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Effectiveness of an electronic health record embedded evidence-based testing algorithm for Clostridioides difficile infection.

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Effectiveness of an electronic health record embedded evidence-based testing algorithm for *Clostridioides difficile* Infection

by

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Dedication

Dedicated to Dr. Anna Smith, who I will always be grateful to for challenging me not to accept "that's the way we've always done it" and aspire for innovative change, and to be relentless in the pursuit of nursing excellence.

Acknowledgment

My deepest gratitude to Dr. Ratchneewan Ross and Dr. Luz Huntington-Moskos for their support and encouragement throughout this project. Thank you to the team members of UofL Hospital's Infection Prevention & Control Dept, Microbiology Department and Nursing Informatics, for without whom this project would not have been successful; LaShawn Scott, Leah Oppy, Gina Stevenson, Crystal Heishman, Dr. Forest Arnold, Joyce Garr, Chuck Johnson, Dr. James Snyder, and Katrina Bates.

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Abstract

Background: *Clostridioides difficile* infection (CDI) commonly impacts hospitalized patients with almost half a million cases of CDI reported in the United States annually. *C. difficile* colonization is more common than infection. Colonized patients may test positive for *C. difficile* organism or its toxin but do not display clinical signs and symptoms. Identifying true infection versus colonization is critical to avoiding inappropriate treatment, unnecessary exposure to antibiotics, and increased cost of care. Implementation of evidenced-based CDI testing criteria can help reduce inappropriate CDI testing and avoid the misidentification of colonized patients as true CDI.

Purpose: The purpose of this project was to evaluate the effectiveness of an evidence-based electronic health record (EHR) integrated CDI testing algorithm in reducing inappropriate CDI testing among adult inpatients.

Methods: A retrospective review of outcomes data were analyzed to assess CDI algorithm effectiveness.

Intervention: Three order rules were implemented into the EHR; (1) Order stopped if negative *C. difficile* result in past 7 days, (2) Order stopped if positive *C. difficile* result in past 28 days, and (3) Order stopped if patient has received a laxative within 48 hours. These rules were developed as “hard stops” which clinicians could not bypass.

Results: A significant reduction was achieved in both the number of CDI tests performed and CDI testing rate (61% decrease; z= -19.90, $p<.001$). Statistically significant decrease was also found for Hospital onset CDI rate (57% decrease; z= -17.64, $p<.001$) and Standardized Infection Ratio (SIR) (51.7% decrease; z= -37.58, $p<.001$).

Discussion: Implementation of an evidence-based EHR integrated CDI testing algorithm is an effective way to reduce the number of inappropriate CDI tests performed and testing rates.

Keywords: *Clostridioides difficile*, *C. difficile*, electronic health record, clinical decision support, EHR

While progress has been made over the last 10 years, healthcare associated infections (HAI) remain a significant challenge for healthcare leaders. On any given day, it is estimated that one in 31 hospitalized patients are affected by at least one HAI (Centers for Diseases Control and Prevention, 2018). *Clostridioides difficile* infection (CDI) is one type of HAI that commonly impacts hospitalized patients with almost half a million cases of CDI reported in the United States annually (Guh et al., 2020). With the introduction of high sensitivity laboratory testing methods for CDI, a new challenge is distinguishing between true infection versus colonization of *C. difficile*. Implementation of evidence-based testing criteria serves several purposes including to reduce false positives that can occur from colonization (not true infection) and associated consequences from misdiagnosis, such as, exposure to unnecessary antimicrobials used in the treatment of CDI, extended length of stays, and missed or delayed diagnosis of true cause of disease falsely attributed to CDI (Boly, Reske, & Kwon, 2020).

Background

Clostridioides difficile is a gram-positive anaerobic spore-forming bacteria shed in feces. It produces two types of exotoxins, toxin A and toxin B, responsible for the infectious disease that results from this bacterium. Clinical symptoms of CDI include diarrhea, fever, loss of appetite, nausea and abdominal pain, and accounts for 15-25% of all episodes of antibiotic associated diarrhea (Centers for Disease Control and Prevention [CDC], 2021). The Centers for Disease Control and Prevention (2019) report each year an estimated quarter million people require hospital care for CDI with 12,800 associated deaths. Risk factors for the development of CDI include antibiotic use, older age (>65), gastrointestinal surgery, long length of stay in healthcare settings, a serious underlying illness and immunocompromising conditions (CDC, 2021).

C. difficile colonization, also referred to as asymptomatic carriage of *C. difficile*, is more common than infection. Colonized patients may test positive for *C. difficile* organism or its toxin but do not display clinical signs and symptoms (CDC, 2021). Data show that 7 to 18% of hospitalized patients are colonized and for those with an extended length of stay (>4 weeks) that can increase to 50%. Risk factors for asymptomatic carriage include recent hospitalization, chemotherapy, and acid-suppressive medications; however, exposure to antibiotics was not reported as a risk factor for colonization. Colonization of *C. difficile* is also common among Long-term care residents and less frequently in the community setting (Donsky, Kundrapu and Deshpande, 2015).

Nucleic acid amplification testing (NAAT), commonly used as either single step testing or part of a multi-test algorithm, is highly sensitive and, yet cannot differentiate between *C. difficile* colonization and infection (Kraft et al, 2019). Thus, following evidence-based testing guidelines is important in ensuring accurate identification and guiding appropriate treatment of true CDI. Axenfeld and colleagues (2021) found that nearly half of all CDI testing orders were inappropriate among hospitalized patients. Identifying true infection versus colonization is critical to avoiding inappropriate treatment, unnecessary exposure to antibiotics, and increased cost of care (McDonald et al., 2018).

