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Nosocomial Antibiotic-Associated Clostridium Difficile Infections: An Organizational Assessment

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Nosocomial Antibiotic-Associated *Clostridium Difficile* Infections: An Organizational Assessment

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Abstract

Clostridium difficile (*C. difficile)* is a toxigenic, spore-forming bacteria that lives in the gastrointestinal (GI) tract of healthy individuals without harm to the host due to the protection offered by the natural intestinal flora. Antibiotics can disrupt the intestinal flora and create an environment within the GI tract that promotes the infectious growth of *C. difficile*. *C. difficile* infections (CDIs) are the most common cause of antibiotic-associated diarrhea, are highly contagious, and can result in an increased risk of morbidities and mortality to individuals affected. Recent studies and literature reviews identified the use of probiotic therapy in patients receiving antibiotics to be an effective prophylactic intervention for decreasing antibiotic-associated CDI occurrence. The purpose of this organizational assessment was to compile organizational data concerning nosocomial CDIs as a prerequisite to future practice changes regarding the use of probiotics for the prevention of nosocomial antibiotic-associated CDIs. The organizational assessment conducted within two separate hospitals concluded parallel results that 3rd generation cephalosporins, glycopeptides, and penicillin/beta lactamase inhibitors were the top three contributing antibiotic classes resulting in CDIs. Specifically, patients receiving vancomycin, Rocephin, Zosyn, or cefepime were at a significantly increased risk for contracting a nosocomial CDI. Mortality rates from CDIs were significantly higher than the national average at 24.7% in Hospital A and 44% in Hospital B. Mortality rates combined with the calculated hospital costs over six months, $219,252 and $83,050 respectively, showed evidence of a need for change. Based on current literature and the results of this organizational assessment, the project leaders recommend developing an updated clinical practice policy that includes the use of prophylactic probiotics in immunocompetent patients who are prescribed an offending antibiotic during their hospital stay.

Nosocomial Antibiotic-Associated *Clostridium Difficile Infections*: An Organizational Assessment

Clostridium difficile (*C. difficile)* infections account for an average of 500,000 community and hospital-acquired illnesses in the United States per year (Dieterle et al., 2019). *C. difficile* is a highly contagious infection that promotes the destruction of the epithelial lining in the colon. Its infectious process produces colonic inflammation that can result in diarrhea, stomach pain, nausea, loss of appetite, toxic megacolon, and death (Lamont et al., 2020). *C. difficile* infections (CDIs) result in a considerable increase in the risk of morbidity and mortality for those infected. In addition to its negative impact on patients' health, CDIs produce a substantial financial burden, costing organizations up to $16,000 per case and the country roughly 3.2 billion dollars annually in healthcare expenses (Singh et al., 2019; Vernaya et al., 2017).

The increased use of wide-spectrum antibiotics since the early 2000s has led to the continued global rise in the frequency of CDIs (Ma et al., 2020; Steele et al., 2015). Recent studies have found that the use of probiotics in conjunction with antibiotics decreases a patient's risk of contracting an antibiotic-associated CDI by up to 60%, and decreases the risk of adverse gastrointestinal events related to antibiotic administration by up to 20% (Steele et al., 2015).

At a suburban Midwestern hospital (Hospital A) and an urban Midwestern hospital (Hospital B) the CDI rates from January 2020-April 2020 were documented as 5.05/10,000 patient days and 1.92/10,000 patient days, respectively. The average cost of these infections to the organization was $3,322 per patient case. New literature suggests the benefit of using probiotic therapy for the prevention of antibiotic-associated CDIs, but current CDI practice policies at these two hospitals do not incorporate the use of this preventative therapy.

Problem Statement

The impact of CDIs on both patients and hospitals indicates a crucial need for a change in practice. To facilitate this practice change, an organizational assessment was conducted amongst the two hospitals of interest that studied the variables related to CDI incidence from July 1st, 2020, to December 31, 2020. The following PICO question was developed to aid in the review of literature: For patients receiving antibiotics, how does administering probiotics compared to the current practice of not implementing *Clostridium difficile* infection preventative measures impact the occurrence of antibiotic-associated *Clostridium difficile* infections*?*

Background

Fifty percent of hospitalized patients receive a minimum of one antibiotic during their hospital stay (Center for Disease Control, 2019). Although imperative for the treatment of life-threatening infections, the use of antibiotics has a significant impact on the intestinal flora and can produce significant GI abnormalities including nausea, diarrhea, and most significantly, a CDI (Dieterle et al., 2019).

C. difficile is a toxigenic, anaerobic, Gram-positive, spore-forming bacteria that can live naturally in the gut, be ingested through food sources, or enter the body as the result of poor hand hygiene (Dieterle et al., 2019; Lamont et al., 2020). *C. difficile* can pass through the GI tract without causing infection in healthy individuals due to the protection offered by the natural intestinal flora. The intestinal microbial disturbance and alteration caused by antibiotic administration creates an environment that promotes the sporulation and vegetative growth of *C. difficile* resulting in toxin production and ultimately a CDI (Dieterle et al., 2019). Among the antibiotics commonly used, research has revealed penicillins, clindamycin, and third-generation cephalosporins to be the primary causative agents of CDIs (Steele et al., 2015).

C. difficile is the primary causative pathogen associated with nosocomial infectious diarrhea in the United States (Dieterle et al., 2019). CDIs are highly contagious and can be spread between patients easily without the proper use of personal protective equipment (PPE) or adequate hand hygiene. CDIs ravage the GI tract leading to mucosal damage and colonic inflammation that presents with symptoms including diarrhea, stomach pain, nausea, loss of appetite, and toxic megacolon. Consequently, 11% of all CDIs result in death (Center for Disease Control, 2019; Dieterle et al., 2019; Lamont et al., 2020).

