Steriliz
SMARTER LIGHT

C.*diff* Study Review:
4 Rochester, NY Hospitals
Including Other Related Relevant Studies

Prepared for:

[HOSPITAL/FACILITY]

Evaluation by:

[NAME]
R-D™ Rapid Disinfector™ System Specialist

Date of Study:

[DATE]

The details of this study are proprietary and shared at the discretion of Steriliz, LLC.

Note: The purpose of the included COMMENTARY sections identifies critical issues in each study and how the R-D can help mitigate them.

Table of Contents

Introduction

The C.*diff* Study Review is a review of several recent studies in addition to an analysis of publicly reported infection data[1], operational utilization data[2] and interventions implemented at four hospitals. The studies identify important considerations when using UVC light as a disinfection intervention.

The First Study: Dr. William Rutala- *Inter-hospital Variation in Time Required for Hospital Room Ultraviolet (UV)-C Irradiation: Preliminary Experience from the Benefits of Enhanced Terminal Room (BETR) Disinfection Study* offers insight of why it is important to understand the need to have UVC devices that measure a UVC dose.

The Second Study: Dr. Curtis J. Donskey- *An Environmental Disinfection Odyssey: Evaluation of Sequential Interventions to Improve Disinfection of Clostridium difficile Isolation Rooms* supports the Rutala study that UVC measurement is important to help eliminate shadowed areas in complex environments.

The Third Study: is an AJIC PUBLISHED STUDY taken from *AJIC: American Journal of Infection Control* that discusses patient's risk for acquiring HAIs based on colonized environments that produce HAI clusters.

The Fourth Study: is *Clostridium difficile Spore Inactivation Study Using Ultraviolet-C Energy performed by MOOG Life Science Laboratories.* This study is the first and only to establish the amount of UVC light necessary to inactivate Clostridium *difficile* using a definitive dose measurement system.

The Fifth and concluding Study: is a review of results taken from a *4 Hospital Community-Wide Study in Rochester, New York.* This collaborative effort offers UVC utilization techniques and recommendations that result in more effective UVC solution outcomes.

In 2011 four competing hospitals located in Rochester, New York teamed up to combat Clostridium *difficile* (C.*diff*). The C.*diff* Collaborative, as it is called, also includes Excellus Blue Cross and Blue Shield and the New York State Department of Health. The Collaborative is presently engaged in an IRB approved study.

All four hospitals implemented three different interventions as part of a bundle in an effort to reduce incidence of Clostridium *difficile* Infection ("CDI"). In January 2012 all the hospitals simultaneously implemented increased hand hygiene protocol and increased antibiotic stewardship. Automated Ultraviolet Disinfection systems were deployed as well however there were differences in when the systems were deployed, whose systems were deployed, and when and how they were utilized. The resulting impact on CDI rates was significant and varied. The lead hospital, Rochester General, achieved a 25.8% drop in nosocomial C.*diff* cases for 2012 compared to 2011.

Clostridium difficile Study

The purpose of this C.*diff* Study Review is to provide a guide to hospitals and health care facilities that will help them better manage and reduce CDI rates resulting in reduced costs to the overburdened healthcare system, reduced pain, suffering and death from CDI, and increased availability to facilities from reduced CDI patient days.

For transparency, please note that the purpose of the included COMMENTARY sections identifies critical issues in each study and how the R-D Rapid Disinfector can help mitigate them.

Background of the Problem

In the U.S each year, more people die from hospital infections than from AIDS, breast cancer and auto accidents combined. These infections are the <u>fourth leading cause of death</u>, with current annual estimates of 2,000,000 infections, more than 100,000 deaths and added costs of \$45 billion[3]. Between 5-10% of all patients admitted to a hospital acquire an infection while in that hospital and nursing homes infections rates are almost 20% annually. Even with such extreme statistics, many industry experts consider the problem to be severely underestimated. C.*diff* accounts for about 500,000 infections and 30,000 deaths[4]. The average total cost for a single inpatient *C. difficile* infection (CDI) is more than \$35,000[5], and the estimated annual cost burden for the healthcare system exceeds \$3 billion[5].

The majority of HAIs acquired today are preventable by improving cleaning and disinfecting activities through increased awareness, enhanced data collection and analysis, and additional advanced disinfecting measures.

Interventions Implemented

The Collaborative implemented the following three interventions at all four hospitals at various times:

- increased hand hygiene
- increased antibiotic stewardship
- added new or additional UVC disinfection systems

Figure 1 below shows the time periods during which the listed interventions were employed at the respective facilities.