Testing recommendations include testing patients with unexplained and new-onset ≥3 unformed stools in 24 hours; not testing asymptomatic patients; not performing repeat testing after negative test during the same episode of diarrhea; and not repeat testing following positive results (also referred to as a “test for cure”) (American Society of Microbiology [ASM], 2010; Dubberke et al., 2014; McDonald et al., 2018).

Inappropriate CDI testing is frequent with reports ranging between 15-62%. Often the use of laxatives in patients experiencing diarrhea is cited as a leading contributor to inappropriate testing. Other causes include lack of clinically significant diarrhea and repeat testing (Baghdadi et al., 2020; Carter & Malani, 2019; Kara et al., 2019; Kelly et al., 2016). Kara et al (2019) assessed reasons for inappropriate CDI testing among clinicians and found leading causes to include clinician perception of risk in not testing, and patient or nurse report of diarrhea that is not documented in the record.

Organizations are increasingly focused on diagnostic stewardship practices, developed as a collaborative effort among clinicians and laboratory professionals, to aid in the appropriate use of laboratory testing with a goal to optimize clinical outcomes and limit the spread of antimicrobial resistance (Patel & Fang, 2018). CDI testing is one area that may benefit from such initiatives.

Literature Review

A comprehensive review of current literature was conducted to evaluate the impact of CDI testing criteria among hospitalized patients. Several professional practice organizations have published recommendations for CDI testing criteria. Table 1 shows a comparison of recommendations from the CDC, the American Society of Microbiology (ASM), the Infectious Diseases Society of America (IDSA)/Society for Healthcare Epidemiology of America (SHEA), and the Association of Professionals in Infection Control and Epidemiology (APIC).

Table 1

CDI testing criteria recommendations

	IDSA/SHEA	CDC	ASM	APIC
	(McDonald et al., 2017)	(CDC, 2021)	(ASM, 2010)	(Carrico et al., 2013)
COMMENTS ON INDICATIONS FOR TESTING	· Consider testing patients with unexplained and new-onset ≥3 unformed stools in 24 hours · Do not test stool from asymptomatic patients, except for epidemiological studies · Testing is not recommended for neonates or infants ≤12 months of age with diarrhea, due to high prevalence of asymptomatic carriage	· Assess for appropriateness of testing: Consider other infectious or non-infectious causes of diarrhea before testing for CDI	· Testing should be limited to patients with ≥non-formed stool in 24 hours unless ileus suspected · Due to high rates of colonization, testing of neonates should only proceed after consultation with the clinician	· Only test patients experiencing diarrhea unless ileus is suspected · Do not screen asymptomatic patients
COMMENTS ON REPEAT TESTING	· Do not perform repeat testing (within 7 days) during the same episode of diarrhea	· Once a patient has a positive CDI test do not repeat testing to detect cure; tests may remain positive for ≥6 weeks	· Repeat testing following positive (test of cure) is not recommended · Repeat testing of negative test in not recommended[a]	· Do not perform "test of cure" · Routine use of repeat testing after negative result is discouraged
OTHER		· Discontinue laxatives and wait for at least 48 hours before testing if still symptomatic		

[a]ASM 2019 publication does not recommend for or against repeat testing after negative NAAT (Kraft et al, 2019)

Most studies reported utilizing some combination of these recommendations. A systematic review by Dunn et al. (2020) found implementation of evidence-based testing

guidelines to be effective in reducing CDI testing, proportion of inappropriate CDI testing, and rates of CDI, in most studies. Reduction in CDI tests varied based on intervention type, from a modest reduction of 14% (Cook et al., 2020) to larger decreases up to 64% (Quan et al., 2018). Many studies also reported reduction in hospital onset-*C. difficile* infection (HO-CDI) rates and decreases in National Healthcare Safety Network (NHSN) CDI Standardized Infection Ratio (SIR) (Block et al., 2018; Cook et al., 2020; Fleming et al., 2019; Kang et al., 2020; Khuvis et al., 2022; Quan et al., 2018).

When integrating CDI testing clinical decision support criteria into the EHR, organizations may choose to utilize a hard stop or soft stop. Powers et al. (2018) defined hard-stop alerts as "those in which the user is either prevented from taking an action altogether or allowed to proceed only with the external override of a third party" and soft-stop alerts as "those in which the user is allowed to proceed against the recommendations presented in the alert as long as an active acknowledgement reason is entered" (p. 1556). A multicenter study comparing use of hard stops versus soft stops found that both interventions were effective in reducing CDI testing rates (33% vs 23%, respectively). However, there was a statistically significant difference when the two intervention types were compared with hard stop interventions showing the greatest impact (Rock, et al., 2021). This difference in effectiveness could be attributed to the fact that providers have been found to frequently override "soft stop" CDI testing interventions (Friedland et al., 2018; Karlovich et al., 2022; Mizusawa, et al., 2019). Table 2 summarizes various EHR embedded CDI testing algorithms and the reported outcomes of "soft stop" versus "hard stop" interventions.

