative damage and cell death.[1,5,6] Indigo-Clean HINS light can be used to destroy bacteria in the air and on hard or soft exposed surfaces, such as door handles, floors, and curtains.[7]

Indigo-Clean light fixtures come in various sizes and light intensities.[1] Room size, ceiling height, layout, and purpose affect the choice of light and the number and placement of the fixtures.[1,2]

The lights have two disinfection modes: the first, "white disinfection," is used while the room is occupied, when ambient lighting is needed. The second, "indigo disinfection," provides more disinfection without the ambient light, and it is intended for use when the room is unoccupied.[1] Modes can be switched either manually, using a wall switch, or automatically, via an overhead sensor.[1] The lights have a lifespan of 125,000 hours.[1]

While the light is on, HINS lighting provides continuous environmental disinfection.[7,8] Laboratory tests of Indigo-Clean HINS lighting indicate it can destroy many of the pathogens commonly associated with health care-associated infections (HAIs), such as *Staphylococcus aureus* (including methicillin-resistant strains), *Klebsiella pneumoniae*, *Acinetobacter baumannii*, and *Pseudomonas aeruginosa*.[1,9] To date, there is no evidence that HINS light can destroy viruses.[10] The lighting is intended to be used in addition to standard cleaning and disinfection.[11]

AVAILABILITY IN CANADA

Indigo-Clean is available in Canada through Kenall Manufacturing and its local representatives (Clifford Yahnke, Director, Clinical Affairs, Kenall Manufacturing, Kenosha, WI: personal communication, 2017 June 22).

Blue-violet lights do not require a medical device licence from Health Canada, but the manufacturer must ensure that their products comply with the *Radiation Emitting Devices Act* and *Radiation Emitting Devices Regulations*[12] (Renelle Briand, Media Relations Officer, Health Canada and the Public Health Agency of Canada, Ottawa, ON: personal communication, 2017 July 12).

WHAT DOES IT COST?

According to the manufacturer, list prices for Indigo-Clean lighting fixtures range from US$300 to US$3,000. The costs will depend on the number of lights in the room and the following parameters (which take into account the need both to disinfect and to illuminate the space):

- room size
- number of light fixtures currently in the room
- room occupancy (or usage pattern)
- room purpose (for example, as an operating room, examination room, or bathroom).

Benchmarks for typical room costs are:

- operating room = approximately US$30,000
- patient bathroom = US$600 to $1,200
- emergency department examination room = US$2,000 to $4,000.

The product is designed to last for 10 years and comes with a standard five-year warranty (Clifford Yahnke: personal communication, 2017 July 13).

WHAT IS THE EVIDENCE?

We identified seven studies that evaluated HINS lighting for reducing bioburden (i.e., the amount of bacteria living on a surface) in burn units and intensive care units (ICUs) in Scotland,[8,13,14] and in patient rooms, waiting areas, and procedure and operating rooms in the US.[15-18] The studies differ in their approach to evaluating HINS light — for example, in the size and purpose of the area being disinfected, the duration of the study, how long the HINS lights were turned on, and the outcome measured. Generally, the studies involved taking samples from high-touch surfaces in rooms before, during, and after HINS lights were used and comparing the amount of bacterial contamination.

Reduction in Bioburden

In Scotland, ROLEST researchers found that HINS lighting reduced bacterial levels

by 27% to 91% in burn unit rooms[13,14] and by 61% in an outpatient burn clinic.[13] In ICU rooms, they found that overall Staphylococcal bacterial levels were reduced by 38% to 67%.[8] In the US, contamination of ICU rooms with S. *aureus* was reduced by 88% after one week and by 94.9% after two weeks of HINS light use.[16] A Wisconsin hospital study of the gastroenterology laboratory (i.e., the waiting room and procedure room) showed a 20% to 40% reduction in bioburden on various surfaces.[17] A pilot of the Indigo-Clean lights in a Tennessee hospital operating room found an average reduction in bacterial levels of 88% 15 days after the lights were installed.[18] Evidence of the impact of reduced bioburden on HAIs is still needed.[4]

Effect of HINS Light on Antimicrobial-Resistant Organisms and C. *Difficile*

Three studies reported the effect of HINS lights on antimicrobial-resistant organisms.[14,15,17] ROLEST researchers found a reduction in methicillin-resistant S. *aureus* (MRSA) contamination in burn unit rooms of between 56% and 62%.[14] In a US study of patient rooms, over a period of up to 48 hours, there was a 100% reduction in MRSA and vancomycin-resistant *Enterococci*, and an 88% reduction in A. *baumannii* when using the disinfection mode.[15] Over 72 hours, lights in disinfection mode reduced *C. difficile* spores by 50%.[15] Further research on the impact of HINS lights on specific pathogens, including vancomycin-resistant *Enterococci*, MRSA, and *C. difficile*, is underway at ROLEST.[17]

Duration of HINS Light Use

Greater reductions in bioburden occurred the longer the lights were in use, and bacterial levels increased when the lights were turned off.[8,14-16] The lower intensity of the ambient mode light increased the disinfection time.[15]

Safety

HINS lighting can be used while patients or staff are in the room without disrupting workflow or requiring precautions to prevent entry during disinfection.[1,7]

The potential effects of blue light on retinal aging and sleep-wake cycle disruption are still being studied.[17,19] Blue light could cause skin damage in patients taking medications that cause photosensitivity, but it is not thought to cause skin cancer.[19] At 405 nm, HINS light is below the wavelengths associated with damage to the retina or those that influence mood and sleep.[4] The safety of using HINS lighting in neonatal ICUs has not yet been studied.

