Perspectives on Efficacy Standards

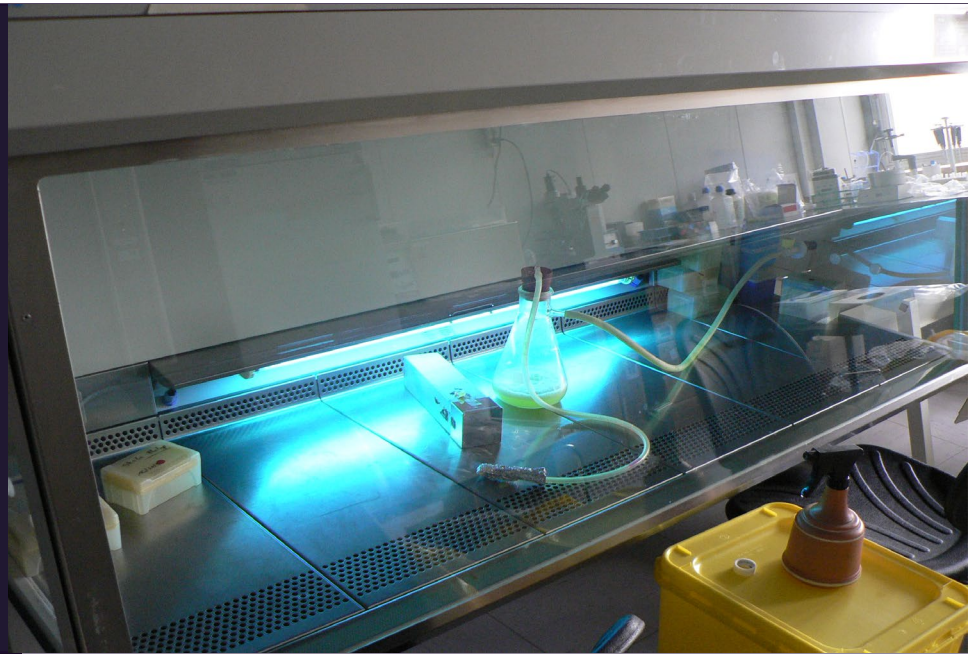
Development of a Standard Test Method for Validating the Antimicrobial Efficacy of Whole Room UV Devices

Matthew Hardwick, PhD
ResInnova Laboratories

ResInnova

INTRO

- Ultraviolet germicidal irradiation has a long history
  - 1st documented in mid– late 19th century*
  - Water treatment (early 1900s)
  - Air decontamination (1930s)
  - Surface decontamination (?????)



*Schmarda LK. Der Einfluss des Lichtes auf die Infusionsthierchen. Med Jahrbüucher des k. k. Österreichischen Staates. 1845;54:257–70.
Downes A, Blunt TP. The influence of light upon the development of bacteria. Nature. 1877;16:218.

Whole Room Disinfection

- Introduced to healthcare around 2007
- Industry has grown dramatically recently
- Do these devices work?
  - Numerous research articles
  - Clinical trials
  - Consistency is an issue (Boyce/Donskey 2019)

Federal Regulation

- EPA kicked the can down the road in 1976
  - Regulation without Registration
  - FIFRA section 2(q)(1) and section 7
- Therefore, no guidance or standards regarding efficacy testing
- Lead to different approaches in testing and confusion for the consumer

Testing Standards

Testing Standards

International Standards Organization (ISO)

“International Standards make things work. They give world-class specifications for products, services and systems, to ensure quality, safety and efficiency. They are instrumental in facilitating international trade.”

Testing Standards

ASTM International

“Over 12,000 ASTM standards operate globally. Defined and set by us, they improve the lives of millions every day. Combined with our innovative business services, they enhance performance and help everyone have confidence in the things they buy and use.”

Testing Standards

- American National Standards Institute (ANSI)
- NSF International
- ANSI/NSF 55

Testing Standards

Goals

- Quality
- Consistency
- Consumer Confidence

Testing Standards

ASTM E3135-18

Standard Practice for Determining Antimicrobial Efficacy of Ultraviolet Germicidal Irradiation Against Microorganisms on Carriers with Simulated Soil

IUVA Testing Standard

Goals

- Provide clarity on the antimicrobial efficacy of the UV device in a controlled setting
- Utility to manufacturers and benefit the industry
- *Improve public health*

IUVA Testing Standard

Scope

The antimicrobial efficacy of a UV generating device will be evaluated by inoculating a specific strain of a known micro-organism on a test carrier and exposing it to the UV device using a standard test protocol. After exposure, the test carrier will be assayed and quantified for surviving microbes to determine the log reduction achieved by the device.

IUVA Testing Standard

UV Devices

- All whole room UV devices emitting radiation in the UV spectrum (200-400 nm)
- Includes portable and self-propelled devices
- Includes devices that deploy as multiple units

IUVA Testing Standard

Testing Facility

- *Still in development*
- Includes a full patient room with a side bathroom
- Performed in an accredited laboratory/organization

IUVA Testing Standard

Testing Organisms

- *Still in development*
- *Clostridioides difficile* (*C. difficile*) spores
  - Considered the most difficult to kill of the relevant HAI-pathogens
  - Spores prepared according to EPA MB-28-04

IUVA Testing Standard

Testing Organisms (cont)

- Spores to be plated on stainless steel disks according to ASTM E2197
  - Plated with 5% serum load as the organic carrier
    - ASTM E3135-18

IUVA Testing Standard

Testing System

- Inoculated disks will be positioned at distinct spots to reflect relevant/important surfaces
  - Bedrails and center of the bed
  - Shaded areas (underside of the overbed table)
  - Near and far positions on the floor
  - Key areas of the bathroom

IUVA Testing Standard

Testing System (cont)

- Positioning and exposure time of the UV device according to manufacturer's recommendation
- Device positioning and UV exposure *should* reflect real-world use of the device
  - In other words, the data should reflect how the device will be used in a healthcare setting

IUVA Testing Standard

Other Important Considerations

- Description of the Testing Chamber/Room
- Environmental Conditions
- Pass/Fail Criteria
- Report Format

Thank You!

- Troy Cowan
- Ashish Mathur
- John Boyce
- IUVA Healthcare Working Group

ResInnova

www.resinnovalabs.com

8807 Colesville Rd
Suite 300
Silver Spring, MD 20910