AIPI

May 2019

The Voice of The Customer is Critical to Success
(…but they usually speak another language)

Outline

- Listening
- Using the Comparative Effectiveness Approach
- Summary of the Needs (that everyone understands)
- Addressing the needs – Background & Physics 101
- The Output of the Process

Setting The Stage

We will use the development of an ultraviolet technology from voice of customer through saleable product – to highlight innovation, assessing needs, and understanding ultraviolet disinfection.

Discuss key underlying needs, the critical nature of not necessarily learning to speak the customer's "language", but being able to hear, understand, and translate what was heard

Why am I here? The “right time”

In team formation, there must be a reason to be together to form a team.

To ask the customer about a need to be satisfied, there must be a reason to be with them – at least an idea of their need and some basis of possible solutions is one approach

“Okay, it’s time to innovate!” - This is unrealistic…

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Einstein

“If I have one hour to solve a problem, I’ll spend the first 55 minutes understanding what the problem is and the last 5 minutes solving it.”

Listening

Hear
Understand
Translate

#1 job - “The Listener”

Solution

This story starts after a problem has been identified and we have a basic idea of possibly how to solve it, very loosely defined, if at all.

What would the solution look like?

Customer Needs & Using Comparative Effectiveness as a guide

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CES

Comparative Effectiveness Studies (CES) utilize eight parameters to critically evaluate technologies, methods, or solutions.

Each assessment for the eight parameters provides quantitative and/or qualitative measures to assign the result of each assessment.

Allows us to hear what the customer is saying

CES

Acceptability: What is acceptable?

What are the characteristics of an acceptable solution?

Adoption: Would this be used if we had it?

What characteristics of the solution would allow or block adoption of the solution?

Appropriateness: Is it reasonable to use this?

What characteristics would make a solution that is appropriate for the issue being addressed?

Costs: What does the cost picture look like?

What are the factors around costs that need to be considered in a good solution?

Feasibility: Practically speaking, can this be done?

What characteristics would make the solution be seen as practical?

Fidelity: Will we use this continually?

What are the characteristics of the solution that will cause it to be used on an on-going basis?

Penetration: How far through our facility will we deploy this?

What characteristics would the solution have that would allow the broadest application possible?

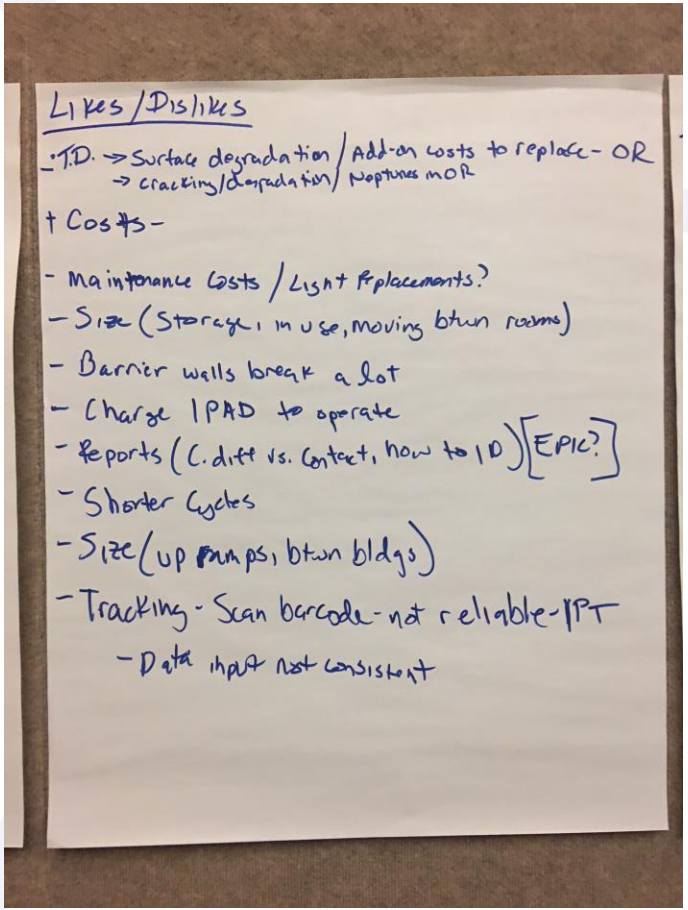
Sustainability: Once we start, will we continue?

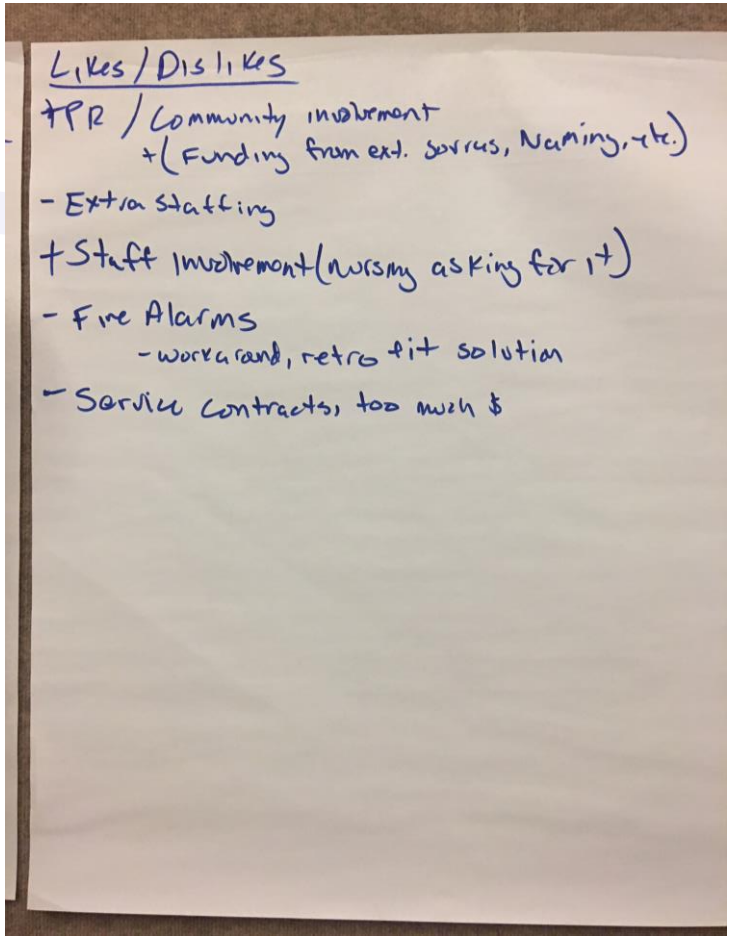
What characteristics would the solution have that allow it to remain a viable robust solution for the longer term?

Hear, Understand, Interpret

Review of Comparative Effectiveness as a Design Tool

…a number of needs





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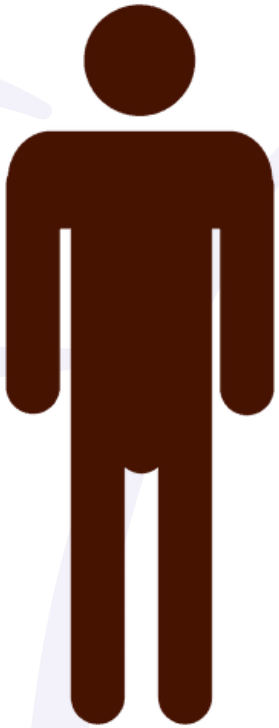

Needs Translated

X, Y, Z Solution

- <40 pounds / 18 Kgs, ideally lighter by 50%
- < 24”/50cm at widest side
- Setup and take down < 60 seconds, ideally 30
- < 5 minute cycles, longer if desired
- 2 forms of automatic safety
- No residue, no damage
- 1-2-3 / A-B-C operation
- Effective in soil/no soil
- Just close the door
- No waiting before or after
- Minimal/no on-going service
- Tested and shown to have efficacy
- Small form factor
- Ease of use
- Low cost
- Automate settings / eliminate touch
- Use facility wide
- Scalable
- Unbox and press start

Operationalizing is key

What is available and why is it interesting?

Do any satisfy needs clearly?

–Background, Evaluation and Decisions

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Cleaning compliance of **patient room** surfaces not at acceptable levels

- Carling (2008) studied cleaning compliance across 23 acute care facilities and found that overall compliance of key surfaces was 49% (range 35-81%), indicating half of high touched surfaces were not being routinely cleaned during discharge (terminal) cleaning of patient rooms.
  - Cleaning compliance varied significantly by surface (bathroom light switch = 20%, sink = 82%).
  - High variability between hospitals, with the cleaning compliance by surface in a different order for each hospital.

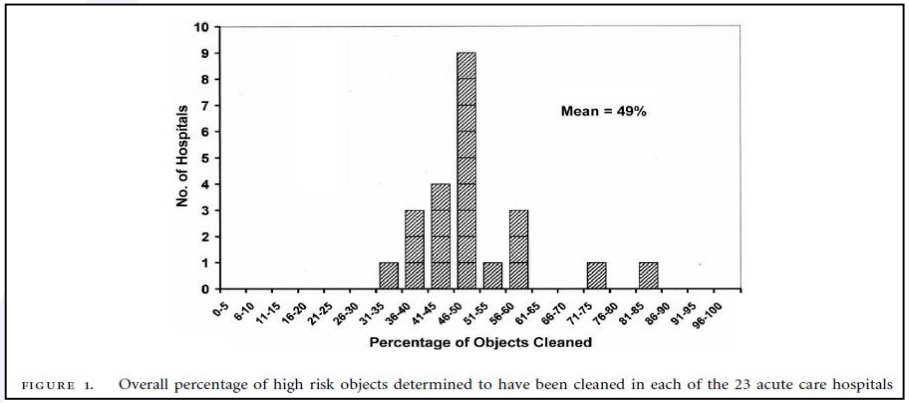


FIGURE 1. Overall percentage of high risk objects determined to have been cleaned in each of the 23 acute care hospitals

Carling, et al, “Identifying Opportunities to Enhance Environmental Cleaning in 23 Acute Care Hospitals”, Infect Control Hosp Epidemiol, 2008; 29: 1-7.

