

COLORADO INFECTION PREVENTION COLLABORATIVE C.DIFFICILE INFECTIONS







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EXECUTIVE SUMMARY

Healthcare-associated infections (HAIs) are among the top 10 leading causes of death in the United States.¹ The World Health Organization (WHO) estimates that every day approximately 247 people die in the United States from a healthcare-associated infection. This is equivalent more than 90,000 deaths annually.² These infections place a significant financial burden on the healthcare system at a time when many are watching the bottom line. Estimates for the annual direct cost of HAIs to inpatient hospitals run between \$28.4 billion and \$33.8 billion.²

This tool kit is the result of a collaborative effort between the Colorado Department of Public Health and Environment (CDPHE), the Colorado Hospital Association (CHA), and participating acute care hospitals, long-term care facilities, and ambulatory surgical centers. In 2009, CDPHE was awarded American Recovery and Reinvestment Act (ARRA) funding through the Centers for Disease Control and Prevention (CDC) to assist Colorado healthcare facilities in their efforts to eliminate HAIs. A portion of this funding was dedicated to the implementation of an Infection Prevention Collaborative.

Colorado healthcare facilities were surveyed to identify two focus areas for prevention. Surgical-site infections (SSI) and *Clostridium difficile* infections (CDI) were selected from a list of potential healthcare-associated targets. Goals of the project include working toward achieving national five-year prevention targets established by the U.S. Department of Health and Human Services. The goal for CDI prevention was to reduce the median healthcare-facility onset-incidence rate in Colorado by at least 15% of baseline by November 17, 2011. The goal for SSI prevention was a reduction in SSI standardized incidence ratio (SIR) by at least 25% from baseline. The Collaborative aimed to reach these goals by achieving 90%–95% adherence rates to evidence-based preventive measures. This tool kit compiles resources used by partners participating in the Infection Prevention Collaborative to reach project goals. The purpose is to provide healthcare facilities with a compendium of resources inclusive of the most current recommended practices for prevention of the two chosen targets, SSI and CDI. Healthcare facilities have also provided their own improvement stories describing their efforts in implementing and sustaining core preventive strategies during the project. These improvement stories provide an invaluable resource for others to learn from the experiences of similar institutions.

This tool kit is organized into the following sections:

COLLABORATION

Preventing HAIs cannot be accomplished by a single person, a single department, or even a single facility. Infection prevention and control is an enormous charge that cannot be achieved in a silo. Infection preventionists are key members of the healthcare team, and they must continue to collaborate with key stakeholders within their healthcare facilities, as well as across acute and non-acute settings, to win the battle against HAIs.

continued >

"Collaboration, rather than competition, should be the hallmark of elimination efforts."³

- Peter Pronovost, Author of Safe Patients, Smart Hospitals



COLORADO INFECTION PREVENTION COLLABORATIVE

EXECUTIVE SUMMARY

<u>Prevention of</u> <u>C. Difficile infections (CDI)</u>

This section will provide resources and an overview of evidence-based practices related to the prevention of *C. difficile* in the healthcare environment. The following topics are covered and are based on preventive measures implemented during the project:

- Surveillance and lab-testing methods
- Hand hygiene compliance
- Environmental cleaning
- Contact precautions and isolation
- Antibiotic stewardship

A data summary for the collaborative focus area is also included at the end of this section.

<u>Prevention of</u> <u>Surgical-Site Infections (SSI)</u>

This section will provide resources and an overview of evidence-based practices related to the prevention of surgical site infections in hospitals and ambulatory surgical centers. The following topics, based on preventive measures implemented during the project, are covered:

- Surveillance
- Surgical-site checklist
- Appropriate administration of antibiotics
- Preoperative prevention measures
- Intra- and postoperative prevention measures

A data summary for the collaborative focus area is also included at the end of this section.



COLORADO INFECTION PREVENTION COLLABORATIVE



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COLLABORATION

In recognition of the unacceptable morbidity and mortality associated with HAIs, the Association for Professionals in Infection Control (APIC), the Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA), the Association of State and Territorial Health Officials (ASTHO), the Council of State and Territorial Epidemiologists (CSTE), Pediatric Infectious Disease Society (PIDS), and the Centers for Disease Control and Prevention (CDC) jointly published a white paper— *Moving toward Elimination of Healthcare-Associated Infections: A Call to Action*—to propose a framework of prevention to ultimately eliminate these infections.³

The authors outline the importance of implementing evidence-based practices, aligning financial incentives to promote strategies that will reduce HAIs, addressing gaps in knowledge, and making efforts to monitor progress through data collection. Additionally, there is acknowledgment by the authors, as well as other experts in the field, that collaborative relationships among diverse groups in the healthcare community are necessary components to the successful implementation of preventive efforts.

Collaboration is defined as working jointly with others or together, especially in an intellectual endeavor. It is also cooperating with an agency or instrumentality with which one is not immediately connected.⁴ Collaboration is more than teamwork. Effective collaboration is a dynamic process that involves shared planning, decision making, problem solving, goal setting, and effective communication.⁵

Collaboration must occur among diverse groups—including hospital leadership and administration, healthcare providers, patients, consumers, and legislators—in order to win the battle against HAIs.³ Fostering internal relationships will ensure that needed action is taken and that momentum to reach project goals is sustained. External relationships should not be ignored, as fellow infection-prevention staff can broaden one's own knowledge and lead to innovative solutions to common problems. Collaboration with specific clinical groups, such as surgical teams and infectious-disease specialists, can help the infection preventionist eliminate avoidable healthcare-associated infections. While this goal may seem lofty, it is attainable. Collaborative relationships can help to build creative approaches to the implementation of best practices and ensure adequate frameworks are in place to work toward the elimination of HAIs.

FACTORS INFLUENCING SUCCESS IN COLLABORATION⁶

This diagram illustrates six factors that must be addressed for any collaborative partnership to be successful. Consider whether these factors are being addressed in improvement projects requiring teamwork and expertise from others.



"Alone we can do so little. Together we can do so much."

– Helen Keller



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THE FACTS ABOUT CLOSTRIDIUM DIFFICILE

Clostridium difficile (*C. difficile*) is a spore-forming gram-positive bacteria that is a common cause of antibiotic-associated diarrhea and more serious intestinal conditions, such as colitis and even death. Ingestion of the spores creates the production of toxins, promoting the onset of symptoms, including diarrhea, abdominal pain, nausea, and loss of appetite.⁷

QUICK FACTS:

The rate and severity of *Clostridium difficile*-associated disease (CDAD) have been increasing across a variety of hospital and healthcare settings in the United States.

- Hospital discharges with diagnoses of CDI more than doubled from 2001 to 2005, from 149,000 cases to more than 300,000.⁸
- Deaths due to CDI have also increased with 5.7 per million deaths in 1999 and 23.7 per million being reported in 2007.⁹

Much of the increased severity in disease is thought to be associated with the more virulent strain known as BI/NAP1/027.

For each patient suffering a hospital-acquired *C. difficile* infection¹⁰:

- An average of 2.6 to 4.5 days is added to the length of stay.
- An additional \$2,470–\$3,669 in costs is added per episode.
- An additional \$5,042–\$7,179 is added to inpatient costs in the six months following diagnosis.
- Discharge to a long-term care facility is twice as likely, increasing the spread of CDI to these facilities.

According to the CDC, *C. difficile* is being reported in "low-risk" populations, including healthy people in the community and peripartum women.

C. *difficile* surpasses MRSA as the leading cause of nosocomial infections in community hospitals.¹¹

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THE FACTS ABOUT CLOSTRIDIUM DIFFICILE

PREVENTION

This compendium of practice recommendations was sponsored and authored by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). Partners in this work were the Association for Professionals in Infection Control and Epidemiology (APIC), The Joint Commission, and the American Hospital Association (AHA). The full compendium of strategies to prevent HAIs was published in October 2008. The document presented in this tool kit is intended to highlight practical recommendations designed to aid acute care hospitals in their prevention efforts against *Clostridium difficile*. The table below describes the strength and quality of evidence used to develop each recommendation. Following this table is a summary of basic practices for prevention and monitoring of CDI, which are recommended for all acute care hospitals. For a more detailed discussion of these and additional supplemental strategies, refer to the full compendium. This document is available at the end of this section.

CATEGORY/GRADE	DEFINITION			
STRENGTH OF RECOMMENDATION				
А	Good evidence to support a recommendation for use			
В	Moderate evidence to support a recommendation for use			
С	Poor evidence to support a recommendation for use			
QUALITY OF EVIDENCE				
Ι	Evidence from one or more properly randomized controlled trials			
II	Evidence from one or more well-designed clinical trials, without randomization; from cohort or case-control analytic studies (preferably from more than one center); drawn from multiple time series; or from dramatic results from uncontrolled experiments			
III	Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees			

Adapted from the Canadian Task Force on the Periodic Health Examination.¹²



COLORADO INFECTION PREVENTION COLLABORATIVE

THE FACTS ABOUT CLOSTRIDIUM DIFFICILE

Best practices for prevention and monitoring of C. *difficile*:

- 1. Use contact precautions for infected patients, with a single-patient room preferred (A-II for hand hygiene, compendium of strategies to prevent HAIs S17 A-I for gloves, B-III for gowns, and B-III for single patient room).
- 2. Ensure cleaning and disinfection of equipment and the environment (B-III for equipment and B-II for the environment).
- 3. Implement a laboratory-based alert system to provide immediate notification to infection-prevention-andcontrol personnel and clinical personnel about patients with newly diagnosed CDI (B-III).
- 4. Conduct CDI surveillance and analyze and report CDI data (B-III).
- 5. Educate healthcare personnel, housekeeping personnel, and hospital administration about CDI (B-III).
- 6. Educate patients and their families about CDI, as appropriate (B-III).
- 7. Measure compliance with Centers for Disease Control and Prevention or World Health Organization hand hygiene and contact-precaution recommendations (B-III).

Special approaches for the prevention of CDI when control is difficult:

These special approaches are recommended for use in locations and/or populations within the hospital for which outcome data and/or risk assessment suggest lack of effective control despite implementation of basic practices.

Minimize C. *difficile* transmission by healthcare personnel:

- 1. Intensify the assessment of compliance with process measures (B-III).
- 2. Perform hand hygiene with soap and water as the preferred method before exiting the room of a patient with CDI (B-III).
- 3. Place patients with diarrhea under contact precautions while *C. difficile* test results are pending (B-III).
- 4. Prolong the duration of contact precautions after the patient becomes asymptomatic until hospital discharge (B-III).

Minimize CDI transmission from the environment:

- 1. Assess the adequacy of room cleaning (B-III).
- 2. Use sodium hypochlorite (bleach)–containing cleaning agents for environmental cleaning. Implement a system to coordinate with the housekeeping department if it is determined that sodium hypochlorite is needed for environmental disinfection (B-II).

Reduce the risk of CDI acquisition:

1. Initiate an antimicrobial stewardship program (A-II).

Approaches that should not be considered a routine part of CDI prevention:

- 1. Do not test patients without signs or symptoms of CDI for C. *difficile* (B-II).
- 2. Do not repeat *C. difficile* testing at the end of successful therapy for a patient recently treated for CDI (B-III).

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S81 INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY OCTOBER 2008, VOL. 29, SUPPLEMENT 1

SUPPLEMENT ARTICLE: SHEA/IDSA PRACTICE RECOMMENDATION

Strategies to Prevent Clostridium difficile Infections in Acute Care Hospitals

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PURPOSE

Previously published guidelines are available that provide comprehensive recommendations for detecting and preventing healthcare-associated infections. The intent of this document is to highlight practical recommendations in a concise format designed to assist acute care hospitals in implementing and prioritizing their *Clostridium difficile* infection (CDI) prevention efforts. Refer to the Society for Healthcare Epidemiology of America/Infectious Diseases Society of America "Compendium of Strategies to Prevent Healthcare-Associated Infections" Executive Summary and Introduction and accompanying editorial for additional discussion.

SECTION 1: RATIONALE AND STATEMENTS OF CONCERN

1. Increasing rates of CDI

C. difficile now rivals methicillin-resistant *Staphylococcus aureus* (MRSA) as the most common organism to cause healthcare-associated infections in the United States.⁴

a. In the United States, the proportion of hospital discharges in which the patient received the International Classification of Diseases, Ninth Revision discharge diagnosis code for CDI more than doubled between 2000 and 2003,¹ and CDI rates continued to increase in 2004 and 2005 (L. C. McDonald, MD, personal communication, July 2007). These increases have been seen in pediatric and adult populations, but elderly individuals have been disproportionately affected.¹ CDI incidence has also increased in Canada and Europe.²⁻⁴

b. There have been numerous reports of an increase in CDI severity.²⁻⁶

c. Most reports of increases in the incidence and severity of CDI have been associated with the BI/NAP1/027 strain of *C. difficile.*²⁻⁶ This strain produces more toxins A and B in vitro than do many other strains of *C. difficile*, produces a third toxin (binary toxin), and is highly resistant to fluoroquinolones.

