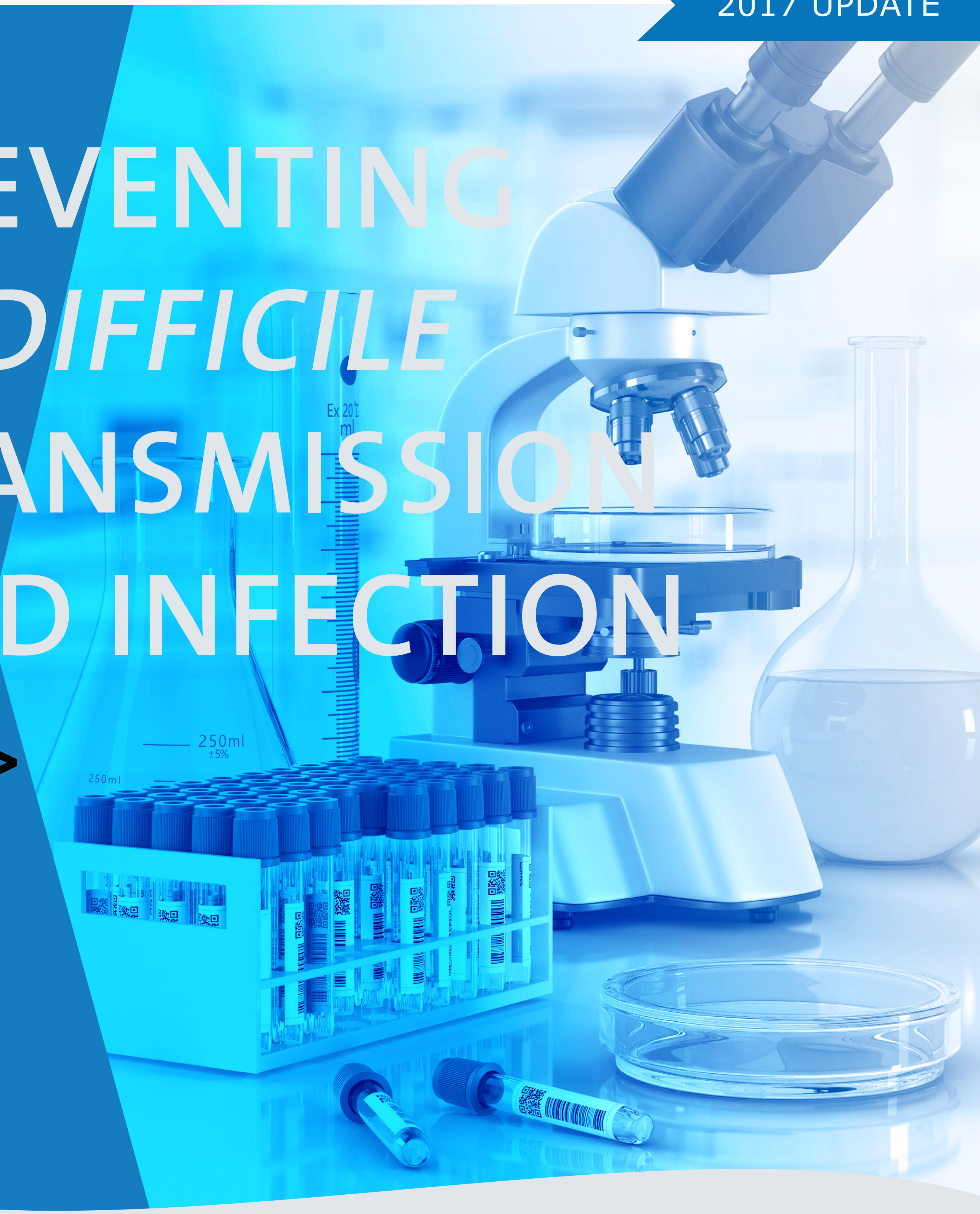
HRET
HEALTH RESEARCH & EDUCATIONAL TRUST

2017 UPDATE

PREVENTING *C. DIFFICILE* TRANSMISSION AND INFECTION



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CLOSTRIDIUM DIFFICILE INFECTION *CHANGE PACKAGE*

ACKNOWLEDGEMENTS

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How to Use this Change Package

This change package is intended for hospitals participating in the Hospital Improvement Innovation Network (HIIN) project led by the Centers for Medicare & Medicaid Services (CMS) and Partnership for Patients (PFP); it is meant to be a tool to help you make patient care safer and improve care transitions. This change package is a summary of themes from the successful practices of high performing health organizations across the country. It was developed through clinical practice sharing, organization site visits and subject matter expert contributions. This change package includes a menu of strategies, change concepts and specific actionable items that any hospital can implement based on need or for purposes of improving patient quality of life and care. This change package is intended to be complementary to literature reviews and other evidence-based tools and resources.

PART 1: AEA DEFINITION AND SCOPE

CURRENT DEFINITION OF THE PROBLEM: *Clostridium difficile (C. difficile)* is an anaerobic, spore-forming bacteria spread through fecal-oral transmission.[1] A *C. difficile* infection (CDI) colonizes the large intestine and releases two toxins that can cause a number of illnesses including diarrhea, colitis and sepsis. Nonetheless, colonized patients do not always present symptoms. CDI transmission in hospitals occurs primarily from contaminated environments and through the hands of health care personnel.[2,3] CDI spores are resistant to the bactericidal effects of alcohol and the most commonly used hospital disinfectants. Antimicrobial therapy is the most important risk factor for CDI infection; the antibiotics destroy normal gut flora, allowing for the overgrowth of CDI. While all patients taking antibiotics are at risk of CDI, longer courses of antibiotic therapy and multiple courses of antimicrobials increase CDI risk.

Magnitude of the Problem and Why this Matters

CDI is the most frequently reported health care-associated infection.[1] A 2011 Centers for Disease Control and Prevention (CDC) surveillance study found that CDI caused almost half of a million infections and directly led to approximately 15,000 deaths in one year.[4] A majority of these deaths occur in Americans aged 65 or older. Additional health care costs related to CDI are estimated at $4.8 billion for acute care facilities alone.[5] Cases commonly appear in outbreaks and clusters in health care facilities.[6] However, the CDC study estimates that only one-quarter of CDIs occur in hospitals, with other cases occurring in nursing homes and community settings.[7] As a result, CDI prevention efforts should focus on community- and facility-based antimicrobial stewardship and preventing disease transmission.

PART 2: MEASUREMENT

A key component to making patient care safer in your hospital is to track your progress toward improvement. This section outlines the nationally recognized process and outcome measures for which you will be collecting and submitting data for the HRET HIIN. Collecting these monthly data points at your hospital will guide your quality improvement efforts as part of the Plan-Do-Study-Act (PDSA) process. Tracking data in this manner will provide valuable information to study the data across time, and determine the effectiveness of your hospital's improvement strategies in reducing patient incidents. Furthermore, collecting these standardized metrics will allow the HRET HIIN to aggregate, analyze and report its progress toward reaching the project's 20/12 goals across all AEAs.

Nationally Recognized Measures: Process and Outcome

Please download and reference the encyclopedia of measures (EOM) on the HRET HIIN website for additional measure specifications and for any updates after publication at: http://www.hret-hiin.org/data/hiin_eom_core_eval_and_add_req_topics.pdf

> HIIN Evaluation Measure

- Standardized infection ratio (SIR) for patients with CDI (NQF 1717) — NHSN submitting facilities only
- Facility-wide CDI rate

PART 3: APPROACHING YOUR AEA

> Suggested Bundles and Toolkits:

- The Centers for Disease Control issued a checklist to aid in assessing the core elements of an antimicrobial stewardship program. This tool is available at: http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html
- Rationale for Hand Hygiene Recommendations after Caring for a Patient with *Clostridium difficile* Infection, retrieved at: https://www.shea-online.org/images/patients/CDI-hand-hygiene-Update.pdf
- Strategies to Prevent *Clostridium difficile* Infections in Acute Care Hospitals: 2014 Update, retrieved at http://www.jstor.org/stable/10.1086/676023#full_text_tab_contents
- The Hand Hygiene Audit Tool, retrieved at: http://www.cdc.gov/dialysis/PDFs/collaborative/Hemodialysis-Hand-Hygiene-Observations.pdf
- Health Research & Educational Trust (HRET) Hospital Improvement Innovation Network. 2016 UP Campaign Set Up Tool. Retrieved at http://www.hret-hiin.org/Resources/up_campaign/17/up_campaign_setup_tool.pdf
- For key tools and resources related to preventing and reducing CDI, visit www.hret-hiin.org

Investigate Your Problem and Implement Best Practices

DRIVER DIAGRAMS: A driver diagram visually demonstrates the causal relationship between your change ideas, secondary drivers, primary drivers and your overall aim. A description of each of these components is outlined in the table below. This change package reviews the components of the driver diagram to help you and your care team identify potential change ideas to implement at your facility and to show how this quality improvement tool can be used by your team to tackle new process problems.

