

## An Update from the Yale Healthcare/UV Workshop

# Developments in IUVA's Initiative for a UV Disinfection Efficacy Standard

**Troy E. Cowan, MS**, Vision Based Consulting, LLC ([troy@visionbasedconsulting.us](mailto:troy@visionbasedconsulting.us))

**John Lyon, Ph.D.**, Vision Based Consulting, LLC (retired)

### Workshop overview

On Sept. 27, the IUVA's Healthcare/UV Working Group held a workshop to gather information and discussed issues on proposed efficacy standards for UV disinfecting devices. This workshop, originally suggested by the board in April, evolved from a small gathering of 20 to 57 people registered, and, ultimately, more than 70 attending. Attendees came from many backgrounds, some from the West Coast, a few from Canada and one person from as far away as Uruguay. It proved to be an exciting and timely event.

Workshop sessions were held in a classic medical classroom auditorium, the perfect venue for the presenters to deliver their message and for the audience to ask their questions. Chaired by Meredith Stines and coordinated by Troy Cowan, the Healthcare/UV Working Group, coordinated the workshop through, and worked with, Dr. Richard (Rick) Martinello of the Yale New Haven Hospital and the Yale School of Medicine (YSM), who hosted the sessions, side events and a follow-on working group meeting.

### Special guests

Senior representatives from the Department of Health and Human Services (HHS), the Department of Energy, the National Institute of Standards and Technology (NIST) and Department of Commerce, as well as the Yale School of Medicine participated in the workshop.

- Dr. Don Wright, deputy assistant secretary for health and director, Office of Disease Prevention and Health Promotion, represented Admiral Brett P. Giroir, M.D., the HHS assistant secretary for the Department of Health.



**Figure 1.** Originally planned for 20 people, it was “standing room only” for the workshop.



**Figure 2.** Special guests were, clockwise from top left, Dr. Don Wright, Dr. Terry Fossum, Barbara VanDyke and Dr. Dianne Poster.

- Dr. Terry Fossum, special assistant to the secretary, represented Rick Perry, the energy secretary.
- Dr. Dianne Poster, former special assistant to the director, represented Dr. Walter Copan, the undersecretary of Commerce for Standards and Technology and NIST director.
- Barbara VanDyke, senior analyst with Crosswind Media & Public Relations, brought specialization in healthcare issues for the Department of Commerce.

### Sessions abstract

The session panels covered topics that included “HAI Issues in Healthcare,” “HAI Mitigation Programs,” “Issues in Assessing UV-C Efficacy” and “UV-C Efficacy Standard – What’s Required.” Session presenters included medical researchers, practicing physicians, healthcare facility management professionals and UV device manufacturer executives, all interacting and dialoguing on the issues in a true workshop manner (presentations may be found at iuva.org). The resulting “mind meld” educated all about the realities of dealing with healthcare acquired infections (HAIs) in healthcare facilities and introducing positive change with the application of UV light.

### Workshop session details

Kicking off, Gary Cohen, executive director of IUVA, welcomed the attendees and affirmed IUVA’s commitment to promoting UV-C standards to help combat HAIs.

This led into Dr. Steven Choi, YSM and Yale New Haven Health’s inaugural chief quality officer and associate dean for clinical quality, setting the stage for the day with an insightful and fascinating introduction to the setting of pioneering physicians in pursuit of mal “airs” and malaises in pre-antibiotic days, highlighting how Dr. Ignaz Semmelweis, the “Father of Hand Hygiene,” might not have died from sepsis if his physicians had only followed his teachings.



Dr. Steven Choi

The four session panels followed with the morning panels facilitated by Martinello and in the afternoon by Cowan:

#### Panel 1: HAI issues in healthcare

*The burden of HAI, HAI surveillance and HAI public reporting*

Workshop and working group co-lead Martinello laid out the day’s events and presented a brief history and scope of HAIs and the clinical environment in which they are found. Here, and throughout the day, he illustrated the challenge of both researching interventions and their resulting implementations

in the very busy operations of hospitals and general caregiving.

Jessica Scott, Yale New Haven Hospital’s director of quality services, then mapped out how HAIs are tracked and reported across the healthcare community and the resources the public can use to be an informed healthcare consumer (e.g., The LeapFrog Group).

