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SPLASHBLOCKER®

A Novel Barrier Control to Protect Healthcare Workers from Infection Transmission and Hazardous Drug Exposure When Flushing Toilets

Assessment of Protection from Toilet Plume Aerosol

White Paper – Premier Applied Sciences®
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PREMIER® SPLASHBLOCKER®

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White paper on assessment of protection from toilet plume aerosol

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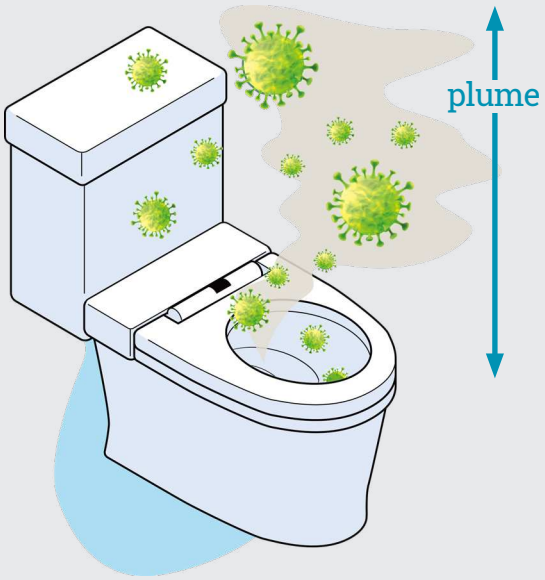


As part of the User Experience Assessment, this paper discusses findings from Splashblocker, LLC's initial 2019 user survey and Premier's subsequent 2020 User Experience Assessment capturing meaningful discussion from phone interviews with frontline healthcare workers and leaders who completed a 30-day product trial.

Introduction – Microbials and Cytotoxic Chemicals Can Spread in Toilet Plumes

National Inpatient Sample data show that an estimated 687,200 healthcare-associated infections (HAI) occurred in U.S. acute care hospitals in 2015.[1] The Centers for Disease Control and Prevention (CDC) estimates that on any given day, approximately 1-in-31 hospital patients has at least one HAI.[2] HAI risk factors may include hospital infection control practices.[3] Contaminated surfaces may promote transmission of HAI-associated pathogens including *Clostridioides difficile* (*C. difficile*) and methicillin-resistant *Staphylococcus aureus*.[4] Pathogens may spread from shared equipment, on hospital staff gowns, hands or gloves, or from coughs, sneezes or contact with other body fluids.[4]

Microbial Spread in Toilet Plumes

Microbial spread may also come from airborne water and other particles created from toilet flushing ("toilet plume aerosol") that results in a mist or fine spray that spreads through the air and can land on surfaces, be breathed in and travel through ventilation systems.[5-10] More than 25 percent of post-flush cultures test positive for infectious microorganisms that can cause HAIs for patients, personnel or visitors, including *Enterococcus faecalis*, *Enterococcus faecium* and *C. difficile*.[11] Viruses such as adenovirus can be detected on 78 percent of surfaces and in 81 percent of aerosol in clinical settings.[8] Toilet water can also still be contaminated even after repeated flushing.[7,12-13] While potential disease transmission from toilet plumes is not clear, reports from the global severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, the virus that causes COVID-19) outbreak note the presence of the virus in feces samples.[14-30] One anecdotal description described the potential of toilet flushing and hand dryers to spread virus particles.[26] Fecal-oral transmission may also occur in some populations.[16-17]

Urine or feces may also harbor cytotoxic antineoplastic drug residue[31] – one study reported residue in the bathrooms and kitchens of patients receiving chemotherapy.[32] Another study reported contamination of bathroom floors in hospitals.[33] For patients receiving chemotherapy, hazardous drugs remain in human waste, urine and body fluids anywhere between 48 to 72 hours after a chemotherapy treatment,[34] which may present the potential for staff and caregiver exposure to it. In fact, chemotherapy agents have been detected in caregivers' urine samples.[35]

> *We know from decades worth of EPINet occupational exposure incident data, that healthcare workers are experiencing far more blood and body fluid exposures to the eyes, nose, and mouth than any area. These are extremely high risk exposures given the vulnerability of mucus membranes and transmission of droplets, aerosols, and airborne diseases. We must do more to protect them and control these risks.*
>
> — **Amber Mitchell**, DrPH, MPH, CPH
> President/Executive Director
> International Safety Center

Healthcare Worker Exposure

Exposure to cytotoxic medications and pathogens poses serious risks to healthcare workers through inhalation, absorption through the skin, accidental injection or exposure, or contact with contaminated hands.[36] Due to globally emerging infectious diseases such as drug-resistant pathogens and the more recent SARS-CoV-2 virus, there may be increased risk of exposure to hazards generated by toilet plumes.