AIM			
	PRIMARY DRIVER	SECONDARY DRIVER	**Change Idea**
		SECONDARY DRIVER	**Change Idea**
	PRIMARY DRIVER	SECONDARY DRIVER	**Change Idea**

AIM: *A clearly articulated goal or objective describing the desired outcome. It should be specific, measurable and time-bound.*

PRIMARY DRIVER: *System components or factors that contribute directly to achieving the aim.*

SECONDARY DRIVER: *Action, interventions or lower-level components necessary to achieve the primary driver.*

CHANGE IDEAS: *Specific change ideas which will support or achieve the secondary driver.*

Drivers in This Change Package

PREVENT CDI			
	ANTIMICROBIAL STEWARDSHIP	ANALYZE ANTIMICROBIAL USE AND DETERMINE THE APPROPRIATENESS OF THE SELECTED TREATMENT	**Change Idea**
		LIMIT ANTIMICROBIAL USE THROUGH PRE-AUTHORIZATION AND FORMULARY CONTROLS	**Change Idea**
	RAPID IDENTIFICATION AND DIAGNOSIS	RULE OUT CDI IN PATIENTS WITH DIARRHEA	**Change Idea**
	PREVENT CDI TRANSMISSION	ESTABLISH GUIDELINES FOR USING CONTACT PRECAUTIONS	**Change Idea**
		ESTABLISH, MAINTAIN AND MONITOR AN EFFECTIVE HAND HYGIENE PROGRAM	**Change Idea**
		ENVIRONMENTAL CONTROLS	**Change Idea**
		MONITOR ENVIRONMENTAL CLEANING	**Change Idea**

Primary Driver:

ANTIMICROBIAL STEWARDSHIP

Antimicrobial stewardship is a program that promotes appropriate selection, dose, route and duration of antimicrobial therapy.[8] The primary goal is to optimize clinical outcomes while reducing unintended consequences of antimicrobial use such as toxicity, colonization of pathogenic organisms and antibiotic resistance. A secondary goal of antimicrobial stewardship is to reduce the health care costs associated with diseases such as CDI and antimicrobial resistance. Comprehensive programs in large academic medical centers and smaller community hospitals have consistently demonstrated reductions in antimicrobial use that ranged from 22 percent to 36 percent with annual savings of $200,000 to $900,000.[8] Effective antimicrobial stewardship programs can be financially self-supporting, improve patient care and save lives.

Secondary Driver > ANALYZE ANTIMICROBIAL USE AND DETERMINE THE APPROPRIATENESS OF THE SELECTED TREATMENT

Studies have shown that as much as 30 percent to 50 percent of all antibiotic use is inappropriate. Inappropriate use includes a longer than necessary duration of therapy, treatment of nonbacterial diseases and treatment of contaminants or colonizers and meaningless duplicate therapy (e.g., treatment with multiple antibiotics targeting anaerobes simultaneously).[9] Additionally, clinical outcomes, including cure and failure rates, have been shown to improve with an antimicrobial stewardship program.[10] Monitoring and analyzing antimicrobial use by disease, unit and practitioner can increase organizational knowledge of opportunities for stewardship.

Change Ideas

> Monitor Healthcare Effectiveness Data and Information Set (HEDIS) performance measures on antibiotic utilization in pharyngitis, upper respiratory infections and acute bronchitis.[11]

> Analyze the data for specific infections (e.g., urinary tract infections) and determine the appropriateness of the selected treatment.

> Evaluate the use of antimicrobials among patients with CDI and provide feedback and recommendations to medical staff and facility leadership regarding treatment options.

> Determine if antimicrobial agents at higher risk of contributing to CDI are de-escalated or discontinued if CDI is suspected.

> Eliminate redundant combination antimicrobial therapy.[8]

> Adopt guidelines for managing community-acquired pneumonia using a shorter course of therapy.[12]

> Educate prescribing clinicians about the appropriate selection and use of antimicrobials, including dose, timing and duration of treatment.

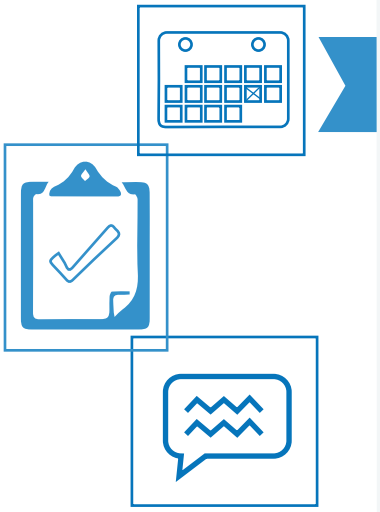
> Engage the clinical microbiology laboratory and infection prevention departments in optimizing surveillance and investigating outbreaks.

> Focus efforts on reducing the use of certain antibiotic classes associated with CDI, such as cephalosporins, clindamycin and fluoroquinolones.[13]

> Optimize antimicrobial dosing based on individual patient characteristics, causative agent, infection site and drug characteristics.

Suggested Process Measures for Your Test of Change

- Number of patients who were prescribed a specific antimicrobial (e.g., a fluoroquinolone) for a specific category of infection (e.g., urinary tract infection).
- Percentage of patients who appropriately received a specific antimicrobial (e.g., a fluoroquinolone) based on best evidence.
- Percent of surgical patients who received an appropriate weight-based antimicrobial preoperative dose.
- Percentage of patients who received an appropriate antibiotic for the specific surgical procedure performed, based on best evidence.



Secondary Driver > LIMIT ANTIMICROBIAL USE THROUGH PRE-AUTHORIZATION AND FORMULARY CONTROLS

Limiting the formulary and requiring pre-authorization for certain antibiotics is a key strategy in reducing unnecessary use of antibiotics. This structure helps prevent unnecessary duplicate coverage as well as misuse, leading to improved microbial resistance patterns.[14]

Change Ideas

> Obtain cultures before starting antibiotics and streamline or de-escalate empirical antimicrobial therapy based upon culture results.

> Enlist a multidisciplinary team to develop standardized order sets incorporating local microbiology and resistance patterns.

> Develop antimicrobial order forms to facilitate implementation of agreed-upon practice guidelines.

> Ensure all orders have clear documentation of dose, duration, and indications for antimicrobial therapy.

> Develop clinical criteria and guidelines to promote and facilitate the conversion from parenteral to oral agents.

> Require an antibiotic timeout, reassessing antibiotic appropriateness and necessity after 48 to 72 hours.

Suggested Process Measures for Your Test of Change

- Percentage of patients who had all relevant cultures obtained before the first dose of antibiotics was administered.
- Percentage of parenteral to oral conversions that followed guidelines.
- Number of pre-authorizations requested and the number denied.
- Percentage of patients who had an antibiotic timeout after 72 hours of therapy.

Hardwire the Process

Using Donabedian's Quality Framework (structure plus process leads to outcome),[15] (1) remove unnecessary antibiotics from the formulary, (2) restrict options for duplicate antibiotics and antibiotics for special circumstances, (3) provide ongoing surveillance of antibiotic use by pharmacy, and (4) escalate to physician leaders as necessary—all of which leads to improved accuracy of antibiotic use. When these strategies are combined with clinician feedback and real-time intervention, care is safer, antimicrobial resistance is reduced, and money is saved.[10,16]

Primary Driver:

RAPID IDENTIFICATION AND DIAGNOSIS

Rapid diagnosis will lead to prompt treatment and implementation of contact precautions that can limit the spread of CDI in the environment of care.[17] The major risk factors for colonic CDI are antibiotic exposure, hospitalization and advanced age. While the most common clinical presentation of CDI is diarrhea, patients with severe CDI may also present with sepsis and abdominal pain in the absence of diarrhea. Diagnoses of CDI will be more accurate if clinicians use higher-sensitivity tests, reduce the frequency of testing for an episode of diarrhea, and pay attention to key risk factors in the patient's history.[18] It is key, however, to recognize that tests with higher sensitivity may over diagnose true CDI in patients with a low pretest probability of having the disease.

An enzyme immunoassay (EIA) test for glutamate dehydrogenase (GDH), an enzyme produced by CDI, is 96 percent to 100 percent sensitive for the presence of the organism. However, this EIA does not test for the CDI toxins and cannot distinguish between nonpathogenic and pathogenic strains of the bacteria. The EIA tests for both toxins A and B to identify pathogenic strains, but these tests are only 70 percent to 80 percent sensitive.[18] Though the toxin tests are relatively inexpensive, their low sensitivity for identifying pathogenic strains reduces their value.

Polymerase chain reaction (PCR) tests have a sensitivity of 90 percent or greater and a specificity of 95 percent or greater.[20] Some facilities use a two-step approach as a method of detection: 1) the stool is first tested for GDH and toxins and 2) indeterminate results then undergo PCR analysis.

DIAGNOSIS OF CDI Test interpretation is related to the patient's clinical condition and the probability that the patient has CDI. CDI is a clinical diagnosis; no test makes the diagnosis of CDI. While sensitivity and specificity are important, the accuracy of any test is best determined by its predictive value. Predictive value is determined by sensitivity, specificity and prevalence of a condition in the population being tested ("pretest probability"). Positive predictive value (PPV) means that the test will be positive when the disease is present. Negative predictive value (NPV) means the test will be negative when the disease is absent. When the chances of finding the disease are low, even the most specific and sensitive tests will have a low PPV. In fact, with a typical inpatient population where approximately 10 percent to 15 percent of patients carry C. difficile, the PPV for PCR is less than 50 percent.[5] This means that more than half of the positives can be false positives. Note that "false positive" in this situation does not mean the presence of C. difficile without disease; it means that the test falsely identified the bacteria as a being a toxin capable of CDI.

