Department of Veterans Affairs

Memorandum

Date: MAR 2 9 2012

From: Acting Assistant Deputy Under Secretary for Health for Operations and Management for Clinical Operations (10NC)

Subj: Implementation of Guideline for Prevention of *Clostridium difficile* Infection (CDI) in Veterans Health Administration (VHA) Acute-Care Facilities (VAIQ # 7210267)

To: Network Directors (10N1-23)
Facility Directors (00)

1. To support the Secretary's initiative to decrease health care associated complications, the National Infectious Diseases Service (NIDS) expanded the Methicillin-Resistant *Staphylococcus* Aureus (MRSA) Prevention Initiative to include other pathogens in Fiscal Year (FY) 2011. This expanded initiative had been renamed the Multi-drug Resistant Organisms (MDRO) Prevention Initiative and an associated Task Force has been chartered. Based on recommendations from the Task Force, the first focus of the expansion will be on the health care associated complication of CDI.

2. A workgroup consisting of infection control professionals and infectious diseases experts, in collaboration with the Centers for Disease Control and Prevention (CDC), NIDS and MDRO Prevention Initiative project management team developed the Guideline for Management of *Clostridium difficile* Infection in VHA Inpatient Acute-Care Facilities (see attached).

3. In FY 2012, there will be a series of three required training webinars hosted by the MDRO Prevention Initiative project management team with VHA facility MRSA Prevention Coordinators. These calls will introduce the basic tenets of the CDI Prevention Initiative, building upon the successful bundle of practices used in the MRSA Prevention Initiative which resulted in significant nationwide reductions of MRSA health care associated infections in VHA. The topic of the first webinar will be the CDI disease process. The second webinar will expand on CDI guideline implementation at the facility level, and the third webinar will focus on monitoring and measures associated with the CDI Prevention Initiative. This initiative will expand into the Community Living Centers and outpatient venues in the future.

4. There will be a mandatory initial call with all facility MDRO Prevention Coordinators (MPCs) and Veterans Integrated Service Network liaisons to give further details regarding the implementation of the CDI guideline and upcoming webinars, discuss funding, and to address other relevant questions and issues. Someone from the MDRO Prevention Initiative office will reach out to facility MPCs within ten business days to coordinate a conference call time.

Subj: Implementation of Guideline for Prevention of *Clostridium difficile Infection* (CDI) in Veterans Health Administration (VHA) Acute-Care Facilities (VAIQ # 7210267)

5. Acute-care facilities are required to implement change in processes as indicated in the Guideline for CDI within 90 days of signature of this memorandum. Monitoring and reporting of identified CDI cases for the first phase of this initiative will be completed only for patients admitted to inpatient acute-care facilities. In order to evaluate the program, data will be entered into the VHA National Inpatient Evaluation Center (IPEC) database. CDI Data Reporting Guidelines will be issued to the MRSA Prevention Coordinators at VHA acute-care facilities.

6. Questions and concerns regarding the implementation process should be referred to Dr. Martin Evans, MDRO Prevention Initiative Director, via email VHAMRSAProgramOffice@va.gov or by telephone at (859) 381-5821.

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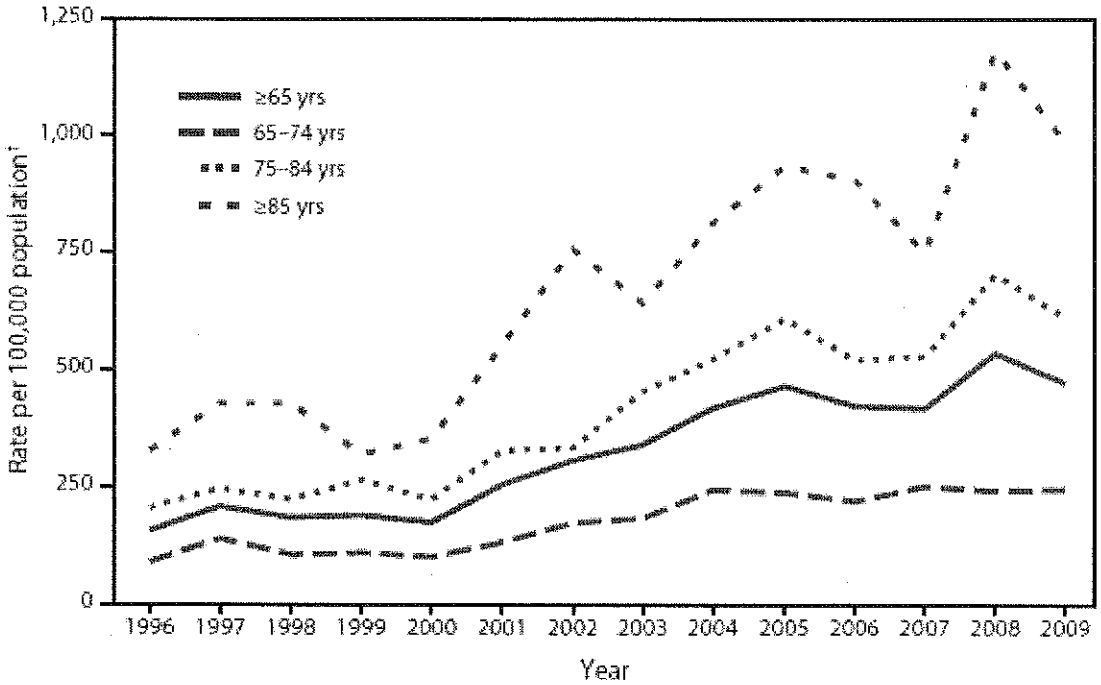
Attachment