2. Outcomes associated with CDI

CDI is associated with increased lengths of hospital stay, costs, morbidity, and mortality among adult patients. Data on the changing epidemiology of CDI in pediatric patients are limited and are confounded by the prevalence of asymptomatic carriage of *C. difficile* among children younger than 12 months of age.^{7,8}

a. CDI increases mean length of hospital stay from 2.6 days to 4.5 days.^{9,10}

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b. Attributable costs of inpatient CDI have been estimated to be \$2,470-\$3,669 per episode. Attributable inpatient costs during the 6 months after CDI diagnosis are \$5,042-\$7,179.^{10,11} US hospital costs for CDI management have been estimated to be \$3.2 billion per year.¹²

c. Patients with CDI were almost twice as likely to be discharged to a long-term care facility than were propensity score–matched control individuals.⁹

d. CDI has recently been associated with an attributable mortality rate of 6.9% at 30 days after diagnosis and 16.7% at 1 year.^{34,9}

3. Changing risk factors and possible decrease in CDI treatment response rates

a. Fluoroquinolones, previously infrequently associated with CDI, have been found to be one of the primary predisposing antimicrobials in recent studies.^{3,6,13,14}

i. Virtually every antibiotic has been associated with CDI. Cephalosporins, ampicillin, and clindamycin remain important predisposing antibiotics.

b. Gastric acid suppression has been recognized as a risk factor for CDI in some studies.^{14,15}

i. Some studies suggest that the association between gastric acid suppression and CDI are related to other important risk factors, such as severity of illness and age.^{14,16}

ii. Gastric acid suppression may be an important risk factor for CDI outside of healthcare facilities.¹⁵

c. Several studies suggest that rates of response to treatment of CDI with metronidazole are declining; these studies include a randomized, prospective, blinded, and severity-stratified study that demonstrated statistically superior rates of response to vancomycin treatment for severe disease but not for mild disease, compared with metronidazole treatment.^{17,19}

SECTION 2: STRATEGIES TO DETECT CDI

1. Surveillance definitions

Definitions for CDI surveillance in the United States and Europe have recently been published.^{20,21}

a. In the United Kingdom, all cases of CDI in patients older than 65 years of age have been reported to the healthcare-associated infection surveillance system for National Health Service Acute Trusts in England since January 2004.²² Reporting for all CDI cases in patients older than 2 years of age started in April 2007.²³

b. The Canadian Hospital Epidemiology Committee, a joint initiative of the Canadian Infectious Diseases Society and the Canadian Nosocomial Infection Surveillance Program, used a standard definition for CDI surveillance to track nosocomial CDI over a 4-month period in 1997 and after 2005 in healthcare facilities across Canada²⁴ (M. Miller, MD, personal communication, December 2007).

c. Data are lacking to determine the ideal definition for

healthcare-associated CDI. However, this is a minor limitation in light of the need for a standardized surveillance definition for CDI. The following information focuses on the definitions for CDI surveillance in the United States and Europe.^{20,21}

i. A CDI case is defined as a case of diarrhea or toxic megacolon without other known etiology that meets 1 or more of the following criteria: (1) the stool sample yields a positive result of a laboratory assay for *C. difficile* toxin A and/or B, or a toxin-producing *C. difficile* organism is detected in the stool sample by culture or other means; (2) pseudomembranous colitis is seen on endoscopic examination or surgery; and (3) pseudomembranous colitis is seen on histopathological examination.

ii. Several CDI definitions are proposed, including community-associated CDI; community-onset, health-care facility-associated CDI; and recurrent CDI. Health-care facilities should track at least healthcare facility-onset, healthcare facility-associated CDI (Table 1).^{20,21}

iii. Surveillance for CDI is limited by the use of nonculture-based methods to diagnose CDI, such as stool toxin assays, which have lower sensitivity than does *C*. *difficile* stool culture.^{20-32,24-27}

2. Identifying patients with CDI

Positive results of diarrheal stool tests for toxigenic *C. difficile* or its toxins are the most common methods used to identify patients with CDI.^{20-22,24}

a. Positive results of diarrheal stool tests should automatically be sent to infection prevention and control professionals and to clinicians caring for the patient.

b. Only diarrheal stools should be tested for *C. difficile* or its toxins. A positive result of a test for toxigenic *C. difficile* and/or its toxins in a patient with diarrhea is considered to be diagnostic for CDI. However, some centers permit *C. difficile* testing of nondiarrheal stools. In such cases, review of patient records is required to ensure that the patient has symptoms consistent with CDI.

i. Because of the high prevalence of asymptomatic carriage of toxigenic *C*. *difficile* among infants younger than 1 year of age, testing should be conducted only for infants with diarrhea along with investigation of alternative causes of diarrhea.^{7,8} Detection of *C*. *difficile* toxin should not be assumed to be causative of diarrhea in these infants, although infants older than 6 months of age who are colonized have been shown to have a higher frequency of all-cause diarrhea than do noncolonized infants.^{28,29}

c, A minority of patients have CDI diagnosed by visualization of pseudomembranes by endoscopy and/or histopathologic analysis, without positive stool test results.

3. Methods for surveillance of CDI

a. Conducting CDI surveillance to determine CDI rates provides a measure to determine the burden of CDI at a

CDI case type	Definition
Healthcare facility onset, healthcare facility associated Community onset, healthcare facility associated	Symptom onset >48 h after admission to a healthcare facility Symptom onset in the community or ≤ 48 h after admis-
	last discharge from a healthcare facility
Community associated	Symptom onset in the community or ≤48 h after admis- sion to a healthcare facility, provided that symptom onset was >12 weeks after the last discharge from a healthcare facility
Indeterminate onset	Case does not fit any of the above criteria for an exposure setting (eg, onset in the community >4 weeks but <12 weeks after the last discharge from a healthcare facility)
Unknown	Exposure setting cannot be determined, because of a lack of available data
Recurrent	Episode occurred ≤8 weeks after the onset of a previous episode, provided that CDI symptoms from the earlier episode resolved

TABLE 1. Clostridium difficile Infection (CDI) Surveillance Definitions

NOTE. Definitions are from McDonald et al.²⁰ and Kuijper et al.²¹ When laboratory-based reporting of symptoms is used, the date and time of stool specimen collection can be used as a surrogate for symptom onset. If data on the time a patient was admitted (in addition to date) and/or the time stool was collected for testing are not available, CDI can be considered to be healthcare facility onset if stool is positive for toxigenic *C. difficile* or a *C. difficile* toxin after the third calendar day after hospital admission, where the first day is the day of admission (ie, a patient admitted on Monday with stool first positive for *C. difficile* toxin on Thursday or later is considered to have healthcare facility–onset CDI).

healthcare facility. These data are also used to assess the efficacy of interventions to prevent CDI. When they are reported back to healthcare providers and hospital administrators, CDI rates can be applied as a tool to improve adherence to CDI preventive measures.

b. Surveillance can be performed on specific wards or units and/or at the level of the entire healthcare facility.

c. Laboratories performing *C. difficile* testing should report results to infection prevention and control professionals daily. The CDI rate can be expressed as the number of CDI case patients per 10,000 patient-days.

i. This rate is calculated as follows: (number of case patients/number of patient-days per reporting period) \times 10,000 = rate per 10,000 patient-days.¹⁹

ii. To convert the rate per 10,000 patient-days to the rate per 1,000 patient-days, divide the rate by 10 (conversely, to convert a rate from 1,000 patient-days to 10,000 patient-days, multiply the rate by 10).

d. Because of a lack of published data on CDI surveillance using similar case-finding methods and surveillance definitions, specific definitions for what constitutes an "outbreak" or "hyperendemic" rate cannot be provided at this time.

i. An outbreak can be defined as an increase in CDI rate in time and/or space believed to be greater than that expected by chance alone.

ii. A hyperendemic rate can be defined as a persistently elevated CDI rate compared with past rates or compared with rates in other, similar healthcare facilities.

SECTION 3: STRATEGIES TO PREVENT CD1

1. Existing guidelines and recommendations

a. Published guidelines for the management of CDI are few, and only some address CDI prevention.^{22,25-27}

i. Most data published on CDI prevention are from before-after studies conducted in response to outbreaks. Often, several concomitant interventions are performed, making it difficult to determine the relative importance of one intervention compared with another. Before-after studies are also limited by time-related biases that are difficult to adjust for in the absence of a control group or properly conducted analyses, such as interrupted time series analysis.^{30,31} However, 2 recent studies have used these techniques, demonstrating the importance of antimicrobial stewardship and its role in preventing CDI.^{31,32}

b. Less is known about the mechanisms and prevention of *C. difficile* transmission, compared with other antimicrobial-resistant gram-positive organisms, such as MRSA and vancomycin-resistant enterococcus (VRE). Although these 3 organisms have many common epidemiologic characteristics, *C. difficile* and VRE, in particular, share risk factors for transmission.⁵⁵ The major difference among these 3 organisms is that *C. difficile* forms spores, whereas the other 2 do not. The formation of spores has novel (as yet unknown) implications for methods of hand hygiene and environmental disinfection, because *C. difficile* spores are resistant to the bactericidal effects of alcohol and most hospital disinfectants. c, General strategies to prevent CDI, per previously published guidelines,^{22,24 27} include the following:

i. Methods of reducing the risk of CDI if the organism is encountered by the patient

 (a) Follow antimicrobial usage restriction and stewardship guidelines.

ii. Methods of preventing the patient from being exposed to *C. difficile* (disinfection and barrier methods)

(a) Avoid the use of electronic thermometers; the handles become contaminated with *C. difficile.*

(b) Use dedicated patient care items and equipment; if items must be shared, clean and disinfect the equipment between patients.

(c) Use full barrier precautions (gowns and gloves) for contact with patients with CDI and for contact with their body substances and environment (contact precautions).

(d) Place patients with CDI in private rooms, if available; give isolation preference to patients with fecal incontinence if room availability is limited.

(e) Perform meticulous hand hygiene based on Centers for Disease Control and Prevention or World Health Organization guidelines before and after entering the room of a patient with CDI, with soap and water or an alcohol-based hand-hygiene product (in routine settings or settings of endemicity). Perform hand hygiene with soap and water preferentially, instead of alcohol hand hygiene products, after caring for a patient with CDI in outbreak settings or settings of hyperendemicity. Ensure that proper hand-hygiene techniques are used when hand washing with soap and water is employed.³⁴

(f) Perform environmental decontamination of rooms housing patients with CDI, using sodium hypochlorite (household bleach) diluted 1 : 10 with water, in an outbreak setting or setting of hyperendemicity.

(g) Educate healthcare personnel and hospital administration about the clinical features, transmission, and epidemiology of CDI.

d. Other important principles to be aware of when caring for patients with CDI include the following:^{22,25-27}

i. Perform testing for *C. difficile* only on unformed diarrheal stools (toxin testing of formed stool is strongly discouraged).

ii. Do not give prophylactic antimicrobial CDI therapy (eg, with metronidazole or vancomycin) to patients at high risk for CDI.

iii. Do not treat or attempt to decolonize asymptomatic *C*, *difficile* carriers. Antimicrobial therapy is not effective for decolonization.

iv. Do not conduct repeated testing for *C. difficile* if a patient has had a stool sample positive for *C. difficile*, unless symptoms resolved with treatment and then returned after treatment (ie, do not perform test of cure in patients successfully treated for CDI).

2. Infrastructure requirements

a. Trained infection prevention and control personnel

i. Infection prevention and control personnel must have knowledge about risk factors for and methods to prevent CDI. They must also be trained in how to determine when a case of CDI is healthcare associated and how to calculate CDI rates.^{20,21}

b. Method to identify patients with CDI

i. Infection prevention and control personnel must be able to identify patients with CDI as soon as possible after their condition is diagnosed. This is necessary to ensure that patients are placed under contact precautions in a timely fashion. These data can also be used to calculate CDI rates.

c. Ability to place patients with CDI under contact precautions

i. Contact precautions require the ability to place patients in a private room (preferably) or to cohort patients with CDI, as well as to place materials necessary for compliance with contact precautions (eg, gowns and gloves) in an easily accessible space outside of the patient's room.

ii. Place a sign indicating that the patient is under contact precautions outside of the patient's room.

iii. If there is a limited number of single-bed rooms, patients with stool incontinence should preferentially be placed in these rooms.

iv. If it is necessary to cohort patients, cohort patients who are colonized or infected with the same organism(s) (eg, do not cohort patients with CDI who are discordant in their VRE or MRSA colonization status).

v. Have systems in place to facilitate communication among infection prevention and control, admitting, nursing, and housekeeping departments and develop contingency plans for conditions of limited bed availability.

d. Provide educational materials for patients, family members, and healthcare personnel that include explanations of CDI, why contact precautions are necessary, and the importance of hand hygiene.

e. Provide adequate resources and training for housekeeping personnel to ensure proper cleaning of rooms.

3. Initiating a CDI prevention program

a. Pilot test the intervention in 1 patient care location to assess efficacy.

i. Perform CDI surveillance to determine locations where CDI rates are highest.

ii. Initiate the prevention program where there is a high concentration of patients at risk for CDI, such as an intensive care unit or an oncology ward.

iii. Start in 1 patient care location.

(a) Identify opportunities to improve the system for identifying patients with CDI.

(b) Identify opportunities to improve the process for placing patients with CDI under contact precautions and to minimize problems for family members, visitors, and healthcare personnel.

iv. Obtain the support of hospital administration and local physician and nursing leadership before starting the program.

b. Use process and outcome measures to determine whether the intervention is effective.

c. Replicate the CDI infection prevention and control program in other patient care areas when it is determined that the systems developed are effective.

SECTION 4: RECOMMENDATIONS FOR IMPLEMENTING PREVENTION AND MONITORING STRATEGIES

Recommendations for preventing and monitoring CDI are summarized in the following section. They are designed to assist acute care hospitals in prioritizing and implementing their CDI prevention efforts. Criteria for grading the strength of recommendation and quality of evidence are described in Table 2.

I. Basic practices for prevention and monitoring of CDI: recommended for all acute care hospitals

A. Components of a CDI prevention program

1. Use contact precautions for infected patients, with a single-patient room preferred (A-II for hand hygiene, A-I for gloves, B-III for gowns, and B-III for single-patient room).^{22,25-27}

 Place patients with CDI under contact precautions to help reduce patient-to-patient spread of the organism.

i. Place patients in private rooms when available.

ii. Don gown and gloves on entry to the patient's room.

(a) Gloves should be changed immediately if visibly soiled and after touching or handling surfaces or materials contaminated with feces.

iii. Remove gown and gloves before exiting the room.

iv. Conduct Centers for Disease Control and Prevention- or World Health Organization-compliant hand hygiene on exiting the patient's room.

v. Cohorting patients with CDI is acceptable when single, private rooms are not available.

(a) Place patients with stool incontinence preferentially in private rooms.

(b) Do not cohort patients who have discordant status of infection or colonization with other epidemiologically important organisms (eg, VRE and MRSA).

(c) Remove gowns and gloves and perform hand hygiene when moving from one patient to another.

