Introduction:

The resurgence of Ebola in West Africa and the recent cases in the US and Spain have caused considerable concern for healthcare facilities as they struggle to develop effective emergency preparedness plans that will isolate and allow for effective treatment of symptomatic Ebola patients while safeguarding the hospital staff and community. In August 2014, the CDC recommended general Infection Prevention and Control practices and procedures for Ebola, and addressed specific environmental infection control concerns in their Interim Guidance for Environmental Infection Control in Hospitals for Ebolavirus. Unfortunately, for facilities who wish to use UV whole room treatment technologies, there currently is very little guidance.

This paper will outline key points that healthcare facilities should consider when choosing an environmental protection strategy against Ebola that includes UV Treatment. We will describe the approach that CDC and EPA have taken to bridge the gap between efficacy claims of common hospital associated pathogens and Ebola, a less common and currently untestable pathogen, in order to choose appropriate manual disinfectants. We extend the use of their approach, and show how it can be applied to provide guidance for the use of UV whole room treatment devices. Using these principals, we are able to provide an approach for obtaining a UV claim against Ebola.

Manual Environmental Cleaning & Disinfection – Accepted approach for Ebola Claims:

For some pathogens that are emerging, or that are hard to isolate or handle safely in the laboratory (such as Ebola), there often is no predetermined route to obtain an EPA registered sanitization or disinfection claim against that organism. In that case, a new microbiological analysis protocol must be developed following EPA guidelines. This is a time consuming process and involves method selection, optimization, validation, and final approval components. Sometimes a surrogate organism must be chosen to represent the target organism to reduce safety risks or to improve the ability to cultivate and reproducibly deliver an organism for test purposes. When the pathogen of concern is causing a significant public health risk, the CDC and EPA often bridge the gap by identifying acceptable disinfectant products that may be used while effective test protocols are being developed. The gap is typically bridged by drawing on well-established pathogen hierarchy data, known efficacy data, and peer-reviewed studies.

For germicidal formulations, in 2008 the EPA recognized the pathogen hierarchy shown in Table I as guidance for the selection of disinfectants to be used against emerging viruses. This hierarchy ranks classes of microorganisms by order of their relative susceptibility to hard surface disinfectants. The top of the list represents the hardest to kill (bacterial endospores) where the bottom of the list are those organisms most susceptible to disinfectants.
Table I
Pathogen Hierarchy

<table>
<thead>
<tr>
<th>Descending order of resistance to germicidal chemicals</th>
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<tbody>
<tr>
<td><strong>Bacterial Spores</strong></td>
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<tr>
<td><strong>Mycobacteria</strong></td>
</tr>
<tr>
<td><strong>Nonlipid, Nonenveloped, or Small Viruses</strong></td>
</tr>
<tr>
<td><strong>Fungi</strong></td>
</tr>
<tr>
<td><strong>Vegetative bacteria</strong></td>
</tr>
<tr>
<td><strong>Lipid, Enveloped, or medium-sized viruses</strong></td>
</tr>
</tbody>
</table>

Using this hierarchy and the wealth of micro- efficacy testing data from EPA registered disinfectants, the CDC developed recommendations specifically for Ebola.\(^1\) Even though Ebola virus is an *enveloped* virus, and expected to be easier to kill, the CDC recommends the use of EPA-registered hospital disinfectants with kill claims against harder to kill *non-enveloped viruses* in order to disinfect rooms of suspected or confirmed Ebola cases. At this time there is no epidemiologic evidence of Ebolavirus transmission via contaminated environment surfaces, but the CDC chose this route as an extra precaution to “reduce the potential of risk posed by contaminated surfaces in the patient care environment”.\(^2\)

**Use of UV Treatment Devices:**

Typical UV whole room treatment devices kill pathogens in the UV-C range (200-280 nm), and are intended to be used as a supplement to manual cleaning and disinfection. When working with UV technology, evaluating microorganism claims for different devices involves additional complexity since the EPA does not currently provide a route for obtaining EPA registered claims using UV. The implications of this are: 1) a fundamental lack of standardization of test methods and 2) a lack of oversight of the claims made by device manufacturers. As a facility looking to augment standard manual disinfectant protocols, it can be challenging to discern fact from fiction.

With that said, it’s well documented that UV-C is a highly effective germicide\(^7,8\), so well in fact that Kowalski’s UV handbook states that “given sufficient exposure time, any exposed pathogen can be inactivated”\(^9\). The CDC recognized the utility of UV technology by referencing a paper by Sagripanti and Lytle\(^10\) in their Interim Guidance Document. The study demonstrated the efficacy of UV against Ebola and showed that compared to other enveloped viruses, Ebola was quite sensitive to inactivation by ultraviolet light. However given that there are currently no EPA approved UV pathogen claims, it is
difficult for a facility to understand how claims are made by UV manufacturers for common healthcare associated pathogens and for emerging organisms.

Using the CDC Bridge the Gap Precedence for UV Whole Room Disinfectant Technology:

Following the CDC precedence for liquid disinfectants, examining the UV pathogen hierarchy is a good starting point when determining if a specific device has the potential to support a claim against Ebola or other emerging pathogens.

