Evolving Technologies for Decontaminating Healthcare Environments

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HAI Prevalence and Impact

The development of health care-associated infections (HAIs) remains a major national patient safety issue with upwards of 1.7 million infections and 99,000 deaths occurring annually. The overall direct cost of HAIs to hospitals has been reported to be in the range from $28 billion to $45 billion. (1)

Recent analysis of data from the Agency for Healthcare Research and Quality (AHRQ) indicates that facilities incur increased costs ranging from 47% to 70% for medical harms such as Catheter-related bloodstream infections (CRBSIs) and catheter-associated urinary tract infections (CAUTI) when patient re-admissions are considered. (2)

HAIs responsible for

1.7 Million

Infections Annually

99,000

Deaths Annually

Pathogen Transmission

The routes of transmission of nosocomial pathogens in healthcare settings have been well researched. (3) Patients colonized or infected with pathogens may:

- shed organisms onto their skin, bedding, or clothing such as gowns
- contaminate nearby environmental surfaces
- contaminate portable equipment used in their care

The available evidence suggests that pathogen transfer occurs frequently. Wolfensberger and colleagues' recent review of the published literature indicates transfer frequencies of pathogens from patients and their environment to healthcare provider (HCP) hands, gloves, and gowns are 33%, 30%, and 10%, respectively. HCP behaviors that only entailed contact with an environmental source led to transfer frequencies > 40% for pathogens such as ethicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant Enterococcus (VRE), and *Clostridium difficile*. (4)

One recent study underscores the potential for patient shedding of pathogens onto their hospital gowns which, in turn, may act as sources for further transmission onto fomites. Researchers examined the burden of MRSA on multiple areas of clothing worn by patient carriers, including at the neck, chest, waistline, sleeve cuffs, and pockets. MRSA was recovered from 74% of sampled gown sites. Further assessment was made as to the potential for transfer of the organism from the clothing of MRSA carriers to HCP gloves. MRSA transfer occurred 62% of the time when fingertips of sterile gloves were contacted with contaminated areas of clothing of identified carriers. When MRSA carriers were placed in wheelchairs, 50% of 10 carriers transferred MRSA to a wheelchair surface within 20 minutes. (5)

An estimated 20%-40% of HAIs are attributed to cross infection from organisms on the hands of health care personnel. (6) Contamination of the hands of HCPs results from direct contact with a colonized or infected patient or from contaminated fomites, hands thus serving as the vector to additional surfaces or to a new susceptible patient. The hands of HCPs are just as likely to be contaminated by touching an environmental source as would be by direct contact with a patient. (7) The risk of further pathogen transfer increases knowing that observations have noted that HCPs wash their hands to lesser degrees after contact with a patient's environment than when directly contacting the patient. (8)

Environmental Transmission and HAIs

In acute care settings, the patient environment is "...defined as the area inside the curtain, including equipment, medical devices, furniture, telephone, personal belongings, and the bathroom." (9) Multiple studies indicate that the patient environment plays an important role in the transmission of many HAI-related pathogens including Methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant Enterococcus (VRE), gram-negative organisms such as Pseudomonas aeruginosa, and *Clostridium difficile*. (10-12) A recent study, conducted in eight ICUs, assessing the degree of environmental contamination with potentially pathogenic organisms close to and distant from the patient found that 15.2% of the hands of HCPs were contaminated, followed by 10.9% of areas close to the patient and 9.1% in areas distant to the patient. Molecular typing indicated identical strains among patients, environmental surfaces, and the hands of HCPs. (13)

In addition to the patient's nearby environment, studies indicate extensive contamination of floors (14,15) and periphery items such as privacy curtains with pathogens that are associated with HAIs. (16) Many studies indicate that healthcare personnel attire and personal devices become contaminated after contact with the patient or environmental sources and therefore may in themselves become the source for further organism transmission. (17)