ISSUES TO CONSIDER

To provide comfortable lighting, HINS lights emit fairly low energy, which reduces their antimicrobial effect.[4] Extended use of HINS lighting increases its effectiveness. To date, the studies in patient rooms have not used HINS lighting overnight, and one study noted that a dimmer option might be desirable.[8] Studies on patient and staff comfort levels for blue-violet light are underway in Scotland.[4]

Some bacteria are more susceptible to HINS light than others, and the germicidal effects of HINS light are less powerful than those of ultraviolet (UV) light.[3,5,6,20,21] The HINS light is also less effective on covered or indirectly exposed surfaces.[4,8] The effectiveness of HINS lighting could also be affected by furniture colours and fabrics that reflect or absorb light, which may be a consideration when planning an installation.[4]

Decontamination with HINS light can take several hours, whereas it takes minutes with pulsed-xenon UV light.[20] High doses of HINS light are needed to destroy C. *difficile* spores, and HINS light alone will not likely be sufficient for C. *difficile* decontamination.[4] However, one study found a lower concentration of chlorinated disinfectant may be needed when used in combination with HINS lighting, which would potentially decrease health care workers' exposure to hazardous chemicals.[6]

No special staff training is needed to use Indigo-Clean lighting.[11]

Unlike UV and bleach disinfectants, HINS light does not degrade rubber and plastic, which may reduce damage to hospital equipment.[4,6] While Indigo-Clean requires the replacement of existing overhead light fixtures,[7] LEDs use less energy, have a longer lifespan, and need less maintenance than traditional lighting.[4,11]

It does not appear likely that bacteria will develop resistance to blue-violet light;[4] however, some researchers are investigating this possibility.[22-24]

Related Developments

Pre-clinical research has found that HINS light may help to prevent surgical infections, decontaminate wounds, and destroy bacteria that cause foodborne illness.[3,4,20,25-30]

ROLEST researchers are examining the ability of HINS light to inactivate viruses, such as Norovirus,[25] and the antimicrobial effects of pulsed HINS LEDs that could reduce energy costs and produce more comfortable lighting.[20]

There is also renewed interest in historic methods of hospital design that maximize sunlight and fresh air to help prevent infections.[31]

Looking Ahead

The ECRI Institute estimates that between 40% and 60% of US health care facilities are likely to adopt HINS lighting.[7] Studies to date have focused on reduction of bioburden. Evidence of the impact of HINS lighting on preventing HAIs is still needed.[4,7,32,33]

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A Pulsed-Xenon UV Light Disinfection System for Hospital Rooms

Xenex Disinfection Services (San Antonio, Texas), currently markets a pulsed-xenon UV light (PX-UV) room disinfection system under the brand name LightStrike.[1] The PX-UV system is an add-on to standard terminal room cleaning and disinfection and requires less time than other no-touch room disinfection technologies.[2]

Image courtesy of Xenex Disinfection Services

HOW IT WORKS

The LightStrike PX-UV system is a portable robotic device measuring about 48 cm x 40 cm x 100 cm, with a moving section that contains a xenon gas flash bulb.[3] A trained operator places the device at one or more locations around the space to be disinfected and activates it remotely for cycles of about five minutes at each location.[3] When activated, the xenon lamp emits short pulses of 200 nm to 300 nm wavelength UV light, which includes UV-C light.[4] UV-C light is readily absorbed by bacteria and viruses, damaging their genetic material and making it difficult for them to replicate or to produce new microorganisms that are able to survive.[5]

AVAILABILITY IN CANADA

The LightStrike system is available in Canada and in use in Canadian health care facilities (Melinda Hart, Media Relations, Xenex Disinfection Services, San Antonio, TX: personal communication, 2017 Jun 29).[6] UV light-emitting devices do not require a medical device licence from Health Canada, but the manufacturer must ensure that their products comply with the *Radiation Emitting Devices Act* and *Radiation Emitting Devices Regulations*[7] (Renelle Briand, Media Relations Officer, Health Canada and the Public Health Agency of Canada, Ottawa, ON: personal communication, 2017 July 12).

WHAT DOES IT COST?

The cost of the LightStrike system in Canada, including one year of service, is US$137,250 for the X4 model and US$147,750 for the X5 model (Melinda Hart: personal communication, 2017 Jun). The cost of leasing the device was reported to be US$3,000 per month for one machine[8] and less than US$5,000 per month for two machines.[9]

Two studies, co-authored by the manufacturer, estimated a potential in-hospital cost savings of US$300,000 over 15 months[10] and greater than US$730,000 over 22 months[11] through prevented health care associated infections when PX-UV was added to cleaning and disinfection practices at two US facilities.

WHAT IS THE EVIDENCE?

