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Use of Novel Approaches to Reduce *C. Difficile* in an Inner City Hospital

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Introduction:

C. difficile is a spore-forming, Gram-positive anaerobic bacillus that can lead to antibiotic-associated diarrhea and sepsis.[1]

C. diff is shed in feces, so any surface, device or material that becomes contaminated with feces can serve as a reservoir for *C. diff* spores, which can be transferred to patients mainly via the hands of healthcare personnel who have touched a contaminated surface or item.[2]

Additionally, *C. diff* spores may remain in the environment for as long as 5 months or more and be passed to the next individual occupying the hospital or nursing home room. Proper environmental cleaning is essential to prevent the infection of the next room resident. *C. diff* is also carried by animals, including cows, horses, and pigs; increased by the use of certain antibiotics such fluoroquinolones, cephalosporin's, and clindamycin; use of Proton Pump Inhibitors (PPI), and use of alcohol hand rubs by healthcare workers.[3,4]

Important C. diff Facts to Consider:

- According to a recent CDC report, C. diff caused nearly half a million infections in U.S. hospitalized patients in 2011. That year, about 29,000 patients died within 30 days of the *C. diff* diagnosis, with 15,000 of those deaths directly attributable to the infection.

- *C. diff* infections, or CDIs, account for 10 percent of all HAIs in hospitalized patients. The excess cost of a CDI per patient is estimated at around $11,000.[3 Part] of that excess cost comes from the increased length of stay for a patient with a CDI. When a CDI occurs, it adds roughly 3.3 days onto the average length of stay for a patient.[3]

- CDIs make up 5 percent of the excess costs in U.S. hospitals associated with all HAIs (whereas central line-associated bloodstream infections represent 36 percent of excess costs in U.S. hospitals and catheter-associated urinary tract infections represent 2 percent.[3]

- Over the last 10 years, the rate of CDIs were highest in the following regions: Northeast (eight CDI discharges per 1,000 total discharges), Midwest (6.4/1,000), South (5/1,000) and West (4.8/1,000). Between 2001 and 2010, *C. diff* mortality was highest in the Midwest (7.3 percent). This is also accentuated by circulating toxigenic strains leading to greater severity of CDI. [4]

- CDI pressure on hospitals and hospital admissions is further aggravated due to community onset as noted above by external factors. Hospital may be experiencing a 5 to 10-fold increase in community prevalence rates. (NHSN, PC)[5] In patients being admitted to hospital the colonization rate is 4.4-15%. In skilled facilities, the number may be as high as 50%. (Cohen,2010)[6]

- Recent data from CDC suggest that there are 4 factors predicting HO CDI rates (hospital acquired): 1. Test being used; 2. medical school affiliation; 3. facility bed size; 4. and CO-CDI prevalence rate. (Dudeck,2013)[7]

As discussed above, *Clostridium difficile* infections (CDI) in the hospital and healthcare environment are difficult to control despite expanded vigilance and attempts to prevent transmission. Increased sensitivity in testing has contributed to higher detection rates due to higher sensitivity of the assays.

This paper describes how a 300-bed inner city hospital was able to bring their infection rates and SIRS (Standard Infection Ratios) under control by adjusting their isolation and environmental cleaning protocols for patients with recent onset of diarrhea.

Background and Methods:
Concerned over the low sensitivity of EIA *C. diff* toxin assays, in late 2013 (November), this facility changed the algorithm for CDI testing to testing by ELISA (EIA) for CD Antigen (GDH) and CD Toxins A and B, followed by PCR for Toxin B if EIA was negative for Toxin with a positive GDH Antigen test. This more sensitive approach has increased the detection rate, and therefore the facility's Hospital Acquired Infection (HAI) rates as well as the SIR for CDI. Using the EIA for Toxin alone, the sensitivity for detection was in the 60-65% range. With PCR, sensitivity and specificity approaches 95-100%. The number of patients being admitted from outside facilities with CDI had also increased. These are determined to be community onset (CO-HCFA) unless recently discharged from another healthcare institution ($\leq$ 4 weeks earlier). The National Health and Safety Network (NHSN) have increased the surveillance for these occurrences by collecting FAC-Wide-In data as a Lab ID data from hospitals. The clinical definition remains a laboratory determined parameter and does not recognize pre-existing conditions. If a patient is admitted to the hospital after a recent occurrence of CDI, redevelops diarrhea, and is retested greater than three days' post admission, this is charged as a HAI to the hospital regardless of where the infection may have originated. This lab based reporting without context makes it even more difficult for a hospital to reduce their HAI Rates or SIRs (known as HO Hospital onset vs CO Community onset) for CDI. The epidemiology of CDI as described in a paper by Freeman et.al (2010) [3] indicates that both the geographic distribution and strain differences affects the respective rates reported as noted above.
The hospital has an average census of 100 patients, has a 10 bed ICU, a cardiac step down unit, a progressive step down telemetry unit, a medical surgical unit and a "clean" medical surgical unit. The facility sees 100+ patients daily in their emergency room, has a Family Practice Clinic, a Wound care center, and a variety of other provider practices which are all accounted for in the NHSN data base. It also has Family Practice Resident program. In addition, the hospital has a Long Term Acute Care Hospital (LTAC) and out sourced Dialysis units in their facility which have separate reporting NHSN ids, but many patients are transferred from this facility to the hospital for procedures. Lab work is performed by the hospital and the EVS service is also contracted to the hospital. The LTAC has its own challenges as it receives patients from many other local hospitals and long term care facilities. These facilities add to the *C. diff* pressure for the hospital.

