

The Five Pillars Of Safety In Healthcare **Appendix**

Prevasive USA[™]

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Noroxycdiff[®] 360

A preventative solution, providing sporicidal disinfection of all surfaces typically encountered in a healthcare environment.

EPA registered daily defense against C.diff Spores

Kills C.diff spores in 2 minutes

Efficacy

Kills C.diff spores in 2 minutes

Kills Norovirus

Kills 99.999% of most germs in 30 seconds

- MRSA
- VRE
- HBV
- HIV
- E.Coli
- Salmonella
- Klebsiella Pneumonia
- Pseudomonas Aeruginosa
- Acinetobacter Baumannii
- Influenza A: H1N1 Multi-drug resistant Bacteria
 - Other Bacteria, Viruses, and Fungi

Areas of Use

- Operating Rooms
- Patient rooms and bathrooms
- ICU Areas



Features

- EPA Registered
- Broad spectrum microbial action
- Bleach Free disinfectant, sanitizer, and sporicide
- Effective bactericide and viriucidal disinfectant in the presence of 5% blood serum
- Effective bactericide and viriucidal disinfectant in the presence of organic soil
- FDA clearance under 40 CFR §180.940 for use as a sanitizer on food contact surfaces
- Made in the USA

Does not contain

- Bleach
- Ammonia
- Phosphates

• Food preparation and contact areas Glass and Mirrors

- Stainless Steel
- High touch surfaces including hospital bed rails, bed tables, door handles, sinks, telephones, etc.



- One step hospital-use germicidal disinfectant cleaner
- Formulated to prevent cross-contamination on hard, non-porous surfaces
- Single-use, non-corrosive, product for most surfaces, with no rinse/wipe required
- Ready-to-Use HMIS Safety Rating of 1-0-0, with no PPE reauired
- Removes mineral deposits
- Improve room turnover times
- In-Use safely applied electrostatically
- Leaves no visible residue
- **Evaporates** completely
- No rinsing required
- Clear drying formula

C. Diff (*Clostridium difficile*) caused almost half a million infections among patients in the United States in a single year, according to a study released by the Centers for Disease Control and Prevention (CDC)

A Proof of Concept Case Study

Situation

At the request of a 13-hospital system in North Carolina, Crothall Healthcare implemented the Noroxycdiff 360 Electrostatic Spray Application protocol system wide during July 2018, as an adjunct to existing Terminal Discharge cleaning and disinfection protocols.

Initially, Crothall was instructed to utilize the Noroxycdiff 360 protocol upon discharge of all CDI contact precaution patient rooms as an alternative to their previously utilized UV disinfection process.

Crothall has since begun implementing the Noroxycdiff 360 protocol to include all contact precaution rooms, emergency departments, wheel chair corrals, and selected high occupancy patient and visitor waiting rooms.

The Process

As an alternative to UV and H2O2 Fogging, Noroxycdiff, in its in-use concentration, can be safely applied electrostatically, providing 100% coverage of all surfaces typically encountered in the healthcare environment. To treat 100% of all surfaces in a typical patient room, the process takes less than five minutes to complete. As previously stated, Noroxycdiff requires no rinsing or wiping. The room is ready for re-occupancy as soon as the surfaces are allowed to air dry; typically around five minutes, which provides a significant impact to room turnover times.

Additionally, Noroxycdiff's material compatibility profile means that it can be applied to every surface, hard and soft, including delicate electronics, monitors, keyboards, and medical equipment, without causing surface damage.

A detailed, step-by-step, pictorial of the process implemented by Crothall can be found by visiting www.noroxycdiff.com and clicking on the link for Noroxycdiff 360.

Results/Impact

Receptivity and adoption of the Noroxycdiff 360 adjunct protocol has been well received by the applicators for its convenience and simplicity.

* No issues have been reported by staff or patients regarding odors/smells or respiratory discomfort.

* Room turnover times have been slashed by less than half.

* While still early in our data collection, preliminary HAI reductions are encouraging when incorporating the Noroxycdiff 360 protocol into existing cleaning and disinfection processes. When comparing quarterly CDI cases for the same period, 2017 vs. 2018, system wide CDI cases dropped from 32 to 13; a 60% reduction!Further reductions are anticipated as the Noroxycdiff 360 protocol is expanded into other areas of the facilities.





