**AN ANALYSIS OF INTERVENTIONS AIMED AT DECREASING HOSPITAL-ASSOCIATED *CLOSTRIDIUM DIFFICILE* CASESIN COMMUNITY HOSPITAL A**

by

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**ABSTRACT**

Interventions aimed at reducing the number of hospital acquired infections of *Clostridium difficile* are important tools to reduce the mortality and morbidity connected with the infection. The public health significance of *C. difficile* is the fact that *C. difficile* has contributed to approximately 14,000 deaths per year. To limit the negative impact of *C. difficile* in hospital settings, the Centers for Disease Control and Prevention (CDC) recommend several interventions that can be implemented to try and reduce the spread of *C. difficile* between patients. Examples of these interventions include the isolation of patients in private rooms, the use of gloves and gowns by all staff and visitors when entering a patient's room, the use of soap and water before and after entering all patient rooms, environmental cleaning of patient rooms, and judicious use of antibiotics. By reducing *C. difficile* infections, the negative outcomes to the patients can be reduced along with the extra cost to the healthcare system due to the infections. This paper describes and analyzes the number of positive *C. difficile* tests before (FY07 to FY09) and after (FY10 to FY12) implementation of two specific interventions in Community Hospital A located in Allegheny County which were referred to as the antimicrobial stewardship program and the cleaning room protocol. These data on *C. difficile* tests and aggregate measures of patient-associated data, which included average age and length of stay, were collected from the archived annual reports and contain information from July 2006 to June 2012 or Fiscal Year 07 to Fiscal Year 12 (FY07 to FY 12). These data were from a specific community hospital located in Allegheny County. This community hospital was referred to as Community Hospital A for the purpose of this paper. The evaluation of the data revealed that there was a significant decrease in the number of healthcare-associated *Clostridium difficile* infections.

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**1.0 INTRODUCTION**

*C. difficile* is the most common cause of healthcare-associated diarrhea and has been linked to more than 14,000 deaths per year, with more than 90% of deaths occurring in persons 65 years of age and older ("Making Health," 2012). From 2000 to 2009, the rate of *C. difficile* infections (CDIs) increased from 33,000 to 111,000, whereas other hospital acquired infections have decreased ("Making Health," 2012). It is believed that upwards of 80% of all CDIs are healthcare-associated. Healthcare-associated infections are defined as infections that patients acquire while receiving healthcare treatment for other issues ("Healthcare-Associated Infections," 2012). The CDIs identified as healthcare-associated are usually attributed to *C. difficile* that would normally not cause active infections in healthy adults ("Frequently Asked," 2012).

The lack of an active infection in healthy adults is due to the fact that *C. difficile* in the gut and naturally occurring colonic flora have a commensal relationship and the natural flora create a protective effect in healthy adults against CDIs ("Frequently Asked," 2012). In the gut of healthy adults, the bacteria are considered colonized and do not cause an infection or lead to overt symptoms. While colonized with the bacteria, asymptomatic carriers still shed the bacteria in their stool ("Patient Information," 2012), which may lead to an active infection or transmission of the bacteria to susceptible patients. An active CDI usually occurs when the protective flora in the gut are disrupted through the use of antibiotics. The antibiotics indiscriminately kill off many of the bacteria in the gut, and the *C. difficile* bacteria can proliferate and cause an active infection. This active infection can cause symptoms to emerge in patients ("*Clostridium difficile* Colitis," 2013).

The risk factors for CDI include the aforementioned use of antibiotics, and also have been linked to the use of medications that reduce gastric acid (Gould & McDonald, nd). Exposure to the microorganism itself has also been identified as a risk factor for developing a CDI. Exposure to the microorganism is increased in a hospital setting due to the higher rates of the microorganism in hospitals compared to outside the hospital setting ("C. difficile: Risk factors," 2011). An additional risk factor for CDIs is age. It has been reported that those over the age of 65 are at a 10-fold higher risk than those below the age of 65 ("C. difficile: Risk factors," 2011). A final risk factor for developing a CDI is length of hospital stay. As length of hospital stay increases, the risk of developing a CDI also increases (Johnson et al., 1998).