We identified 18 studies of PX-UV disinfection systems.[3,8-24] 10 of which were co-authored by the manufacturer.[8,10,11,13,14,17,19,20,24,25] Two studies were conducted in the UK,[3,18] and the rest took place in the US.[8-17,19-25] None of the studies were randomized controlled trials; however, one such trial is currently underway in Michigan.[26]

The PX-UV system was typically deployed at various locations throughout the space being disinfected (usually in two to three places, such as around the patient bed and in the bathroom) for a cycle of five minutes per location (10 minutes per location in operating rooms).

CLINICAL EFFECTIVENESS

Bioburden and Surface Contamination

There were 10 studies that evaluated the ability of PX-UV to reduce bioburden and destroy surface bacteria.[3,8,12,14-16,18,21-23] Using samples taken from high-touch surfaces around the room before and after terminal cleaning, and after PX-UV disinfection, the studies found PX-UV further reduced residual bacteria, including vancomycin-resistant *Enterococci* (VRE),[3,12,21] methicillin-resistant *Staphylococcus aureus* (MRSA),[14,21] and C. *difficile*.[21] One study found PX-UV was as effective as bleach for reducing C. *difficile* contamination (with an 83% reduction for PX-UV compared with a 70% reduction for bleach),[8] and another noted that the five minute disinfection cycle may not be sufficient to destroy all VRE.[3] One study also found that using a mercury UV-C disinfection system (a device that produces UV-C light using a bulb that contains mercury vapour) was more effective than PX-UV in reducing levels of VRE, MRSA, and C. *difficile* spores, but that neither system completely eliminated these organisms.[21]

Preventing Infections

There were 10 studies that examined rates of health care-associated infections (HAIs),[9-11,13,17,23,24] surgical site infections,[19,20] or device-acquired infections[22] before and after implementing PX-UV disinfection. Adding PX-UV disinfection reduced the number of HAIs caused by C. *difficile*,[9-11,17,24] MRSA,[11,13,24] and VRE.[11,24]

Surgical site infections were also reduced after PX-UV was implemented,[19,20] but one study found a reduction only in wounds considered clean before surgery.[20] PX-UV did not affect the rate of device-acquired infections.[22]

Many studies note it is difficult to determine the true effect of PX-UV on infection rates because of confounding factors, such as hand washing audits, education programs, antibiotic stewardship initiatives, mandatory public reporting of C. *difficile* infections, the use of dedicated housekeepers for terminal cleaning, or other quality improvement programs started around the same time as PX-UV.[9,10,13,19,20,23,24]

USER EXPERIENCE

An ECRI Institute user experience survey found that, on a five-point scale (one being "Unacceptable" and five being "Excellent"), Xenex systems were rated at around a four in overall impressions, ease of use, features, performance, and reliability.[27] A UK study reported that two-thirds of staff found the device easy to move and were comfortable incorporating it into existing processes, but only one-third agreed that set-up was easy.[18]

SAFETY

No safety issues with PX-UV disinfection were reported in the literature. An ECRI Institute brief identified no safety alerts or product recalls.[4] PX-UV systems must be used in empty rooms to avoid irritation to eyes and skin[14] and prolonged exposure to UV light can cause skin cancer.[5] The LightStrike system includes safety features such as motion sensors to shut off the machine if movement in the room is detected.[3]

One study also reported using blackout curtains in areas with glass windows or walls.[24] Xenex provides customized blackout curtains to place over privacy curtains in multi-occupancy rooms or bays to provide additional light blocking. The curtains are intended to reduce the amount of visible light and UV light exposure for device operators, patients, and visitors (Melinda Hart: personal communication, 2017 Aug 9).

ISSUES TO CONSIDER

Selection of a non-manual disinfection system depends on a number of factors, including labour costs, intended use, availability, and the practicality of implementing the system in a particular health care facility.[28-30] A 2017 paper presents a business case model for selecting UV-C disinfection systems and outlines the elements to consider when acquiring these technologies.[31]

CLEANING TIME AND ROOM TURNOVER

In Canadian health care facilities the median cleaning time for private rooms is between 30 and 60 minutes and is longer in semi-private or ward rooms.[32] PX-UV disinfection is used in addition to terminal cleaning for 10 to 21 minutes.[3,8-24] One US study[12] found it took about 19 minutes from calling for the device to when the room was ready.[12] Another US study reported that setting up the device took two to three minutes in addition to the disinfection cycles.[14] Also in the US, one study found using PX-UV disinfection added a total of 51 minutes per patient discharge, including 31 minutes to bring the device to the room and set up blackout curtains as needed.[24]In the UK, one study[3] reported a total time for disinfection of 25 minutes, and another[18] found that it took about 50 minutes to retrieve, use, and return the device, but that this time did not impact room turnover.

