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Implementation of a Probiotic Intervention Among Medical-Surgical Patients: An Evidence-Based Practice Quality Improvement Project

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A DNP project submitted in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice

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Abstract

Introduction: Clostridium difficile infection (CDI) is the most prevalent nosocomial infection pathogen responsible for antibiotic associated diarrhea. CDI is a significant cause of morbidity and mortality rates of medical patients and has increased due to frequent broad spectrum antibiotic usage. CDI is associated with a mortality rate of 25% amongst medical patients. At this catholic hospital in the Northeast of the United States, there is currently no official intervention implemented to prescribe a probiotic when patients are started on antibiotics. Evidence supports that probiotics agents have demonstrated modest success in the risk reduction of CDI to patients receiving antibiotic therapy.

Purpose: The purpose of this quality improvement project is to educate nurses and physicians about the benefits of probiotics, implement an algorithm for providers to prescribe probiotics when prescribing antibiotics, then track probiotic prescription rates and CDI incidence rates.

Intervention and Setting: This quality improvement project was implemented on a 26-bed adult Medical-Surgical Unit in an acute in the Northeast of the United States. Probiotic educational sessions were delivered to nursing and physician staff. After the educational sessions were given, when an antibiotic was ordered for a patient, the nursing staff would obtain an order for a probiotic. Once the probiotic was administered, then those patients were monitored for acute diarrhea and any discharge diagnosis for acute diarrhea or CDI.

Evaluation: Prior to the project implementation the rate of probiotic prescription was 0%. After the intervention probiotic prescription increased by 15%. The readmission rate of patients prescribed a probiotic was 6%, but the readmission was due to other medical problems, not CDI.

Of the patients who received the probiotic, the percentage of them having acute diarrhea as a discharge diagnosis was 0%.

Discussion: CDI is a significant cause of morbidity and mortality rates among medical-surgical patients. According to the evidence, there are numerous probiotic protocols that are evidence-based, that have been implemented in hospitals across the country as standard of practice. The CDI score for this acute facility is 0.347% giving the hospital a C ranking. The best score a hospital can receive is 0.000%, average score of hospitals in the USA is 0.575. An evidence-based probiotic algorithm would be best practice for this hospital to implement as a standard of practice to improve the CDI incidence rates.

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Phase 1: Problem Identification, Development of Clinical Question, and Evidence Review Background and Significance of Problem

Clostridium Difficile Infection (CDI) is the most prevalent nosocomial infection pathogen responsible for antibiotic-associated diarrhea (Segar, Srirangara, Hanifah, Joseph, & Seetha, 2017). It is a significant cause of morbidity and mortality among hospitalized patients and CDI rates have dramatically increased due to frequent usage of broad-spectrum antibiotics among hospitalized patients (Segar et al., 2017). Clostridium Difficile Infection is associated with a mortality rate of 25% among hospitalized patients (Segar et al., 2017). When hospitalized patients develop CDI because of an antibiotic, prolonged hospitalization can occur, increasing healthcare costs, resulting in a costly penalty for the institution. These CDIs can be considered a hospital acquired infection putting healthcare institutions at risk for penalties brought on by Centers of Medicare and Medicaid (CMS) and denial of reimbursement (Segar et al., 2017).

The evidence reveals that probiotics can be effective in reducing CDI rates in medical surgical patients receiving antibiotic therapy (Lau & Chamberlain, 2016). There have been mixed results in studies and quality improvement projects implemented in various healthcare institutions. According to Lau & Chamberlain (2016), Simpson & Lyon (2019), and Stern et al., (2016), a decrease of 0.11% to 1.23% in CDI rates after probiotic use was seen. However, Slain et al, (2019) found no statistically significant difference in the CDI rates after probiotic use.

Description of Local Problem:

Patients are admitted with a variety of infections for which antibiotics are prescribed. When a patient is ordered an antibiotic there is no intervention implemented to reduce the potential of acquiring CDI. Nurses lack knowledge about probiotics and their benefits,

consequently, they are unable to advocate for patients to be prescribed probiotics. When a patient is prescribed an antibiotic and then develops CDI, this event can lead to longer hospitalizations, further harm to the patient and increased health care costs. When a patient develops CDI because of an antibiotic administered in the hospital, this is classified as a hospital acquired infection. When such an event occurs the hospital is subject to a penalty which in turn can jeopardize the hospital's reimbursement.

Focused Search Question:

"In Medical-Surgical patients receiving antibiotic therapy (P), how effective is a probiotic protocol (I), versus no probiotic protocol (C) in reducing the CDI incidence rate (O)?"

External Evidence:

In 2019 an acute Medical Center in Oregon implemented a probiotic protocol by starting adult patients on probiotics within two days of starting antibiotics. The probiotic dose and antibiotic doses were administered two hours apart. They continued the probiotic course for at least one week and up to four weeks post-antibiotics (Segar et al., 2017). The indication for the probiotic were patients who are at risk for developing CDI. After implementation, the hospital saw a decrease in CDI rates by 15% (Segar et al., 2017).

In another article, all adults admitted to a 330-bed community hospital who were prescribed an antibiotic automatically received a probiotic (Slain et al., 2019). Clostridium difficile infection rates were compared during the three-year period before and after the automatic implementation of the probiotic protocol. Rates of CDI did not differ before and after protocol implementation (Slain et al., 2019).