Probiotics are live microorganisms that, when given orally, have the potential to attenuate the negative effects of antibiotics on the intestinal flora. Due to their ability to restore the normal intestinal flora and impede the infectious growth of *C. difficile*, probiotics are a potential strategy for preventing antibiotic-associated CDIs (Goldenberg et al., 2017). Probiotics are available in numerous strains and species, and therefore their prophylactic effectiveness and safety profile is dependent on the strain of probiotic used, the route, and the timing of administration (Goldenberg et al., 2017; World Gastroenterology Organisation [WGO], 2017). Short-term probiotic use has been proven to be safe and effective for immunocompetent patients (Goldenberg et al., 2017). The use of probiotics in immunocompromised and debilitated patient populations should be avoided due to the increased risk of rare negative side effects including endocarditis and antimicrobial resistance (Goldenberg et al., 2017). These populations include those with HIV/AIDS, cancer, transplant recipients, patients on immunosuppressants, and those with autoimmune diseases (Goldenberg et al., 2017).

Literature Review

In an attempt to gain a deeper understanding of the benefits of probiotic therapy for the prevention of CDIs, a literature review was conducted using the PICO question mentioned

above. The international electronic databases included in this literature search were the Cochrane Database of Systematic Reviews (CDSR), EBSCO, Medline, and the Otterbein University library database. Additionally, web searches were conducted to reveal the current clinical guidelines available. The search terms used included: *Clostridium difficile, C. difficile*, probiotics, risks, benefits, antibiotic use, antibiotic therapy, and antibiotic-associated. The Boolean phrase "and" was used to connect these terms and produce relevant literature results. All literature utilized in this review was peer-reviewed, written in English, and published within the past five years. A level of evidence synthesis table summarizing the literature discovered can be found in Appendix A. An outcomes synthesis table summarizing the literature can be found in Appendix B.

The CDSR is internationally recognized as the "gold standard for high-quality, trusted information" (Cochrane, 2020). A 2017 systematic review conducted by the CDSR investigated the use of probiotics of any strain and any dose for the prevention of antibiotic-associated CDIs (Goldenberg et al., 2017). "Probiotics for The Prevention of *Clostridium difficile*-Associated Diarrhea in Adults and Children" included 39 randomized control trials that collectively studied 8,672 patients. The findings of this CDSR stated that probiotics have the highest quality evidence among the cited prophylactic therapies for antibiotic-associated CDIs, for they reduce the occurrence of antibiotic-associated CDIs by 60%, reduce the occurrence of antibiotic-associated diarrhea by 40%, and reduce the occurrence of other antibiotic-associated adverse gastrointestinal symptoms by 17% (Goldenberg et al., 2017). Goldenberg et al. (2017) concluded that probiotic strain *S. boulardii* or a combination of the *Lactobacillus acidophilus* and *Lactobacillus casei* strains at a dose of 10-50 billion CFUs per day are the most efficacious. The recommendation was based on moderate certainty evidence with a note that probiotic guidelines

should be continuously updated as new evidence emerges regarding strain and dosage (Goldenberg et al., 2017).

Clinical guidelines are systematically developed using the most recent evidence-based literature for use as a tool for practitioners to assist in making safe and appropriate patient care decisions (National Institute of Health, 2020). Clinical guidelines are regarded as level one evidence, the strongest evidence available to guide clinical decisions (Winona State University, 2020). The GI origin of CDIs inspired the search of GI specialty guidelines regarding the use of probiotics for the prevention of antibiotic-associated CDIs. The current clinical guidelines recommendations released by the American Society of Colon and Rectal Surgeons, the World Gastroenterology Organisation, and the American Gastroenterological Association support the use of probiotics for the prevention of antibiotic-associated CDIs (Steele et al., 2015; Su et al., 2020; WGO, 2017). Based on current evidence, the American Society of Colon and Rectal Surgeons recognized the *Lactobacillus acidophilus, Lactobacillus casei,* and *S. boulardii* probiotic strains to be most effective in the treatment of CDIs (Steele et al., 2015). The American Gastroenterological Association recognized *S. boulardii*, the two-strain combination of *Lactobacillus. acidophilus* and *Lactobacillus. casei*, the three-strain combination of *Lactobacillus. acidophilus, Lactobacillus*. *delbruekii subsp. bulgaricus,* and *Bifidobacterium. Bifidum*, or the four-strain combination of *L. acidophilus, L. delbruekii subsp. bulgaricus, B. bifidum,* and *Streptococcus salivarius subsp*. to be most effective in the treatment of CDIs (Su et al., 2020). The WGO recognized *Lactobacillus acidophilus* 50 CFUs twice daily and *Lactobacillus casei* 40 CFUs twice daily or the use of Yogurt with *Lactobacillus casei, L. bulgaricus,* and *Streptococcus thermophilus* 10^7-10^8 twice daily to be most effective in the treatment of CDIs (WGO, 2017). Due to the low-quality level of evidence concerning the strains

and dosages to be used, these organizations agree that further studies should be completed, and guidelines should be continuously updated as new evidence emerges (Steele et al., 2015; Su et al., 2020; WGO, 2017).