*Device related infections – CLABSI, CAUTI, and VAP; C. difficile, MDROs, and the environment; and Surgical Site Infections (SSI)*

Michael Aniskiewicz, Yale New Haven Hospital, revealed the overall perspective of healthcare associated infections and their sources from the perspective of an Infection Prevention Site Lead at a 1,500-plus bed hospital. Potential sites of infections being surgical, catheter associated urinary tract and blood stream infections were discussed along with the importance of understanding antibiotic resistance.

Dr. Curtis Donskey of the Louis Stokes VA Medical Center in Cleveland, Ohio, presented thoughtful insights from years of

page 6 ►

**hönle**group



**One-Stop UV-Supplier  
for Ballast Water Treatment Systems**

Special Components for Special NEEDS:

- MEDIUM Pressure Lamps
- LOW Pressure Lamps
- Electronic POWER Supplies
- UV-Sensors
- Quartz sleeves

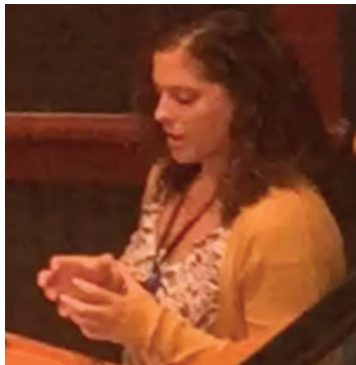
[uvtechnik.com](http://uvtechnik.com)





practice and research in infection prevention and treatments. His clinical and experimental research to understand the impacts of UV light on a variety of microbes helped to align attendees' comprehension of empirical and experimental design for testing geometries, materials and fluence on measurements of disruption of infectious agents and made it clear that there are opportunities for UV to help reduce the transmission of HAIs and to address some deficiencies in hospital environmental control measures.

Nicole Colandrea, an infection preventionist at Yale New Haven Hospital, focused on experiences with surgical site infections (SSIs) in the literature and in her clinical practice yielding perspective on a natural focus of lay audiences. Participating in the discussion, Dr. Maxwell Laurans, chief and director, Perioperative Services at Yale New Haven Hospital and assistant professor of neurosurgery, YSM, affirmed that chief amongst the precautions needed to prevent SSIs were maintaining a sterile field and disinfecting environmental surfaces – a recurring theme throughout the day.



**Figure 3.** Nicole Colandrea discussed surgical site infections (SSIs).

### **Panel 2: HAI mitigation programs**

*Infection prevention programs and mitigation of HAIs; Healthcare facility cleaning programs and issues; and UV-C disinfection overview (mechanism, history, data and gaps)*

Dr. David Banach of the University of Connecticut presented the practitioner's perspective of infection prevention in a working hospital, including contact isolation protocols, organizational strategies and performance and process measures. Some key questions constantly thwart infection prevention practitioners every work day: "How well are we cleaning the patient-care environment? How well are we cleaning, disinfecting and sterilizing our equipment and instruments? Who is responsible for the different aspects of cleaning?" and "How do we compensate when there's insufficient training and inadequate time for cleaning?"

George Pressley of ABM (the management company for the environmental cleaning services to Yale New Haven Hospital) then outlined the daily operation of Yale hospital environmental services programs and practices that are

so important to hospital environmental management and operations, as well as patient comfort and respect. The perspective was vital to the audience as it helped meld the experimental and instrument leaders with the hospital practices that will be the home of UV light devices.

John Jordan, Craig Coulbourn and Cathy Campbell, also of ABM, shared presentations further delving into the operations of making hospitals safe from infectious agents and development of comprehensive cleaning practices and cleaning testing done to safe rooms for occupation by incoming patients. Their bottom line: hospital environmental services providers need disinfection devices that are simple to use and dependable, that actually disinfect and don't use up more resources than they save.



**Figure 4.** Cathy Campbell, with ABM, said UV devices should be simple to use, dependable, work and save money.

### **Panel 3: Issues in assessing UV-C efficacy**

*Considerations for UV-C efficacy test standard of UV devices in healthcare settings; and Germicidal UV-C lamp approaches and applications for reduction*

Dr. Ashish Mathur, Ultraviolet Devices Inc., outlined the state of the art in UV lamp and LED technologies and instrumental capabilities for stanching microbes. The wide variation in device configurations and features such as user interface, safety, software and data reporting, as well as the wide variations in UV wavelengths employed (e.g., UV-C at 254 nm, pulsed xenon with wavelengths of 200 to 315 nm, far UV at 222 nm, and visible radiation at 405 nm for creating reactive oxygen species) offer great value and optimization potential for the user. These variations are increasing with the advent of UV LEDs with output wavelengths from 254 nm to 270+ nm. Moreover, when those variations are cross-walked against the variability in UV dose required to be effective (see Table 1), the number of considerations to be accounted for, including the variability of natural biotic systems, is complex.