EXAMPLES (SEE APPENDIX II) Since the likelihood of CDI (pretest probability) is linked to the clinical situation, a 50-year-old inpatient with loose stools who has not had antibiotics has a much lower likelihood of having CDI than an 80-year-old who has been on antibiotics. In the example shown in Appendix II, the PCR test results for the 50-year-old will have a much lower PPV (a higher false positive rate) than the 80-year-old. If the 50-year-old has had a recent laxative or has just started tube feeding, the PPV is even lower (false positives will likelihood will be higher).

EMERGING APPROACHES As a result, even the PCR tests can over diagnose CDI, as illustrated in Appendix II, and can lead to increased antibiotics, resistance and cost. Cognizant of the need to not underdiagnose CDI, coupled with the desire to not over diagnose CDI (and unnecessarily treat

the patient with antibiotics), some hospitals, like the University of California Davis Medical Center, are performing toxin assays routinely with PCR and have found that virtually all patients with clinically active C. difficile were positive for both.[21]

Secondary Driver > RULE OUT CDI IN PATIENTS WITH DIARRHEA

There are many causes of diarrhea when it develops in a hospitalized patient. Given the significant increase in volume and severity of CDI over the last decade, hospitals appropriately try to quickly identify, treat and isolate CDI cases. The prevalence of CDI colonization in the community is 3 percent to 7 percent. In patients being admitted to the hospital, the colonization rate ranges from 4.4 percent to 15 percent. For patients in skilled nursing facilities, the rate of colonization can be as high as 50 percent.[2] Age, source of admission, history of hospitalization, and recent use of antibiotics all contribute to the likelihood that a particular patient will have CDI.

Studies show that only about 5 percent to 10 percent of patients who acquire diarrhea in the hospital do so because of CDI.[2] Underlying medical conditions, tube feeding, laxatives and medications other than antibiotics are among the many non- CDI causes of diarrhea. Simply stated, more inpatients have diarrhea than have CDI. Given the need for identifying CDI, and the need to not over diagnose CDI, hospitals should optimize practices for rapid and accurate diagnosis, using laboratory tools to aid in clinically determining the presence or absence of CDI.

Change Ideas

> Establish CDI testing criteria for diarrhea (e.g., three or more loose stools per day for at least one to two days)[22] (See Appendix III).

> Assess patients with diarrhea to determine if they have taken laxatives in the prior 24 to 48 hours as a possible explanation of symptoms.

> Establish laboratory criteria for CDI testing (e.g., only liquid or unformed stools that conform to the shape of the container will be tested). Adopt the "if the stool ain't loose, the test is of no use" rule.[22]

> Employ rapid diagnostic testing methods that facilitate prompt CDI diagnosis, isolation and treatment.

> Use a diagnostic test, such as polymerase chain reaction (PCR), that will enhance the sensitivity and specificity of CDI diagnosis, but beware of over diagnosis and possible false positives.

> Interpret the diagnostic test results only after considering the patient's clinical condition and pretest probability of having CDI, to maximize the positive predictive value of the tests and avoid false (incorrect) diagnosis and unnecessary treatment.

> Create a "hard stop" to discontinue an order for a CDI stool screening if the patient is admitted with a history of diarrhea yet fails to have an episode in the first two days of admission.

Suggested Process Measures for Your Test of Change

- Monthly audit of the number and percentage of stool specimens sent to the clinical lab that met the designated CDI criteria (e.g., loose or watery stool).

Hardwire the Process

> Implement hard stops to prevent testing of solid stools or repeat testing of a patient.

> To reduce false positive PCR tests, consider soft stops to alert the physician, using a standard process, when there are questions regarding whether a specific patient should be tested for CDI. Patients with low pretest probability would not have tests sent, or if sent, would have heightened clinical review to assess for CDI should those tests be positive.

> Consider using both PCR and toxin immunoassays: If both are positive, the diagnosis of CDI is highly likely; if the PCR is positive but toxin is negative, the patient may be a carrier without CDI or the result may be a false positive.

Primary Driver:

PREVENT CDI TRANSMISSION

Prompt CDI diagnosis is the first step in outbreak prevention and will trigger the isolation precautions and infection control practices designed to prevent CDI transmission.[23] Fecal incontinence is common in patients with CDI, and the CDI spores can be a significant threat to other patients and staff in the environment of care. Since the fecal-oral route is the primary mode of CDI transmission within inpatient health care facilities, contact precautions should be instituted quickly after diagnosis.

Secondary Driver > ESTABLISH GUIDELINES FOR USING CONTACT PRECAUTIONS

Early identification of patients with CDI and of those suspected of having CDI provides the opportunity to stop the spread of CDI. Since the organism can be spread by direct human to human contact or by indirect means through fomites[3,24] (e.g., bed rails, equipment, rectal thermometers), contact precautions are critical to prevent spreading infection to staff, visitors and other patients (see Appendix IV). "Adherence to the components of contact precautions will help to break the chain of infection. Fecal incontinence and an increased potential for extensive and prolonged environmental contamination by the organism make patients with CDI a significant threat for disseminating and transmitting the disease. Using presumptive isolation and contact precautions is recommended while awaiting the results of screening for patients who develop health care-associated diarrhea."[24]

Change Ideas

> Consider visual cues, such as signs and colored tape placed on the floor, to identify restricted areas.

> Reiterate the proper use of gloves during contact precautions and adhere to the practice of universal gloving.

> Require gowns as part of contact precautions. While the practice of gowning has not been specifically studied as part of CDI prevention, the CDC recommends their use when using CDI contact precautions.[24]

> Continue contact precautions for the duration of the patient's hospitalization unless the diarrhea has resolved and the patient has been transferred to another room.

> Implement chlorhexidine gluconate bathing.[25]

> Establish protocols to cohort CDI patients if private rooms are limited or unavailable.

> Educate families and visitors regarding the need to follow contact precautions and effective processes for donning and removing personal protective equipment.

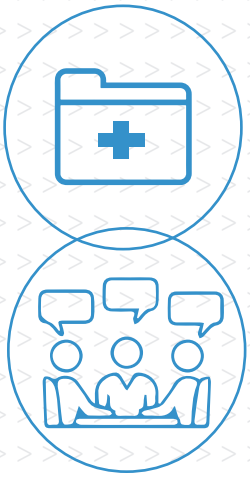
Suggested Process Measures for Your Test of Change

- Real-time measurement and intervention of length of time from the moment CDI is suspected to the time contact precautions are implemented.
- Regular audits measuring time from the moment CDI is suspected to the time contact precautions are implemented.

- Regular audits regarding availability of all contact precaution supplies necessary for staff and visitors to adhere to proper precautions.
- Regular audits measuring compliance with discontinuation of contact precautions when no longer clinically necessary.

Secondary Driver > ESTABLISH, MAINTAIN AND MONITOR AN EFFECTIVE HAND HYGIENE PROGRAM

Effective hand hygiene is the cornerstone of a comprehensive and effective infection prevention program. Hand hygiene is a key component of the HRET Up Campaign, to prevent health care-associated conditions.[26] Hand hygiene is particularly important for CDI prevention as CDI patients have significant diarrhea and commonly shed spores into their environment. The proper use of disposable gloves can significantly reduce the chances that other staff and visitors will be exposed to the spores. Since "contamination of the skin and clothing of health care personnel occurs frequently during removal of contaminated gloves or gowns,"[27] and since CDI spores may be resistant to alcohol-based hand sanitizers, using soap and warm water before and after treating patients is preferred.[24] Note that the Society for Healthcare Epidemiology of America recommends that health care settings continue using alcohol-based hand sanitizer if a CDI outbreak has not occurred. These hand sanitizers are associated with a decrease in infections with other pathogens such as *Staphylococcus aureus*.



Change Ideas

> Engage patients, visitors and families as partners in CDI prevention by explaining the importance of hand hygiene for the patient and all family members and visitors, and by teaching them effective hand hygiene techniques.[28]

> Provide patients with a hand sanitizer and emphasize they should routinely use it after toileting and prior to eating.

> Adopt hand hygiene awareness programs to reinforce the importance of hand hygiene.

> Establish a method of monitoring hand hygiene compliance (see Appendices V and VI).

> Adopt or adapt creative hand hygiene posters and other educational tools to attract attention and promote learning and understanding.

Suggested Process Measures for Your Test of Change

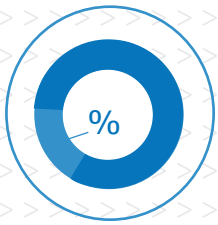
- Real-time adherence to strict hand hygiene protocols. Consider reporting absolute numbers of failures in addition to rates, as absolute numbers represent the opportunities for health care-associated transmission of CDI to real patients.
- Real-time percentage of adherence to de-gloving protocols.
- Percentage of visitors receiving instructions about hand hygiene importance and technique.
- Percentage of patients on contact precautions for CDI that have received education regarding the importance of hand hygiene.

Secondary Driver > ENVIRONMENTAL CONTROLS

The hospital environment plays a significant role in transmitting CDI. Because CDI is shed in feces, any environmental surface that becomes contaminated with feces can serve as a source of transmission. CDI spores can survive on surfaces for as long as five months. CDI spores were found in 49 percent of the hospital rooms occupied by patients diagnosed with CDI, and in 29 percent of the rooms of asymptomatic CDI carriers. The most heavily contaminated areas were hospital room floors, bed rails and bathrooms.[29] The disinfectants that have historically been used in health care environments

are quaternary ammoniums and phenolics, neither of which are sporicidal.[30,31] Environmental Protection Agency-registered sporicidal agents are now available and should be used for general surface disinfection. As important as selecting the correct cleaning solution is ensuring that cleaning staff are well trained in how to use the cleaning supplies. Environmental staff should understand where particular cleaning solutions should be used, the frequency of cleaning required and the amount of contact time needed for effectiveness.



