Clostridium difficile Infection *(C. difficile)*

2016 UPDATE

Change Package

PREVENTING C. DIFFICILE TRANSMISSION AND INFECTION

American Hospital Association®

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
PARTNERSHIP FOR PATIENTS℠
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How to Use this Change Package

This change package is intended for hospitals participating in the Hospital Engagement Network HEN 2.0 project led by the Centers for Medicare & Medicaid Services (CMS) 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 choose to implement based on need and to begin testing 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: ADVERSE EVENT AREA (AEA) DEFINITION AND SCOPE

Clostridium difficile (C. difficile) is an anaerobic, spore-forming bacteria spread through fecal-oral transmission.[1] *C. difficile* 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. *C. difficile* transmission in hospitals occurs primarily from contaminated environments and through the hands of health care personnel.[2,3] *C. difficile* 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 *C. difficile* infection; the antibiotics destroy normal intestine flora, allowing for the overgrowth of *C. difficile.* While all patients taking antibiotics are at risk of *C. difficile*, longer courses of antibiotic therapy and multiple courses of antimicrobials increase *C. difficile* risk.

Magnitude of the Problem

C. difficile is the most frequently reported hospital-acquired pathogen.[4] A 2011 Centers for Disease Control and Prevention (CDC) surveillance study found that *C. difficile* caused almost half of a million infections and directly led to approximately 15,000 deaths in one year.[5] A majority of these deaths occur in Americans aged 65 or older. Additional health care costs related to *C. difficile* are estimated at $4.8 billion for acute care facilities alone.[6] Cases commonly appear in outbreaks and clusters in health care facilities.[7] However, the CDC study estimates that only one-quarter of *C. difficile* infections occur in hospitals, with others occurring in nursing homes and community settings.[8] As a result, *C. difficile* prevention efforts should focus on antimicrobial stewardship and preventing disease transmission.

HEN 1.0 Progress

From 2011 – 2014, the AHA/HRET HEN the focused on reducing the rate of health care associated *C. difficile infections.*

HEN 2.0 Reduction Goals

Reduce health care facility-onset of *C. difficile* by 40 percent by September 23, 2016

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 that you will be collecting and submitting data on for the AHA/HRET HEN 2.0. 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 your data in this manner will provide valuable information you need to study your data across time, and determine the effect your improvement strategies are having in your hospital at reducing patient harm. Furthermore, collecting these standardized metrics will allow the AHA/HRET HEN to aggregate, analyze and report its progress toward reaching the project's 40/20 goals across all AEAs by September 2016.

Nationally Recognized Measures: Process and Outcome

Please download and reference the encyclopedia of measures (EOM) on the HRET HEN website for additional measure specifications and for any updates after publication at www.hret-hen.org/engage/resources/EOM-AdditionalTopics.pdf

HEN 2.0 EVALUATION MEASURE

Standardized Infection Ratio (SIR) for patients with *C. difficile* (NQF 1717) - NHSN submitting facilities only.

Facility-wide *C. difficile* rate.

SUGGESTED PROCESS MEASURES

Hand hygiene consistent with recommended guidelines.

Adherence rate to contact precautions consistent with recommended guidelines.

Adherence rate to protocols and adequacy of environmental cleaning.

Percentage of days for which an antimicrobial agent is administered

PART 3: APPROACHING YOUR AEA

Suggested Bundles and Toolkits

- The CDC issued a checklist to aid in the assessment of 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: http://www.shea-online.org/Portals/0/CDI%20hand%20hygiene%20Update.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 Observations Tool, retrieved at: http://www.cdc.gov/dialysis/PDFs/collaborative/Hemodialysis-Hand-Hygiene-Observations.pdf.
- For key tools and resources related to preventing and reducing *C. difficile*, visit www.hret-hen.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 is organized by reviewing the components of the driver diagram to (1) help you and your care team identify potential change ideas to implement at your facility and (2) 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 which 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/achieve the secondary driver.*

Drivers in This Change Package

Prevent *C. difficile*	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 *C. difficile* in Patients With Diarrhea	Change Idea
	Prevent *C. difficile* Transmission	Establish Guidelines For the Use of Contact Precautions	Change Idea
		Establish, Maintain and Monitor an Effective Hand Hygiene Program	Change Idea
		Environmental Controls	Change Idea
		Monitor Environmental Cleaning	Change Idea