Table 2

CDI EHR interventions and outcomes

	STUDY	INTERVENTION	OUTCOME
HARD STOP	Kwon et al., 2019	EHR ordering restriction preventing repeat CDI test <96 hours from negative result and <10 days from positive result	Statistically significant reduction in pre-intervention testing rates (9.12 per 100 admissions) compared to post-intervention testing rates (6.94 per 100 admissions) (p <.01)
	Liu et al., 2020	EHR ordering restriction preventing repeat CDI test in patients with laxative use ≤ 48 hours, negative CDI test within 7 days, or positive CDI test within 14 days.	Statistically significant decline in CDI tests ordered (~28%).
	Mizusawa et al., 2019	EHR ordering restrictions in patients with laxative use ≤48 hours, negative CDI test within 7 days, or positive CDI test within 14 days.	Statistically significant reduction in weekly CDI tests per 1000 inpatient days at all facilities (24-37%) (p<.001).
	Quan et al., 2018	EHR CDI test order restrictions for (1) diarrhea (≥3 liquid stool in 24hr), (2) no alternative cause for diarrhea, (3) no laxative in 24 hours, (4) no previous CDI test within 7 days, and (5) age >1 year. Criteria 1-2 require clinician attestation, criteria 3-5 were auto populated.	Statistically significant reduction in pre-intervention testing rates (284 per 10,000 pt days) compared to post-intervention testing rates (268 per 10,000 pt days) (P= .02). Reduced inappropriate testing by 64%, HO-CDI rates by 54%, and average quarterly HO-CDI SIR by 51% (P<.001).
SOFT STOP OR CLINICAL DECISION SUPPORT (CDS)	Cook et al., 2020	EHR embedded best practice advisory recommending against CDI testing in patients receiving at least one laxative or stool softener at the time testing was ordered.	Statistically significant decrease in CDI tests ordered per month (14%, p=.0001). A 16.5% decrease in HO-CDI cases.
	Baghdadi et al., 2020	EHR testing guide discouraging testing in patient without clinically significant diarrhea, laxative use within 24 hours, or receiving tube feedings. Part of multi-intervention project.	Reduction in monthly HO-CDI. Reduction in isolation days.
	Block et al., 2018	EHR embedded CDS to discourage CDI testing in patients who received laxatives within last 48 hours, repeat testing within 12 weeks of a positive test, or repeat testing within 7 days of a negative test. Part of multi-intervention project.	A statistically significant decrease in HO-CDI SIR from pre-intervention1.2 to post-intervention 0.87(p=.011). Decrease in HO-CDI rate.
	Fleming et al., 2019	EHR embedded CDS matrix to confirm clinically significant diarrhea, no laxative use within 24 hours, and CDI symptoms or risk factors, prior to CDI testing.	A statistically significant reduction in total CDI tests (27%) (p<.0001). Statistically significant reduction in HO-CDI event incident rate (p <.03) and reduction in SIR to <1.
	Friedland et al., 2018	EHR alerts based on diarrhea documentation, laxative use, prior CDI testing	Statistically significant decrease in inappropriate CDI testing (53% post-intervention vs 40% pre-intervention; p=0.004).
	Khuvis et al., 2022	EHR CDI order with integrated CDS algorithm discouraging testing in patients <2yrs age, had positive test in last 30 days, negative test in last 7 days, absence of >3 loose stools in 24 hours or laxatives within 48 hours.	A statistically significant reduction in the rate of CDI orders (33%; p<.0001). Reduction in HO-CDI (57%; p=.003) and reduction in SIR to 0.368.
	Sperling et al., 2019	EHR CDI order with integrated CDS to assess for ≥3 loose stool in 24 hours, no laxative use within 24 hours or patient receiving tube feeding without other signs/symptoms of CDI.	A 42% reduction in CDI test rate (test per 10,000 pt-days) and 59% reduction in HO-CDI rate.

	White et al., 2017	EHR based order-set discouraging CDI testing in patients who had received laxatives within last 36 hours.	Decrease in proportion of inappropriate CDI testing (p=.02) and increase in discontinuation of laxative use.
MIXED	Kang et al., 2020	Multi-intervention CDI testing criteria. Intervention 1 included clinical decision support indicating laxative administration within 24 hours, CDI test results within past 7 days and frequency/quality of stool documented in last 24hr. Intervention 2 included nurse education on criteria for stool frequency/quality. Interventions 3 included EHR automated ordering restriction for GI panel >2 days past admission, CDI pCr after laxative use within 24hr, and repeat CDI testing within 7 days.	Statistically significant reduction in baseline testing mean rate (15.9 per 1,000 pt days) compared to post-interventions testing mean rate (8.1 per 1,000 pt days) (p<0.001). Statistically significant reduction in HO-CDI rate (p=.003) and decrease in SIR to <1.
	Karlovich et al., 2022	Multi-intervention CDI testing criteria. 1)CDI testing alert to the ordering provider if patient had received laxative within 24 hours. 2) Automatic cancellation of CDI test orders that did not have a specimen collected within 24 hours. 3) EHR embedded CDI test screening questions for patients hospitalized > 3 days requiring justification if patient did not have clinically significant diarrhea based on documentation or had received laxative within 24 hours and had an abnormal white count (orders could be canceled by laboratory personnel if not justified by provider).	Decrease in CDI tests rate from 12.8 test per 1,000 pt days in pre intervention period to 7.5 test per 1,000pt days in post-intervention period (P<.01)

Some studies reported initially implementing a paper CDI testing form then transitioned to EHR embedded criteria (Sperling et al., 2019). Lenz et al (2021) described the use of a nurse driven paper testing checklist which reduced CDI tests by 31% and CDI rates by 56%. For organizations where EHR integrated builds may not be an option, a paper checklist could be an effective alternative.