The need to decrease rates of CDIs in hospitals has become increasingly important among infection control programs across the United States due to the identification of an epidemic strain of *C. difficile* in 2000 (Gerding, 2010) (Kohn et al., 2000). The BI/NAP1/027 strain has been linked to several outbreaks throughout the United States and has been connected to more severe disease and increased mortality than the previously identified strains (Gerding, 2010).

Interventions aimed at decreasing the incidence of CDIs and preventing the proliferation of the organism in hospitals is complicated given that 7 to 26% of those colonized with the *C. difficile* bacterium are asymptomatic (Cohen et al., 2010). Due to asymptomatic patients still being able to transmit the disease, interventions aimed at decreasing cases of CDIs need to be implemented hospital-wide and not focus solely on patients with diagnosed CDIs.

**2.0 *CLOSTRIDIUM DIFFICILE* BACTERIUM**

The *C. difficile* bacterium is a spore-forming, Gram-positive anaerobic bacillus that produces two exotoxins, toxin A and toxin B ("Frequently Asked," 2012). The bacterium has two forms: one is an active, infectious form, and the other is an inactive, noninfectious form. The inactive spore form has been shown to last for several months in the environment (Mitchell et al., 2012).

The most common route of *C. difficile* infection is ingestion of the *C. difficile* spore through contaminated food. Both symptomatic and asymptomatic infected individuals shed the bacterium through their feces, and subsequently the spores can contaminate surfaces and food ("C. difficile: Risk factors," 2011). Once ingested, the spores target the colon of the patient. While in the colon, the spore germinates into the growing form and begins to proliferate if the naturally protective flora has been disturbed. This disruption has mostly been linked to antimicrobial use that negatively impacts the natural flora in the gut. Once established in the colon, the bacterium can begin to produce the two exotoxins which can lead to symptoms of the infection (Gould et al., nd).

According to the CDC, symptoms of CDI are watery diarrhea (at least three bowel movements per day for more than two days), fever, loss of appetite, nausea, and abdominal pain and tenderness (Surawicz et al., 2013). Complications of CDI can result in pseudomembranous colitis, toxic megacolon, sepsis, perforations of the colon, and death ("*Clostridium difficile* Excerpt," 2010).

Transmission of the bacterium between infected patients and uninfected patients in the hospital has been linked to healthcare workers. Due to lack of correct hand hygiene, the spores remain on the healthcare worker's hands and can then be transmitted to another patient's room. The contamination of an uninfected patient's room with the *C. difficile* bacteria spores can lead to the cycle of the spores entering the patient's body through ingestion.

Diagnosis of CDI is based on clinical symptoms along with laboratory results. The CDC defines CDI as the acute onset of diarrhea with documented toxigenic *C. difficile* or its toxin with no other documented cause for diarrhea (Surawicz et al., 2013). The three most commonly used tests are a stool test, colon examination, and imaging tests ("C. difficile: Tests," 2012). The stool test is used most frequently because it is the least invasive and most cost effective test. This test involves taking a stool sample from the patient and employing an enzyme immunoassay, polymerase chain reaction or tissue culture assay ("C. difficile: Tests," 2012).

The treatment of CDIs is based on the severity of the disease and is broken down into the categories of mild to moderate, severe, and complicated (Shen et al., 2008). The initial treatment of CDIs usually involves discontinuation of the antibiotic that is thought to be creating an environment favorable for the CDI. In 20% of the patients, the discontinuation of the offending antibiotic results in resolution of the infection within 2 to 3 days ("Patient Information," 2012). In more complicated cases that do not resolve within that time frame, potent antibiotic treatment is needed and prescription of a regimen of metronidazole and vancomycin is used (Gerding et al., 2007). These treatments do not always resolve the infection, and the recurrence of *C. difficile*-associated diarrhea and pseudomembranous colitis occurs in up to 20% of patients after the standard antibiotic treatments. These standard and extended treatments due to hospital-acquired CDIs have been estimated to cost anywhere from $5,042 to $7,179 per case with a national estimate of $897 million to $1.3 billion annually ("Vital Signs: Preventing," 2012).