Operating rooms cleaning compliance also very poor

- A 6 hospital study by Jefferson (and Carling) showed that (similarly to patient rooms) operating room cleaning compliance was ~25%.
- Some surfaces were cleaned as frequently as 70%, while others were as infrequently as <10%, showing a wide range in cleaning compliance.
- A lack of consistent cleaning compliance is driving interest in other solutions, such as no touch disinfection.

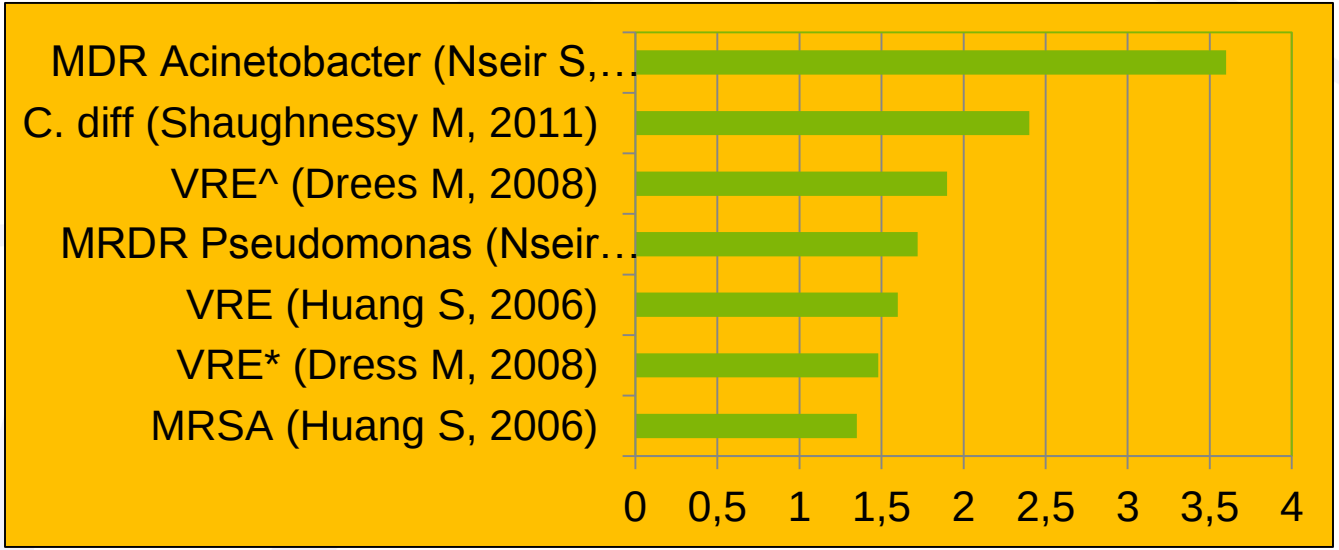
TABLE 2. Thoroughness of Cleaning

Object	Mean proportion cleaned (%)	Lowest proportion cleaned (%)	Highest proportion cleaned (%)	Standard deviation	95% CI
Main door	34.3	0	72	30.5	2.3 to 66
Main field light	33	0	65	23	9 to 56
Telephone	29.8	13	50	16	13 to 46
Anesthesia machine	28	10	50	17	7.5 to 49
Bovie control	22	0	67	26	0 to 54
Second OR door	21.7	5	65	22	1 to 44
Anesthesia cart	20.6	0	73	31	0 to 59
Main light switch	14.5	3	20	7	7.3 to 22
Second field light	14.2	0	27	12	1 to 34
Storage cabinet handle	5.6	0	17	8	1 to 15
Mean	**24.9**	**9**	**50**	**15**	**9.3 to 40**

Jefferson, et al, “A novel technique for identifying opportunities to improve environmental hygiene in the operating room ”, AORN J. 2011;93:358-364.

Risks Associated with the Environment

- Patients admitted into a room previously occupied by colonized or infected patient were significantly more likely to contract an infection



Prior room occupant infected; ^Any room occupant in prior 2 weeks infected

Otter, “Evidence that contaminated surfaces contribute to the transmission of hospital pathogens and an overview of strategies to address contaminated surfaces in hospital settings”. American Journal of Infection Control, 2013; 41: S6-S11.

Bundles are acknowledged tools

American Journal of Infection Control 41 (2013) S20-S30

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Original research article

Best practices in disinfection of noncritical surfaces in the health care setting: Creating a bundle for success

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Key Words:
Environmental cleaning
Cleaning bundles
Healthcare cleaning

Because increasing evidence suggests that the environment plays a role in transmission of health care-associated infections, more attention is focusing on environmental cleaning and improving its efficacy. Creating and sustaining a successful cleaning and disinfection program should include several key components using a bundle approach and requires ongoing commitment within the institution.

Because there is a growing body of evidence that the environment plays a role in the transmission of health care-associated infections (HAIs),[1-5] more attention is being focused on environmental cleaning and ways of improving the efficacy of the cleaning process to decrease the spread of HAIs in the health care setting.[6,7] Several studies have shown that there is increased risk of acquiring a HAI for patients placed in rooms where the previous occupant was colonized or infected with a pathogenic organism.[7-10] Current guidelines recommend that health care facilities clean noncritical surfaces on a regular basis, when spills occur, and when these surfaces are visibly soiled.[11,12] However, because several studies have reported that cleaning practices are often suboptimal,[13,14] it is now recognized by the Centers for Disease Control and Prevention and professional societies that there is a need for a system for monitoring adherence to recommended cleaning practices to ensure consistent cleaning and disinfection of surfaces in patient rooms.[15] Several studies have shown that monitoring and providing feedback to the housekeeping staff can show significant improvement in their cleaning practices,[13,14] but others have demonstrated that the improvement is not always sustainable.[16] Administrative leadership and interdepartmental involvement are necessary to achieve success, and sustainability requires an ongoing commitment within the institution.

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CREATING A BUNDLE FOR SUCCESS

Similar to the Institutes for Healthcare Improvement bundle models for central lines and ventilators to prevent HAIs, an evidence-based care bundle is also needed for a successful environmental cleaning and disinfection program. Key components of this bundle should include the following: policies and procedures to delineate cleaning responsibilities among staff; selection of appropriate cleaning products; determining the method of application for the products; and to educate, monitor, and give feedback to the staff. All of these elements are required to create a bundle for a successful cleaning and disinfection program.

Creating policies and procedures

The first step in creating a successful environmental cleaning program is to form a multidisciplinary task force as described by Dumigan et al.[17] The team should comprise members from administration, nursing, environmental services, infection prevention (hospital epidemiologist, infection preventionist), materials management, biomedical engineering, pharmacy, and epidemiology laboratory personnel. Every discipline that has any role in the cleaning process needs to be represented so that policies and procedures can be effectively defined. The policies need to clearly define the cleaning task, the responsible service to perform the task, the cleaning frequency, and the products to be used. Figure 1 is an example of a grid that defines these items in a cleaning policy.

Following the Spaulding definitions, which categorize levels of disinfection based on the object's intended use and risk for infection in the use of that item, noncritical surfaces in the health care setting are those that only touch intact skin, and these require

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Adjunct Technologies

What are **adjunct technologies?**

- Adjunct Technologies are tools used in addition to existing practices
- These technologies are **not** a substitute for manual cleaning.
- Manual cleaning is **always** required prior to the use of additive technologies to remove biofilms, dirt, debris, smears and other soils
- These additive technologies are best thought of as insurance

Examples of adjunct technologies are UVC systems, aerosolized hydrogen peroxide, hydrogen peroxide vapor, and some variants.

Leading epidemiologists all point to the value of additional disinfection technologies as powerful, effective, and needed to cover gaps in manual cleaning processes.

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Major article

Effectiveness of ultraviolet devices and hydrogen peroxide systems for terminal room decontamination: Focus on clinical trials

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Key Words:
Health care–associated infections
ultraviolet light
ultraviolet C
pulsed xenon
hydrogen peroxide systems
room decontamination
surface environment

Over the last decade, substantial scientific evidence has accumulated that indicates contamination of environmental surfaces in hospital rooms plays an important role in the transmission of key health care–associated pathogens (eg, methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant enterococci, *Clostridium difficile*, *Acinetobacter* spp). For example, a patient admitted to a room previously occupied by a patient colonized or infected with one of these pathogens has a higher risk for acquiring one of these pathogens than a patient admitted to a room whose previous occupant was not colonized or infected. This risk is not surprising because multiple studies have demonstrated that surfaces in hospital rooms are poorly cleaned during terminal cleaning. To reduce surface contamination after terminal cleaning, no touch methods of room disinfection have been developed. This article will review the no touch methods, ultraviolet light devices, and hydrogen peroxide systems, with a focus on clinical trials which have used patient colonization or infection as an outcome.

Multiple studies have demonstrated that ultraviolet light devices and hydrogen peroxide systems have been shown to inactivate microbes experimentally plated on carrier materials and placed in hospital rooms and to decontaminate surfaces in hospital rooms naturally contaminated with multidrug-resistant pathogens. A growing number of clinical studies have demonstrated that ultraviolet devices and hydrogen peroxide systems when used for terminal disinfection can reduce colonization or health care–associated infections in patients admitted to these hospital rooms.