Change Ideas

> Form a multidisciplinary team, including housekeeping, purchasing, and infection prevention, to review, evaluate and make recommendations regarding new disinfectant agents and infection control practices.

> Use disposable equipment or dedicate equipment to a single patient (e.g., blood pressure cuffs, thermometers, commodes).

> Use commode liners to limit splashing or contamination when emptying.

> Use fecal contamination clean-up kits for spills or uncontrolled stools.

> Identify and remove environmental sources of CDI (e.g., replace electronic thermometers with disposables).

> Create a visual cue that will show that a piece of equipment has been cleaned, such as paper strip or sign.

> Use audible timers to ensure appropriate contact time for cleaning agents.

> Clearly define who is responsible for cleaning ventilators, IV pumps and other critical patient care equipment. Ensure cleaning materials or wipes are within easy reach to facilitate cleaning.

> Use specialized privacy curtains that can be replaced without a ladder and appropriately cleaned.

> Attach disposable, plastic adhesive shields to privacy curtains to prevent glove or hand contact and contamination.

> Spray 3% hydrogen peroxide disinfectant solution on nonshielded areas of the privacy curtains during daily room cleaning and at patient discharge.

> Use a two-step cleaning protocol incorporating mobile, automated equipment that releases ultraviolet-C radiation or hydrogen peroxide vapor.

Suggested Process Measures for Your Test of Change

- Percentage of proper cleaning contact time using audible timers.
- Percentage of rooms equipped with either (1) specialized privacy curtains that can be easily replaced and cleaned or (2) curtains that have disposable, plastic adhesive shields attached to them.

Secondary Driver > MONITOR ENVIRONMENTAL CLEANING

Monitoring is required to ensure that cleaning and disinfection practices are consistent and effective. It is important to weigh the risks and benefits of the various auditing methods and select those that best fit your facility. Direct observation of cleaning practices provides immediate feedback, but it is time- and labor-intensive and may be a poor indicator of routine practice. While swab cultures are simple to perform, they can be costly to process and the results can be delayed from 24 to 72 hours. Agar slide cultures provide a simple way to quantify viable microbial surface contamination.

Fluorescent markers provide immediate results, allow for timely feedback, and furnish visual evidence that the surface has been adequately cleaned. Fluorescent markers, however, do not provide a colony count, so that reduction of bacteria can be logged. One of the best monitoring processes commonly used today is adenosine triphosphate (ATP) bioluminescence which measures organic debris. ATP bioluminescence does not identify an actual pathogen, but it does serve as a surrogate marker for biological contamination.[24]

Change Ideas

> Directly observe room cleaning and provide immediate feedback, recommendations and recognition to cleaning staff.

> Use swab cultures to demonstrate the effectiveness of cleaning or identify opportunities for improvement.

> Use Agar slide cultures to quantify microbial surface contamination.

> Use fluorescent markers to indicate physical removal of an applied substance.

> Use ATP bioluminescence, which provides immediate feedback, to measure organic debris as a surrogate marker for biological contamination.

> Implement a program to recognize and acknowledge the efforts of environmental services team members (see Appendix VI).

> Include terminal room cleaning test results as a standing item on infection prevention or quality committee agendas.

Suggested Process Measures for Your Test of Change

- Using real-time data collection, percentage of rooms that are monitored for adherence to your hospital's preferred form of environmental cleaning process(es).
- Absolute number of rooms monitored for environmental cleaning found to not have been cleaned in adherence to your hospital's preferred form of environmental cleaning process(es).
- Absolute number by unit and/or percentage of environmental services team members recognized or acknowledged for their cleaning processes.

Hardwire the Process

> Use a nurse-driven protocol such as a diarrhea decision tree (see Appendices VIII, IX and X) to trigger contact precautions and CDI testing.

> Develop a process for rapidly providing test results to the patient care area to ensure isolation precautions are initiated promptly.

> Establish standard processes for staff, patient, families and visitors to practice hand hygiene, and monitor compliance.

> Establish cleaning protocols for cleaning solutions that are effective against CDI spores.

> Develop equipment cleaning and disinfection procedures specifying assignments and appropriate use (e.g., determine who cleans what and how).

> Adopt protocols for monitoring effectiveness of environmental cleaning.

> Develop checklists to use when auditing and evaluating cleaning practices (see Appendix X).

Choice of Tests and Interventions for CDI Reduction

> There are many potentially effective interventions to reduce the risks of CDI. Improvement teams should begin their efforts by asking: "What is the greatest need at our facility? Where can we have the greatest impact?"

> Do not wait for the protocol or electronic health record (EHR) to arrive to implement prevention strategies. Conduct small tests of change using the resources available and then upgrade the processes, equipment and technology over time.

IMPLEMENT SMALL TESTS OF CHANGE	PDSA Example: Choose a protocol to adopt
PLAN	Adopt protocols for monitoring effectiveness of environmental cleaning.
DO	Test one protocol with one environmental services (EVS) professional cleaning one room.
STUDY	Was the protocol clear and understandable? Were all the necessary materials present? Was it possible to complete the protocol successfully and in a timely manner?
ACT	What did you learn from this test? What needs to be changed in order to make the next test more likely to succeed? If the test worked well, is it time to recruit one or two more EVS professionals to test and see if others can perform as well or find out what needs to be altered to enhance spread? Plan your next small test of change. How soon can you test it?

Potential Barriers

- Physicians may resist restrictions to antibiotic prescribing.
- Physicians may feel pressure from patients to prescribe antibiotics.[32]
- Pharmacists may be reluctant to call physicians about inappropriate antibiotics or combinations of antibiotics.
- Clinicians may confuse a positive test for CDI with a case of CDI, rather than interpreting the test within the clinical context.
- Clinicians and EVS professionals may push back against hand hygiene oversight.
- Patients, families and visitors may be reluctant to "call out" staff who do not appear to be following proper precautions and cleaning.
- Leadership WalkRounds™ [33] may be perceived to be punitive, and staff, patients and families may not speak out.

Enlist administrative leadership as sponsors to help remove or mitigate barriers

- A multidisciplinary team including senior leadership executive champions working with physician and pharmacy champions is a key to developing successful antimicrobial stewardship.
- Minimizing physician resistance to changing antibiotic prescribing habits is best achieved by sharing the literature that shows the effectiveness of an antibiotic stewardship program for improving cures, reducing failures and reducing microbial resistance. Administrative leaders should not emphasize "saving money" as the key objective. Physicians are much less likely to respond positively to the latter approach and may be more reluctant to participate in an antibiotic stewardship program.[34]
- Understanding by administrative leadership of the difference between a positive CDI test and the presence of CDI is important in overseeing and leading effective CDI prevention programs.
- Conduct Leadership WalkRounds™ to listen to and understand the concerns of staff, patients and families and identify specific barriers; create a culture of improvement rather than one of blame.[33]

Change not only the practice, but also the culture

Multidisciplinary teamwork and trust are required to develop and implement (1) a successful antimicrobial stewardship program, (2) methods to rapidly identify and diagnose CDI and (3) optimal protocols to prevent spread of CDI. It starts with small tests of change pioneered by new multidisciplinary dyads and triads collaborating to try something once and see what can be learned. Larger successes are built upon small successes. These successes then help to build new lines of communication and slowly change the culture. Silos break down and minds open to new ideas. As the organization finds newer and more successful ways to work collaboratively to reduce CDI, it becomes more competent and ready to tackle other opportunities to improve patient care.

PART 4: CONCLUSION AND ACTION PLANNING

CDI prevention is multifaceted and cannot be accomplished in silos (see Appendix X). Breaking down the approaches into the three primary drivers (antibiotic stewardship, rapid identification and diagnosis, and preventing transmission) can help organizations attack CDI simultaneously from different angles. Look at the secondary drivers and the change ideas. Build upon others' learnings. Gather small multidisciplinary groups of champion clinicians and administrators and design very small tests of change, then take those learnings and design new tests. Quickly repeat this PDSA cycle, learning iteratively. Improvement cannot be created in a meeting room. Improvement happens while learning from doing, and small tests allow for quick learning cycles and more rapid achievement of improvement goals.

PART 5: APPENDICES

APPENDIX I: TOP TEN CHECKLIST

Associated Hospital/Organization: HRET HIIN

Purpose of Tool: A checklist to review current interventions or initiate new ones for CDI prevention in your facility

Reference: www.hret-hiin.org

Clostridium Difficile infections (CDI) Top Ten Checklist

- Develop or enhance your antibiotic stewardship program to ensure optimal antibiotic prescribing and reduce overuse and misuse of antibiotics.
- Evaluate the use of antibiotics by infection type and by unit to better understand where the opportunities for stewardship exist; be sure to include patients with urinary tract infections and lower respiratory infections.
- Evaluate the use of antimicrobials among patients with CDI and provide feedback to medical staff and facility leadership.
- Develop processes to minimize testing of patients at low probability for CDI to minimize false positive polymerase chain reaction results for CDI.
- Establish a lab-based alert system to immediately notify the infection prevention team and providers of newly-identified patients with positive CDI lab results. Ensure the system includes holiday and weekend notification.
- Remembering that CDI is a clinical diagnosis and not a lab diagnosis, develop processes where discussion occurs between physicians and other clinicians when a lab test for CDI is reported as positive.
- Establish cleaning protocols for a cleaning solution that is effective against CDI spores.
- Utilize a monitoring system to evaluate and validate effective room-cleaning, and to provide feedback, reward and recognition to those responsible.
- Engage and educate patients, visitors, families and community partners (e.g., home care agencies, nursing homes) to prevent CDI across the continuum of care.
- Establish and maintain an effective, creative, innovative and engaging hand hygiene program.