In 2012-13, the hospital's rate for HAI CDI was and average of 6-7/10,000 patient days. This rate exceeded targets set by the hospitals governing bodies as well as insurance carriers and other regulators. Expected acceptable targets vary and are being continuously reevaluated by regulatory agencies. Recently the baseline for NHSN facility assessment was changed from the 2011 baseline to 2015 derived baselines. The protocols for terminal cleaning of the *C. diff* rooms in 2013 utilized bleach wipes and a phenolic product with a micro-fiber rag. In searching for interventions and in consultation with infectious disease physicians, the facility initiated and added a nurse driven CDI protocol (Figure 1) that allowed for immediate placement of patients admitted or developing diarrhea in enteric contact (enhanced contact) precautions with three or more Bristol stools, category 5-7[8] in a 12-hour period in early 2014. With patient isolation, the protocol allowed the ordering of CDI testing by methods described earlier. The Infection Preventionist also partnered with the clinical pharmacy staff to monitor antimicrobial suitability and PPI use in patients. The daily clinical rounds served to remind staff about the importance of proper hand washing and gowning. The visitors were also educated about *C. diff*

whenever possible. The Environmental Service staff with direction from Infection Prevention Committee then integrated a new final step to the terminal cleaning protocol. This new technology known as SteraMist™ Binary Ionization Technology® (BIT™), (TOMI, Beverly Hills, CA), converts a 7.8% hydrogen peroxide solution into a Hydroxyl Radical mist. This EPA registered solution is passed thru an atmospheric cold plasma arc where activation occurs. Activation creates a mist/fog containing a high concentration of Reactive Oxygen Species, mainly the Hydroxyl Radical. The mist/fog referred to as Activated Ionized Hydrogen Peroxide (AIHP) is delivered via a handheld application system to the terminal cleaning of CDI rooms after the base cleaning with bleach wipes and a general all-purpose cleaner. The phenolic disinfectant previously in use was completely removed from the facility. The ionized properties of the mist/fog allow for uniform distribution and address hard to reach areas commonly missed in manual cleaning. Bleach wipes were only used for daily high touch cleaning while the patient positive for *C. diff* occupied the room. For terminal cleans the general purpose cleaner was used followed by the AIHP SteraMist technology approved by EPA for *C. diff* spores. (In 2014-15, the bleach wipes were used in terminal cleans until EPA clearance for spores was achieved). The advantage of the technology is ease of use and rapid mobile application to target affected areas and rooms. Room turnover is less than 25 minutes with no residual odor or annoying surface film. Application of SteraMist was performed by trained EVS personnel.

An additional intervention was added in late 2014 and 2015. Since curtains always serve as a reservoir of pathogens especially on the leading surfaces, we added disinfectant containing curtains (All in One Medical, London) to the ICU, Emergency department, and the Cardiac step down unit. These curtains were then added to all areas of the hospital in July 2015. There are several citations for disposable curtains and the use of plastic shields on the leading edge of fabric curtains adding credibility to this intervention. (HRST, 2016) [9] Curtains were regularly cultured for pathogens over a 9 month period using an agar paddle test. The imbedded disinfectant is an EPA registered Quaternary Ammonium compound called Fantex[tm] (IU *BSENISO20743).*

Results: (Table 1, Fig. 2)

