Tru-D SmartUVC

UVC Disinfection: *Proven by Science*

By Alice Brewer, Director of Clinical Affairs, Tru-D SmartUVC

The BETR-D Study:

The first and only randomized clinical trial on UVC Disinfection

---

Background

According to the Centers for Disease Control and Prevention (CDC), there are more than 700,000 hospital-acquired infections (HAIs) every year in the U.S., and more than 75,000 of those patients die as a result.[1] With HAI rates increasing and more superbugs discovered each year, it is critical for hospitals to provide the cleanest environments possible to protect patients and staff from infections.

Since its inception in 2007, UVC disinfection has been proven by multiple studies to be an effective means of enhanced terminal room disinfection to help stop the spread of HAIs such as *C. diff*, MRSA, VRE, Ebola and many more. This paper outlines the first and only randomized clinical trial on UVC disinfection, the *Benefits of Enhanced Terminal Room-Disinfection* (BETR-D) study, its results as well as subsequent studies that have resulted from the BETR-D study.

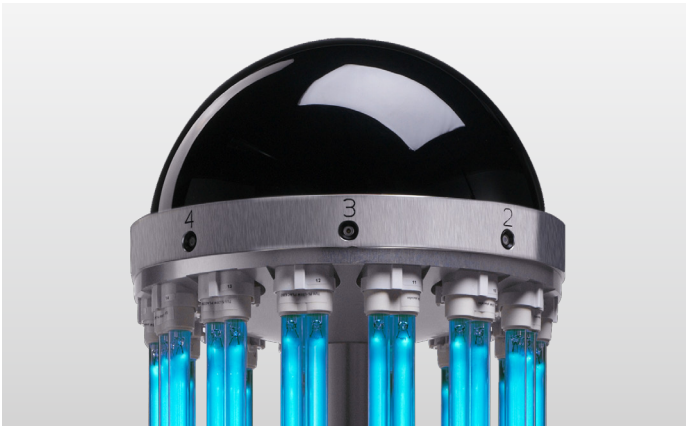
How UVC Works

Ultraviolet light is a form of light, invisible to the human eye, that exists on the electromagnetic spectrum between X-rays and visible light. UVC wavelengths are between 200 and 300 nanometers, making them germicidal – meaning they are capable of inactivating microorganisms, such as bacteria, viruses and protozoa. The high energy from short wavelength UVC light is absorbed in the cellular RNA and DNA, damaging nucleic acids and preventing microorganisms from infecting and reproducing. This absorption of UVC energy forms new bonds between nucleotides, creating double bonds or "dimers." Dimerization of molecules, particularly thymine, is the most common type of damage incurred by UVC light in microorganisms. Formation of thymine dimers in the DNA of bacteria and viruses prevents replication and inability to infect. This quality makes UVC a chemical-free and environmentally-friendly method of disinfecting any space, but especially health care facilities, where germs and pathogens are prevalent.

Tru-D SmartUVC's Technology

Tru-D SmartUVC is a portable UVC disinfection system that delivers an automated, measured dose of UVC light to consistently disinfect an entire room during one cycle. Tru-D operates from one placement within the room, ensuring significant pathogen reduction in direct and shadowed areas and eliminating the threat of human error in the disinfection process. The robot's cloud-based data-tracking technology transfers usage data to a customized portal to provide real-time results through concise graphics and exportable reports.

Other UVC disinfection methods that rely on a fixed cycle time and multiple positions around the room provide inefficient disinfection and missed areas. Tru-D's Sensor360® technology minimizes that risk by calculating the time needed to react to room variables – such as size, geometry, surface reflectivity and the amount and location of equipment in the room. Tru-D SmartUVC's cornerstone for success is the ability to measure the proper UVC dose for thorough room disinfection. A disinfecting dose of UVC is a function of time and intensity. Tru-D will never compromise the proper time to deliver an adequate disinfecting dose to ensure patient safety.