 Ensure that adequate supplies for contact precautions are readily available.

i. Management leaders are responsible to ensure that necessary barrier-equipment supplies (eg, gowns and gloves) and hand-hygiene products are readily available.

ii. Assign responsibility for monitoring the availability and restocking of supplies to specific healthcare personnel.

c. Criteria for discontinuing contact precautions

i. The Centers for Disease Control and Prevention currently recommends contact precautions for the duration of illness when caring for patients with CDI.³⁶ Some experts recommend continuing contact precautions for at least 48 hours after diarrhea resolves. Areas of controversy include the following:

(a) Asymptomatically colonized patients (including, in many cases, those successfully treated for CDI)

TABLE 2.	Strength of	Recommendation	and Quality	of Evidence
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Category/grade	Definition				
Strength of recommendation					
A	Good evidence to support a recommendation for use				
В	Moderate evidence to support a recommendation for use				
C	Poor evidence to support a recommendation				
Quality of evidence					
I	Evidence from ≥1 properly randomized, controlled trial				
п	Evidence from ≥1 well-designed clinical trial, without randomization; from cohort or case-control analytic studies (preferably from >1 center); from multiple time series; or from dramatic results from uncontrolled experiments				
m	Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees				

NOTE. Adapted from the Canadian Task Force on the Periodic Health Examination.35

continue to shed *C. difficile* spores, but the number of spores and degree of contamination is not as great as for patients with active CDI. There are currently no data to support isolation of these asymptomatic patients.³⁷⁻³⁹

(b) Prolonging the duration of contact isolation for patients with CDI is recommended when CDI is not effectively controlled by the use of basic practices (see below: II. Special Approaches for the Prevention of CDI). Similarly, there are no data to indicate the efficacy of this practice at this time.

 Ensure cleaning and disinfection of equipment and the environment (B-III for equipment and B-II for the environment).

a. C. difficile spores contaminate the environment in which patients are housed and the equipment used to care for them.^{26,27,37,39} This includes the following:

i. Furnishings in the room, including over-bed tables, bed rails, furniture, sinks, floors, commodes, and toilets

ii. Patient care equipment that directly touches patients, such as thermometers, stethoscopes, and blood pressure cuffs

iii. "High-touch" (ie, frequently touched) surfaces, such as door knobs and intravenous fluid pumps

b. C. difficile appears to contaminate very few surfaces outside patient rooms.³⁷

c. Contaminated surfaces and equipment are potential reservoirs for transmission of *C. difficile*.

i. Recent guidelines have outlined environmental disinfection protocols.⁴⁰ There are no US Environmental Protection Agency–registered products specific for inactivating *C. difficile* spores. Data are conflicting as to whether inactivation of spores is necessary to prevent *C. difficile* transmission, especially in a setting of endemicity.

 ii. Facilities should consider using a 1 : 10 dilution of sodium hypochlorite (household bleach) for environmental disinfection in outbreak settings and settings of hyperendemicity in conjunction with other infection prevention and control measures (see below: II. Special Approaches for the Prevention of CDI). The bleach solution should have a contact time of at least 10 minutes.⁴¹
 d. Develop and implement protocols for disinfection of equipment and the environment.

i. On a routine basis, assess adherence to protocols and the adequacy of cleaning.

ii. Assess the adequacy of cleaning before changing to a new cleaning product (eg, bleach). If cleaning is not adequate, address this before changing products (see below: II. Special Approaches for the Prevention of CDI).

iii. Because of the high turnover of housekeeping personnel, educate personnel on proper cleaning technique frequently. Ensure that education is provided in the personnel's native language. e. Dedicate noncritical patient care items, such as blood pressure cuffs, stethoscopes, and thermometers, to a single patient with CDI.

i. When this is not possible, ensure adequate cleaning and disinfection of shared items between patient encounters. Ensure that the manufacturers' recommendations for contact time of disinfectants are followed.

3. Implement a laboratory-based alert system to provide immediate notification to infection prevention and control personnel and clinical personnel about patients with newly diagnosed CDI (B-III).

a. To place patients with CDI under contact precautions in a timely manner, it is important that an alert system be developed between the laboratory and both infection prevention and control personnel and clinical personnel caring for the patient. This alert system should immediately notify infection prevention and control and clinical personnel when a patient has newly diagnosed CDI.

b. There are a variety of methods by which this information can be transmitted, but some options include fax alerts, phone call and pager alerts, or automated secure electronic alerts.

i. The alert system should not rely on fax transmissions alone, because there may be delays from the time the transmission is received to the time it is seen by an appropriate healthcare provider.

c. Alert patient care areas of positive test results immediately, so that these patients can be placed under contact precautions.

d. When a patient has active CDI, communicate the CDI status when transferring the patient to another healthcare facility, so that appropriate precautions can be implemented at the accepting facility.

4. Conduct CDI surveillance and analyze and report CDI data (B-III).

a. At a minimum, calculate healthcare facility-onset, healthcare facility-associated CDI rates at the unit/ward and organizational levels (Table 1).^{20,21}

b. Provide CDI data and other CDI prevention process and outcome measures to key stakeholders, including senior leadership, physicians, nursing staff, and other clinicians.

c. Provide the process and outcome measures outlined in the "Performance Measures" section below to appropriate hospital staff and administrators on a regular basis. The frequency with which these data are provided will depend on the hospital's existing reporting structure and the type of data collected. These data can be added to routine quality assessment and performance improvement reports.

 Educate healthcare personnel, housekeeping personnel, and hospital administration about CDI (B-III). a. Include risk factors, routes of transmission, local CDI epidemiology, patient outcomes and treatment, and prevention measures (including Centers for Disease Control and Prevention and World Health Organization recommendations regarding proper hand hygiene, contact precautions, and management of multidrug-resistant organisms).^{34,42,43}

6. Educate patients and their families about CDI, as appropriate (B-III).

a. Although often not considered part of a program to reduce transmission of multidrug-resistant organisms, proper education may help to alleviate patient fears regarding being placed in isolation.⁴⁴

i. Include information about anticipated questions: general information about CDI, colonization versus infection, the hospital's CDI prevention program, the components of and rationale for contact precautions, and the risk of transmission to family and visitors while in the hospital and after discharge. Helpful materials might include patient education sheets in appropriate language(s) and the use of patient education channels, Web sites, or VHS tapes and DVDs.

7. Measure compliance with Centers for Disease Control and Prevention or World Health Organization hand-hygiene and contact precaution recommendations (B-III).

a. Patient-to-patient transmission of *C. difficile* is thought to occur primarily through transient contamination of the hands of healthcare personnel with spores.

b. Glove use when caring for patients with CDI or touching surfaces in their rooms has been shown to be effective at preventing the transmission of *C. difficile*.

c. Hand-hygiene practices in compliance with Centers for Disease Control and Prevention or World Health Organization guidelines are critical to *C. difficile* control and prevention. Evidence-based recommendations for implementation and assessment of hand-hygiene programs in healthcare settings have been published.⁵⁴

i. Area of controversy: There are concerns regarding reliance on alcohol-based hand-hygiene products, because alcohol is not sporicidal. Conversely, hand washing with soap and water is associated with much lower compliance. In settings where CDI is endemic, it appears the potential decrease in efficacy of alcohol-based hand-hygiene products for removing spores, compared with hand washing, may be offset by the increase in hand-hygiene adherence with alcohol-based hand-hygiene products, if contact precautions are followed (ie, if gloves and gowns are worn) when caring for patients with CDI.⁴⁵

B. Accountability

1. The hospital's chief executive officer and senior man-

agement are responsible for ensuring that the healthcare system supports an infection prevention and control program that effectively prevents CDI and the transmission of epidemiologically significant pathogens.

Senior management is accountable for ensuring that an adequate number of trained personnel are assigned to the infection prevention and control program.

Senior management is accountable for ensuring that healthcare personnel, including licensed and nonlicensed personnel, are competent to perform their job responsibilities.

4. Direct healthcare providers (such as physicians, nurses, aides, and therapists) and ancillary personnel (such as house-keeping and equipment-processing personnel) are responsible for ensuring that appropriate infection prevention and control practices are used at all times (including hand hygiene, standard and isolation precautions, and cleaning and disinfection of equipment and the environment).

Hospital and unit leaders are responsible for holding personnel accountable for their actions.

6. The person who manages the infection prevention and control program is responsible for ensuring that an active program to identify CDI is implemented, that data on CDI are analyzed and regularly provided to those who can use the information to improve the quality of care (eg, unit staff, clinicians, and hospital administrators), and that evidencebased practices are incorporated into the program.

 Personnel responsible for healthcare personnel and patient education are accountable for ensuring that appropriate training and educational programs to prevent CDI are developed and provided to personnel, patients, and families.

 Personnel from the infection prevention and control program, the laboratory, and information technology departments are responsible for ensuring that systems are in place to support the surveillance program.

II. Special approaches for the prevention of CDI

Perform a CDI risk assessment. These special approaches are recommended for use in locations and/or populations within the hospital that have unacceptably high CDI rates despite implementation of the basic CDI prevention strategies listed above.

There are several unresolved issues regarding CDI prevention. This is apparent when reviewing the rankings of each recommendation on the basis of the quality of the data to support it. As a result, implementation of the recommendations beyond the basic practices to prevent CDI should be individualized at each healthcare facility. One may consider a "tiered" approach in which recommendations are instituted individually or in groups; additional "tiers" are added if CDI rates do not improve, with implementation of basic practices as the first tier.

A. Approaches to minimize C. difficile transmission by healthcare personnel

1. Intensify the assessment of compliance with process measures (B-III).

a. Contact precautions: Gowns and gloves should be worn by all healthcare personnel who enter the rooms of patients under contact precautions.

b. Hand hygiene: Hand hygiene should be performed on entry and exit from patient rooms. When hand washing is performed, determine whether proper techniques are being used (eg, hand washing for at least 15 seconds).³⁴

c. If hand-hygiene compliance or techniques are not adequate, conduct interventions to improve hand-hygiene compliance and techniques.

2. Perform hand hygiene with soap and water as the preferred method before exiting the room of a patient with CDI (B-III).

a. Ensure proper hand-hygiene technique when using soap and water.³⁴

b. Be aware that hand-hygiene adherence may decrease when soap and water is the preferred method.

i. Additional education may be necessary to remind healthcare workers that alcohol-based hand-hygiene products are superior to hand washing for non-spore-forming organisms (eg, MRSA).

3. Place patients with diarrhea under contact precautions while *C. difficile* test results are pending (B-III).

a. To decrease transmission, it is essential to place symptomatic patients under contact precautions as soon as diarrhea symptoms are recognized.

b. If the results of *C. difficile* testing are negative, the patient has a low pretest probability of CDI, and the patient is continent of stool, contact precautions can be discontinued.

i. Because of concerns about the low sensitivity of enzyme immunoassays, clinical suspicion of CDI should outweigh negative test results for patients with a high pretest probability of having CDI.

4. Prolong the duration of contact precautions after the patient becomes asymptomatic until hospital discharge (B-III).

a. Patients may still shed C. difficile in their stool after diarrhea resolves.⁴⁶⁻⁴⁸

B. Approaches to minimize CDI transmission from the environment

1. Assess the adequacy of room cleaning (B-III).

a. If room cleaning practices are deemed to be inadequate, focus on improving room cleaning techniques.

b. Important issues to address include proper dilution of cleaning products, adequacy of cleaning technique, cleaning "high-touch" surfaces, frequency of changing rags/ mop water, and moving from "clean" areas to "dirty" areas.

i. Create a checklist based on cleaning protocols and perform observations to monitor cleaning practice.

ii. Environmental culture for *C. difficile* is difficult to perform and requires specialized media; therefore, it is not routinely recommended.⁴⁹

c. Consider environmental decontamination with sodium hypochlorite if room cleaning is deemed to be adequate but there is ongoing CDI transmission (see below).

2. Use sodium hypochlorite (bleach)-containing cleaning agents for environmental cleaning. Implement a system to coordinate with the housekeeping department if it is determined that sodium hypochlorite is needed for environmental disinfection (B-II).

a. Area of controversy: Data on the ability of diluted sodium hypochlorite or other sporicidal agents used for environmental decontamination to control CDI have not been consistent. However, a beneficial effect has been reported when bleach has been used in outbreak settings or settings of hyperendemicity, typically in conjunction with other enhanced CDI control measures.^{40,50-53}

b. When diluted sodium hypochlorite is instituted for environmental decontamination, it is necessary to coordinate activities with housekeeping staff.

i. Clinical, infection prevention and control, and housekeeping staff will need to determine the location, type, and frequency of diluted sodium hypochlorite use. For instance:

(a) All rooms, only rooms of patients with CDI, or outside of patient rooms?

(b) Daily cleaning or terminal cleaning only when the patient is discharged or transferred?

c. When diluted sodium hypochlorite is used, it is important to address the following issues:

i. Avoid toxicity to patients and staff and damage to equipment and the environment from bleach use. Sodium hypochlorite can be corrosive and irritating to patients, housekeeping staff, and other healthcare personnel.

ii. The sodium hypochlorite solution must be mixed fresh daily.

d. When sodium hypochlorite will be used only in the rooms of patients with CDI, a system will need to be created to identify these patients to the housekeeping staff.

C. Approaches to reduce the risk of CDI acquisition

1. Initiate an antimicrobial stewardship program (A-II), 22,25-27,32,54,35 a. Assess the appropriateness of antimicrobial prescribing practices.

i. Restrict antimicrobials that are strongly associated with CDI and promote appropriate antimicrobial use.