Legend:

UVC R-D System — green	UVC TRU-D System — red	Hand Hygiene & Antibiotic Stewardship — blue

Facility	Intervention	2011-Q4	2012-Q1	2012-Q2	2012-Q3	2012-Q4
Rochester General	UVC R-D System	green	green	green	green	green
	UVC TRU-D System					
	Hand Hygiene & Antibiotic Stewardship		blue	blue	blue	blue
Unity	UVC R-D System			green	green	green
	UVC TRU-D System					
	Hand Hygiene & Antibiotic Stewardship		blue	blue	blue	blue
Highland	UVC R-D System			green	green	green
	UVC TRU-D System	red	red	red	red	red
	Hand Hygiene & Antibiotic Stewardship		blue	blue	blue	blue
Strong	UVC R-D System			green	green	green
	UVC TRU-D System	red	red	red	red	red
	Hand Hygiene & Antibiotic Stewardship		blue	blue	blue	blue

Figure 1 – Time periods during which Intervention was employed.

Clostridium difficile Study

Figure 1 shows increased hand hygiene and increased antibiotic stewardship began at all four hospitals on about January 1, 2012.

UVC disinfection with the R-D System began at Rochester General on September 7, 2011 and at the other three hospitals on about April 1, 2012.

UVC disinfection with the TRU-D System was only performed at Highland and Strong from mid 2009.

Recent Scientific Studies & Relevancy

Four recent studies that are of particular significance to the use of UVC for surface disinfection are presented herein. Included are a brief overview of each with highlighted excerpts that are most significant along with a reference for the full study and a commentary on the important take away.

Study #1: DR. WILLIAM RUTALA-
https://idsa.confex.com/idsa/2013/webprogram/Paper41051.html

Inter-hospital Variation in Time Required for Hospital Room Ultraviolet (UV)-C Irradiation: Preliminary Experience from the Benefits of Enhanced Terminal Room (BETR) Disinfection Study

This excerpt is taken from Dr. Rutala's on-going UNC / Duke Study which thus far concluded the following:

- The Tru-D SmartUVC™ prolonged terminal room cleaning times more than 30 minutes.
- The cycle time to complete the UV-C light treatment varied significantly between hospitals.
- Time variation may have been related to differences in the amount and type of materials in rooms; room design, layout, and size; and/or reflectivity due to differences in paint and size/location of windows.
- UV-C light emitters without built-in programs to measure the total dose of irradiation are likely to either under or overestimate the time necessary to adequately disinfect patient rooms.

COMMENTARY:
Systems that don't measure either over or under dose resulting in dangerous patient vulnerability. Systems that use remote sensors deliver the necessary amount (dose) of UVC in the shortest possible time. Conclusion - you've got to measure.

Clostridium difficile Study

Study #2: DR. CURTIS J. DONSKEY-
http://www.medscape.com/viewarticle/803364

An Environmental Disinfection Odyssey: Evaluation of Sequential Interventions to Improve Disinfection of *Clostridium difficile* Isolation Rooms

Brett Sitzlar, BS,1 Abhishek Deshpande, MD, PhD,1 Dennis Fertelli,1 Sirisha Kundrapu, MD,2 Ajay K. Sethi, PhD,3 and Curtis J. Donskey, MD1,2
1. Case Western Reserve University School of Medicine, Cleveland, Ohio
2. Geriatric Research Education and Clinical Center, Louis Stokes Cleveland Veterans Affairs Medical Center, Cleveland, Ohio
3. Department of Population Health Sciences, University of Wisconsin, Madison, Wisconsin
Address correspondence to Curtis J. Donskey, MD, Geriatric Research Education and Clinical Center, Louis Stokes Cleveland Veterans Affairs Medical Center, 10701 East Boulevard, Cleveland, OH 44106 (curtisd123@yahoo.com).

Objective: Effective disinfection of hospital rooms after discharge of patients with *Clostridium difficile* infection (CDI) is necessary to prevent transmission. We evaluated the impact of sequential cleaning and disinfection interventions by culturing high-touch surfaces in CDI rooms after cleaning.
Design: Prospective intervention.
Setting: A Veterans Affairs hospital.
Interventions: During a 21-month period, 3 sequential tiered interventions were implemented: (1) fluorescent markers to provide monitoring and feedback on thoroughness of cleaning facility-wide, (2) addition of an automated ultraviolet radiation device for adjunctive disinfection of CDI rooms, and (3) enhanced standard disinfection of CDI rooms, including a dedicated daily disinfection team and implementation of a process requiring supervisory assessment and clearance of terminally cleaned CDI rooms. To determine the impact of the interventions, cultures were obtained from CDI rooms after cleaning and disinfection.