These and many other pathogens have been known to persist on environmental surfaces from hours to days, and in the case of spore-forming organisms, months. Gram-positive organisms can persist in the environment for >12 months in the case of Staphylococcus aureus and >46 months for Enterococcus spp. (18) Candida auris, an emerging pathogen, has remained detectable after seven days on test surfaces in laboratory settings. (19) Further complicating the issue of contamination of hospital environmental surfaces are findings that indicate that admission of a patient colonized or infected with such organisms as MRSA, VRE, or *Acinetobacter*, increases the risk of acquisition of these organisms by a newly admitted patient to the same room. (20,21) The risk has been recently examined in a large study of 10,289 HAIs occurring over seven years in four hospitals. (22) The findings indicate that patients with HAIs had a nearly six-fold increase in the odds of infection when a prior bed occupant was colonized or infected with a pathogen and a nearly five-fold increase of acquisition from a colonized or infected roommate.

Greater evidence of the epidemiological link between patients and their environment was provided by a recent prospective cohort study at two academic medical centers. (23) Bacterial cultures of the environment (bed rails, overbed table, armrest of chair, sink, toilet seat, and shower floor) were obtained after terminal disinfection of the room and prior to the next patient admission. Microbiological swabs were obtained of the nares, oropharynx, axilla, and perineum at each study visit. All specimens were collected on the day of admission and continued on study days three and seven and each week after study enrollment. Using microbiologic and molecular methodologies, the researchers surmised Microbiological Bacterial Transfer (MBT) as environment to patient transfer when one of four "marker" organisms (MRSA, VRE, multidrug-resistant-*Acinetobacter*, and *C. difficile*) was found on environmental surfaces prior to identification in patient specimens. Of the 80 study patients, 11.3% were asymptomatically colonized with a multidrug-resistant organism (MDRO). Most significantly, the authors found that despite terminal room cleaning, 55% of the rooms were found to be contaminated with an MDRO when sampled on the day of patient admission. *C. difficile* was detected in 26.3% of rooms; VRE in 22.5% of rooms; MRSA in 18.8% of rooms; and MDRO *Acinetobacter* in 11.3% of rooms. Of note, multiple MDROs were detected in 23.8% of rooms.

Although the study found that the average levels of surface contamination to be low, they were clearly sufficient for documented transmission to patients. MBT events occurred in 12 patient encounters (18.5%), with six of the encounters (50%) associated with molecularly identical strains of an MDRO. Overall, 7.5% of all hospital room encounters showed transfer of a clonally identical MDRO strain. Most MBT transmissions occurred within three days of admission into a newly cleaned room leading to both asymptomatic and symptomatic infection among the patients. The authors went on to state:

> *Our observation of low-level bacterial contamination highlights another important limitation in current literature: there is no consensus method for assessing or defining a surface as "clean"....if microbial transmission occurs early, readily, and frequently between patients and the environment...the standard hospital cleaning practice of performing a detailed room disinfection only at the end of patient stay (i.e., terminal cleaning) may be inadequate to prevent the acquisition of MDROs through the environment... these results should compel us to develop new technologies and interventions to achieve safe continuous environmental disinfection within the healthcare setting.*

Adequacy of Room Decontamination

How frequent patient rooms should be decontaminated has not been scientifically determined. Whether rooms are cleaned daily, bi-weekly, or terminally cleaned after patient discharge, the pivotal question is how adequate were the surfaces of the individual room components disinfected? Several well conducted studies have concluded that adequate cleaning of patient rooms is lacking. In a large study (23 acute care hospitals, 1119 rooms) where researchers used a fluorescent solution applied on room surfaces located in a patient's immediate environment and a hand-held ultraviolet light device, Carling and researchers determined that only 49% of the surfaces were adequately cleaned. (24) Carling et al used a similar design to assess environmental cleaning in intensive care units (ICUs) in 16 hospitals. Results in this study were also reported to be inadequate, with only 57.1% of surfaces cleaned appropriately. (25)