III. Approaches that should not be considered a routine part of CDI prevention

1. Do not test patients without signs or symptoms of CDI for C. difficile (B-II).

a. C. difficile toxin tests have been studied in patients with symptoms of CDI and a high pretest probability of having CDI. A positive C. difficile toxin test result for a patient without symptoms has a high probability of being a false-positive result.

i. Only stool culture for *C. difficile* has been confirmed to identify patients with asymptomatic *C. difficile* colonization. The sensitivity, specificity, and negative and positive prediction values of antigen and toxin assays are unknown for asymptomatic patients.

 b. Obtaining stool specimens requires nursing time to collect and laboratory technician time to perform the test and report results.

c. A positive toxin test result for an asymptomatic patient may result in the initiation of unnecessary treatment for CDI, which may increase the patient's risk of developing CDI in the future.⁵⁶

d. Do not place patients with asymptomatic C. difficile colonization under contact precautions.

i. Area of controversy: Previous research has demonstrated that asymptomatically colonized patients can be a source of transmission of *C*. *difficile* and that patients can remain colonized after symptoms cease.^{38,39,47,49} However, asymptomatically colonized patients are less likely than symptomatic patients to contaminate their surrounding environment or serve as a source of transmission. In some settings, the duration of contact precautions can be extended if there is concern that asymptomatically colonized patients represent a significant source of potential *C*. *difficile* exposure.

e. Do not attempt to decolonize asymptomatic patients, because this has not been effective and may increase the patient's risk of developing CDI in the future.⁵⁶

2. Do not repeat *C. difficile* testing at the end of successful therapy for a patient recently treated for CDI (B-III).

a. A positive test result may result in unnecessary prolongation of contact precautions and CDI treatment.

i. In some settings, contact precautions may be extended until hospital discharge after symptom resolution (see above). However, there are insufficient data to recommend extending the duration of contact precautions on the basis of whether *C. difficile* or its toxins can be detected in the patient's stool.

b. A positive test result at the end of therapy does not predict who will develop a recurrence or relapse.¹⁸

c. Repeated *C. difficile* testing does not provide any useful clinical information but requires nursing time to collect the specimen and laboratory technician time to perform the test and report results.⁴⁸

IV. Unresolved issues

Use of gowns and gloves by family members and other visitors

a. The utility of requiring family members and other visitors to wear gowns and gloves to prevent *C. difficile* transmission is unknown.⁵⁷ The risk that family members and other visitors will transmit *C. difficile* between patients is likely to be related to the degree of contact the visitor has with the patient and the patient's environment, whether the visitor performs hand hygiene, and the degree of interaction the visitor has with other patients. At a minimum, family members and other visitors should be instructed to perform hand hygiene whenever entering or leaving the patient's room.

 Standing orders or nurse-driven protocols to test all patients with diarrhea for C. difficile

a. Nurses frequently know, before the treating physician does, when a patient has diarrhea

 Admitting-based alert systems that notify infection prevention and control and clinical personnel about readmitted or transferred patients with a history of CDI

a. This information can be integrated into a computerized database used during admission and registration or a separate electronic or paper-based database.

i. If an alert system is implemented, patients with a history of CDI should be placed under contact precautions if they are readmitted only if they have symptoms consistent with CDI at admission. Asymptomatic patients with a history of CDI do not require contact precautions.

ii. The duration that the alert should remain active is unknown. Nearly all cases of recurrent CDI occur within 90 days after the last episode. On the basis of this fact, it is reasonable to discontinue the alert 90 days after the last episode of CDI. However, healthcare facilities may not be aware of recurrent episodes of CDI that are diagnosed and managed in outpatient settings, so an arbitrary cutoff based on the last known episode of CDI may inadvertently remove patients with ongoing recurrent CDI.

 Ongoing assessment of CDI knowledge and intensified CDI education among healthcare personnel

a. Re-educate staff if prior CDI training occurred more

than 12 months earlier or if overall knowledge is deemed to be inadequate.

i. Include housekeeping personnel in educational efforts.

5. Restricting the use of gastric acid suppressants^{14,16}

SECTION 5: PERFORMANCE MEASURES

I. Internal reporting

These performance measures are intended to support internal hospital quality improvement efforts and do not necessarily address external reporting needs. The process and outcome measures suggested here are derived from published guidelines, other relevant literature, and the opinions of the authors. Report process and outcome measures to senior hospital leadership, nursing leadership, and clinicians who care for patients at risk for CDI.

A. Process measures

1. Compliance with hand-hygiene guidelines

a. Preferred measure for hand-hygiene compliance

i. Numerator: number of observed proper hand-hygiene episodes performed by healthcare personnel.

ii. Denominator: total number of observed opportunities for hand hygiene.

iii. Multiply by 100 so that the measure is expressed as a percentage.

b. If hand hygicne with soap and water is the preferred method of hand hygiene when caring for patients with CDI, also assess proper hand washing techniques (minimum duration of 15 seconds).

i. Numerator: number of proper hand washing episodes with proper technique.

ii. Denominator: total number of hand washing episodes observed.

iii. Multiply by 100 so that the measure is expressed as a percentage.

2. Compliance with contact precautions

 a. Preferred measure of contact precautions compliance *i*. Numerator: number of observed patient care episodes in which contact precautions are appropriately implemented.

ii. Denominator: number of observed patient care episodes in which contact precautions are indicated.

iii. Multiply by 100 so that the measure is expressed as a percentage.

3. Compliance with environmental cleaning

a. One specific measure of compliance for use in all hospitals cannot be recommended. However, many hospitals use checklists and environmental rounds to assess the cleaning process and cleanliness of equipment and the environment (see above).

B. Outcome measures

Perform ongoing measurement of the incidence density of CDI to permit longitudinal assessment of the processes of care.

 CDI rates should be calculated according to the recently published recommendations and as described above.^{20,22}

a. See Table 1 for case definitions.

i. Numerator: number of CDI cases in the population being monitored (the specific cases included in the numerator depends on the definition used; see Table 1).

ii. Denominator: total number of patient-days in the population being monitored.

iii. Multiply by 10,000 so that measure is expressed as number of cases per 10,000 patient-days.

b. To convert the rate per 10,000 patient-days to 1,000 patient-days, divide the rate by 10 (conversely, to convert a rate from 1,000 patient-days to 10,000 patient-days, multiply the rate by 10).

II. External reporting

There are many challenges in providing useful information to consumers and other stakeholders while preventing unintended adverse consequences of public reporting of healthcare-associated infections.³⁶ Recommendations for public reporting of healthcare-associated infections have been provided by the Hospital Infection Control Practices Advisory Committee,⁵⁹ the Healthcare-Associated Infection Working Group of the Joint Public Policy Committee,⁶⁰ and the National Quality Forum.⁶¹

Given the absence until recently of standardized CDI surveillance definitions and the difficulties in ascertaining the specific time and location of *C. difficile* acquisition, specific recommendations for external reporting of CDI rates cannot be made at this time.

A. State and local requirements

 Hospitals in states that have mandatory reporting requirements for CDI must collect and report the data required by the state.

For information on local requirements, check with your state or local health department.

B. External quality initiatives

1. Hospitals that participate in external quality initiatives must collect and report the data if required by the initiative.

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"Clostridium Difficile"

What is Clostridium difficile infection?

Clostridium difficile [pronounced Klo-STRID-ee-um dif-uh-SEEL], also known as "*C. diff*" [See-dif], is a germ that can cause diarrhea. Most cases of *C. diff* infection occur in patients taking antibiotics. The most common symptoms of a *C. diff* infection include:

Watery diarrhea Fever Loss of appetite Nausea Belly pain and tenderness

Who is most likely to get C. diff infection?

The elderly and people with certain medical problems have the greatest chance of getting *C. diff*. *C. diff* spores can live outside the human body for a very long time and may be found on things in the environment such as bed linens, bed rails, bathroom fixtures, and medical equipment. *C. diff* infection can spread from person-to-person on contaminated equipment and on the hands of doctors, nurses, other healthcare providers and visitors.

Can C. diff infection be treated?

Yes, there are antibiotics that can be used to treat *C. diff.* In some severe cases, a person might have to have surgery to remove the infected part of the intestines. This surgery is needed in only 1 or 2 out of every 100 persons with *C. diff.*

What are some of the things that hospitals are doing to prevent C. diff infections?

To prevent *C. diff.* infections, doctors, nurses, and other healthcare providers:

- Clean their hands with soap and water or an alcohol-based hand rub before and after caring for every patient. This can prevent C. diff and other germs from being passed from one patient to another on their hands.
- Carefully clean hospital rooms and medical equipment that have been used for patients with C. diff.
- Use Contact Precautions to prevent C. diff from spreading to other patients. Contact Precautions mean:
 - Whenever possible, patients with C. diff will have a single room or share a room only with someone else who also has C. diff.
 - o Healthcare providers will put on gloves and wear a gown over their clothing while taking care of patients with *C. diff.*
 - o Visitors may also be asked to wear a gown and gloves.
 - o When leaving the room, hospital providers and visitors remove their gown and gloves and clean their hands.

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- Patients on Contact Precautions are asked to stay in their hospital rooms as much as possible. They should not go to common areas, such as the gift shop or cafeteria. They can go to other areas of the hospital for treatments and tests.
- · Only give patients antibiotics when it is necessary.

What can I do to help prevent C. diff infections?

Make sure that all doctors, nurses, and other healthcare providers clean their hands with soap and water or an alcohol-based hand rub before and after caring for you.

If you do not see your providers clean their hands, please ask them to do so.

- Only take antibiotics as prescribed by your doctor.
- Be sure to clean your own hands often, especially after using the bathroom and before eating.

Can my friends and family get C. diff when they visit me?

C. diff infection usually does not occur in persons who are not taking antibiotics. Visitors are not likely to get *C. diff*. Still, to make it safer for visitors, they should:

- Clean their hands before they enter your room and as they leave your room
- Ask the nurse if they need to wear protective gowns and gloves when they visit you.

What do I need to do when I go home from the hospital?

Once you are back at home, you can return to your normal routine. Often, the diarrhea will be better or completely gone before you go home. This makes giving *C. diff* to other people much less likely. There are a few things you should do, however, to lower the chances of developing *C. diff* infection again or of spreading it to others.

- If you are given a prescription to treat C. diff, take the medicine exactly as prescribed by your doctor and pharmacist. Do not take half-doses or stop before you run out.
- Wash your hands often, especially after going to the bathroom and before preparing food.
- People who live with you should wash their hands often as well.
- If you develop more diarrhea after you get home, tell your doctor immediately.
- Your doctor may give you additional instructions.

merican Hospital

If you have questions, please ask your doctor or nurse.





COLORADO INFECTION PREVENTION COLLABORATIVE C.DIFFICILE INFECTIONS







C. DIFFICILE SURVEILLANCE

Bacillus difficilis, first isolated from the stool of healthy neonates in 1935, earned its name because of the difficulty researchers experienced in isolating the bacterium and its slow culture growth. Renamed *Clostridium difficile* in the 1970s, the bacterium continues to prove difficult to contain, and our ability to prevent its spread through the healthcare environment remains a challenge.¹³

Surveillance of *Clostridium difficile* – associated disease, or CDAD, is important now more than ever as we face new strains of disease, the emergence of new risk groups, and the increasing spread of disease to the community. Surveillance provides us with the necessary information to predict, observe, and minimize harm of the disease and increases our knowledge about risk factors and prevention.

Previous surveillance activities have led to the discovery of new risk groups, including perinatal women and healthy individuals with no known exposure to the healthcare environment or antibiotics. It has also led to the discovery of the emergence of the BI/NAP1/027 strain, which is thought to be responsible for more severe and frequent outbreaks of disease in recent years.

The interim recommendations for surveillance discussed in this tool kit were published by the Society for Healthcare Epidemiology of America (SHEA) in 2007 and are primarily intended for use by inpatient facilities; however, they may also be adapted and used in community-based settings. The full recommendation is provided at the end of this section and is also available at http://www.journals.uchicago.edu/doi/pdf/10.1086/511798.

According to the recommendations, the main purposes¹⁴ of surveillance of *Clostridium difficile* are to:

- Guide the implementation of interventions to control CDAD in healthcare facilities.
- Monitor the impact of these interventions.
- Detect outbreaks of disease and compare CDAD infection rates among institutions.
- Understand the emergence of community disease and disease in previously low-risk populations.

From a hospital's perspective, the main goal of surveillance activities will be to detect outbreaks of CDI within the hospital environment so that the proper preventive measures can take effect and additional resources may be allocated as needed.



COLORADO INFECTION PREVENTION COLLABORATIVE

C. DIFFICILE SURVEILLANCE

SURVEILLANCE METHODS

There are two basic methods for surveillance of *C. difficile*.¹⁵ Each facility should employ the method that works best for their organization based on internal resources and infection control needs. Facilities participating in the Infection Prevention Collaborative utilized the second option—laboratory surveillance with the National Healthcare Safety Network—described below.

Option #1

Medical chart-review identification of clinical disease involves creating a line listing of all positive *C. difficile* cases throughout your facility by reviewing charts of CDI patients.

MINIMUM DATA COLLECTION ELEMENTS				
PATIENT-SPECIFIC DATA	FACILITY-SPECIFIC DATA			
□ Identifier (MRN, DOB)	Number of patient days for the facility or unit being monitored (CDI rates should be expressed in cases per 10,000 minute of the should be expressed in cases per			
Date of admission				
□ Date, location, and time of stool collection	10,000 patient days)			
Date of discharge				
Date patient's symptoms began (i.e., diarrhea onset)				

	OPTIONAL DATA COLLECTION ELEMENTS				
PATIENT-SPECIFIC DATA		FACILITY-SPECIFIC DATA			
	Test type used for diagnosis		Volume of tests being ordered by the facility		
	Underlying diagnoses in the patient		Number of prescriptions for metronidazole and		
	Treatment given to patient for CDI		vancomycin		
	Procedures that may have contributed to infection or illness (e.g., endoscopy)		Overall antibiotic use rate in the facility or unit being monitored		
	Previous and recent admissions to your or another		Age distribution of the patient population		
	facility		Rate of colectomies being performed		
	Location of the patient prior to admission (e.g., home, long-term care, assisted living, etc.)				
	Location of patient upon discharge (home, long-term care, assisted living, etc.)				

Option #2

Laboratory surveillance involves working with the lab to create a list of all patients who had positive *C. difficile* tests and include any of the above data elements that are selected for monitoring by your facility. You may also choose to utilize the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN), a voluntary and secure Internet lab-based surveillance system. The NHSN system also allows for tracking of preventive-process measures. For more information visit: <u>http://www.cdc.gov/nhsn/mdro_cdad.html</u>.



COLORADO INFECTION PREVENTION COLLABORATIVE C. DIFFICILE INFECTIONS

C. DIFFICILE SURVEILLANCE

CDAD EXPOSURE SURVEILLANCE DEFINITIONS

For accurate surveillance, facilities should make use of shared definitions of disease exposure, as outlined in the diagram below. These definitions were created to provide a starting point for hospital surveillance activities and for comparison of rates between facilities. At a minimum, it is recommended that facilities monitor all healthcare-onset and healthcare-facility-associated CDI cases in order to be able to detect outbreaks. Decisions to report on Community Onset-Healthcare Facility Associated (CO-HCFA) and Community Associated-CDAD (CA-CDAD in addition to Healthcare Onset-Healthcare Facility Associated (HO-HCFA) should be determined by each institution based on the goal of surveillance, capacity, and the facility's ability to accurately report and classify the data.¹⁶ Benefits to monitoring community-onset and community-acquired cases include the ability to compare rates between facilities using these shared definitions, as well as the ability to learn more about the source of transmission in strains found in the community.



