Would it be Helpful to Infection Control Professionals to Have the FDA Regulate Whole-Room UVC Devices?

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TITLE PAGE

Title: Would it be Helpful to Infection Control Professionals to Have the FDA Regulate Whole-Room UVC Devices?

Short Title: Survey on UVC Device FDA Regulation

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HIGHLIGHTS:

- The FDA does not currently regulate whole-Room UVC devices.
- 82% of surveyed IC professionals felt FDA regulation of UVC devices would be helpful.
- 84% surveyed felt “thoroughness of disinfection” was the most important attribute.
- 13.5% surveyed felt “ease of use/time required” was the most important attribute.

ABSTRACT

A two-question survey was performed at the 2022 Annual Meeting of the Association of Professionals in Infection Control (APIC) regarding whole-room Ultraviolet C (UVC) disinfection devices. 96 questionnaires were completed. 82.3% indicated FDA regulation of UVC devices would help them, 5.2% responded they would not and 12.5% were neutral. 84.4% ranked thoroughness of disinfection as the most important attribute of a whole-room UVC device. 13.5% indicated ease of use and time required as most important.

KEY WORDS:

Ultraviolet-C light decontamination
Health care−associated infections
Patient room disinfection
UV-C disinfection Hospital disinfection

INTRODUCTION

Ultraviolet “C” (UVC) whole-room devices have been used for decades to supplement chemical disinfection in the healthcare environment with varying levels of success and acceptance. A 2018 report showed most healthcare workers (HCW) in a hospital setting thought daily UVC decreases the patients’ risk of acquiring infection [1]. In a related 2019 study 89% of HCW felt the use of UVC as an adjunct to routine cleaning increased confidence that rooms are clean [2].

The US Food & Drug Administration FDA does not regulate UVC whole-room disinfection emitters as they do not meet medical device criteria. [3]. Such devices are intended to disinfect medical devices in the healthcare setting and therefore could be considered within the FDA

purview. Contained chambers, such as used for disinfecting a mobile phone are regulated, but this regulation 21CFR880.6600(a) specifies “this classification does not include self-contained, open chamber, UV radiation disinfection devices intended for whole room disinfection in a healthcare environment” [4].

In 2021, the National Institute for Standards and Technology (NIST) published a perspectives article authored by physicians on what healthcare whole-room UVC device standards should look like. Recommendations included using an actual hospital room or high-fidelity mockup with curtains, furnishings, materials and finishes and required $\log_{10}$ reductions of *Clostridiodes difficile* cultures at dozens of likely contaminated sites [5].

Infection Control (IC) and Prevention professionals are trained to implement evidence-based interventions as the most trusted means to protect patients whose lives depend on those decisions. However, the lack of UVC whole-room device standards, regulations and certifications can hinder device purchase and implementation decisions of equipment intended to maintain an optimal level of healthcare environmental disinfection.

We therefore conducted a survey to determine if Infection Control professionals would find it helpful if whole-room UVC disinfection were regulated by the FDA and to rank the importance of attributes of such devices.

MATERIALS & METHODS

This study is considered exempt from Institutional Review Board requirements as no personal data were collected and no human subjects were involved.

A voluntary 2-item questionnaire was offered to attendees within the exhibit area of the 2022 Annual Meeting of the Association of Professionals in Infection Control in Indianapolis, Indiana during the 3-day conference.

A piece of paper explained that there are currently no FDA/EPA regulations, standards nor certifications for whole-room UVC devices. The paper asked: “Would it be helpful to IC professionals to have the FDA regulate whole-room UVC devices?” and gave choices of yes, no, or neutral. The second asked: “Please rank in order of importance the following 3 attributes of a UVC whole-room disinfection device”. The three attribute choices were: automated reporting of device, thoroughness of disinfection, and ease of use & time required.

Completed questionnaires were folded and placed into a slot in the top of a sealed box. Participants were asked to keep the pen used for the questionnaire in an effort to decrease the risk of fomite disease transmission at the meeting.

Answers from the questionnaires were entered into a spreadsheet. A 95% confidence level was selected to determine the survey margin-of-error (MOE) using an online calculator using the formula MOE=z-score times population standard deviation divided by the square root of the sample size [6].

RESULTS

96 questionnaires were completed and reviewed. Although comments were permitted on the reverse side of the paper, no participant added comments. All questionnaires were accepted as valid without blanks nor ambiguous responses.

With a sample size of 96 and a defined 95% confidence level, the mathematically calculated margin-of-error is 10% when the actual population size of Infection Control and Prevention professionals is any number greater than 1000 [6].

Figure 1 shows the breakdown of answers to the question whether it would be helpful to have the FDA regulate whole-room UVC devices. Of the 96 respondents, 79(82.3%) replied yes, FDA regulations would help, 12(12.5%) were neutral, and 5(5.2%) indicated FDA regulations would not help.

Figure 1: Responses to the question: “would it be helpful to IC professionals to have the FDA regulate whole-room UVC devices?”