Research Summary

Purpose:

This prospective efficacy study is a collaborative between Safety and Disaster Solutions, Inc. and EVS Protects, LLC and it compares the ACC results of three comparison categories: baseline (no cleaning/disinfection), after cleaning and disinfection with Virex Plus Disinfectant (US) and after application of Noroxycdiff using the Victory brand electrostatic sprayer. The purpose of this study is to evaluate the effectiveness of Noroxycdiff application in reducing bacteria on selected high touch surfaces in inpatient hospital rooms and bathrooms within the intensive care unit, as measured by bacteria culture and aerobic colony count (ACC) results.

Sample Collection

- A total of 162 swab samples were collected from one acute care hospital facility located in Michigan.
- The Copan flocked nylon swab (<u>https://www.copanusa.com/sample-collection-transport-processing/floqswabs/</u>) was used with SRK transport media. SRK is a broad-spectrum neutralizer that is buffered to preserve collected cells (Bazaco et al., 2011).
- All samples were collected by a single, TouchPoint employee who was trained by EVS Protects in proper environmental sampling.
- Multidrug resistant organism (MDRO) patient rooms (only) were sampled after discharge.
- Sampling templates were used, ensuring a consistent sampling area of 100 cm² per sample.
- From each room, the following three (3) selected high-touch surfaces were sampled (Guh & Carling, 2010); Ferreira et al., 2011):
 - Bedside table (TBL)
 - Toilet Seat (TLS)
 - Bedside rails (BedR)
- For each high touch surface, three samples were collected in the following manner (Figure 1):
 - At baseline (immediately before cleaning/disinfection)
 - Ten (10) minutes after cleaning/disinfection (Huang et al., 2015), (Boyce et al., 2011) with Virex (Virex Plus Disinfectant, US), a one-step Environmental Protective Agency (EPA) registered, accelerated hydrogen peroxide, cleaner-disinfectant product or with bleach (Clorox Healthcare® Bleach Germicidal Wipes) product.
 - Five (5) minutes after application of Noroxycdiff using the Victory electrostatic sprayer, per the product distributor.



Figure 1: Sampling scheme per room.

- Cleaning and disinfection was performed using Virex or a bleach product as follows:
 - Virex product
 - November 12th
 - Room #169
 - November 13th
 - Room #'s 4202, 3089, 4128
 - November 14th
 - Room #'s 124, 126, OV05
 - November 19th
 - Room #'s OV19, OV13, OV07
 - November 20th
 - Room #'s 4079, 2159, 2117
 - November 21st
 - Room #'s 3188, 3180, 3167
 - Bleach product
 - November 22nd
 - Room #'s 4046, 4040
- Once cleaning and disinfection was complete and the appropriate dry time was met, Noroxycdiff was applied using a Victory-brand, electrostatic sprayer per the onsite training and manufacturer's instructions for use.
- All samples were recorded on chain of custody (CoC) sheet, signed and dated.
- All samples were transported in cold conditions (6°C/43°F) using frozen ice packs with the CoC sheet to the microbiology lab using overnight shipping.

Methodology

- Samples were processed at a microbiology laboratory that is accredited by ANSI, IAS, and OSHA in the US and the Standards Council of Canada (SCC) in Canada.
- All samples were confirmed cold (at or below (6°C/43°F) upon arrival to the microbiology test laboratory.
- All samples, n=162, were analyzed for total aerobic colony counts (ACC) and reported as colony forming units (CFU)/cm².
- Samples were plated in triplicate.
- Upon receipt, each swab was vortexed and plated (dilution factor = 10 for all samples) according to the EVS Protects/Q Laboratory validated protocol for aerobic colony enumeration from environmental swab samples.
- Samples were plated by spread plate method in triplicate on blood agar.
- Samples were incubated at 37°C for 48 hours. After 48 hours, colonies were counted, and CFU/sample reported. CFU/sample was converted to CFU/cm².
- The upper limit of detection is >570 CFU/cm². The lower limit of detection is <0.01 CFU/cm². Therefore, the upper limit or lower limit whole number was used in calculations where appropriate.
- Pass/Fail criteria for Quantitative testing: ACC (Mulvey et al., 2011)
 - \circ Pass is < 2.5 CFU/cm²
 - Fail is $\geq 2.5 \text{ CFU/cm}^2$
- All statistical analysis was performed using GraphPad Prism version 8.0.0 for Windows, GraphPad Software, San Diego, California USA, www.graphpad.com.

Statistical Summary

Three comparison categories were evaluated and compared: baseline (no cleaning/disinfection), after cleaning and disinfection with Virex and after application of Noroxycdiff with the Victory brand electrostatic sprayer with n=48 in each group, for a total of 144 samples.