Health care–associated infections (HAIs) remain an important source of patient morbidity and mortality. Based on a large sample of U.S. acute care hospitals, approximately 4% of patients on any given day have at least 1 HAI.[1] Overall, there were an estimated 722,000 HAIs in U.S. acute care hospitals in 2011; approximately 75,000 hospital patients with an HAI died during their hospitalization. It has been estimated that the source of pathogens causing an HAI in the intensive care unit was the patients' endogenous flora (40%-60%); cross-infection via the hands of health care personnel (HCP; 20%-40%); antibiotic-driven changes in flora (20%-25%); and other (including contamination of the environment; 20%).[2] Further, contamination of the hands of HCP could result directly from patient contact or indirectly from touching contaminated environmental surfaces.[3] It has been shown that the gloves or hands of HCP are just as likely to become contaminated from touching a patient as touching an environmental surface in a patient's room.[4,5]

Over the last decade, substantial scientific evidence has accumulated that contamination of environmental surfaces in hospital rooms plays an important role in the transmission of several key health care–associated pathogens, including methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), *Clostridium difficile*, *Acinetobacter* spp, and norovirus.[6–11] In general, all of these pathogens share the following characteristics:

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Conflicts of Interest: Dr Boyce is a consultant to Bioquell; Drs Boyce, Rutala, and Weber are consultants to Clorox.

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http://dx.doi.org/10.1016/j.ajic.2015.11.015

Scientific literature contains more than 40 studies measuring either the biocidal effect of UV-C light on microorganisms or the impact on HAI rates

•Nagaraja A, et al, “Clostridium difficile infections before and after use of ultraviolet disinfection”, Am J of Infect Cont, 2015; 43: 940-945.

•Haas JP, “Implementation and impact of ultraviolet environmental disinfection in an acute care setting”, Am J of Infect Cont, 2014; 42: 586-590.

•Catalanotti A, “Influence of pulsed-xenon ultraviolet light-based environmental disinfection on surgical site infections”, Am J of Infect Cont, 2016; 44: e99-e101.

•Miller R, et al, “Utilization and impact of a pulsed-xenon ultraviolet room disinfection system and multidisciplinary care team on Clostridium difficile in a long-term acute care facility”, Am J of Infect Cont, 2015; 43: 1350-1353.

•Levin J, et al, “The effect of portable pulsed xenon ultraviolet light after terminal cleaning on hospital-associated Clostridium difficile infection in a community hospital”, Am J of Infect Cont, 2013; 41: 746-748.

•Vianna PG, et al, “Impact of a pulsed xenon ultraviolet light on hospital-acquired infection rates in a community hospital”, Am J of Infect Cont, 2016; 44: 299-303.

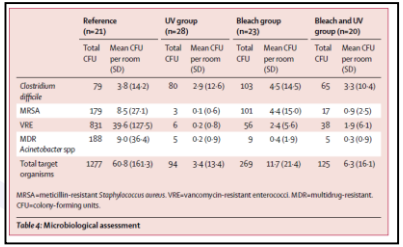
•Pegues DA, et al, “Impact of ultraviolet germicidal irradiation for no-touch terminal room disinfection on Clostridium difficile infection incidence among hematology-oncology patients”, Infect Cont and HospEpidemiol, 2017; 38 (1): 39-44.

•Napolitano NA, et al, “The effectiveness of UV-C radiation for facility-wide environmental disinfection to reduce health care-acquired infections”, Am J of Infect Cont, 2015; 43: 1342-1346.

•Anderson DJ, et. al. “Enhanced terminal room disinfection and acquisition and infection caused by multi-drug-resistant organisms and Clostridium difficile (the benefits of enhanced terminal room disinfection study): a cluster-randomised, multicentre, crossover study”. Lancet, 2017: 389: 805-814.

Large UV study showed reductions in HAI rates

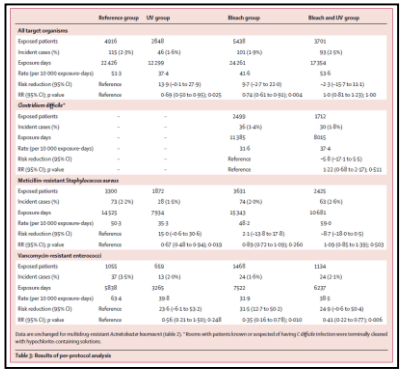
- A nine hospital study (funded by the CDC) over 28 months examined the impact of using UV on patient room discharge cleaning with either bleach or quat disinfectants.
- Key findings:
  - Use of UV lowered the infection rate for target organisms from 51.3 to 33.9 per 10,000 exposure days for rooms cleaned with quat disinfectants.
  - HAI rates were lower if the room was cleaned with bleach, but did not achieve significance (p=0.116).
  - C. diff incidence was not significantly different after using UV on discharge cleaning. MRSA rate was lower, but not statistically significant (p=0.104). VRE had the best rate improvement overall, but using bleach without UV also improved VRE rates.
  - Cleaning compliance was >90% for all groups. Since this applied to the reference group, it may have masked rate decreases that would have been present with typical compliance rates of ~50%.
- **Headline**: 33% reduction in HAI rates



	Reference (n=21)		UV group (n=28)		Bleach group (n=23)		Bleach and UV group (n=20)	
	Total CFU	Mean CFU per room (SD)	Total CFU	Mean CFU per room (SD)	Total CFU	Mean CFU per room (SD)	Total CFU	Mean CFU per room (SD)
Clostridium difficile	79	3·8 (14·2)	80	2·9 (12·6)	103	4·5 (14·5)	65	3·3 (10·4)
MRSA	179	8·5 (27·1)	3	0·1 (0·6)	101	4·4 (15·0)	17	0·9 (2·5)
VRE	831	39·6 (127·5)	6	0·2 (0·8)	56	2·4 (5·6)	38	1·9 (6·1)
MDR *Acinetobacter* spp	188	9·0 (36·4)	5	0·2 (0·9)	9	0·4 (1·9)	5	0·3 (0·9)
Total target organisms	1277	60·8 (161·3)	94	3·4 (13·4)	269	11·7 (21·4)	125	6·3 (16·1)

MRSA=meticillin-resistant *Staphylococcus aureus*. VRE=vancomycin-resistant enterococci. MDR=multidrug-resistant. CFU=colony-forming units.

Table 4: Microbiological assessment



	Reference group	UV group	Bleach group	Bleach and UV group
All target organisms				
Exposed patients	4916	3848	5438	3701
Incident cases (%)	115 (2·3%)	45 (1·6%)	101 (1·9%)	93 (2·5%)
Exposure days	22 426	12 299	24 261	17 354
Rate (per 10 000 exposure days)	51·3	37·4	41·6	53·6
Risk reduction (95% CI)	Reference	13·9 (−0·4 to 27·9)	9·7 (−2·7 to 22·4)	−2·3 (−15·7 to 11·1)
RR (95% CI); p value	Reference	0·69 (0·50 to 0·95); 0·025	0·74 (0·54 to 0·93); 0·004	1·0 (0·81 to 1·23); 1·00
Clostridium difficile*				
Exposed patients	–	–	2499	1712
Incident cases (%)	–	–	35 (1·4%)	30 (1·8%)
Exposure days	–	–	11 385	8065
Rate (per 10 000 exposure days)	–	–	31·6	37·4
Risk reduction (95% CI)	–	–	Reference	−5·8 (−17·1 to 5·5)
RR (95% CI); p value	–	–	Reference	1·22 (0·68 to 2·17); 0·511
Meticillin-resistant *Staphylococcus aureus*				
Exposed patients	3300	1872	3631	2426
Incident cases (%)	73 (2·2%)	18 (1·0%)	74 (2·0%)	63 (2·6%)
Exposure days	14 525	7934	15 343	10 681
Rate (per 10 000 exposure days)	50·3	35·3	48·2	59·0
Risk reduction (95% CI)	Reference	15·0 (−0·6 to 30·6)	2·1 (−13·8 to 17·8)	−8·7 (−18·0 to 0·5)
RR (95% CI); p value	Reference	0·67 (0·44 to 0·94); 0·013	0·93 (0·72 to 1·09); 0·260	1·09 (0·85 to 1·39); 0·503
Vancomycin-resistant enterococci				
Exposed patients	1055	659	1468	1134
Incident cases (%)	27 (2·5%)	13 (2·0%)	24 (1·6%)	24 (2·1%)
Exposure days	5838	3265	7522	6237
Rate (per 10 000 exposure days)	63·4	39·8	31·9	38·5
Risk reduction (95% CI)	Reference	23·6 (−6·1 to 53·2)	31·5 (12·7 to 50·2)	24·9 (−0·6 to 50·4)
RR (95% CI); p value	Reference	0·56 (0·21 to 1·01); 0·248	0·35 (0·16 to 0·78); 0·010	0·41 (0·22 to 0·77); 0·006

Data are unchanged for multidrug-resistant *Acinetobacter baumannii* (table 2). * Rooms with patients known or suspected of having *Clostridium difficile* infection were terminally cleaned with hypochlorite-containing solutions.

Table 3: Results of per-protocol analysis

- Anderson DJ, et. al. “Enhanced terminal room disinfection and acquisition and infection caused by multi-drug-resistant organisms and Clostridium difficile (the benefits of enhanced terminal room disinfection study): a cluster-randomised, multicentre, crossover study”. Lancet, 2017: 389: 805-814.