Use of CDI testing algorithms have also been described in high-risk populations including hospitalized patients with hematopoietic stem cell transplant (HSCT) and solid organ transplant (SOT). Nix et al. (2021) implemented several criteria including requiring ≥ 3 stools in 24 hours, documented signs and symptoms of CDI, no laxative use in 72 hours, and no positive test within 14 days. Outcomes included a 63% reduction in CDI tests and >50% reduction in CDI events. This study was also the only study to report impact on oral vancomycin days of therapy

(>50% reduction) and reduction in VRE colonization and infection. Madden and Sifri (2019) also reported statistically significant reduction in CDI testing among solid organ transplant patients (33% decrease, $p<0.001$). The testing criteria included two elements: (1) alert when duplicate order requested within 28 days; and (2) provider attestation that patient had ≥3 stools in 24 hours plus signs/symptoms of CDI or risk factors. The criteria were intended to function as clinical decision support and were not built as a "hard stop" meaning orders could be completed even if testing criteria was not met. Neither study reported any adverse events within the population related to implementation of the testing criteria. Overall, studies that reported on safety found EHR embedded CDI testing criteria to be safe and with no attributed adverse safety events (Liu, et al., 2020; Madden, Enfield, & Sifri, 2019; Mizusawa et al. 2019).

In addition to reducing inappropriate CDI tests, and *C. difficile* infections several studies reported an associated cost savings. Kang et al. (2020) reported an estimated quarterly cost savings of over $8,000 in laboratory testing costs after implementation of evidence-based CDI testing criteria. A cost analysis performed by Madden et al. (2019) showed an estimated annual cost savings of over $44,000 associated with reduced testing costs and unnecessary CDI treatment. The average retail cost of a single course of oral antibiotic therapy for CDI ranges from $788 –$4,977 depending on the type of oral therapy utilized (GoodRx.com, n.d.). The cost of an individual CDI test has been estimated around $32 (Madden, et al, 2019; Yen et al., 2018).

Additional benefits described in the literature include reducing isolation days and reducing waste from use of isolation PPE materials (Baghdadi, et al., 2020). Potential challenges with implementing electronic health record-based CDI testing criteria include potential alert fatigue, time and cost of development and implementation, and obtaining provider buy-in (Khoury et al., 2018).

Rationale

The rationale to implement an EHR embedded CDI testing algorithm was based on several factors, including high incident of infection and inappropriate CDI testing. The healthcare facility's Healthcare Associated Infection (HAI) Workgroup first met in February 2017 with a goal to identify opportunities to reduce institutional HAIs, and develop and implement action plans to reduce rates. The facility rate of hospital onset *C. difficile* infection (HO-CDI) was reported as being worse than the national benchmark on both Medicare.gov Hospital Compare and by the Leapfrog Group. The CDC National Healthcare Safety Network (NHSN) standardized infection ration (SIR) was reported at 1.505, indicating >50% more incidents of HO-CDI cases than expected based on a risk adjusted national benchmark for like hospitals.

Hospital onset CDI cases, occurring in a 3-month period, were reviewed and findings were shared with the workgroup. Significant findings included 10 out of 14 (71%) HO-CDI cases were among patients who had received laxatives within 3 days of CDI testing. Two out of 14 (14%) HO-CDI cases had CDI tests ordered but were not collected for several days due to the patient not having active diarrhea. The case reviews did not include assessment of repeat testing after negative test during the same episode of diarrhea nor repeat testing following a positive result. However, the Microbiology Manager reported these concerns as subjective findings within the department.

Purpose

The purpose of this project was to evaluate the effectiveness of an evidence-based electronic health record (EHR) embedded *C. difficile* infection (CDI) testing algorithm in

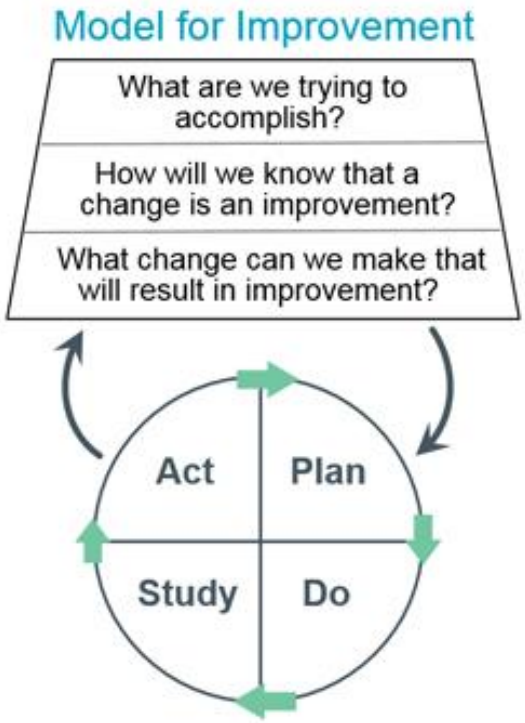
reducing inappropriate CDI testing. The primary aim of this project was to evaluate the impact of the EHR integrated CDI testing algorithm on the number of CDI tests performed and the CDI test rate (CDI test per 1,000 patient days) at baseline and post-intervention. Secondary aim was to evaluate the impact of the EHR integrated CDI testing algorithm on HO-CDI rate (CDI cases per 10,000 patient days) and NHSN *C. difficile* SIR at baseline and post-intervention.

