Why surface materials matter in health care settings

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Antimicrobial organisms are responsible for some common health care-associated infections. Credit: CDC

Health care facilities serve as havens for patients seeking treatment for disease and injury. However, they can also be home to a hidden world of microbes, lurking in places and devices that lead to life-threatening infections.

According to the U.S. Centers for Disease Control and Prevention (CDC), 1 in 31 patients will acquire at least one health care-associated infection (HAI)—including infections with antibiotic-resistant organisms—while being treated for something unrelated.

For centuries, it was believed that if everyone would do a better job cleaning, disinfecting and sterilizing when required, HAIs (and overall infections in the community setting) would be eliminated. However, data show this is not the case.

Patients who occupy a room where a previous patient had an HAI have a 25% chance of acquiring the same infection, despite best efforts to follow required protocols for terminally cleaning and disinfecting the room.

Furthermore, patients who have symptomatic infection may shed larger amounts of infectious microbes through body fluid and contaminate surrounding surfaces.

Surface type and building structure are, therefore, important components of the equation, which necessitate an organized effort to understand the root causes and develop multimodal solutions that support ongoing efforts to stop the spread of HAIs within health care facilities.

The problem: Microorganisms are opportunistic

Reducing the number of HAIs and microbial spread is complex and challenging. Recommended solutions are difficult to sustain because the root causes (specifics pertaining to how microbes persist and spread in health care settings) are invisible, misunderstood and often not even considered part of the problem.

Yet, pathogenic organisms can survive on surfaces and within surfaces

for weeks, months and even years, despite cleaning and disinfection. Surfaces where microbes tend to settle include, but are not limited to, textiles—such as privacy curtains, bed linens and pillows—as well as hard surfaces inside patient rooms and bathrooms (e.g., toilets, floors, soap dispensers and sink drains).

Patient care equipment, including blood pressure cuffs, suctioning systems and medical devices (e.g., endoscopes, IV's, ventilators and others) are also susceptible. Exacerbating this difficult and complex issue is the ongoing problem of microbial biofilms (wet and dry), which amplify the challenge of complete surface decontamination.

Essentially, we are dealing with a microbial problem at a macro level. Whether we like it or not, the invisible, microbial world is opportunistic and unforgiving, placing patients in health care settings (who are often immunocompromised) on the defensive. Therefore, when it comes to the construction of built environments in health care settings, microbes should be appropriately respected as the tie that binds every step from product conception, to development, writing of instructions for use (IFUs) and FDA clearance of medical devices.

Long before cleaning and disinfection become critical tasks for patient safety, there are a variety of evaluations that should be considered. Unfortunately, those connections are not always made. The transfer of organisms between patients and surfaces may not be considered until after a product has already been designed and manufacturers are writing their instructions for use.

The selection of building materials and the construction of innovative products intended to make patient care safer often occur without evaluation of required infection prevention guidelines, or an understanding of whether the products and materials being specified can be cleaned and disinfected using hospital grade EPA registered

disinfectants.

Currently, there are no regulatory guidelines or standards that require testing to establish compatibility between devices and the disinfectants that are being used within health care facilities. Therefore, products are purchased every day that challenge the very best health care professional to efficiently and effectively clean and disinfect surfaces and equipment using standard, hospital-grade disinfectants, which often consist of harsh chemicals that have the potential to damage devices, support a hidden world of opportunistic microbes (ready to populate newly exposed surface layers) and, ultimately, put patients at risk.

In the same way humans, other animals, plants and even microbes can be colonized by microorganisms, so can buildings. In short, when specifics pertaining to how microbes persist and spread in health care settings are not considered prior to product design, downstream infection prevention practices are more likely to fail. A healing environment can't be achieved unless it can be effectively cleaned and disinfected. So how do we move this needle?

A different view for a solution: Building design and surface materials matter

Everyone who is involved in decision making and execution of the design, equipment and disinfection of health care facilities must be well-informed about how microbes populate and interact with various surfaces and materials.

Let's take the example of the universal patient bathroom, which has become a standard in health care facilities. First, we have a toilet without a lid (this is a plumbing building code requirement). Significant research about toilet plumes, provides data about contamination that takes place

when a toilet is flushed. An invisible plume of aerosolized droplets of water and pathogens from human waste is forced up to 5 ft. into the air, and those particles may remain suspended in the air for a short time before landing on surfaces within 5 ft. of the toilet. This should logically draw attention to the surrounding surfaces upon which contaminates might settle. Do the walls, floor, handrails, etc. support efficient and effective disinfection practices?

Deeper investigation reveals additional chinks in the armor. The ceramic tile that is routinely used in patient bathrooms creates hundreds of seams on the walls and floor and provides a supportive environment for microbes to attach. The resulting environment is difficult, if not impossible, to clean and properly disinfect daily. Tile and grout require different methods of care and maintenance, as outlined by manufacturers in product care and maintenance documents. However, these materials are not cleaned and disinfected the same way by every person or across health care facilities.

Additionally, the IFUs for brushed stainless steel handrails, which are used to meet standard ADA requirements in patient bathrooms, clearly state that abrasive cleaners containing chlorides or quaternary salts should not be used on these surfaces. The instructions also specifically state that one must clean and polish with the grain of the stainless steel to ensure the removal of soil and microbes from the ridges and grooves created by the brushed texture. This bathroom has inadvertently been designed in a way that supports microbial contamination and makes cleaning and disinfection difficult, at best.