Healthcare Workers and Caregivers Struggle to Avoid Exposure to Infectious Diseases and Cytotoxic Chemicals from Toilet Plumes

Guidelines

Recent guidelines recommend stringent safe handling precautions, including eye and face protection to limit exposure to splashing.[37] The Oncology Nursing Society (ONS) recommends wearing personal protective equipment (PPE) such as gloves, chemotherapy gowns, respiratory masks and face shields.[38] The U.S. Pharmacopeia 800 Hazardous Drugs Handling in Healthcare Settings[39] establishes requirements for handling body fluids, and the CDC National Institute of Occupational Safety and Health[7] has summarized occupational risks of toilet plume exposures and advocates for safer practices. The ONS further recommends applying a plastic-backed chuck pad over the toilet before flushing.[38] Despite these guidelines and recommendations, there are still concerns about handling safety, disposal and landfill costs, chuck pads being costly and not readily available, and routine noncompliance.

Healthcare Worker Experience

A published survey[40] of nurse managers revealed several reasons for caregiver noncompliance with PPE use when disposing of human waste including urgent patient situations, nurses being too busy or rushed and precautions being "too extreme." In addition, EPINet occupational mucocutaenous exposure incident data[41] indicate that 88.1 percent of healthcare workers' infectious exposures are to the eyes, nose and mouth, and less than 6.9 percent of workers exposed are wearing any kind of face protection (e.g., protective eye wear, face shield, surgical mask). In a recent opinion article in the *Journal of Hospital Infection*, Carmen McDermott, MD, Internal Medicine specialist in Seattle, WA, adds that "transmission of virus shed in faeces through bioaerosols may be an under-recognized infection control issue for healthcare facilities with high numbers of patients shedding virus in stool."[27]

Nurses have long advocated for safer practices, controls and patient bathroom design, including having lids installed on hospital toilets[42] (most hospital toilets do not have lids because sprayer fixtures are required for cleaning patient urinals, bedpans and commodes, and a lid is another surface to clean because it can harbor dangerous pathogens). However, these efforts have had limited success, despite the fact that disposal of contaminated human excreta may cause staff to be routinely exposed to bloodborne and infectious diseases, as well as harmful chemicals via inhalation or direct skin contact from toilet plumes, which in turn may cause occupational illness and/or infection. At best, many healthcare workers practice "flush and run," flushing the toilet and quickly leaving the room. Anyone who then enters the bathroom may be exposed to bioaerosols that may linger in the air for 3-6 hours.[7]

> *The aerosolization effect that can occur in toilets, leading to microdroplets that can be inhaled or persist on surface areas, raises some real concerns regarding epidemiologic spread. It may also be helpful in understanding why this rapid spread can occur when not linked to known contact with those positive for COVID-19.*
>
> *Turning our attention to the toilets is something we need to do. It's very prudent for those caring for patients in the hospital.*
>
> — **David A. Johnson**, M.D., Gastroenterologist, Eastern Virginia Medical School, Medscape, April 9, 2020

SARS-CoV-2 Microdroplets

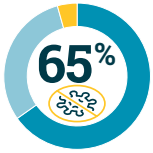
In July 2020, 239 scientists from 32 countries presented an open letter to the World Health Organization that outlined the evidence for airborne transmission of COVID-19, appealing for the need "to recognize the potential for airborne spread of COVID-19 – there is significant potential for inhalation exposure to viruses in microscopic respiratory droplets (microdroplets) at short to medium distances (up to several meters, or room scale), and we are advocating for the use of preventive measures to mitigate this route of airborne transmission."[25] A month later, more than 680 built environment experts from 51 countries presented a petition in support of the letter to urge public health leaders to adopt and advance indoor environment best

practices to help protect building occupants from the spread of COVID-19.[43] The experts stated that they "strongly support the medical and health professionals' model of doing no harm and applying the precautionary principles. We urge the World Health Organization (WHO) to work with built environment experts and recommend the adoption of indoor environment best practices to protect building occupants worldwide."

