UV Antimicrobial Devices Used to Combat HAIs in Medical Facilities: Is There a Need to Establish Voluntary Industry Efficacy Standards for Their Use?

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Introduction

It is well documented and highly publicized that health care-associated infections (HAIs) are a serious, preventable health problem (Cowan 2016). In its session on June 26, 2014, the US House of Representatives Subcommittee on Research and Technology found that HAIs are the most common complication of hospital care. Estimates from the Centers for Disease Control and Prevention (CDC) indicate that HAIs cause or contribute to upwards of 99,000 deaths annually in the US.

The CDC has stated recently that one in every 25 hospital patients will be treated for an HAI. Of all the HAIs that are caused by pathogens, the two that are hardest to treat are *Clostridium difficile* (*C. diff*), which causes nearly 14,000 deaths per year, and methicillin-resistant *Staphylococcus aureus* (MRSA), which causes more than 11,000 deaths per year (White House 2014).

Infectious disease research demonstrates that HAIs can be reduced by incorporating antimicrobial ultraviolet (UV) devices into cleaning protocols; however, the health care community has been slow to adopt their application. Failure to embrace the technology may well be caused by the uncertainties about the efficacy of the devices vs. the cost to acquire and implement, requiring additional research and motivation to overcome the resulting inertia. The intent of this article is to stimulate dialogue on ways the UV industry can help overcome that inertia.

UV treatment is an effective way to combat HAIs

For more than a century, UV light in the shorter wavelengths (e.g., 200-290 nm, or the UV-C band) has been known to inactivate pathogens' DNA, preventing the pathogens from multiplying without harmful side effects. UV-C devices were well used in the health care industry of the 1940s and 1950s, typically to control tuberculosis. Over time, costs for sustaining the equipment safely when compared to advances in tubercular medications ultimately led to a decline in the popularity of UV technology.

In the 50 years that followed the advent of multiple drug resistant organisms (MDROs) and their evolving antibiotic immu-

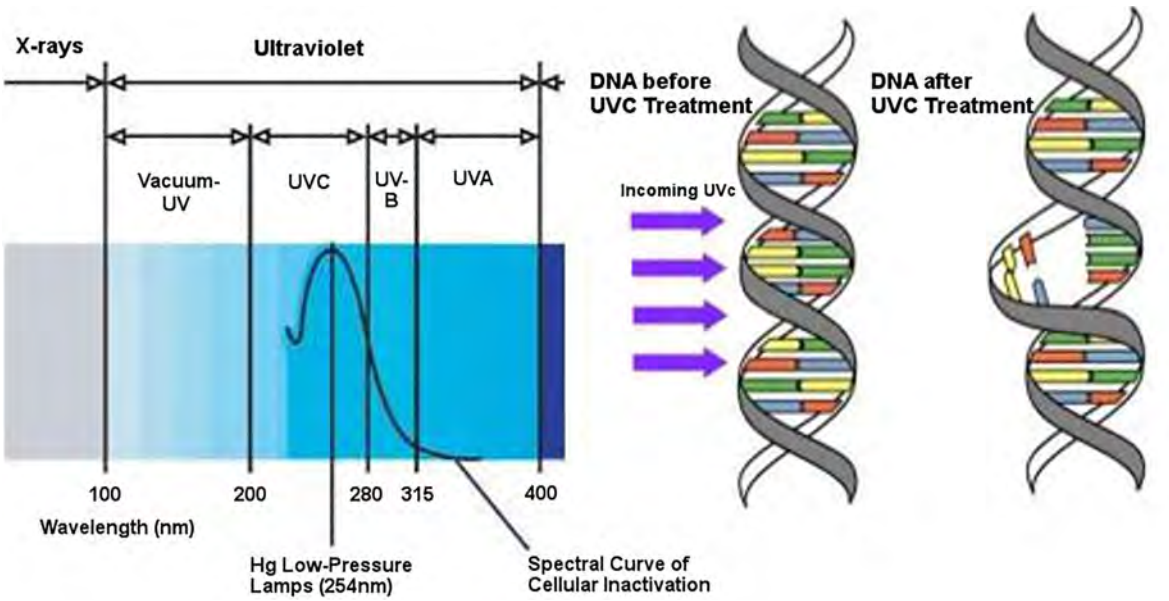

Figure 1. UV spectrum with DNA

nities, UV-C's known capability to inactivate such pathogens, including those causing HAIs, has become increasingly important, especially as MDROs neither build up a tolerance to UV-C effects nor develop mutations with UV-C resistance (Jinadatha et al. 2014). The source of UV-C light (mercury, xenon, LEDs, etc.) is not as important, as long as the appropriate UV-C wavelength light is delivered in the correct antimicrobial dose, defined in terms of the UV-C device's power, time of exposure and distance from the target, specific to each pathogen of interest (Bolton and Cotton 2008).