APPENDIX II: CASE EXAMPLES ILLUSTRATING THE EFFECT OF PRETEST PROBABILITY ON THE LIKELIHOOD THAT TESTS WILL GENERATE TRUE POSITIVES INSTEAD OF FALSE POSITIVES (POSITIVE PREDICTIVE VALUE)

Associated Hospital/Organization: HRET HIIN

Purpose of Tool: Illustrate that even with highly sensitive and specific tests, for patients with low pretest probability of *C. difficile* Infection (CDI), a high percentage of positive test results will be false positives.

Reference: www.hret-hiin.org

PATIENT 1

- Age 50
- Admitted from home
- No recent prior acute or long-term care hospitalization
- 3 loose stools after admission
- No antibiotics administered in past 14 days
- Pretest probability of CDI is 4.4 – 15% (mean 10%)[2]

Test to identify CDI toxin genes (PCR)

> Sensitivity = 95%

> Specificity = 95%

> Pretest probability of CDI (prevalence)= 10%

For a population of 1,000 patients like Patient 1:

> 100 patients would have CDI

> 900 would not have CDI

> The test with a sensitivity of 95% would identify 95 of the 100 patients with CDI (95 true positives) and miss 5 of the 100 with CDI (5 false negatives)

> The test with a specificity of 95% would accurately be negative for the 95% of the 900 patients without CDI (855 true negatives) but would also misidentify 5% of the 900 without CDI as (45 false positives) as falsely having CDI.

Of the 95 + 45 (140) total positives the test identified, only 95/140 = **68% would be true positives (PPV). The false positive rate would be 32%!**

Of the 855 + 5 (860) total negatives the test identified, 855/860 = **99.5% would be true negatives (NPV). The false negative rate would be 0.5%**

Note: *If the patient had a pretest probability of 5%, more than one-half of the positive test results would be false.*

PATIENT 2

- Age 80
- Admitted from skilled nursing facility
- 3 loose stools since admission
- On antibiotics for presumed urinary tract infection
- Pretest probability of CDI is approximately 50%[35]

Test to identify CDI toxin genes (PCR)

> Sensitivity = 95%

> Specificity = 95%

> Pretest probability of CDI = 50%

For a population of 1,000 patients like Patient 2:

> 500 patients would have CDI

> 500 would not have CDI

> The test with a sensitivity of 95% would identify 475 of the 500 patients with CDI (475 true positives) and miss 25 of the 100 with CDI (25 false negatives)

> The test with a specificity of 95% would accurately be negative for the 95% of the 500 patients without CDI (475 true negatives) but would also misidentify 5% of the 900 without CDI as falsely having CDI (25 false positives).

Of the 475 + 25 (500) total positives the test identified, 475/500 = **95% would be true positives (PPV). The false positive rate would be 5%.**

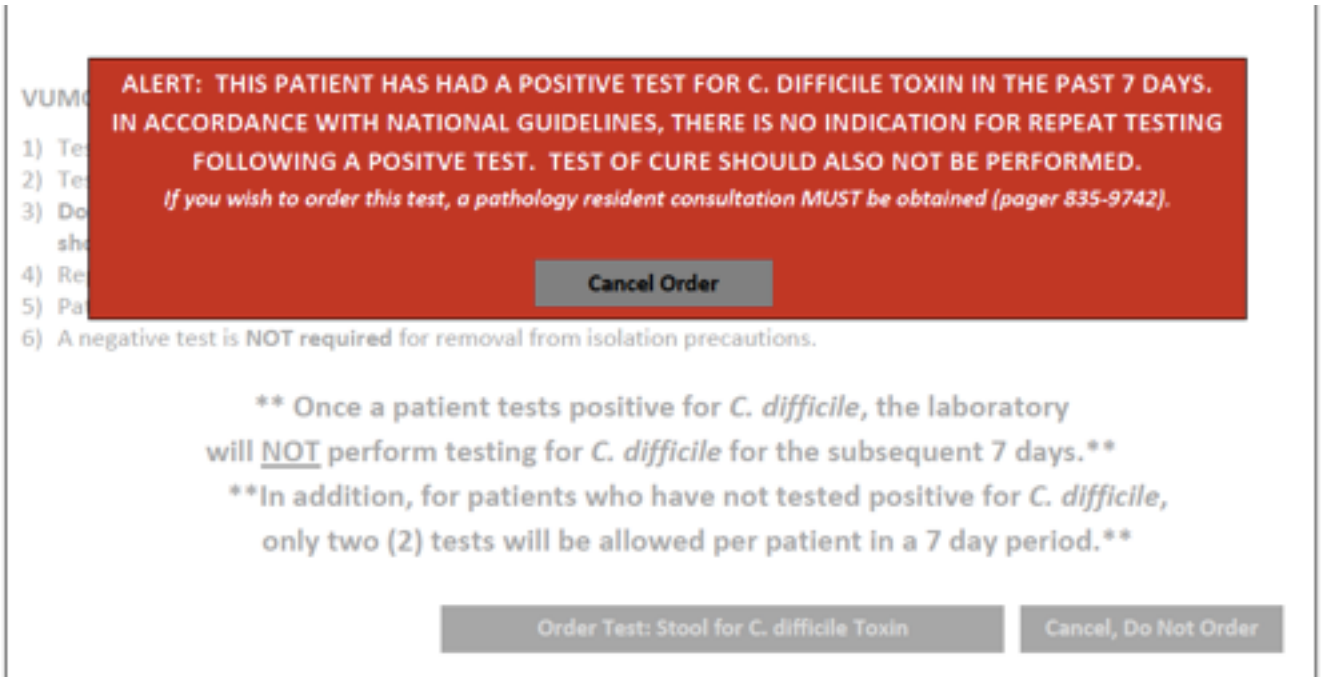
Of the 475 + 25 (500) total negatives the test identified, 475/500 = **95% would be true negatives (NPV). The false negative rate would be 5%.**

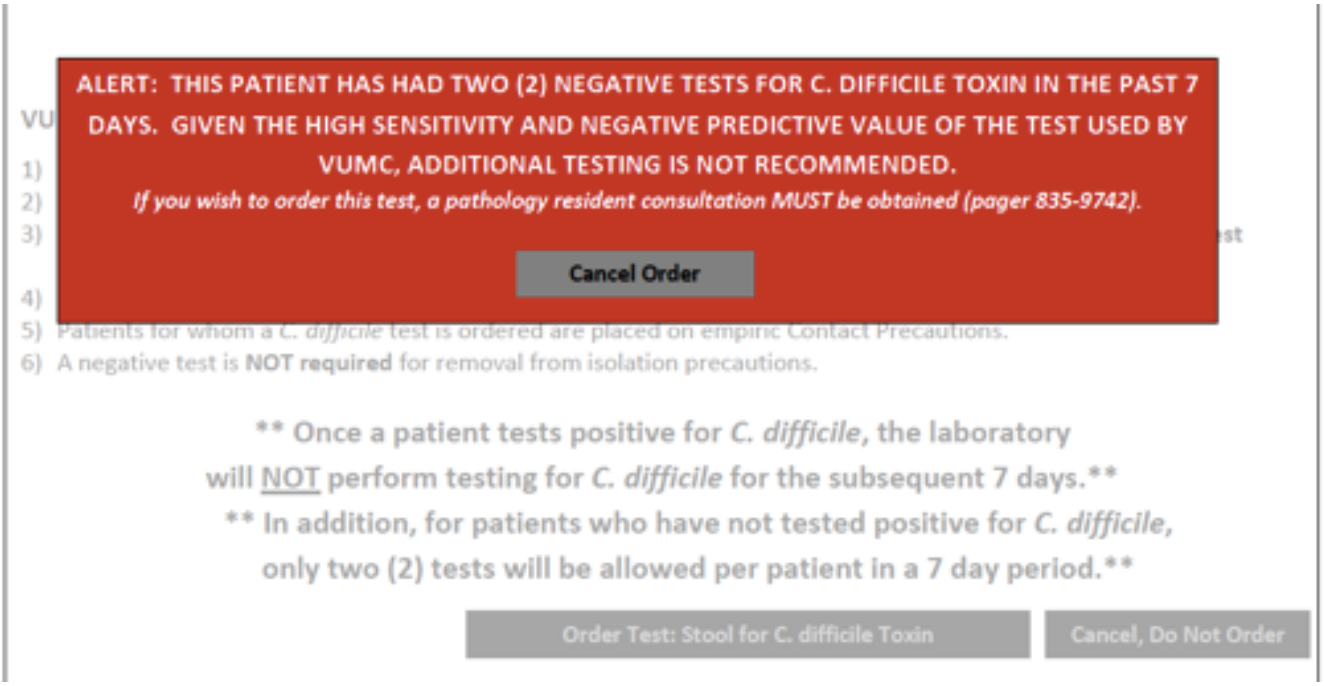
APPENDIX III: VANDERBILT EHR SCREENSHOTS

Associated Hospital/Organization: Vanderbilt University Medical Center, Nashville, Tennessee

Purpose of Tool: Provides electronic alerts to help educate staff and prevent unnecessary CDI stool testing.