The potential of microorganism spread or exposure to cytotoxic materials, drug-resistant pathogens and viruses such as SARS-CoV-2 demonstrates an increasingly urgent need to protect healthcare workers from exposure to toilet plumes. Lessening exposure may result in fewer adverse health effects from handling and disposing of human waste containing chemotherapeutics, antineoplastics and other potentially infectious microbials.

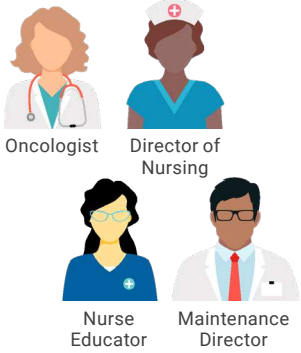
Summary of Pre-survey

- 21/23 had never seen Splashblocker
- 2/23 heard about Splashblocker via Oncology Nursing Society (ONS) webpage/ONS Congress booth



- 15/23 **yes**, had a method of protection, i.e., flush and run, goggles, gloves, gowns, face shield, "stand as far back as possible"
- 7/23 had **no** method of protection
- 1/23 **maybe** had a method of protection

Distribution of Roles Included:



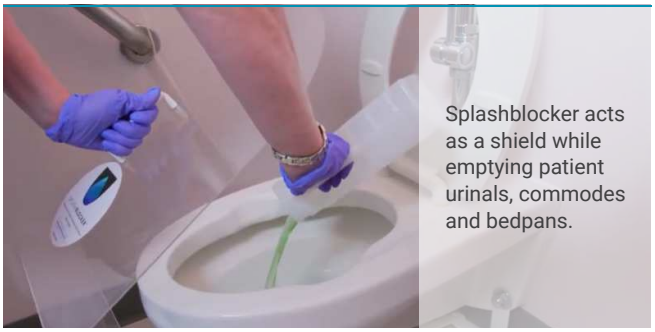
Testing a Toilet Shield as Protection from Toilet Plume Aerosol

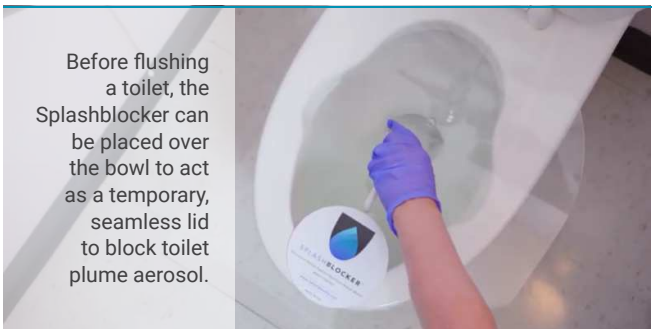
Nurses and caregivers need a way to quickly and readily protect themselves from exposure while disposing of potentially infected or chemotherapeutically-tainted human waste, which can also help hospitals and healthcare settings reduce the spread of infectious diseases. The inventor of the Splashblocker, an oncology nurse with more than 15 years of experience, saw an opportunity to enhance safety in the workplace beyond "flush and run" and using costly blue chucks for disposing human waste, blocking potential splashback and toilet plume aerosol, thereby reducing staff and caregiver exposure risk.

Splashblocker is a barrier control device made from chemical-resistant, BPA-free polymer materials that can sustain regular use as well as cleaning and disinfection. It can be used as a protective shield in two ways:

+ It acts as a shield between a person's face and a toilet while emptying patient urinals, commodes and bedpans.
+ It acts as a shield covering the toilet when a caregiver flushes the toilet to form a temporary, seamless lid.

Feedback throughout the development process led to design improvements such as making the device in one molded piece that is easier to clean and improving the resin mixture to a medical-grade, chemical-resistant durable resin that prevents warping.





