Required Doses: Variability and Refining Measurements

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Background

- **UV light is increasingly used in conjunction with manual disinfection processes to reduce transmission of pathogens in healthcare facilities**

- **Level to which healthcare-associated pathogens need to be reduced on surfaces to prevent transmission is unknown**
  - **Experts believe that reducing pathogens by 2-3 $\log_{10}$ may be sufficient**

- **For optimal utilization of UV light for disinfection of surfaces, end-users may find it helpful to know:**
  - **UV doses delivered by devices to various surfaces in patient rooms & other clinical areas**
  - **Doses of UV required to adequately reduce healthcare-associated pathogens**

- **Most data on UV doses needed to reduce microorganisms by 2-3 $\log_{10}$ were derived in water or other fluid media**
  - **For organisms that are not healthcare-associated pathogens**
  - **Doses may not reflect those needed for pathogens on hard surfaces**
  - **Doses for healthcare-associated pathogens vary tremendously**

Malayeri AH et al. IUVA News Sept 2016:18
Hijnen WA et al. Water Res 2006;40:3
Mitchell JB et al. J Appl Microbiol 2019;126:58

Variables Affecting UVC Doses Required to Reduce Microorganism Counts

Variable	Comment
Inoculum preparation	May be quite variable for *Clostridioides difficile*
Inoculum size (number of CFUs)	Size: 10^4 - 10^5, 10^5, 10^6, 10^5 - 10^7
Inoculum dispersal onto carrier	Area over which inoculum is spread (drop vs spread over carrier surface)
UV exposure conditions	Inoculum in liquid suspension, suspended in air, placed on agar plate, dried on solid carrier
Carrier material and size	Material: stainless steel, laminate, glass, plastic, aluminum Size (diameter in mm): 10, 20, 40 Size (area in cm^2): 25, 35
Presence and type of organic load	5% or 10% fetal calf serum; 0.03%, 0.3% or 10% bovine serum albumin; ASTM E2197
Pathogen strain studied	E.g., various strains of *E. coli, C. difficile*, MRSA and VRE
Spore formation by microorganism	*C. difficile, Bacillus subtilis*
Relative humidity and temperature	Decreased UV sensitivity with higher humidity and lower temperature
Method for recovery of viable microorganisms after exposure to UV-C	Carrier submerged in liquid; swab; RODAC plate
Type of radiometer/spectrometer	ILT-254; ILT-1700; ILT-2000; General Tools UVC254SD; Ocean Optics JAZ + VIS grating

Cadnum JL et al. Infect Control Hosp Epidemiol 2016;37:555
Boyce JM & Donskey CJ Infect Control Hosp Epidemiol 2019;40:1030