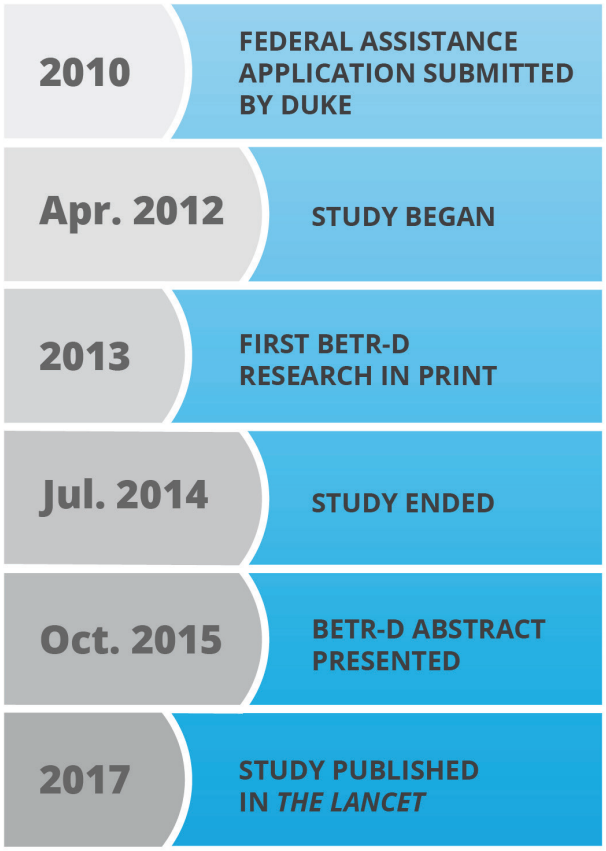
Why Every Surface Matters

Germs and pathogens can live anywhere — in shadowed areas, low-use spaces such as room corners or around various surgical product tables — which is why every touchable surface should be a priority. Tru-D is the trusted choice for health care professionals because of its up to 99.9 percent efficancy that can only be accomplished through its method of UVC dose measurement.[2,3] Multiple independent studies from epidemiological thought leaders and experts in disinfection and sterilization practices validate Tru-D as an effective, single placement approach proven to disinfect the entire room. This is accomplished by measuring the proper dose of UVC energy that reaches the walls and is reflected back to the center of the room.

History of the BETR-D Study

Researchers sought to determine UVC's effectiveness at reducing the risk of acquisition and infection of four major superbugs. Tru-D was selected by Duke University and the BETR-D Research Team as the only automated disinfection system to be included in the first randomized clinical trial on UV disinfection after successful internal trials and because published, third-party data on Tru-D proved reliable, repeatable results. Also, Tru-D was the only robot that could guarantee an effective baseline of disinfection throughout the room due to its measurement capability with its patented Sensor360® technology.

Some initial studies were completed to determine the effectiveness of Tru-D against VRE, *C. diff*, MRSA and Acinetobacter in patient rooms. The data confirmed Tru-D was able to eliminate all four pathogens, including *C. diff*, in real-world settings.[2,4]



About the BETR-D Study

The BETR-D study, the most comprehensive study on UVC disinfection to date and the only randomized clinical trial on UVC disinfection, was a cluster randomized, multicenter crossover study with 2x2 factorial design to evaluate the impact of enhanced terminal room disinfection on acquisition and infection caused by multidrug-resistant organisms (MDROs).[6]

The two-year, $2M, CDC-funded study led by principal investigator Dr. Daniel J. Sexton and lead investigator Dr. Deverick Anderson at Duke University and Duke Infection Control Outreach Network (DICON), collected data across nine hospitals and nearly 22,000 disinfection cycles for more than 300,000 patient days. The study was conducted between 2012-2014 throughout the DICON and was published in January 2017 in *The Lancet*.

$2M	**CDC-funded study**
30%	**Reduced risk of infection**
11%	**Hospital-wide *C. diff* reduction**
314k	**Total patient days – all hospitals**
9	**Hospitals – varying size & census**
22,000	**Total # of rooms disinfected**
33	**Minutes – median cycle time**
+4	**Minutes to cleaning time with UV**
90%	**Tru-D utilization**
91%	**Hand hygiene compliance**

BETR-D Study Protocols

Researchers compared four different cleaning and disinfection scenarios: standard cleaning with quaternary ammonia, enhanced cleaning with quaternary ammonia and Tru-D, enhanced cleaning with bleach and enhanced cleaning with bleach and Tru-D. Each hospital randomly rotated through the four cleaning protocols in each of four, seven-month phases.

The BETR-D study aimed to disinfect all contact precaution rooms; during the 28-month trial, Tru-D was deployed in 16,220 of 18,411 eligible contact precaution rooms with the median hospital compliance against contact precaution rooms being 89 percent (86 percent-92 percent). In order to achieve this high level of compliance, the authors urge environmental services leadership to work with infection prevention and bed control departments to ensure that enhanced strategies are prioritized in appropriate rooms.