Initial Trial

Splashblocker, LLC conducted a 2018-19 survey of 44 staff members at 18 hospitals and healthcare systems across the U.S. who tested the Splashblocker. Of these, 31 were nurses, seven were nursing assistants, two were patient care technicians, one was a safety coordinator, one was a center director and one did not

indicate a role. The respondents most frequently noted the protective benefit of the device for staff and other caregivers, stating:

> *It helps protect me when disposing of bodily fluids of patients receiving chemotherapy. It's an extra line of protection against exposure.*

> *It protects caregivers from any kind of exposure. Its use should be supported by all nurses and PCTs. I will bring this to our employee health manager.*

> *I feel I am protecting myself better since I am in a hurry and don't always follow all of the hazardous drug precautions.*

> *I feel more confident emptying urinal and urine catchers. I don't have to worry about the risk of anything splashing back on me.*

Respondents also noted that, compared with chuck pads and other disposable pads, the Splashblocker was easier to use, more professional, more efficient, more sanitary and less wasteful and costly. They also saw the value of using less plastic and being more environmentally friendly and safe. These initial results signaled substantial usefulness and interest, which led to and informed the structure for a second trial.

Second Trial – Premier User Experience Assessment with COVID-19 Perspective

In 2020, Premier Applied Sciences, in partnership with Splashblocker, LLC, sought to understand the role of external protective devices in the midst of the COVID-19 pandemic and their usefulness as novel barrier controls to protect healthcare workers from infection transmission, including SARS-CoV-2, *C. difficile* and hazardous drug exposure when flushing toilets.

Splashblocker Is:

Light-weight: It weighs less than 1.5 pounds.

Easy-to-use: The product handle fits all hands.

Readily available: It can be hung next to a toilet, but does not touch the wall.

Durable: It is made from polycarbonate and has a life expectancy of one to two years.

Easy-to-clean: It can be cleaned after each use with disinfectant wipes.

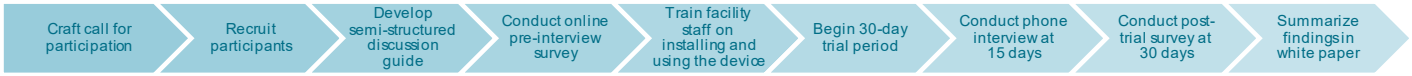
Transparent: It is made from transparent medical grade material so a user can see what is put into the toilet and can see that the urinal or bedpan has been properly cleaned and sanitized after using the toilet sprayer.

Environmentally friendly: It is made of medical-grade, chemical resistant, BPA-free copolyester Eastman Tritan that is safer for the public and the environment. The Splashblocker is also recyclable.

Patented: The Splashblocker product is covered by US D782,635 and other patents pending and foreign patents. All rights reserved.

For more information on this product, visit:
splashblocker.com

Premier User Experience Assessment



Premier conducted a user experience assessment that included a 30-day trial of the Splashblocker with three healthcare organizations. Each participating site received toilet shields to accommodate one per room plus 10 percent extra to ensure the site had an adequate supply to maintain one per room during the 30-day assessment. Video and written instructions on how to properly use and clean the shield were also provided. Premier sent an online pre-interview survey and facilitated a semi-structured 1-hour phone interview with each participant site during the assessment period.

The participant sites and care settings included a general hospital with adult and children's units, a skilled nursing facility (SNF) significantly impacted by COVID-19 and a cancer center with bone marrow transplant patients. Premier interviewed nurse leaders, nursing assistants involved in direct patient care, environmental services team members and a central supply leader. These interviewees rounded on their units to observe and gather feedback from the larger group of staff participating in the trial. Splashblocker, LLC paid participants to cover the costs of time for the assessment interview, survey and product testing.

None of the test facilities had heard of or used the term "toilet plume aerosol." Staff used various terms like "splashback" or "the splash." All agreed that the term "toilet plume" gets attention and follow-up questions. "Flush and run" was the default protection strategy in all facilities as some means of protection again toilet plume. Most staff were aware of the danger of splashback from the toilet, but they did not have a good solution. The SNF also used the phrase "stretch and dump."

...the SNF central supply trainer used the phrase,

"It protects YOU!"

which hit home with the staff.

Just as in the 2018-19 surveys, the protective capability of the Splashblocker was a repeated comment and theme. In training, the SNF central supply trainer used the phrase, "It protects you!" which hit home with the staff. In the cancer center, months before this trial, the "younger staff of childbearing age" told the leader they were worried about exposing themselves to toxic drugs from flushing patients' waste. They questioned why the toilets didn't have toilet lids. The leader thus began her quest for a solution and saw the Splashblocker on the Oncology Nursing Society community website. She viewed it as a "portable toilet lid," presented it to the leadership team and the team "loved it." Further, COVID-19 has made safety a higher priority in job satisfaction considerations for staff who are worried for their own safety and about taking infection home to their families. It has also affected patient safety. Due to the pandemic, the cancer center had moved patients to private rooms, but they will most likely go back to semi-private rooming at some point. However, semi-private room occupancy brings with it a heightened awareness of infection risk.