Guideline for the Prevention of *Clostridium difficile* Infection in VHA Inpatient Acute-Care Facilities

BACKGROUND

Data from a National Hospital Discharge Survey show that *Clostridium difficile* infection (CDI) rates among older hospitalized patients are increasing in the United States (Figure)[1].



In VA, the estimated incidence of CDI among Veterans, based on ICD-9-CM codes from 2010, was approximately 10.4 cases/1,000 discharges with 2% of patients over age 65 carrying the diagnosis of CDI during that year. Since the average length of stay is 4-5 days for most inpatients, the incidence may be as high as 20 cases/10,000 patient-days. Although comparable data are sparse, a statewide survey of Ohio hospitals in 2006, which looked at only hospital-onset CDI cases, reported an incidence of 6.4 to 7.9 cases/10,000 patient-days[2].

Because CDI is an important cause of morbidity and mortality among Veterans in acute-care inpatient facilities, the Multi-Drug Resistant Organism (MDRO) Prevention Initiative of the VA Infectious Diseases Service will implement an Initiative to decrease the incidence and prevalence of this disease among our patients.

RECOMMENDATIONS FOR THE CONTROL OF CDI

The CDI Bundle

To decrease the incidence of *C. difficile* infection in the acute care setting, VHA will employ a bundle of infection control strategies comprised of 1) environmental management, 2) hand hygiene, 3) Contact Precautions for those with symptomatic CDI, and 4) a cultural transformation where infection control becomes everyone's business. This compares to the MRSA bundle as follows:

Table 1. Comparison of CDI and MRSA Bundles

CDI Bundle	MRSA Bundle
Environmental Management	Active Surveillance
Hand Hygiene	Hand Hygiene
Contact Precautions	Contact Precautions
Cultural Transformation	Cultural Transformation

Note that principles of the CDI Bundle follow those of the successful MRSA bundle except that there will be a formal emphasis on Environmental Management and active surveillance will not be done.

Environmental management

A. *C. difficile* room cleaning and disinfection. Cleaning and disinfection is a two-step process. Step 1: Use a detergent to clean. The detergent removes soil and organic material and allows the disinfectant to have a maximum effect. Step 2: Use a disinfectant to inactivate microorganisms. In general, detergents for cleaning do not disinfect and disinfectants do not clean.

1) Terminal/discharge room cleaning and disinfection

a) Step 1: Use an Environmental Protection Agency (EPA)-registered hospital detergent to clean surfaces in rooms, paying particular attention to high-touch surfaces (e.g., bed rails, bed surfaces/controls, overbed tables/handles, nurse call bells/buttons, telephones, TV remote controls, bedside table/drawer handles, supply cart, light switches, faucet handles, sinks, toilet handles/seat, bathroom grab bar, intravenous pump, etc.[3]).

b) Step 2: After dirt and organic material have been removed from surfaces with the detergent, use an EPA-registered hospital disinfectant that has been approved for elimination of *C. difficile* spores.

1) Follow the manufacturer's directions and approved VA Environmental Programs Service guidelines when preparing chemicals and during the cleaning process.

2) The product should be applied to the surface and remain wet based on the manufacturer's instructions for use as a disinfectant.

3) A combination product (detergent/sporicide) can be used for items a) and b) above, but a combination product still requires 2 steps. Always clean the surface prior to disinfecting.

c) Appropriate times for terminal cleaning and disinfection include 1) upon transfer within the facility, 2) upon discharge from the facility, or 3) after the patient is released from Contact Precautions for CDI (see *Infection Prevention and Control* section below).

d) Items sent from CDI isolation rooms to Sterile Processing Services (SPS) or other areas for cleaning and disinfection should be wiped down with an EPA-registered hospital detergent/disinfectant in accordance with manufacturer's guidelines, or be bagged or covered with fluid-impermeable material before removal from the room.

e) Use an EPA-registered hospital detergent/disinfectant to clean any reusable medical equipment (RME) present (e.g., vital sign monitors, pulse oximeters, blood pressure cuffs, etc.) in accordance with manufacturer's guidelines.