Systematic reviews and meta-analyses are regarded as level one evidence, the strongest evidence available to guide clinical decisions (Winona State University, 2020). In addition to the CDSR and clinical guidelines, this literature search found two systematic reviews and one systematic review/meta-analysis that support the use of probiotics for the prevention of antibiotic-associated CDIs (Dieterle et al., 2019; Ma et al., 2020; Simson & Lyon, 2019). This literature unanimously agreed that the use of probiotics was safe and effective in attenuating the negative GI effects of antibiotics and in decreasing the occurrence of antibiotic-associated CDIs in immunocompetent individuals (Dieterle et al., 2019; Ma et al., 2020; Simson & Lyon, 2019). Dieterle et al. (2019) recommended Bio-K, a probiotic containing three bacterial species, *Lactobacillus acidophilus* (CL1285), *Lactobacillus casei* (LBC80R), and *Lactobacillus rhamnosus* (CLR2), given orally within 36 hours of the start of antibiotic therapy and continued for five days past the duration of antibiotic therapy to be most effective based on a study conducted over 10 years including 44,835 patients (Dieterle et al., 2019). Ma et al. (2020) found the probiotic strains *Lactobacillus casei* and *Lactobacillus acidophilus* 50-100 billion units twice daily to be safe and effective in the prevention of antibiotic-associated CDIs. Simpson & Lyon (2019) concluded that probiotics should be started within two days of antibiotic therapy initiation, but did not recommend a strain or dosage.

This literature review was successful in examining the numerous variables involved in this practice change inquiry including the success of probiotic use for the prevention of antibiotic-associated CDIs, the most effective strains and doses of probiotics for the prevention

of antibiotic-associated CDIs, the risks associated with probiotic use, and the current clinical guideline recommendations regarding the use of probiotics for prevention of antibiotic-associated CDIs. Based on current evidence, probiotics have the potential to become a preventative strategy against antibiotic-associated CDIs. However, the literature points to a need for more high-quality research to deem a practice change necessary. Policy updates should continue to evolve as new evidence emerges about the success of specific strains, doses, administration timing, and the risks associated with each probiotic therapy option (Goldenberg et al., 2017).

Project Description and Design

Theoretical Framework

The John Hopkins Nursing Evidence-Based Practice model (JHNEBP) was used as the framework for this project (Dang & Dearholt, 2017). Permission to use this model as the framework for this Doctor of Nursing Practice (DNP) final scholarly project (FSP) was granted from the John Hopkins Medicine Institution through email (see Appendix C). The JHNEBP model utilizes three phases, practice question, evidence, and translation (PET) to facilitate the successful implementation of current evidence-based literature into practice (Dang & Dearholt, 2017).

Phase one, the practice question phase of the JHNEBP model, utilizes a six-step process that aided in the development of the project's foundation. In this phase, an interprofessional team is recruited and the problem is defined (Dang & Dearholt, 2017). The following evidence-based practice (EBP) question was developed for use in phase one: How does administering probiotics impact the occurrence of antibiotic-associated *Clostridium difficile* infections in immunocompetent patients? The stakeholders were identified as the patients, physicians, nurses,

infection prevention team, pharmacy, and the organization. Meetings took place weekly among the primary team members, the two DNP students heading the project, to discuss project progress and updates. Being a team project, the open line of communication facilitated by these meetings allowed for continuity of a shared vision, common goals, and shared knowledge, which ultimately created an environment for a successful partnership (Moran et al., 2020).

Phase two, the evidence phase of the JHNEBP model, utilizes a five-step process that aided in the facilitation of a thorough literature search (Dang & Dearholt, 2017). The details of the evidence can be found in the literature review section of this report. A level of evidence synthesis and outcomes table can be located in Appendix A. The literature review revealed gaps in the research that assisted in determining the need for an organizational assessment regarding the variables associated with antibiotic-associated CDIs.

Phase three, the translation phase of the JHNEBP model, utilizes an eight-step process that aided in the facilitation of project implementation (Dang & Dearholt, 2017). Clinical project mentors who are infection prevention specialists at the organizations of interest were selected to assist the project leaders in accessing data and resources available within the care sites and to combat organizational project obstacles (Moran et al., 2020). Using the data acquired by the mentors, the project leaders conducted an organizational assessment regarding CDI variables at each care site. Because the literature points to a need for more, high-quality research to deem a practice change necessary, the completed organizational assessment and data analysis will be disseminated to the hospitals' research teams to assist with the evolution of policy change and for use in future projects related to this topic.

Project Objectives

The overall goal of this project was to determine areas of improvement related to hospital-acquired antibiotic-associated *C. difficile* infections. The objectives of this project were:

1. To conduct an organizational assessment regarding the development and treatment of hospital-acquired antibiotic-associated CDIs.
2. To analyze the data collected in the organizational assessment and determine facility variables related to the incidence of hospital-acquired antibiotic-associated CDIs.
3. To provide the organization with statistical knowledge concerning the incidence of hospital-acquired antibiotic-associated CDIs to be used to guide future research and/or practice change.

Methodology

This project utilized retrospective quantitative data provided by the clinical mentors and a literature review to determine the need for an organizational assessment regarding the incidence of nosocomial antibiotic-associated CDIs. This project was reviewed by the hospital's Nursing Evidence-Based Practice Review Committee (NEBPRC) and the Otterbein Institutional Review Board (IRB) (see Appendix D) to facilitate the protection of the human subjects involved throughout the project. Following bi-organizational approval, an organizational assessment was conducted to determine the organizational variables contributing to the incidence of hospital-acquired CDIs. The data gathered in the organizational assessment was statistically analyzed and a report was produced and disseminated to the organizations for future use.

Population

The population sample for this organizational assessment included all hospitalized patients who contracted a hospital-acquired CDI from July 1, 2020, to December 31, 2020.

Instruments & Data Collection

Electronic medical record (EMR) audits provide a researcher or project leader with access to valid and reliable data (Agency for Healthcare Research and Quality, 2013). The project mentors provided the project leaders with a list of all patients who contracted facility-acquired CDIs from July 1, 2020, to December 31, 2020. Following bi-organizational approval, individualized EMR chart audits were completed by the project leaders using the provided patient lists to determine the following:

- The number of hospital-acquired CDIs from July 1, 2020, to December 31, 2020
- Was the patient who contracted a CDI on recent antibiotic therapy?
- Previous antibiotic therapy type and drug class
- The financial impact of hospital-acquired CDIs on the organization
- The incidence of CDI recurrence
- The current treatment modalities being utilized for CDIs by each care site
- Patient survival to discharge or incidence of hospital mortality after CDI occurrence
- Were the patients with CDIs hospitalized previously within the last 90 days?