STAFF REQUIREMENTS AND TRAINING

The manufacturer provides staff training for using the system and trains an on-site technician to provide routine maintenance and repairs.[33] One study noted that no additional staff were needed when the system was implemented in their facility.[9]

USE IN SEMI-PRIVATE ROOMS AND WARD ROOMS

There is limited evidence of PX-UV device use in hospitals outside of the US,[3,18] and we found only two studies where the device was clearly used in rooms occupied by more than one patient.[9,17] One study noted that two-bed rooms often could not be treated because a patient was still in the room; however, often the bathroom could still be treated.[9] This study did not indicate if blackout curtains were available for use.[9]

DEVICE PLACEMENT AND IMPLEMENTATION

Researchers in one US study found that the efficacy of PX-UV disinfection was reduced as the distance of the device from bacterial samples increased; thus, they recommended that commonly touched surfaces be placed close to the system for optimal exposure.[21] As part of the implementation process, the manufacturer will help the facility develop a disinfection protocol optimized for room layout, patient type, patient turnover, and the types of pathogens most common to the facility.[33] One study noted that the device logged each cycle and uploaded information to an online portal to track use and correct placement by staff.[10]

RELATED DEVELOPMENTS

The efficacy of PX-UV against Ebola virus and anthrax spores[34] and for disinfecting personal protective equipment exposed to Ebola virus[35] has been studied.

Two recent CADTH Rapid Response reports examining evidence for other portable, non-manual disinfection systems (including technologies that use steam, ozone, UV light, and hydrogen peroxide) found limited clinical effectiveness evidence and no cost-effectiveness evidence.[30,36]

Other portable UV-C light disinfection systems that use mercury bulbs to produce UV-C are available.[37] A recent ECRI Institute overview of two mercury UV-C systems, the Tru-D UV-C Disinfection System (Tru-D SmartUVC LLC, Memphis TN) and the Optimum-UV System (Clorox Healthcare, Oakland, CA), and the Xenex system found limited evidence for all three devices.[38]

A recent multi-centre randomized controlled trial found that adding a mercury UV-C disinfection system to standard terminal cleaning decreased

the risk of MRSA infection in patients occupying rooms previously occupied by infected patients, but there was no difference in the risk of acquiring C. *difficile*, MRSA, or VRE infections when UV-C was added to terminal room disinfection that included bleach.[39]

LOOKING AHEAD

The ECRI Institute noted that measuring bioburden reduction is of limited use and that more research, including randomized controlled trials with clinically important outcomes such as infection rates or colonization rates (i.e., the presence of bacteria on patients), is needed.[4]

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A Countertop UV-C Light Disinfection System for Mobile Devices

Mobile devices such as smartphones and tablets are widely used in health care facilities, but they can be potential sources of infection-causing bacteria and viruses.[1-10] Countertop devices such as the CleanSlate UV Sanitizer (CleanSlate UV/Limestone Labs, Toronto, Ontario) use ultraviolet-C light (UV-C) to destroy microorganisms on mobile devices.[11] These technologies may help reduce the transmission of pathogens by providing a convenient way to disinfect mobile devices, and particularly those that could otherwise be damaged using chemical disinfection methods.[12,13]

Image courtesy of CleanSlate UV

HOW IT WORKS

The CleanSlate UV Sanitizer is intended for disinfecting personal and facility-owned mobile devices and other small portable devices used by health care workers, patients, and visitors to health care facilities.[14] Bacteria on the surfaces of the mobile devices absorb the UV-C light, which damages their genetic material and makes it difficult for them to replicate.[14,15] The CleanSlate UV is large enough to simultaneously disinfect either one tablet, two to four smartphones, or nine pagers.[13]

The CleanSlate UV Sanitizer works as follows:[11,13,14]

- The user places a mobile device onto a clear quartz disinfection tray and closes the lid.
- After the lid is closed, the tray moves back into a chamber containing six UV-C light bulbs (three above the tray and three below).
- While the system is running, the user washes his or her hands.
- After a disinfection cycle of about 30 seconds, the lid opens automatically, and the user removes the device.

To help prevent cross-contamination from unwashed hands, the CleanSlate UV's lid is made of antimicrobial copper (Taylor Mann, CEO CleanSlate UV, Toronto, ON: personal communication 2017 July 18).

AVAILABILITY IN CANADA

The CleanSlate UV Sanitizer device is currently available and in use by three hospitals in Canada (Taylor Mann: personal communication 2017 July). Several other countertop UV-C disinfection systems are commercially available.[12]

UV light-emitting devices do not require a medical device licence from Health Canada, but they are regulated under the *Radiation Emitting Devices Act* and *Radiation Emitting Devices Regulations*[16] (Renelle Briand, Media Relations Officer, Health Canada and the Public Health Agency of Canada, Ottawa, ON: personal communication, 2017 April 26).

WHAT DOES IT COST?

The cost of the CleanSlate UV Sanitizer ranges from US$6,500 to US$8,000 per device, depending on the number of devices purchased and the distributor used. Devices can also be leased for US$325 to US$450 per month, which includes the price of replacement bulbs (Taylor Mann: personal communication 2017 July).

The ECRI Institute estimates the total cost of owning a CleanSlate UV Sanitizer over three years to be US$8,600, including the cost of the device, replacement bulbs, service, replacement parts, and other consumables such as alcohol swabs to clean the interior of the device.[12]

WHAT IS THE EVIDENCE?

Clinical Effectiveness

According to the manufacturer, one clinical efficacy study is currently underway (Taylor Mann: personal communication, 2017 July).