2) Daily room cleaning and disinfection

a) High touch surfaces[3] should be cleaned daily with an EPA-registered detergent/disinfectant.

b) A product approved by EPA for eliminating *C. difficile* spores is preferred, but not required, for daily use.

3) Monitoring and feedback to Environmental Management Service (EMS) staff

a) EMS Quality Assurance programs should include monitoring of the thoroughness of cleaning by EMS staff and should be documented. Feedback to EMS staff on performance should be given routinely.

b) Bacterial cultures should not be used for monitoring except in a research setting. Recommended methods for monitoring include:

1) Observation of performance,

2) Fluorescent marker, or

3) Adenosine triphosphate (ATP) bioluminescence assay.

B. Education

1) There should be a yearly update for EMS employees to cover:

a) The epidemiology of *C. difficile* and MDROs,

b) The important role of EMS in controlling *C. difficile* and MDROs,

c) Current status of VA programs to control *C. difficile* and MDROs.

2) EMS should have a feedback process for staff to make suggestions on ways to improve cleaning and methods for monitoring MDROs as a whole.

Infection Prevention and Control

Hand Hygiene:

Hand hygiene should be in compliance with VHA Directive 2011-007 (Required Hand Hygiene Practices)[4]. Instruct visitors and healthcare workers to wash hands with an antimicrobial soap and water after caring for or having contact with patients with CDI[4-5]. It may be of value to develop a sign or other indicator(s) to alert healthcare workers and visitors to the need for use of soap and water instead of alcohol-based hand sanitizers in these situations. Alcohol-based hand sanitizers should remain for general use in the hospital, however, because they lead to greater overall hand hygiene adherence and are effective in preventing transmission of non-spore forming organisms. Furthermore, there is limited evidence that adoption of these products leads to increased CDI rates[6].

Contact Precautions:

Patients with confirmed CDI, as well as those with suspected CDI awaiting test results, should be placed in Contact Precautions[7] with dedicated equipment[5].

Healthcare workers entering a Contact Precautions room for a patient with CDI should don gown and gloves upon room entry and discard the items before exiting the room.[7]

Patients with confirmed CDI and their families should receive education regarding *C. difficile* infection and transmission prevention strategies to use in the hospital and at home. These patients should be kept in Contact Precautions for the duration of diarrhea plus at least 48 additional hours after diarrhea resolves. They may, however, go home or be transferred to another facility in the interim if ready for discharge.

There should be no tests done to determine "cure" of CDI before transferring the patient to another facility. If the patient with CDI is transferred to another facility, his/her CDI status should be reported and documented as part of the transfer communication process.

If rates of patients with symptomatic CDI remain unacceptably high despite implementation of basic prevention measures[5], it may be necessary to consider keeping patients in Contact Precautions until discharge from the hospital, since patients may shed *C. difficile* spores for an extended period after resolution of diarrhea[8-9]. This decision should be made by local Infection Prevention and Control personnel. If the availability of isolation beds becomes an issue, priority could be given to patients who are incontinent and cannot, or do not, follow basic personal hygiene practices.

It is recommended that compliance with Contact Precautions be monitored.

A private room should be used if possible, especially if the patient is incontinent of stool.

Use of electronic rectal thermometers should be avoided because the handles may become contaminated with *C. difficile* spores[10]. Limiting devices such as stethoscopes, blood pressure cuffs, pulse oximeters, glucometers and other Reusable Medical Equipment (RME) that are normally used for multiple patients should be considered. If sharing of RME must occur, the equipment should be adequately cleaned and disinfected between patients according to manufacturer instructions.

Transport of patients outside their rooms should be limited in the acute care setting to medically-necessary purposes[7].

Readmission:

Patients with a history of CDI should be placed in Contact Precautions *if they have diarrhea* at the time of readmission.

Screening and decolonization:

Asymptomatic patients should not be screened for *C. difficile*[5].

Metronidazole and vancomycin should not be used for decolonization or prophylaxis of CDI[11].

Antimicrobial stewardship:

A separate initiative for antimicrobial stewardship complementary to the CDI Prevention Initiative has begun.