While resources identifying the required UV doses for inactivating various pathogens can be found in numerous publications and studies, no one scientific standard exists.

UV antimicrobial technologies and devices are multiplying rapidly

A typical internet search can readily find more than 40 manufacturers of "UV sterilizers" of all types (air, water and surface), to include as many as 17 makers of UV antimicrobial devices, intended for surface disinfection primarily in health care facilities, each with its own advantages and disadvantages. What can be discovered is interesting:

- Most used "traditional" low-pressure mercury lamp light sources that continuously emit UV-C primarily at 253.7 nm.
- At least two manufacturers utilize newer technology xenon lamps, which emit broad spectrum light (including UV-C) in short, intense pulses.
- Several firms use light emitting diodes (LEDs) to create very small UV-C devices, enabling increased design flexibility in their application, albeit at a lower power. LEDs can be "tuned" to emit UV wavelengths other than 254 nm by varying the materials used in their manufacture, enabling even more application options.

In part, thanks to the spectral diversity found in the newer UV sources, there has been an increased interest in finding additional wavelengths of interest – from vacuum-UV (100-200 nm) to violet-blue light (>400 nm) that may produce antimicrobial benefits.

- Vacuum-UV (a.k.a., Far-UV) used in portable, handheld devices have led to claims of achieving 99.9% disinfection rates in a matter of seconds, rather than minutes. This is attributed to the more energetic radiation in the shorter wavelengths and the reduced distance to the target (~10 cm). In some cases, these devices require additional user-safety precautions (e.g., protective eyewear) due to exposure of the operator to direct UV emissions during operation (Nerandzic et al. 2012).
- Violet-blue light at 405 nm was used in a high-intensity, narrow-spectrum light environmental disinfection system (HINS-light EDS), tested as an alternative to UV-C in disinfecting rooms (both air and surfaces). The main advantage was – if proven effective – this wavelength would have minimal harmful effects to people, enabling its use 24/7 in occupied areas (Maclean et al. 2014).

> "The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 7 requires that production of pesticides, active ingredients or devices be conducted in a registered pesticide-producing or device-producing establishment. ("Production" includes formulation, packaging, repackaging, labeling and relabeling.) Production in an unregistered establishment is a violation of the law." (EPA 2016)

Current UV antimicrobial device standards are many, but none cover "efficacy"

Existing federal protections

Due to jurisdictional and statutory responsibilities, a number of governmental agencies are addressing the use of microbial UV radiation within the boundaries of their chartered and/or regulatory purvey. These are primarily found in the Environmental Protection Agency (EPA) and the Department of Health and Human Services (HHS), with each having multiple, sometimes overlapping roles in multiple offices.

Within the EPA there are three offices with primary responsibility for UV applications – Office of Resource Conservation and Recovery (ORCR), within the Office of Land and Emergency Management; the Office of Water (OW), and the Office of Pesticide Programs (OPP), within the Office of Chemical Safety and Pollution Prevention. Each has developed guidance or rules generally based on media and the legislation covering that media. For treating solid wastes and any hazardous materials or waste media covered by RCRA/CERCLA, ORCR governs the approved use of UV radiation in guidance for cleaning up chemical and biological materials. EPA's OW, acting under the Clean Water Act, has developed UV radiation guidance and methods for sanitizing wastewater and drinking water.

Perhaps more significantly for addressing HAIs, EPA's OPP works on UV radiation as an antimicrobial pesticide under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It also has created and oversees the guidance for cleanup and sanitization of indoor spaces, such as hospitals and clinics using

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antimicrobial biocides and pesticides, and oversees the registration of antimicrobial devices and factories producing those devices.

In this regard, uniform standardization for UV-C's for disinfection is an admitted responsibility of the EPA, and moreover, one that the EPA Office of Inspector General (OIG) has noticed and a corrective action promised in the form of uniform standards for hospital level disinfection. In the EPA Inspector General's Office issued Report No. 11-P-0029, it was recommended that EPA redesign "…its process to verify antimicrobial effectiveness." (EPA 2010) After the administrator signed off on the Final OIG Report and its funded Corrective Action Plan, it would seem that OPP would have been empowered to establish efficacy standards for UV-C antimicrobial devices; unfortunately, the EPA would in hindsight appear to have been unaware of the UV-C impacts on antimicrobials and this has not been done.