Reference: : Permission provided on December 8, 2015, by Tom Talbot, MD, MPH, Chief Hospital Epidemiologist, Vanderbilt University Medical Center





APPENDIX III: VANDERBILT EHR SCREENSHOTS *(continued)*

Associated Hospital/Organization: Vanderbilt University Medical Center, Nashville, Tennessee

Purpose of Tool: Provides electronic alerts to help educate staff and prevent unnecessary CDI stool testing.

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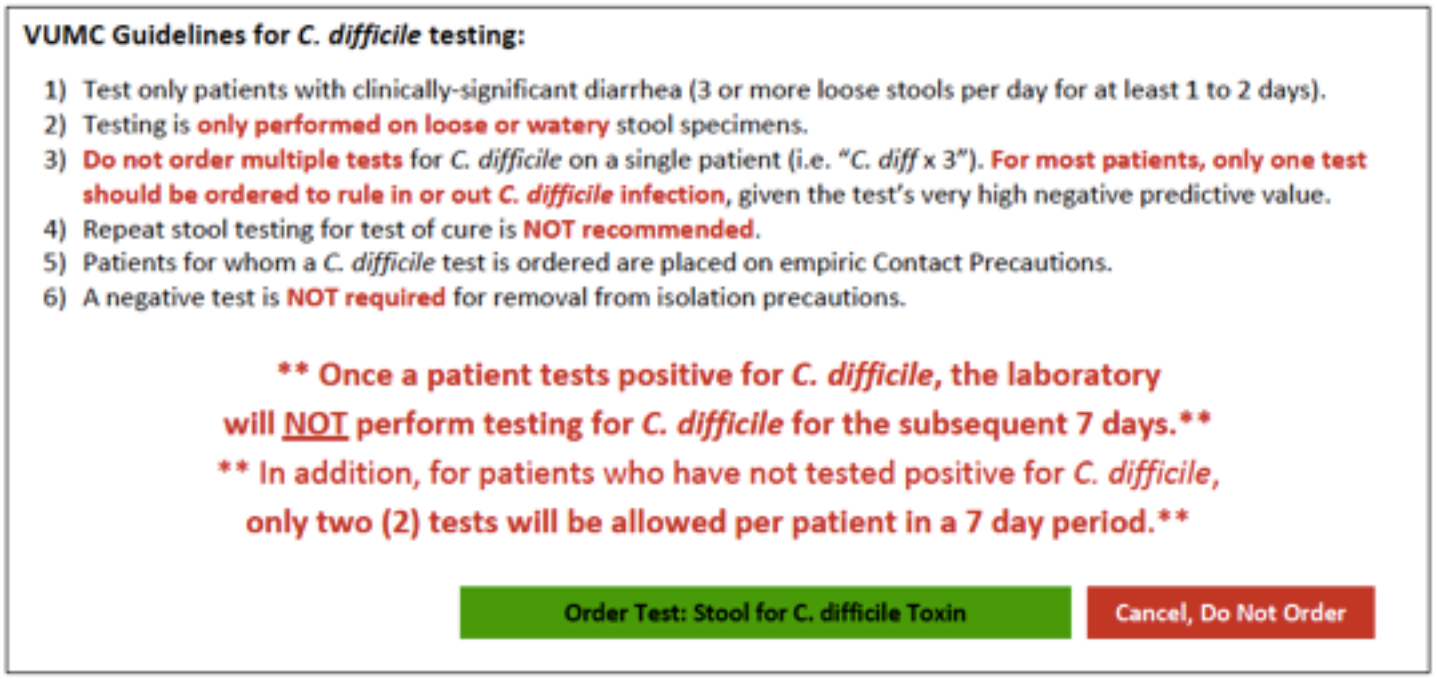


VUMC Guidelines for *C. difficile* testing:

1) Test only patients with clinically-significant diarrhea (3 or more loose stools per day for at least 1 to 2 days).
2) Testing is **only performed on loose or watery** stool specimens.
3) **Do not order multiple tests** for *C. difficile* on a single patient (i.e. "*C. diff* x 3"). **For most patients, only one test should be ordered to rule in or out *C. difficile* infection**, given the test's very high negative predictive value.
4) Repeat stool testing for test of cure is **NOT recommended**.
5) Patients for whom a *C. difficile* test is ordered are placed on empiric Contact Precautions.
6) A negative test is **NOT required** for removal from isolation precautions.

**** Once a patient tests positive for *C. difficile*, the laboratory will NOT perform testing for *C. difficile* for the subsequent 7 days.****

**** In addition, for patients who have not tested positive for *C. difficile*, only two (2) tests will be allowed per patient in a 7 day period.****

Order Test: Stool for C. difficile Toxin | Cancel, Do Not Order

APPENDIX IV: ENHANCED PRECAUTIONS SIGN

Associated Hospital/Organization: California Pacific Medical Center (CPMC), San Francisco, California

Purpose of Tool: Alerts staff and visitors when contact precautions are required as well as the necessary hand hygiene and personal protective equipment.

Reference: Permission provided on December 8, 2015, by Karen Anderson, MT, MPN, CIC, Manager, Infection Prevention and Control, CPMC

ENHANCED CONTACT PRECAUTIONS

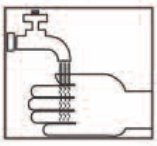
ALL FAMILY & VISITORS REPORT TO NURSES' STATION

TODA FAMILIA Y VISITANTES DE REPORTARSE
A LA ESTACION DE ENFERMERAS

Enhanced Contact Precautions are in addition to Standard Precautions.
All patients will be treated with Standard Precautions at all times.

GLOVES REQUIRED when entering the room

GOWN REQUIRED when entering the room



PRIVATE ROOM REQUIRED

Use **SOAP and WATER ONLY** for hand hygiene

DISINFECT all surfaces with **BLEACH**

WHEN CONTACT PRECAUTIONS NO LONGER INDICATED, FLIP SIGN OVER AND KEEP POSTED DURATION OF ADMISSION

APPENDIX IV: ENHANCED PRECAUTIONS SI *(continued)*

Associated Hospital/Organization: California Pacific Medical Center (CPMC), San Francisco, California

Purpose of Tool: Alerts staff and visitors when contact precautions are required as well as the necessary hand hygiene and personal protective equipment.

Reference: Permission provided on December 8, 2015, by Karen Anderson, MT, MPN, CIC, Manager, Infection Prevention and Control, CPMC

APPENDIX V: HAND HYGIENE AUDIT TOOL WITH GUIDE TO HAND HYGIENE OPPORTUNITIES

Associated Hospital/Organization: Centers for Disease Control and Prevention

Purpose of Tools: The audit tools and checklists below are intended to promote CDC-recommended practices for infection prevention in hemodialysis facilities.

Reference: http://www.cdc.gov/dialysis/PDFs/collaborative/Hemodialysis-Hand-Hygiene-Observations.pdf

CDC Dialysis Collaborative *Facility Name:*_____ *Date:*_____ *Start time:*_____ *AM / PM*

*Day: M W F Tu Th Sa Shift: 1st 2nd 3rd 4th Observer:*_____ *Location within unit:*_____

Audit Tool: Hemodialysis hand hygiene observations

(Use a "√" for each 'hand hygiene opportunity' observed. Under 'opportunity successful,' use a "√" if successful, and leave blank if not successful)

Discipline	Hand hygiene		Describe any missed attempts (e.g., during medication prep, between patients, after contamination with blood, etc.):
	Hand hygiene opportunity	Opportunity successful	

Discipline: **P**=physician, **N**=nurse, **T**=technician, **S**=student, **D**=dietitian, **W**=social worker, **O**=other

Duration of observation period = _____ minutes Number of successful hand hygiene opportunities observed = _____

Total number of patients observed during audit = _____ Total number of hand hygiene opportunities observed during audit = _____

** See hand hygiene opportunities on back page

Making dialysis safer for patients

National Center for Emerging and Zoonotic Infectious Diseases

Division of Healthcare Quality Promotion

APPENDIX V: HAND HYGIENE AUDIT TOOL WITH GUIDE TO HAND HYGIENE OPPORTUNITIES *(continued)*

Associated Hospital/Organization: Centers for Disease Control and Prevention

Purpose of Tools: The audit tools and checklists below are intended to promote CDC-recommended practices for infection prevention in hemodialysis facilities.