All data collected during EMR chart audits were inputted anonymously into an Excel spreadsheet to ensure the protection of the private healthcare information of all patients involved.

Timeline

This project originated from organizational problem identification through the combination of a thorough literature review and a retrospective quantitative data audit regarding hospital-acquired CDIs. Using the information obtained in the problem identification process, a

project proposal was developed to acquire permission for project continuation including further data collection and analysis. Following DNP committee approval, the project proposal was sent and approved by the hospital's NEBPRC and the Otterbein University IRB. With permission, the project leaders completed EMR chart audits as part of the organizational assessment during February/March of 2021. The data retrieved in the EMR audits was analyzed during May/June of 2021. After analysis, the data was organized and evaluated to then be disseminated to the organizations' research teams at the conclusion of this project. A final presentation of the finalized results of this DNP FSP will take place in the Spring of 2022 prior to graduation.

Budget

The primary cost of this project was the time of the project leaders. The time spent by the project's key investigators consists of conducting chart audits, facilitating meetings, reaching out to key stakeholders for new viewpoints and project support, outcomes management, and data analysis. Time was budgeted between the team leaders to ensure all duties were completed within a timely manner and by specified deadlines.

Outcomes & Evaluation

Data Analysis

The data collected in the organizational assessment was uploaded into an Excel document. Descriptive statistics were used to analyze quantitative data which allowed the project leaders to provide basic information about the outcomes of the organizational assessment and to emphasize the relationship between the dependent and independent variables. Qualitative data was used to evaluate patterns and assess deviations in the outcomes.

Results

Hospital A

At a large, suburban, Midwestern hospital from July 1, 2020, to December 31, 2020, a total of 66 hospital-acquired CDIs occurred. The 66 cases of CDIs over the studied six-month period resulted in a cumulative incidence of 5.972 per 10,000 patient days. 84.8% of the patients who contracted a hospital-acquired CDI were on recent antibiotic therapy. 91% of the patients on recent antibiotic therapy were being treated with a cephalosporin (3rd generation > 4th generation > 1st generation > 2nd generation), a penicillin/beta lactamase inhibitor, or a glycopeptide antibiotic. A complete breakdown of all antibiotic classes that contributed to CDIs can be found in Appendix F. The top offending antibiotics related to CDI infections were vancomycin, Rocephin, Zosyn, and cefepime. A graph of all offending antibiotics can be found in Appendix G. 15% of patients contracted a hospital-associated CDI and were not on recent antibiotic therapy. Of the five patients on antibiotic therapy, but not on a top offending antibiotic, one case was a recurrent CDI. Of the 10 patients who were not on antibiotic therapy previous to contracting a CDI, two cases were recurrent, one patient lived in a long-term care facility prior to entering the hospital, and four patients had been previously hospitalized within the last three months. Patients receiving medical-surgical care had the highest risk of contracting a CDI (48.5%) followed by critical care patients (31.8%), and finally by patients residing on an intermediate care unit (19.7%) (see Appendix H) The total incidence of CDI recurrence was 7.1%. Of the patients that contracted nosocomial CDIs, 51.5% had previously lived in a long-term care facility or had been hospitalized within 90 days prior to infection. The incidence of hospital mortality after CDI occurrence and treatment was 24.7%.

There were a variety of treatment modalities used for patients with CDIs including vancomycin, Flagyl, or a combination of the two medications. A complete list of treatment modalities and length of treatment can be found in Appendix E. Organizational cost per CDI is

$3,322 per case, totaling $219,252 over six months for the 66 cases described in this organizational assessment.

Hospital B

At a medium, urban, Midwestern hospital, from July 1, 2020, to December 31, 2020, there were 25 hospital-acquired CDIs. The 25 cases of CDIs over the studied six-month period had a cumulative incidence of 4.371 per 10,000 patient days. 92% of patients who contracted a CDI were on recent antibiotic therapy. 88% of patients who developed a hospital-acquired CDI received an antibiotic from one or more of the following drug classes: cephalosporins (3rd generation = 4th generation > 1st generation = 2nd generation = 5th generation), penicillin/beta lactamase inhibitors, or glycopeptides. A complete breakdown of all antibiotic classes that contributed to CDIs can be found in Appendix F. Only three patients who contracted a hospital-acquired CDI were not exposed to an antibiotic from one of those three classes. vancomycin, Zosyn, Rocephin, and cefepime were the top four contributing antibiotics A graph of all offending antibiotics can be found in Appendix G. Of note, 76% of patients were being managed on multiple antibiotics prior to developing a CDI. 24% of patients developed a recurrent CDI during the studied time frame. Only one patient (4%) was not on recent antibiotic therapy prior to the development of their CDI. Critical care patients were at the highest risk for developing a CDI (40%), followed by medical-surgical patients (32%), and intermediate patients (28%) (see Appendix H). Of the patients who contracted a CDI, 52% had a previous hospital admission within 90 days prior to their CDI diagnosis. 44% of patients who contracted a hospital-acquired CDI did not survive to discharge.

CDIs at Hospital B were treated with either vancomycin or a combination of vancomycin and Flagyl. The dose, route, and length of treatment were extremely variable among patients and

can be found in Appendix E. Organizational cost per CDI was $3,322 per case, totaling $83,050 over six months for the 25 cases described in this organizational assessment.

