LETTERS TO THE EDITOR

Need for Uniform Standards Covering UV-C Based Antimicrobial Disinfection Devices

To the Editor—Healthcare-associated infections (HAIs) are a serious, preventable health problem. On June 26, 2014, the U.S. House Subcommittee on Research and Technology described HAIs as the most common complication of hospital care, citing the Centers for Disease Control and Prevention (CDC) estimates that HAIs cause or contribute to as many as 99,000 deaths annually.[1] More recently, the CDC stated that 1 in every 25 hospital patients will be treated for an HAI.[2] The 2 most difficult pathogens to prevent are *Clostridium difficile* (*C.diff*), which causes nearly 20,000 deaths per year,[3] and methicillin-resistant *Staphylococcus aureus* (MRSA), which causes nearly 19,000 deaths per year.[4] Both are preventable with antimicrobial UV-C devices.

UV-C Ultraviolet Light Technology Transition

UV-C kills HAI pathogens, with maximum bactericidal effect at a wavelength of 250 nm. Studies by Michelle M. Nerandzic, Curtis J. Donskey, Deverick J. Anderson, and the CDC Prevention Epicenters Program continue to validate this century-known fact.[5] A 2014 study by Jinadatha et al[6] affirmed that pathogens neither build up a tolerance to UV-C effects nor develop mutations with UV-C resistance. The source of UV-C light (mercury, xenon) is not important as long as the right UV-C wavelength light is delivered in the correct antimicrobial dosage (ie, time and distance). UV-C devices were the preferred antimicrobial technology of the 1940s and 1950s until costs of sustaining the equipment safely and advances in tuberculosis medications led to a decline in popularity. Today, the rise of multidrug-resistant bacteria creates a real need for more effective environmental disinfection, enabling a more prominent, renascent role for UV-C devices.

The Case for UV-C Device Efficacy Standards

Today, at least 15 different manufacturers provide antimicrobial UV-C devices to the healthcare industry. To compare UV-C device effectiveness, a technical baseline is necessary before operations and cost can be evaluated. Some manufacturers rely upon light intensity as a measure of efficacy; others use percentage of pathogen reduction after the recommended treatment cycle; and still others report percentage reduction in hospital infection rates when combined with other cleaning regimens that vary from hospital to hospital. Some tests are based on *C. diff*, some on MRSA, and others on *Escherichia coli*. Without a uniform federal standard, it is difficult for healthcare systems to sort out which UV-C devices work best for their needs.

Fundamentally, according to Sarah Snow, "Since there are no Environmental Protection Agency (EPA)–approved protocols to validate micro-efficacy claims for UV devices, the industry faces a lack of standardized test methods and oversight on the claims made by device manufacturers."[7]

Furthermore, many *ICHE* articles over the last few years report that different strains of bacteria have been tested using different pathogen concentrations and different carrier fluids under different, sometimes uncontrolled, environmental conditions. The countless studies and articles published by influential journals like *ICHE* beg the question. Without uniform efficacy standards, is it not difficult or even impossible to compare the effectiveness of current UV-C devices? Perhaps a formal review of the heterogeneity of clinical research methods used for UV-C would be useful.

EPA Regulators Set Efficacy Standards

Most people do not associate UV-C devices with EPA oversight, which is mandated by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In accordance with FIFRA, the EPA defines "antimicrobial pesticides" as those chemicals, products or devices intended to "disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms" to include bacteria and viruses. In 1982, EPA established efficacy standards and test protocols covering 1-time use antimicrobial hand sanitizers.[8] In 2016, EPA added copper efficacy protocols for contact surfaces.[9] To save time and money, the EPA is currently considering a pathogen hierarchy to simplify antimicrobial testing.

The EPA Needs to Address the Efficacy Issue Head-On

In 2010, the EPA Office of the Inspector General (OIG) issued Report No. 11 -P-0029, recommending that "… EPA redesign its process to verify antimicrobial effectiveness. The new program should have a testing program that provides reasonable efficacy assurances for all registered … hospital-level disinfectants..." On February 25, 2011, the EPA Administrator endorsed the Final OIG Report. Since then, the resulting corrective action plan has failed to address UV-C technology or devices, even though it was required by EPA Order 2750, "EPA's Audit Management Process."

Although mandated by FIFRA to regulate both antimicrobial products and devices, the EPA's limited resources may not have allowed it to keep pace with technology development.

The Challenge

Do the medical experts performing the peer reviews or scientists who perform the studies, the hospital administrators or the third-party scientists, industry representatives or even the EPA have a responsibility to step up and take an action

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advocating and implementing UV-C efficacy standards? "Professional organizations in infection prevention and occupational health are well positioned to take leadership in this effort by establishing joint committees and engaging with funders to set priorities and a time table to move the research and improved practice guidance forward."[10] This isn't a heavy lift for all who work toward the greater good to push for so obvious a solution.

The EPA needs to treat antimicrobial devices the way they treat all their other antimicrobial products, and efficacy standards for UV-C devices need to be established. This may not be impossible for the EPA to achieve alone, but the EPA may require the voice and considered involvement of the broader group. Physicians, researchers, administrators, insurers, and families of patients and victims may choose to be involved in urging the EPA to include antimicrobial devices in the protocol of efficacy standards. Such correspondence may be addressed to Lance Wormell, Chief, Regulatory Management Branch II Antimicrobials Division, Office of Pesticide Programs, U.S. Environmental Protection Agency (Wormell.Lance@epa.gov).

UV-C devices save lives. It is time for the EPA to establish an UV-C device efficacy standard.

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Response to Cowan on Need for UV-C Antimicrobial Device Standards

To the Editor— Novel ultraviolet-C (UV-C) disinfection devices are currently flooding the infection control market due to the well-documented microbicidal efficacy of UV-C irradiation and appealing modern upgrades in mobility, safety, and monitoring of devices. This trend in the market is apparent with a quick glance through the pages of widely circulated infection control magazines, where multiple UV-C device advertisements may be present in a single issue. As noted by Cowan, at least 15 different manufacturers provide UV-C devices to the healthcare industry, but only a few devices are supported by peer-reviewed studies, and there are currently no guidelines to define what constitutes an effective level of pathogen reduction or standardized methodology for evaluating UV-C killing efficacy.

We share the concern Cowan has presented and have made efforts to bring awareness to the need for direct comparison of devices and standardization of methodology. In a recent study, we introduced the need for a platform to directly compare the many UV-C devices on the market.[1] Under uniform testing conditions, we found no difference in the efficacy of the 2 analogous UV-C