What should a UV-C Antimicrobial Efficacy Standard Look Like?

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Background

Contaminated surfaces in healthcare facilities may contribute to the transmission of pathogens implicated in hospital-acquired infections (HAIs), such as *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *Enterococci* (VRE), gram-negative rods (*Acinetobacter spp.* and *Enterobacteriaceae*) and norovirus. While patient rooms are regularly cleaned and disinfected using manual techniques, evidence suggests that the adequacy of cleaning is often suboptimal, particularly when the focus is only on those surfaces perceived to be high-risk or frequently contacted (high-touch) (Carling et al. 2008). Inadequate cleaning using manual techniques prompted the development of no-touch systems that can decontaminate objects and surfaces in the patient environment. These technologies employ the use of ultraviolet (UV) light or hydrogen peroxide. Automated UV room disinfection devices have seen increasing use in healthcare facilities with the goal of greater reduction of microorganism contamination.

Automated UV disinfection devices that continuously emit UV-C in the range of 254 nm wavelengths can be placed in patient rooms after patient discharge and terminal cleaning has been performed. Some of these systems can achieve up to four log or more disinfection of VRE and MRSA and *C. difficile* by 1 to 3 log. Manufacturers' protocols for UV treatment devices vary – some encourage supplementing with standard cleaning protocols; others encourage using the UV device only.

Current standards and practices

Chemical disinfectants are heavily regulated by the EPA for FIFRA compliance, where manufacturers are required to back up efficacy claims per individual pathogens with third-party validation using EPA test protocols. However, there are currently no established efficacy standards for UV devices. UV devices are only regulated by the EPA under FIFRA as pesticidal devices, but unlike pesticidal products, they do not require EPA registration (EPA 2018). Data to support claims is expected, and false or misleading claims cannot be made about the effectiveness of devices. The devices must be produced in an EPA-registered establishment. Additionally, some states require state registration.

The lack of an efficacy standard for such devices has resulted in manufacturers using different approaches to make efficacy claims. This lack of standardization has created confusion in the healthcare industry. At present, infection prevention specialists cannot accurately compare performance of UV devices and make informed purchasing decisions. Some manufacturers claim reduction of microbial burden; others claim the reduction of HAIs. Specific data requirements have not yet been established, but performance-based language – such as sanitizer, disinfectant or sterilizer – often is used. Furthermore, without an efficacy standard, hospital device users are unable to follow any re-validation protocol for

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Figure 1. Examples of commercially available room UV disinfection devices

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continued device effectiveness. Lastly, some manufacturers make misleading public health claims regarding their device that could discredit the UV industry. Establishment of a UV efficacy test standard that is utilized by manufacturers would benefit the industry and healthcare facilities and, ultimately, aid in the overall mission of public health.

Important considerations for UV efficacy standard

There is a growing multitude of whole room UV disinfection devices available to the healthcare industry each having their unique physical design and technical attributes. Figure 1 (on page 17) shows some of the commercially available UV room disinfection devices for use in healthcare settings.

The lack of uniformity between devices presents a unique challenge to come up with an efficacy standard that would be applicable for all these devices. The standard would have to account for several factors that contribute to the efficacy of UV-C devices, such as wavelengths employed, treatment protocols, testing environment, test pathogens, test carriers, carrier inoculation, carrier placements, treatment time, dose measurement apparatus, etc.

Some of the important factors that impact the efficacy of UV devices are discussed below:

Form factor

Currently, three form factors are utilized by UV device manufacturers for whole room disinfection. The most common configuration utilizes multiple lamps fixed vertically on a base platform, typically in a circular configuration. An alternate configuration utilizes a single lamp arrangement which is moved vertically up and down during the treatment cycle. Whole room disinfection is achieved by single or multiple placements of the UV device in the room. An alternate arrangement is provided by a manufacturer, where the UV lamps are located on arms that can be oriented at different angles. A very different form factor is utilized whereby the UV light fixtures are mounted in the ceiling of the room.

UV wavelengths

While multiple types of light sources may be used (mercury, pulsed xenon, LEDs, etc.), the wavelengths emitted by the UV devices have an important bearing on the efficacy of the device. The varying susceptibility of different microorganisms to different wavelengths has been studied (Figure 2) (EPA 2006).