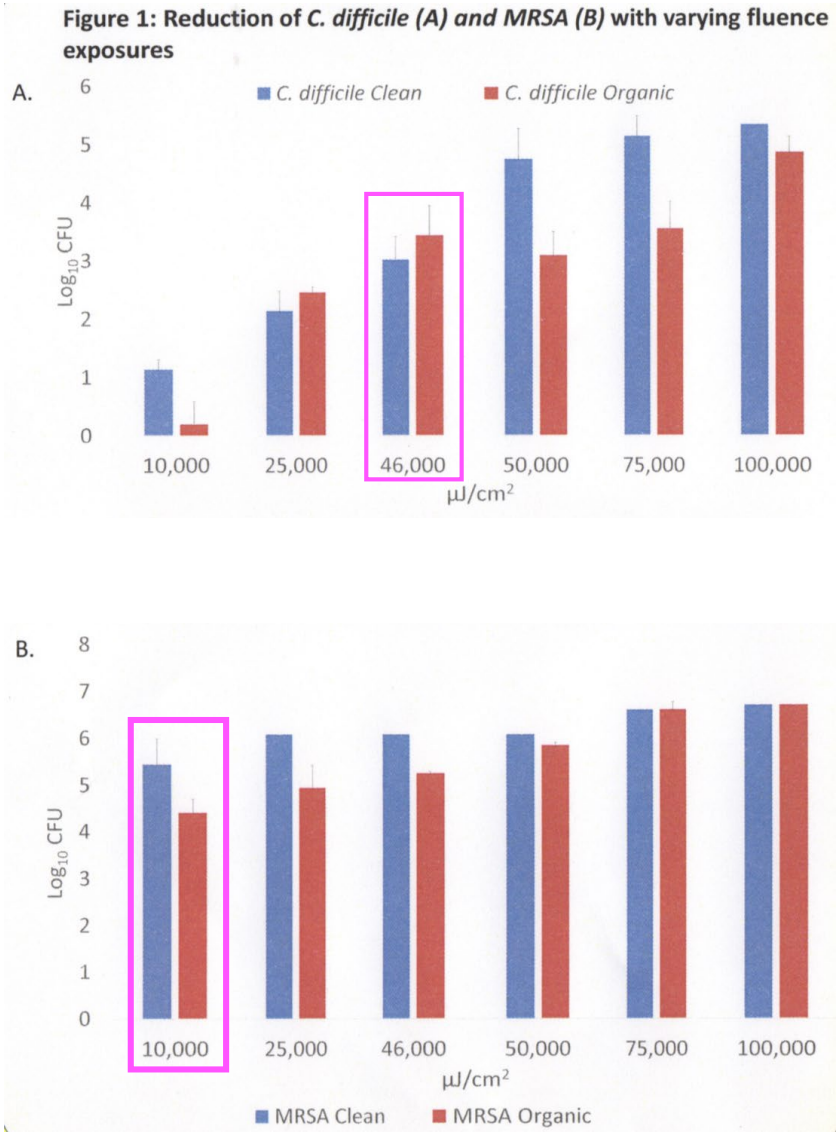
Variability of UVC Dose Required to Achieve 3 log_{10} Reduction of Selected Pathogens

Author	Organism	Strain Tested	UV-C Source	Carrier Type	UV Dose (uWs/cm^2)	Log_{10} Reduction
Moore[21]	*C. difficile*	NCTC 11209 027 027	UV Cabinet	Stainless steel	318,000 636,000 1,590,000	3.55[a] 1.44 2.18
Rutala[22]		027	Mobile device	Formica	~600,000	3.35[b]
Boyce[12]		ATCC 9689	Mobile device	Stainless steel	67,567 342,667	1.0–3.0[b] >2–3.0[b]
Alhmidi[34]		ATCC 43598	Disinfection device	Touchscreen	~111,000	3.2[a]
Mitchell[24]		ATCC 70057	Collimated beam	Stainless steel Formica	16,000[c] 16,000	3.0[b] 3.0[b]
Rutala[22]	MRSA	USA 300	Mobile device	Formica	~300,000	4.1[b]
Boyce[12]		Clinical isolate	Mobile device	Stainless steel	8,800	3.0[b]
Alhmidi[34]		USA 800	Disinfection device	Touchscreen	111,000 223,000	3.7[a] 4.1[a]
Mitchell[24]		ATCC 43300	Collimated beam	Stainless steel Formica	6,164[c] 11,727[c]	3.0[b] 3.0[b]
Moore[21]	VRE	Clinical isolate	UV cabinet	Hospital surfaces	318,000	1.5 to >5.4[b]
Boyce[12]		Clinical isolate	Mobile device	Stainless steel	29,000	3.0[b]
Mitchell[24]		ATCC 4352	Collimated beam	Stainless steel Formica	11,228[c] 12,44[c]	3.0[b] 3.0[b]
Moore[21]	MSSAd	NCTC 10788	UV cabinet	Stainless steel	318,000	6.2 to >7.2[a]
Moore[21]	*A. baumannii*	Clinical isolate	UV cabinet	Hospital surfaces	318,000	2.3 to >5.7[b]
Moore[21]	*K. pneumoniae*	Environment isolate	UV cabinet	Hospital surfaces	318,000	1.0 to >5.3[b]
Moore[21]	*E. coli*	NCTC 10418	UV cabinet	Stainless steel	318,000	>5.8[a]
Moore[21]	*Ps. aeruginosa*	NCTC 6749	UV cabinet	Stainless steel	318,000	>6.1[a]