So, in response to the administrator's Corrective Action Plan, EPA concentrated on creating efficacy standards for chemicals used in antimicrobial disinfection. Today there is a broad range of disinfection products from metals (copper protocols) to chemicals and unregistered but yet otherwise FIFRA-compliant UV-C devices. As it turns out few UV devices have registered their manufacturing facilities compliant with FIFRA regulations. Fewer still have actually been officially determined to be antimicrobial devices.

HHS has several groups that have roles and responsibilities. The Food and Drug Administration (FDA) reviews all devices used in medical treatment and alternative food processing technologies using UV radiation to disinfect. HHS' CDC has responsibility for monitoring bacteriological and viral vectors and their impact on human populations and have been conducting studies to discover applied solutions to stop epidemic outbreaks. Within CDC, the National Institute for Occupational Safety and Health (NIOSH) is concerned with workplace and worker safety and has developed guidance and standards for UV radiation, including exposure limits for humans.

This overlaps with other FDA requirements under Federal Food, Drug and Cosmetic Act (Chapter 5, Subchapter C: Electronic Product Radiation Control), where the FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating radiation-emitting electronic products to protect the public from hazardous and unnecessary exposure to radiation (FDA 2016).

What is the government doing?

Jurisdictionally for HAIs, there is the potential for substantial overlap between the use of UV-C's for disinfection (EPA) and those that actually are used on patients during a medical procedure (FDA). Several governmental and nongovernmental organizations have worked on or around these issues. Typically, the efforts are incremental, and the outcome is that there are no uniform efficacy standards.

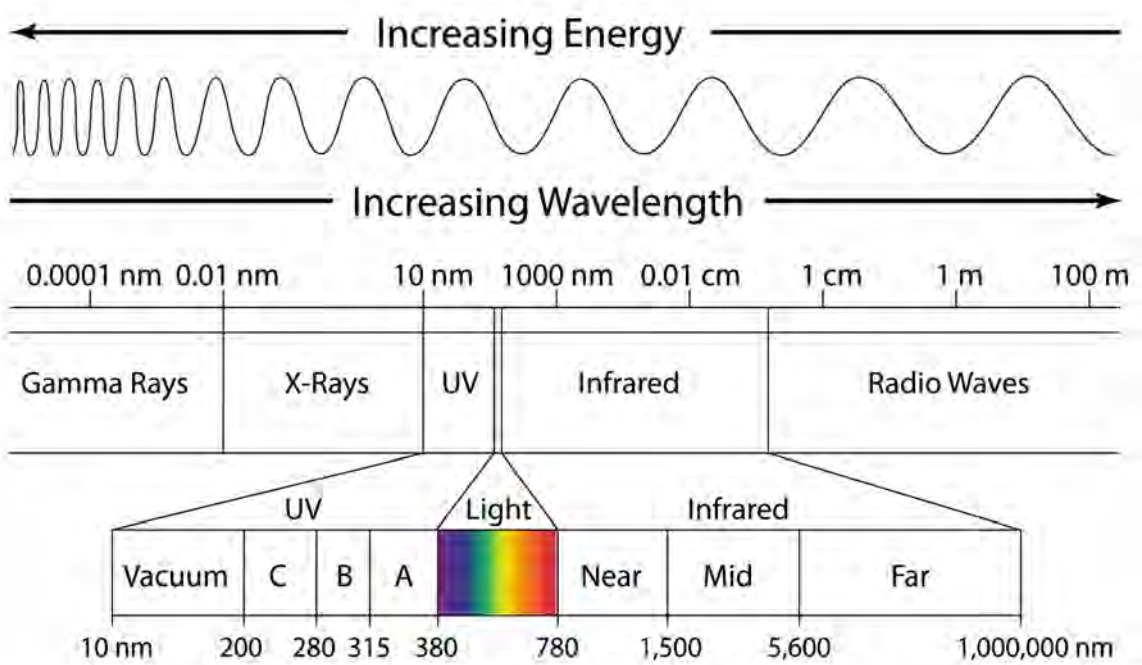

Figure 2. Electromagnetic spectrum

The Antimicrobials Division of EPA's OPP is the statutory responsible party for FIFRA compliance. As it relates to antimicrobials, they have established efficacy standards for chemical disinfectants, which require the antimicrobial chemical industry to list the recommended treatment protocols and the efficacy expected by individual pathogen claimed to be covered, backed up by third-party laboratory tests. No similar rules exist governing the efficacy of UV antimicrobial devices, either generically or by pathogen.