Outcomes

The outcomes of this project were determined based on the project objectives listed above. Project outcomes are as follows:

- Objective 1: To conduct an organizational assessment regarding the development and treatment of hospital-acquired antibiotic-associated CDIs.
    - Outcome: An organizational assessment was completed regarding the development and treatment of hospital-acquired antibiotic-associated CDIs.
- Objective 2: To analyze the data collected in the organizational assessment and determine facility variables related to the incidence of hospital-acquired antibiotic-associated CDIs.
    - Outcome: Data related to hospital-acquired antibiotic-associated CDIs was collected and analyzed. A summary of the data can be found above.
- Objective 3: To provide the organizations with statistical knowledge concerning the incidence of hospital-acquired antibiotic-associated CDIs to be used to guide future research and/or practice change
    - Outcome: Conclusions and recommendations were made related to the incidence of hospital-acquired antibiotic-associated CDIs. These statements were distributed to the organizations and can be found below.

Barriers

The primary barrier this project was presented with was the chance of skewed data as the result of the COVID-19 pandemic. The project facilitators conducted the organizational assessment over six months to reduce the risk of skewed data. Additionally, as staff at the

organization continued to focus their efforts on issues surrounding the COVID-19 pandemic, email correspondence and meeting facilitation were occasionally delayed between project leaders and key stakeholders.

Conclusions & Recommendations

The organizational assessment and data analysis conducted separately from Hospital A and Hospital B regarding hospital-acquired CDIs from July 1, 2020, to December 31, 2020, concluded cephalosporins, glycopeptides, and penicillin/beta lactamase inhibitors to be the top three contributing antibiotic classes resulting in CDIs. Specifically, patients receiving vancomycin, Rocephin, Zosyn, or cefepime were at a significantly higher risk for contracting a CDI. CDI occurrence rates increased during the studied time period as compared to those from January 2020 to April 2020 in both Hospital A and Hospital B from 5.05 to 5.97 cases per 10,000 patient days and from 1.92 to 4.37 cases per 10,000 patient days, respectively. The average national mortality rates from nosocomial CDIs are around 11% while the mortality rates from nosocomial CDIs in this organizational assessment were 24.7% and 44% for Hospital A and Hospital B, respectively (Center for Disease Control, 2019; Dieterle et al., 2019; Lamont et al., 2020).

Although the organizations are using the recommended antibiotics for the treatment of CDIs, vancomycin and Flagyl, the initial antibiotic modality, treatment route, and the length of treatment were extremely variable between cases (see Appendix E). The inconsistency in treatment in addition to the increased rate of infection, the high recurrence rate of CDIs, significant hospital cost, increased length of stay, and increased morbidity and mortality rates analyzed in this assessment show the need for a practice versus literature evaluation. The project leaders encourage the organizations to further investigate their standard CDI treatment in terms

of the type of antibiotic prescribed, antibiotic route, and length of treatment. Standardization may improve patient outcomes and length of stay. Additionally, current literature, including a systematic review by the Cochrane Database of Systematic Reviews, recommends the consideration of the use of prophylactic probiotics in appropriate patient populations (Goldenberg et al., 2017). To decrease consequences to both hospitals and patients, the project leaders recommend the development of an updated practice policy based on current evidence-based literature to standardize treatment modalities and integrate the use of prophylactic probiotics in patients who are immunocompetent and prescribed an offending antibiotic during their hospital stay. Educating staff on the results of this organizational assessment, proper PPE and handwashing, as well as any future practice changes, will be critical if the organizations wish to decrease their rates of nosocomial CDIs.

Summary

CDIs account for an average of 500,000 community and hospital-acquired illnesses in the United States per year (Dieterle et al., 2019). CDIs are highly contagious and can result in an increased risk of morbidities and mortality to individuals affected. Recent studies identified the successful use of probiotics for the prevention of antibiotic-associated CDIs (Goldenberg et al., 2017). The combination of the consequences of CDIs and the newly published literature prompted clinical inquiry. This organizational assessment was conducted to assist the organizations of interest with collecting and analyzing updated data regarding nosocomial CDIs. The data analysis showed an association between antibiotic therapy and the subsequent development of a CDI, as well as evidence of high mortality rates in those who contracted a CDI.

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Appendix A

Levels of Evidence Synthesis Table

Level of Evidence for Interview Questions	Systematic Review/Meta-analysis of randomized controlled trials/Clinical Guidelines	Single randomized controlled trials	Quasi-experimental studies/ nonrandomized controlled trials	Cohort or case-control studies	Systematic review/meta-analysis of qualitative studies	Single qualitative or descriptive studies/ evidence implementation and quality improvement projects	Expert opinion/Background Information
1	X						
2			X				
3	X						
4	X						
5	X						
6	X						
7	X						
8	X						
9	X						

Studies in alpha order: 1, Dieterle et al.; 2, Dudzicz et al.; 3, Goldenberg et al.; 4, Ma et al.; 5, Shen et al.; 6, Simpson & Lyon; 7, Steele et al.; 8, Su et al.; 9, World Gastroenterology Organization

Appendix B

Outcomes Synthesis Table

	1	2	3	4	5	6	7	8	9
Outcome: # of antibiotic-associated CDIs								N/A	N/A

Studies in alpha order: 1, Dieterle et al.; 2, Dudzicz et al.; 3, Goldenberg et al.; 4, Ma et al.; 5, Shen et al.; 6, Simpson & Lyon; 7, Steele et al.; 8, Su et al.; 9, World Gastroenterology Organization

Appendix C

Johns Hopkins Permission Confirmation

Thank you for your submission. We are happy to give you permission to use the JHNEBP model and tools in adherence of our legal terms noted below:

- You may not modify the model or the tools without written approval from Johns Hopkins.
- All reference to source forms should include "©The Johns Hopkins Hospital/The Johns Hopkins University."
- The tools may not be used for commercial purposes without special permission.

If interested in commercial use or discussing changes to the tool, please email ijhn@jhmi.edu.