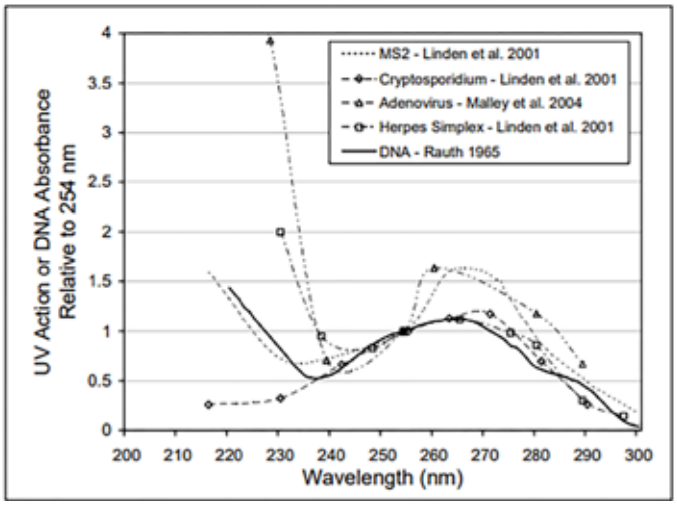

Figure 2. Microorganism and DNA susceptibility as a function of wavelength. Source: Adapted from Rauth (1965), Linden et al. (2001) and Malley et al. (2004)

The majority of the UV devices currently used in the industry employ low-pressure mercury lamps that continuously emit UV-C primarily at 253.7 nm wavelength, which is well known to inactivate the DNA of bacteria, virus and fungi. Some devices utilize pulsed xenon lamps, which emit a broad-spectrum light in the 200 to 315 nm wavelength. Conceptual devices also have been introduced that utilize

light sources that emit specific wavelengths in the far UV (207-222 nm) spectrum. Violet-blue light at 405 nm has also been introduced in ceiling fixtures and found to be effective, albeit slow, for bacterial pathogens.

Device output

The efficacy of a UV device is based on the overall UV output delivered by the device in all directions. The overall UV output is dependent on the lamp intensity, number of lamps, height of the lamp, lamp configuration on device, reflectors and other physical attributes. An important aspect to consider, which is sometimes ignored, is the performance of the lamp(s) over time. Depending on the type and quality of the lamp, the lamp output and therefore the device efficacy may decrease over time. The efficacy standard would have to recognize this as an important variable and include measurement and reporting of the lamp output used for efficacy measurements.

Treatment protocol

Variation in treatment protocol recommended by different UV manufacturers for their devices makes it difficult for hospital device users to compare the efficacy of the devices to achieve whole room disinfection. Treatment protocols vary from single placement or multiple placements in a room. Multiple placements are conducted by using one device sequentially or using multiple devices simultaneously. Several studies have been conducted by key researchers to highlight the advantages of multiple placements to achieve acceptable disinfection levels at surfaces in direct and indirect line of sight of the UV devices (Rutala et al. 2016). Variations also arise from recommended treatment times by different manufacturers – while some recommend using fixed treatment times to be used per placement cycle, others use room mapping software, reflected dose measurements or measured dose on target surfaces, etc. to dictate the treatment time for their UV device.

Room type and configuration

The room size and configuration are closely related to the treatment protocol to be used by the UV device. UV-C irradiance, dosage and antimicrobial effect received from a mobile UV-C device varies substantially based on location in a room relative to the UV-C device (Boyce et al. 2016a, Kanamori et al. 2016). It is important to recognize that UV-C light is a "line of sight" technology, meaning that destruction of microorganisms can be achieved when they are in a direct line of sight of the UV device. Efficacy decreases in shadowed areas or areas not in direct path of UV light. This may require more than one placement of a UV device in an area with many hard-to-reach surfaces and/or increase in treatment times.