Reference: http://www.cdc.gov/dialysis/PDFs/collaborative/Hemodialysis-Hand-Hygiene-Observations.pdf

Guide to Hand Hygiene Opportunities in Hemodialysis

Hand hygiene opportunity category	Specific examples
1. Prior to touching a patient	• Prior to entering station to provide care to patient • Prior to contact with vascular access site • Prior to adjusting or removing cannulation needles
2. Prior to aseptic procedures	• Prior to cannulation or accessing catheter • Prior to performing catheter site care • Prior to parenteral medication preparation • Prior to administering IV medications or infusions
3. After body fluid exposure risk	• After exposure to any blood or body fluids • After contact with other contaminated fluids (e.g., spent dialysate) • After handling used dialyzers, blood tubing, or prime buckets • After performing wound care or dressing changes
4. After touching a patient	• When leaving station after performing patient care • After removing gloves
5. After touching patient surroundings	• After touching dialysis machine • After touching other items within dialysis station • After using chairside computers for charting • When leaving station • After removing gloves

Please make note of the following during this session.			
	Yes	No	Comments
There is a sufficient supply of alcohol-based hand sanitizer			
There is a sufficient supply of soap at handwashing stations			
There is a sufficient supply of paper towels at handwashing stations			
There is visible and easy access to hand washing sinks or hand sanitizer			

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APPENDIX VI: "ONE ROOM AT A TIME" CERTIFICATE

Associated Hospital/Organization: WakeMed Health & Hospitals, Raleigh, North Carolina

Purpose of Tools: Recognition/acknowledgment tool for environmental services workers who are noted to adhere to hospital standards for room cleaning

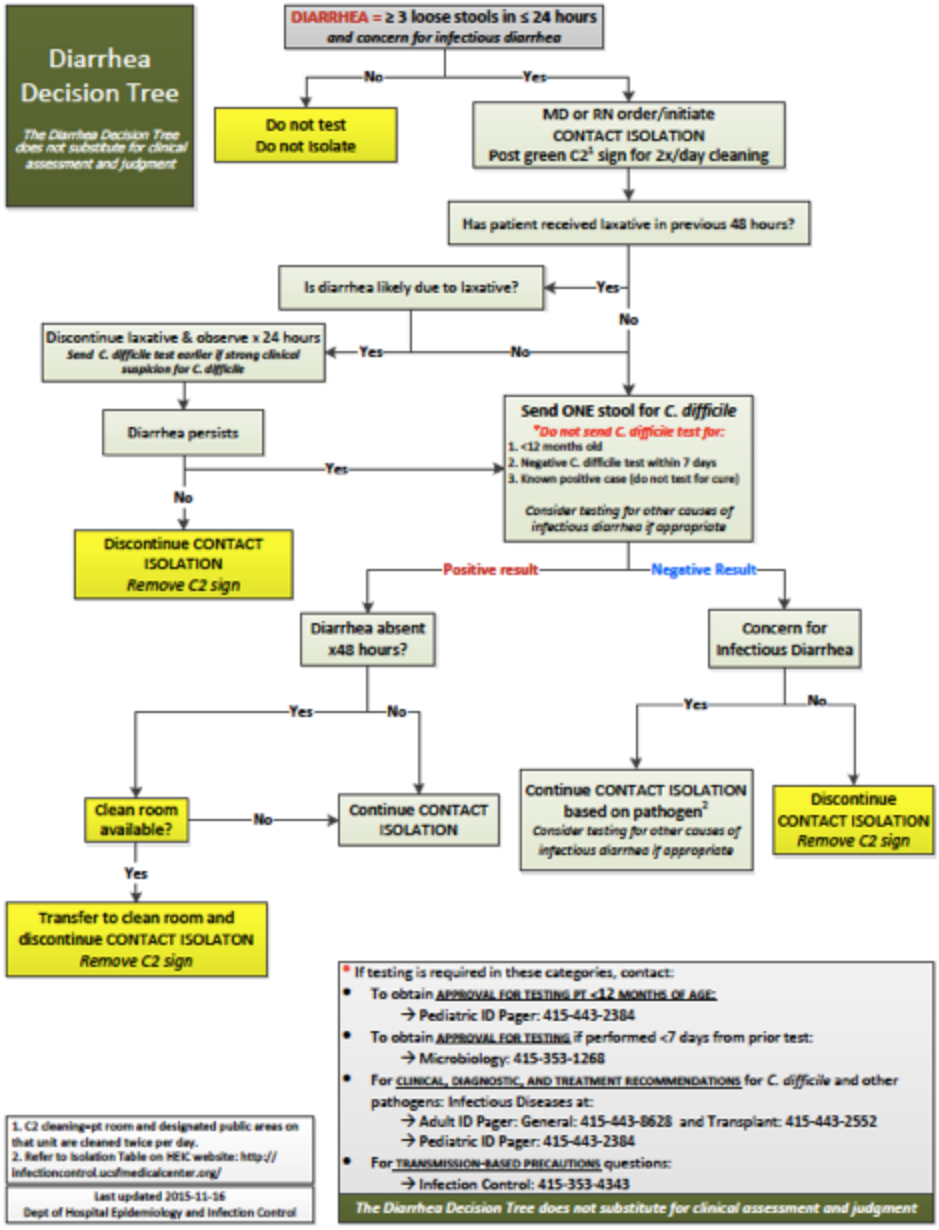
Reference: Permission provided on December 8, 2105, by Vickie Brown, RN, MPH, CIC, Director Infection Prevention, WakeMed Health & Hospitals

APPENDIX VII: DIARRHEA DECISION TREE

Associated Hospital/Organization: University of California, San Francisco, California (UCSF)

Purpose of Tool: Assists staff in determining which patients with diarrhea require enhanced contact precautions

Reference: Permission provided on December 8, 2015, by Amy Nichols, RN, MBA, CIC, Director, Epidemiology and Infection Control, UCSF Medical Center

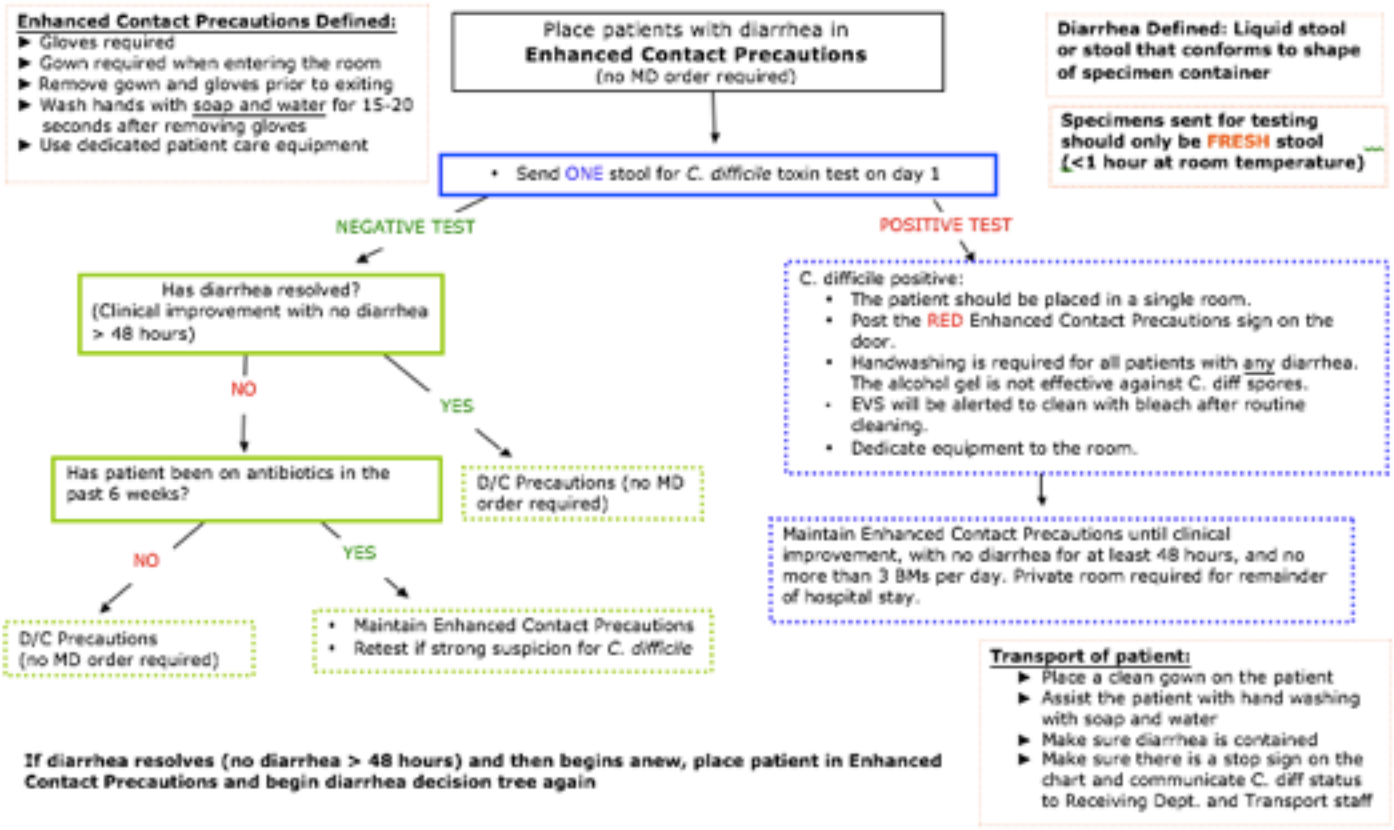


APPENDIX VIII: DIARRHEA/ENHANCED PRECAUTIONS DECISION TREE

Associated Hospital/Organization: California Pacific Medical Center (CPMC), San Francisco, California

Purpose of Tool: Assists staff in determining which patients with diarrhea require enhanced contact precautions

Reference: Permission provided on December 8, 2015, by Karen Anderson, MT, MPH, CIC, Manager, Infection Prevention and Control, CPMC