The hospital's results with the new isolation/testing order set, new lab diagnostics, new disinfectant curtains (2015-16) and use of the AIHP technology show infection rates have dropped to 3.1/10,000 for calendar 2014, rose to 8.9/10,000 for 2015, and decreased to 6.19/10,000 for 2016. Rates do not take into account factors affecting CDI findings as does the SIR's calculation which is one of the reasons the CDC changed to the SIR metrics. The data reflected in Table 1 is based on the 2011 baseline. Since 2014 the facility has maintained SIR's of 0.391 to 0.738. With the SIR being less than 1, the facility shows improvement, but is finding it difficult to control small outbreaks. Their institutional target is a SIR of 0.41 which is very aggressive, but is still not zero. The facility found the occurrence of CDI is not service location dependent, and small clusters have occurred in the Med-Surgical units, the Medical ICU, and the General Step down units. The units get 3 or 4 positive patients in a 3-5 day period, followed by none for a few weeks. The in-coming Community Acquired Infections range is from 0-3 per month for this period. (Table 1) The cumulative CO rate showed an increase in 2015 which is mirrored in the hospital admission prevalence rate Table 2 and Table 3. 2015 was a challenging year across all aspects. In 2016 the CO, HO and overall prevalence rate were reduced resulting in more acceptable numbers. This finding was not attributable to any particular factor but may reflect better antimicrobial choices, delivery and de-escalation; PPI awareness, and more appropriate timing of testing through clinical rounding and *C. diff* protocol. (Fig. 1) It is important to note that individual quarter evaluation will show quarters with SIRS as low 0.277 for 4th quarter 2016, (data not shown, NHSN 2016) but a mini outbreak in any quarter will affect the yearly SIR's value as detailed above.

The disinfectant curtains have shown no measurable contaminants after 6 months of use. 1/67 curtains showed 1 colony of *Staphylococcus sp.* Additional cultures on 40 curtains showed one colony on 40 paddles taken from the Emergency room and the ICU. There is no claim as a sporicidal for the disinfectant imbedded in the curtains, but the curtains were misted with SteraMist during the Terminal cleaning with no ill effect to the fabric assuring a spore free environment. There is no direct correlation of curtains to *C. diff* rates or achieved SIR's, but they do reduce bacterial load in the patient environment and minimize the effect of lack of hand washing by visitors and healthcare workers when handling the curtains. The compatibility of the SteraMist and curtains further lower the endemic bacterial load on surfaces. They also reduce the room turn-over time between patients.

Conclusion:

Actual NHSN data for the hospital population suggests that the prevalence rate for incoming patients has risen since 2013 adding to the *C. diff* pressure, (Table 1). In each incoming case, the staff is reminded to wash their hands with soap and water, wear gowns, and isolate the patient immediately upon the finding of diarrhea. Visitors are asked to wear gowns and gloves as well. The IP, Pharmacy staff, and attending actively monitor antibiotic regimens during daily clinical rounds to shorten antimicrobial therapy and substitute antibiotics to replace high incidence CDI associated antibiotics when clinically possible. PPI use is discouraged and appropriate substitution is done when possible.

The AIHP technology added as a final step in the terminal clean protocol is EPA registered for use as a Hospital/Healthcare disinfectant and is now cleared by EPA for a 6-log *C. diff* spores kill. The hospital will further streamline the cleaning protocol by discontinuation of bleach wipes as noted above. The use of AIHP in combination with the active isolation and antibiotic interventions has greatly reduced the hospital's *C. diff* burden. By moving to stricter isolation protocols and incorporating AHIP technology into EVS cleaning protocols, this hospital has been able to stabilize their CDI rates even with the use of increasingly sensitive *C. diff* detection methods and increased community prevalence rates. The ICU has lowered their incidence of *C. diff* significantly since the use of SteraMist is done after every discharge and is employing the disposable disinfectant curtains. (Table 3) The impact of the 2015 Base lining is not yet clear but will definitely increase pressure to reduce infections due to the higher resulting SIRS.

The AHIP BIT technology now EPA cleared for *C. diff* spores is an indispensable part of the arsenal to control CDI in both in-patient and out-patient facilities. Continued antibiotic stewardship vigilance as well as proper PPI utilization in active cases will help further reduce the burden of CDI for patients. It is clear that CDI disease detection and control is not a simple fix. The presence and transmission of *C. diff* Is multifactorial and requires vigilance from all parties. Disinfection and antimicrobial stewardship are key to reducing CDI and transmission.