OVERALL AIMS: PREVENT *C. DIFFICILE*

Primary Driver > Antimicrobial stewardship

Antimicrobial stewardship is a program that promotes appropriate selection, dosing, route and duration of antimicrobial therapy.[9] 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 *C. difficile* and antimicrobial resistance. Comprehensive programs in both large academic medical centers and smaller community hospitals have consistently demonstrated reductions in antimicrobial use that ranged from 22 to 36 percent with annual savings of $200,000 to $900,000.[10] 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 30-50% of all antibiotic use is inappropriate. Inappropriate use includes a longer than necessary duration of therapy, treatment of non-bacterial diseases, treatment of contaminants or colonizers and meaningless duplicate therapy (e.g., treatment with multiple antibiotics targeting anaerobes simultaneously).[11] Additionally, clinical outcomes, including both cure and failure rates, have been shown to improve with an antibiotic stewardship program.[12] Monitoring and analysis of antimicrobial use by disease, unit and practitioner can lead to 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.[13]
+ 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 *C. difficile* and provide feedback and recommendations to medical staff and facility leadership regarding treatment options.
+ Determine if antimicrobial agents at higher risk of contributing to *C. difficile* are de-escalated or discontinued if *C. difficile* is suspected.
+ Eliminate redundant combination antimicrobial therapy.[14]
+ Adopt guidelines for the management of community-acquired pneumonia using a shorter course of therapy.[15]
+ Educate prescribing clinicians regarding the appropriate selection and use of antimicrobials, including dose, timing and duration of treatment.
+ Engage the clinical microbiology laboratory and infection prevention departments in optimization of surveillance and investigation of outbreaks.
+ Focus efforts on reducing the use of certain antibiotic classes associated with *C. difficile*, such as cephalosporins, clindamycin and fluoroquinolones.[16]
+ Optimize antimicrobial dosing based upon 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
+ Percentage of surgical patients who received an appropriate weight-based antimicrobial pre-operative 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.[17]

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 48-72 hours.

Suggested process measures for your change ideas:

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

Hardwiring

Using Donabedian's Quality Framework (Structure plus Process leads to Outcome)[18], (1) removal of unnecessary antibiotics from the formulary, (2) restriction of options for duplicate antibiotics and antibiotics for special circumstances, (3) ongoing surveillance of antibiotic use by pharmacy and (4) escalation to physician leaders as necessary, lead 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.[19,20]

Primary Driver > Rapid identification and diagnosis

Rapid diagnosis will lead to prompt treatment and implementation of contact precautions that can limit the spread of *C. difficile* in the environment of care.[21] The major risk factors for colonic *C. difficile* are antibiotic exposure, hospitalization and advanced age. While the most common clinical presentation of *C. difficile* is diarrhea, patients with severe *C. difficile* may also present with sepsis and abdominal pain in the absence of diarrhea. Diagnoses of *C. difficile* 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.[22]

+ An enzyme immunoassay (EIA) test for glutamate dehydrogenase (GDH), an enzyme produced by *C. difficile*, is 96-100 percent sensitive for the presence of the organism. However, this EIA does not test for the *C. difficile* toxins and cannot distinguish between non-pathogenic and pathogenic strains of the bacteria. The EIA tests for both toxins A and B do identify pathogenic strains, but these tests are only 70-80 percent sensitive.[23] 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.[24] Some facilities use a two-step approach as a method of detection: 1) the stool is first tested for GDH and toxins 2) indeterminate results then undergo PCR analysis.

Diagnosis of C. difficile

+ Test interpretation is related to the patient's clinical condition and the probability that the patient has *C. difficile. C. difficile* is a clinical diagnosis; no test makes the diagnosis of *C. difficile*. 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 ("pre-test 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 10-15 percent of patients carry *C. difficile*, the PPV for PCR is <50 percent.[25] 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 *C. difficile.*

Examples (See Appendix II)

+ Since the likelihood of *C. difficile* (pre-test 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 *C. difficile* 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 *C. difficile,* as illustrated in Appendix II, and can lead to increased antibiotics, resistance, and cost. Cognizant of the need to not under diagnose *C. difficile* coupled with the desire to not over diagnose *C. difficile* (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.[26]

Secondary Driver > Rule out *C. difficile* 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 *C. difficile* over the last decade, hospitals appropriately try to quickly identify, treat and isolate *C. difficile* cases. The prevalence of *C. difficile* colonization in the community is 3-7 percent. In patients being admitted to the hospital the colonization rate ranges from 4.4-15 percent. But in skilled nursing facility patients the rate of colonization can be as high as 50 percent.[27] Age, source of admission, history of hospitalization and recent use of antibiotics all contribute to the likelihood that a particular patient will have *C. difficile*.

Studies show that only about 5-10 percent of patients who acquire diarrhea in the hospital do so because of *C. difficile*.[28] Underlying medical conditions, tube feeding, laxatives and medications other than antibiotics are among the many non-*C. difficile* causes of diarrhea. Simply stated, more inpatients have diarrhea than have *C. difficile*. Given the need for identification of *C. difficile* and also the need to not over-diagnose *C. difficile*, hospitals should optimize practices for rapid and accurate diagnosis using laboratory tools to aid in the clinical determination of the presence or absence of *C. difficile*.