At the SNF, several patients tested the Splashblocker in their bathrooms, using it as a lid when flushing. In the cancer center, patients were "intrigued by them" when they were put into the bathrooms.

Respondents commented that training was important and motivational, and it helped staff to understand the purpose and use of the product via the demonstration video, the evidence on toilet plume aerosol and observation of how the shield protects users. Sites conducted training in small groups, one-on-one and with a train-the-trainer approach.

The housekeeping/environmental services staff and facilities staff also participated in training. All collaboratively agreed on a cleaning process and schedule. The hospital shared that it took extra effort to convince the plant facilities director that cleaning would be done, but once the process was in place, everyone agreed to it. The SNF cannot store anti-microbial wipes in patient bathrooms where patients could access them and harm themselves. Therefore, the staff worked with housekeeping to ensure regular cleaning. Also, housekeeping staff at the SNF used the Splashblocker as part of the toilet cleaning process. They would clean the toilet, cover it with the shield and flush. Then they would clean the shield.

Hospital staff sometimes used chuck pads as a makeshift solution to cover the toilet. Additionally, the cancer center was considering chuck pads as part of their recommended policy, given lack of a better solution. The respondents noted that chuck pads come at a cost, can sometimes clog pipes if they are

flushed and the pads themselves become hazardous waste if used to dispose of waste containing toxic drugs. Therefore, they appreciate the reusability of the Splashblocker to offset cost and reduce environmental waste.

The SNF and cancer center stated they would like to add the Splashblocker to their care protocols. The hospital stated it would consider adding the Splashblocker as they develop a more refined process for rinsing bedpans and a consistent way to clean the shield.

Suggestions for Product Improvements

Survey and interview respondents shared insights on questions that arose from testing the product:

+ Managing use in rushed situations
+ Handling the Splashblocker while also managing a sprayer on a toilet, as well as the bedpan or urinal or commode. A lot of exposure comes from rinsing with the hopper arm.
+ Ensuring the long-term integrity of the product after daily uses and cleanings
+ Figuring out storage in small bathrooms if there is no convenient place to hang it and ensuring storage does not impede contamination prevention measures so as not to spread microbes on walls, floors, or sinks

Respondents had a few ideas for product improvements, including:

+ Disposable covers that could be put on the product before use and removed after use to aid in cleaning and minimizing contamination
+ Adding wall protection to keep the wall from getting wet after hanging the shield back on the wall after use and cleaning

Splashblocker, LLC is considering these comments and ideas for future product improvements.

For more information on this study, contact:
premierstudies@premierinc.com

Mounting Evidence

Conclusion and Next Steps

Although infection spread via toilet plume is an underrecognized issue, it clearly needs to be addressed, especially as more information is published about the dangers of aerosol spread of the SARS-CoV-2 virus and other infectious agents. Toilet plume aerosol may be the last thing on anyone's mind as an infection-spread issue, yet applying protective measures such as the Splashblocker may be an easy-to-implement first step in quality improvement to enhance healthcare worker and patient safety. It's a simple solution for a long-term issue that will still be around even after the pandemic is over.

The Splashblocker presents a possible solution to enhance awareness of toilet plume aerosol and improve protection against exposure to potentially infectious toilet plumes. It may also help improve environmental sustainability and provide cost savings by reducing the use of one-time-use, disposable chuck pads and minimizing hazardous waste disposal fees. Implementing training and use of the device can help medical staff and caregivers quickly start to protect themselves and patients.

The user experience assessment and surveys provided valuable information to help Splashblocker, LLC determine its next steps in product improvement, development and distribution. The company is now forming a scientific advisory group comprising experts in infectious disease, infection prevention, public health, nursing, environmental services and occupational health and safety. They will develop an efficacy study to determine how significant the decrease in toilet plume aerosol actually is when using the Splashblocker. The group expects to start the study in the next year.

In the meantime, Splashblocker, LLC is working on a new and simpler design in which the shield and handle are one molded piece.

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