Trick et al (2018) and Simpson & Lyons (2019), conducted quality improvement projects, where probiotic protocols were automatically implemented on adult Medical-Surgical units. The CDI rates were examined pre- and post-interventions. The CDI rate was lower in the probiotic group as compared to the control group; with a significant decrease in CDI rates during the final six months of the studies (Trick et al. 2018 & Simpson & Lyons (2019).

Internal Evidence:

The site of implementation of this quality improvement project currently does not have a probiotic algorithm in place, neither do the other local hospitals in the area. This urbanized catholic hospital located in the Northeast of the United States, scored a 0.347% for CDI compared to the best possible score a hospital can receive which is a score of 0.00%. The average hospital score in the US is 0.575% with the highest score being 1.770% (Hospital Safety Grade.org, 2021). A CDI score of 0.347% puts this hospital with a ranking of C (Hospital Safety Grade.org, 2021). According to the Hospital Safety Grade (2021), an A ranking signifies an excellent score, a B ranking signifies a good score, a C ranking signifies an average/fair score, a D ranking signifies a below the average performance, and a F ranking signifies a poor performance.

Evidence Appraisal, Summary, and Recommendations

Databases reviewed were CINAHL, Google Scholar, Medline, and Cochrane Review of Systematic Reviews. Keywords searched were “antibiotic associated diarrhea”, “probiotic and antibiotic”, “probiotic protocol in hospitals”, and “C-Diff mortality rate”. Two level one articles met the search criteria; two level four met the search criteria. The articles that were mainly used were single blinded random controlled trials. The articles selected were quality improvement

studies. The review of the evidence was mixed with some of the studies finding the probiotic protocol effective, while others did not see a statistical significance. See appendix B that displays the Evidence Table for Systematic reviews which contains pertinent information from each article selected. See appendix C for Evidence Synthesis table and Appendix D for outcome synthesis.

Phase 2: Project Planning

Project Goals

1. To educate providers and staff on the benefits and effectiveness of probiotics.
2. Implement the probiotic algorithm protocol.
3. To evaluate the number of probiotic prescriptions pre- and post-intervention.
4. Evaluate the effectiveness of probiotics by assessing the CDI rates and readmission rates of those patients that received the intervention.

Framework

The planned framework for this project was the Plan-Do-Study-Act (PDSA) cycle. The Institute for Healthcare Improvement (IHI, 2021) utilizes the PDSA cycle to aid in quality improvement projects. The PDSA cycle starts with three questions: (1) “What are we trying to accomplish?” (2) “How will we know that a change is an improvement?” (3) “What change can we make that will result in improvement?” (IHI, 2021, p.2).

The plan was to gather pre-intervention data on the percentage of probiotic prescriptions to patients prescribed an antibiotic. The CDI rates of the acute care facility was obtained and compared to the national average CDI scores. Using the above information providers and staff were educated on the problem and the evidence that supports the effectiveness of probiotics. The post-implementation data included the percentage of probiotic prescriptions, the percentage of

patients that were readmitted within 30 days due to CDI, and the percentage of patients that had the discharge diagnosis of acute diarrhea that were prescribed the antibiotic.

Through the implemented intervention the goal was to collaborate with the hospitalists to have them prescribe the probiotic to the appropriate medical-surgical patients. Once the probiotic was ordered those patients were monitored for any acute diarrhea during the hospitalization and for any readmissions for CDI once discharged. When reviewing the clinical data, the author was able to evaluate the effectiveness and sustainability of the probiotic intervention. This evidence-based framework, the PDSA cycle, was used to evaluate the effectiveness of the process on an ongoing basis during the implementation of the project.

Context

The DNP project was implemented in a 347-bed urban acute care hospital located in the Northeastern United States. This probiotic intervention was implemented on a 26-bed adult medical-surgical unit. This urban hospital serves a diverse patient population of uninsured, underinsured, low-income, and privately insured. This catholic hospital provides in-patient services and treats acute illnesses such as cardiac, respiratory, infectious diseases, neurological, orthopedics, gastrointestinal and trauma in nature. This hospital consists of an interdisciplinary team comprising of physicians, nurse practitioners, surgeons, medical residents, registered nurses, physical therapist, occupational therapists, respiratory therapists, social workers, case managers, and senior management staff. Many patients that are diagnosed with bacterial infections are admitted for antibiotic therapy. Therefore, antibiotics are highly prescribed to these hospitalized patients to treat infections that are bacterial in nature.

Key Stakeholders

- Patients
- Providers (Hospitalist)
- Staff Nurses
- Unit Manager
- Infection Control Department

Global Aim

The global aim is to create awareness of the CDI problem, educate providers and nursing staff on the effectiveness of probiotics and to implement a probiotic protocol in an acute medical-surgical unit and assess the CDI rates of the acute care facility.

Barriers to Implementation:

Implementing this probiotic intervention in a high-paced medical-surgical unit posed challenges. This project was implemented during the COVID pandemic which caused many challenges for the hospital and the project. First, the floor had a severe nursing shortage, which resulted in the hiring of numerous travel nurses. Many of the travel nurses felt overwhelmed with the fast-paced unit and the high acuity of patients. Obtaining an order for a probiotic caused one extra item on their list of duties, which led to resistance. Second, there was resistance among the providers to prescribe the probiotic, especially the medical teaching resident staff. Many of the providers demonstrated skepticism on the effectiveness of probiotics in decreasing CDI rates in patients receiving antibiotic therapy. Third, finding the opportunity to gather the physician and nursing staff to conduct a formal educational in-service was very difficult. As mentioned above, this project was implemented during COVID times, in which social distancing was highly

practiced and enforced. This challenge turned the formal session into, hasty, elevator speeches, making it difficult to be concise in such a short period of time.