**Table 1.** Comparison of UV doses required to achieve 99% efficacy, as presented by Dr. Ashish Mathur

| Pathogen                 | UV dose (J cm <sup>-2</sup> ) required |                         |
|--------------------------|--|-------------------------|
|                          | To achieve 99% efficacy                | Compared to Influenza A |
| <i>Aspergillus niger</i> | 330,000                                | 72.4:1                  |
| <i>C. difficile</i>      | 38,500                                 | 8.4:1                   |
| Influenza A              | 4,558                                  | 1:1                     |

This point was further emphasized by Dan Spicer, LightSources, Inc., when he called out the different ways UV devices are applied (e.g., air vs. surface vs. equipment disinfection) and designed (e.g., fixed ductwork installations, mobile devices on rollers, portable hand-carried devices). Spicer’s conclusion was that there is no single silver bullet approach and that an analysis of a full UV-C toolbox is required on a case by case basis.

*Variations in testing protocols and efficacy studies*

Dr. Curtis Donskey focused on the crosscuts between experimental and operation applications of UV in the clinical environment and what he and his colleagues have learned. He described the variations in testing protocols, which included how one considers distance (i.e., between the UV source and the target), shadowing (i.e., direct vs. indirect exposure), carrier used for the target (e.g., stainless steel vs. glass, carrier size and shape, horizontal vs. vertical orientation) and the amount of organic load assumed (i.e., organic coating that might shield the target pathogen from some fraction of the delivered UV dose).



**Figure 5.** Dr. Curtis Donskey discussed the subtleties of testing UV devices.

His conclusions: 1) measuring UV output may be valuable as an adjunct to microbiologic results, given that standard protocols for measuring UV are needed; and 2) whenever possible, in vitro testing should be correlated with real world performance in healthcare settings when comparing results.

**LightTech LightSources**  
ISO 9001:2015 Registered

**Innovation and leadership for UV Lamp Technology**

With 35 Years of UV lamp Design, Engineering & Manufacturing experience, We are the One-Stop-Manufacturer for **All** your UVC, UVB & UVA needs

- HID/MPUV UVC & UVA
  - Press seal
  - Neck down vacuum seal
- Low Pressure UVC
  - Hard Quartz, Linear, Compact & Bent
  - Soft Glass - Linear & Compact
  - Amalgam - Spot & Pellet Technology (240W-1200W) {T5 to T12 dia.}
- UVC Lamps 185 nm, 254 nm
- UVB Lamps 295 nm, 310 nm, 320 nm
- UVA Lamps 350 nm, 369 nm
- Actinic Lamps 421 nm
- Low Pressure UVC, UVB, UVA Sub Miniature CCFL's (3.0mm to 6.0 mm dia. )

**Custom Designs are our Specialty...**

**We don't have Customers... We have Business Partners ...for Life!**

*Variations in pathogen activation data and current efforts to resolve them*

Dr. John Boyce, an infectious diseases specialist and infection prevention investigator, comingled the theoretical with the practical and revealed valuable insights especially tailored to the audience in part from his participation in the working group. He made the points that most infection control professionals and environmental services personnel: 1) lack familiarity with UV output (irradiance) from the available mobile UV devices; and 2) don't have access to credible data on UV doses (fluence) necessary to inactivate pathogens. This makes it very difficult to compare mobile UV devices currently marketed.

Regarding UV dose (fluence) requirements, he presented data showing how much variation there is in reported fluence data between researchers, in one case showing *C. diff.* ranging from 67.5 to 342.7 mJ/cm<sup>2</sup> for meeting a 2 log<sub>10</sub> reduction – a difference factor of five times, making both data points subject to interpretation. Boyce concluded that:

- Standardizing laboratory methods and test conditions may help in establishing ranges of UV doses required to inactivate specific pathogens; and
- Agreement on criteria of a “lethal dose” for pathogens would be helpful, such as a 3 log<sub>10</sub> (99.9%) reduction of pathogens or a D90 (90%) reduction.