In a recent study, researchers reported quantitative measures of the microbial bioburden (MB) of items (TV remote, telephone, call button, bed rails, door handles, IV poles, overbed table, and toileting surfaces) contained in routine cleaned or terminally cleaned rooms of patients with MDRO or *C. difficile*. (26) The mean MB from rooms routinely cleaned was 2700 colony-forming units (CFU/100 cm2) and 353 CFU/100 cm2 from room items in terminally cleaned rooms. MDROs were recovered from 34% of surfaces in routinely cleaned rooms and 17% from items where the rooms were terminally cleaned. Of further concern, *C. difficile* was recovered from 50% of routine cleaned rooms in which the patient had not been identified with the organism. Overall, routine cleaned rooms were approximately eight times more contaminated than terminal cleaned rooms.

A number of other factors may directly impact optimal levels of environmental cleaning. Shortages of EVS personnel, reported by more than 50% of hospitals in a recent survey, (27) often leads to "cutting corners", e.g., reducing cleaning frequency of rooms or equipment. The efficacy of disinfectants themselves may be impacted by several factors: inappropriately low concentration due to over-dilution; inadequate contact time with the surface; type of surface material used for healthcare furniture, other surfaces, and equipment; varying kill times for different types of bacteria or viruses; application techniques (e.g., solution vs. wipes), potential contamination of disinfectant solutions, and type and care of mops or cloths. (28,29)

Studies Assessing Improvements of Room

Several important points should be considered when discussing improvements in patient room disinfection.

1. First, many efforts to improve the level of room cleaning/disinfection which include the implementation of disinfectant product substitution, improved education, designation of responsibility for cleaning specific items, monitoring to determine the thoroughness of room cleaning with feedback of results to environmental staff, and use of cleaning checklists (3) have been associated with significant improvement in cleaning practices. Pathogens such as VRE (30) and MRSA, (31) have been shown to be reduced on environmental surfaces after improved practices. (32,33) However, studies assessing improvements in room cleaning reported that approximately 5%-30% of surfaces remained potentially contaminated. (34)

2. Second, the effect of improved cleaning and disinfection on patient acquisition of pathogens, appears to be modest. Reductions in environmental contamination with *C. difficile* have been reported (35), however a large 16 hospital study did not observe any reduction in the incidence of *C. difficile* infection (CDI) after introduction of environmental service (EVS) performance monitoring and feedback. (36) A further review of the literature reported changes in MRSA, VRE, and CDI from 0% to 49% with revision in cleaning practices, with one study demonstrating an 83% reduction in VRE bacteremia. (3) A potential contributing factor to achieving optimal outcomes may be suboptimal disinfection in rooms housing patients who have not been identified with a pathogen, i.e., asymptomatic carriers or unidentified infected patients.

3. Third, monitoring of cleaning practices, which include traditional visual inspection, microbiological sampling, and non-microbiological testing such as fluorescent markers used as surrogates for residual contamination and quantification of adenosine triphosphate (ATP) levels to determine persistence of organic material, are not assessed uniformly due to a lack of acceptable standards in levels of residual contamination. (37) Discrepancies in observed levels of cleaning of high-touch surfaces has been reported between EVS supervisors (82.5%) and study personnel (52.4%) in a single healthcare facility. (38)

4. Fourth, is the issue of which specific room surfaces are most associated with pathogen spread. Housekeeping surfaces in patient rooms are traditionally divided into objects frequently touched ("high-touch") and those touched by HCPs less frequently ("low-touch"). High-touch surfaces include doorknobs, bedrails, light switches, and toileting surfaces. Low-touch surfaces include walls, ceilings, mirrors, window sills, and flooring in patient rooms. (8) Most studies on improving cleaning practices in patient rooms limited the design to cleaning of high-touch surfaces, although such sites have not been associated with increasing the risk of transfer of pathogens to HCPs hands or gloves or increased risk of patient-to-patient transmission of pathogens. Rather than focusing on specific room items, cleaning efforts should be made to improve the "thoroughness" of room decontamination as the bacterial load of "high-touch" surfaces is similar to less frequently contacted surfaces. (39)