...The second intervention period occurred from March 1, 2012, through June 30, 2012 (4 months). In addition to the period 1 interventions, 2 portable UV room disinfection devices (Tru-D; Lumalier) were used as an adjunct to standard cleaning and disinfection in CDI rooms.

...In a real-world setting, we found that 35% of CDI rooms had residual spores detectable by culture after standard terminal cleaning and operation of the devices...One potential explanation is that the devices are more effective in eradicating pathogens from areas receiving direct versus indirect exposure to UV (i.e., 2–4-log reduction in *C. difficile* spores with direct exposure vs. 1–2.4-log reduction with indirect exposure).

COMMENTARY:
An important conclusion of the Donskey study is that systems that use reflected light sensors do not allow for repositioning during a treatment thereby leaving shadowed areas that are not fully disinfected. This problem can be mitigated by running multiple treatments at different locations within the room at a cost of taking several hours to disinfect a single patient room. Systems that do not measure UVC dose at all would have to be run for even longer periods of time with the *hope* of providing a lethal dose, albeit with no definitive measurement dose delivery. The problem of shadows is even worse for point source systems that use one xenon lamp, for example.

Clostridium difficile Study

Study #3: AJIC PUBLISHED STUDY-
http://www.ncbi.nlm.nih.gov/pubmed/22336109

AJIC: American Journal of Infection Control

A multilevel model of methicillin-resistant *Staphylococcus aureus* acquisition within the hierarchy of an Australian tertiary hospital

Fiona Kong, MPubHealth
David L. Paterson, MBBS, PhD
Michael Coory, MBBS, PhD
Archie C.A. Clements, PhD

Hospitals without universal single room accommodations typically contain multibed cubicles within wards. In this study, we examined whether the variation in a patient's risk for acquiring methicillin-resistant *Staphylococcus aureus* (MRSA) in a major tertiary hospital was greatest at the bed, cubicle, or ward level, and quantified the risk of MRSA acquisition associated with exposure to MRSA-colonized/infected patients within the same bed, cubicle, and ward at differently distributed lag times. Nested tri-level hierarchical logistic regression models with random effects were used for non-multiresistant MRSA (nmMRSA) and multiresistant MRSA (mMRSA). The models were internally validated. Receiver operating characteristic curves were used to compare the models predictive capability. The odds of new nmMRSA acquisition were 6.06-fold (95% credible intervals [CrI], 3.93- to 9.34-fold) greater in bed-weeks when a nmMRSA-colonized/infected patient was in the same cubicle 2 weeks earlier. The odds of mMRSA acquisition were 5.12-fold (95% CrI, 4.02- to 6.51-fold) greater in bed-weeks when a colonized/infected patient was in the same ward 2 weeks earlier. The between-cluster variance was highest at the ward level. Patients were at greater risk if there was a colonized/infected patient in the same cubicle or ward 2 weeks earlier. Our findings indicate that focusing on the relevant cubicles and wards during this high-risk period can help target infection control resources more efficiently.

COMMENTARY:
This study emphasizes the importance of cleaning the entire ward or unit once a "cluster" is confirmed.

Clostridium difficile Study

Study #4: MOOG PUBLISHED STUDY-
http://steriliz.us/documents/MOOG-Clostridium_*difficile*_Spore_Inactivation_Study_Using_Ultraviolet-C_Energy.pdf

Clostridium difficile Spore Inactivation Study Using Ultraviolet-C Energy

May 2012

All information contained herein cannot be duplicated or released without the expressed written consent of Steriliz, LLC.

OBJECTIVE: To determine inactivation rates for *Clostridium difficile* spores by irradiating inoculated coupons with ultraviolet-c (UV-C) energy generated and measured by the R-D™ Rapid Disinfector™ UV-C System (the System) and its remote "challenge devices".

METHOD: This study was carried out in a controlled laboratory environment setting. *Clostridium difficile* spores were placed in a laboratory room, in direct line of sight of the UV-C emitter device (the Emitter). This study only used definitive, preselected UV-C dose settings and was not based on treatment time or the distance the coupons were located from the Emitter. The dose delivered was measured by the System's remote UV-C sensor "challenge devices". Independent tests were performed using six (6) different UV-C doses with three (3) coupons for each dose. After each controlled UV-C dose was delivered to each set of coupons the remaining viable *Clostridium difficile* spore colony counts were determined to compute the reduction from positive control coupons that were not irradiated.