Quality Improvement Model

The Institute for Healthcare Improvement (IHI) promotes the use of the Model for Improvement which is a framework to guide improvement work and accelerate change (Institute for Healthcare Improvement [IHI], 2016). As shown in Figure 1, this model includes two parts; (1) three fundamental questions used to set aims, establish measures, and select changes, and (2) the Plan-Do-Study-Act (PDSA) cycle (IHI, 2016). This framework was selected for this quality improvement project because of the model design, which facilitates rapid cycle change. The model supports implementation of the intervention on a small scale (single unit), refining the intervention, and then expanding implementation to a larger scale (built into the EHR and applied facility wide), followed by outcome evaluation (IHI, 2016).

Figure 1

IHI Model for Improvement



(Langley et al., 2009) Permission to use from Jossey-Bass Publishers.

Methods

Design

This quality improvement (QI) project includes a retrospective review of outcomes data to assess the effectiveness of the intervention. This project meets criteria for quality improvement because it intends to reduce variations in care, specifically through implementation of standardized testing criteria for patients within the facility. By implementing the testing criteria into the EHR it also serves to streamline workflow and improve efficiency. These are all characteristics of a QI project (Ginex, 2017). This project was submitted to the University of

Louisville IRB (#22.1037) and deemed Non-Human Subjects Research (NHSR). Project approval was also obtained from the facility's Interdisciplinary Research and Evidence Based Practice Council.

Setting and Population

The project was implemented in an academic medical center located in downtown Louisville, Kentucky. The facility is licensed for 404-beds and provides services as the regional level 1 trauma center, an accredited stroke center, and cancer center. This healthcare facility provides care to several special populations including burn care, hematopoietic stem cell transplants, high risk obstetrics, and level III neonatal intensive care. The population for this project includes all facility ordering providers, including physicians, advanced practice nurses, and physician assistants, who are credentialed within the organization and the patients whom they may order CDI laboratory testing on while in the emergency department and/or inpatient locations. Excluded are the neonatal intensive care unit, nursery, and ambulatory settings due to use of different EHR systems.

Laboratory Methods

The Microbiology Department only tests liquid stools which are noted to form to the collection container. A multiple step testing algorithm is utilized. Only the final interpretive result is reported to the clinician and published in the electronic health record. Initial stool testing involves both a glutamate dehydrogenase (GDH) antigen assay and toxin A/B test, as part of a first step. If both results are consistent as positive or negative, then results are reported as such. If there is a discrepancy between these results, then a Polymerase chain reaction (PCR) test is

completed. This testing methodology was implemented prior to the baseline time period and remained unchanged throughout the study.

Intervention

A multidisciplinary group, which included stakeholders from Infection Prevention and Control department, Microbiology department, nursing informatics, quality and safety, and nursing leadership, assembled in 2017 with a goal of reducing hospital-onset CDI rates. After reviewing recent HO-CDI cases, it was determined that one opportunity for improvement was regarding the establishment of evidence-based testing criteria which could help standardize care and reduce variation. A CDI testing algorithm was developed based on published clinical practice guidelines. In June 2017, this algorithm was first implemented as a paper checklist, which was completed by nursing staff prior to submitting stool for CDI testing (appendix A). Initial implementation began on a single Intensive Care Unit and with additional inpatient locations incorporated over several months. The paper checklist was shown to be effective, however it was cumbersome for staff. Approval was received from leadership to develop the EHR embedded CDI testing criteria, based on the paper checklist. Successful implementation was achieved in July 2019. The CDI checklist was integrated into the electronic health record (EHR) as several automated ordering rules and applied to all patient care locations in the facility which used the EHR system, which included all adult inpatient location, the emergency department, and surgical services locations.

There were three order rules implemented into the EHR; (1) Order stopped if negative *C. difficile* result in past 7 days, (2) Order stopped if positive *C. difficile* result in past 28 days, and (3) Order stopped if patient has received a laxative within 48 hours. These rules were developed as "hard stops" which clinicians could not bypass. A "C diff alert" message appears notifying the

ordering provider of the reason for the order restriction (Appendix B). Any testing exceptions required approval from an Infectious Diseases provider.

Ordering providers and nursing staff were educated prior to implementation using various methods of communication including email, posted information flyers, and in-person via attendance at key stakeholder meetings. The intervention received prior approval from the Diagnostic Stewardship Committee, Infection Prevention and Control Committee, Subcommittee for Antimicrobial Stewardship, and Medical Executive Committee.

Since implementation of the evidence-based EHR embedded CDI testing algorithm in 2019, a comprehensive evaluation of the intervention's effectiveness had not been performed. Thus, this project served to determine intervention effectiveness through collection and analysis of outcomes data. The baseline period is defined as January 1, 2016 through December 31, 2016. Post-intervention period is defined as January 1, 2020 through December 31, 2020. The period between July 2017 and July 2019 is defined as the intervention period during which multiple PDSA cycles of the intervention took place until final project intervention was achieved. A retrospective review of data was performed to determine intervention effectiveness.

Table 3

Gantt Chart for Project Implementation

Objective	2017-2019	2022 Q4	2023 Q1	2023 Q2
Development and implement of EHR embedded CDI testing algorithm				
Obtain project buy-in and approval from stakeholders				
Collaborate with Infection Prevention & Control personnel to obtain baseline (2016) and post-intervention (2020) outcomes data including: • CDI tests performed • CDI test rate (test per 1,000 patient days)				

• HO-CDI rate • CDI SIR				
Analyze outcomes data				
Present data to project stakeholders and assess intervention effectiveness.				
Implement changes if indicated (outside scope of this project)				

There were no direct expenses for this project. Indirect expenses may include time and labor cost associated with data collection and analysis. There were no direct revenues associated with this project. The organization may benefit from cost savings in laboratory testing costs and laboratory technician time, attributed to the original intervention of a EHR embedded CDI testing algorithm.