Laboratory testing using a prototype device found that the CleanSlate UV achieved a reduction of viable methicillin-resistant *Staphylococcus aureus* bacteria and *Clostridium difficile* spores of more than 99% during a 30-second UV disinfection cycle on pre-cleaned surfaces.[17]

A case study of the CleanSlate UV system in a neonatal intensive care unit and operating room, which was reported on the manufacturer's website, found that 79% of mobile devices were contaminated with bacterial pathogens prior to disinfection.[18] After using the CleanSlate UV Sanitizer, a 100% reduction in these pathogens was reported,[18] but information on the test method used to measure contamination was not provided.

Testing by the ECRI Institute found that the CleanSlate UV Sanitizer generated dosages of UV-C light sufficient to achieve a 99.9% reduction in C. *difficile* spores on clean surfaces using the default disinfection cycle.[13]

Safety

No information about the safety of the CleanSlate UV Sanitizer was identified.

UV light can irritate the eyes and skin, and prolonged exposure can cause skin cancer.[19] It is important that countertop UV-C disinfection systems include safety features (for example, automatically shutting off if opened or locking while in use) to prevent direct or indirect exposure to UV-C light.[12] They should also be sealed to prevent UV-C light from escaping the device while in use.[20] The ECRI Institute evaluation of CleanSlate UV found it met ECRI's safety criteria, including compliance with international standards, after evaluating whether UV-C radiation can escape the device and the safety features of the device.[13,20]

The dose of UV-C light that countertop UV-C disinfection systems produce should not cause materials commonly used in mobile devices to generate by-products that would be a concern for human health.[20]

ISSUES TO CONSIDER

Facilities considering purchasing a countertop UV-C disinfection system should consider the following:[20]

- features (for example, the number of mobile devices it can disinfect simultaneously, device security when in use, or software to track use)
- placement and potential users (for example, at facility entrances for use by anyone entering the building)
- compliance (for example, policies and procedures for when the system must be used and radio-frequency identification tags that track when a device is disinfected)
- personal device disinfection (for example, clear policies for which devices should be disinfected)
- maintenance (for example, periodic cleaning and bulb replacement).

Countertop UV-C disinfection systems are intended to be used after a device has been manually cleaned (that is, after visible dirt or debris is removed).[12]

To ensure that disinfection occurs, countertop UV-C disinfection systems should not operate when a bulb is missing or burned out.[12] The CleanSlate UV Sanitizer has a smart ballast system to monitor bulb status (Taylor Mann: personal communication 2017 July).

UV-C light can degrade some materials, such as plastics.[13] The ECRI Institute recommends that organizations check with the manufacturers of the mobile devices they intend to disinfect to determine if they will be affected by the CleanSlate UV Sanitizer device.[13]

RELATED DEVELOPMENTS

The CleanSlate UV system is also being marketed to the food processing industry as a way to prevent contamination of food products.[21]

The ECRI Institute recently reviewed four other countertop UV-C disinfection devices,[12] the KR615 (AUVS LLC, South Hill, VA),[22] the Flashbox-mini (ClorDiSys Solutions Inc., Branchburg, NJ),[23] the ReadyDock Duo (ReadyDock Inc., West Hartford, CT),[24] and the ReadyDock RD5 (ReadyDock Inc.).[25]

Researchers have also proposed a number of "common sense" protocols that organizations may also consider for disinfecting mobile devices.[26-28] These include setting up device cleaning stations,[27] creating disinfection reminders,[28] and avoiding mobile device use in rooms under contact precautions.[26]

LOOKING AHEAD

Although countertop UV-C disinfection devices appear to produce sufficient doses of UV-C to destroy bacteria, evidence on clinical outcomes related to using these devices to disinfect mobile devices in health care settings is still needed.[12,13,22,24,25]

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Antimicrobial Compressed Salt for High-Touch Surfaces

A Canadian inventor who is familiar with the antimicrobial properties of sodium chloride (table salt) from his work in the meat industry has partnered with University of Alberta researchers to develop Outbreaker compressed salt surfaces, which reduce transmission of bacteria in hospitals and other facilities.[1,2]

Image courtesy of Outbreaker Solutions

HOW IT WORKS

Outbreaker products (Outbreaker Solutions, Edmonton, AB) are composed of more than 99% compressed sodium chloride — and, as such, are similar to salt licks (blocks of salt manufactured for livestock).[3,4] Current Outbreaker products include doorknobs, bed rails, toilet handles, and taps.[1] The fixtures have a smooth texture that feels similar to ceramic.[4] The products are intended to reduce transmission of bacteria that gather on these frequently touched surfaces in the patient environment.

Antimicrobial surfaces work in one of three ways:[5]

- by changing the surface texture, reducing the ability of bacteria to adhere
- by including an antimicrobial additive in the surface that kills or slows the growth of bacteria
- by using a material with natural antimicrobial properties, such as copper, silver, zinc, or, in this case, salt.