Appendix D

Organization's NEBPRC Determination

Allison M. Bruce
Paxton N. Schwaderer
Otterbein University

October 9, 2020

RE: Nosocomial Antibiotic-Associated *Clostridium Difficile* Infections: An Organizational Assessment

Dear Ms. Bruce and Ms. Schwaderer

The Nursing Evidence-Based Practice Review Committee (NEBPRC) has reviewed the proposal referenced above. Clear evidence was submitted to justify the need for practice change. The evidence synthesis was well done and supports the proposed plan.

The NEBPRC has determine that the project proposal you submitted does not meet the Federal definition of research as cited in CFR 45-46:102. According to the Federal Code, research is defined as:

> (l) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.

You have permission to implement the plan as written proving that the unit manager at the intended intervention site is in agreement. Upon completion of the project and before dissemination (poster or manuscript), you must submit the results so that [redacted] can review the presentation to ensure Health Insurance Portability and Accountability Act (HIPAA) compliance.

Congratulations on your progress towards this worthy endeavor.

Otterbein University IRB Determination

OTTERBEIN UNIVERSITY

INSTITUTIONAL REVIEW BOARD

_____ Original Review
_____ Continuing Review
_____ Amendment

Dear **Dr. Ballard,**

With regard to the employment of human subjects in the proposed research:

HS # 20/21-19
Ballard, Schwaderer, & Bruce: Nosocomial Antibiotic-Associated Clostridium Difficile...

It is the determination of the IRB that the proposed work is not human subjects research, and IRB review is not required.

Date: 19 October 2020

Signed: Meredith C Frey
Chairperson

(Revised January 2019)

Appendix E

Hospital A Treatment Modalities

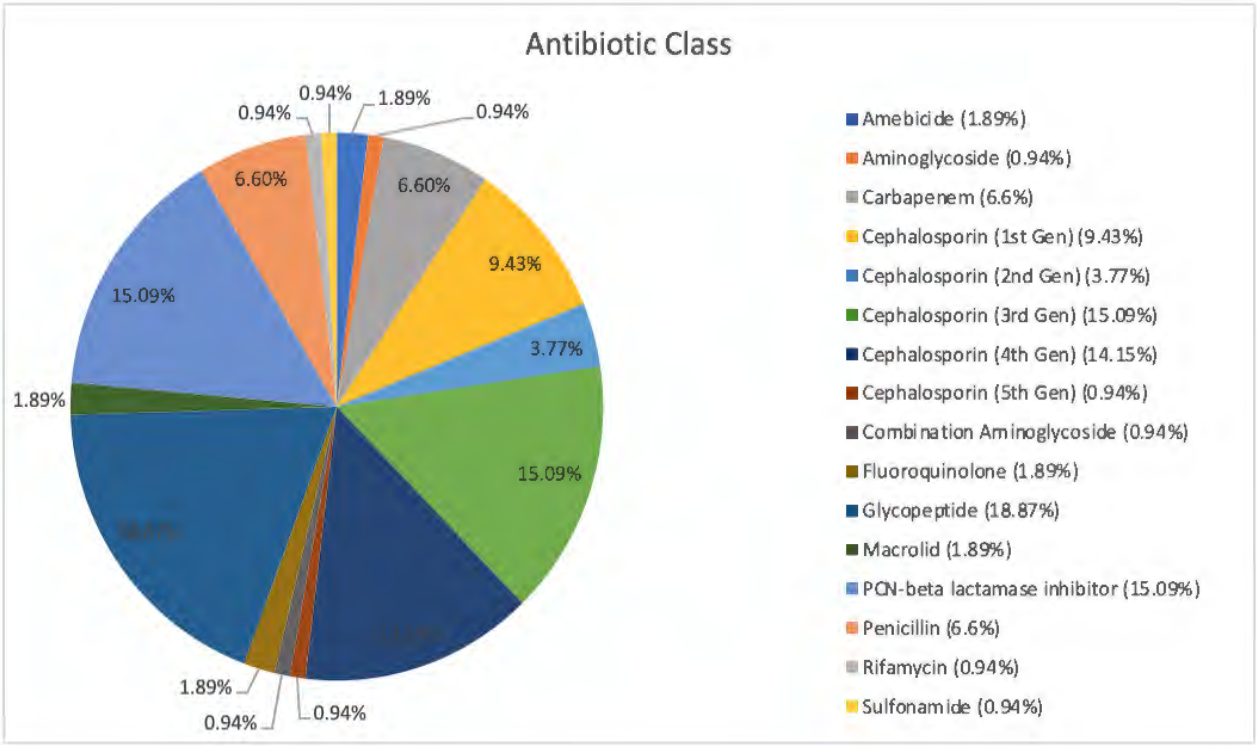
Treatment type	# of patients who received treatment type
IV Flagyl	1
PO Flagyl	1
PO vancomycin 125mg QID for 10+ days	59
PO vancomycin 125mg QID + IV Flagyl	2
PO vancomycin 500mg QID + IV Flagyl 500mg TID for 10+ days	3