Advanced Technologies

Hospitals are increasingly investigating alternate solutions to supplement traditional practices in disinfection of the patient environment due to failures associated with achieving thorough patient room cleaning, whether due to inadequate or overlooked cleaning of objects, lack of proper supervision and monitoring, lack of resources, low levels of hand hygiene, or other factors. Among these new technologies are antimicrobial coatings of surfaces and use of ultraviolet light (UV) or hydrogen peroxide vapors or aerosolization.

Coated Surfaces

One example of emerging environmental technology is the development of "self-disinfecting" surfaces coated with heavy metals such as copper or silver, elements which have demonstrated innate antimicrobial properties. These metals act by binding to key nucleic acids and proteins within the bacterial cell leading to death. Studies have indicated that copper-impregnated equipment surfaces reduce bacterial contamination (40-43), but have had mixed success in effecting HAI rates. One study failed to demonstrate no significant reductions in rates (44), while another multicenter study reported a significant decrease from 0.081 to 0.034 in HAI rate. (45) Coating surfaces with copper requires a substantial financial investment, with estimates ranging from $5,000 to $15,000 per patient room. (28)

UVC / HP Background

Among the best studied of new "no touch" room disinfection technologies are mobile robots that incorporate the automated emission of chemical vapors, aerosols, or UV. Chemical vapor and aerosolizing technology uses hydrogen peroxide as the primary disinfecting agent. The majority of UV or hydrogen peroxide (HP) systems provide the technology using a portable machine that is set up in the patient's room as per the individual manufacturer's instructions.

UV-C

UV irradiation eradicates organisms by breaking the molecular bonds in DNA. Systems using UV-C produce wavelengths between 200-270 nm, a zone which lies in the known germicidal range of the electromagnetic spectrum (200 to 320 nm). A second UV device that uses pulse-xenon technology (UV-X) is also widely available. Factors such as organic load, pathogen type, intensity, surface types, distance of the surface from the device, placement of the machine in the room, exposure time, room size and configuration, and air movements contribute to the efficacy of UV. (46)

Weber and colleagues provide insight on nine studies assessing the efficacy of UV irradiation in reducing microbial loads on intentionally contaminated environmental surfaces. (34) Several important points can be deduced from these results:

- use of UV for 15-20 minutes achieved a > 3-$\log_{10}$ reduction in vegetative bacteria including MRSA, VRE, and *Acinetobacter* baumanii
- *C. difficile* spores are also decreased by > 3-$\log_{10}$ as seen with other vegetative bacteria, but require extended UV treatment times of 35 to 100 minutes
- increasing the distance from the device reduced the killing efficacy for MRSA, VRE, and *C. difficile*
- the effectiveness of UV was reduced when the surface was not in the direct line-of-sight of the UV emission
- spreading the inoculum over a wider area increased the ability to kill the organisms. (47-51)

Manufacturers recommend that facilities using UV may need supplemental room treatments after the initial decontamination cycle. This would entail re-positioning the mobile unit with consideration of surfaces that may not have had direct line-of-site exposure during the first decontamination cycle, including adjoining or "opposite" surfaces of bed rails, furnishings, and equipment, (52), rolling or stationary computers along with accessories like keyboards and mice, (53) as well as the surfaces of adjoining bathrooms. (54,55) The importance of providing optimal "line-of-site" positioning during UV decontamination becomes clearer when light intensity is considered. A simulation trial in which the researchers coated the walls of test rooms with reflective paint resulted in enhanced intensity of ultraviolet light on indirect surfaces in the trial rooms and, in turn, was associated with significant $\log_{10}$ reductions of both MRSA and *C. difficile* test organisms. (56)