RESULTS: In this test the effectiveness of UV-C radiation in reducing the spore count of *Clostridium difficile* ranged between 3.4 - 4.4 $\log_{10}$ after delivering a measured dose ranging from 45,903 to 159,693 μW-sec/cm^2.

CONCLUSION: The R-D Rapid Disinfector UV-C System was highly effective in reducing *Clostridium difficile* spores on contaminated surfaces.

COMMENTARY:
This study is the first to establish the amount of UVC light necessary to inactivate Clostridium *difficile* (C.*diff*) at greater than 3 $\log_{10}$ using a definitive dose measurement system.

To achieve a 99.96% (3.4 $\log_{10}$, 2500:1 reduction) spore count reduction, a dose of 46,000 uW-sec/sq-cm must be delivered to the pathogen. There is no way of determining whether that dose has been delivered to the point of interest unless a remote UVC sensor is used.

Clostridium difficile Study

Study #5: 4 Hospital Community-Wide Study – Rochester, NY

Two prominent research doctors specializing in infection control have written and received *IRB* (Institutional Review Board) approval for four Rochester, NY hospitals to conduct the only national community-wide study to help eradicate *C.diff.* The study includes use of eight Steriliz *R-D Rapid Disinfector* systems donated by the John and Jayne Summers Foundation. Their study commenced in 2012.

This C.*diff* study Review is independent from the IRB study however the UVC system utilization data presented herein is the same as that used by the IRB study.

The reported CDI information contained herein is publicly available from the New York State Department of Health at:
http://www.health.ny.gov/statistics/facilities/hospital/hospital_acquired_infections/2012/docs/hospital_acquired_infection.pdf

When a UVC system was selected for the study, systems that did not measure were not considered. The R-D Rapid Disinfectors were selected because it provides definitive data with respect to actual delivered dose of UVC light to multiple locations in the rooms being treated. Without such data there is no way to determine how much UVC energy was delivered, if any. Additionally, the Systems provide a multitude of online real-time reports and notifications that help identify where and when C.*diff* clusters occur within the facility thereby facilitating a rapid, measured response from the hospitals infection control and environmental services teams to address the problem.

Preliminary results of this study are very positive and differences in protocol and different systems have yielded varying results thereby providing a clear understanding of which systems and techniques yield the best results.

Protocol

Protocol for implementation of UVC room disinfection systems is broken down into two distinct areas: 1) how each individual room was prepared for UVC disinfection and how UVC disinfection took place; and 2) whether rooms were disinfected as "one offs" or as part of a unit-wide "cluster" decontamination.

A secondary component to protocol was which UVC system was used – the R-D Rapid Disinfector or the TRU-D system or both.

Room Preparation

Upon discharge of a C.*diff* patient each hospital's environmental services staff cleaned the room using normal cleaning products including chlorine bleach based chemicals for C.*diff* inactivation. After performing the "terminal clean" and prior to resetting the room UVC disinfection was performed using the specific manufacturer's operating instructions. Once UVC disinfection was complete then the room was reset with new privacy curtains, towels, bed linens, etc.

UVC Disinfection Procedure

For each of the respective UVC disinfection systems the manufacturer's instructions were adhered to as follows:

R-D Rapid Disinfector – In the case of a single room the emitter was placed on one side of the bed, all four sensors were placed in four different target locations, the room was exited and disinfection initiated. Once the two sensors on the same side of the bed received the full 46,000 uW-sec/sq-cm of UVC energy (the "C.*diff* dose" as published and referenced above) then the job was "paused", the operator entered the room and "repositioned" the emitter to the other side of the bed. The operator then exited the room and "resumed" the disinfection job and the system continued to emit UVC energy until the remaining two sensors received the full 46,000 uW-sec/sq-cm of UVC energy (the "C.*diff* dose"). Since this is a science based system (not an unscientific time or distance based system like those that do not measure UVC dose) the system emits UVC energy until all sensors being used (4 sensors in a typical patient room and 1 or 2 in a bathroom) have received the published dose of UVC energy necessary to realize a 3.4 $\log_{10}$ inactivation of C.*diff* spores at each remote sensor location. Average treatment time for this scenario in a 12 x 12 patient room is about 9 minutes.

Note: treatment time has been observed and recorded to be as short as 6 minutes and as long as 60 minutes depending upon room wall, ceiling and floor colors and material (these factors determine reflectivity of UVC energy – the better the reflectivity the faster the treatment time, and visa-verse), how many pieces of furniture are in the room, ceiling height, etc. The point here is that the R-D Rapid Disinfector system measures actual delivered UVC dose and

dynamically and definitively accounts for all the variations in the room and automatically adjusts the exposure time such that the C.*diff* killing dose is delivered to all remote sensor locations in the shortest amount of time, every time.