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Deverick Anderson's recently published follow up to this study is interesting

In summary:
Use "UV" only for targeted specific cleans due to logistical issues

Due to: How long it takes, how few there are, how cumbersome they are

Operationalizing is key

First Generation systems are tower style units

- Existing systems use fixed bulb location tower style units
- Germicidal spectrum light – from pulsed xenon and mercury vapor bulbs
- Units vary in size and number of bulbs and cost
- Some units use sensors to determine the room size and set the cycle length based on that information; use a “puck” to measure dose at a location and run until “X” dose is applied at that point; measure reflected dose and run until a specific value is reflected to the sensor; or run for set cycle length

UV-C has been heavily tested and found effective against viruses, bacteria, and spores

- Boyce JM, et al, “Terminal decontamination of patient rooms using an automated mobile UV light unit”, Infect Cont and Hosp Epidemiol, 2011; 32 (8): 737-742.
- Sitzlar B, et al, “An environmental odyssey: Evaluation of sequential interventions to improve disinfection of Clostridium difficile isolation rooms”, 2013; 34 (5): 459-465.
- Mahida N, “First UK evaluation of an automated ultraviolet-C room decontamination unit (Tru-D)”, J of Hosp Infect, 2013; 84: 332-335.
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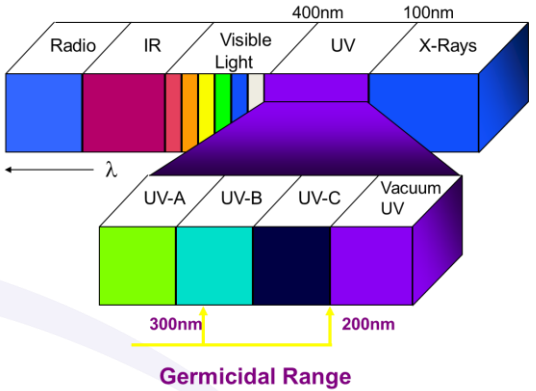
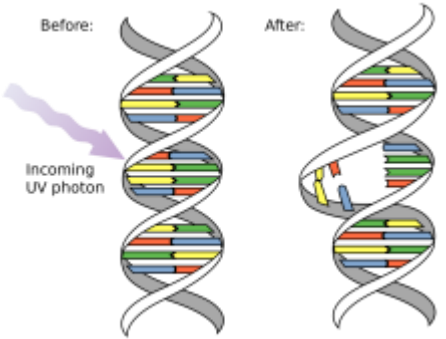
- Boyce JM, et al, “Impact of room location on UV-C irradiance and UV-C dosage and antimicrobial effect delivered by a mobile UV-C light device”, Infect Cont and Hosp Epidemiol, 2016; 37 (6): 667-672.

What exactly is UV in the “C” spectrum
&
How is it being delivered today

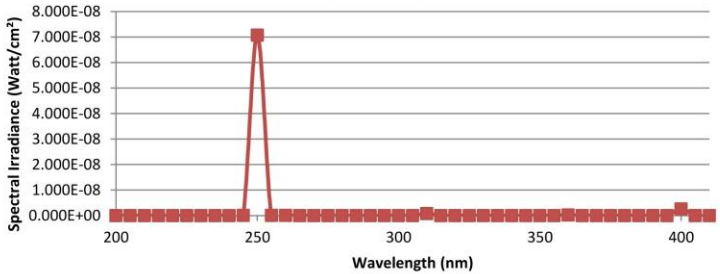
What is ultraviolet C (UVC) light?



- UV is a form of light (i.e. electromagnetic radiation)
- It is invisible to the human eye
- Has been used to disinfect air and water for decades
- It is most effective at light wavelengths of 254 nanometers
- UV light can be UVA (black light), UVB (tanning beds), or UVC (disinfection)
- UVC light waves kill pathogens by deactivating their DNA (dimerization), destroying their ability to multiply and cause disease and can kill potentially dangerous pathogens, such as MRSA, VRE, *C. difficile, Acinetobacter,* and norovirus.

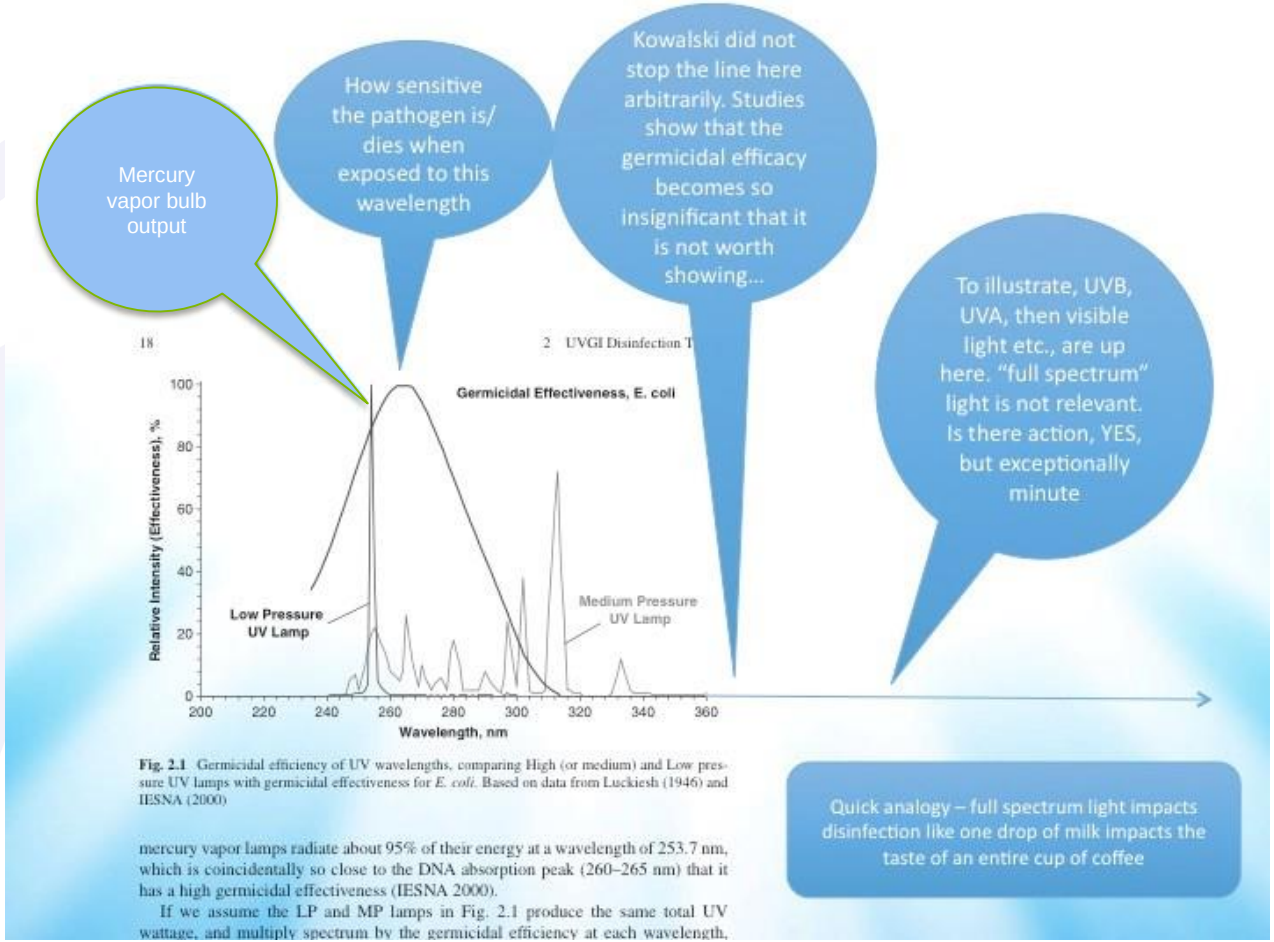


Monochromatic UVC output wavelength



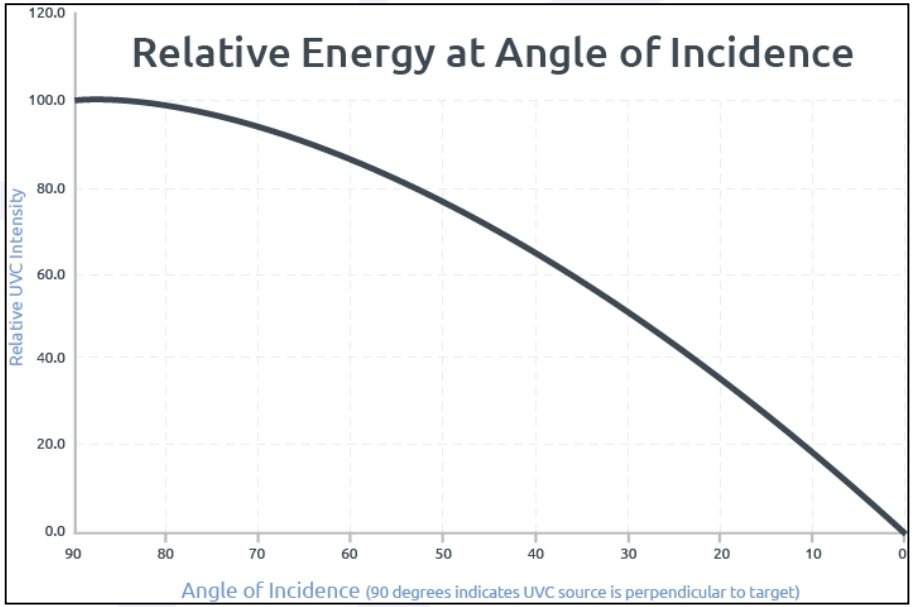
The germicidal efficacy of UVC occurs at specific at wavelengths of energy.