Change Ideas

+ Establish *C. difficile* testing criteria for diarrhea (e.g., three or more loose stools per day for at least one to two days).[29] (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 *C. difficile* 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.[30]
+ Employ rapid diagnostic testing methods that facilitate prompt *C. difficile* diagnosis, isolation and treatment.
+ Utilize a diagnostic test, such as Polymerase Chain Reaction (PCR), that will enhance the sensitivity and specificity of *C. difficile* diagnosis, but beware of over-diagnosis and possible false positives.
+ Interpret the diagnostic test results only after considering the patient's clinical condition and pre-test probability of having *C. difficile* in order to maximize the positive predictive value of the tests and avoid false (incorrect) diagnosis and unnecessary treatment.

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 *C. difficile* 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.
+ In order 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 *C. difficile;* patients with low pre-test probability would not have tests sent, or if sent, would have heightened clinical review to assess for *C. difficile* should those tests be positive.
+ Consider using both PCR and toxin immunoassays: if both are positive the diagnosis of *C. difficile* is highly likely. If the PCR is positive but toxin is negative, the patient may be a carrier without *C. difficile* or the result might be a false positive

Primary Driver > Prevent *C. difficile* transmission

Prompt *C. difficile* diagnosis is the first step in outbreak prevention and will trigger the isolation precautions and infection control practices designed to prevent *C. difficile* transmission.[31] Fecal incontinence is common in patients with *C. difficile* and the *C. difficile* 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 *C. difficile* transmission within inpatient health care facilities, contact precautions should be instituted quickly after diagnosis.

Secondary Driver > Establish guidelines for the use of contact precautions

Early identification of patients with *C. difficile* and of those suspected of having *C. difficile* provides the opportunity to stop the spread of *C. difficile*. Since the organism can be spread by direct human to human contact or by indirect means through fomites[32,33] (e.g., bed rails, equipment, ear thermometers, etc.), contact precautions are critical to preventing infections of 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 *C. difficile* a significant threat for dissemination and transmission of the disease. The use of presumptive isolation and Contact Precautions have been recommended while awaiting the results of screening for patients who develop health care-associated diarrhea."[34]

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 *C. difficile* prevention, the CDC recommends their use when taking *C. difficile* contact precautions.[35]
+ Continue contact precautions for the duration of hospitalization unless the diarrhea has resolved and the patient has been transferred to another room.
+ Implement chlorhexidine gluconate bathing.[36]
+ Establish protocols to group *C. difficile* 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 length of time from the moment *C. difficile* is suspected to the time of implementation of contact precautions
+ Regular audits measuring time from time *C. difficile* is suspected to the time of implementation of contact precautions
+ Regular audits regarding availability of all necessary contact precaution supplies required 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 particularly important for *C. difficile* prevention as *C. difficile* patients have significant diarrhea and commonly shed spores into their environment. The proper use of disposable gloves can significantly reduce the chance that other staff and visitors will be exposed to the spores. However, since "contamination of the skin and clothing of health care personnel occurs frequently during removal of contaminated gloves or gowns,"[37] and since *C. difficile* spores may be resistant to alcohol-based hand sanitizers, the use of antibacterial soap and warm water before and after treating patients is preferred.[38] Note that the Society for Healthcare Epidemiology of America recommends that settings continue the utilization of alcohol-based hand sanitizer if a *C. difficile* 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 *C. difficile* prevention by explaining the importance of hand hygiene for the patient and all family and visitors and by teaching them effective hand hygiene techniques.[39]
+ Provide patients with a hand sanitizer and emphasize its routine use 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 Appendix V).
+ 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

+ Observe and measure in 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 nosocomial transmission of *C. difficile* to real patients
+ Observe and measure in real time percentage of adherence to degloving protocols
+ Observe and measure the percentage of visitors instructed regarding hand hygiene importance and technique
+ Percentage of patients on contact precautions for *C. difficile* that have education documented regarding the importance of hand hygiene

Secondary Driver > Environmental controls

The hospital environment plays a significant role in the transmission of *C. difficile*. Because *C. difficile* is shed in feces, any environmental surface that becomes contaminated with feces can serve as a source of transmission. *C. difficile* spores can survive on surfaces for as long as five months. *C. difficile* spores were found in 49 percent of the hospital rooms occupied by patients diagnosed with *C. difficile*, and in 29 percent of the rooms of asymptomatic *C. difficile* carriers. The areas found to be most heavily contaminated were hospital room floors, bed rails and bathrooms.[40]
The disinfectants that have historically been used in health care environments are quaternary ammoniums and phenolics, neither of which are sporicidal.[41,42] Environmental Protection Agency (EPA) registered sporicidal agents are now available and should be used for general surface disinfection. Equally 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 and 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 *C. difficile* (e.g., replace electronic thermometers with disposables).
+ Create a visual cue that will show a piece of equipment has been cleaned, such as a paper strip or sign.
+ Utilize 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 percent hydrogen peroxide disinfectant solution on non-shielded areas of the privacy curtains during daily room cleaning and at patient discharge.
+ Utilize a two-step cleaning protocol incorporating mobile, automated equipment which releases ultraviolet-C radiation or hydrogen peroxide vapor.