Salt is a natural substance that inhibits the growth of bacteria — partly through dehydration, and also by upsetting the enzyme activity of microorganisms and damaging their DNA.[6] Salt is essential to human and animal life, and it has a long history of use in food preservation and flavouring, in pharmaceuticals, home remedies (for example, as a mouthwash and wound cleanser), and agriculture and industrial products.[7]

AVAILABILITY IN CANADA

Pilot evaluations of Outbreaker products are under way at several Alberta facilities.[4] The company expects to launch the first products in Canada in late 2017 (Brayden Whitlock, Outbreaker Solutions, Edmonton, AB: personal communication 2017 May 7). Outbreaker technology is patented in Canada and several other countries.[2]

No compressed sodium chloride antimicrobial product has yet been authorized in Canada, but these would be regulated under the *Natural Health Products Regulations*[8] for antimicrobial claims and the *Pest Control Products Act*[9] for sanitizer claims. Claims are generally limited to "reduces bacterial contamination," as specific pathogen claims are not permitted under the *Pest Control Products Act* (Renelle Briand, Media Relations Officer, Health Canada and the Public Health Agency of Canada, Ottawa, ON: personal communication: 2017 April 26).

WHAT DOES IT COST?

The price of Outbreaker products in Canada is not yet known, but as the raw material to build the surface (salt) is inexpensive, the price will be very accessible (Brayden Whitlock: personal communication 2017 May).

WHAT IS THE EVIDENCE?

Studies assessing the benefit of antimicrobial surfaces often measure the reduction of surface bacteria following contact with the intervention — which, in this case, consists of Outbreaker products. To determine the per cent reduction in the number of microorganisms present on the surface, the following studies measured the amount of bacteria present after contact compared with a control surface of stainless steel.

Laboratory results posted by the manufacturer report that Outbreaker technology reduced levels of surface bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *Enterococcus faecalis*, and *Clostridium difficile* (whether vegetative cells or spores is not clear), by 90% to 100% compared with a stainless steel surface one minute after contact.[10] However, the test method used (contact agar) does not allow for detection of a 100% decrease in the viable count, and the test method's limit of detection was not stated (Dr. Michelle Alfa, AlfaMed Consulting, Winnipeg, MB: personal communication 2017 July 31).

A 2016 pilot study assessed the time it took for compressed sodium chloride to inactivate MRSA (relative to a stainless steel control surface) and compared it with copper surface inactivation of MRSA in a laboratory setting.[3] The compressed sodium chloride surface reduced MRSA contamination by 85% in the first 20 seconds and by 94% within the first 60 seconds, compared with 30% to 35% (at 20 seconds) and 71% to 73% (at 60 seconds) for copper surfaces.[3]

In conditions of environmental stress, some bacteria can remain viable (but dormant) and cannot be detected by culture tests,[11] which may lead to underestimating the levels of bacteria present.[11] Further studies are needed to clarify whether compressed salt surfaces destroy bacteria or only inhibit their ability to grow on culture media.

SAFETY

Sodium chloride is considered to be a chemical of low concern for human risk.[12] However, if exposed to high temperatures, it can produce a vapour that is an eye irritant, and high doses of ingested salt can be toxic to humans and animals.[12]

ISSUES TO CONSIDER

The reduction of bacteria achieved by Outbreaker products is likely less than what current Health Canada guidance[13] requires for surface sanitizers and disinfectants on hard surfaces (> 99.9% reduction) (Dr. Michelle Alfa: personal communication 2017 August 4). However, the Health Canada guidance document does not indicate the desired level of eradication for antimicrobial surfaces.[13]

The extent to which temperature, moisture, and organic matter interfere with the effectiveness of the Outbreaker compressed salt surfaces is still being assessed.[3]

In addition to planners and architects, discussions about introducing antimicrobial surface technologies should include infection prevention and control and other staff who are involved in providing services in that area.[5,14] Particular issues to consider with antimicrobial coatings include the following:[5]

- which surfaces should be antimicrobial
- the purpose of the surface and where will it be located — for example, is it a wet or dry area? is it in an area that is constantly being cleaned, such as an isolation room, or somewhere like the hospital lobby?
- whether the coating will be active continuously or only for a period of time — and, if the latter, how often the surface will need to be replaced
- what cleaning and disinfecting solutions can be used (some antimicrobial surfaces will not work while covered in cleanser or will be deactivated by the solutions)
- how easy the surface is to clean and maintain
- how durable the surface is
- what benefits and disadvantages the surface has (e.g., environmental or safety concerns, or any risk for the development of antimicrobial resistance).[5,15]

RELATED DEVELOPMENTS

Copper surfaces are another antimicrobial surface option that can reduce bacterial contamination.[14,16] However, a recent systematic review found that the few studies that measured the impact of copper surfaces on HAIs were flawed (i.e., at high risk for bias) and that the reduction in bacterial levels was likely "modest."[17] Moreover, copper surfaces appear to need a longer period of time to take effect against microorganisms, and they are expensive relative to standard fixtures.[3,14,18]

Various other antimicrobial surfaces are available or in development, including anti-adhesive surfaces and coatings impregnated with antimicrobial or photosensitive agents, such as titanium dioxide.[19]

Other University of Alberta researchers have developed another antimicrobial use for salt: as a coating for surgical masks to destroy airborne respiratory viruses such as influenza.[4,20]

LOOKING AHEAD

The European Commission has funded a four-year project, Anti-Microbial Coating Innovations to Prevent Infectious Disease, to create a stakeholder network of those involved in developing, regulating, and using antimicrobial coatings to prevent HAIs.[15]

The impact of using compressed salt surfaces on HAI rates remains to be demonstrated.[3] Further testing of the effectiveness of Outbreaker surfaces against MRSA and other microorganisms is under way.[3]