Several trials have examined the effectiveness of UV-C devices on decontaminating patient rooms after patient discharge. In nine published studies using either UV-C or ultraviolet pulsed xenon devices (UV-PX), pathogens such as MRSA, VRE, and *Acinetobacter* spp. were reduced in 10-25 minutes, with three studies using 2-3 cycles. *C. difficile* cycle times ranged from 10-45 minutes. The frequency of positive surface sites post-treatment was <11%, while $\log_{10}$ reductions were all reported as two or less. (42)

The first randomized clinical trial to assess a UV-C "no-touch" technology is the Benefits of Enhanced Terminal Room Disinfection (BETR-D) study, the results of which were published in 2017. (57) This crossover trial conducted at nine hospitals examined three strategies for enhanced room decontamination: use of a quaternary ammonium compound plus UV-C, bleach only, or bleach plus UV-C. Treated rooms were those that housed a patient identified with MRSA, VRE, or *C. difficile*. Outcomes measured included subsequently admitted patients acquiring an HAI with one of the target pathogens. Both hand hygiene and terminal room cleaning measurement compliance showed no differences at baseline or among the three study groups. The study concluded that the addition of a UV-C device to the standard disinfection strategy during terminal decontamination decreased the acquisition of a target organism by approximately 10% to 30%, suggesting that the environment is responsible for a significant portion of MDRO acquisition (23). No significant differences were found in the incident rates of target organisms when using bleach or bleach plus UV-C when compared to use of a quaternary ammonium compound alone.

Insights provided by the authors of the BETR-D study on implementation challenges encountered with UV-C devices indicated the need to overcome two key barriers: establishing priorities for room selection and overcoming time constraints to allow environmental staff sufficient time to employ the enhanced terminal disinfection method prior to admission of the next patient. (58) In this study, the assigned hospital staff required an additional 10-20 minutes for each enhanced terminal disinfection strategy for rooms in which patients were to be admitted from an emergency room. Furthermore, use of the UV-C device was limited to only 60% of "seed" rooms. (59)

Hydrogen Peroxide

HP is an oxidizing agent that produces hydroxyl radicals that kill microorganisms by disrupting DNA, membrane lipids, and other critical cell structures. HP decontaminating technology is designed to project either dry mist or noncondensing or condensing vapor onto patient rooms surfaces over a specified time period. H_2O_2 vapor systems use a concentration of 30%-35% H_2O_2, while the aerosolized systems combine 5%-7% H_2O_2 with <50 ppm Ag cations. Mobile decontaminating systems using HP have been well studied.

Trials using pathogens inoculated onto test disks and subjected to HP vapor were inactivated within 90 minutes, (60) while spore biologic indicators were reduced by >6 $\log_{10}$. (61) Inactivation of several important viruses has also been demonstrated using the system. (62)

Advanced decontaminating technology using HP has also demonstrated significant reductions in MRSA, VRE, and multidrug-resistant gram-negative bacteria on contaminated surfaces in hospital rooms, (29, 63) with reported reductions of 86%-100% in pathogens in ten published studies. (34) Multiple clinical trials have been conducted to assess the effect of HP room decontamination on HAIs.

In one trial conducted for 30 months on six high-risk units in a large acute care hospital, use of HP decontamination after discharge of a patient with a known MDRO was demonstrated to reduce the risk of a subsequently admitted patient of acquiring the same organism by 64%, with VRE accounting for a major portion of the decrease. (64) The risk of acquiring *C. difficile*, MRSA, and multidrug-resistant gram negative bacteria although reduced, was not significant. A recent meta-analysis of the impact of no-touch disinfection technology on HAIs reported a statistically significant reduction in *C. difficile* infection (CDI) rates in UV system studies with high baseline CDI rates but not in settings with initially low baseline rates. The authors analysis of five studies using HP did not find a statistical reduction in CDI rates. (65)