Suggested Process Measures for Your Test of Change

+ Percentage of proper cleaning 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

To ensure that cleaning and disinfection practices are consistent and effective, monitoring is required. 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 anywhere 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. [43]

Change Ideas

+ Directly observe room cleaning and provide immediate feedback, recommendations and recognition to cleaning staff.
+ Utilize swab cultures to demonstrate the effectiveness of cleaning or identify opportunities for improvement.
+ Use agar slide cultures to quantify microbial surface contamination.
+ Utilize fluorescent markers to indicate physical removal of an applied substance.
+ Utilize 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 service 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

+ Percentage of rooms that are monitored for adherence to your hospital's preferred form of environmental cleaning process(es)
+ 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)
+ Number by unit and/or percentage of environmental service team members recognized or acknowledged for their cleaning processes

Hardwire the Process

+ Utilize a nurse driven protocol such as a diarrhea decision tree (see Appendices VII and III) to trigger contact precautions and *C. difficile* 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, family and visitor hand hygiene, and monitor compliance.
+ Establish cleaning protocols for cleaning solutions that are effective against *C. difficile* 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).

PDSA IN ACTION | TIPS ON HOW TO USE THE MODEL FOR IMPROVEMENT

Choice of Tests and Interventions for *C. difficile* Reduction:

- There are many potentially effective interventions to reduce the risks of *C. difficile*. 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 "the EHR" to arrive to implement prevention strategies. Conduct small tests of change using the resources available, and then upgrade the processes/equipment/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 Environment Services (EVS) professional cleaning one room.

STUDY

Was the protocol clear and understandable?

Were all of 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 to 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?

Identify Potential barriers

- Physicians may resist restrictions to antibiotic prescribing.
- Physicians may feel pressure from patients to prescribe antibiotics.[44]
- Pharmacists may be reluctant to call physicians about inappropriate antibiotics or combinations of antibiotics.
- Clinicians may confuse a positive test for *C. difficile* with a case of *C. difficile*, 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 are not appearing to follow proper precautions and cleaning.
- Leadership WalkRounds™ [45] 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 key to the development of successful antibiotic stewardship.
- Minimizing physician resistance to changing antibiotic prescribing habits is best achieved by leading with the literature that shows the effect of an Antibiotic Stewardship Program (ASP) on improving cures, reducing failures and reducing microbial resistance. Administrative leadership should not lead with "saving money" as the key objective. Physicians are much less likely to respond to this latter approach and may increase their reluctance to participate in an ASP.[46]
- Administrative understanding of the difference between a positive *C. difficile* test and the presence of *C. difficile* is important in overseeing and leading effective *C. difficile* prevention programs.
- Conduct Leadership WalkRoundsTM to understand the concerns of staff, patients and families and identify specific barriers; create a culture of improvement rather than one of blame.[47]

Change not only "The Practice," but also "The Culture"

Development and implementation of (1) a successful ASP, (2) methods to rapidly identify and diagnose *C. difficile*, and (3) optimal protocols to prevent spread of *C. difficile* requires multidisciplinary teamwork and trust. It starts with small tests of change pioneered by new multidisciplinary dyads and triads partnering to try something once and see what can be learned. Larger successes are built upon small successes. Successes then build new lines of communication and slowly the culture changes. Silos are broken down and minds open to new ideas. As the organization finds newer and more successful ways to work together to reduce *C. difficile*, it becomes better able to tackle other opportunities to improve patient care.

PART 4: CONCLUSION & YOUR NEXT STEPS

C. difficile prevention is multi-faceted and cannot be accomplished in silos. Breaking down the approaches into the three primary drivers (antibiotic stewardship, rapid identification and diagnosis and prevention of transmission) can help organizations attack *C. difficile* simultaneously from different angles. Look at the secondary drivers and the change ideas. Check out the references and the Top Ten Checklist. Build upon others' learnings. Gather small multidisciplinary groups of champion clinicians and administrators and design very small tests of change, then take the learnings from them and design new tests. Quickly repeat this PDSA cycle, learning iteratively. Improvement cannot be created in a meeting room. Improvement happens when we learn from doing, and small tests allow for quick learning cycles, and more rapid achievement of improvement goals.