Measures

The measures collected as part of this project include CDI tests, CDI testing rate (CDI tests per 1,000 patient days), HO-CDI rate (HO-CDI cases per 10,000 patient days) and NHSN CDI SIR.

CDI tests is defined as the number of monthly CDI test results reported by the microbiology department. Because the microbiology department utilizes a multi-test algorithm, only the final interpreted result of the testing algorithm is used and counted as one test. Data were retrieved from TheraDoc® CDI results report, selecting both *positive* results and *negative* results and reported as a monthly value for the time periods of 1/1/2016-12/31/2016 (baseline) and 1/1/2020-12/31/2020 (post-intervention). The report was obtained from the Infection Prevention & Control (IP&C) Department.

TheraDoc ® clinical surveillance system is an electronic database that interfaces with the facility's electronic health record. Laboratory tests, demographic data, pharmacology data and other elements of the health record cross into the database allowing for data aggregation, system alerts and surveillance work (Priemer, Inc., 2022)

CDI test rate is defined as the number of monthly CDI tests (see definition above) per 1,000 patient days. Data were collected as a monthly value for the time periods of 1/1/2016-12/31/2016 (baseline) and 1/1/2020-12/31/2020 (post-intervention). Both CDI tests and patient days were obtained from the IP&C Department.

HO-CDI rate is defined as the number of healthcare-onset (HO) *C. difficile* infections (CDI) per 10,000 patient days. HO-CDI definition is based on NHSN *Clostridioides difficile* (*C. difficile*) LabID Event surveillance definitions from the Multidrug-Resistant Organism & *Clostridioides difficile Infection* (NHSN MDRO & CDI) Module. Positive CDI tests are reviewed by the IP&C Department and determined to meet or not meet criteria based on the NHSN CDI definition. The IP&C department obtained data on patient days and produced a monthly CDI rate based on this information. Data were collected as monthly values for the time periods of 1/1/2016-12/31/2016 (baseline) and 1/1/2020-12/31/2020 (post-intervention). Data were obtained from the IP&C Department.

NHSN CDI SIR is defined by the CDC's NHSN MDRO & CDI Module (2022), which states "the standardized infection ratio (SIR) is calculated by dividing the number of observed events by the number of predicted events. The number of predicted events is calculated using probabilities estimated from negative binomial models constructed from 2015 NHSN data, which represents the baseline population." (p.32). HO-CDI cases and patient days are reported into NHSN by the IP&C Department. Data were retrieved from the CDC NHSN database from the

report titled “CDI LabID Event SIR”. Data were retrieved as an annual value for the time periods of 1/1/2016-12/31/2016 (baseline) and 1/1/2020-12/31/2020 (post-intervention). Data were obtained from the IP&C Department.

Measures collected were for the purpose of determining impact of the EHR embedded CDI testing algorithm which was implemented for the purpose of reducing inappropriate CDI testing. Inappropriate CDI testing is defined as repeat testing after a negative result during the same episode of diarrhea, repeat testing after a positive result (“test for cure”) during the same episode of diarrhea or testing when a patient has received a laxative <48hours.

Project outcomes include intervention impact on CDI test volumes, CDI testing rate, HO-CDI rate, and NHSN CDI SIR, when comparing baseline and post-intervention values. Intervention effectiveness is evaluated based on these outcome measures.

Data Analysis

Descriptive statistics are utilized to express monthly CDI tests performed and monthly CDI test rate. Percent change in baseline and post-intervention outcome values was performed. A proportion Z-test was utilized to assess for statistical significance of baseline and post-intervention CDI testing values. Statistical analysis was completed using Epi-Tools (Sergeant, ESG, 2018. Ausvet Pty Ltd, http://epitools.ausvet.com.au).

Results

The number of CDI tests, CDI testing rate, HO-CDI rate, and NHSN HO-CDI SIR outcome data from the period of 1/1/2016-12/31/2016 (baseline) and 1/1/2020-12/31/2020 (post-intervention) were evaluated. There were 1,191 CDI tests performed during the baseline period compared to 617 in the post-intervention period. This represented a decrease of 574 tests (1,191-

617). The rate of CDI test completed (CDI tests per 1, 000 patient days) was 13.87 and 5.39 at baseline and post-intervention period, respectively. This represented a statistically significant decrease of 61.1% (z= -19.90, p<.001). Hospital-onset CDI rates were 8.73 cases per 10,000 patient days at baseline and 3.75 cases per 10,000 patient days in the post-intervention period. This represents a statistically significant decrease of 57% (z = -17.64, p<.001). The NHSN CDI SIR was 1.349 at baseline. Post-intervention CDI SIR rate was 0.652, a statistically significant decrease by 51.7% (z = -37.58, p<.001) (Table 4).