**3.0 INTERVENTIONS**

In light of the increasing rates of CDIs in the United States and the additional costs incurred by the healthcare system due to CDIs ("Making Health," 2012), interventions have been developed to decrease the rates of healthcare-acquired *C. difficile.* One intervention that has been established to decrease the rates of CDIs is the use of an antimicrobial stewardship program ("Antimicrobial Stewardship," 2012). Antimicrobial stewardship programs are put into place to try and make certain that patients truly need to be prescribed antimicrobials and also that they receive the correct antibiotic at the right dose ("Get Smart," 2010).

This intervention was utilized at a community hospital located in Allegheny County and referred to as Community Hospital A. Community Hospital A at the beginning of FY10. There were several waves of incorporation into the hospital that began first with staff education meetings. The staff who attended the meetings were composed of all levels of staff at the hospital that ranged from the president of the hospital, medical doctors, nurses, housekeeping staff, and pharmacists. Although some of the staff voluntarily participated in the meetings, the head unit nurses, pharmacists, and medical doctors on the Infection Control Board were required to attend. At the meetings, positive outcomes of the proper use of antimicrobials and the negative impacts of improper use were presented through handouts and PowerPoint presentations. Also presented was information on the most commonly CDI-associated antibiotics: ampicillin, fluoroquinolones, third generation cephalosporins, and clindamycin (Pseudomembranous).

Another part of the multifaceted intervention was to empower the nursing staff department. The intervention involved putting into place a policy that allowed the nursing staff to order a *C. difficile* toxin test without a physician's order. Once a toxin test was ordered, the nursing staff was required to notify the attending physician and accurately record the reason for placing the order.

Following the education presentation and empowerment of nursing staff, the Infection Control Department of the hospital began a hospital-wide surveillance of patients who were prescribed antimicrobials. For the first month of the program, the department would track these patients and verify that they were prescribed the correct antimicrobial for their infection. If the patient was found to be prescribed antimicrobials incorrectly, the unit where the patient was being treated was informed and further education by the Infection Control Department of the attending staff was carried out. The surveillance was reduced after one month due to declines in the amount of nonessential antimicrobials and only a sample of patients prescribed antimicrobials were investigated for proper use of antimicrobials. This sample surveillance continues to be a part of the antimicrobial stewardship program at Community Hospital A as of April 2013.

Along with the antimicrobial stewardship program, at the beginning of FY10, the implementation of a new cleaning protocol was introduced throughout the entire hospital. The new cleaning protocol constituted the use of bleach products in all patient rooms throughout the hospital. The bleach products used were floor cleaning supplies and furniture wipes. Before this intervention was put into operation, the protocol for cleaning patient rooms was that only patients with identified infections would have their rooms cleaned with bleach products. The new protocol identified bleach as the product that should be used in all patient rooms regardless of diagnosed infections. Bleach is useful for combating *C. difficile* because it has been shown to kill *C. difficile* spores quickly and fully; whereas alcohol based cleaning products have been shown to be ineffective (Jabbar et.al., 2010).

These two interventions are important tools aimed at lowering the number of infections and healthcare-associated cost while also improving patient health and care. By reducing the number of nonessential antimicrobial prescriptions, the number of antimicrobial resistant pathogens may also be reduced. This reduction is important due to the rising numbers of antibiotic resistant organisms that are becoming increasingly more difficult to treat ("Healthcare-Associated Infections," 2012). Also, by cleaning all patient rooms in the same manner, asymptomatic patients' risks of transmitting diseases to uninfected patients are reduced. Utilizing prevention measures such as these two interventions to combat disease and development of CDIs is an important step in tackling the larger problem of all healthcare-associated infections. It is estimated that prevention measures such as antimicrobial stewardship programs and hospital-wide bleaching of patient rooms may be able to reduce all healthcare-associated infections by up 70% and save the healthcare system 20 to 31.5 billion dollars annually ("Healthcare-Associated Infections," 2012).