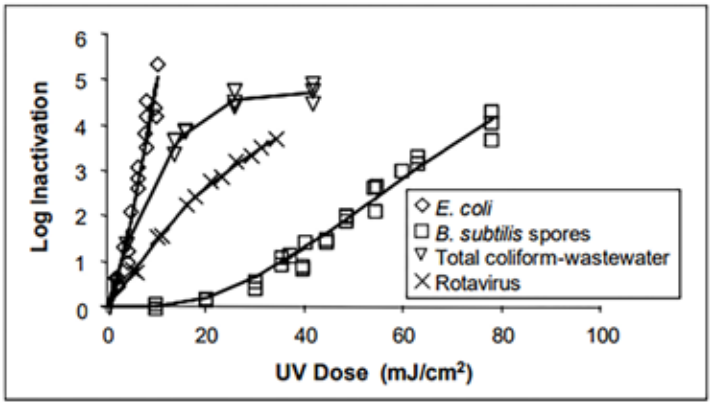

Figure 3. Log reduction of different microorganisms as a function of UV dose. Source: Adapted from Chang et al. (1985)

Pathogen type

It is well known that different pathogens exhibit varying susceptibility to UV with vegetative bacteria and viruses typically easier to inactivate than spores or fungi. While UV systems can achieve up to four log or greater reduction of

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VRE and MRSA, the log reduction achieved for C-diff spores will be much lower for the same UV treatment period (see Figure 3 on page 19). Furthermore, the susceptibility of the microorganism with increasing levels of UV dose may not be linear and would be different from one microorganism to another (Boyce et al. 2016b; EPA 2006).

UV dose target values

One common misapplication of UV devices is the estimation of UV dose required to achieve a certain log reduction for a target pathogen. The required UV dose for a microorganism forms the basis of design and application for all UV systems. It is the required dose which dictates the collective intensity output and configuration of all UV lamps for any UV device. The UV dose required to inactivate a microorganism is completely dependent on the value of the UV rate constant for that microorganism.

While there are multiple reported studies on UV rate constants available in the literature, these studies have been conducted with different experimental set-ups, different UV wavelengths, different strains of microorganisms and on different media (water, air and surface) (Kowalski 2009, Bolton et al. 2016). Also, the impact of soiling or organic matter present with the microorganism – as well as soft surfaces, such as privacy curtains and upholstery, etc. – has not been studied in detail. UV-C devices typically show diminished micro-efficacy when used on soiled or soft surfaces. Since most of the studies have concentrated on water media, the relevance of these studies on surface media is not clear. Due to lack of industry consensus on the UV dose requirements for different microorganisms, there is considerable variability in the UV systems offered by different manufacturers, with all claiming effectiveness against the microbes.

Another important question where there is little industry consensus is the level of "clean" that would be acceptable by infection control preventionists in hospitals for the deployment of these whole room disinfection devices. While some propose minimum two log reduction requirements, others recommend having three or greater log reductions to be attained for high-touch surfaces.

Suggested scope of UV device efficacy test standard

The main objective of an efficacy test standard is to quantify the antimicrobial efficacy of a UV room disinfection device in a controlled and reproducible setting. Considering the above factors governing the efficacy of the UV device, the following items would need to be addressed to determine the scope of the test standard:

- Should the scope be limited to measurement of the output of the UV device as a measure of its efficacy, or should the efficacy be evaluated against some target microorganisms?
- Should the efficacy test be conducted in a laboratory setting or in a simulated room with fomites present in a typical hospital room?
- Selection of target microorganisms
- Sample preparation using industry standard techniques
- Consensus on minimum UV dose level to be achieved for selected microorganisms (may require a separate study)
- Measurement of UV intensity of lamp and/or using industry standard test method and instrumentation (may require development)
- Should the standard stipulate minimum efficacy (log reduction) requirements for selected microorganisms?
- Test protocol to be used: standardized or as per manufacturers' recommendations
- Detailed specification of the UV device evaluated including device name, model number, manufacturer and device picture
- Test facility to conduct the testing

Further, the test standard needs to be inclusive for all types of devices at various stages of maturity. It might, therefore, be appropriate to provide different levels of certification. One level certifies the UV-C output of the device, and the other certifies the efficacy in terms of log reduction against target microorganisms. Finally, the efficacy standard should be easy to implement, be reproducible and accepted by healthcare professionals.

While the task of developing the efficacy standard may appear daunting, it can be achieved with collaborative efforts between all the stakeholders involved. The recently formed IUVA Healthcare Working Group is doing exactly that and already has started making headway into the process of coming up with an industry-wide accepted efficacy test standard for room disinfection devices. ■

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