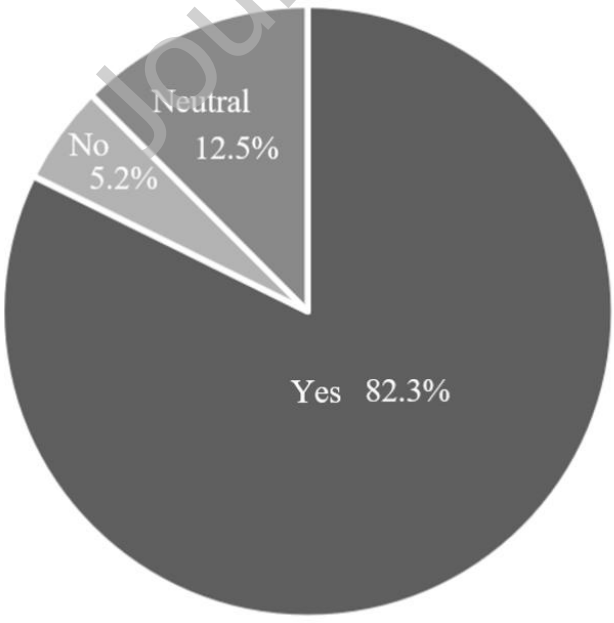
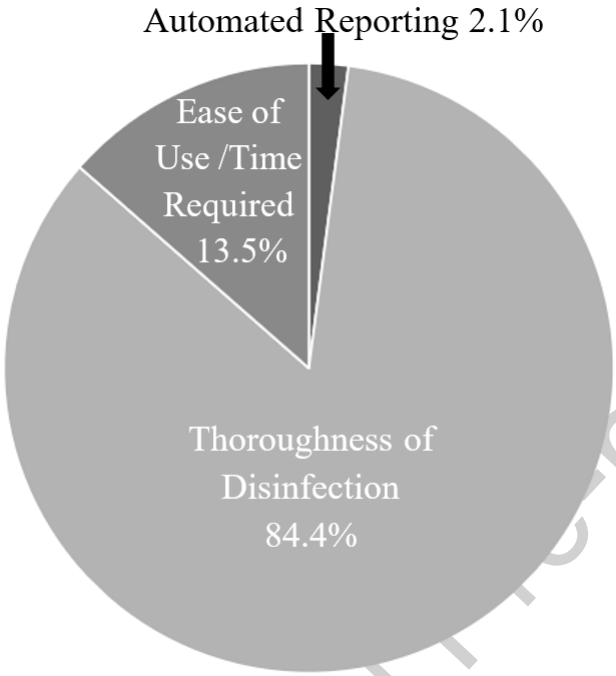


Figure 2 shows that of the three UVC whole-room device attributes, 81(84.4%) ranked "thoroughness of disinfection" as the most important. 12(13.5%) ranked "ease of use & time required" as most important. Only 2(2.1%) ranked automated reporting as most important.

Figure 2: Respondents ranking attributes as most important:



Only 3(3.1%) of respondents ranked thoroughness of disinfection as the least important of the three attributes. 4 of the 5 respondents who replied that FDA regulations would not help nevertheless ranked thoroughness of disinfection as the most important attribute of a UVC whole-room device.

DISCUSSION

The results show that 82.3(±8.2)% Infection Control professionals feel FDA regulations of whole-room UVC devices would be helpful. This may be of interest to the FDA which has thus far excluded their oversight.

It is not surprising that 84.4(±8.4)% Infection Control professionals consider “thoroughness of disinfection” to be the most important attribute of a whole-room UVC disinfecting device while only 2% consider it the least important attribute. The measurement of “thoroughness of disinfection” is beyond the scope of this article and addressed elsewhere [5].

This study like all surveys has limitations. Participants stopped at an exhibit booth of a UVC manufacturer and bias is introduced as respondents likely had an interest in UVC devices where many infection control personnel may not. Although a 10% margin-of-error and 95% confidence levels are generally acceptable statistically, error may still occur.

There are many attributes of UVC whole-room devices that vary among the plethora of device manufacturers. Beyond the three attributes listed as choices, acquisition and operating cost, service, reliability, safety, warranties, availability and other factors influence purchasing and deployment decisions.

Additional healthcare stakeholders including patients, environmental services, bed control, risk management, and financial officers may feel other device attributes are more important than thoroughness of disinfection.

These data support that 84% of infection control professionals surveyed indicate they would benefit from FDA regulation of whole-room UVC devices and that thoroughness of disinfection is the main parameter that must be evaluated and regulated.

Conflicts of Interest Statement:

AK and/or his family have financial interest in Dimer UV, LLC, a manufacturer of Ultraviolet C emitters within and outside of healthcare.
LJ owns and operates Be Local Marketing and is a paid consultant to Dimer UV.
No mention or reference is made to Dimer UV, nor its products and no endorsement is made to any particular technology.
Material support for this study was de minimis and incorporated into existing Dimer UV schedules and funding. The survey was conducted at the Dimer UV booth within the exhibit area at the APIC 2022 Annual Meeting in Indianapolis.

ACKNOWLEDGEMENTS

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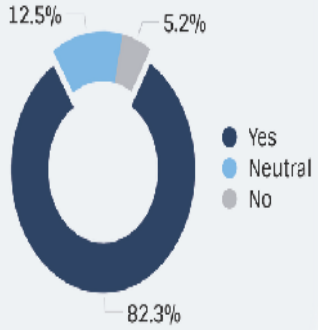
Survey of Infection Control/Prevention Professionals on FDA Regulation of Whole-Room UVC Devices

Would it be helpful to IC professionals to have the FDA regulate whole-room UVC devices?

There are currently no FDA/EPA regulations, standards nor certifications for whole-room UVC devices.

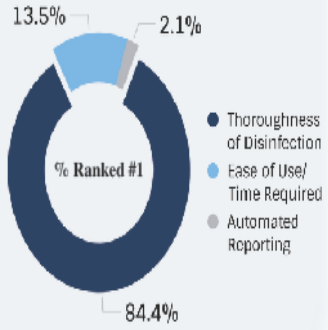
82.3% of IC professionals would find the FDA regulation of UVC devices helpful.



Please rank in order of importance the following 3 attributes of a UVC whole-room disinfection device.

IC professionals consider "Thoroughness of Disinfection" as the most important attribute of a whole-room UVC device.

Other stakeholders, including CFOs, EVS, Bed Control, etc. may have different rankings.



Data with margin of error of 10% and 95% confidence level.

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