Professional societies, industry associations and other NGOs

Several nongovernmental organizations (NGOs) and professional societies have conducted research, testing of devices and protocols, and voluntarily developed industry-accepted guidance and standards for UV radiation on some media types like air and water. UL/ANSI (Underwriters Laboratory/ American National Standards Institute) has addressed waterborne bacteria and viruses by developing minimum requirements for water media and UV radiation exposures to control bacteria and viruses. ASHRAE has developed design and building standards that includes an entire chapter in its handbook on UV air and surface treatment. Voluntary industry standards often are incorporated into government regulations (e.g., building codes) and used to further provide scientific and engineering substance to regulations by reference.

To date, this standard setting has not been done in the UV community, as evidenced by lack of industry-wide consensus on product credibility. This is demonstrated by recent Federal Trade Commission (FTC) rulings against two start-up UV companies for making efficacy claims without any scientific justification (FTC 2015). Another example of the lack of defined industry norms of efficacy and performance is found in the multiple court suits between vendors (Becker's Hospital Review 2015), where both sides successfully argued the other's advertising was misleading in its comparisons against the competitor.

Consumers' dilemma

The use of UV-C devices in disinfection protocols to reduce infectious pathogens is increasing. Airliners soon may have bathrooms with UV-C LED strips to reduce pathogens while in flight. Hospital beds are being designed with built-in UV-C lighting to reduce pathogens between room cleanings. Surgical suites, infectious disease wards, hallways and cafeterias and health care facility bathrooms are being modified to adapt UV devices into their mammoth facility air returns to control airborne pathogens. All could be rapidly implemented, given a consistent set of standards for UV pathogen reduction, to save billions of dollars and save countless lives. Consumers of any new technology are always concerned about how to ensure they get devices that work as advertised, and that they're getting the right technology and device to fit their requirements. Absent a credible industry standard, what can consumers use to make safe, prudent decisions?

> Studies of EC (environmental cleaning) funded by manufacturers of cleaning agents or disinfection technologies, create a potential conflict of interest. "These conflicts introduce real or perceived biases into the evidence base and may lead to skepticism by EVS (environmental services) professionals and infection control experts about the results of these studies," resulting in concerns that "industry funding of published research may deter adoption of disinfection and monitoring technologies." (Leas et al. 2015).

Efficacy is multidimensional

In the attempt of any group to address efficacy, there is the hope that a variety of conditions and applications can be covered with one broad stroke of a pen. But there are obviously many dimensions to be addressed, from the choice of target pathogens, to the choice of testing environments and protocols. With little uniformity, it is difficult to compare units and select the best fit for applications which run the gamut from hospital rooms, clinics, elder care facilities to ambulances and medivacs.

This appears to be a daunting task. Likely the "let the government do it" approach will not see the allocation of resources or time for such an effort even though the need is compelling. Nor will industry be able to impact the outcome.

What can industry do?

Causal observation of what government has done over the years confirms that the process is time-consuming, incremental and likely expensive. One wishes to make the process simpler and more focused. This is particularly true with the urgency of the issue, and truly, with lives hanging in the balance awaiting the creation of standards for efficacy and the testing of UV-C devices.

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One approach that has been successful in a variety of situations is for industry and professional societies to develop guidance and standards and establish a certification process using those standards. Industry standardization can be completed in a timely manner, especially compared to government-driven efforts. The industrial certification approach delivers a consensus result. Through leadership by industry and professional societies, respected and knowledgeable colleagues can craft guidance, protocols, testing and standards. The professional societies (IUVA, UL/ANSI, IEEE, AAMI, et al.) can contribute knowledge and research, and supply peer review to the development and acceptance of the guidance and standards.

The resulting guidance and standards can be nested with government needs. Government through reference can incorporate guidance and standards.

Conclusion

Given that governmental efforts are present but limited and incremental, it remains to industry and health care professionals and professional societies to approach and address HAIs through UV radiation treatment guidance and efficacy standards. A consensus approach can be successful, timely, cost-efficient and generate results with known statistical efficiency and known costs of implementation and operation.

Efficacy standards need to bypass the system's intrinsic inertia and implement through the industry's leadership and good works of our professional societies.

What are you willing to do? ■

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