DEFINITIONS OF CDAD EXPOSURE CATEGORIES ¹⁴				
Healthcare Onset-Healthcare Facility Associated (HO-HCFA)	Symptoms occur 48 hours or more following admission to a healthcare facility.			
Community Onset-Healthcare Facility Associated (CO-HCFA)	Symptoms occur when the patient is in the community or within the first 48 hours after admission to a healthcare facility, as indicated by the (*) in the above diagram. Patient must not have had an overnight stay in any other healthcare facility in the previous four weeks.			
Community Associated-CDAD (CA-CDAD)	Symptoms occur when the patient is in the community or within the first 48 hours after admission to a healthcare facility. Patient must not have been admitted to a healthcare facility in the previous 12 weeks.			
Indeterminate	Patient has been diagnosed with CDAD but does not fit into any of the above exposure categories.			
Unknown	Patient has been diagnosed with CDAD, but there is a lack of data available to accurately classify the patient's exposure status.			
Recurrent	Patient has been diagnosed with CDAD but had also been diagnosed sometime during the previous eight weeks.			

COLORADO INFECTION PREVENTION COLLABORATIVE

C. DIFFICILE INFECTIONS

An accurate diagnosis of the *C. difficile* patient is crucial for several reasons. Upon diagnosis, the patient may be placed under isolation and treatment begins. Antibiotic regimens may change and other treatments may be changed or stopped. What if this patient was incorrectly diagnosed? The patient was tested and had a positive result, but the test was inaccurate. This patient may be placed with those who do have CDI and will be prescribed unnecessary treatments, potentially increasing their risk for CDI, and their true diagnosis may not be investigated. False-negative tests may result in equally precarious situations. Unfortunately, rather than having one recommended test for diagnosing patients with CDI, there are a multitude of options—none of which are perfect. This section describes some of the testing methodologies available and provides an overview of current recommendations.

<u>RECOMMENDATIONS</u>

In 2010, SHEA-IDSA published an update on their 1995 guidance of clinical practice for CDI in adults. The full guideline is available at the end of this section and provides recommendations for testing¹⁶:

- 1. Testing for *C. difficile* or its toxins should be performed only on unformed stool, unless ileus is suspected. (B-II)
- 2. Testing of asymptomatic patients is not clinically useful, including test of cure. This testing is only recommended for epidemiological studies. (B-III)
- 3. Stool culture is the most sensitive test and is essential for epidemiological studies. (A-II)
- 4. Although stool culture is not clinically practical because of its slow turnaround time, the sensitivity and specificity of stool culture followed by identification of a toxigenic isolate, as performed by an experienced laboratory, provides the standard against which other clinical test results should be compared. (B-III)
- 5. Enzyme immunoassay (EIA) testing for *C. difficile* toxin A and B is rapid but less sensitive than the cell cytotoxin assay, and it is thus a suboptimal alternative approach for diagnosis. (B-II)

- 6. Toxin testing is most important clinically, but is hampered by its lack of sensitivity. One strategy to overcome this involves a two-step method that uses EIA detection of GDH (glutamate dehydrogenase) as an initial screening and then the cell cytotoxicity assay or toxigenic culture as the confirmatory test for GDH-positive stool samples only. (B-II)
- 7. Polymerase chain reaction (PCR) testing appears to be rapid, sensitive, and specific, and it may ultimately address testing concerns. More data on utility are necessary before this methodology can be recommended for routine testing. (B-II)
- 8. Repeat testing during the same episode of diarrhea is of limited value and should be discouraged. (B-II)

COLORADO INFECTION PREVENTION COLLABORATIVE
C. DIFFICILE INFECTIONS

TESTING METHODS^{16,17,18}

There are many testing options available for the diagnosis of CDI. Facilities must weigh several factors when deciding which testing will be used.

DIAGNOSTIC TEST TYPE	ADVANTAGES	DISADVANTAGES	ADDITIONAL COMMENTS	BRAND NAMES
EIA for Toxin A and B (Enzyme Immunoassay)	 Rapid results (~2 hours) Inexpensive Easy to use High specificity (75%-100%) 	 Low sensitivity (63%–94%) Some only test for toxin A, not A and B, so some strains may be missed 	 Most widely used test Identifies toxins Repeat testing leads to greater risk of false positives 	 Premier (Meridian) Remel ProSpectT TechLab
Cell Cytotoxin Assay	 More sensitive than EIA tests for toxin (67%–100%) High specificity Identifies toxins 	 Results may vary with experience level of lab tech Not all labs equipped to perform test Takes time (24–48 hours) 	 Historical gold standard Must be transported to labs or refrigerated within 2 hours or toxin may degrade (also true for EIA) 	
Antigen (GDH)	 Rapid results (15-45 minutes) Sensitive (85%-95%) Low cost High negative predictive value makes for a good first-line screen 	Does not detect toxinNot 100% sensitive	• Ideal for use in 1st-line screening, followed by a toxin-specific test	• TechLab <i>C. difficile</i> Check
Toxigenic Culture	High sensitivityHigh specificity	Time consumingLabor intensive	 Stool is cultured, and a toxin assay is performed New "gold standard" 	
Stool Culture	• Most sensitive (89%– 100%)	 Time consuming (48–96 hours) Labor intensive Non-toxin specific 	• Should be used in conjunction with another test as it is not specific	
Polymerase Chain Reaction (PCR)	Rapid (minutes)More sensitive than EIADetects toxins	 Requires special equipment Current tests can be more costly than EIA 	 Newer test More studies need to be done with PCR before it can be recommended for routine testing 	 Cepheid Xpert C. difficile Gen Probe Prodesse pro- Gastro cd BD GeneOhm C. difficile Assay
Algorithm Testing	 Enhances sensitivity and positive predictive value Lowers costs by eliminating costly follow-up on patients with negative screening tests 	• More time consuming as more tests are conducted	• Algorithm testing involves using 2- to 3-step method beginning with an initial lower-cost screen, followed by toxin type testing	• Example: GDH screen followed by cell cytotoxin assay or EIA



COLORADO INFECTION PREVENTION COLLABORATIVE C. DIFFICILE INFECTIONS

REPEAT TESTING

The most common method for CDI testing is EIA for toxin A and B. However, false negative results are problematic. Practitioners may decide to repeat an EIA test if CDI is suspected. Repeat testing can potentially decrease the positive predictive value of tests and only minimally increases the number of patients that are correctly diagnosed.^{20,21} SHEA-IDSA states that repeat testing of a patient during the same episode of diarrhea is not very valuable and should be discouraged (B-II).¹⁶ Health facilities may consider instituting a policy regarding specific guidance on repeat testing to eliminate confusion.

COLONIZATION

An estimated 7%-11% of adult inpatients of acute care facilities are thought to be colonized with *C. difficile*. This figure is slightly lower at long-term-care facilities, with approximately 5%-7% of adults being colonized. In the community population, colonization is estimated to occur in about 2% of adults.¹⁴ Children are thought to have higher rates of colonization compared to adults. Healthcare workers have also been shown to have low rates of colonization, approximately 1.5%-1.7%.⁹

What is the risk of a patient who is colonized with C. difficile of developing CDI?

At present, colonized patients appear to be at reduced risk of developing symptomatic CDI compared with patients colonized with other organisms. Some studies indicate colonization may be seen as protective against a patient developing symptomatic disease.²² The patient who is newly exposed to a strain of *C. difficile* in the hospital environment is thought to be at greater risk of disease development.¹³

Should patients who are known to be colonized but are not symptomatic be isolated and placed under contact precautions?

The patient who is colonized with *C. difficile* is not thought to pose as much of a risk of contamination to other patients as symptomatic patients due to the increased contamination of the surrounding environment. It's controversial as to whether asymptomatic carriers are responsible for transmission of *C. difficile* to others, but current guidelines do not recommend putting into isolation.

Is treatment and decolonization recommended in asymptomatic carriers?

Current guidelines do not recommend identifying patients or healthcare workers for purposes of decolonization (A-III). Testing of patients with no symptoms is not recommended (B-III). Treatment of those colonized with *C. difficile* is also not recommended (B-I).¹⁶



COLORADO INFECTION PREVENTION COLLABORATIVE

TOOL KIT ARTICLE ABSTRACTS

• Recommendations for Surveillance of *Clostridium difficile*-Associated Disease.

The article included in your tool kit, "Recommendations for Surveillance of *Clostridium difficile*-Associated Disease," describes in detail interim recommendations for surveillance. The recommendations are based upon the most current evidence in the literature and are intended for use by inpatient and community healthcare facilities. It is imperative that healthcare facilities make use of shared definitions in order to help us understand the changing epidemiology and emergence of new risk factors in the development of disease.

McDonald LC, Coignard B, Dubberke E, et al. Recommendations for Surveillance of *Clostridium difficile*–Associated Disease. *Infect Control Hosp Epidemiol* 2007; 28:140–145. • Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults: 2010 Update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA).

The article included in your tool kit, "Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults: 2010 Update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA)," was developed to improve the diagnosis and management of *C. difficile* in adult inpatients. The article is included because it discusses many issues pertinent to infection control, including a discussion of laboratory testing methods, environmental prevention measures, and hand hygiene.

Cohen SH, Gerding DN, Johnson S, et al. Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults: 2010 Update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). *Infect Control Hosp Epidemiol* 2010; 31 (5):431–455.

COLORADO INFECTION PREVENTION COLLABORATIVE C. DIFFICILE INFECTIONS

ORIGINAL ARTICLE

Recommendations for Surveillance of *Clostridium difficile*–Associated Disease

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BACKGROUND. The epidemiology of *Clostridium difficile*-associated disease (CDAD) is changing, with evidence of increased incidence and severity. However, the understanding of the magnitude of and reasons for this change is currently hampered by the lack of standardized surveillance methods.

OBJECTIVE AND METHODS. An ad hoc C. difficile surveillance working group was formed to develop interim surveillance definitions and recommendations based on existing literature and expert opinion that can help to improve CDAD surveillance and prevention efforts.

DEFINITIONS AND RECOMMENDATIONS. A CDAD case patient was defined as a patient with symptoms of diarrhea or toxic megacolon combined with a positive result of a laboratory assay and/or endoscopic or histopathologic evidence of pseudomembranous colitis. Recurrent CDAD was defined as repeated episodes within 8 weeks of each other. Severe CDAD was defined by CDAD-associated admission to an intensive care unit, colectomy, or death within 30 days after onset. Case patients were categorized by the setting in which *C. difficile* was likely acquired, to account for recent evidence that suggests that healthcare facility–associated CDAD may have its onset in the community up to 4 weeks after discharge. Tracking of healthcare facility–onset, healthcare facility–associated CDAD should be performed only in conjunction with tracking of healthcare facility–onset, healthcare facility–associated CDAD was defined by symptom onset more than 12 weeks after the last discharge from a healthcare facility. Rates of both healthcare facility–onset, healthcare facility–associated CDAD and community-onset, healthcare facility–associated CDAD should be expressed as case patients per 10,000 patient-days; rates of community-associated CDAD should be expressed as case patients per 10,000 patient-days; rates of community-associated CDAD should be expressed.

Infect Control Hosp Epidemiol 2007; 28:140-145

Clostridium difficile is an anaerobic, spore-forming bacillus that is responsible for a spectrum of C. difficile-associated disease (CDAD), including uncomplicated diarrhea, pseudomembranous colitis, and toxic megacolon, which can, in some instances, lead to sepsis and even death.' C. difficile is the most commonly recognized cause of diarrhea in hospitalized patients; it has been recommended that patients who develop diarrhea more than 3 days after admission be tested only for C. difficile as the possible infectious etiology for their symptoms,² The main modifiable risk factor for CDAD is antimicrobial use, which increases risk through an alteration in the patient's normal lower-intestinal flora and, in some instances, also selects for highly antimicrobial-resistant strains of C. difficile.3 It is thought that the alteration in the complex ecology of the large bowel provides C. difficile an opportunity to thrive and produce disease.1

Recent increases in CDAD incidence and severity⁴⁻⁸ have highlighted the need for standardized reporting definitions and surveillance methods.^{8 10} CDAD surveillance can serve several purposes. Currently, the primary purposes, from a public health standpoint, are to guide the implementation of interventions to control CDAD in healthcare facilities (HCFs) and to monitor the impact of such interventions. These purposes may be achieved by detecting outbreaks and disease trends in individual HCFs and by comparing CDAD rates among similar institutions. To properly make such comparisons, standardized case definitions are needed. Additional public health purposes of CDAD surveillance include understanding the emergence of community disease, severe or recurrent, and disease in previously low-risk populations.

Much of the science pertaining to CDAD surveillance, both inside and outside HCFs, is still in its infancy and is evolving rapidly, as the changing epidemiology unfolds. This article is intended to put forth interim recommendations for surveillance, including case definitions. These recommendations primarily address CDAD surveillance for inpatient healthcare

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DEFINITIONS

An HCF is defined as any acute care, long-term care, longterm acute care, or other facility in which skilled nursing care is provided and patients are admitted at least overnight.

personnel responsible for infection surveillance and control.

A CDAD case is defined as a case of diarrhea (ie, unformed stool that conforms to the shape of a specimen collection container) or toxic megacolon (ie, abnormal dilation of the large intestine documented radiologically) without other known etiology that meets 1 or more of the following criteria; (1) the stool sample yields a positive result for a laboratory assay for *C. difficile* toxin A and/or B, or a toxin-producing *C. difficile* organism is detected in the stool sample by culture or other means; (2) pseudomembranous colitis is seen during endoscopic examination or surgery; and (3) pseudomembranous colitis is seen during histopathological examination. The CDAD case definition may be implemented for laboratory-based reporting systems by focusing only on criterion 1, if the laboratory routinely performs tests for *C. difficile* only on unformed stools.