Timeline:

November 2020-March 2021

- Evidence Search Plan
- Meeting with Project Advisor
- Meeting with Practice Mentor
- Meeting with Nursing Management Staff

May-August 2021

- Project Proposal Presentation Delivered

February-March 2022

- Implementation

April-May 2022

- Data Analysis

April 2023

- Final Manuscript and Presentation

Resources

The author anticipated resources such as people and capital throughout the implementation of this project. People involved in this QI project were the author, practice mentor, registered nurses, physicians, unit manager and patients who were prescribed the probiotic. Estimated expenses were the author's registered nurse salary times the number of hours spent to educate staff, reviewing the EHR, the providers' salary, and the cost of the probiotic. The total cost to implement the project was estimated to be $1200.00.

Ethical Merit

Table 1 (see appendix A) exhibits the completed quality improvement tool. Answers to questions 1 through 10 are marked "yes". For questions 11 through 14, the answers that are marked "no" indicating that this project meets criteria for a quality improvement project and does not qualify as human subjects' research and therefore, does not require the Institutional Review Board of Sacred Heart University. The hospital where the project was implemented did not meet criteria as a research project, therefore did not require IRB review. The project was approved by the management and quality department.

Data Collection Plan

The author collected and compared data pre- and post-implementation of the probiotic intervention from the electronic health record (EHR). The data was recorded in a manual log. The manual log was stored in a locked desk, only the author had access to the locked desk. No personal patient information was recorded in the log, just the patient's initials, admitting diagnosis, and reason for antibiotic. The author used the EHR to tally up the percentage of probiotic prescriptions written prior and after the intervention was implemented. The author also viewed the EHR for any development of acute diarrhea while the patients were receiving the probiotic during antibiotic therapy. Readmission of those specific patients receiving the probiotic intervention within thirty days was also assessed.

Data Analysis Plan

The goal was to review 2 months (8 weeks) of data and obtain feedback from the staff to evaluate if the probiotic intervention was beneficial. The EHR was reviewed with the following four analyses:

1. The number of probiotic prescriptions made to patients receiving antibiotic therapy prior to the implementation of the probiotic algorithm.
2. The number of patients who qualified for probiotic therapy and received probiotic therapy.
3. The percentage of the population who were discharged with CDI.
4. The percentage of the population who were readmitted within 30 days of discharge with diagnosis of acute diarrhea and/or CDI.

Phase 3: Implementation

Implementation of Project

Plan: Once the project proposal was presented to the DNP advisor and Practice mentor and approved by both university and facility then the implementation was initiated. During this phase, the project goals were determined, the type of data to be collected was decided, the methodology on educating the involved stakeholders about the probiotic intervention was determined. Inclusion criteria was determined for patients eligible to receive the probiotic.

Do: The inclusion criteria for patients to receive the probiotic intervention included adult patients on a medical-surgical unit, who were prescribed antibiotic therapy, oral or intravenous; patients able to tolerate oral intake; have no history of dysphagia; white blood cell count above 3,000. All immunocompromised, pregnant and patients with admitting diagnosis of small bowel obstruction were excluded. Educational sessions about the probiotic intervention and inclusion criteria were communicated at the start of implementation. Once the probiotic intervention was implemented then data collection also started. The percentage and number of probiotic prescriptions were monitored via the EHR; patients who received the probiotic during hospitalization were monitored for acute diarrhea through screening the EHR and via Cortex

communication with staff nurses. The EHR was screened for patients with any discharge diagnosis of acute diarrhea or CDI who received the probiotic. Patients discharged who received the probiotic were monitored for readmission caused by CDI within 30 days via the EHR. Once the data was collected, the percentage of probiotic prescription was compared pre- and post-intervention; the percentage of patients who developed CDI or acute diarrhea while receiving the probiotic and the percentage of readmission rate of those specific patients was calculated. During the project providers and nursing staff were reminded of the intervention through huddles, interdisciplinary morning rounds, by elevator speeches and Cortex electronic reminders.

Study: Over the course of 8 weeks, the author reviewed the EHR checking for the number of probiotic prescriptions, patient adherence, and any incidences of CDI or acute diarrhea. During the implementation of the first PDSA cycle, challenges were encountered, such as lack of time to deliver the educational sessions because of the increased number of COVID patients on the floor and because the unit was mainly staffed with agency nurses. Nurses asking for a probiotic prescription from providers was an additional task on their list that was oftentimes being ignored. The COVID pandemic posed a problem causing much fatigue for providers and nursing staff causing them to forget about the probiotic intervention. The second cycle of the PDSA, the educational sessions were condensed down to elevator speeches, only patients being followed by the hospitalist service were utilized for the project because buy-in was achieved by hospitalist. Electronic Cortext reminders were sent to nurses and physicians about ordering the probiotic for eligible patients.