Table 4

Percentage change of CDI test rates, HO-CDI rates, and SIR along with proportion z-tests

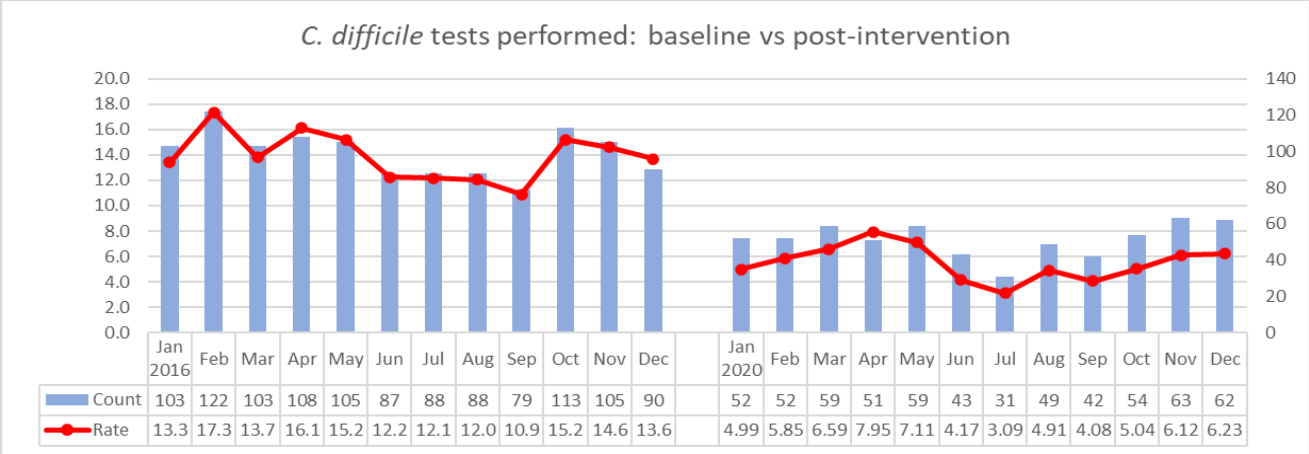
	Baseline (2016)	Post-intervention (2020)	% change	Proportion z-test	95% CI
Rate of CDI tests	13.87	5.39	-61.1	19.90***	[0.0495, 0.0583]
HO-CDI rate	8.73	3.75	-57.0	17.64***	[0.0338, 0.0412]
SIR	1.349	0.652	-51.7	-37.58***	[0.0049, 0.0081]

*Note: *** statistical significance at p<.001*

Monthly count and rates for *C. difficile* tests performed for both baseline and post-intervention periods are reports in Figure 2.

Figure 2

CDI tests performed by month



Of note, there was a significant increase in patient days between baseline and post-intervention periods, 85,865 and 114,547 respectively. This is attributed to a net increase of 20 inpatient beds after renovation and addition of a new burn unit and inpatient psychiatric unit during the intervention period.

Discussion

Clostridioides difficile infection is a common healthcare associated infection, affecting over half a million US patients a year (CDC, 2019). However, colonization is more common than infection. Implementation of evidence-based testing criteria serves to reduce false positives that can occur from inappropriate testing. Evidence-based guidelines from multiple professional practice organizations were utilized to develop the CDI ordering rules and support safe and effective process change. During the intervention period, multiple PDSA cycles occurred as the algorithm was first trialed on a single unit, as a paper order form, and then ultimately built into the EHR and applied facility wide. Successful implementation required teamwork from Infection Prevention & Control, Microbiology, Nursing Informatics and ordering providers. Information

Technology Analysts played an important role in assisting in EHR build and validation. Once the final CDI testing algorithm was fully implemented and functioning as intended, outcomes data could be evaluated for intervention effectiveness. A significant reduction was achieved in both the number of CDI tests performed (48% decrease) and CDI testing rate (61% decrease). Because of the increase in patient days seen between the baseline and post-intervention period, the CDI testing rate may be the best reflection of the impact of the testing algorithm. Published studies reported a wide range of outcomes. Our findings of a 61% reduction in CDI testing rate are greater than most, though there was no standard approach to reporting outcomes seen in the literature, making it more difficult to compare studies. The choice to utilize "hard stop" ordering rules instead of "soft stop," which could be overridden by the ordering provider, or a clinical decision support model, likely is the reason we were able to achieve such a large reduction in CDI tests and testing rates. This finding supports other studies which found greater impacts when hard stop interventions were utilized (Rock, et al., 2021).

The present QI project showed a significant reduction in reported hospital-onset *C. difficile* infection rates and the CDI SIR. Many of the published studies also reported significant reductions in these measures. In this project, a greater than 50% reduction in HO-CDI rates and SIR was achieved. Reduction in CDI cases could be attributed to reducing false positive tests (positives related to colonization and not infection) Thus, utilization of a CDI testing algorithm may be effective in not just reducing testing volumes, but also infection rates.

Additional benefits to achieving a reduction of CDI tests through implementation of the EHR embedded CDI testing algorithm may include some cost savings. Based on an average CDI test cost of $32, as estimated by Madden et al. (2019) and Yen et al. (2018), implementation of the CDI algorithm and the resulting reduction in tests performed has an estimated annual costs

savings of $18,000 due to cost avoidance of unnecessary CDI testing. Additional cost savings may be achieved when inappropriate CDI tests are reduced and thus misdiagnosis of *C. difficile* infection is also reduced; this includes cost avoidance of unnecessary CDI pharmaceutical treatments and PPE utilized when patients are placed in isolation precautions.

Limitation

Implementation of the EHR embedded CDI testing algorithm was part of a multi-intervention effort to reduce *C. difficile* infection rates. The reduction of CDI rates and SIR values cannot be solely attributed to the EHR algorithm implementation alone. Additional interventions included ordering provider and nursing education on *C. difficile* isolation, use of personal protective equipment, and hand washing, implementation of UV light disinfection as an adjunct to the already established terminal cleaning protocol of all *C. difficile* isolation rooms, and education regarding stool collection and rejection of non-liquid specimens for both nursing and microbiology staff.