**4.0 DATA COLLECTION**

In Community Hospital A when a CDI is suspected in the hospital, the attending nurse or medical doctor orders a test through the hospital laboratory. The specimen is submitted to the hospital laboratory and undergoes diagnostic testing. At Community Hospital A, the test used from FY07 to FY12 tested for the presence of the toxin produced by *C. difficile* and is one of the recommended tests by the CDC ("Frequently Asked," 2012). The test results are entered by lab personnel into the hospital database. Once positive tests are entered into the system, the Infection Control Department is electronically alerted through pager and e-mail messages. Positive CDIs are further investigated by the Infection Control Department in order to deduce if the infection meets the criteria of being healthcare-associated. The positive tests are categorized as either healthcare-acquired or community-acquired based on the case definition of from the CDC ("Technical Information," 2012) and amount of time that has passed between hospital admission and positive test result. For this study, all positive tests being analyzed had been categorized as healthcare-acquired. The data available for analysis were from Community Hospital A's annual reports for fiscal years 07 to 12. The data that was analyzed from these reports were the total number positive CDI tests, total tests ordered, number of patient days, number of antibiotic associated CDIs, the number of not antibiotic associated CDIs, the number of patient days, the average age of patients, and the average length of stay. These data were only available in summary form for the hospital for each fiscal year.

*C. difficile* infection is a mandatory reportable condition in Pennsylvania according to Act 52 ("Technical Report," 2010). Positive healthcare-acquired *C. difficile* tests are reported to the National Healthcare Safety Network (NHSN) by hospitals, ambulatory surgical centers, birthing centers, and nursing homes ("Technical Report," 2010). NHSN is used to track healthcare-associated infections in the United States and is a part of the CDC.

**5.0 DATA ANALYSIS**

To determine if the interventions initiated in FY10 in Community Hospital A had an impact on the number of positive healthcare-acquired CDIs, data were collected from Community Hospital A's annual reports. The annual reports were created at the end of each fiscal year by the Infection Control Department. The data in this report were collected and presented internally by the Infection Control Department at the Infection Control Committee meeting every two months during FY07 to FY12. The annual reports were used to present data from Community Hospital A at annual board meetings involving the entire hospital system. The annual reports contained information on the total number of positive CDIs broken into two categories: healthcare-acquired and community-acquired. The healthcare-acquired category was further divided into antibiotic-associated or not antibiotic-associated. Additional information on the total number of patient days, average age of patients and average length of stay of patients were also included in the annual reports. In addition to the annual reports, data were gathered from the hospital laboratory pertaining to the total number of tests ordered through FY07 to FY12.

After these data were compiled into a single Excel spreadsheet, an additional variable named "intervention" was added to identify the variables as before (1) or after (2) the application of the interventions. The before variable contained measurements from FY07 to FY09, and the after variable included measurements from FY10 to FY12. These data were then imported into SAS 9.3 for analysis. Frequency tests on the healthcare-acquired CDIs, total number of patient days, average age of patients, average length of stay of patients and total number of tests for FY07 to FY12 were carried out. These frequency tests gave information on the trends of these numbers during this time frame. Two sample independent t-tests were carried out to investigate if there was any evidence of statistical significance between the before and after variables.

**6.0 RESULTS**

**6.1 *CLOSTRIDIUM DIFFICILE* INFECTIONS**

The overall trend of CDIs in Community hospital A was a decline in the rates from FY07 to FY12. These rates are illustrated in Figure 1 and are reported per 1,000 patient days. The rates were based on the number of positive tests and number of patient days. The highest rates were in FY07 and FY08 at 2.04 and 2.0 and the lowest rates were reported in FY11 and FY12 at 0.7 and 0.39, respectively. It can be seen that during FY07 and FY08, the number of CDIs remained steady and then a dramatic drop begins after FY08 and continues to decline sharply all the way to FY12.

Amongst all *C. difficile* test results that were positive in Community Hospital A during FY07 to FY12, a decrease in total positive tests were seen. This decrease is illustrated in Figure 2. This figure illustrates that over half of the positive test results (63%) came from the years before the interventions were put into place (FY07-FY09). The lowest percentage of positive test results came from FY11 and FY 12 at 12% and 7%, respectively.

The positive test results are also illustrated in Figure 3 along with the corresponding total number of tests ordered for the fiscal year. This figure demonstrates that the total number of tests being ordered is decreasing through time, and the total number of positive test results is also decreasing through time. Through FY07 to FY12 a decrease in the total number of tests ordered was seen. In FY07 a total of 2,192 tests were ordered and in FY12 a total 1,505 tests were ordered. This reduction amounted to a decrease of 687 tests ordered. Also a decrease in total number of positive tests was seen through FY07 to FY12. In FY07 a total of 126 positive test results were recorded and in FY12 a total of 26 positive test results were recorded. This resulted in a decrease of 100 positive test results over a period of six fiscal years.