Act: After the first PDSA cycle, the prescription rate of probiotics was poor due to the previously mentioned challenges. After the evaluation of the first cycle, changes were made. The changes consisted of only including the patients admitted under the hospitalist service. The

utilization of the electronic staff Cortex system was added to remind the nursing and hospitalist staff to follow the probiotic algorithm. Educational sessions were condensed to elevator speeches (short presentations) at morning huddles and morning medical rounds. The second PDSA cycle were implemented, an improvement in the rate of probiotic prescriptions written was noted. Refer to appendix E to view the number of probiotic prescriptions for each cycle chart.

Phase 4: Evaluation

Prior to the implementation of this quality improvement project, there were no prescriptions written for probiotics for patients prescribed an antibiotic. After the implementation of this quality improvement project, the percentage of probiotic prescriptions increased to 15%. A total of 65 patients qualified for the probiotic but only 40 patients received the probiotic order (62%). Refer to appendix F to view the graph of these results. Of the 40 patients who received the probiotic intervention there were no (0%) cases of CDI during hospitalization and none of the patients had a discharge diagnosis of acute diarrhea, ICD-10 code R19.7. The readmission rate for of those 40 patients was 6%. However, reasons for those readmissions were due to medical problems unrelated to CDI and/or acute diarrhea. Refer to Appendix G for chart of this result.

Phase 5: Dissemination

The results of the data collection will be shared with the practice mentor and unit manager. The unit manager will share the results with senior management at leadership meetings. The results and outcomes will also be presented to the infection control staff and communicated to senior management who will set the motion in having an electronic order set implemented. Internal dissemination will also include presenting the results in morning staff huddles and interdisciplinary rounds.

External dissemination included a poster presentation of the project delivered at Sacred Heart University to professors and students. The author may also submit the abstract of the probiotic intervention to a nursing journal and an infectious disease journal.

Key Lessons Learned

In implementing this quality improvement project, the author learned that it is imperative to conduct a comprehensive literature review on the topic, to have evidence to support your topic when obtaining buy-in from stakeholders. While obtaining buy-in much skepticism was identified, making the implementation challenging. Being present constantly to champion the project was essential in having a successful implementation of the probiotic intervention. The lack of full-time presence and COVID restrictions posed challenges in implementing this project. Finding ways to have the staff nurses remember to ask providers for probiotic prescription was challenging due to being unable to be present full-time. Challenges called for creative strategies such as using the electronic staff Cortexting System and conducting elevator speeches at huddles and morning unit medical rounds to help this project move forward.

Sustainability Plan

To achieve sustainability of the probiotic intervention at this catholic hospital, the results of the project will need to be disseminated internally to senior and regional management in hopes to start the process of having an electronic order set approved. Once the order set is approved, then it can be implemented, so when an order for an antibiotic is placed the order set will pop up for the probiotic. Once the order set is in place, probiotic use can be a standard of practice when patients are prescribed antibiotics to keep CDI rates at a minimum.

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Appendix A

Table 1:

Differentiating Quality Improvement and Research Activities Tool

Question	Yes	No
1. Is the project designed to bring about immediate improvement in patient care?	X	
2. Is the purpose of the project to bring new knowledge to daily practice?	X	
3. Is the project designed to sustain the improvement?	X	
4. Is the purpose to measure the effect of a process change on delivery of care?	X	
5. Are findings specific to this hospital?	X	
6. Are all patients who participate in the project expected to benefit?	X	
7. Is the intervention at least as safe as routine care?	X	
8. Will all participants receive at least usual care?	X	
9. Do you intend to gather just enough data to learn and complete the cycle?	X	
10. Do you intend to limit the time for data collection in order to accelerate the rate of improvement?	X	
11. Is the project intended to test a novel hypothesis or replicate one?		X
12. Does the project involve withholding any usual care?		X
13. Does the project involve testing interventions/practices that are not usual or standard of care?		X
14. Will any of the 18 identifiers according to the HIPAA Privacy Rule be included?		X

Adapted from Foster, J. (2013). Differentiating quality improvement and research activities. Clinical Nurse Specialist, 27(1), 10–3. https://doi.org/10.1097/NUR.0b013e3182776db5

Appendix B

Search Question in PICO format: In Medical Surgical patients receiving antibiotic therapy (P), how effective is a probiotic intervention (I) versus no probiotic protocol (C) in reducing the CDI incidence rate (O)?

Article Number	First Author year	Purpose	Evidence type, level of evidence	Sample, Setting	Major Variables Study and their definitions	How major variables were measured	Findings that help answer question	Worth to Practice/project, quality of evidence.
1	Slain, (2019).	Aim of study was to see how widespread preventative use of the probiotic use via automatic protocol in hospitalized patients receiving antibiotic therapy affected CDI rates.	Evidence based practice quality improvement project, VI.	A community hospital a 330-bed facility. Adult patient over the age of 18, receiving antibiotic therapy.	**Clostridium Difficile** was characterized as a significant opportunistic infection across North America and Europe among hospitalized patients receiving antibiotic therapy. **Probiotic** Was characterized as a means of a preventative measure to prevent CDI from occurring.	A Poisson regression model was utilized for comparison before and after protocol implementation. Overall rates of CDI were assessed using ICD-9 code 008.45 for admitted patients.	Rates of HA-CDI appeared to be similar between the pre-protocol and protocol period, with average yearly rates of 0.988 and 0.895 cases/1000 patient-days.	The methodology of implementing the protocol can be used in implementing an actual protocol, despite lower level of evidence.