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Shark Skin-Like Micropatterned Surfaces to Reduce Bacterial Adhesion

Discovered through research for the US Office of Naval Research, Sharklet (Sharklet Technologies Inc., Aurora, CO) micropatterns have been used for many years to prevent marine organisms from attaching to submarines and ships. A shark's skin has flexible, textured scales that make moving through water easier and help prevent marine microorganisms (for example, algae) from adhering.[1] As the brand name suggests, Sharklet mimics the natural texture and pattern of shark skin.[1] The technology is now available as semi-transparent adhesive film intended to reduce bacterial transmission from high-touch surfaces in health care and other settings.[2,3]

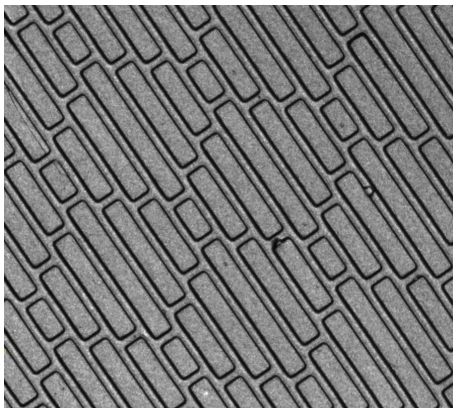

Image courtesy of Sharklet Technologies, Inc.

HOW IT WORKS

Under a microscope, Sharklet appears as raised "riblets" that are 2 micrometres (µm) wide, four µm to 16 µm in length, and 3 µm high (one µm = one millionth of a metre).[4] The riblets are arranged in a repeating diamond-like pattern.[4] The Sharklet surface has tiny air pockets that form water-repelling, unstable surfaces that discourage the formation of biofilm (i.e., collections of microorganisms that stick to surfaces under wet conditions).[5]

Sharklet's mechanism of action stems from the micropattern itself. It does not destroy bacteria; rather, the size and shape of the pattern limit the ability of bacteria to adhere to the surface.[6] Because Sharklet does not use chemical additives or antimicrobial substances, there is less risk for developing antimicrobial resistance.[2]

Sharklet adhesive film is a thin layer of acrylic on a vinyl adhesive layer. The film is intended to be placed permanently on surfaces. The film can be cut to fit various surfaces, but it works best on flatter surfaces. (Jaclyn Strom, Product Development Engineer, Sharklet Technologies, Inc., Aurora, CO: personal communication, 2017 May 3).

AVAILABILITY IN CANADA

Sharklet can be shipped internationally to Canada and elsewhere from its US headquarters (Jaclyn Strom: personal communication, 2017 May 3).

In Canada, Sharklet is a micro-texture that inhibits bacterial growth on surfaces and, on its own, is not regulated as a medical device. Moreover, it does not fit the definition of a pesticide because non-biocidal coatings and films do not fall under the *Pest Control Products Act*.[7] However, if the manufacturer develops medical devices that contain Sharklet, these would be subject to the licensing requirements of the *Medical Devices Regulations*[8] (Renelle Briand, Media Relations Officer, Health Canada and the Public Health Agency of Canada, Ottawa, ON: personal communication, 2017 July 12).

WHAT DOES IT COST?

Sharklet adhesive film comes in rolls that are 54 inches wide and 150 feet long. Each roll costs about US $650 (or about $10.20 per square metre). The product can also be customized (for example, by altering the type of material or adhesive used or the thickness of the film) to match specific needs. Customization may increase the price, but costs decrease for larger quantity orders (Jaclyn Strom: personal communication, 2017 May 3).

WHAT IS THE EVIDENCE?

We identified only one in-hospital study (a conference presentation)[9] and one simulation study[10] of the Sharklet adhesive film in an emergency department scenario. The remaining publications and conference abstracts were all laboratory-based.[2,4-6,11-16]

LABORATORY RESEARCH

In the lab, studies of Sharklet and other shark skin-inspired micropatterned surfaces (including studies on medical device surfaces[5,6,11,13,14]) have found reduced bacterial adhesion or colonization of *Staphylococcus aureus* and *S. epidermidis*,[5,12,14] methicillin-sensitive and methicillin-resistant *S. aureus*,[2,13,14] *Escherichia coli*,[6,13] *Serratia marcescens*,[11] *Pseudomonas aeruginosa*,[12,13] *Acinetobacter baumannii*,[13] *Mycobacterium abscessus*,[4] and *Klebsiella pneumoniae*.[13] Notably, the control surface used for most of the studies was a smooth silicone elastomer, which may not reflect bacterial colonization on actual hospital equipment and surfaces.