TRU-D – In the case of a single room the emitter was placed on one side of the bed near the foot board. The operator exited the room and initiated disinfection. This system measures UVC light back at the top of the emitter. The system was set to 22,000 uW-sec/sq-cm (not the published dose for C.*diff* but the dose recommended by the manufacturer). Since this is not a time based system the system runs until all sensors, located on the top of the emitter, have received the manufacturer recommended dose of UVC energy. From Strong Memorial and Highland Hospital data, average treatment time for this scenario in a 12 x 12 patient room is about 45 minutes.

Note: treatment time manually recorded by Strong and Highland is as long as several hours depending upon room wall color, surface absorption rate of UVC energy, how many pieces of furniture are in the room, ceiling height, etc. Again, the point here is that the system dynamically accounts for all the variations in the room and automatically adjusts the exposure time such that their published dose is received back at the emitter reflected from surfaces in the room.

Upon completion of the UVC disinfection the room is reset with new privacy curtains, towels, bed linens, etc.

Clostridium difficile Study

Treatment Data

Figure 2 below illustrates raw disinfection treatment data automatically recorded and reported for each of the four hospitals over the 16 month period beginning on September 1, 2011 and ending on December 31, 2012. This data is only for the R-D Rapid Disinfector Systems because the TRU-D systems that Highland and Strong hospitals have do not provide reporting. All data from the TRU-D system at those two hospitals was provided by the hospitals as Excel spreadsheets and is incomplete.

Hospital	Q4 '11 – Q1 '12	Q2 '12 – Q4 '12	TOTALS
Rochester General	444	682	1,126
Highland	-	469	469
Strong	-	291	291
Unity	46	605	651

Figure 2 – Disinfection jobs by date range

In the upper section of Figure 2 above the table lists the number of disinfection jobs performed at each of the four hospitals for the two different time periods.

The lower section of Figure 2 above details the number of disinfection jobs performed on a week by week basis at each of the respective hospitals. The graphs all have the same scale factor so a line of a specific height in one graph represents the same number of jobs for a line of the same height in any other graph. Each hospital has two R-D Rapid Disinfectors and the particular system being used is indicated by either a green or blue color. In a given week when both systems were used you can see a stacked bar with both colors shown.

Clostridium difficile Study

There were significant UVC usage differences between hospital protocols and interventions which included when UVC use began, how frequent UVC was used, how often UVC "cluster cleans" were performed, and which UVC products were used:

- The four Rochester, NY hospitals each received 2 R-D Rapid Disinfectors for use in each of their respect hospitals for a total of 8 systems between them. They began using them in 2011 and 2012 as shown in Figure 2 above. Highland and Strong also have 1 TRU-D UVC disinfection system each and have been using them since 2009.

- **Rochester General** - Usage began in September 2011, 6 months ahead of the other 3 hospitals. RGH implemented frequent proactive UVC use – usage compared to the other three hospitals ranged between 2-4 times more disinfection jobs over the 16 month period analyzed. RGH performed 8 "cluster cleans" and uses the R-D Rapid Disinfectors exclusively.

- **Highland** - Usage began 6 months after Rochester General. Highland performed 1 "cluster cleans" and 7 partial "cluster cleans" (60% -80% of rooms on a unit) with the R-D systems. There were a number of jobs performed with the TRU-D system however the data was collected manually and is difficult to analyze, because there is no automatic data recording on them.

- **Strong** - Usage began 6 months after Rochester General. Strong performed no "cluster cleans" and 2 partial "cluster cleans" (60% -80% of rooms on a unit) with R-D systems. There were a number of jobs performed with the TRU-D system however the data was collected manually and is difficult to analyze, because there is no automatic data recording on them.

- **Unity** – Usage began 6 months after Rochester General. Unity performed 1 "cluster cleans" and uses the R-D Rapid Disinfectors exclusively.

- All 4 hospitals began increased hand hygiene and antibiotic stewardship on January 1, 2012.

- <u>The only known difference in the interventions between the four hospitals is when and how UVC disinfection was implemented.</u>

Clostridium difficile Study

Cluster Response

Recalling the AJIC study from page 7, whenever a unit or ward has a contact precaution patient, then all patients in that unit/ward are at higher risk of contracting that type of infection. The unit/ward is presumed colonized.

During the 16 month review period all the hospitals except Strong initiated a "cluster clean" response using only the R-D Rapid Disinfector to treat at least 80% of the patient rooms within a unit when it was deemed that a cluster had developed (for example: a cluster is when there are 2 or more contract precaution patients in a unit/ward within a two week period).