Target Organisms	Terminal Disinfection Strategies	Strategy Classification
• MRSA • VRE • *C. difficile* • MDRO - Acinetobacter	A: Reference = Quaternary ammonium (QAC)* B: UV Group = QAC + UV C: Bleach Group = Bleach disinfectant D: Bleach and UV Group = Bleach	A: Standard B: Enhanced C: Enhanced D: Enhanced

Results

The study found that among the four organisms – MRSA, VRE, Acinetobacter, and *C. diff* – using quaternary ammonium disinfectant plus UVC decreased the risk of acquisition by about 30 percent.

The BETR-D study confirmed that manual cleaning is not enough and that the environment plays a large role in the transmission of infections. Results proved that enhanced terminal room disinfection strategies that utilized Tru-D SmartUVC reduced the risk of acquisition and infection of target MDROs by a cumulative 30 percent among patients who entered the same room.

"*Enhanced disinfection technology should be used. If you don't already have it, you need it in your budgets. Minimally, you must add No Touch Technology to your manual cleaning practices upon discharge of a patient on contact or enteric contact isolation.*" [5] *– Dr. William A. Rutala, BETR-D researcher*

Impacts on *C. diff*

When comparing reductions in the rate of *C. diff* between the bleach and bleach + UV study arms, there was an 18 percent reduction in the rate of *C. diff*. In the bleach group, the rate of *C. diff* was 35.9 per 10,000 exposure days over the course of the study, while in the bleach + UV arm, the rate was 29.5 per 10,000 exposure days. In spite of the fact that there was not a statistically significant reduction in the relative risk of transmission of *C. diff*, UV did demonstrate an impact on the acquisition of *C. diff* among patients.

"If you move to a more macro level, when you look at all the patients who come into the hospital, ***we actually did see the C. diff rate decrease by about 11%****"* [8] *- Dr. Deverick Anderson, lead investigator of the BETR-D Study*

Studies within the Study

As the BETR-D study is now published, subsequent studies utilizing the data collected during the BETR-D study have and will be released. A recent paper in *Infection Control and Hospital Epidemiology* details the implementation process of the BETR-D study.[7] The new paper, *Implementation Lessons Learned From the Benefits of Enhanced Terminal Room (BETR) Disinfection Study: Process and Perceptions of Enhanced Disinfection with Ultraviolet Disinfection Devices*, discusses logistical and administrative processes utilized during the BETR-D trial and lessons learned that are pertinent to future utilization of UVC disinfection devices in other hospitals.

One of the biggest barriers for implementing UVC disinfection is "room under pressure," or the urgency to turn a room for the next patient. The BETR-D study authors found this to be more of a perception than a reality. During a pretrial period, the researchers tracked the amount of time to get a patient to a room, and it was found there was always sufficient time to run a standard UVC cycle before the patient arrived.[7] Moreover, the original BETR-D study concluded adding enhanced UVC disinfection only increased cleaning time by an average of four minutes.[6]

The authors noted that administrative leaders are often conflicted on whether or not to use UV disinfection due to the need to promptly admit patients waiting in the emergency department or waiting area. The study authors stated, ***"We believe that this conflict needs to be viewed as a safety issue because enhanced disinfection using UV devices is an evidence-based strategy to improve patient safety."*** The authors further explained that when they tracked the amount of time required to bring a patient to a room labeled as "under pressure" they observed that, "In our experience, this pressure was related more to perception than an actual barrier to use of the UV device…there was always sufficient time to run a standard UV device cycle."[7]

This most recent paper concluded that implementation of UV requires recognition and mitigation of two key barriers 1) timely and accurate identification of rooms requiring UV and 2) overcoming time constraints to allow EVS time to use UV.

The Future of UVC Disinfection

Tru-D's basis of scientific evidence and widespread adoption throughout prestigious hospital systems continue to drive market acceptance of UV disinfection technology. As more evidence of UV disinfection's efficacy becomes available, enhanced terminal room disinfection strategies will likely become a standard of care for all hospitals. In fact, following the BETR-D study, a total of 28 Tru-Ds have been purchased among the nine participating hospitals. Key researchers in infection control and hospital epidemiology continue to stress the importance of enhanced disinfection. And just as the researchers continue to purchase Tru-D and utilize it in their individual hospitals, they have validated this technology as a very important step forward for hospitals and is a very significant complement to hospitals' infection reduction armamentarium.