Hospital B Treatment Modalities

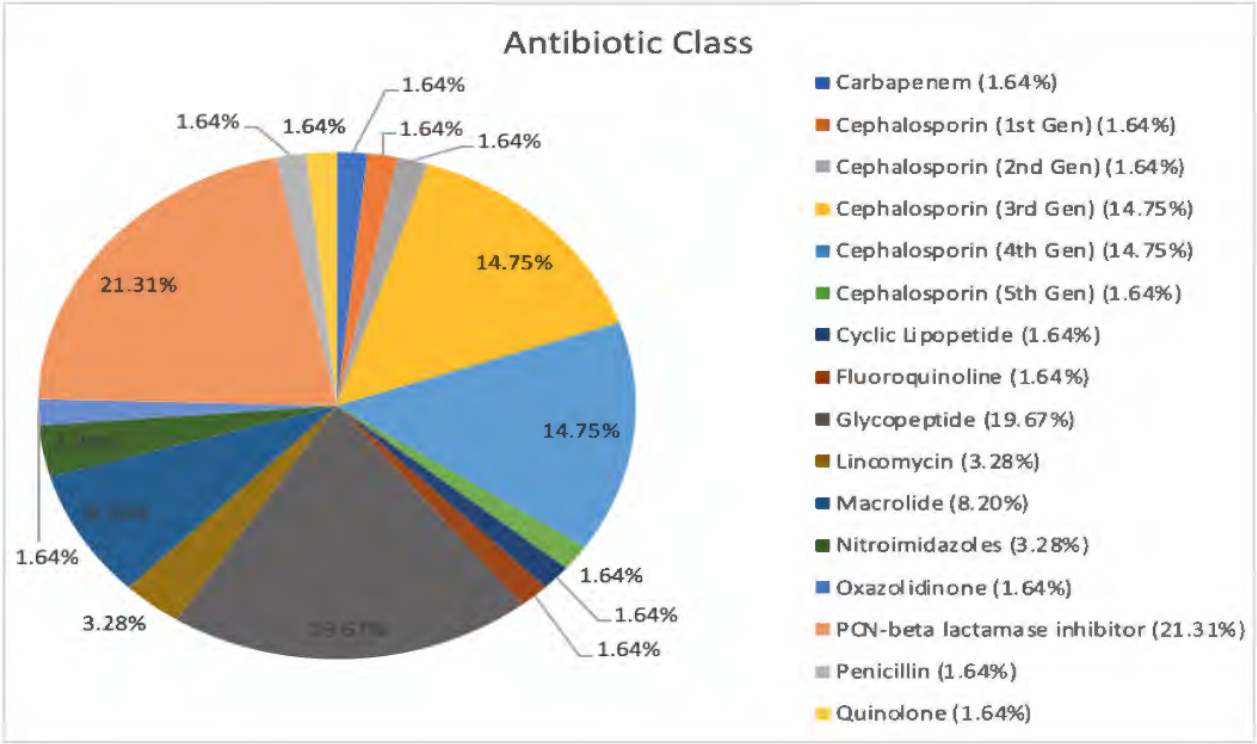
Treatment Type	# of patients who received treatment type
IV Flagyl 500 mg + PO vancomycin 125 mg qid for 10 days	3
IV vancomycin 1750 mg + vancomycin enema 500 mg	1
PO vancomycin 125 mg qid for 10 days	7
PO vancomycin 125 mg qid for 7 days	5
PO vancomycin 125 mg qid for 14 days	4
PO vancomycin 125 mg qid for 3 days	2
PO vancomycin 125 mg qid for 20 days	1
PO vancomycin 500 mg qid + vancomycin enema 500 mg + IV Flagyl	2