Cultural Transformation

It is the intent of this Initiative to interrupt the transmission of *C. difficile* and decrease the number of patients at risk for *C. difficile* infection or colonization. Facilities are given the responsibility to define and implement appropriate precautions, and the freedom to be flexible to meet the needs of patients yet maintain the goal of preventing disease transmission. The goal should be to nurture an institutional culture change or transformation where Infection Prevention and Control becomes everyone's responsibility and a natural component of care during each patient encounter. In keeping with the tenets of culture change, all healthcare providers should be actively engaged in, and work with facility leadership, MDRO Prevention Coordinators, Infection Prevention and Control Professionals, and other staff to implement changes that prevent the transmission of *C. difficile*.

Laboratory testing/diagnosis

Clinicians should be encouraged to assess new admissions for the presence of diarrhea, and to submit specimens for testing for CDI only if the patient has had ≥3 liquid stools within 24 hours.

Only diarrheal stools (defined as stools that take the shape of their container) should be tested for *C. difficile* or its toxins. Other specimens sent for *C. difficile* testing should be rejected by the laboratory.

Tests available for diagnosis of CDI have variable sensitivity and specificity (Table 2). A molecular method is preferred and should be used for VA clinical specimens because of its high sensitivity and specificity and fast turn-around time.

The toxin A/B EIA or GDH assays, used alone, are not preferred because of their relatively low sensitivity. When the GDH assay is used alone as a screening test for toxigenic strains, it has a false positivity rate close to 20% since it detects both toxigenic and non-toxigenic strains of the organism[12]. When the GDH assay and toxin A/B EIA are combined as a two-step method, the assay may have suboptimal sensitivity because of variability in the sensitivity of the screening GDH test when used against different *C. difficile* strain types (O27 vs. non-O27)[13], and the low sensitivity of the confirmatory component (toxin A/B EIA)[14-18]. Society for Healthcare Epidemiology of America-Infectious Diseases Society of America (SHEA-IDSA) Guidelines recommend a two-step method using GDH with positives confirmed by the cell culture cytotoxin assay or toxigenic culture[5], but this approach is not preferred for the purposes of this Initiative because of the laboratory expertise and turnaround time required.

Table 2. Performance of tests for *C. difficile*[13-17, 19]

Test	Sensitivity (%)	Specificity (%)	Turn-Around Time
Toxin A/B enzyme immunoassay (EIA)	40-80	90	hours
Glutamate dehydrogenase (GDH)	70-80	<90	hours
Combined GDH & toxin A/B EIA	56-90	>90	hours
DNA amplification (molecular)	>90	>97	hours
Cell culture cytotoxin assay	70-80	>97	2 to >3d
Toxigenic culture	>90	95-97	2 to >3d

Negative tests for *C. difficile* should not be repeated within a 7-day period[20]. Repeated testing may increase the perceived CDI rate if it enriches false positives due to imperfect specificity[19, 21].

Only one stool per patient should be tested per week unless approved by the Clinical Laboratory Service.

Testing should never be done as a test of cure or to assess the cause of continuing diarrhea since *C. difficile* may persist in the gastrointestinal tract

for a prolonged time without causing disease. If diarrhea continues, consider consultation with Gastroenterology for colonoscopy.

It may be useful to track the time between requests for stool to be sent to the lab and the time that the stool is actually sent if timely collection of stool samples is an issue.

Initiative Evaluation and Case Reporting

A clinically confirmed CDI case will be defined as a patient with 1) diarrhea, and 2) a stool test result positive for the presence of toxigenic *C. difficile* or its toxins or colonoscopic or histopathologic findings of pseudomembranous colitis[5].

For the purposes of this Initiative, CDI laboratory testing will be done, and cases identified, only when the test is ordered by a physician during the evaluation of a compatible illness. Testing for *C. difficile* or its toxins will not be done for asymptomatic patients.

Monitoring and reporting of identified CDI cases for the first phase of this Initiative will be done only for patients admitted to inpatient acute-care facilities. The Initiative will expand into the Community Living Center and outpatient venues in the future.

Data will be collected only on a facility level and for Spinal Cord Injury Units.

Data elements will be similar to those used by the Center for Disease Control and Prevention's National Healthcare Safety Network (NHSN) (available at http://www.cdc.gov/nhsn/PDFs/pscManual/12pscMDRO_CDADcurrent.pdf) with modifications specific to VA.

Data will be entered monthly by each facility into the VA Inpatient Evaluation Center (IPEC) database. A CDI Data Reporting User Manual will be made available with complete instructions on data entry.

Goal

The goal of this CDI Prevention Initiative is to reduce national healthcare facility-onset (those occurring >48 hours after admission)[5] CDI case rates to zero or by 30% below baseline within two years of full implementation of the program.

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THIS GUIDELINE WAS DEVELOPED BY AN EXPERT ADVISORY GROUP FOR *C. DIFFICILE*.

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