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5. NHSN personal communication 2015

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7. Dudeck, MA et al. 2013;http://www.cdc.gov/nhsn/pdfs/mrsa-cdi/RiskAdjustment-MRSA-CDI.pdf

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www.hret-hen.org

Table 1: Results

*With the new isolation/testing order set and use of the AIHP technology, infection rates/SIR

	Pre-intervention Rate	Post intervention HAI (HO) rate	# Exp CDI (determined By NHSN)	SIR* (2011 baseline)	CDI In Patient Admission CO Prev. Rate	CDI Prevalence-Inpatient CDIF Overall Prevalence	Testing and Interventions
2012-13 FACWIDEIN	6.439/10,000 patient days		n/a	1.158	0.162	n/a	Used EIA 1st 10 mos; new testing *initiated* 11/1/13
1/2014-12/2014 FACWIDEIN		3.176/10,000	6	0.361	0.512	0.662	New Testing algorithm; *added* new isolation protocol
8/2014-3/2015 FACWIDEIN		3.30/10,000	4	0.391	0.775	1.025	New Testing algorithm; added; new isolation protocol; *added* SteraMist
1/2015-12/2015 FACWIDEIN		8.9/10,000	16	0.858	0.883	1.491	New Testing algorithm; new isolation protocol; SteraMist; *added* Disinfectant curtains
1/2016-12/2016		6.19/10,000	11	0.739	0.360	0.672	New Testing algorithm; new isolation protocol; SteraMist; Disinfectant curtains

*Data extracted from NHSN data base

Table 2: All locations Summary Community Prevalence Counts

Summary Yr.	location	months	Cdif _admPrevCOCount	#adms	CDI_CO Prev Rate
2014	FACWIDEIN	12	22	4297	0.512
2015	FACWIDEIN	12	32	3622	0.883
2016	FACWIDEIN	12	15	4169	0.360

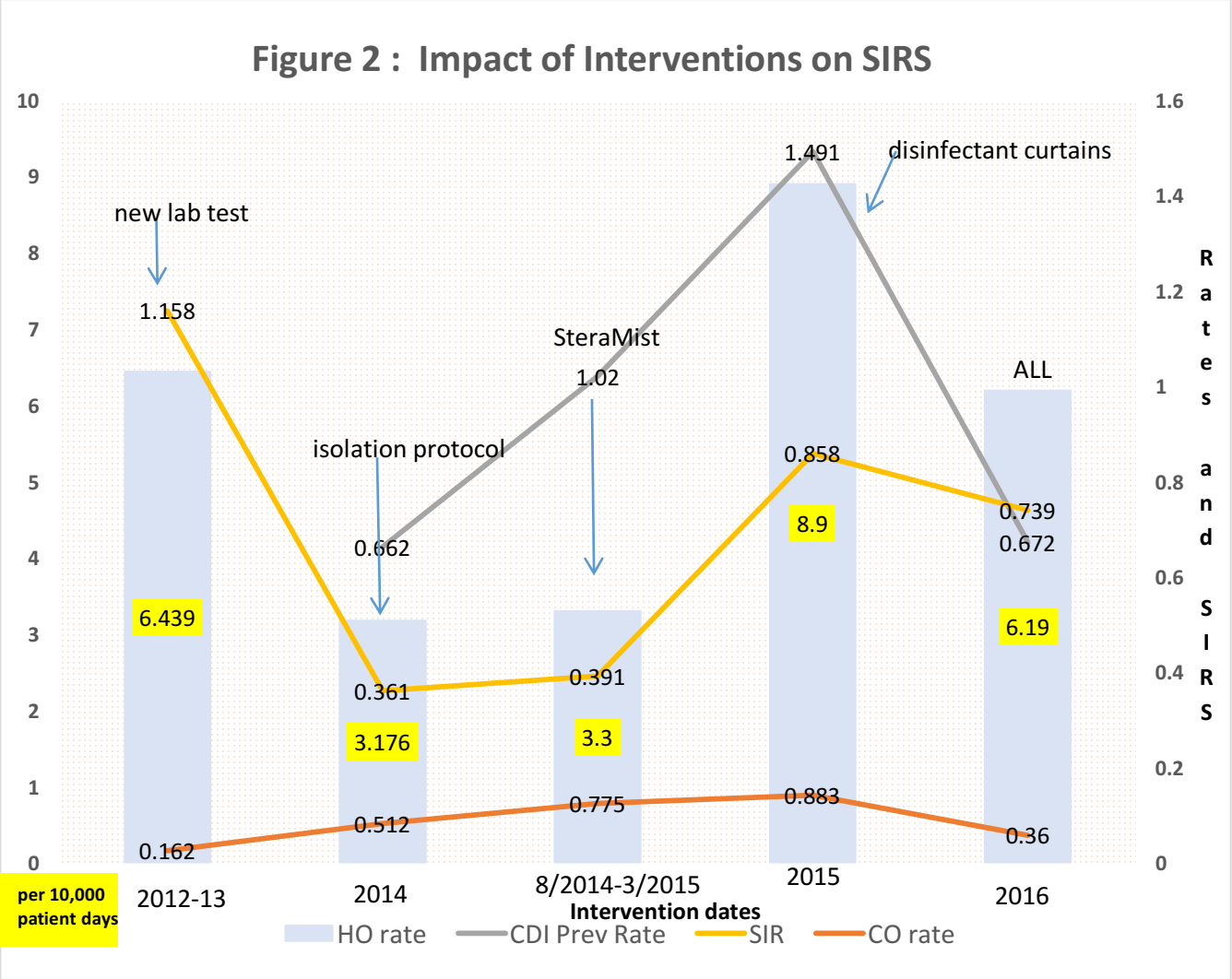
Table 3: ICU Location Only Summary Community Prevalence Counts