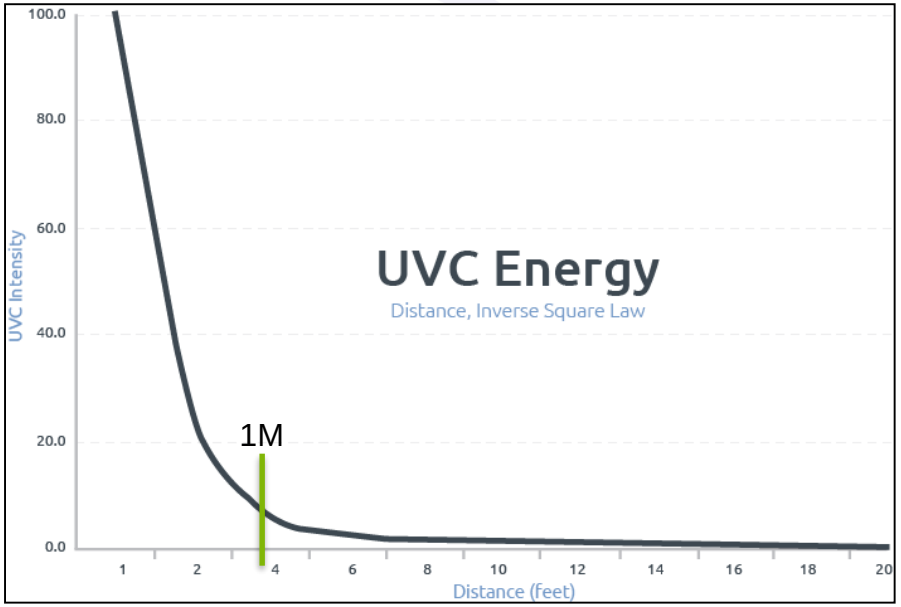
Mercury vapor efficiently generates “near” to peak wavelength energy



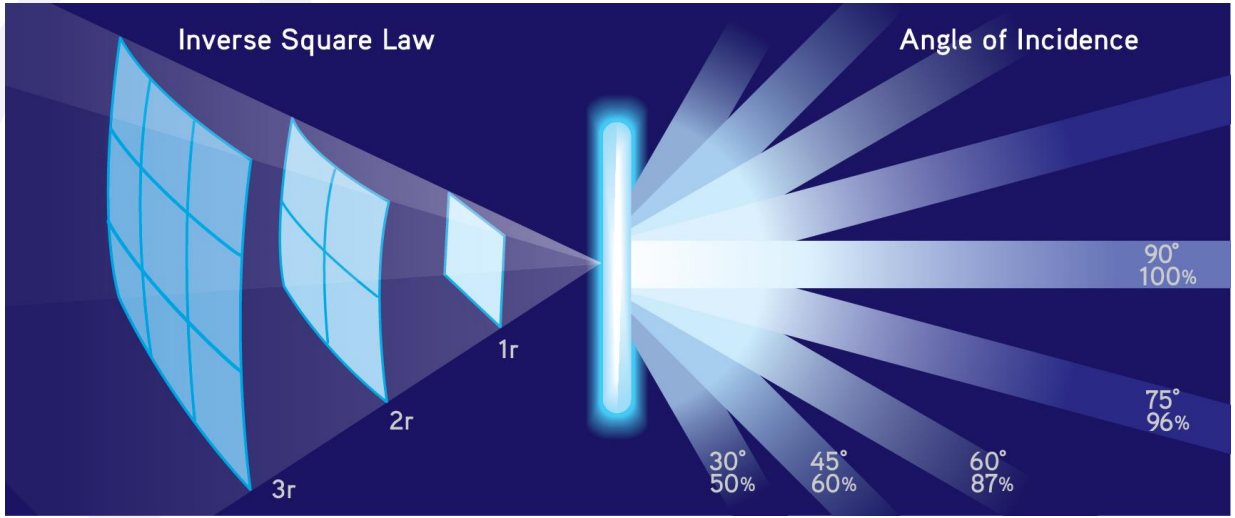
The Science of UVC – In Summary

Effectiveness is determined based on distance and angle of incidence

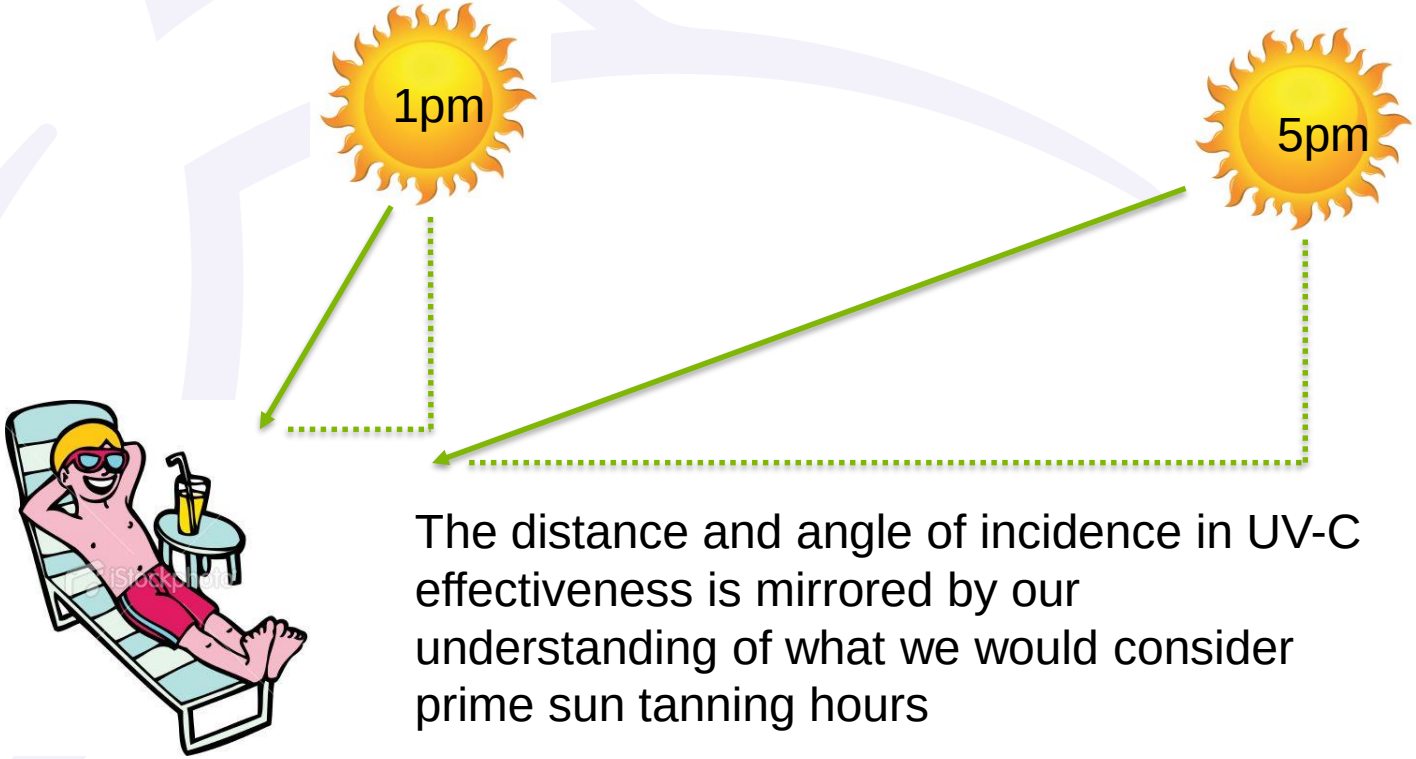




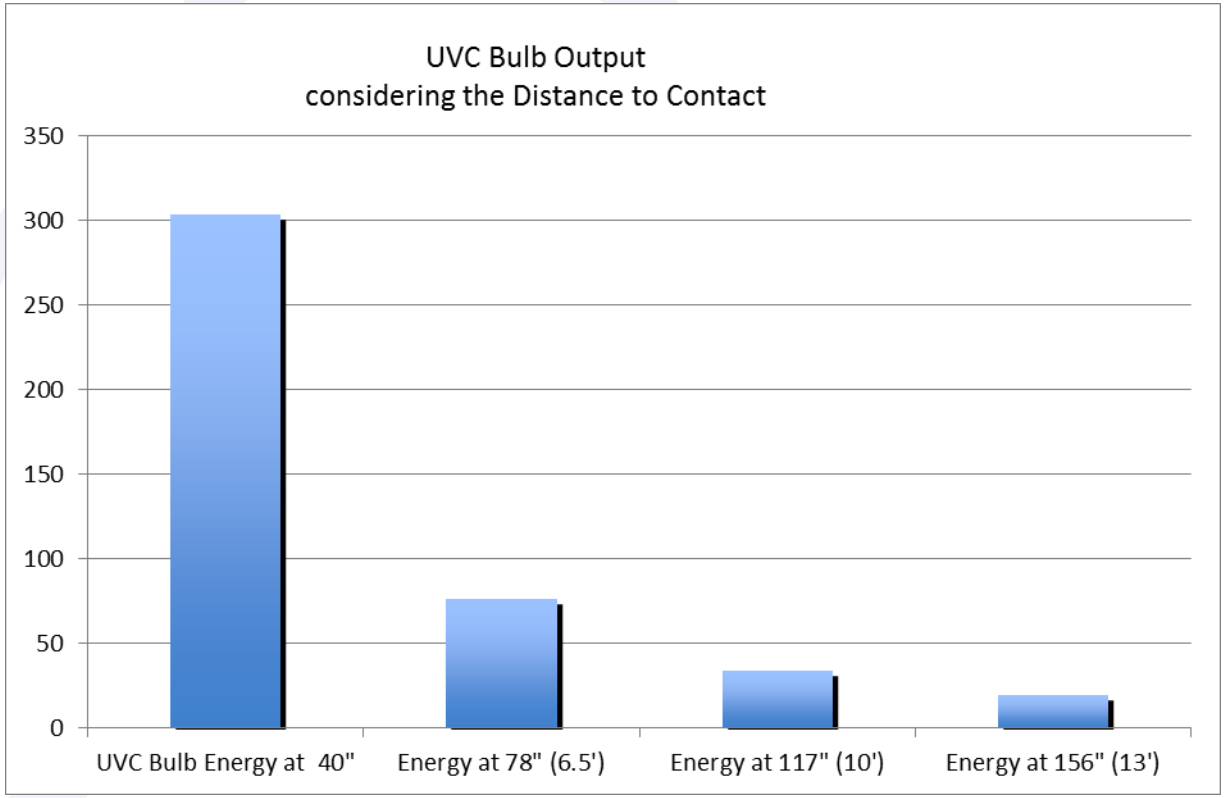
How ultraviolet light (UV-C) works (the science behind the application)