**6.2 ANTIBIOTIC ASSOCIATION**

Additional investigation into the positive test results and whether or not they were antibiotic-associated is illustrated in Figure 4. This figure shows that the number and fraction of positive tests have a downward trend along with the number of antibiotic-associated positive tests. Through FY07 to FY12 a decrease in the number of antibiotic-associated positive results were documented. In FY07 of the 126 positive test results, 123 were antibiotic-associated and in FY12 of the 26 positive test results, 23 were found to be antibiotic-associated. The total reduction of antibiotic-associated positive test results was 100 over a period of six fiscal years.

**7.0 STATISTICAL SIGNIFICANCE**

Further analysis was carried out on the data collected from Community Hospital A to investigate if these visual trends were statistically significant. Multiple independent two sample t-tests were carried out on several variables. The variables used for the two sample t-tests included: tests ordered, total patient days, number of not antibiotic-associated tests, the average age of patients, and the average length of stay. The results of this analysis are displayed in Table 1. At the alpha = 0.05, the results in this table show statistical significance in several variables that were tested. The variables that showed a significant difference before and after the interventions were the total number of tests ordered and total patient days. No significant difference was seen in the number of not antibiotic-associated tests, the average age of patients, or the average length of stay.

Chi-square analysis was carried out on the total number of positive tests and antibiotic associated positive tests. The results of the chi-squared tests are displayed in Table 2. Both the total number of positive tests and antibiotic associated positive tests had statistical significance with p-values below the accepted alpha value of .05.

**8.0 DISCUSSION**

The data analysis presented in the prior section displays a trend of an overall decline in the rate of positive CDIs through FY07 to FY12. This negative trend starts before the implementation of the interventions, but continues to decrease substantially through the observed time frame. Also by basing the rate on patient days, the trend shows that even though there was a significant difference between total patient days before and after the intervention groups, the negative trend still holds true through FY07 to FY12.

The data also illustrated a significant decline in the total number of positive healthcare-acquired CDIs before and after the interventions. The total number of the CDIs in FY07 to FY09 was 328, and after the intervention (FY10 to FY12) the total number was 157. This decline was found to be significant by the t-test performed on the before and after groups. One reason that could explain this decline could be that the interventions put into place are working as intended. The implementation of the cleaning protocol could be reducing the risk of an asymptomatic patient transmitting infection to a susceptible patient. In addition to the cleaning intervention possibly having an effect on the number of CDIs, the data also indicated a reduction in the number of antibiotic associated CDIs. The data showed that before the intervention, the number of antibiotic associated CDIs was 320 and after the intervention the number was 142. One reason that the total number of positive CDIs declined during this period could be that the reduction in the number of antibiotics being prescribed in the hospital could lead to less CDI development.

The data analysis was used to test the hypothesis that two risk factors, age and length of stay, may have impacted the results. Both of these risk factors have been shown to affect the probability of developing a CDI ("C. difficile: Risk," 2011) (Johnson et al., 1998). Both of these risk factors showed no significant difference between the before and after interventions groups, and therefore should not have impacted the results from the analysis of the total number of positive CDIs.

Besides the risk factors of age and length of stay in the hospital, the total number of *C. difficile* tests ordered was also analyzed. The number of tests being ordered did show a significant difference in the before and after groups. This reduction in the total number of tests being ordered is shown in Figure 5. This reduction could be possibly explained by the reduction in antibiotics being prescribed and therefore lessening the need for more tests to be ordered.

CDIs are an important healthcare-associated infection and create a large burden on not only the healthcare system in terms of cost, but on patient mortality and morbidity. Evaluation of interventions is one way to assess if they are impacting the situation in the way that they were designed. Through this study it can be demonstrated that there are significant differences in the number of positive CDIs at Community Hospital A before and after the intervention placement and that the interventions did have an effect on the positive numbers of healthcare-associated CDIs. The interventions used were preventative measures and resulted in significant decreases in the CDIs that were attributed to Community Hospital A. This decline saved not only hospital resources but also increased patient health due to less morbidity and mortality that is associated with CDIs.