Two additional laboratory-based studies of Sharklet surfaces for health care environments have been reported in conference presentations.[15,16] The first study assessed bacterial attachment of *S. aureus* on a new, more transparent version of Sharklet adhesive film intended for use on electronic touch screens, hand-held devices, and other monitor screens.[15] The new film was considered as effective as the original film at reducing the attachment of *S. aureus* (a 56% reduction compared with a 75% reduction, respectively).[15] The second study, which assessed bacterial attachment on regular Sharklet adhesive film, found a reduction of surface bacteria adhesion (i.e., levels of methicillin-resistant and methicillin-sensitive *S. aureus*) ranging from 76.5% to

87.4%.[16] The average transfer of bacteria from Sharklet surfaces to a gloved fingertip was 16%, whereas there was 67% transfer of bacteria from smooth surfaces.[16]

SIMULATION RESEARCH

A manufacturer-sponsored study investigated *S. aureus* transfer and contamination on three pieces of medical equipment (a code-cart, a cardiac defibrillator shock button, and a medication vial) with Sharklet-covered surfaces compared with transfer and contamination on unpatterned surfaces.[10] The equipment was used by 11 physicians in an emergency resuscitation scenario with a training mannequin.[10] On average, all equipment with Sharklet surfaces had less bacterial transfer, but the difference in bacterial levels was only significant for the defibrillator shock button.[10]

HOSPITAL CONTAMINATION STUDY

A study in an Austrian hospital, which was reported as a conference poster, assessed contamination on cleaned (once per week with detergent) and un-cleaned Sharklet wall panel surfaces compared with un-cleaned control wall surfaces in six different hospital spaces (including an operating room, a bathroom, a waiting room, a laboratory, and two corridors).[9] At six months, the Sharklet wall surfaces had bacterial levels that were approximately 90% less than those found on the control wall surfaces.[9]

SAFETY

No safety issues were noted in the studies of Sharklet adhesive film for environmental surfaces.

Because of machine limitations, the Sharklet adhesive film has tiny seams (every nine inches in both directions) where there is no micropattern (Jaclyn Strom: personal communication, 2017 May 3). Evidence regarding the impact of these seams on bacterial adhesion is needed, as is information on the use of Sharklet adhesive film on surfaces where a good grip is needed for safety reasons, such as on handrails.

ISSUES TO CONSIDER

Biofilms form in wet conditions; whether a surface that reduces bacterial biofilm formation is appropriate for mainly dry high-touch hospital surfaces is not yet known.

Information on the durability of self-disinfecting surfaces, and whether their effectiveness is affected by environmental conditions such as temperature, humidity, cleaning processes, and level of bioburden, is currently lacking.[17]

We did not find any published studies of Sharklet's impact on adhesion and transmission of viruses. A 2014 news item quoted a company investigator who claimed to have found that Sharklet's effect on viruses was similar to its effect on bacteria, but no further information was provided.[18]

RELATED DEVELOPMENTS

Sharklet micropatterns are also being investigated for use in catheters and other implantable medical devices to reduce the accumulation of microorganisms. For example, they could be used to reduce catheter-related bacterial infections and blood clots or airway blockages caused by the build-up of mucous in endotracheal tubes, or to prevent clouding of intraocular lenses used in cataract surgery.[5,13,19,19-22]

A trial of Sharklet for preventing infections in patients with urinary tract catheters is underway at the University of British Columbia in Vancouver.[23] The company is also developing a wound dressing based on Sharklet technology.[3]

Other antimicrobial surface technologies are available, including coatings impregnated with antimicrobial agents (such as triclosan), metallic surfaces (such as silver or copper), and antimicrobial paint.[24]

LOOKING AHEAD

While laboratory studies indicate Sharklet can reduce contamination of many types of bacteria on various surfaces, real-world evidence that this will translate to reduced rates of health care-acquired infections is still needed.[4,17,24]

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Mini-Roundup: Recent Reports from CADTH and Other Agencies

CADTH *Issues in Emerging Health Technologies* Bulletins

- Patient-controlled carbon dioxide tissue expansion for breast reconstruction
- Emerging drugs for Duchenne Muscular Dystrophy
- A transdermal glucagon patch for severe hypoglycemia
- Flash glucose monitoring system for diabetes
- Point-of-care glycated hemoglobin testing to diagnose type 2 diabetes
- Prevention of plantar ulcers in people with diabetic peripheral neuropathy using pressure-sensing shoe insoles
- Islet cell replacement therapy for insulin-dependent diabetes
- A hybrid closed-loop insulin delivery system for the treatment of type 1 diabetes

CADTH Horizon Scan Roundup 2017

Part 1 of the *Horizon Scan Roundup* for 2017 is now available. This list reports on new and emerging technologies published by CADTH and other agencies in the first half of this year.

CADTH has just published a Rapid Response report on the evidence for using antimicrobial paint to reduce health care-acquired infections in health facilities.

The British Columbia Ministry of Health is updating their Best practices for hand hygiene in all healthcare settings and programs. The new guidelines are expected to be available in fall 2017.

Public Health Ontario's Provincial Infectious Diseases Advisory Committee (PIDAC) is updating their Best practices for environmental cleaning for prevention and control of infections in all health care settings. The new (3rd) edition will be posted on the PIDAC web page.

Recent Horizon Scanning Reports from Other Agencies

Agencies Included in the Mini-Roundup below:

- Health Policy Advisory Committee on Technology (HealthPACT) Australia
- National Institute for Health and Care Excellence (NICE) UK

Infectious Disease and Infection Control

- Eazyplex SuperBug kits for detecting carbapenemase-producing organisms (NICE)
- MALDI-TOF for detection of antibiotic resistant bacteria (update) (HealthPACT)
- Rapid sepsis detection (HealthPACT)

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