Working group member Barry Hunt, from the Canadian Coalition for Healthcare Acquired Infection Reduction, lent many practical observations of UV light implementations in Canadian hospitals, as well as sharing implementation protocols. This included a discussion on the current regulatory updates being considered related to disinfection in the Canadian healthcare system, and how a new UV efficacy standard in the US could be considered for implementation across Canada, as well.

**Panel 4: UV-C efficacy standard – what's required**

*UV-C measurement – status and current issues – standardizing vocabulary on UV dose*

Alice Brewer of Tru-D and Hunt described the current state of how the disinfection power of UV light is defined and measured in the scholarly literature and proposed standardized sets of definitions to clear up current inconsistencies. For example, they proposed that *k* values be defined as the UV dose required to attain a 99.9% reduction (3 Log<sub>10</sub>) in colony forming units (CFUs). This appears to be a significant but realistic test threshold for surface disinfection efficacy. In the technology marketplace, standard terminology lends

to easing adoption, integration and implementation of new practices into vendor solutions.

*Pathway to developing a UV-C standard*

Dr. Cameron Miller shared the NIST programmatic efforts in standards development and characterizations and calibration of instruments and their capabilities. He described a four-step approach:



**Figure 6.** Dr. Cameron Miller describes NIST's role in developing standards for industry.

1. Standardizing measurement methods;
2. Modeling UV exposure;
3. Establishing the standard *k* values for inactivating target organisms; and
4. Verification of the model and its implementation

The result could be implemented in a test bed facility for actual biological demonstrations and testing in a controlled, standardized environment.

*Real time measurement of contamination levels – microwave monitoring of microbial degradation with UV sources*

Dr. Dianne Poster, NIST, spoke to her colleagues' efforts to measure pathogen concentrations and degradation in real time that result from UV exposure, thereby potentially reducing lab culturing of the pathogens' measure of CFUs. Rather, using the change in impedance exhibited by dead cells compared to living cells, one could infer the changing ratio of dead to living cells as cells were inactivated. They were able to do a rudimentary experiment with benign yeast cultures that showed a doubling of cellular “death” rates in the lab samples observed. Next steps are more rigorous experiments leading to models for UV-photolysis.

**At the end of the day**

An informal evaluation was made at closing to gather reactions to the day's event. A reception followed, hosted by LightSources and the Yale School of Medicine, encouraging more discussions and information sharing. These efforts continued through the dinner hour and evening, with experts finding common ground.

From the day's sessions and working group meeting which followed, a soft consensus was reached on the following:

- The value of commingling and open sharing between industry, science and medicine, engineering, and the



operational and practical afforded a rich opportunity for content and learning.

- Efficacy standards and testing protocols are needed; and they should be performance-based as opposed to prescriptive and must address different sources such as lamps and LEDs. They must be sufficiently flexible to encompass a wide range of room geometries (e.g., patient rooms, ORs, ERs, reception areas) and different test protocols (radiometers, test strips and other indicators, various biota).
- The biggest surprises were that there are no healthcare standards for how clean things need to be and that HAI impacts aren't a higher priority with the public.

### About the IUVA Healthcare/UV Working Group

In keeping with its mission to “make the use of Ultraviolet Technology a leading technology for public health and environmental applications,” IUVA has recognized that UV technologies have credibility issues due to the lack of accepted efficacy or methods performance standards, which impede the credibility of UV in the healthcare industry.

In response, the IUVA Healthcare/UV Working Group was formed to address development of industry-wide, consensus-based efficacy standards for UV antimicrobial devices used to attack HAI and MDRO pathogens in healthcare facilities.