Using the Sapiro-Wilk test, the distribution of the data was evaluated for normality and found to be nonparametric (p<0.0001) or not normally distributed. Using the strictest cut-off value for the Grubbs test (alpha=0.0001), one outlier was found in each of the comparison categories leaving n=47 for each comparison group for a total of 141 samples. No significant change in the overall conclusions was found after the removal of these three (3) data points from the analysis. Unless otherwise indicated (Table 2 and Figure 1), these outliers (shown in Table 1) are not included in the analysis.

A matched, Friedman test (a One-Way ANOVA for non-parametric data) and the Dunn's test was used to compare the overall CFU/cm² recovered for each comparison group (Virex cleaned rooms only). Overall, there were statistical differences in CFU/cm² between the major comparison categories. Compared to baseline contamination levels, there was a statistically significant reduction in contamination levels recovered after cleaning and disinfecting with Virex (p<0.0001) as well as after treatment with Noroxycdiff via the electrostatic sprayer (p<0.0001). In addition, compared to after cleaning and disinfection with Virex, there was a statistically significant reduction in contamination after treatment with Noroxycdiff via the electrostatic sprayer (p=0.0203). This was confirmed using the Wilcoxon matched-pairs signed rank test (p=0.0010).

The toilet seat (item "TLS") had the highest overall bioburden levels prior to cleaning (33.7 CFU/cm²) followed by the patient bedside table (item "TBL") with 1.76 CFU/cm².

Overall % reductions and log reductions were calculated using the following formulas:

Log Reduction = $Log10(average baseline CFU/cm^2) - Log10(average comparative group CFU/cm^2)$

% Reduction = (average baseline CFU/cm2) – (average comparative group CFU/cm²) (average comparative group CFU/cm²)

Note:

In the existing cleaning and disinfection protocol, a bleach product (Clorox Healthcare Bleach Germicidal Wipes) is used. Therefore, sampling of bleach cleaned rooms was performed in order to compare the standard practice of using bleach plus the electrostatic application of Noroxycdiff to using Virex with the electrostatic application of Noroxycdiff (a less caustic option). This sampling occurred on 11/22/2019 and was performed in rooms that were cleaned/disinfected with a bleach product (in place of Virex), for a total of n=18 samples. This data (n=18) is reported and analyzed separately, presented at the end of this report.

Results

Table 1: Results for all samples collected.Reported as average CFU/cm² (reflecting the
triplicate plating of each sample). Data shown to 3
significant figures.ACD-V=After Cleaning & Disinfection using Virex
AES=After Electrostatic Spray Application*Outliers determined using
Grubb's test (alpha=0.0001).

Data	Room #	itam	Ave	rage CFU	'cm
Date		Ittill	Baseline	ACD-V	AES
		TBL	0.333	0.267	0.233
11/12/2019	169	TLS	15.2	0.933	< 0.01
		BedR	0.300	0.267	0.10
		TBL	0.0667	0.0333	< 0.01
	4202	TLS	0.933	0.0333	< 0.01
		BedR	0.633	0.200	< 0.01
		TBL	0.667	0.0667	0.03
11/13/2019	3089	TLS	0.500	0.100	< 0.01
11/10/2019	2007	BedR	<0.01	<0.01	0.0333
		TBL	0.800	< 0.01	<0.01
	4128	TLS	17.7	0.0333	0.100
	1120	BedR	0.267	0.0667	0.0333
		TRI	0.100	0.0667	<0.0333
	124	TIS	200	0.0007	0.0333
	127	PadP	0.100	<0.01	<0.01
		TDI	0.100	<0.01 0.0667	<0.01 0.0222
11/14/2019	126		0.107	0.0007	0.0333
11/14/2019	120	PodD	0.700	0.200	0.155
		TRI	3.40	0.200	0.200
	0V05	TIS	176	0.200	0.0333
	0,003	BedR	2 50	0.207	0.0333
		TRI	1.13	<0.01	<0.0333
	OV19	TIS	1.15	0.0667	> 0.01
	011	BedR	0.100	<0.0007	0.0667
		TRL	0.100	3 53	0.00333 0.300 0.0333 <0.01 2.2* 0.0667 0.03 0.07 0.30 0.333 <0.01
11/19/2019	OV13	TLS	18.7	0.03	
11,19,2019	0113	BedR	0.13	1 40	0.30
	OV07	TBL	7.00	<0.01	0.333
		TLS	3.73	< 0.01	< 0.01
		BedR	0.0333	< 0.01	0.0333
		TBL	1 27	0.367	< 0.01
	4079	TLS	0.900	0.167	< 0.01
		BedR	0.100	0.0667	< 0.01
	19 2159	TBL	7.27	1.23	0.0667
11/20/2019		TLS	13.8	0.233	0.167
		BedR	4.20	0.0667	0.0333
		TBL	4.00	< 0.01	< 0.01
	2117	TLS	>570*	2.10	< 0.01
		BedR	0.133	0.100	< 0.01
		TBL	0.467	0.0667	0.133
	3188	TLS	0.333	< 0.01	0.0333
		BedR	0.233	0.100	0.167
		TBL	0.467	0.0333	0.0667
11/21/2019	3180	TLS	1.03	< 0.01	< 0.01
		BedR	0.967	0.100	0.200
		TBL	0.900	0.100	< 0.01
	3167	TLS	54.6	300.2*	0.400
		BedR	0.0333	0.0667	< 0.01