A recurrent CDAD case is defined as an episode of CDAD (ie, one that meets the criteria for a CDAD case) that occurs 8 weeks or less after the onset of a previous episode, provided that CDAD symptoms from the earlier episode resolved with or without therapy. The recurrent CDAD case definition may be implemented for laboratory-based reporting systems on the basis of the following stipulations: (1) an additional positive result of a laboratory test performed on a specimen collected 2 weeks or less after the last specimen that tested positive represents continuation of the same CDAD case, (2) an additional positive result of a laboratory test performed on a specimen collected 2-8 weeks after the last specimen that tested positive represents a recurrent CDAD case, and (3) an additional positive result of a laboratory test performed on a specimen collected more than 8 weeks after the last specimen that tested positive represents a new CDAD case.

A case patient with severe CDAD is defined as a case patient who meets any of the following criteria within 30 days after CDAD symptom onset (or, in the case of laboratory-based reporting, within 30 days after the index laboratory test): (1) history of admission to an intensive care unit for complications associated with CDAD (eg, for shock that requires vasopressor therapy); (2) history of surgery (eg, colectomy) for toxic megacolon, perforation, or refractory colitis; and (3) death caused by CDAD within 30 days after symptom onset (eg, as listed on the death certificate or recorded in the medical record by a clinician caring for the patient).

CDAD case patients are further defined by their exposures (Figure), as follows.

1. A patient classified as having HCF-onset, HCF-associ-

ated CDAD is defined as a patient with CDAD symptom onset more than 48 hours after admission to an HCF.

2. A patient classified as having community-onset, HCFassociated CDAD is defined as a patient with CDAD symptom onset in the community or 48 hours or less after admission to an HCF, provided that symptom onset was less than 4 weeks after the last discharge from an HCF.

3. A patient classified as having community-associated CDAD is defined as a patient with CDAD symptom onset in the community or 48 hours or less after admission to an HCF, provided that symptom onset was more than 12 weeks after the last discharge from an HCF.

4. A patient classified as having indeterminate disease is defined as a CDAD case patient who does not fit any of the above criteria for an exposure setting—for example, a patient who has CDAD symptom onset in the community but who was discharged from the same or another HCF 4-12 weeks before symptom onset.

5. A patient classified as having unknown disease is a CDAD case patient for whom the exposure setting cannot be determined because of lack of available data—for example, a patient who has CDAD symptom onset in the community or 48 hours or less after HCF admission and for whom available medical records are not sufficient to exclude discharge from an HCF 12 weeks or less before symptom onset.

SURVEILLANCE RECOMMENDATIONS

Use of the Definitions

Depending on the purposes of surveillance, all or only some of the above case definitions may be appropriate for use. For example, if the sole purpose is to track and compare HCFassociated CDAD, indeterminate cases may not need to be differentiated from community-associated CDAD cases; instead, both indeterminate and community-associated CDAD could be reported in aggregate or not reported at all. If the



FIGURE. Time line for definitions of *Clostridium difficile*–associated disease (CDAD) exposures. Case patients with symptom onset during the window of hospitalization marked by an asterisk (*) would be classified as having community-onset, healthcare facility– associated disease (CO-HCFA), if patient was discharged from a healthcare facility within the previous 4 weeks; would be classified as having indeterminate disease, if the patient was discharged from a healthcare facility between the previous 4-12 weeks; or would be classified as having community-associated CDAD (CA-CDAD), if the patient was not discharged from a healthcare facility in the previous 12 weeks. HO-HCFA, healthcare facility–onset, healthcare facility–associated CDAD. purpose is only to track new incident cases, reporting of recurrent cases may not be necessary (ie, use of an 8-week "lock out" period during which a patient cannot be classified as a case patient again). Finally, if the purpose is only to track disease trends in the community, only community-associated CDAD cases need to be reported.

Use of the HCF-Onset, HCF-Associated Definition Versus the HCF-Onset, HCF-Associated and Community-Onset, HCF-Associated Definitions Combined

The decision to report community-onset, HCF-associated cases in addition to HCF-onset, HCF-associated cases should be made by HCFs and surveillance systems on the basis of their ability to categorize cases correctly and the capacity of the reporting infrastructure. The scientific background and rationale for including community-onset, HCF-associated cases is provided in the Appendix. However, there are additional principles that should be considered for use of the HCF-onset, HCF-associated case definition alone or in combination with the community-onset, HCF-associated case definition.

1. If interfacility comparisons are to be made, they should be made using only the same definitions (ie, the HCF-onset, HCF-associated case definition alone or in combination with the community-onset, HCF-associated case definition).

2. Community-onset, HCF-associated cases should be attributed to the reporting period during which the case patient was discharged from the HCF before CDAD symptom onset. For example, if a patient was discharged on June 25 and was readmitted with CDAD on July 12, the case should be assigned to June. Because of the need to assign communityonset, HCF-associated cases to the previous inpatient stay, HCFs and surveillance systems that choose to use this definition should make allowance for a 1-2 month delay in finalizing case numbers and rates for the reporting period.

3. Community-onset, HCF-associated cases should be attributed to the HCF from which the patient was last discharged, providing the patient was an inpatient of that HCF for more than 48 hours. In essence, inclusion of communityonset, HCF-associated cases in CDAD reporting is a form of postdischarge surveillance that, for success in most surveillance systems, assumes that the majority of patients who develop symptoms of CDAD soon after discharge return to the same HCF for care. However, it is anticipated that some surveillance systems could also successfully track communityonset, HCF-associated case patients discharged from different HCFs by identifying the HCF from which the patient was last discharged in the case report. If this is possible, another category could be assigned for such case patients-namely, patients with community-onset, HCF-associated from another facility CDAD. A name or identifier of the other facility from which the patient was last discharged may also be reported in some systems.

 Reporting of community-onset, HCF-associated cases should only be performed in addition to reporting of HCF- onset, HCF-associated cases; rates of each type of case should be calculated and tracked independently. The rate of HCFonset, HCF-associated cases is considered the minimum surveillance required for healthcare settings. Tracking and feedback of each rate independently will allow comparison of rates of HCF-onset, HCF-associated CDAD with data from HCFs and surveillance systems that do not track rates of community-onset, HCF-associated CDAD.

Denominators for and Expression of CDAD Rates

Rates of HCF-onset, HCF-associated cases and rates of community-onset, HCF-associated cases should be expressed, for feedback and comparative purposes, as case patients per reporting period (ie, per month, for most HCFs and surveillance systems) per 10,000 patient-days. The calculation of this rate is [number of case patients per reporting period / number of inpatient days per reporting period] \times 10,000 = rate per 10,000 inpatient-days.

Because this rate reflects the per-day patient risk of *C. difficile* transmission and disease risk factors (eg, antimicrobial exposures), it is the most useful across different types of HCFs with varying average lengths of patient stay. These rates are also useful for comparison of disease incidence between wards or units within an HCF in which such ward- or unit-specific denominators are available.

For those systems designed to track community-associated CDAD, rates should be calculated and expressed as case patients per 100,000 population during the reporting period (ie, usually person-years). Rates of severe CDAD should be expressed as a percentage of the CDAD cases that occurred during the reporting period along with the absolute number of severe cases.

Additional Recommendations

Cases may be reported either as individual events or in aggregate as the count of cases per reporting period, along with recommended denominator data. Individual case reports offer the opportunity to collect additional data that could allow future refinement of case definitions, answer important research questions, or suggest the underlying risk of CDAD in different patient populations (eg, to determine the age distribution of case patients). It may also be useful to collect HCF-level data on a periodic basis. For example, the type of diagnostic test(s) used, the volume of tests ordered, the number of prescriptions of oral metronidazole and vancomycin, the overall antimicrobial use in the HCF, and the age distribution of the patient population. Although possibly too burdensome to collect on an ongoing basis, these data could assist in the creation of more-meaningful comparisons of rates.

CONCLUSIONS

In summary, although the data to support the above-outlined definitions are far from complete, early evidence suggests that these definitions may help to direct surveillance and reporting initiatives. Additional studies are urgently needed to answer several questions. For example, what proportion of probable CDAD cases are currently diagnosed and treated empirically and, therefore, will not fulfill the laboratory, endoscopic, or histopathologic criteria outlined above? Although the experience at one hospital suggests that 1% of cases or fewer are diagnosed using the endoscopic or histopathologic criteria," it is unknown whether, in some hospitals, these criteria are necessary to capture most cases.12 Are there significant differences in CDAD rates, depending on the diagnostic tests and the testing algorithms used? Do rates based on HCFonset, HCF-associated cases alone correlate with rates based on HCF-onset, HCF-associated cases and community-onset, HCF-associated cases combined across a number of HCFs? Can typing of C. difficile strain be used to better define the epidemiology of CDAD cases occurring soon after discharge from HCFs? Even before these questions can be answered, it is expected that the principles set forth here will improve methods for surveillance and will lead to a better understanding of how best to prevent C. difficile transmission and the development of CDAD.

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APPENDIX

RATIONALE FOR REPORTING COMMUNITY-ONSET, HCF-ASSOCIATED CDAD IN ADDITION TO HCF-ONSET, HCF-ASSOCIATED CDAD

Inpatient stay in an HCF is a recognized risk factor for CDAD. For example, recent reports suggest that rates of CDAD in acute care facilities range from 3 to 25 case patients per 10,000 patient-days, with most rates for facilities where CDAD is endemic being between 5 and 10 case patients per 10,000 patient-days.^{10,13-15} In contrast, rates of CDAD among persons living in the community without recent healthcare contact are 8-25 case patients per 100,000 person-years.¹⁶⁻¹⁹ Although some reports suggest that the risk of CDAD among patients without recent HCF exposure may be increasing,^{20,21} the majority of CDAD cases still involve persons with ongoing or recent HCF exposure.^{9,21-24} One study showed that, whereas the risk of developing CDAD was 1,300-fold greater in acute care facilities than in the community, the density of antimicrobial usage was only 37-fold greater in acute care facilities.¹⁹ Although some of this increased risk in HCFs is related to the advanced age of patients, the severity of illness, and the types of antimicrobials used, it also points to the propensity for persons to be newly exposed to *C. difficile* organisms in HCFs, where there is a concentration of symptomatic patients with CDAD.²⁵

In addition to an increased risk of CDAD, HCF exposure is associated with an increased risk of C. difficile colonization. Rates of asymptomatic colonization with C. difficile range from 7% to 11% among asymptomatic adult inpatients of acute care facilities^{25,26} and from 5% to 7% among elderly patients in long-term care facilities.27,28 In at least 2 studies, the risk of colonization was shown to increase during hospitalization, suggesting a cumulative daily risk of exposure to the healthcare environment.25,29 Although 2 recent reports from Japan suggest that rates of carriage among asymptomatic adults without recent HCF exposure may be higher than previously thought,30,31 these studies either involved culture of specimens from the same patient on multiple occasions, suggesting transient colonization,30 or involved the use of newly developed molecular methods that have not been similarly applied to patients in HCFs.34 Historically, rates of carriage among asymptomatic adults without recent HCF exposure were found to be generally less than 2%,32,33 A recent study involving infants and very young children, in whom rates of asymptomatic carriage are known to be higher than in adults,32 suggested that person-to-person transmission is responsible for carriage.34

Although the usual incubation period from exposure to onset of CDAD symptoms is not known with certainty, persons who remain asymptomatically colonized with C, difficile, compared with persons colonized with other multidrug-resistant pathogens, over longer periods of time appear to be at decreased, rather than increased, risk for development of CDAD.25,35-37 The protection afforded by more longstanding colonization may be mediated by the boosting of the body's serum levels of antibody to C. difficile toxins A and B.35,36 However, protection is also observed in humans and animal models when colonization occurs with nontoxigenic strains.37,38 Whatever the mechanism of protection afforded by asymptomatic colonization, it is the patient who is newly exposed to C. difficile, rather than the patient already colonized with C. difficile, who is at an increased risk for development of CDAD during stay at an HCF.

The period between exposure to *C. difficile* in an HCF inpatient and the development of CDAD was estimated in 1 study to be less than 7 days.³⁹ This is to be distinguished from the increased risk of CDAD that can persist for many weeks after cessation of antimicrobial therapy because of prolonged perturbation of normal intestinal flora.⁴⁰ Despite ear-
lier evidence of a relatively short incubation period (ie, less than 7 days), more recent evidence suggests that CDAD acquired in HCFs may have its onset after discharge.^{9,22,24} Although CDAD symptom onset may occur in patients as many as 2-3 months after discharge,^{9,24} limited data suggest that the majority of patients with delayed-onset cases have CDAD symptom onset within 4 weeks after discharge.²²

The likelihood that HCF transmission is responsible for these delayed-onset cases is suggested by several epidemiologic observations. First, as elucidated by close questioning, some of these patients had their earliest symptom onset before discharge.22 Second, the incidence among persons recently discharged from HCFs appears to be much higher than the incidence among persons without recent HCF exposure. Third, when compared with outpatient control subjects who were also recently discharged, patients with CDAD onset after discharge had longer lengths of previous inpatient stay, suggesting a longer period of exposure during which transmission could have occurred.9 Finally, a significant correlation has been observed over time between the number of HCFonset, HCF-associated case patients and the number of community-onset, HCF-associated case patients recorded monthly within a single HCF (Centers for Disease Control and Prevention, unpublished data). There is less correlation between these numbers if HCF-associated case patients include patients who were transferred to another HCF, suggesting that inpatient stay at another HCF carries with it an independent, increased risk of C. difficile exposure. This supports the recommendation that case patients be attributed to the last HCF facility from which the patient was discharged.

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SHEA-IDSA GUIDELINE

Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults: 2010 Update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA)

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Since publication of the Society for Healthcare Epidemiology of America position paper on *Clostridium difficile* infection in 1995, significant changes have occurred in the epidemiology and treatment of this infection. *C. difficile* remains the most important cause of healthcare-associated diarrhea and is increasingly important as a community pathogen. A more virulent strain of *C. difficile* has been identified and has been responsible for more-severe cases of disease worldwide. Data reporting the decreased effectiveness of metronidazole in the treatment of severe disease have been published. Despite the increasing quantity of data available, areas of controversy still exist. This guideline updates recommendations regarding epidemiology, diagnosis, treatment, and infection control and environmental management.