2	Trick, (2018)	To evaluate probiotics for the primary prevention of Clostridium difficile infection among hospital patients	Evidence based practice quality improvement project, VI.	A 694-bed teaching hospital.	CDI was defined as watery diarrhea three or more occurrences in one day. Probiotic was defined as healthy microorganism supplements to help keep the gut well balanced.	Major Variables were measured by when patient started to receive the probiotic when antibiotic therapy started, data was collected on age, sex, race-ethnicity, daily exposure to probiotic and antibiotic, timing of initial probiotic relative to initial antibiotic dose, presence of tube feeding, comorbidities, prior hospitalizations at the same facility, preadmission location, use of	Compared to the first 6 months of the intervention, a significant decrease in CDI during the final 6 months incidence rate ratio, 0.6; 95% confidence interval 0.4-0.9.	Quality of evidence moderate. Can use how the protocol was implemented.

						Proton pump inhibitors and severity of illness and risk of mortality recorded at discharge. This data was inputted in a proprietary software embedded in the electronic record. In a conditional logistic regression model, probiotic and antibiotic exposure days were summed up and cumulative exposure for each patient was modeled. C-Diff assays were performe		

						d more in the baseline than the interventi on period.		
3	Starn , (201 6)	To identify the relationsh ip of antibiotic administr ation to the incidence of C-Diff in a hospital setting while determini ng the effectiven ess of probiotic administr ation. To provide the hospital with a recomme ndation on the cost-efficiency of the probiotic protocol.	Retrosp ective case-control design. Stage V.	9950 adult patients. In a suburban hospital, 328 bed hospital.	The dichotomou s dependent variable was whether the patient developed HCFA-CDI. Independent variables included demographi cs, antibiotic class, and the number of doses of probiotic administere d. C-Diff was defined as diarrhea leading to pseudomem branous colitis, toxic megacolon. Health care facility associated CDI is defined as CDI more than 48 hours after admission	A standardi zed data collection tool was based on the literature review. Data from the retrospect ive medical review was download ed into SPSS V.22 and screened for accuracy. Data was analyzed by a statisticia n based on binary logistic regressio n model. A binary logistic regressio n model was conducte	Care effectiv eness was not found.	The quality of evidence was moderate due to limitation s of the study design. Data was limited to what was available in the electronic medical records.

					or less than 4 weeks after discharge from a hospital. Probiotic defined as live microorganisms consumed as supplements of food, they interact with the human's body's normal flora to provide benefits, such as the development of a prospective barrier.	d with a probiotic as the binary predictor and HCFA-CDI as the outcome variable.		
4	Simpson, (2019).	To evaluate the efficacy of probiotics for the prevention of CDI in adult hospitalized patients taking	A systematic review and meta-analysis of RCT.I	6261 adult hospitalized patient taking antibiotic therapy.	Definitions were not included.	Trials were included if the intervention was for CDI prevention and if the probiotics were used. Control groups received	The risk for CDI was lower in the probiotic group (range 0%-11%) than in the control group (0%-	Level of Evidence high. This was a high-quality meta-analysis of RCT did demonstrate that probiotics are effective if

		antibiotics.				matching placebo in all trials.	40%), when data was pooled from all 19 studies (relative risk=0.42%; 95% CI, 0.30-0.57.The median incidence of CDI in the control group from all studies was 4%, which yielded a number needed to treat (NNT) of 43 (95% CI,36-58). Compared with control group there was a signific	administered within 1-2 days of initiating antibiotic therapy.

							ant reduction in CDI if probiotics were started with 1 to 2 days of antibiotic initiation (RR=0.32; 95% CI, 0.22-0.48.	
5	Lau, (2016).	To examine the impact of probiotics on the incidence of CDI among adults in hospital settings.	A Systematic Review and Metanalysis of RCT. I	A comprehensive literature review of all RCT assessing the use of probiotics in the prevention of CDI in patients receiving antibiotic therapy. 26 RCTs involving 7,957 patients were	C-DIFF was a gram-positive, spore forming, and toxin-producing anaerobic rod bacterium. Probiotics were defined as live microbial food supplements and have been hypothesized to counteract disturbances in	RCTs comparing the use of any strain or dose of a specified probiotic with a placebo or no intervention, control group, probiotics initiated with three days of starting antibiotic therapy and continued for at	In the RCTs, fewer patients in the probiotic group developed CDI, compared to the control group who received placebo or no supplement. Meta-analysis showed a	Quality of evidence was good, strong evidence and confidence to implement probiotic use as a preventative measure to CDI, to adult patients receiving antibiotic therapy.

				analyzed.	intestinal flora and reduce colonization by pathogenic bacteria.	least the entire duration of antibiotic treatment.	significantly lower risk of developing CDI in the probiotic group compared to the control group (RR=0.395; 95% CI, 0.294-0.531.	

C-Diff, CDI, Probiotic effectiveness, Probiotic Protocol, C-Diff associated Diarrhea, C-Diff Mortality Rates.