The process of how and when a "cluster clean" was indicated and how that indication is transmitted to infection control staff yielded a patent pending "CLEAN SWEEP" [TM] software program that is integrated into the R-D Rapid Disinfector system online software and e-mail notifications. This component of the online software provides an invaluable tool for infection control and environmental services to identify potential problematic areas in a unit/ward.

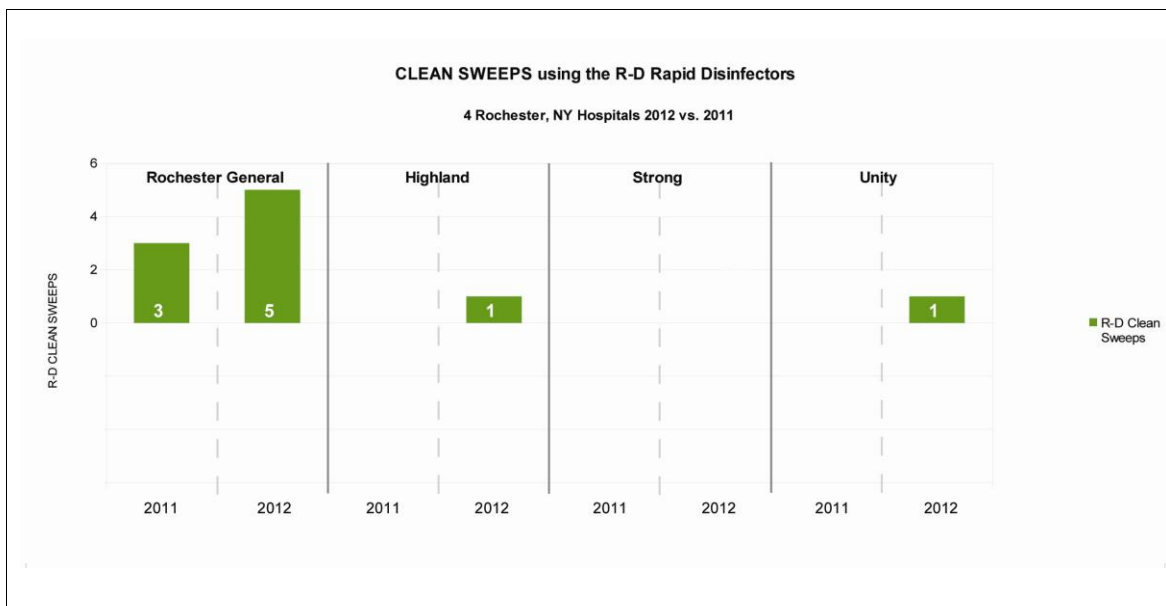Figure 3 below shows the number of CLEAN SWEEPS for 2011 and 2012.

Figure 3 – CLEAN SWEEPS using only the R-D Rapid Disinfector

C.*diff* Change 2012 vs. 2011

Figure 4 below shows the change in CDI cases at the four Rochester, NY hospitals for 2012 as compared to 2011. CLEAN SWEEPS are shown in green and the resulting change in C.*diff* cases, both number of cases and percent change, for 2012 vs. 2011, in red.
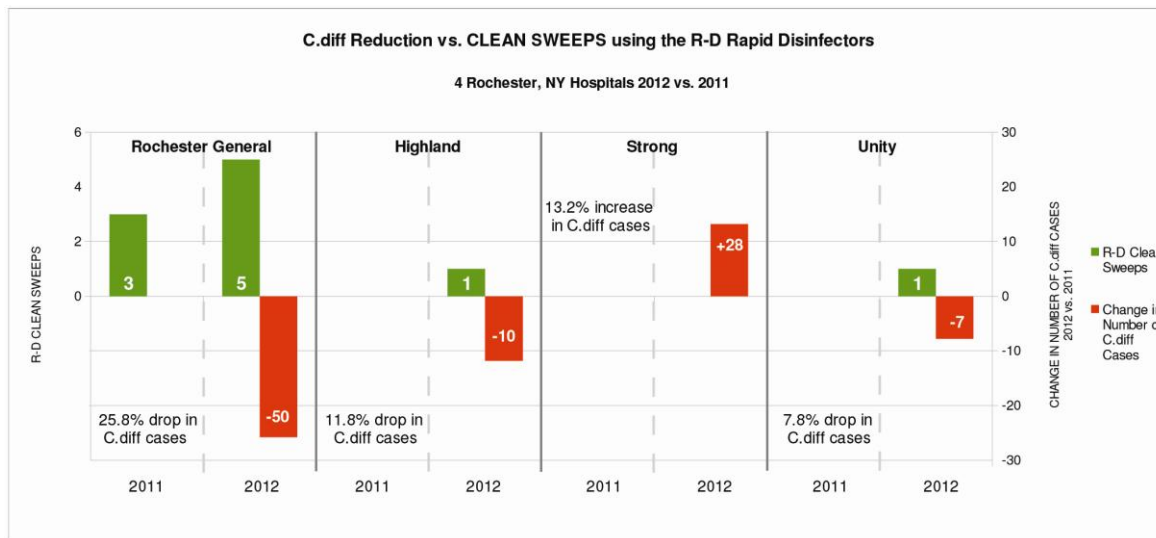