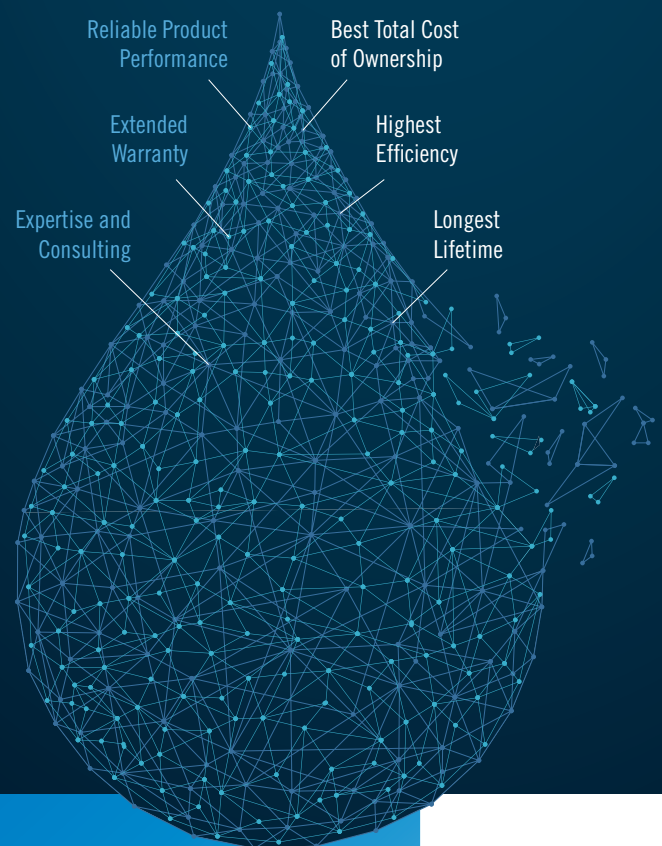
The end goal is to garner industry-wide recognition of standards for UV devices used in healthcare facilities, promoting wide-spread use of UV technologies, leading to a HAI reduction of near 35% in the near term and virtually eliminating them in the long term. Accordingly, the working group will use its specific knowledge and experience to provide global guidance and coordinate industry-wide programs and deliverables, in furtherance of this goal and the IUVA's outreach to the healthcare industry.

The working group's objectives include the following:

- Develop consensus-based efficacy standards and associated testing protocols for UV disinfecting devices used in the healthcare industry
- Coordinate review and approval of standards by nationally and/or internationally recognized regulatory bodies, leading to their acceptance as industry wide, consensus-based standards in accordance with OMB Circular A-119

# No risk. More fun.

Enjoy long lasting and  
efficient solutions.



Contact us at: [hng-uv@heraeus.com](mailto:hng-uv@heraeus.com)  
[www.heraeus-noblelight.com](http://www.heraeus-noblelight.com)



Because clean water  
is a matter of trust:  
Think UV. Think Heraeus.

- Serve as the representative body for ongoing administration, maintenance, management and oversight of standards, to include developing a validated UV roadmap for healthcare and developing and executing an interagency communication plan
- Advocate across the healthcare and UV industries by developing joint initiatives and nurturing alliances, presenting arguments, interventions, engagements and education. Spread the message via papers at conferences and submitting articles for journals, as well as stakeholder outreach

The working group will communicate its efforts and outputs via presenting papers at conferences and publishing articles in the peer-reviewed literature, as well as through stakeholder outreach and engagement. Membership is open to any IUVA member or organization, subject to approval by the chair.

A significant communications pathway has been initiated, and substantial work has begun. ■

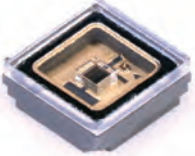


**Figure 7.** The collaborative mood between the healthcare and industrial communities ran throughout the day.

# DOWA

## Deep UV LEDs for Disinfectant Applications

- High Performance and High Reliability 3535 SMD package.
- Bare Chip is Available

|   |                                  |                                  |                                  |                                  |
|---|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
|  | <b>D series</b><br>If=100mA      | <b>M series</b><br>If=350mA      | <b>L series</b><br>If=600mA      | <b>Z series</b><br>If=800mA      |
| <b>280nm</b>  | <b>Po=11mW</b><br><b>Vf=5.2V</b> | <b>Po=25mW</b><br><b>Vf=5.4V</b> | <b>Po=45mW</b><br><b>Vf=6.0V</b> | <b>Po=75mW</b><br><b>Vf=6.9V</b> |
| <b>275nm</b>  |                                  |                                  |                                  | <b>NEW</b>                       |
| <b>265nm</b>  | <b>NEW</b>                       | <b>Po=16mW</b><br><b>Vf=5.8V</b> |                                  |                                  |

<http://www.ultraviolet-led.com>  
<http://www.dowa-electronics.co.jp>

For more information, please contact "electronics@dowa.co.jp"

DOWA ELECTRONICS MATERIALS CO.,LTD.