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Appendix C

Evidence Synthesis Table

Level of Evidence Synthesis Table

Article Number	1	2	3	4	5
Level I: Systematic review or meta-analysis	X	X			
Level II: Randomized controlled trial					
Level III: Controlled trial without randomization					
Level IV: Case-control or cohort study				X	
Level V: Systematic review of qualitative or descriptive studies					
Level VI: Qualitative or descriptive study, CPG, Lit Review, QI or EBP project			X		X
Level VII: Expert opinion					

1. Lau, C. & Chamberlain. (2016). Probiotics are effective at preventing Clostridium difficile-associated diarrhea: a systematic review and Meta-analysis. *International Journal of General Medicine,* 9: 27-37. DOI: 10.2147/IJGM.S98280.
2. Simpson. & Lyon.C. (2019). Do Probiotics reduce C-Diff risk in hospitalized patients? A systematic review and meta-analysis say, "Yes," but that does not necessarily mean they will start appearing on hospital formularies. *The Journal of Family Practice,* 68(6), 351-354.
3. Slain, D., Georgulis, A., Dermitt, R., Morris.L. & Colodny, S.M. (2019). Impact of an automatic hospital protocol on Clostridium difficile Infection (CDI) rates and CDI antibiotic usage in a community hospital setting. *Journal of Infection Prevention,* 1-7. DOI: 10.1177/1757177419892309.
4. Starn, E., Hampe, H., & Cline, T. (2016). The Cost-efficiency and Care Effectiveness of Probiotic Administration with Antibiotics to Prevent Hospital-Acquired Clostridium

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5. Trick, W.E., Sokalski, S.J., Johnson, S., Bunnell, K.L., Levato, J. Ray, M.J., & Weinstein, R.A. (2018). Effectiveness of Probiotic for Primary Prevention of Clostridium difficile Infection: A Single-Center Before and After Quality Improvement. *Infection Control & Hospital Epidemiology, 39(7),* 766-769.