Figure 4 - C.*diff* Reduction vs. CLEAN SWEEPS using the R-D Rapid Disinfector

A review of Figure 4 shows that in a given time period performing more CLEAN SWEEPS resulted in greater reduction of CDI cases. It is important to note that both Highland and Strong continued to use their TRU-D system but since the TRU-D system they have does not record and report data TRU-D data was not included in this review.

In this comparison of 2012 to 2011 it's interesting to see the number of cases at Highland down and the number of cases at Strong up. One explanation for this comes from the Donskey study (on page 6) that found 35% of CDI rooms that were treated with the TRU-D system had residual spores. When you couple this information with the fact that Highland performed 1 CLEAN SWEEP completely with R-D and Strong did no CLEAN SWEEPS completely with R-D, then one may conclude that the results are as expected. In any case, one must conclude rooms that are contaminated with C.*diff* spores that are treated with an unknown dose of UVC light may be left with dangerous levels of residual spores – this is a conclusion of the Rutala study (on page 5). There is only one way to ensure a 99.9% C.*diff* inactivation using UVC light: UVC light must be measured at multiple locations in the room being treated, each and every time.

Conclusion

The problem of reducing HAI's in healthcare settings is complex and non-trivial. In the case of Clostridium *difficile*, the problem is compounded because of the off-host viability of spores.

The results for the four Rochester hospitals are summarized in Figure 5 below.

Hospital	CDI Cases		Change	$$ Savings
	2011	2012		
Rochester General	194	144	-50	$1,250,000
Highland	85	75	-10	$250,000
Strong	212	240	28	-$700,000
Unity	90	83	-7	$175,000
Average cost per CDI case – 2010 Rochester Collaborative				$25,000

Figure 5 – CDI Reduction and Cost Savings

The results presented herein support the need for frequent pro-active use of UVC light as an adjunct disinfection measure. In particular, the concept of Clean Sweeps when applied as developed by the four Rochester Hospitals and Steriliz appears to have significantly greater reduction of CDI cases than just one-off cleaning of CDI patient rooms.

With the proper UVC disinfection system and operating protocol, results similar to Rochester General may be accomplished in any healthcare facility.

When selecting a UVC disinfection device it is important to understand and recognize that a scientific "system" is needed – not just a tower of lights with a timer or a single pulsing lamp.

The key components needed to provide proper dose delivery and metrics to help drive the use of such a system include:

- DOSE – The dose necessary to achieve a 3+ $\log_{10}$ of C.*diff* is 46,000 uW-sec/sq-cm. Unless this dose is confirmed to be delivered UVC disinfection as an adjunct tool will more than likely not be successful.

- MEASURE – The ability to measure the delivered dose of UVC light at remote locations throughout the room being treated is the critical differentiator. Other systems may claim they "measure" but in reality they do not measure UVC dose delivered – either they guess or use some sort of smoke and mirror algorithm – in any case, there is no substitute for measuring delivered UVC.

Clostridium difficile Study

- RECORD – Management of a comprehensive HAI reduction program necessitates real-time online data recording. When your facility has multiple disinfection systems you will need to have all the data posted in one place for review and analysis.

- REPORTING – All the data in the world won't do any good if you don't have a way to generate and review reports. The key to successful UVC disinfection management lies with meaningful reports that help guide you through critical decisions like when and where to perform Clean Sweeps. Utilization reports that are automatically transmitted to management is a must – if the system isn't being used it cannot reduce CDI.

The R-D Rapid Disinfector is a UVC disinfection system that was designed by a team of scientists in Rochester, NY. With direct feedback from all their hospital and nursing home customers, the R-D has evolved into the most sophisticated UVC Disinfection System in the world. This is a System made for infection control professionals with significant input from infection control professionals.