The generalized UV Pathogen Hierarchy shown in Table II provides guidance on the microbial susceptibility to UV-C light among various species. The hierarchy of susceptibility to UV-C light is notably different than that referenced for chemical disinfectants discussed above. In general with UV-C, vegetative bacteria are easier to inactivate, and fungi require the highest UV dosage for inactivation. It is interesting to note that bacterial spores, such as *C. difficile*, are intermediate on the UV Dose Hierarchy.

<table>
<thead>
<tr>
<th>Table II</th>
<th>Generalized UV Dose Hierarchy\textsuperscript{11}</th>
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</thead>
<tbody>
<tr>
<td>Listed by Decreasing Inactivation Difficulty</td>
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</tr>
<tr>
<td>Fungal Spores</td>
<td></td>
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<tr>
<td>Fungal Cells/Yeast</td>
<td></td>
</tr>
<tr>
<td>Bacterial Spores</td>
<td></td>
</tr>
<tr>
<td>Viruses</td>
<td></td>
</tr>
<tr>
<td>Vegetative Bacteria</td>
<td></td>
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</tbody>
</table>

Going one step beyond general classes of organisms, there is also a wealth of literature data available on the UV dosage required for inactivation of specific pathogens. UV dosages for non-enveloped viral pathogens such as adenovirus, norovirus, poliovirus, and rotavirus range from 18,000-84,000 μw-sec/cm² for a 2-log kill.\textsuperscript{12,13} In comparison, the UV dosage required to inactivate enveloped Ebolavirus is significantly less – for a 2-log kill Ebolavirus requires \(2000^{10}-5300^{14}\) μw-sec/cm² for a 2-log kill.

Historically UV doses have been listed by either their \(D_{90}\) (90% inactivation) or \(D_{99}\) values (2 log reduction). In order to address the more stringent needs for healthcare applications, 3-4 log reductions (99.9% -99.99% microbial kill) or greater are typically obtained for target microorganisms as validated via laboratory testing.

Comparisons of known and predicted pathogen doses can be used to determine the effectiveness of a UV-C device at a given exposure time and distance. Using the CDC precedence for liquid disinfectants, recommendations for UV-C treatment to inactivate Ebolavirus should be based on what is known to
be effective against at least one of the following non-enveloped viruses (norovirus, rotavirus, adenovirus, poliovirus).

For example, if a device is known to be able to provide a 2 log kill for Rotavirus in 5 minutes at 8 feet, and Rotavirus is estimated to require of dose of ~18,599 μw-sec/cm², then it is quite reasonable to expect that the device should be adequate to provide a 2 log kill for Ebola which is predicted to require 2000-5300 μw-sec/cm² under the same conditions. In a similar fashion, if the device has been shown to have a higher log kill against a hard to kill non-enveloped virus, then it can be expected to have that same log kill or greater against the easier to kill enveloped Ebolavirus.

Current Microorganism Efficacy Testing Varies:

Without an EPA approved protocol to validate micro-efficacy claims, manufacturers are generating data using different test methods, making it difficult to compare claims from one device to another. Reputable device manufactures use respected 3rd party test laboratories to generate micro-efficacy data and there should be full transparency about the test conditions used such as the irradiation time, distance, substrate, carrier load, and density as well as for the log reductions obtained.

A Comprehensive Bundled Approach: Utilization of UV-C Treatment Devices to Augment Standard Cleaning & Disinfection:

A key finding in the study by Sagripanti and Lytle^10 and work by Bausch^15 is that the environmental conditions can impact the effectiveness of the pathogen inactivation. The presence of organic matter such as dried blood can shield the virus from the UV light and reduce the effectiveness. Coupling this with studies that have shown that only 50% of high-risk surfaces in the healthcare setting are properly cleaned^16, there is a strong case for the use of both manual disinfection protocols followed by UV whole room treatment. UV-C room treatment provides a supplement to, not a replacement of, standard cleaning and disinfection protocols^17, and provides another weapon in the battle against pathogens that cause Healthcare Associated Infections (HAIs).

Clorox Healthcare is the only manufacture that offers both a full range of manual disinfectant chemistries and whole room UV treatment. In addition to highly effective manual bleach based, peroxide based, and quaternary based one-step, ready-to-use, EPA registered hard surface disinfectants^18, Clorox offers the Optimum-UV^TM which has been shown by 3rd party laboratory micro-efficacy data to provide a 99.992% reduction of C. difficile and >99.999% reduction of MRSA, in 5 or 2 minutes respectively, at a distance of 8 feet.

Conclusion:

Bridging the Gap from common healthcare associated pathogen claims to emerging organisms is a process that involves known pathogen hierarchy, micro-efficacy data, and peer reviewed studies. This process can also be applied to UV whole room treatment technologies leveraging the precedence set by the CDC and EPA for liquid disinfectants. Using these principals, we have provided an approach for obtaining a UV claim against Ebola based on the efficacy of UV devices against non-enveloped viruses.
References:

13. The response to UV exposure is often described in terms of UV inactivation dosage or UV rate constants. For example, the UV dose required to inactivate 99% of the organism (2 log kill) is referred to as the D_{99} dose. UV Doses are typically listed by either their D_{90} (90% inactivation) or D_{99} values, and different sources use different units (i.e., J/m², μW-sec/cm², or mw-sec/cm²) for the dose, so care must be taken when comparing referenced dose values. In general, the D_{99} value is approximately twice the value listed for D_{90}.
18. Clorox Healthcare Surface and Hands Portfolio Brochure: NI-22718