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EXECUTIVE SUMMARY

This guideline is designed to improve the diagnosis and management of *Clostridium difficile* infection (CDI) in adult patients. A case of CDI is defined by the presence of symptoms (usually diarrhea) and either a stool test positive for *C. difficile* toxins or toxigenic *C. difficile*, or colonoscopic or histopathologic findings revealing pseudomembranous colitis. In addition to diagnosis and management, recommended methods of infection control and environmental management of the pathogen are presented. The recommendations are based on the best available evidence and practices, as determined by a joint Expert Panel appointed by SHEA and the Infectious Diseases Society of America (IDSA) (the SHEA-IDSA Expert Panel). The use of these guidelines can be impacted by the size of the institution and the resources, both financial and laboratory, available in the particular clinical setting.

I. Epidemiology: What are the minimum data that should be collected for surveillance purposes and how should the data be reported?

1. To increase comparability between clinical settings, use available standardized case definitions for surveillance of (1) healthcare facility (HCF)-onset, HCF-associated CDI; (2) community-onset, HCF-associated CDI; and (3) community-associated CDI (Figure 1) (**B-III**).

2. At a minimum, conduct surveillance for HCF-onset, HCF-associated CDI in all inpatient healthcare facilities, to detect outbreaks and monitor patient safety (**B-III**).

3. Express the rate of healthcare-associated CDI as the number of cases per 10,000 patient-days (B-III).

4. If CDI rates are high compared with those at other facilities or if an outbreak is noted, stratify rates by patient location in order to target control measures (B-III).

II. Diagnosis: What is the best testing strategy to diagnose CDI in the clinical laboratory and what are acceptable options?

5. Testing for *C. difficile* or its toxins should be performed only on diarrheal (unformed) stool, unless ileus due to *C. difficile* is suspected (**B-II**).

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6. Testing of stool from asymptomatic patients is not clinically useful, including use as a test of cure. It is not recommended, except for epidemiological studies. (B-III)

7. Stool culture is the most sensitive test and is essential for epidemiological studies (A-II).

8. Although stool culture is not clinically practical because of its slow turnaround time, the sensitivity and specificity of stool culture followed by identification of a toxigenic isolate (ie, toxigenic culture), as performed by an experienced laboratory, provides the standard against which other clinical test results should be compared (B-III).

9. Enzyme immunoassay (EIA) testing for *C. difficile* toxin A and B is rapid but is less sensitive than the cell cytotoxin assay, and it is thus a suboptimal alternative approach for diagnosis (**B-II**).

10. Toxin testing is most important clinically, but is hampered by its lack of sensitivity. One potential strategy to overcome this problem is a 2-step method that uses EIA detection of glutamate dehydrogenase (GDH) as initial screening and then uses the cell cytotoxicity assay or toxigenic culture as the confirmatory test for GDH-positive stool specimens only. Results appear to differ based on the GDH kit used; therefore, until more data are available on the sensitivity of GDH testing, this approach remains an interim recommendation. (B-II)

11. Polymerase chain reaction (PCR) testing appears to be rapid, sensitive, and specific and may ultimately address testing concerns. More data on utility are necessary before this methodology can be recommended for routine testing. (B-II)

12. Repeat testing during the same episode of diarrhea is of limited value and should be discouraged (**B-II**).

III. Infection Control and Prevention: What are the most important infection control measures to implement in the hospital during an outbreak of CDI?

A. Measures for Healthcare Workers, Patients, and Visitors

13. Healthcare workers and visitors must use gloves (A-I) and gowns (B-III) on entry to a room of a patient with CDI.

14. Emphasize compliance with the practice of hand hygiene (A-II).

15. In a setting in which there is an outbreak or an increased CDI rate, instruct visitors and healthcare workers to wash hands with soap (or antimicrobial soap) and water after caring for or contacting patients with CDI (**B-III**).

16. Accommodate patients with CDI in a private room with contact precautions (**B-III**). If single rooms are not available, cohort patients, providing a dedicated commode for each patient (**C-III**).

17. Maintain contact precautions for the duration of diarrhea (C-III).

18. Routine identification of asymptomatic carriers (patients or healthcare workers) for infection control purposes is not recommended (A-III) and treatment of such identified patients is not effective (B-I).

B. Environmental Cleaning and Disinfection

19. Identification and removal of environmental sources of *C. difficile*, including replacement of electronic rectal thermometers with disposables, can reduce the incidence of CDI (**B-II**),

20. Use chlorine-containing cleaning agents or other sporicidal agents to address environmental contamination in areas associated with increased rates of CDI (B-II).

21. Routine environmental screening for C. difficile is not recommended (C-III).

C. Antimicrobial Use Restrictions

22. Minimize the frequency and duration of antimicrobial therapy and the number of antimicrobial agents prescribed, to reduce CDI risk (A-II).

23. Implement an antimicrobial stewardship program (A-II). Antimicrobials to be targeted should be based on the local epidemiology and the *C. difficile* strains present, but restricting the use of cephalosporin and clindamycin (except for surgical antibiotic prophylaxis) may be particularly useful (C-III).

D. Use of Probiotics

24. Administration of currently available probiotics is not recommended to prevent primary CDI, as there are limited data to support this approach and there is a potential risk of bloodstream infection (C-III).

IV. Treatment: Does the choice of drug for CDI matter and, if so, which patients should be treated and with which agent?

25. Discontinue therapy with the inciting antimicrobial agent(s) as soon as possible, as this may influence the risk of CDI recurrence (A-II).

26. When severe or complicated CDI is suspected, initiate empirical treatment as soon as the diagnosis is suspected (C-III).

27. If the stool toxin assay result is negative, the decision to initiate, stop, or continue treatment must be individualized (C-III).

28. If possible, avoid use of antiperistaltic agents, as they may obscure symptoms and precipitate toxic megacolon (C-III).

29. Metronidazole is the drug of choice for the initial episode of mild-to-moderate CDI. The dosage is 500 mg orally 3 times per day for 10–14 days. (A-I)

30. Vancomycin is the drug of choice for an initial episode of severe CDI. The dosage is 125 mg orally 4 times per day for 10–14 days. (B-I)

31. Vancomycin administered orally (and per rectum, if ileus is present) with or without intravenously administered metronidazole is the regimen of choice for the treatment of severe, complicated CDI. The vancomycin dosage is 500 mg orally 4 times per day and 500 mg in approximately 100 mL normal saline per rectum every 6 hours as a retention enema, and the metronidazole dosage is 500 mg intravenously every 8 hours. (C-III)

32. Consider colectomy for severely ill patients. Monitoring the serum lactate level and the peripheral blood white blood cell count may be helpful in prompting a decision to operate, because a serum lactate level rising to 5 mmol/L and a white blood cell count rising to 50,000 cells per μ L have been associated with greatly increased perioperative mortality. If surgical management is necessary, perform subtotal colectomy with preservation of the rectum. (B-II)

33. Treatment of the first recurrence of CDI is usually with the same regimen as for the initial episode (A-II) but should be stratified by disease severity (mild-to-moderate, severe, or severe complicated), as is recommended for treatment of the initial CDI episode (C-III).

34. Do not use metronidazole beyond the first recurrence of CDI or for long-term chronic therapy because of potential for cumulative neurotoxicity (**B-II**).

35. Treatment of the second or later recurrence of CDI with vancomycin therapy using a tapered and/or pulse regimen is the preferred next strategy (**B-III**).

 No recommendations can be made regarding prevention of recurrent CDI in patients who require continued antimicrobial therapy for the underlying infection (C-III).

INTRODUCTION

Summary Definition of CDI

A case definition of CDI should include the presence of symptoms (usually diarrhea) and either a stool test result positive for *C. difficile* toxins or toxigenic *C. difficile*, or colonoscopic findings demonstrating pseudomembranous colitis.

Definition of CDI

The diagnosis of CDI should be based on a combination of clinical and laboratory findings. A case definition for the usual presentation of CDI includes the following findings: (1) the presence of diarrhea, defined as passage of 3 or more unformed stools in 24 or fewer consecutive hours1-8; (2) a stool test result positive for the presence of toxigenic C. difficile or its toxins or colonoscopic or histopathologic findings demonstrating pseudomembranous colitis. The same criteria should used to diagnose recurrent CDI. A history of treatment with antimicrobial or antineoplastic agents within the previous 8 weeks is present for the majority of patients.9 In clinical practice, antimicrobial use is often considered part of the operative definition of CDI, but it is not included here because of occasional reports of CDI in the absence of antimicrobial use, usually in community-acquired cases.10 A response to specific therapy for CDI is suggestive of the diagnosis. Rarely (in fewer than 1% of cases), a symptomatic patient will present with ileus and colonic distension with minimal or no diarrhea.¹¹ Diagnosis in these patients is difficult; the only specimen available may be a small amount of formed stool or a swab of stool obtained either from the rectum or from within the colon via endoscopy. In such cases, it is important to communicate to the laboratory the necessity to do a toxin assay or culture for *C. difficile* on the nondiarrheal stool specimen.

Background

The vast majority of anaerobic infections arise from endogenous sources. However, a number of important clostridial infections and intoxications are caused by organisms acquired from exogenous sources. It is the ability of these organisms to produce spores that explains how *C. difficile*, a fastidiously anaerobic organism in its vegetative state, can be acquired from the environment. *C. difficile* is recognized as the primary pathogen responsible for antibiotic-associated colitis and for 15%–25% of cases of nosocomial antibiotic-associated diarrhea.¹²⁻¹⁴

C. difficile can be detected in stool specimens of many healthy children under the age of 1 year^{15,16} and a few percent of adults.^{17,18} Although these data support the potential for endogenous sources of human infection, there was early circumstantial evidence to suggest that this pathogen could be transmissible and acquired from external sources. Cases often appear in clusters and outbreaks within institutions.^{19,20} Animal models of disease also provide evidence for transmissibility of *C. difficile*.^{21,22} Subsequently, many epidemiologic studies of CDI confirm the importance of *C. difficile* as a transmissible nosocomial pathogen.^{1,9,23-25}

Clinical Manifestations

The clinical manifestations of infection with toxin-producing strains of *C. difficile* range from symptomless carriage, to mild or moderate diarrhea, to fulminant and sometimes fatal pseudomembranous colitis.^{13,14,26} Several studies have shown that 50% or more of hospital patients colonized by *C. difficile* are symptomless carriers, possibly reflecting natural immunity.^{1, 3,5,27} Olson et al²⁸ reported that 96% of patients with symptomatic *C. difficile* infection had received antimicrobials within the 14 days before the onset of diarrhea and that all had received an antimicrobial within the previous 3 months. Symptoms of CDI usually begin soon after colonization, with a median time to onset of 2–3 days.^{15,33,27}

C. difficile diarrhea may be associated with the passage of mucus or occult blood in the stool, but melena or hematochezia are rare. Fever, cramping, abdominal discomfort, and a peripheral leukocytosis are common but found in fewer than half of patients.^{11,13,14,29} Extraintestinal manifestations, such as arthritis or bacteremia, are very rare.^{30 33} *C. difficile* ileitis or pouchitis has also been rarely recognized in patients who have previously undergone a total colectomy (for complicated CDI or some other indication).³⁴ Clinicians should

Category and grade	Definition		
Strength of recommendation			
A	Good evidence to support a recommendation for or against use		
В	Moderate evidence to support a recommendation for or against use		
C	Poor evidence to support a recommendation		
Quality of evidence			
I	Evidence from at least 1 properly randomized, controlled trial		
U	Evidence from at least 1 well-designed clinical trial without randomization, from cohort or case-con- trolled analytic studies (preferably from more than 1 center), from multiple time-series, or from dramatic results from uncontrolled experiments		
m	Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees		

TABLE 1. Definitions of the Strength of Recommendations and the Quality of the Evidence Supporting Them

NOTE. Adapted and reproduced from the Canadian Task Force on the Periodic Health Examination,³⁹ with the permission of the Minister of Public Works and Government Services Canada, 2009.

consider the possibility of CDI in hospitalized patients who have unexplained leukocytosis, and they should request stool be sent for diagnostic testing.^{35,36} Patients with severe disease may develop a colonic ileus or toxic dilatation and present with abdominal pain and distension but with minimal or no diarrhea.^{11,13,14} Complications of severe *C. difficile* colitis include dehydration, electrolyte disturbances, hypoalbuminemia, toxic megacolon, bowel perforation, hypotension, renal failure, systemic inflammatory response syndrome, sepsis, and death.^{11,24,25}

Clinical Questions for the 2010 Update

In 1995, the Society for Healthcare Epidemiology of America (SHEA) published a clinical position paper on *C. difficile*-associated disease and colitis.³⁷ For the current update, the epidemiology, diagnosis, infection control measures, and indications and agents for treatment from the 1995 position paper were reviewed by a joint Expert Panel appointed by SHEA and the Infectious Diseases Society of America (IDSA). The previous document is a source for a more detailed review of earlier studies.

The SHEA-IDSA Expert Panel addressed the following clinical questions in this update:

I. What are the minimum data that should be collected for surveillance purposes, and how should the data be reported? Have the risk factors for CDI changed?

II. What is the best testing strategy to diagnose CDI in the clinical laboratory and what are acceptable options?

III. What are the most important infection control measures to implement in the hospital during an outbreak of CDI?

IV. Does the choice of drug for treatment of CDI matter and, if so, which patients should be treated and with which agent?

PRACTICE GUIDELINES DEFINITION

"Practice guidelines are systematically developed statements to assist practitioners and patients in making decisions about appropriate health care for specific clinical circumstances.^{38(p8)} Attributes of good guidelines include validity, reliability, reproducibility, clinical applicability, clinical flexibility, clarity, multidisciplinary process, review of evidence, and documentation.^{358(p8)}

UPDATE METHODOLOGY

Panel Composition

The SHEA Board of Directors and the IDSA Standards and Practice Guidelines Committee convened a panel of experts in the epidemiology, diagnosis, infection control, and clinical management of adult patients with CDI to develop these practice guidelines.