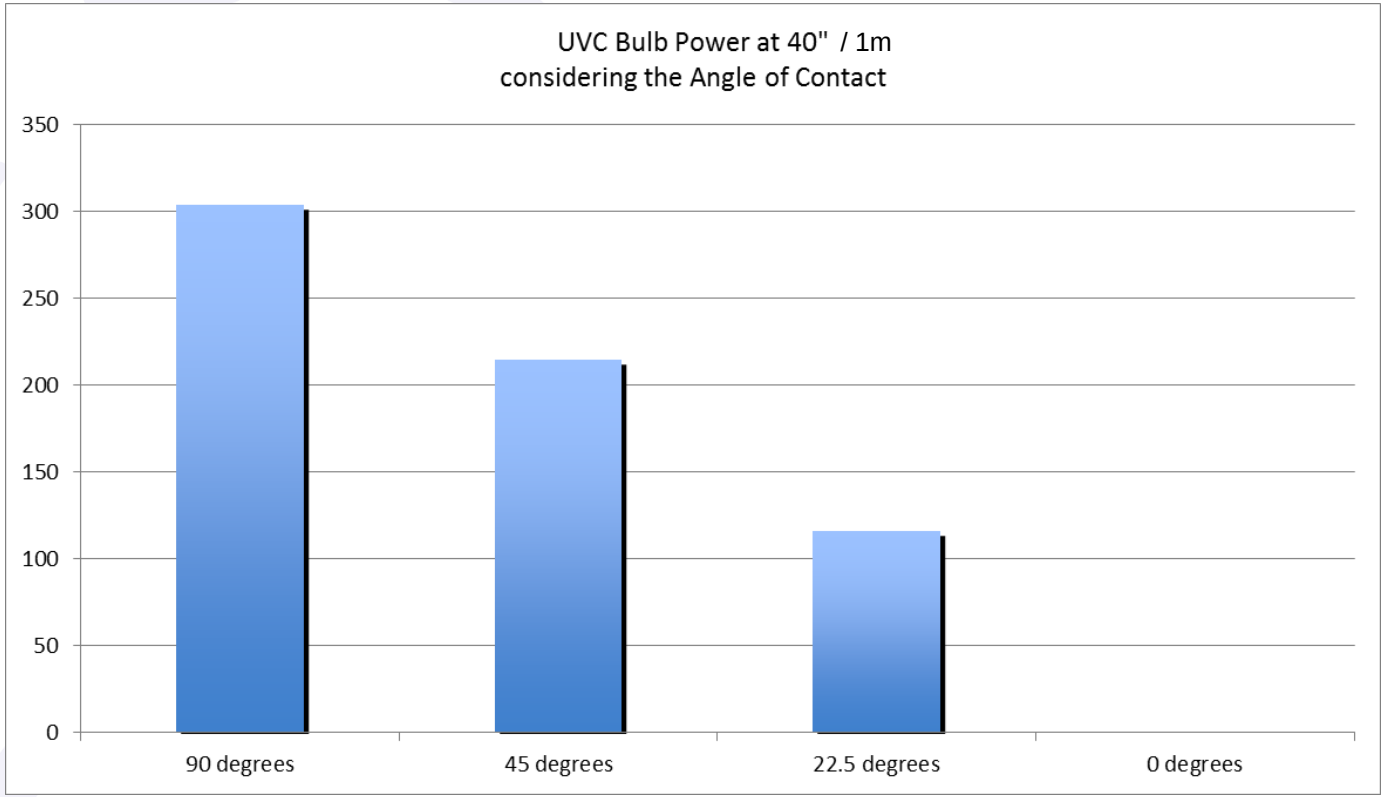


The Angle of Incidence Affects Energy Applied



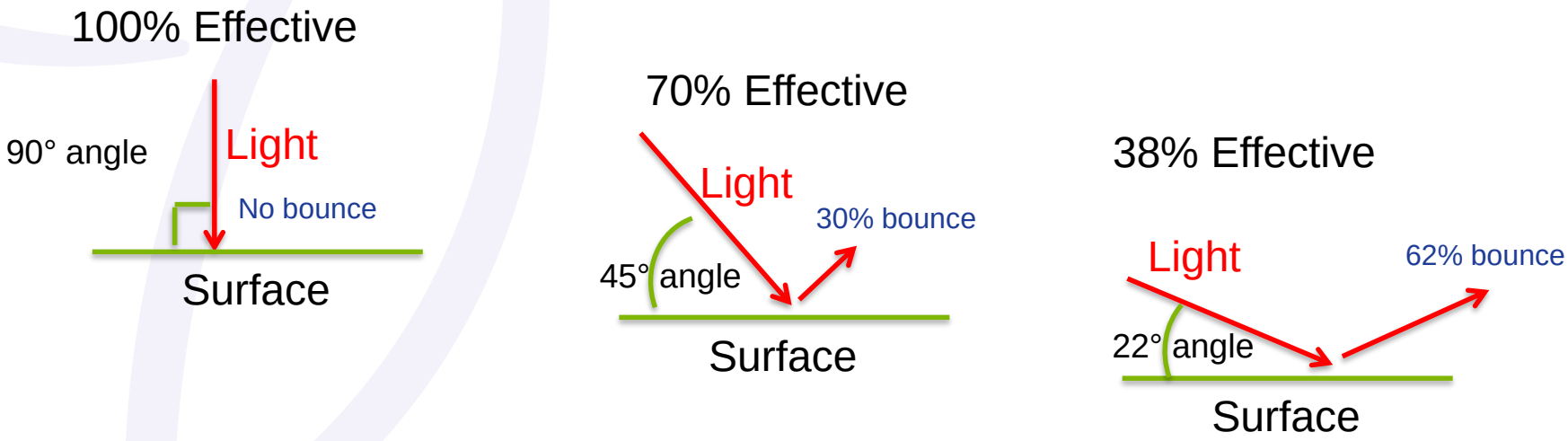
The distance and angle of incidence in UV-C effectiveness is mirrored by our understanding of what we would consider prime sun tanning hours