Several **limitations** need to be considered when assessing the use of mobile UV/HP systems:

- The significant initial capital investment limits use to terminal room cleaning period when patient is discharged
- The requirements to remove both personnel and patients from the room limiting use to terminal cleaning periods
- The potential need for hiring, of dedicated staff to perform the function or at a minimum, training, and allocation of existing environmental staff
- Transportation of device, setup, and monitoring of process
- Organisms may be protected when using UV systems due to shadowing effect, therefore require when possible the placement of furniture and equipment away from walls to allow for indirect decontamination
- Use of HP systems requires sealing of vents and doors prior to initiating the decontamination process
- The addition of enhanced technology decontamination time to a standard terminal room cleaning period (UV requires decontamination times of 15min-100min for vegetative bacteria and *C. difficile* while HP systems require approximately 1.5-8.0 hours for disinfection).
- The processing time for a mobile HP system from setup (requires masking doorways and vents) to residual removal has been shown to be up to four times longer than conventional cleaning (60)

Continuous Full Facility Decontamination

Understanding the evolution and the principle designs of environmental disinfecting technology, and most importantly, the limitations inherent in the methods of operation has lead science to the next level in decontamination concept. Research engineers have designed a continuous disinfection technology using a natural catalytic converter inserted into the ducts of an HVAC system. This new device converts H_2O and O_2 in the air into hydrogen peroxide (H_2O_2). The device uses a multi-wavelength ultraviolet light to illuminate target surfaces consisting of a honeycomb matrix treated with photocatalytic coating consisting of titanium oxide (TiO_2) and other reactive metals added to enhance the overall catalytic effect.

When inserted into the ducts of the HVAC system the device reacts with water molecules in humidity to continuously create predominately H_2O_2 molecules which exit the duct and disperse throughout the targeted area safely covering the surfaces of occupied rooms and patient care areas with effective oxidizing molecules that work to reduce the bioburden of clinically relevant pathogens. Studies currently being conducted using continuous natural catalytic converter decontamination in hospital patient rooms have indicated an average reduction in environmental microburden of between eight and ten-fold as compared to pre-activation baseline samples as documented through environmental sampling of high-touch points. Independent clinical studies of the effectiveness of the continuous disinfection technologies have shown at least a >3 $\log_{10}$ reduction in clinically relevant pathogens associated with environmental contamination (unpublished data).

One added benefit of the technology demonstrated in the hospital trials is the impact on HCP absenteeism. In one trial in a large 527-bed hospital the technology was employed to treat the entire area of the ICU including patient rooms, nurse stations, and work areas. Absenteeism rates were reduced to 752 hours during a four month period from 1316 hours for the same period during the previous year. The decrease represented a 42% reduction and represented a gain of over 80% of a FTE.

Environmental contamination of hospital patient rooms poses a significant risk for the subsequent transfer of pathogens and development of hospital-acquired infections. "No-touch" room decontamination technologies have evolved to address this issue using methodologies that have been well studied. However, mobile technologies have limitations that have been reported in the scientific literature. A newly designed device that delivers continuous decontamination effect using a natural catalytic conversion technology built into HVAC systems has demonstrated preliminary positive results in reducing environmental contamination with pathogens. The technology is the first disinfection solution that is practical to employ throughout an entire facility to address not just highly contaminated patient rooms but all patient rooms, nurse stations, public areas, floors, and work areas. As stated earlier in the CDC Epicenter Reduction Program study authored by Dr. Luke Chen, Dr. Bill Rutala, Dr. David Webster, and colleagues:

> *If microbial transmission occurs early, readily, and frequently between patients and the environment...the standard hospital cleaning practice of performing a detailed room disinfection only at the end of patient stay (i.e., terminal cleaning) may be inadequate to prevent the acquisition of MDROs through the environment...these results should compel us to develop new technologies and interventions to achieve safe continuous environmental disinfection within the healthcare setting." (23)*

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