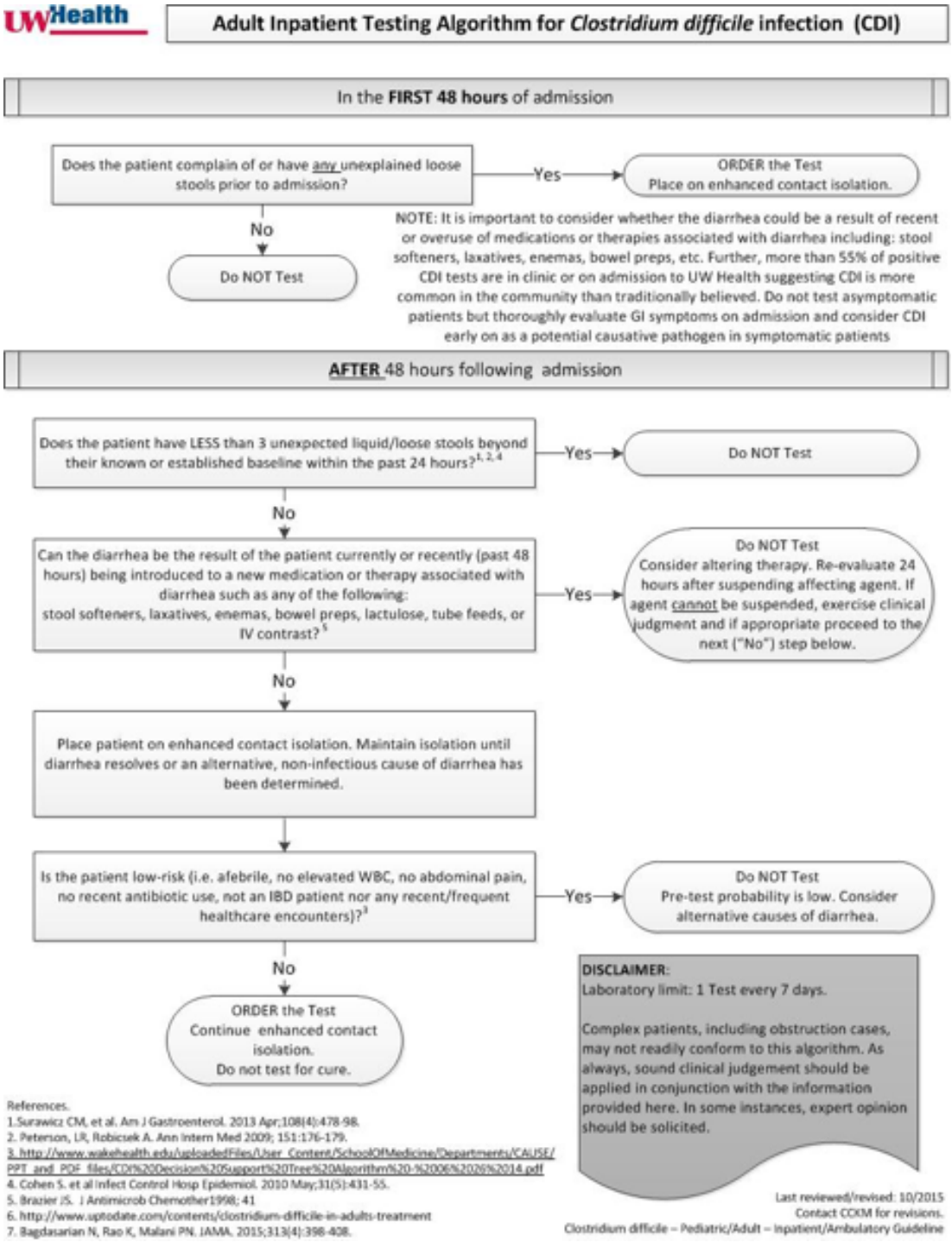


APPENDIX IX: UW HEALTH ADULT INPATIENT TESTING ALGORITHM FOR CLOSTRIDIUM DIFFICILE INFECTION

Associated Hospital/Organization: University of Wisconsin Health

Purpose of Tool: Assists staff in diagnosing CDI

Reference: Permission provided on June 30, 2016 by Marc-Oliver Wright, MT (ASCP), MS, CIC, FAPIC Clinical Infection Control Practitioner UW Health University



APPENDIX X: CDC ENVIRONMENTAL CHECKLIST FOR MONITORING TERMINAL CLEANING

Associated Hospital/Organization: Centers for Disease Control and Prevention

Purpose of Tool: Provides environmental services checklist for terminal room cleaning

Reference: http://www.cdc.gov/HAI/toolkits/Environmental-Cleaning-Checklist-10-6-2010.pdf

CDC Environmental Checklist for Monitoring Terminal Cleaning[1]

Date:	
Unit:	
Room Number:	
Initials of ES staff (optional):[2]	

Evaluate the following priority sites for each patient room:

High-touch Room Surfaces[3]	Cleaned	Not Cleaned	Not Present in Room
Bed rails / controls			
Tray table			
IV pole (grab area)			
Call box / button			
Telephone			
Bedside table handle			
Chair			
Room sink			
Room light switch			
Room inner door knob			
Bathroom inner door knob / plate			
Bathroom light switch			
Bathroom handrails by toilet			
Bathroom sink			
Toilet seat			
Toilet flush handle			
Toilet bedpan cleaner			

Evaluate the following additional sites if these equipment are present in the room:

High-touch Room Surfaces[3]	Cleaned	Not Cleaned	Not Present in Room
IV pump control			
Multi-module monitor controls			
Multi-module monitor touch screen			
Multi-module monitor cables			
Ventilator control panel			

Mark the monitoring method used:

☐ Direct observation ☐ Fluorescent gel
☐ Swab cultures ☐ ATP system ☐ Agar slide cultures

[1]Selection of detergents and disinfectants should be according to institutional policies and procedures
[2]Hospitals may choose to include identifiers of individual environmental services staff for feedback purposes.
[3]Sites most frequently contaminated and touched by patients and/or healthcare workers

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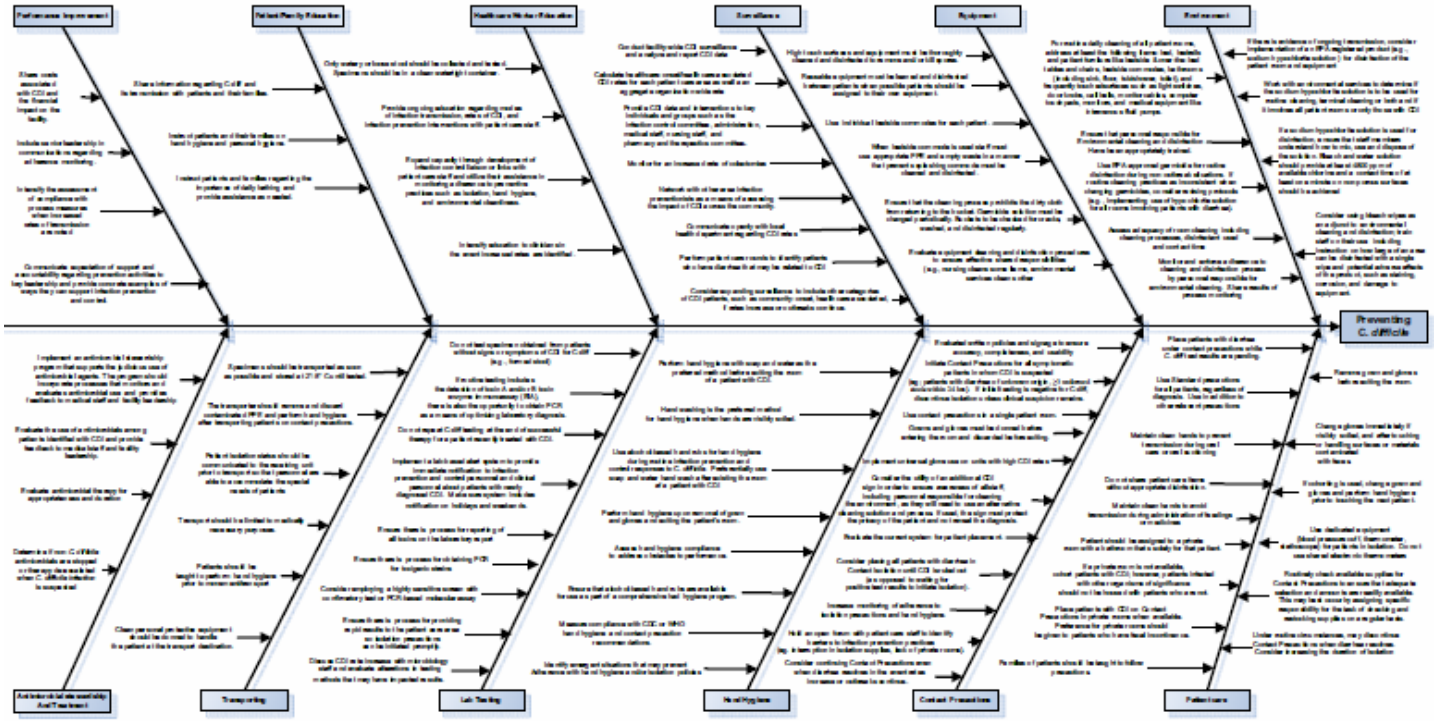
APPENDIX XI: CDI FISHBONE

Associated Hospital/Organization: School of Public Health and Information Sciences, University of Louisville, Louisville, Kentucky

Purpose of Tool: Provides a fishbone diagram of all of possible causative factors in acquiring and transmitting CDI and developing CDI

Reference: Permission provided on December 7, 2015, by Ruth Carrico, PhD, RN, CIC, Associate Professor and Director, Community and Professional Service



Compiled by Ruth Carrico PhD RN CIC, University of Louisville, School of Medicine, Division of Infectious Diseases
Ruth.carrico@louisville.edu
April 2013

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