Table 2: Summary statistics of all data for each comparison group, with and without outliers. Comparison groups are baseline (before cleaning), after cleaning and disinfection with Virex (ACD-V) and after Noroxycdiff electrostatic spray (AES) application.

(A) Outliers included						
All Data	Baseline	ACD-V	AES			
Number of values	48	48	48			
Minimum (CFU/cm ²)	< 0.01	< 0.01	< 0.01			
Maximum (CFU/cm2)	>570	300	2.20			
Range (CFU/cm2)	>570	300	2.20			
Mean (CFU/cm2)	23.2	6.55	0.116			
Std. Deviation	89.2	43.3	0.323			
Std. Error of Mean	12.9	6.25	0.0467			
% Reduction from	71.75%	99.50%				
Log Reduction from	0.549	2.30				

(B)	Outliers Removed			
	Outliers Removed	Baseline	ACD-V	AES
	Number of values	47	47	47
	Minimum (CFU/cm ²)	< 0.01	< 0.01	< 0.01
	Maximum (CFU/cm2)	200	3.53	0.400
	Range (CFU/cm2)	200	3.53	0.400
	Mean (CFU/cm2)	11.6	0.305	0.072
	Std. Deviation	38.6	0.642	0.102
	Std. Error of Mean	5.64	0.0937	0.0149
	% Reduction fron	97.4%	99.4%	
	Log Reduction fron	1 Baseline	1.58	2.21



Figure 1: Overall average CFU/cm^2 with standard deviation bars of all samples collected at baseline (before cleaning), after cleaning and disinfection (C/D) using Virex and after electrostatic spray (ES) application. With and without outliers as indicated above each graph.

Table 3: Descriptive statistics of total CFU/cm² recovered by item at baseline, after cleaning and disinfecting with Virex and after electrostatic spray application. Data shown to 3 significant figures. TBL=Patient Table; TLS=Toilet Seat; BedR=Patient Bedrail

	Baseline		After Cle	aning/Disi (Virox)	nfection	After El A	ectrostatic pplication	Spray	
Descriptive Statistic	TBL	TLS	BedR	TBL	TLS	BedR	TBL	TLS	BedR
Number of values	16	15	16	16	15	16	16	15	16
Minimum (CFU/cm ²)	0.0700	0.330	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010
Maximum (CFU/cm2)	7.27	200	53.40	3.53	2.10	1.40	0.330	0.400	0.300
Range (CFU/cm2)	7.20	199	53.40	3.53	2.10	1.40	0.330	0.400	0.300
Mean (CFU/cm2)	1.76	33.7	0.63	0.378	0.284	0.251	0.0594	0.082	0.0744
Std. Deviation	2.38	64.3	1.1	0.894	0.553	0.415	0.0951	0.123	0.0930
Std. Error of Mean	0.595	16.6	0.28	0.223	0.143	0.104	0.0238	0.032	0.0233
	Log reduction from baseline			0.6696	2.074	0.3978	1.473	2.613	0.9253
	% reduction from baseline			50.97%	98.95%	97.38%	96.63%	99.76%	88.12%



Figure 2: Average CFU/cm² with standard deviation bars recovered by item at baseline (shown left) and after cleaning and disinfecting with Virex (ACD-V) and after electrostatic spray application (AES), (shown right).



Figure 3: Overall % Reduction (Left) and Log Reduction (Right) from Baseline achieved after cleaning and disinfection using Virex (ACD-V) and after electrostatic spray (AES) application (outliers removed).



Figure 4: Overall % Reduction from baseline by item sampled (shown left) and Log Reduction from baseline by item sampled (shown right) achieved after cleaning and disinfection using Virex (ACD-V) and after electrostatic spray (AES) application by item sampled. TBL=Patient Table; TLS=Toilet Seat; BedR=Patient Bedrail.