Appendix D

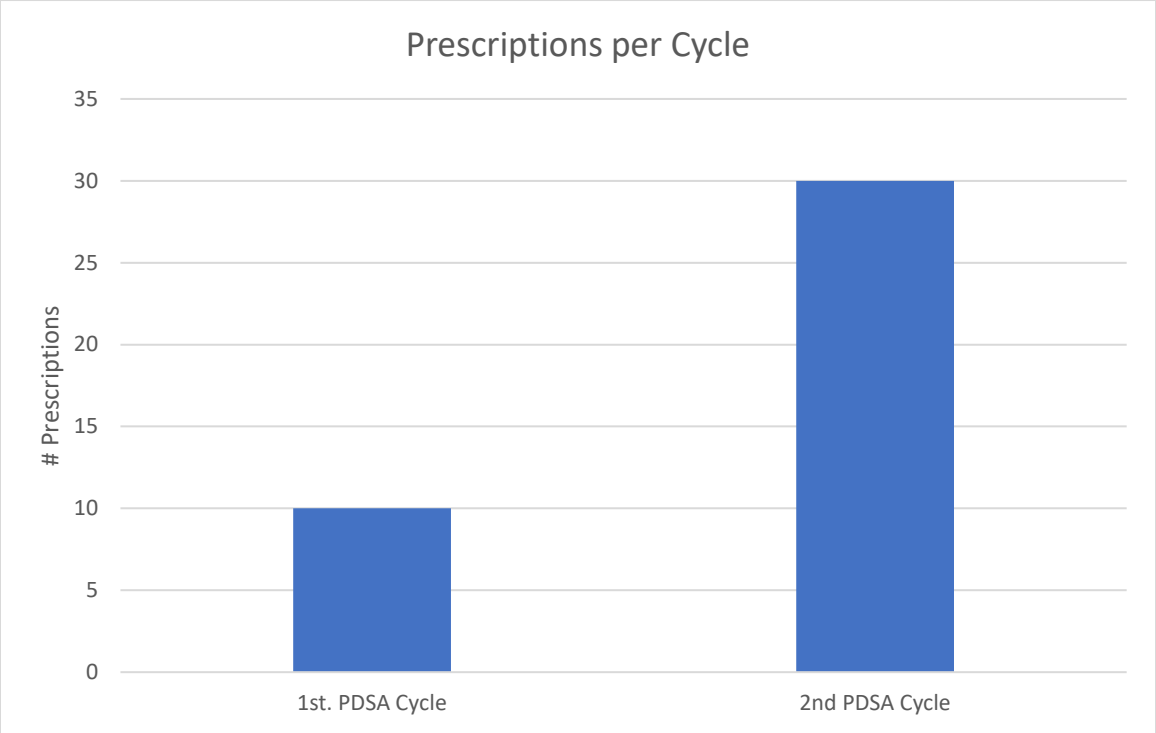
Outcome Synthesis Table

Outcomes Synthesis Table

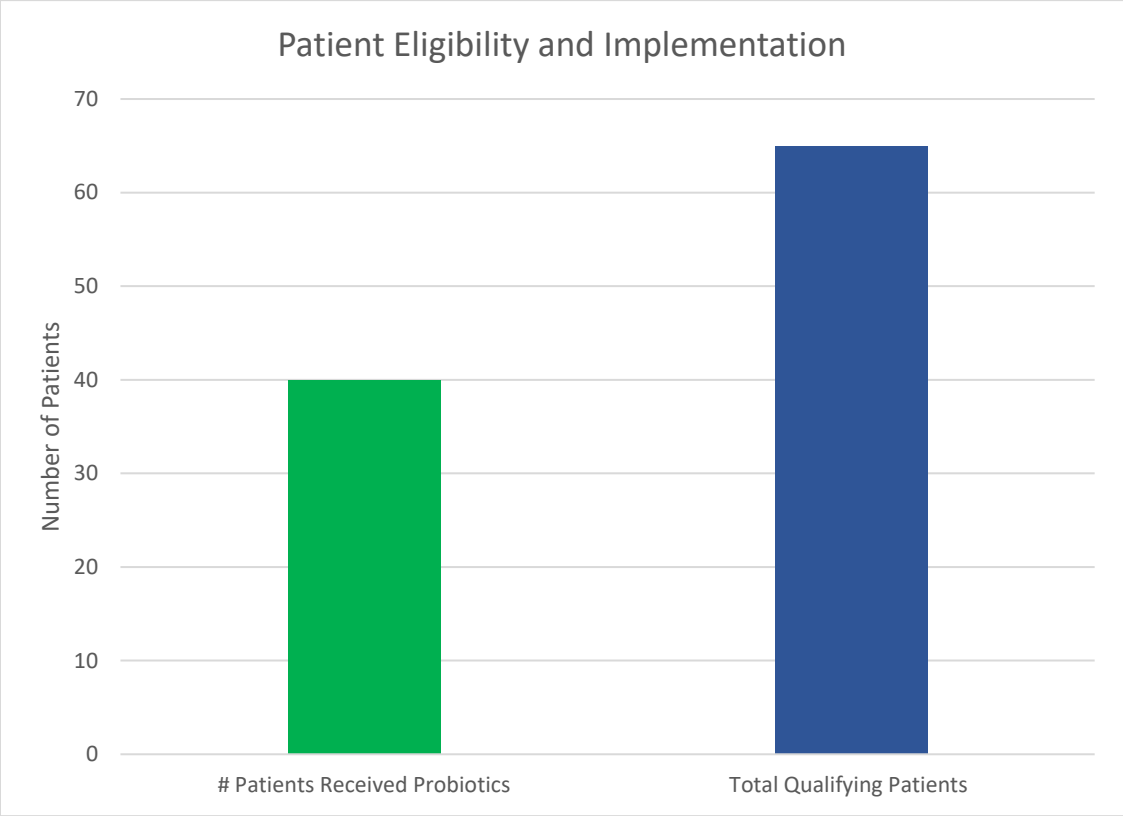
Article Number	1	2	3	4	5
C-Diff Infection (CDI) rate after probiotic use.	60.5% 	0-11% 	ND	1.23% of patients receiving probiotic developed CDI 61/4141.	ND
Readmission rates D/T CDI	NE	NE	NE	NE	NE
Prolonged Length of Stay due to CDI	NE	NE	NE	NE	NE

Key: NE(Not Evaluated), ND (No Statistically Significant Difference)