**9.0 LIMITATIONS**

The major limitation of this study is that the data presented were all aggregate measures. These measures make it difficult to lead to conclusions on an individual basis for patients. These data cannot be used to make inferences about how individual patients were affected by the reduction in positive CDIs in Community Hospital A. These data were therefore not useful for making any conclusions about the intervention impacts on single patients being cared for in Community Hospital A.

Also due to the use of aggregate data, no stratification could be incorporated in this study. If more individual data were able to be gathered, stratification on age could have been used to analyze if all patients were affected similarly by the interventions, or if a certain age group was more greatly affected.

Lastly, the limitation of how patients are screened for CDIs in Community Hospital A do not completely represent all of the positive CDI cases in the hospital. In Community Hospital A the testing procedure begins only when patients display symptoms of CDI like loose stools and watery diarrhea. Yet, it has been reported that as many as 7 to 26% of patients colonized with *C. difficile* are asymptomatic. Another element that may create an issue capturing all CDIs in Community Hospital A is that when a patient is prescribed a laxative they are not supposed to be given a CDI test. This policy was created to limit testing of patients prescribed medication that simulates symptoms of a CDI infection. While the policy may limit some over testing, patients prescribed laxatives may also have a CDI. The combination of asymptomatic patients and elimination of patients prescribed laxatives from CDI testing may lead to underreporting of CDIs.

**10.0 RECOMMENDATIONS**

Two recommendations for this study come from the recording and reporting procedures for CDIs. One recommendation would be to transfer these files to an electronic source since much of the data were still kept in paper form. Due to limited space in Community Hospital A, much of the paper information is only kept for the mandated period of time and then shredded. This made going back further for more information prior to FY07 impossible since hospital records on patient infection information were only kept at Community Hospital A for six years. Moving this information to an electronic source would alleviate the need for paper forms of the records and allow information to be stored in larger numbers for a longer period of time.

A second recommendation is that Community Hospital A create a single database with all healthcare-associated infections. At Community Hospital A, data on HAIs were spread throughout multiple areas of the hospital. As stated previously, the Infection Control Department has much of the data in paper form. These data for CDIs includes the number of total positives and patient days, but the total number of tests requested and antibiotic usage are kept in a separate database in the laboratory. This database is not available through the network and must be manually accessed from the laboratory and then emailed to the Infection Control Department.

**11.0 SUMMARY**

Prevention interventions are hypothesized to be able to lower the number of healthcare-associated infections and save the healthcare system billions of dollars annually. To investigate if these hypotheses are true, two interventions were evaluated at Community Hospital A that were used to try and reduce the total number of hospital-associated CDIs. The two interventions were an antimicrobial stewardship program and a cleaning protocol that used a known *C. difficile* spore killer. Through the use of aggregate data from Community Hospital A, the before and after intervention groups were found to have a statistically significant decline in the total number of positive CDIs. These results lead to the conclusion that prevention interventions can have a positive impact on the burden of healthcare-associated infections.

**APPENDIX: FIGURES AND TABLES**

Figure 1. Number of *Clostridium difficile* positive test results per 1,000 patient days from Fiscal Year 07 to Fiscal Year 12.

Figure 2. Percent of *Clostridium difficile* positive tests, Fiscal Year 07 to Fiscal Year 12.

Figure 3. Number of positive and negative *Clostridium difficile* tests, Fiscal Year 07 to 12.

Figure 4. Number of antibiotic and not antibiotic associated number of *Clostridium difficile* cases, Fiscal Year 07 to 12.

Figure 5. Number of *Clostridium difficile* tests ordered, Fiscal Year 07 to 12.

Table 1. Results of independent two sample t-tests at alpha = .05.

|  |  |
| --- | --- |
| Variable | P-value |
| Total Tests Ordered | 0.014 |
|  |  |
|  |  |
| Not Antibiotic Associated | 0.1242 |
| Total Patient Days | 0.029 |
| Average Age of Patients | 0.8367 |
| Average Length of Stay | 0.5391 |

Table 2. Results of chi-squared tests at alpha = 0.05.

|  |  |
| --- | --- |
| Variable | P-value |
| Positive Tests | 0.0001 |
| Antibiotic Associated | 0.0006 |

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