The R-D Rapid Disinfector provides all the key components discussed above and with its patent pending components provides:

- o Faster treatment times of up to 80% less time than other advanced germicidal technologies. The **impact on time** is significant to healthcare facilities where time between procedures is critical; especially important to facilities with high census levels. The *R-D* has the unique ability to be paused and repositioned in the space being treated resulting in the shortest amount of disinfecting time and reduced and eliminated shadowed areas.

- o Better **data collection** through automated treatment logging and reporting and the ability to use HAI data to drive prevention and measure utilization for more effective disinfecting protocol.

- o Job Reports are generated **real-time** using patent pending *IN-TRAK*™ software and available online to users with password protected access to measure numerous activities throughout the facilities disinfecting process. Ultimately, the goal of collecting HAI data is to drive prevention efforts.

Business Case

Each year in the U.S. there are approximately 500,000 CDI cases resulting in 30,000 deaths[4]. There are just fewer than 1 million hospital beds in the U.S. That means there is 1 case of C.*diff* for every two beds. The average total cost for a single inpatient *C. difficile* infection (CDI) is more than $35,000, and the estimated annual cost burden for the healthcare system exceeds $3 billion[5].

Using these statistics, a 100 bed hospital would experience 50 CDI cases annually at a cost of $1.25 million. One R-D Rapid Disinfector is needed for every 100 beds to provide enough availability to treat all rooms on all discharges. The cost for a system is $75K. Additionally, a FTE to operate the system is $40K per year. Total cost for a system and an operator in the first year is approximately $115K. In subsequent years the cost would be $40K for the FTE and $5K for the extended warranty/service support agreement for a total cost of $45K.

If we assume a reduction in CDI of 20% (less than achieved at Rochester General) then the hospital should realize a savings of 10 cases and $250K per year. In the first year alone the system is fully paid for including labor costs.

Here is a simple spreadsheet model for the above case:

CDI COSTS:		CDI SAVINGS:	
Number of Beds	100		
CDI Cases/Year	50	CDI Case Reduction	20.00%
Cost/Case	$25,000	CDI Cases Less	10
ANNUAL Cost for CDI	$1,250,000	ANNUAL CDI Savings	$250,000
UVC COSTS:			
R-D Cost	$75,000		
FTE Cost	$40,000		

OUTRIGHT PURCHASE		LEASE for 3 YEARS	
1st year costs:		**1st, 2nd & 3rd year costs*:**	
R-D Cost	$75,000	R-D Lease Cost	$27,780
FTE Cost	$40,000	FTE Cost	$40,000
TOTAL COST	$115,000	TOTAL COST	$67,780
ROI year 1:	217%	ROI years 1, 2, & 3:	369%

OUTRIGHT PURCHASE		LEASE for 3 YEARS	
2nd year and on costs:		**Costs – years 4 and on:**	
R-D Cost	$5,000	R-D Cost	$5,000
FTE Cost	$40,000	FTE Cost	$40,000
TOTAL COST	$45,000	TOTAL COST	$45,000
ROI year 2 and on:	556%	ROI year 4 and on:	556%

Lease Assumptions:	ROI Assumptions:
R-D Price $75,000	Return on Investment is defined as
End of Lease Buyout $1	Total Annual Savings divided by
Term 36 months	Total Annual Costs
Interest Rate 7%	in a given year.
Monthly Payment $2,315	
Annual Payments $27,780	

UV Patient Safety Investments SAVE LIVES, PAIN AND SUFFERING and provide a 200%+ ROI in the first year. This model is easily scalable for other size hospitals.

References

1. New York State Department of Health:
   http://www.health.ny.gov/statistics/facilities/hospital/hospital_acquired_infections/2012/docs/hospital_acquired_infection.pdf

2. Operational utilization data records are property of Steriliz, LLC. 95 Allens Creek Rd Building 2-205 Rochester, NY 14618

3. Department of Health & Human Services USA: CDC American Recovery and Reinvestment Act Epidemiology and Laboratory Capacity (ELC) for Infectious Disease Program; Healthcare-Associated Infections (HAIs) Grantee Meeting; CDR; Arjun Srinivasan, MD; October 19-20, 2009

4. One Bacteria, 30,000 Deaths, USA TODAY August 16, 2012

5. APIC Implementation Guide: Guide to Preventing *Clostridium difficile* Infections: ©2013 by the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC); Walsh N. *C. difficile* Inpatient Stays Long, Costly. *MedPage Today*. December 8, 2012.

R-D Rapid Disinfector, R-D, and Rapid Disinfector are trademarks of Steriliz, LLC.

TRU-D is a trademark of Lumalier, Inc.