"We need to say to our CFOs that we need these technologies, and we need to look at the data. The data shows a reduction in infections and we need to invest." [5] *– Dr. William A. Rutala, BETR-D researcher.*

"We think it's an important tool to have to prevent these infections from happening. All nine hospitals in the study have purchased these types of machines to continue to use even though the study has completed." [8] *– Dr. Deverick Anderson, lead investigator of the BETR-D study*

"Enhanced disinfection technology should be used. If you don't already have it, you need it in your budgets. Minimally, you must add No Touch Technology to your manual cleaning practices upon discharge of a patient on contact or enteric contact isolation." [5] *- Dr. William A. Rutala, BETR-D researcher*

About Tru-D SmartUVC

Tru-D's well-controlled randomized clinical trial proved that Tru-D makes a meaningful difference in patient outcomes and provides evidence that Tru-D helps reduce transmission of dangerous infections to at-risk patients. Tru-D provides an unmatched standard of care by reducing infections and improving patient safety while impacting community perceptions, reimbursements and profitability. Tru-D pioneered the UVC disinfection industry in 2007 which has grown exponentially in recent years. Used in conjunction with manual cleaning, Tru-D is deployed after the environmental services staff cleans the room with traditional protocols. Activated by a remote control outside the room, Tru-D administers one cycle of UVC energy from one, central placement in the room. Once the cycle is complete, the operator is notified via audio and/or text message that Tru-D can be moved to the next room. In addition to the BETR-D study, Tru-D's technology has been validated by fifteen other independent, third-party studies.

For more information on Tru-D's technology and/or to watch a video on the power of one placement and one cycle, visit tru-dpowerofone.com.

About Alice Brewer, MPH, CIC

Alice Brewer has spent 10 years as an epidemiologist in both the pharmaceutical industry and health care. Most recently she served as the Director of Infection Prevention for a large, multi-hospital health system in Wisconsin where, through utilization of robust analytics and innovative strategies, she led a 70 percent reduction of HAIs across the health system.

Alice earned a Bachelor's degree in Molecular Biology from the University of North Carolina and a Master's degree in Epidemiology from Indiana University School of Medicine. In 2016, she achieved CIC certification in Infection Control and Epidemiology. She has a record of publications and presentations in the fields of infectious disease and epidemiological research methodology.

References

1. "Healthcare-Associated Infections." Centers for Disease Control and Prevention, 9 Jan. 2018, www.cdc.gov/hai/surveillance/index.html.
2. Rutala, W., et al (2010). Room Decontamination with UV Radiation. *Infection Control and Hospital Epidemiology,* 31(10), 1025-1029.
3. Mahida, N, et al (2013). First UK evaluation of an automated Ultraviolet-C room decontamination device (Tru-D). *Journal of Hospital Infection,* 05(005), 1-4.
4. Anderson DJ, Gergen MF, Smathers E, Sexton DJ, Chen LF, Weber DJ, Rutala WA. Decontamination of targeted pathogens from patient rooms using an automated ultraviolet-C-emitting device. *Infect Control Hosp Epidemiol.* 2013 May;34(5):466-71.
5. Rutala, William A. Role of the Environmental Surfaces in Disease Transmission: "No Touch" Technologies Reduce HAIs. Presentation at the Association for the Healthcare Environment Exchange. 2016 Sept. 25-28; Pittsburgh, PA.
6. Sexton, D., Anderson, D., et al (2017). Enhanced terminal room disinfection and acquisition and infection caused by multidrug-resistant organisms and *Clostridium difficile* (the Benefits of Enhanced Terminal Room Disinfection study): a cluster-randomised, multicentre, crossover study. *The Lancet.* 389(10071), 805-814.
7. Sexton, D., Anderson, D., et al (2018). Implementation Lessons Learned From the Benefits of Enhanced Terminal Room (BETR) Disinfection Study: Process and Perceptions of Enhanced Disinfection with Ultraviolet Disinfection Devices. *Infection Control and Hospital Epidemiology.* Advance online publication. doi: 10.1017/ice.2017.268.
8. Anderson, Deverick, Research Presentation at the Annual DICON Symposium, 2015 November; Greensboro, NC.
9. "Encore: UV Intervention Addressing *C. Difficile* and Other Pathogens." *Voice of America,* www.voiceamerica.com/episode/97203/encore-uv-intervention-addressing-*c-difficile*-and-other-pathogens.