PART 5: APPENDICES

APPENDIX I: *C. difficile* Top Ten Checklist

Associated Hospital/Organization: AHA/HRET HEN 2.0

Purpose of Tool: A checklist to review current or initiate new interventions for *C. difficile* infection prevention in your facility.

Reference: www.hret-hen.org

2016 *C. difficile* Top Ten Checklists

Process Change	In Place	Not Done	Will Adopt	Notes (Responsible and By When?)
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 *C. difficile*, and provide feedback to medical staff and facility leadership.	☐	☐	☐	
Develop processes to minimize testing of patients at low probability for *C. difficile* to minimize false positive polymerase chain reaction results for *C. difficile*.	☐	☐	☐	
Establish a lab-based alert system to immediately notify the infection prevention team and providers of newly-identified patients with positive *C. difficile* lab results; ensure the system includes holiday and weekend notification.	☐	☐	☐	
Remembering that *C. difficile* is a clinical diagnosis and not a lab diagnosis, develop processes where discussion occurs between physicians and other clinicians when a lab test for *C. difficile* is reported as positive.	☐	☐	☐	
Establish cleaning protocols for a cleaning solution that is effective against *C. difficile* spores.	☐	☐	☐	
Utilize a monitoring system to evaluate and validate effective room cleaning, and 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 *C. difficile* 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 PRE-TEST PROBABILITY ON THE LIKELIHOOD THAT TESTS WILL GENERATE TRUE POSITIVES INSTEAD OF FALSE POSITIVES (POSITIVE PREDICTIVE VALUE)

Associated Hospital/Organization: AHA/HRET HEN 2.0

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

Reference: www.hret-hen.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 last 14 days
- Pre-test probability of *C. difficile* is 4.4 – 15 percent (mean 10 percent)[48]

Test to identify *C. difficile* toxin genes (PCR)

- Sensitivity = 95 percent
- Specificity = 95 percent
- Pre-test probability of *C. difficile* (prevalence)= 10 percent

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

- 100 patients would have *C. difficile*
- 900 would not have *C. difficile*
- The test with a sensitivity of 95 percent would identify 95 of the 100 patients with *C. difficile* (95 true positives) and miss 5 of the 100 with *C. difficile* (5 false negatives)
- The test with a specificity of 95 percent would accurately be negative for the 95 percent of the 900 patients without *C. difficile* (855 true negatives) but would also misidentify 5 percent of the 900 without *C. difficile* as (45 false positives) as falsely having *C. difficile*.

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

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

Note: If the patient had a pre-test probability of 5 percent, 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
- Pre-test probability of *C. difficile* is approximately 50 percent[49]

Test to identify *C. difficile* toxin genes (PCR)

- Sensitivity = 95 percent
- Specificity = 95 percent
- Pre-test probability of *C. difficile* = 50 percent

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

- 500 patients would have *C. difficile*
- 500 would not have *C. difficile*
- The test with a sensitivity of 95 percent would identify 475 of the 500 patients with *C. difficile* (475 true positives) and miss 25 of the 100 with *C. difficile* (25 false negatives)
- The test with a specificity of 95 percent would accurately be negative for the 95 percent of the 500 patients without CDI (475 true negatives) but would also misidentify 5 percent of the 900 without *C. difficile* as (25 false positives) as falsely having *C. difficile*.