The post-intervention period occurred in 2020 during the beginning of the COVID-19 global pandemic. Several inpatient units were converted to COVID-19 dedicated units during this time and there was likely a higher prevalence of inpatients with viral respiratory infection in the post-intervention population. Admitting diagnosis and conditions were not evaluated as part of this project to determine if baseline and post-intervention patient populations where significantly different.

The healthcare system has an established method for passive reporting of safety events however, as part of this project, formal review of safety event reporting to evaluate for adverse events related to algorithm implementation was not performed.

Conclusion

In this project, implementation of an evidence-based electronic health record (EHR) integrated *C. difficile* infection (CDI) testing algorithm was an effective way to reduce the number of inappropriate *C. difficile* tests performed and testing rates. Successful implementation is possible when Infection Prevention & Control, Microbiology, and Nursing Informatics collaborate and buy-in is obtained from ordering providers. Leveraging the EHR as a tool to implement testing rules can be an efficient method to progress diagnostic stewardship goals and guide evidence-based care. In addition to reducing CDI tests, secondary benefits may include reduction in HO-CDI rates and CDI SIR., as well as, cost avoidance in CDI testing cost and unnecessary CDI pharmaceutical treatments and PPE use.

Healthcare systems should consider utilizing a “hard stop” EHR embedded testing algorithm over “soft stop” or clinical decision support, to achieve the greatest reduction in both the number of CDI tests performed and the CDI test rate. If a “hard stop” algorithm is utilized, it may be prudent to include a process allowing for CDI testing rule bypass in unique patient situations. Organizations should monitor potential safety events, algorithm effectiveness, and be prepared to update EHR integrated algorithm builds when new evidence-based guidance is introduced.

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Appendix A

Paper *C. difficile* Testing Checklist

Patient label

Clostridium difficile Testing Checklist

(Answer the questions below to determine if *C.difficile* testing is indicated.)

Does patient have ≥3 loose/liquid bowel movements a day?

☐ Yes ☐ No→ *C.difficile* testing is NOT recommended.

Has patient received laxative, bowel prep, and/or enema within the past 48 hours?

☐ No ☐ Yes→ *C.difficile* testing is NOT recommended. Hold laxative, bowel prep and/or enema for minimum of 48hrs and assess for resolution of diarrhea prior to *C.difficile* testing.

Does stool conform to the shape of the container (liquid)?

☐ Yes ☐ No→ Do not send specimen, lab will reject.

Has patient had a negative *C.difficile* stool sample in the past seven (7) days?

☐ No ☐ Yes→ Do not send specimen, lab will reject. Look for other cause of diarrhea.

Has patient had a positive *C.difficile* stool sample in the past 30 days?

☐ No ☐ Yes→ Do not send specimen, lab will reject. Do not test for cure.

Action taken:

- ☐ *C.difficile* testing indicated and sample sent (send checklist with specimen to lab)
- ☐ *C.difficile* testing NOT indicated, prescriber notified and test order canceled (fax checklist to x6807)
- ☐ Other_____

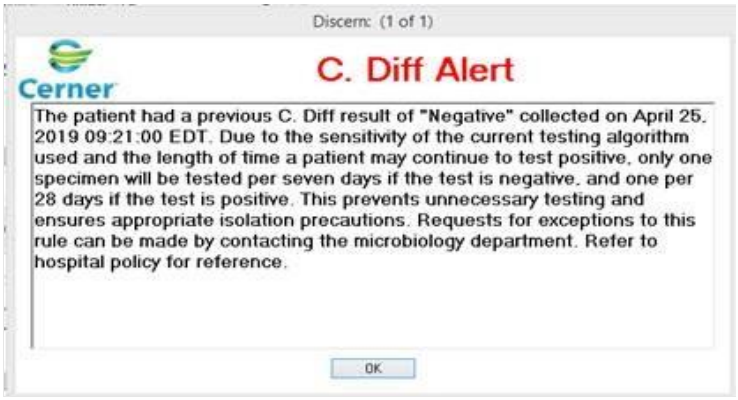
Comments:_____

Not part of the patient's medical record. Contact Infection Prevention & Control with questions (x3794).

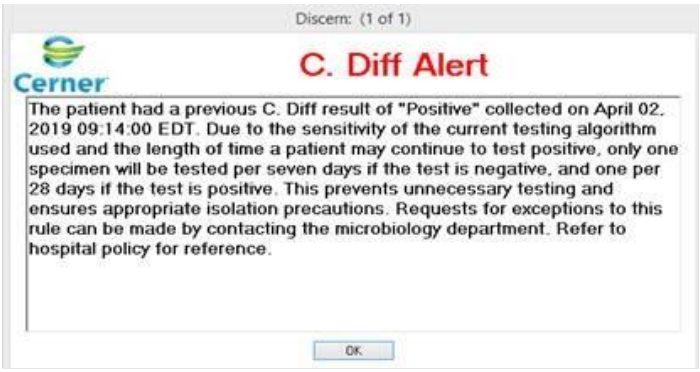
Appendix B

EHR CDI Testing Alerts

1. Order stopped if <u>negative</u> *C. difficile* result in past 7 days



2. Order stopped if <u>positive</u> *C. difficile* result in past 28 days



3. Order stopped if patient has received a laxative within 48hour