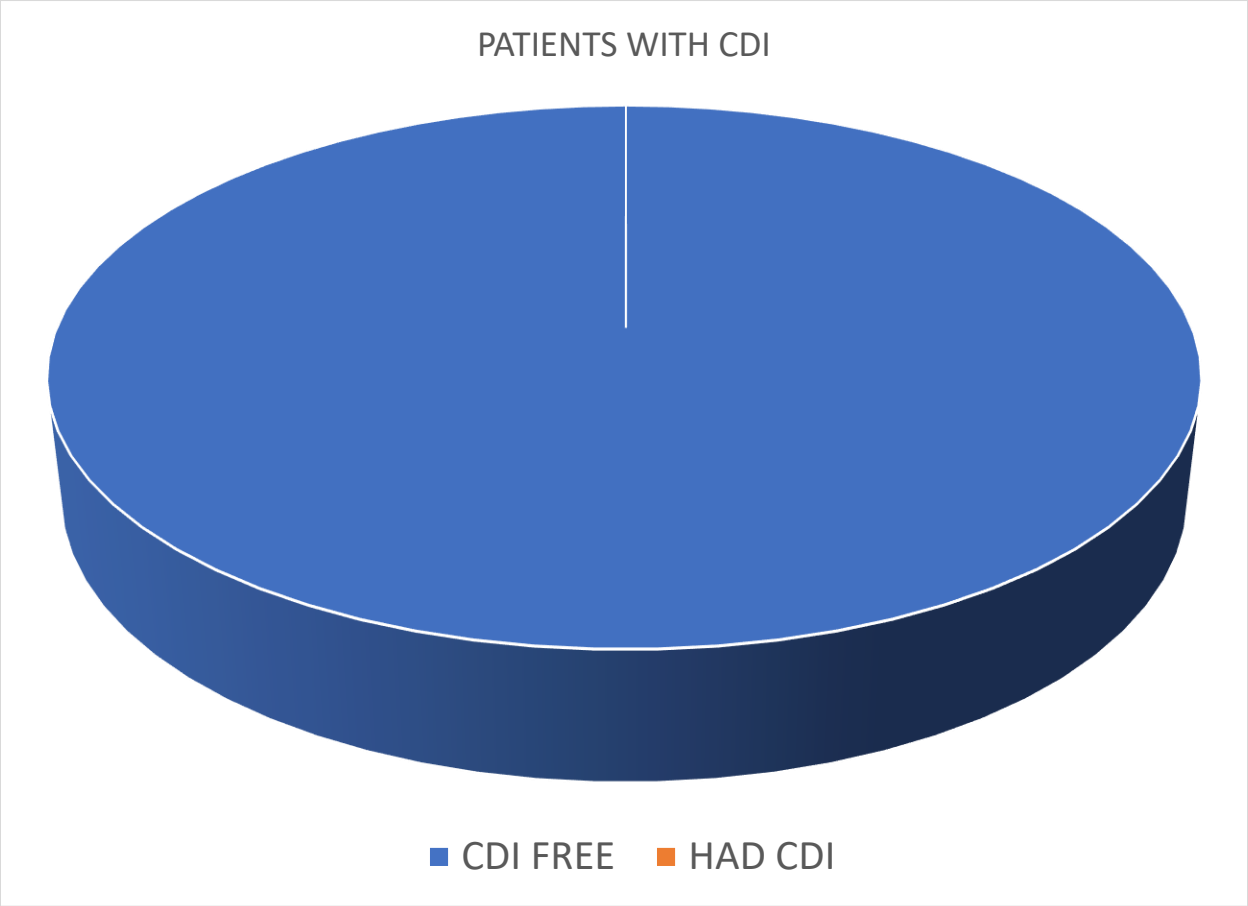
Appendix E


Prescriptions per Cycle
35
30
25
20
15
10
5
0
Prescriptions
1st. PDSA Cycle
2nd PDSA Cycle

Appendix F


Patient Eligibility and Implementation
70
60
50
40
30
20
10
0
Number of Patients
Patients Received Probiotics
Total Qualifying Patients

Appendix G



Appendix H

Poster Presentation

DR. SUSAN L. DAVIS, R.N., & RICHARD J. HENLEY COLLEGE OF NURSING
Sacred Heart University

Implementation of a Probiotic Protocol Among Medical Surgical Patients An Evidence-Based Practice Quality Improvement Project

Monica Bonvicini RN, BSN, (DNP Student), Dr. Sylvie Rosenbloom DNP, APRN, FNP -BC, CDCES, (Project Mentor), Dr. Sahlee Samonte DNP, RN (Practice Mentor)

Rationale

To implement a standard intervention for hospitalized patients on antibiotics to start a probiotic in order to minimize Clostridium Difficile Infections (CDI) rates.

Background

- CDI is a significant cause of morbidity and mortality rates among medical surgical patients and has increased due to frequent usage of broad-spectrum antibiotics in this patient population
- . XXXXX Hospital score for CDI is 0.347. The best score a hospital can receive is 0.000, average score of hospitals in the US is 0.575. XXXX Hospital has a C ranking, with the 0.347. There is room for improvement.
- No intervention exists to prevent CDI to when antibiotics are prescribed to medical surgical patients at XXXXXX Hospital.
- The evidence supports that a probiotic protocol can reduce the CDI if implemented as a standard of practice to hospitalized patients receiving antibiotic therapy.

Methods

Design: EBP-QI project
Setting: Saint Mary's Hospital Medical -Surgical Unit

PDSA Cycle

PLAN:
- Create awareness of the importance and benefits of implementing a probiotic intervention as standard practice.

DO:
- Educating nursing and provider staff on probiotics via short presentations, staff huddles and morning Interdisciplinary Team rounds to order the probiotics upon initiation of an antibiotic. l.

STUDY:
- .Piloting of probiotics prescriptions.

ACT:
- Evaluation of the effectiveness of the probiotic and the number of

PICOT Question

In Medical Surgical patients receiving antibiotic therapy (P) , how effective is a probiotic protocol (I), versus no probiotic intervention (C), in reducing the CDI rates incidence rates (O) ?

Implementation Plan

Plan, Do, Study, Act Cycle

Project Timeline:
- Nov 2020-Mar 2021: Evidence search plan, meeting with project advisor, practice mentor, nursing staff, provider staff, management team.
- May-Aug 2021: Project proposal developed and delivered.
- Late Fall 2021-Jan 2022- Implementation 2 months.
- Feb 2022-March 2022- Data Analysis
- April-May 2022- Final Manuscript and Final Presentation.

Evidence Search & Recommendation

Information Sources: CINAHL, Cochrane Database of Systematic Review, Google Scholar, and MEDLINE,
Key Words: Antibiotic Associated Diarrhea, probiotic, antibiotic, probiotic protocol in hospitals, C-Diff morality rates.
EBP Model: The Plan Do Study Act.

Results: 5 studies were examined. The level of evidence was a mixture of levels 1,4 and 6.

Level of Evidence Table

Article Number	1	2	3	4	5		
Level I: Systematic review or meta-analysis	x	x					
Level II: Randomized controlled trial							
Level III: Controlled trial without randomization							
Level IV: Case-control or cohort study			x		x		x
Level V: Systematic review of qualitative or descriptive studies							
Level VI: Qualitative or descriptive study, CPG, Lit Review, QI or EBP project				x			
Level VII: Expert opinion							

Outcomes

- The percentage of probiotic prescriptions prior to intervention was 0%
- The percentage of probiotic prescriptions after intervention went up to 15%.
- The readmission rate for the patients prescribed the probiotic was 6%, but not readmission was not due to CDI, other medical problems within 30 days.

Sustainability Plan

- Present the outcomes of the project to senior management.
- Having an order set approved and implemented to sustain the probiotic intervention.

Lessons Learned

- A probiotic intervention can be highly beneficial in reducing CDI rates.
- An order set is necessary to maintain compliance of the probiotic intervention.

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