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

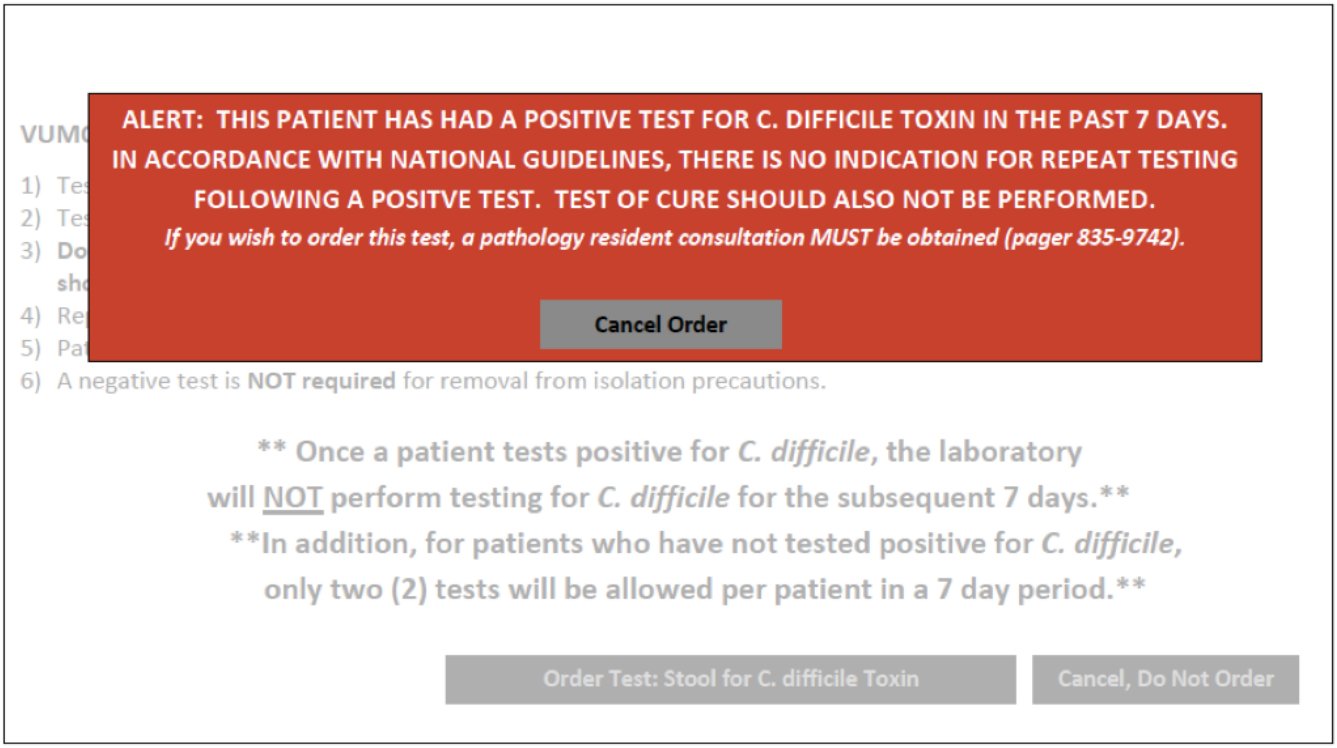
Of the 475 + 25 (500) total negatives the test identified, 475/500 = **95 percent would be true negatives (NPV).**
The false negative rate would be 5 percent.

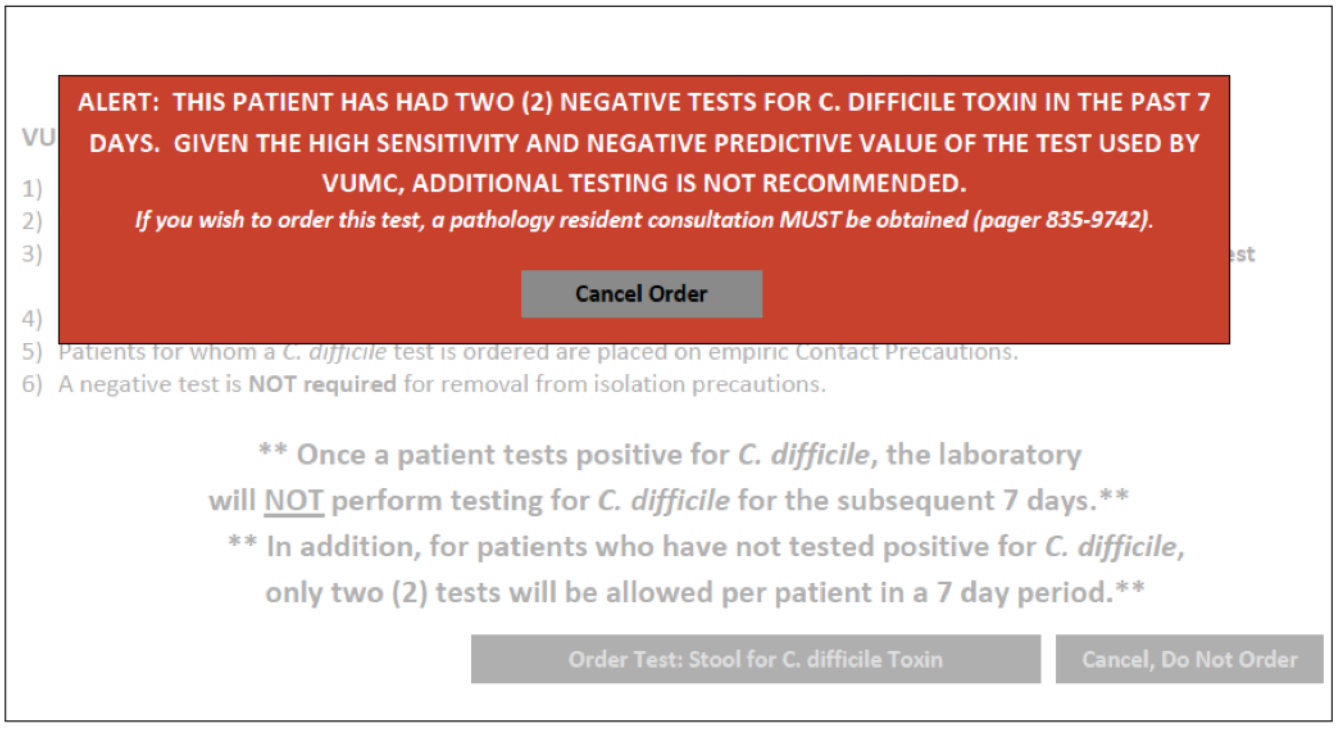
APPENDIX III: VANDERBILT EHR SCREENSHOTS