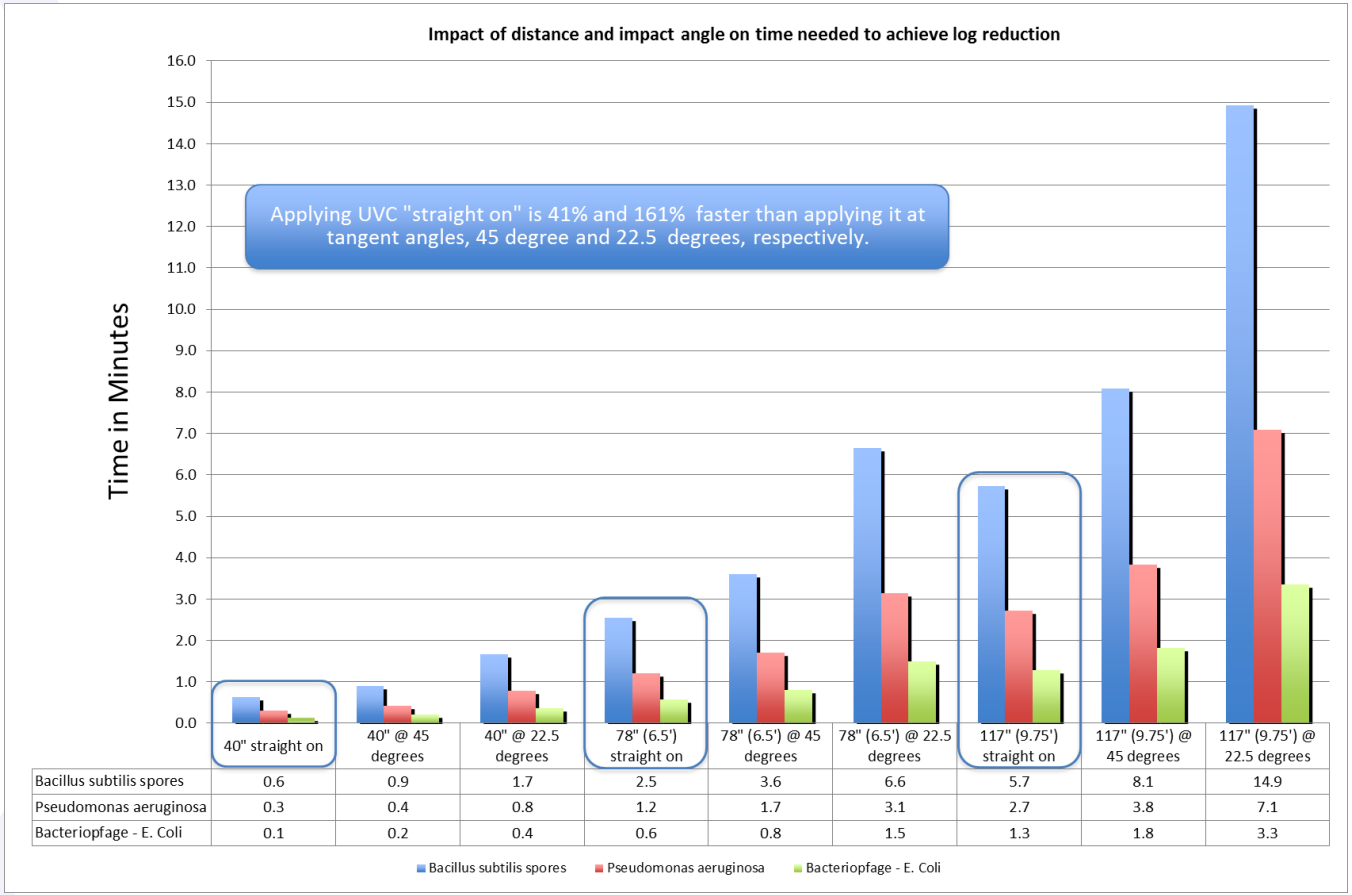

UVC Bulb Output
considering the Distance to Contact
350
300
250
200
150
100
50
0
UVC Bulb Energy at 40"
Energy at 78" (6.5')
Energy at 117" (10')
Energy at 156" (13')


UVC Bulb Power at 40" / 1m
considering the Angle of Contact
350
300
250
200
150
100
50
0
90 degrees
45 degrees
22.5 degrees
0 degrees

UV effectiveness impacted by **angle of incidence**

- UV light intensity **decreases** when the light strikes surfaces at flatter angles
  - Full energy delivered when light is perpendicular to surface (90˚).
  - 70% of energy delivered at 45˚ angle
  - 38% of energy delivered at 22˚ angle (typical UV tower)




Impact of distance and impact angle on time needed to achieve log reduction
Time in Minutes
16.0
15.0
14.0
13.0
12.0
11.0
10.0
9.0
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
Applying UVC "straight on" is 41% and 161% faster than applying it at tangent angles, 45 degree and 22.5 degrees, respectively.
40" straight on
40" @ 45 degrees
40" @ 22.5 degrees
78" (6.5') straight on
78" (6.5') @ 45 degrees
78" (6.5') @ 22.5 degrees
117" (9.75') straight on
117" (9.75') @ 45 degrees
117" (9.75') @ 22.5 degrees
Bacillus subtilis spores 0.6 0.9 1.7 2.5 3.6 6.6 5.7 8.1 14.9
Pseudomonas aeruginosa 0.3 0.4 0.8 1.2 1.7 3.1 2.7 3.8 7.1
Bacteriopfage - E. Coli 0.1 0.2 0.4 0.6 0.8 1.5 1.3 1.8 3.3
Bacillus subtilis spores
Pseudomonas aeruginosa
Bacteriopfage - E. Coli

Impact of Distance and Angle of Incidence on Dose and Log_{10} Reduction – Boyce ICHE 2016

Range of Log_{10} Reductions of MRSA, VRE, and *Clostridium difficile* Achieved with Inoculated Disk Carriers Exposed to UV-C for 5-Minute and 15-Minute Cycles on 3 Occasions at Each Cycle Time

Distance and Orientation of Disks Relative to UV-C Device	Mean UV-C Dosage Measured Adjacent to Disks for 5-Min Cycles, µWsec/cm 2	Range of Log_{10} Reduction with 5-Min Cycles, by Pathogen	Mean UV-C Dosage Measured Adjacent to Disks for 15-Min Cycles, µWsec/cm 2	Range of Log_{10} Reduction with 15-Min Cycles, by Pathogen
1.3 m (4 ft), direct	342,667	MRSA: >4 log VRE: 4 to >4 log	842,000	MRSA: >4 log VRE: >4 log

Time, distance, angle & shade matter – but UV-C kills pathogens

3.3 m (10 ft), direct	67,567	MRSA: 4 to >4 log VRE: 3 to >4 log *C. difficile*: 1–3 log	202.667	MRSA: >4 log VRE: >4 log *C. difficile*: 2–4 log
3.3 m, 0° angle	10,767	MRSA: 4 to >4 log VRE: 2 log *C. difficile*: 0–1 log	29,000	MRSA: 4 to >4 log VRE: 3 log *C. difficile*: 0–2 log
3.3 m, shaded	3,395	MRSA: 1–3 log VRE: 1–2 log *C. difficile*: 0	8,880	MRSA: 3 log VRE: 1–2 log *C. difficile*: 0–1 log

Dr. Boyce ICHE 2016 is a good example of Vertical over-dose to obtain Horizontal under-dose

Range of Log_{10} Reductions of MRSA, VRE, and *Clostridium difficile* Achieved with Inoculated Disk Carriers Exposed to UV-C for 5-Minute and 15-Minute Cycles on 3 Occasions at Each Cycle Time

Distance and Orientation of Disks Relative to UV-C Device	Mean UV-C Dosage Measured Adjacent to Disks for 5-Min Cycles, µWsec/cm 2	Range of Log_{10} Reduction with 5-Min Cycles, by Pathogen	Mean UV-C Dosage Measured Adjacent to Disks for 15-Min Cycles, µWsec/cm 2	Range of Log_{10} Reduction with 15-Min Cycles, by Pathogen
1.3 m (4 ft), direct	342,667	MRSA: >4 log	842,000	MRSA: >4 log
Vertical Surface		to >4 log		VRE: >4 log
				C. difficile: 2 to >4 log
1.3 m, 0° angle	53,900	MRSA: 4 to	148,667	MRSA: >4 log
Horizontal Surface		to >4 log		VRE: 3–4 log
				C. difficile: 2–4 log
1.3 m, shaded	8,547	MRSA: 1–	24,467	MRSA: >4 log
		VRE: 2–3 log		VRE: 2–3 log
		C. difficile: 0		*C. difficile*: 1–2 log
		VRE: 2 log		VRE: 3 log
		C. difficile: 0–1 log		*C. difficile*: 0–2 log
3.3 m, shaded	3,395	MRSA: 1–3 log	8,880	MRSA: 3 log
		VRE: 1–2 log		VRE: 1–2 log
		C. difficile: 0		*C. difficile*: 0–1 log

4 X required dose

Less than required dose

Large overdose of Vertical surface generates less than required Horizontal dose

Time, distance, and angle matter – How much energy is actually applied?

How much energy is actually needed?

UV Dose (mJ/cm^2) Needed For a Given Log Reduction

Log Reduction

	1	2	3	4	5	6	Reference
Staphylococcus aureus ATCC25923	3.9	5.4	6.5	10.4			Chang et al. 1985
Staphylococcus albus	1.84	5.72					Light Sources Inc. 2014
Staphylococcus aureus	2.6	6.6					Light Sources Inc. 2014
Staphylococcus hemolyticus	2.16	5.5					Light Sources Inc. 2014
Staphylococcus lactis	6.15	8.8					Light Sources Inc. 2014
Streptococcus faecalis (secondary effluent)	5.5	6.5	8	9	12		Harris et al. 1987
Streptococcus faecalis ATCC29212	6.6	8.8	9.9	11.2			Chang et al. 1985
Streptococcus viridans	2.0	3.8					Light Sources Inc. 2014
Vibrio anguillarum	0.5	1.2	1.5	2			Liltved and Landfald 1996
Vibrio cholerae ATCC25872	0.8	1.4	2.2	2.9	3.6	4.3	Wilson et al. 1992
Vibrio comma - Cholera	3.375	6.5					Light Sources Inc. 2014
Vibrio natriegens	37.5	75	100	130	150		Joux et al. 1999
Yersinia enterocolitica ATCC27729	1.7	2.8	3.7	4.6			Wilson et al. 1992
Yersinia ruckeri	1	2	3	5			Liltved and Landfald 1996
Spore							
Bacillus anthracis spores - Anthrax spores	24.32	46.2					Light Sources Inc. 2014
Bacillus magaterium sp. (spores)	2.73	5.2					Light Sources Inc. 2014
Bacillus subtilis ATCC6633	24	35	47	79			Mamane-Gravetz an
Bacillus subtilis WN626	0.4	0.9	1.3	2			Marshall et al., 2003
Bacillus subtilis spores	11.6	22.0					Light Sources Inc. 2014
Bacterium							
Aeromonas salmonicida	1.5	2.7	3.1	5.9			Liltved and Landfald 19
Aeromonas hydrophila ATCC7966	1.1	2.6	3.9	5	6.7	8.6	Wilson et al. 1992
Bacillus anthracis - Anthrax	4.52	8.7					Light Sources Inc. 2014
Bacillus magaterium sp. (veg.)	1.3	2.5					Light Sources Inc. 2014
Bacillus paratyphusus	3.2	6.1					Light Sources Inc. 2014
Bacillus subtilis	5.8	11.0					Light Sources Inc. 2014