Boyce JM & Donskey CJ Infect Control Hosp Epidemiol 2019;40:1030

UVC Doses Yielding Log_{10} Reductions of *C. difficile* and MRSA

- Recent laboratory study exposed *C. difficile* and MRSA to doses (fluence) of UVC ranging from 10,000 to 100,000 uJ/cm²
- Carrier: steel disks
- Without [ ] and with [ ] organic load
- Results
  - Doses required to consistently achieve 3 log_{10} reductions were:
    - C. difficile: 46,000 uJ/cm²
    - MRSA: 10,000 uJ/cm²
- Additional studies to determine microorganism UV sensitivity using dose-response curves are needed with other pathogens



Cadnum JL et al. IDWeek 2019 Abstract # 1215
Bolton JR IUVA News 2018;20:27

Needs Assessment

- **IUVA Healthcare/UV Working Group supports the development of:**
  - **More data on doses required to adequately reduce healthcare-associated pathogens**
  - **Standardized method for assessing the efficacy of UV devices used in healthcare**

- **Bolton has suggested the following approaches to standards development:**

  - **Standard protocol for validating UV disinfection devices for surface disinfection which are based on biodosimetry, not unlike protocols for water disinfection recommended by EPA and regulatory agencies in other countries**

  - **Determining UV sensitivity of a standard microorganism using dose-response methods**

Cowan TE Infect Control Hosp Epidemiol 2016;37:1000
Martinello RA IUVA News 2018;20:12
Mathur A IUVA News 2018;20:17
Miller CC et al. IUVA News 2018;20:22
Bolton JR IUVA News 2018;20:27

A Suggested Approach to Determining UV Sensitivity

- **Define a standard surface**
  - **(Should be representative of surfaces encounted in healthcare facilities)**
- **Inoculate standard surface (carrier) with fixed colony count**
- **Install device as recommended by the manufacturer**
- **Activate the device and allow for a warm-up period**
- **Expose standard surface to UV for fixed time period**
  - **Repeat process for varying exposure periods**
- **Compare colony counts of microorganism on exposed & unexposed surfaces**
  - **Determine $\log_{10}$ reductions**
- **Determine dose-response curve for standard microorganism**

Bolton JR IUVA News 2018;20:27

Developing a Standardized Method of Validating Device Efficacy

- IUVA Healthcare/UV Working Group is currently drafting a proposed standard method of validating mobile UV devices used in healthcare settings
- Adoption of some elements of existing standardized methods from ASTM, EPA or other organizations might facilitate approval
- Development of the proposed standard may benefit from:
  - Technical input
  - Communication
  - Collaboration

  with relevant regulatory agencies and standards-setting organizations

Test Variable

- Test organism(s)
- Inoculum preparation
- Standard inoculum size & application technique
- Carrier (coupon) type
- Soil load
- Temperature & relative humidity
- UV exposure (cycle) time
- Distance(s) - device to carrier
- Angle(s) – device to carrier
- Recovery fluid
- Efficacy criteria ($\log_{10}$ reduction)
- Type of radiometer/spectrometer

Thank you for your attention

Examples of Variables to Be Discussed for Validating Device Efficacy

Test Variable	Potential Examples
Test organism(s)	*C. Difficile* ATCC 43598 (ASTM E2839 or E3135) *B. Subtilis* ATCC 6633
Inoculum preparation	Adopt ASTM 2839 -18 method for *C. difficile* (EPA)
Standard inoculum size & application	10^5 or 10^6 CFU; spread over entire surface of carrier
Carrier (coupon) type	Stainless steel disks
Soil load	ASTM E2197 formula (EPA)
Temperature & relative humidity	Similar to conditions in healthcare facilities
UV exposure (cycle) time	Standardized vs recommended by manufacturer
Distance(s) - device to carrier Angle(s) – device to carrier	Consider 4 ft (1.3 m) and 10 ft (3.3 m) 0, 45 and 90 degrees
Recovery fluid	Consider ASTM E2197 protocols
Efficacy criteria	2 - 3 $\log_{10}$ reduction of test organism
Type of radiometer/spectrometer	Input from NIST

Cadnum JL et al. Infect Control Hosp Epidemiol 2016;37:555
Bolton JR IUVA News 2018;20:27
Cadnum JL et al. Infect Control Hosp Epidemiol 2019;40:158
Boyce JM & Donskey CJ Infect Control Hosp Epidemiol 2019;40:1030