Summary Yr	location	months	Cdif _admPrevCOCount	Cdif _admPreCount	CDI_pctAdmPrevCO
2014	1A	7	3	3	100.0
2015	1A	12	7	9	77.778
2016	1A	12	4	5	80.000

Figure 1: *C. diff* Isolation Protocol

Date/Time	FOR PATIENT SAFETY, LEGIBILITY IS ESSENTIAL	INITIALS/NOTES
	Protocol for C-diff Surveillance toxins	
	Any patient meeting the following criteria must have surveillance samples collected on admission for C-diff (C-difficile): (please assess and check applicable criteria) • Patients admitted from a long-term care facility with any unformed stool • Patients admitted with suspicion of C-diff (diarrhea greater than 4 unformed stools in 24hrs) *RN/LPN SIGNATURE:*_____*Date:* _____*Time:* _____	
	note: Surveillance samples for C-diff are to be collected from patients with active diarrhea. • **Patient with an active C-diff infection does not require additional testing (Place on contact enteric isolation Precaution).**	
	For patients meeting any of the above criteria, the following interventions are to be started immediately: • C-diff Toxin ○ Obtain stool sample for C-diff toxin test ○ Label samples appropriately and enter the test request in Meditech ○ Place patient in single – patient room ○ Place Contact with Enteric Precaution Sign on patient's door ○ Obtain Isolation Cart – Ensure that gloves and gowns are easily accessible from patients room ○ Place dedicated stethoscope in patients room ○ Do not share blood pressure apparatus with other patients ○ Wash hands thoroughly with soap and water following contact with patient and or patient's environment (Hand sanitizers are not appropriate for enteric precautions)	
	Patients meeting the above criteria should be placed on Contact with Enteric Precautions in a private room. **Any Patient with a positive C-diff toxin result or positive antigen test and or PCR Posi- tive still on antibiotic therapy for C-diff must be placed on contact with enteric Precautions. discontinuation of precautions can occur 48 hours post antibiotic completion as long as there are no episodes of diarrhea.**	

Fig. 2: Summary of Interventions, infection Rates, and Resulting SIR's



Abstract:

Use of Novel approaches to reduce *C. Difficile* in an Inner City Hospital

Background:

C. diff is a spore-forming, Gram-positive anaerobic bacillus that can lead to antibiotic-associated diarrhea and sepsis, [1]*C. diff* is shed in feces, so any surface, device or material that becomes contaminated with feces can serve as a reservoir for *C. diff* spores.

Clostridium difficile infections (CDI) in the hospital and healthcare environments remain difficult to control in spite of expanded vigilance and antimicrobial interventions. Increased sensitivity in testing contributes to higher detection rates. In late 2013, this facility changed the algorithm for CDI testing: ELISA (EIA) for antigen and Toxins A and B, followed by PCR for Toxin B if EIA is negative for Toxin.

Methods:

In 2012-13, the hospital's rate for HAI CDI was 6.439/10,000 patient days. Protocols for terminal cleaning of the *C. diff* rooms at that time utilized bleach wipes and a phenolic product with a micro-fiber rag. The facility initiated a nurse driven protocol that allowed for immediate placement of patients admitted or developing > 3 diarrhea stools (Bristol 5-7) in enteric contact precautions, and ordered CDI testing. A new technology which converts a 7.8% hydrogen peroxide solution into a Hydroxyl Radical mist was added. The mist/fog referred to as Activated Ionized Hydrogen Peroxide (AIHP) was applied via a handheld system after terminal cleaning of CDI rooms with bleach wipes and an all-purpose cleaner. Potentially hard to reach areas were reached with this approach. Additionally, disinfectant containing curtains were added in 2015-16.

Conclusion:

The use of AIHP in combination with the active isolation, antimicrobial interventions and disinfectant containing curtains has greatly reduced the hospital's *C. diff* burden. By moving to stricter isolation protocols and incorporating AHIP into cleaning protocols, this hospital has been able to stabilize their CDI events even with using increasingly sensitive detection methods and increasing CDI CO-prevalence.