Selection of surface materials for medical devices

Surface material standards for medical devices should also be challenged, beginning with an assessment of whether the individual pieces of equipment, as well as the sum of those parts, can be cleaned,

disinfected and reprocessed, when required. Importantly, a single medical device often contains multiple surface types that require different (and sometimes tailored) methods of cleaning. Failure to consider these specifications is likely to cause damage to the product, which, as stated above, may ultimately put the patient at risk.

Using an endoscope as an example, there are seven different surface materials and connection points at the end of the scope. There are numerous guidelines for reprocessing these scopes, including the CDC Disinfection of Healthcare Equipment, Reprocessing of Endoscopes and Multisociety guideline on reprocessing flexible GI Endoscope 2016 update.

In general, there are five steps, the first being "clean." Clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and a detergent or enzymatic cleaners (leak testing is recommended for endoscopes before immersion). Small toothpick-size brushes are used to manually clean this device before disinfection and sterilization. Could selecting surface materials during early design with cleaning, disinfection and sterilization at the top of mind provide a way to manage this process more easily and with less risk to patients?

Are design materials compatible with disinfectants and sterilants, and if not, when does damage begin to occur? When should products be removed from service because they can't be cleaned and disinfected?

In recent months and years, there has been an increase in Food and Drug Administration (FDA) recalls due to chemical damage from disinfectants. An example of this: on June 30, 2021, the FDA inspected a voluntary recall of CPAP, BIPAP and ventilator products by a major medical device manufacturer due to physical and chemical breakdown of foam, putting patients at risk of injury or death. The damage was

caused by ultraviolet (UV) light disinfection, cleaners or other cleaning methods not recommended by the manufacturer. The FDA had to recall more products with this problem in Dec. 2021.

Instructions for use (IFUs), care and maintenance

Regulatory agencies, such as The Joint Commission and FDA, require health care professionals to follow the manufacturer's IFUs for cleaning, disinfection and reprocessing. Yet, there are existing issues surrounding this requirement. These include a lack of understanding by disinfection companies on the basics of microbiology and the organisms that health care professionals are trying to destroy, as well as conflict between IFUs and Infection Prevention Guidelines and protocols developed by, and used within, individual health care facilities.

A case study co-authored by HSI and The Association of Healthcare Value Analysis Professionals(AHVAP) illustrates the problem. The medical device company was seeking FDA 510K clearance that required them to test their product's ability to be disinfected, but it gave no further guidance.

The company tested one disinfectant wipe, which was a quaternary ammonium product that passed. This disinfection wipe is called out in the IFU for disinfection. The hospital, which was a children's hospital, has an internal policy that does not allow these disinfectants to be used in patient care areas for patient safety reasons. At that point, the health care facility had to figure out what other disinfectant they could use. Unfortunately, the disinfectant selected, a bleach-based product, was incompatible, and damage to the device occurred. The IFU, a short brief of the larger care and maintenance document, failed to clearly state that a bleach-based disinfectant would damage the device.

The case highlights why, before purchasing a product, it is critical to ask

questions related to the product design, whether IFUs and care and maintenance documents support infection prevention guidelines set by the health care facility and if all categories of Environmental Protection Agency (EPA)-registered disinfectants have been tested and validated for compatibility with the surfaces to ensure damage doesn't occur.

Testing and validation

The testing and validation of materials and products is critical and, in some cases, a regulatory requirement (e.g., FDA, EPA). The challenge faced by manufacturers is what testing should be done and what test methods should be used. The Fall 2022 issue of *The Canadian Journal of Infection Control* (*CJIC*) highlighted the fact that a variety of guidelines and standards are available to ensure equipment and surfaces can be cleaned and disinfected for safe use in the clinical setting, but no uniform approach exists for testing and product claims.

When test method guidance from regulatory agencies is vague, it puts manufacturers at a disadvantage. There are multiple standard organizations and testing laboratories that manufacturers can choose from, and the test methods can be altered at each facility. This leads to inconsistencies with testing products and materials and, in the event of microbial testing, inconsistencies in the type of microbe being used.

While the (EPA) has specific testing requirements for disinfection companies, they focus on the kill claims (or log reduction) of specific pathogens (e.g., Mycobacterium tuberculosis, SARS-CoV-2 and Clostridioides difficile). This testing is typically conducted in a laboratory using small (nickel-sized) disks or coupons of non-specific material. These are not representative of medical devices, patient care products or assemblies of materials used in any given health care environment. A critical point is that none of these tests look for compatibility with materials that are actually used in health care settings

to evaluate potential damage at a microbial level. They look to see if a specific pathogen is killed in a set amount of time. Once the test method is concluded, and log reduction is documented, kill claims are listed on the EPA registration product label.

In summary, the belief that better cleaning and disinfection practices alone will reduce the spread of HAIs must be reexamined. The challenges begin long before cleaning and disinfection take place—with surface selection and design. A collaborative effort that brings together a diverse group of thought leaders, health care professionals, manufacturers, scientists and others is critical to explore root causes and develop sustainable solutions that will mitigate the spread of HAIs.

Provided by American Society for Microbiology

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