UV Dose (mJ/cm^2) Needed For a Given Log Reduction

Log Reduction

Virus	Host	1	2	3	4	5	6	
Adenovirus type 15	A549 cell line (ATCC CCL-185)	40	80	122	165	210		Thompson et al. 2003
Adenovirus type 2	A549 cell line	20	45	80	110			Shin et al. 2005
Adenovirus type 2	Human lung cell line	35	55	75	100			Ballester and Malley 2004
Adenovirus type 2	PLC / PRF / 5 cell line	40	78	119	160	195	235	Gerba et al. 2002
Adenovirus type 40	PLC / PRF / 5 cell line	55	105	155				ston-Enriquez et al. 2003
Adenovirus type 41	PLC / PRF / 5 cell line	23.6	ND	ND	111.8			Meng and Gerba 1996
B40-8 (Phage)	B. Fragilis	11	17	23	29	35	41	Sommer et al. 2001
Bacteriopfage - E. Coli	N/A	2.6	6.6					Light Sources Inc. 2014
Calicivirus canine	MDCK cell line	7	15	22	30	36		Husman et al. 2004
Calicivirus feline	CRFK cell line	5	15	23	30	39		ston-Enriquez et al. 2003
Coxsackievirus B3	BGM cell line							
Coxsackievirus B5	Buffalo Green Monkey cell line							
Coxsackievirus B5	BGM cell line							
Echovirus I	BGM cell line							
Echovirus II	BGM cell line							
Hepatitis A	HAV/HFS/GBM							
Hepatitis A HM175	FRhK-4 cell							
Hepatitis A HM175	FRhK-4 cell							
Infectious Hepatitis	N/A							
Influenza	N/A							
MS2 (Phage)	Salmonella typhimurium WG49							
MS2 (Phage)	*E. coli* ATCC 15597							
MS2 (Phage)	*E. coli* HS(pFamp)R							
MS2 ATCC 15977-B1 (Phage)	*E. coli* ATCC 15977–E							
MS2 DSM 5694 (Phage)	*E. coli* NCIB 9481							
MS2 NCIMB 10108 (Phage)	*Salmonella typhimurium* WG49							
PHI X 174 (Phage)	*E. coli* C3000							

UV Dose (mJ/cm^2) Needed For a Given Log Rec

Log Reduction

	1	2	3	4	5	6
Ebertelia typhosa	2.14	4.1				
Escherichia coli O157:H7 CCUG 29193	3.5	4.7	5.5	7		
Escherichia coli O157:H7 CCUG 29197	2.5	3	4.6	5	5.5	
Escherichia coli O157:H7 CCUG 29199	0.4	0.7	1	1.1	1.3	1.4
Escherichia coli O157:H7 ATCC 43894	1.5	2.8	4.1	5.6	6.8	
Escherichia coli	3.0	6.6				
Escherichia coli ATCC 11229	7	8	9	11	12	
Escherichia coli ATCC 11303	4	6	9	10	13	15
Escherichia coli ATCC 25922	6	6.5	7	8	9	10
Escherichia coli K-12 IFO3301	2.2	4.4	6.7	8.9	11.0	
Escherichia coli O157:H7	<2	<2	2.5	4	8	17
Halobacterium elongate ATCC33173	0.4	0.7	1			
Halobacterium salinarum ATCC43214	12	15	17.5	20		
Klebsiella pneumoniae	12	15	17.5	20		
Klebsiella terrigena ATCC33257	4.6	6.7	8.9	11		
Legionella pneumophila ATCC33152	1.9	3.8	5.8	7.7	9.6	
Legionella pneumophila ATCC 43660	3.1	5	6.9	9.4		

Outline

- Listening
- Using the Comparative Effectiveness Approach
- Summary of the Needs (that everyone understands)
- Addressing the needs – Background & Physics 101
- **The Output of the Process**

At this point, Innovation happens, creative solutions are tested, designs are made, and we go back to the customer to ensure that our solution addresses the needs…

We repeat the CES with our partners on site

Ultimately, the solution is provided…

Differentiated Solution

- **Compact disinfection heads –** individually positionable, enables improved angle of incidence and better coverage of horizontal surfaces
- **Portable** – lightweight, compact, robust design, with protective carrying case allows for easy transport
- **Responsible** – sustainable; safe with redundancies to protect users and visitors from UVC exposure
- **Ease of use** – just a push of the button, it simply works, no preventive maintenance required
- **Lowest total cost of ownership** – affordable purchase price, short cycle times, limited maintenance, and low operating costs

Solution continued

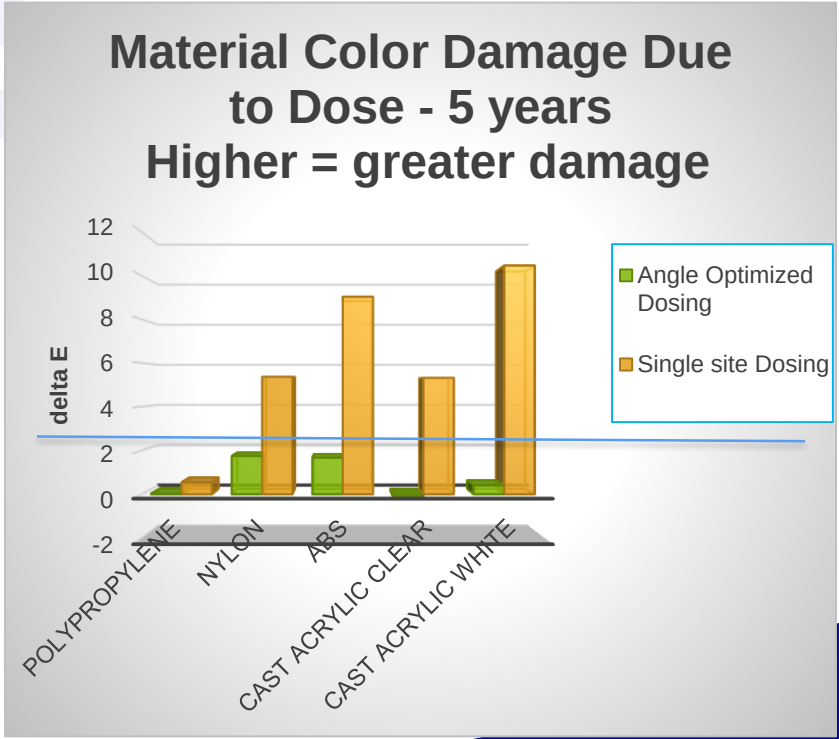
- **Safety -** Unit won't operate with people in the room, Redundant sensors
- **Efficient -** Deliver energy more directly to the surface, Do 'more with less'
- **Short cycle times -** Greater than 3 log reduction in 3 minutes
- **Run multiple units at a time, reduce cycle time –** satisfies broad operational range
- **No prioritized use -** use multiples when and where wanted
- **No preventive maintenance -** UV lights changed every 12,000 - 3-minute cycles or 3,600 - 10-minute cycles

- **Operational issues addressed**

Some aspects that were also noted

International Commission on Illumination (CIE) scale of delta E ranges for estimating the human eye perception of colors.

Delta E values from 1 to 2 are noted as "Perceptible through close observation" and values from 2 to 10 are "Perceptible at a glance."



Effectiveness of Solution Against Key Healthcare Associated Pathogens

More Susceptible

Less Susceptible

Organism Group	Member Group
Vegetative Bacteria	Staphylococcus aureus
	Streptococcus progenies
	Escherichia coil
	Pseudomonas aeruginosa
	Serratia marcescens
Mycobacteria	Mycobacterium tuberculosis
	Mycobacterium bovis
	Mycobacterium leprae
Bacteria Spores	Bacilus anthracis
	Bacilus cereus
	Bacilus subtilis
Fungal Spores	Aspergilus versicolor
	Penicillium chrysogenum
	Stachyhybotrys chartarum

Vegetative bacteria
1.2m $\geq$3 $\log_{10}$ reduction

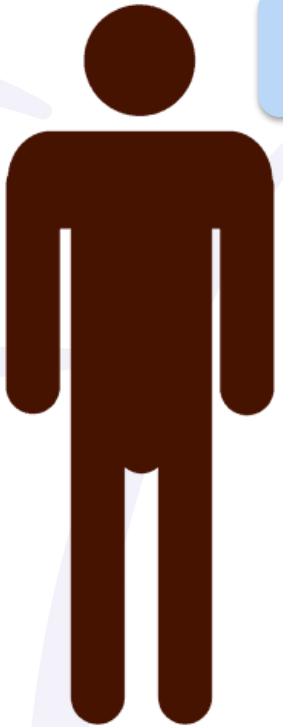
C. difficile spores
1.2m $\geq$3 $\log_{10}$ reduction

Martin SB et al. ASHRE Journal. August 2008

Safety Features

- The Solution has multiple levels of defense to prevent exposure:
  - Base unit has 4- infrared motion sensors and an accelerometer (detects touch/movement)
  - Remote Cover multitasks as the unit control, a yellow “safety cone (visual), and a safety device with a proximity sensor (detects movement of the door) and accelerometer
  - Optional Sentry device - satellite sensor that can be used in rooms/areas with multiple entries
- If any of these safety mechanisms are activated, the device shuts down

Success…



Relative Size Goal

X, Y, Z Solution

Actual Size

Outline

- Listening
- Using the Comparative Effectiveness Approach
- Summary of the Needs (that everyone understands)
- Addressing the needs – Background & Physics 101
- The Output of the Process