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

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

Reference: N/A





APPENDIX III: VANDERBILT EHR SCREENSHOTS (CONTINUED)

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, CA

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

Reference: N/A

ENHANCED CONTACT PRECAUTIONS

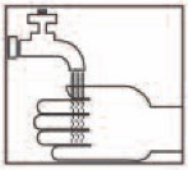
ALL FAMILY & VISITORS REPORT TO NURSES' STATION

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 SIGN FROM CALIFORNIA PACIFIC MEDICAL CENTER (CPMC), SAN FRANCISCO, CA (CONTINUED)

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

Associated Hospital/Organization: Centers for Disease Control and Prevention

Purpose of Tool: 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

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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 Tool: Recognition/acknowledgment tool for environmental services workers who adhere to hospital standards for room cleaning.

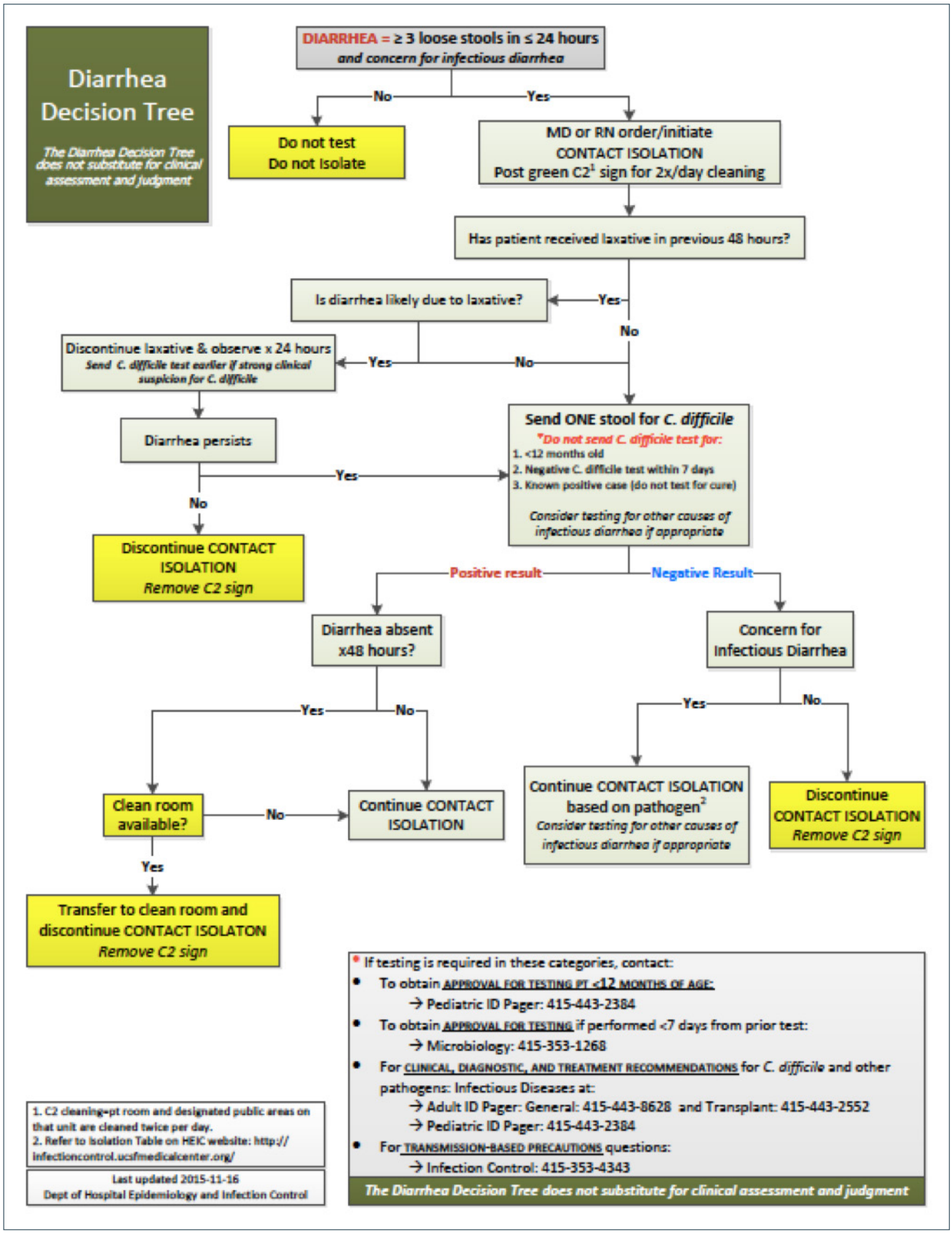
Reference: N/A

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: N/A

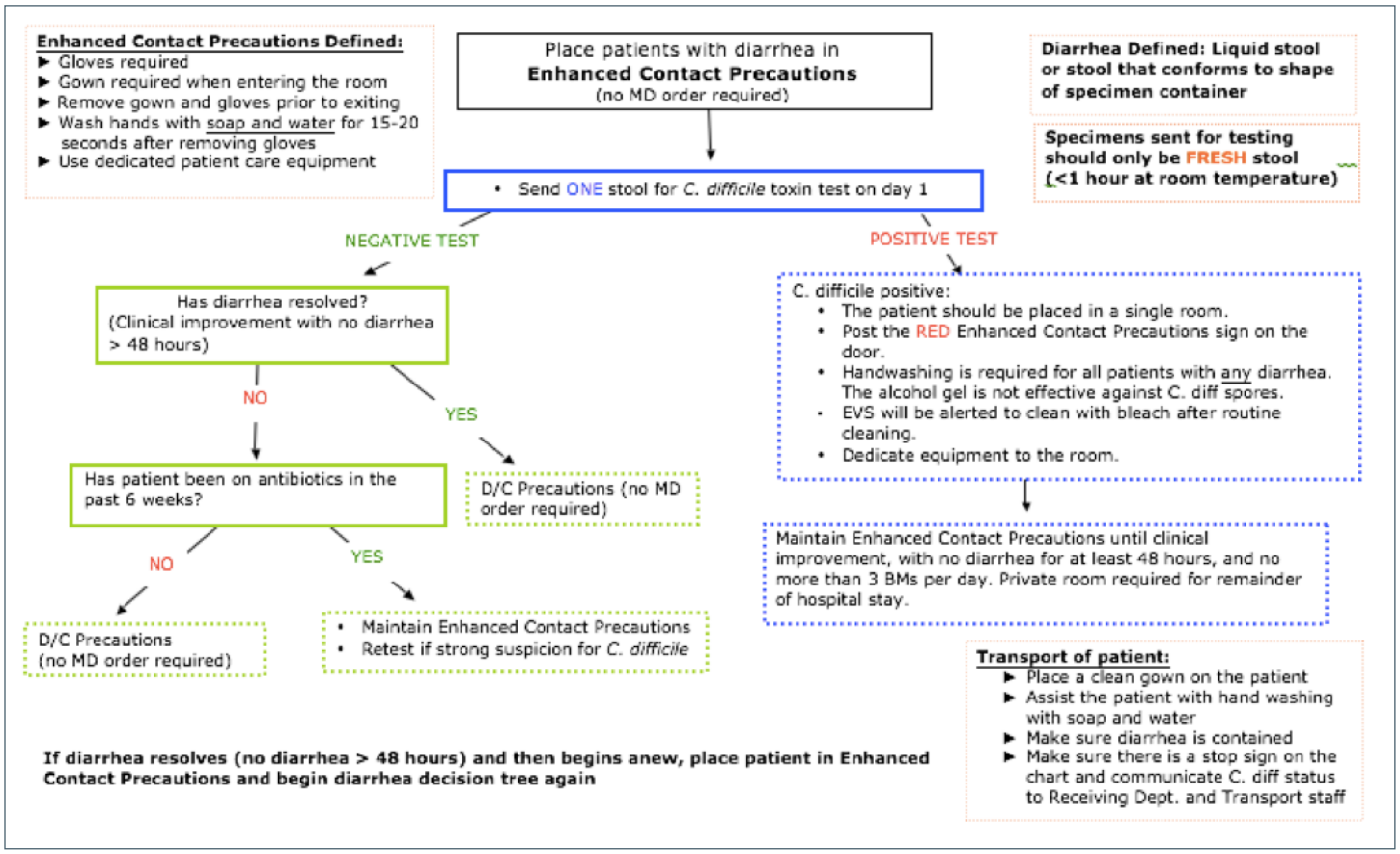


APPENDIX VIII: DIARRHEA/ENHANCED CONTACT PRECAUTIONS DECISION TREE FROM CALIFORNIA PACIFIC MEDICAL CENTER (CPMC), SAN FRANCISCO, CALIFORNIA

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

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

Reference: N/A



APPENDIX IX: CDC ENVIRONMENTAL CHECKLIST FOR MONITORING TERMINAL CLEANING

Associated Hospital/Organization: Centers for Disease Control and Prevention

Purpose of Tool: Provides environmental services 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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