Appendix F

Hospital A Offending Antibiotic Breakdown by Antibiotic Class

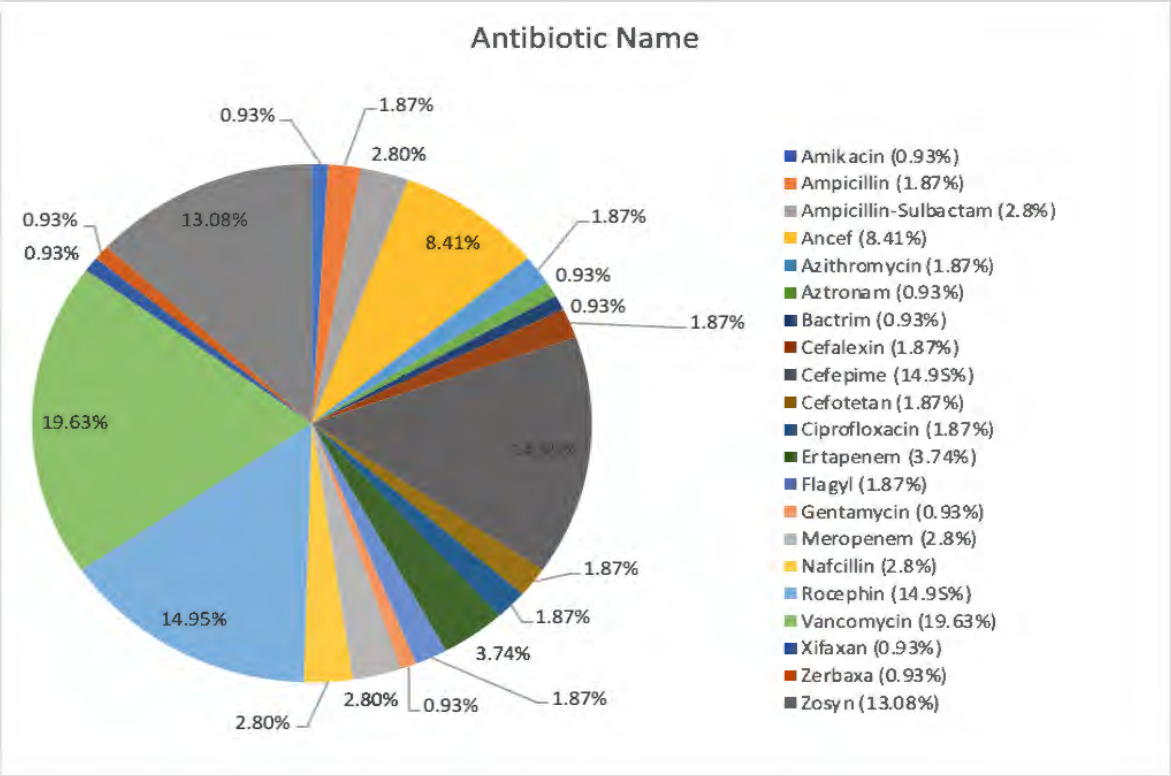


Hospital B Offending Antibiotic Breakdown by Antibiotic Class

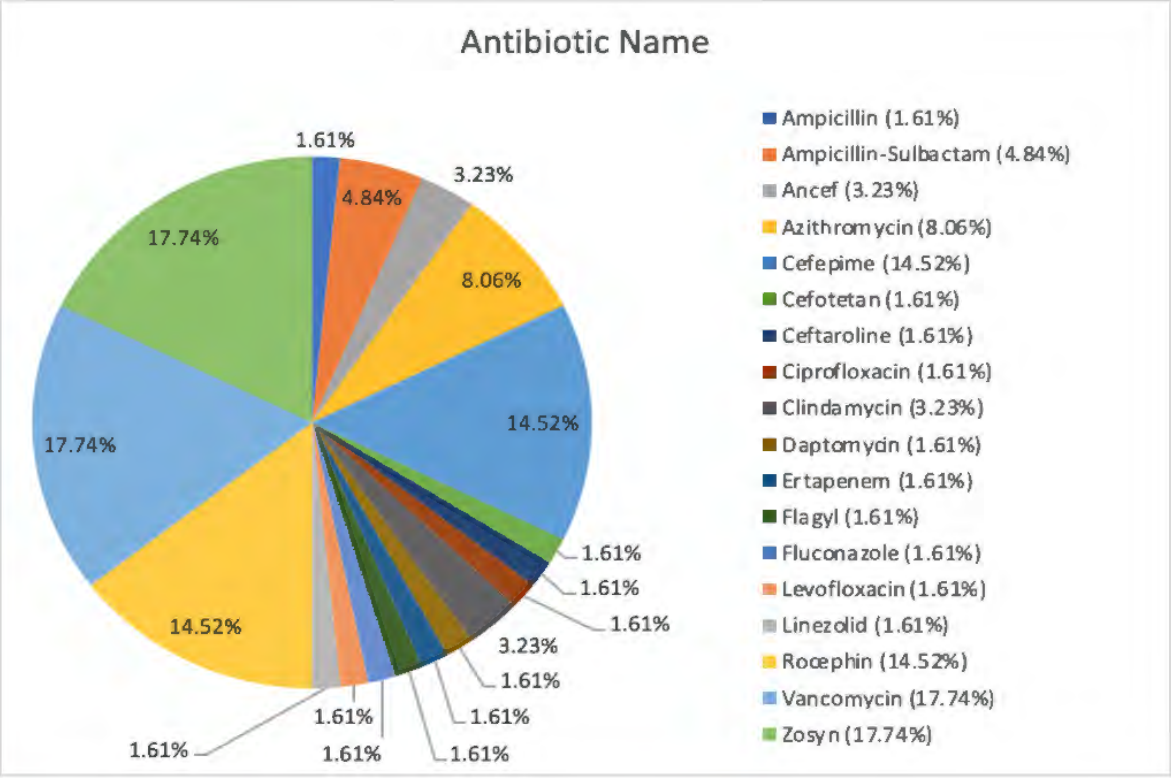


Appendix G

Hospital A Offending Antibiotic Breakdown by Antibiotic Name

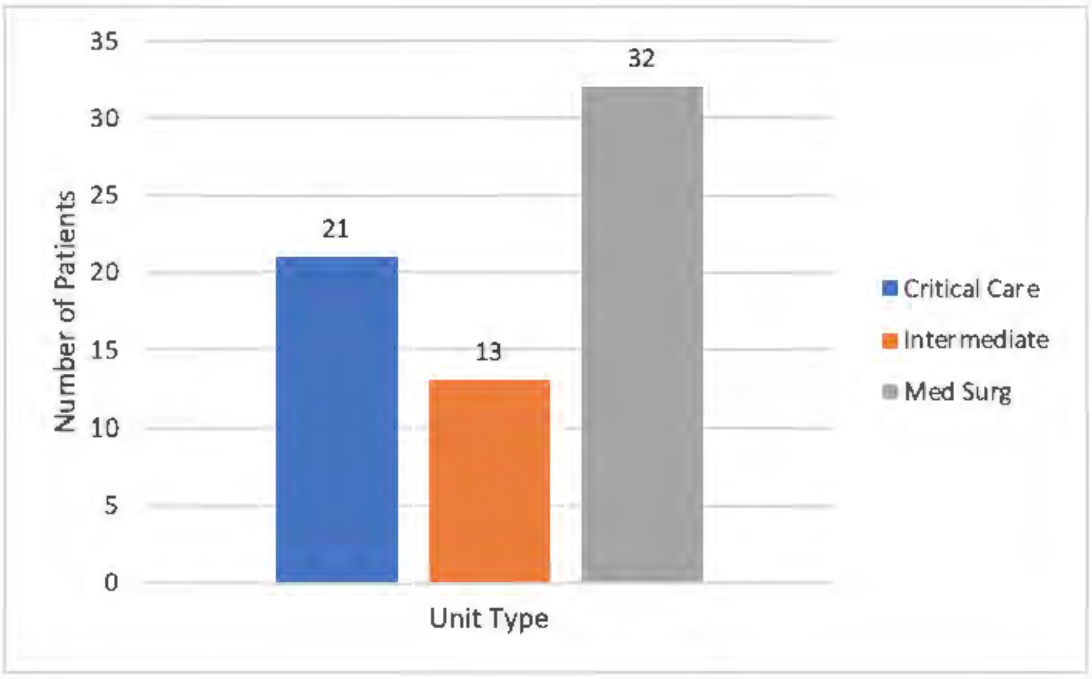


Hospital B Offending Antibiotic Breakdown by Antibiotic Name



Appendix H

Hospital A CDI Breakdown by Unit Type



Hospital B CDI Breakdown by Unit Type