Table 4: One-Way ANOVA using the matched, Friedman test for non-parametric data and the Dunn's test for multiple comparisons of the average CFU/cm² recovered for each comparison group (Virex cleaned rooms only).

One-Way ANOVA: Virox							
Friedman test							
Exact P value <0.0001							
P value summary The means are significantly different ($P < 0.0$							
Number of groups 3							
Friedman statistic	c 57.96						
Dunn's multiple comparisons test	Rank sum diff.	Adjusted P Value					
Baseline vs. ACD-Virox	48	< 0.0001					
Baseline vs. AES	70.5	< 0.0001					
ACD-Virox vs. AES	22.5	0.0203					

Results using bleach

On the last day of sampling, the rooms were cleaned using a bleach product (Clorox Healthcare Bleach Germicidal Wipes) in place of the Virex product for a comparison of overall efficacy between these two products and is shown in Table 5 (given the addition of the Noroxycdiff electrostatic sprayer step). Summary statistics are shown in Table 6.

Table 5: Results for samples collected on 11/22/2019. Reported as average CFU/cm² (reflecting the triplicate plating of each sample). Data shown to 3 significant figures. ACD-B=After Cleaning & Disinfection with bleach product. AES=After Electrostatic Spray Application of Noroxycdiff.

Data	Room #	item	Average CFU/cm ²			
Date			Baseline	ACD-B	AES	
		TBL	2.03	< 0.01	< 0.01	
	4046	TLS	11.1	< 0.01	6.37	
11/22/2010		BedR	0.300	< 0.01	< 0.01	
11/22/2019		TBL	1.10	< 0.01	< 0.01	
	4040	TLS	0.200	< 0.01	< 0.01	
		BedR	53.4	< 0.01	< 0.01	

Table 6: Summary statistics of data pertaining to rooms cleaned/disinfected using bleach, collected on 11/22/2019. Comparison groups are baseline (before cleaning), after cleaning and disinfection with bleach product (ACD-B) and after electrostatic spray (AES) application using Noroxycdiff.

	Baseline	ACD-B	AES
Number of values	6	6	6
Minimum (CFU/cm ²)	0.2	< 0.01	< 0.01
Maximum (CFU/cm2)	53.4	< 0.01	6.37
Range (CFU/cm2)	53.2	< 0.01	6.37
Mean (CFU/cm2)	11.4	< 0.01	1.062
Std. Deviation	21.0	< 0.01	2.601
Std. Error of Mean	8.58	0.00	1.0620
% Reduction from	m Baseline	>99.9%	90.7%
Log Reduction from	m Baseline	>5.00	1.03

Although this is a very small sample set, this data (collected on 11/22/2019) was compared to the rest of the data (collected 11/12/2019 through 11/21/2019) using the unpaired, Kruskal-Wallis with the Dunn's test to compare the mean ranks of nonparametric data (Table 7). The total mean CFU/cm² recovered after cleaning and disinfecting with the bleach product (<0.01 CFU/cm²) was statistically lower than that after using Virex (0.305 CFU/cm²); (p=0.0100) noting that the toilet seat sample from room 4046 is technically an outlier, but the data set is too small to remove it from the analysis. Never-the-less, there was no statistical difference in the level of efficacy achieved after applying Noroxycdiff via the electrostatic sprayer, regardless if the room was cleaned and disinfected with Virex or the bleach product (p=0.6039). Further, there was no statistical difference in the amount of contamination recovered after the room was cleaned with the bleach product compared to after the room was cleaned with Virex and treated with Noroxycdiff via electrostatic spray (p=0.1143).

Table 7: One-Way ANOVA using the matched, Kruskal-Wallis test for non-parametric data and the Dunn's test for multiple comparisons of the average CFU/cm² recovered. Data from Virex cleaned rooms (collected 11/12/2019-11/21/2019) was compared to data from rooms where bleach was used (collected on 11/22/2019).

One-Way ANOVA: Bleach vs Virox							
Kruskal-Wallis test							
P value <0.0001							
P value summary	The means are significantly different ($P < 0.0$)						
Number of groups	5						
Friedman statistic	71.31						
Dunn's multiple comparisons test	Rank sum diff.	Adjusted P Value					
ACD-V vs. ACD-B	52.61	0.0085					
AES-V vs. AES-B	11.12	0.5734					
ACD-Clorox vs. AES-V	32.2	0.103					

In summary, it appears that cleaning and disinfecting with Virex Plus Disinfectant (US) followed by the electrostatic spray with Noroxycdiff is as efficacious as using the bleach product alone. Given the small sample set used to assess and compare the bleach cleaned rooms, additional testing should be performed to confirm these results.

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