Literature Review and Analysis

For the 2010 update, the SHEA-IDSA Expert Panel completed the review and analysis of data published since 1994. Computerized literature searches of PubMed were performed. The searches of the English-language literature from 1994 through April 2009 used the terms "*Clostridium difficile*," "epidemiology," "treatment," and "infection control" and focused on human studies.

Process Overview

In evaluating the evidence regarding the management of CDI, the Expert Panel followed a process used in the development of other SHEA-IDSA guidelines. The process included a systematic weighting of the quality of the evidence and the strength of each recommendation (Table 1).³⁹

Guidelines and Conflict of Interest

All members of the Expert Panel complied with the SHEA and IDSA policy on conflicts of interest, which requires disclosure of any financial or other interest that might be construed as constituting an actual, potential, or apparent conflict. Members of the Expert Panel were provided with the SHEA and IDSA conflict of interest disclosure statement and were asked to identify ties to companies developing products that might be affected by promulgation of the guideline. Information was requested regarding employment, consultancies, stock ownership, honoraria, research funding, expert testimony, and membership on company advisory boards or committees. The Expert Panel made decisions on a case-bycase basis as to whether an individual's role should be limited as a result of a conflict. No limiting conflicts were identified.

Revision Dates

At annual intervals, SHEA and IDSA will determine the need for revisions to the guideline on the basis of an examination of the current literature and the likelihood that any new data will have an impact on the recommendations. If necessary, the entire Expert Panel will be reconvened to discuss potential changes. Any revision to the guideline will be submitted for review and approval to the appropriate Committees and Boards of SHEA and IDSA.

GUIDELINE RECOMMENDATIONS FOR CLOSTRIDIUM DIFFICILE INFECTION (CDI)

I. WHAT ARE THE MINIMUM DATA THAT SHOULD BE COLLECTED FOR SURVEILLANCE PURPOSES, AND HOW SHOULD THE DATA BE REPORTED?

Recommendations

1. To increase comparability between clinical settings, use available standardized case definitions for surveillance of (1) healthcare facility (HCF)-onset, HCF-associated CDI; (2) community-onset, HCF-associated CDI; and (3) community-associated CDI (Figure 1) (**B-III**).

2. At a minimum, conduct surveillance for HCF-onset, HCF-associated CDI in all inpatient healthcare facilities, to detect outbreaks and monitor patient safety (B-III).

3. Express the rate of healthcare-associated CDI as the number of cases per 10,000 patient-days (B-III).

4. If CDI rates are high compared with those at other

facilities or if an outbreak is noted, stratify rates by patient location in order to target control measures (**B-III**). Evidence Summary

Prevalence, incidence, morbidity, and mortality. C. difficile accounts for 20%–30% of cases of antibiotic-associated diarrhea¹² and is the most commonly recognized cause of infectious diarrhea in healthcare settings. Because C. difficile infection is not a reportable condition in the United States, there are few surveillance data. However, based upon surveys of Canadian hospitals conducted in 1997 and 2005, incidence rates range from 3.8 to 9.5 cases per 10,000 patient-days, or 3.4 to 8.4 cases per 1,000 admissions, in acute care hospitals.^{40,A1}

Although there are no regional or national CDI surveillance data for long-term care facilities, patients in these settings are often elderly and have been exposed to antimicrobials, both important risk factors for CDI, suggesting that rates of disease and/or colonization42.43 could potentially be high.43 A recent analysis of US acute care hospital discharges found that the number of patients transferred to a long-term care facility with a discharge diagnosis of CDI doubled between 2000 and 2003; in 2003, nearly 2% of patients transferred on discharge from an acute care hospital to a long-term care facility carried the diagnosis of CDI. Historically, the attributable mortality of CDI has been low, with death as a direct or indirect result of infection occurring in less than 2% of cases.28,40,44 However, the attributable excess costs of CDI suggest a substantial burden on the healthcare system. From 1999-2003 in Massachusetts, a total of 55,380 inpatient-days and \$55.2 million were consumed by management of CDI. An estimate of the annual excess hospital costs in the US is \$3.2 billion per year for the years 2000-2002.45

Changing epidemiology. Recently, the epidemiology of CDI changed dramatically; an increase in overall incidence has been highlighted by outbreaks of more-severe disease than previously observed. An examination of US acute care hospital discharge data revealed that, beginning in 2001, there was an abrupt increase in the number and proportion of patients discharged from the hospital with the diagnosis of "intestinal infection due to *Clostridium difficile*" (*International*



FIGURE 1. Time line for surveillance definitions of *Clostridium difficile*-associated infection (CDI) exposures. A case patient who had symptom onset during the window of hospitalization marked by an asterisk (*) would be classified as having community-onset, healthcare facility-associated disease (CO-HCFA), if the patient had been discharged from a healthcare facility within the previous 4 weeks; would be classified as having indeterminate disease, if the patient had been discharged from a healthcare facility within the previous 4–12 weeks; or would be classified as having community-associated CDI (CA-CDI), if the patient had not been discharged from a healthcare facility in the previous 12 weeks. HO-HCFA, healthcare facility-onset, healthcare facility-associated CDI.

Classification of Diseases, Clinical Modification, 9th edition, code 008.45).⁴⁶ Discharge rates increased most dramatically among persons aged 65 years or more and were more than 5-fold higher in this age group than among individuals aged 45–64 years.

Beginning as early as the second half of 2002 and extending through 2006, hospital outbreaks of unusually severe25 and recurrent47 CDI were noted in hospitals throughout much of Quebec, Canada. These outbreaks were, like slightly earlier outbreaks in the United States,48 associated with the use of fluoroquinolones.25 An assessment found that the 30-day mortality directly attributable to CDI in Montreal hospitals during this period was 6.9%, but CDI was thought to have contributed indirectly to another 7.5% of deaths.25 The etiological agents of outbreaks both in Quebec and in at least 8 hospitals in 6 US states were nearly identical strains of C. difficile.24,25 This strain has become known variously by its restriction endonuclease analysis pattern, B124; by its pulsedfield gel electrophoresis (PFGE) pattern, NAP1 (for North American PFGE type 1); or by its PCR ribotype designation, 027; it is now commonly designated "NAP1/BI/027." This strain accounted for 67%-82% of isolates in Quebec,25 which implies that it might be transmitted more effectively than are other strains. It also possesses, in addition to genes coding for toxins A and B, a gene encoding for the binary toxin. Although the importance of binary toxin as a virulence factor in C. difficile has not been established, earlier studies found the toxin was only present in about 6% of isolates.24 In addition, the epidemic strain has an 18-base pair deletion and an apparently novel single-base pair deletion in tcdC,^{24,25} a putative negative regulator of expression of toxins A and/or B that is located within the pathogenicity locus downstream from the genes encoding toxins A and B. Consistent with the presence of 1 or more of these molecular markers or other yet undiscovered factors responsible for increased virulence, patients infected with the NAP1/BI/027 epidemic strain in Montreal were shown to have more-severe disease than were patients infected with other strains.25

Increased virulence alone may not explain why the NAP1/ BI/027 strain has recently become highly prevalent, as it appears this same strain had been an infrequent cause of CDI in North America and Europe dating back to the 1980s.²⁴ Historic and recent isolates of the NAP1/BI/027 strain differ in their level of resistance to fluoroquinolones; more recent isolates are more highly resistant to these drugs.²⁴ This, coupled with increasing use of the fluoroquinolones in North American hospitals, likely promoted dissemination of a onceuncommon strain. As of this writing, the NAP1/BI/027 strain has spread to at least 40 US states^{24,49} and 7 Canadian provinces,⁵⁰ and has caused outbreaks in England,^{51,52} parts of continental Europe,^{33,54} and Asia.⁵⁵

CDI in populations previously at low risk. In the context of the changing epidemiology of CDI in hospitals, disease is occurring among healthy peripartum women, who have been previously at very low risk for CDI.^{56,37} The incidence might also be increasing among persons living in the community, including, but not limited to, healthy persons without recent healthcare contact.^{56,56-61} However, there are limited historical data against which to compare the recent incidence.⁶²⁻⁶⁴

Routes of transmission and the epidemiology of colonization and infection. The primary mode of C. difficile transmission resulting in disease is person-to-person spread through the fecal-oral route, principally within inpatient healthcare facilities. Studies have found that the prevalence of asymptomatic colonization with C. difficile is 7%-26% among adult inpatients in acute care facilities^{1,27} and is 5%-7% among elderly patients in long-term care facilities. 42,65 Other studies, however, indicate that the prevalence of asymptomatic colonization may be more on the order of 20%-50% in facilities where CDI is endemic.9,66,67 The risk of colonization increases at a steady rate during hospitalization, suggesting a cumulative daily risk of exposure to C. difficile spores in the healthcare setting.1 Other data suggest that the prevalence of C. difficile in the stool among asymptomatic adults without recent healthcare facility exposure is less than 2%.16.17 Newborns and children in the first year of life are known to have some of the highest rates of colonization.68

The usual incubation period from exposure to onset of CDI symptoms is not known with certainty; however, in contrast to the situation with other multidrug-resistant pathogens that cause healthcare-associated infections, persons who remain asymptomatically colonized with *C. difficile* over longer periods of time appear to be at decreased, rather than increased, risk for development of CDI.^{1,5,5,69} The protection afforded by more long-standing colonization may be mediated in part by the boosting of serum antibody levels against *C. difficile* toxins A and B^{5,69}; however, this protection is also observed, both in humans and in animal models, when colonization occurs with nontoxigenic strains, which suggests competition for nutrients or for access to the mucosal surface.^{5,70}

The period between exposure to *C. difficile* and the occurrence of CDI has been estimated in 3 studies to be a median of 2–3 days.^{1,22,27} This is to be distinguished from the increased risk of CDI that can persist for many weeks after cessation of antimicrobial therapy and which results from prolonged perturbation of the normal intestinal flora.⁷¹ However, recent evidence suggests that CDI resulting from exposure to *C. difficile* in a healthcare facility can have onset after discharge.⁷²⁻⁷⁴ The hands of healthcare workers, transiently contaminated with *C. difficile* spores, are probably the main means by which the organism is spread during nonoutbreak periods.^{1,66}

Environmental contamination also has an important role in transmission of *C. difficile* in healthcare settings.^{75:78} There have also been outbreaks in which particular high-risk fomites, such as electronic rectal thermometers or inadequately cleaned commodes or bedpans, were shared between patients and were found to contribute to transmission.⁷⁹

Risk factors for disease. Advanced age is one of the most

important risk factors for CDI, as evidenced by the severalfold higher age-adjusted rate of CDI among persons more than 64 years of age.^{46,80} In addition to advanced age, duration of hospitalization is a risk factor for CDI; the daily increase in the risk of *C. difficile* acquisition during hospitalization suggests that duration of hospitalization is a proxy for the duration, if not the degree, of exposure to the organism from other patients with CDI.¹

The most important modifiable risk factor for the development of CDI is exposure to antimicrobial agents. Virtually every antimicrobial has been associated with CDI through the years. The relative risk of therapy with a given antimicrobial agent and its association with CDI depends on the local prevalence of strains that are highly resistant to that particular antimicrobial agent.⁸¹

Receipt of antimicrobials increases the risk of CDI because it suppresses the normal bowel flora, thereby providing a "niche" for *C. difficile* to flourish. Both longer exposure to antimicrobials, as opposed to shorter exposure,⁴⁷ and exposure to multiple antimicrobials, as opposed to exposure to a single agent, increase the risk for CDI.⁴⁷ Nonetheless, even very limited exposure, such as single-dose surgical antibiotic prophylaxis, increases a patient's risk of both *C. difficile* colonization⁸² and symptomatic disease.⁸³

Cancer chemotherapy is another risk factor for CDI that is, at least in part, mediated by the antimicrobial activity of several chemotherapeutic agents^{84,85} but could also be related to the immunosuppressive effects of neutropenia.86,87 Recent evidence suggests that C. difficile has become the most important pathogen causing bacterial diarrhea in US patients infected with human immunodeficiency virus (HIV), which suggests that these patients are at specific increased risk because of their underlying immunosuppression, exposure to antimicrobials, exposure to healthcare settings, or some combination of those factors.88 Other risk factors for CDI include gastrointestinal surgery89 or manipulation of the gastrointestinal tract, including tube feeding.90 Another potential and somewhat controversial risk factor is related to breaches in the protective effect of stomach acid that result from the use of acid-suppressing medications, such as histamine-2 blockers and proton pump inhibitors. Although a number of recent studies have suggested an epidemiologic association between use of stomach acid-suppressing medications, primarily proton pump inhibitors, and CDI,48,61,91-93 results of other well controlled studies have suggested this association is the result of confounding with the underlying severity of illness and duration of hospital stay.25,47,94

Surveillance. There are few data on which to base a decision about how best to perform surveillance for CDI, either in healthcare or community settings. Nonetheless, interim recommendations have been put forth that, although not evidence-based, could serve to make rates more comparable among different healthcare facilities and systems.⁹⁵ There is a current need for all healthcare facilities that provide skilled nursing care to conduct CDI surveillance, and some local or regional systems may be interested in tracking emerging community-associated disease, particularly in view of the changing epidemiology of CDI. A recommended case definition for surveillance requires (1) the presence of diarrhea or evidence of megacolon and (2) either a positive laboratory diagnostic test result or evidence of pseudomembranes demonstrated by endoscopy or histopathology. If a laboratory only performs *C. difficile* diagnostic testing on stool from patients with diarrhea, this case definition should involve tracking of patients with a new primary positive assay result (ie, those with no positive result within the previous 8 weeks) or a recurrent positive assay result (ie, those with a positive result within the previous 2-8 weeks).

It appears that many, if not most, patients who have the onset of CDI symptoms shortly after discharge from a healthcare facility (ie, within 1 month) acquired C. difficile while in the facility and that these case patients may have an important impact on overall rates. Nonetheless, it is not known whether tracking of healthcare-acquired, community-onset CDI (ie, postdischarge cases) is necessary to detect healthcarefacility outbreaks or make meaningful comparisons between facilities.95 What is clear is that tracking CDI cases with symptom onset at least 48 hours after inpatient admission is the minimum surveillance that should be performed by all healthcare facilities. In addition, if interfacility comparisons are to be performed, they should only be performed using similar case definitions. Because the risk of CDI increases with the length of stay, the most appropriate denominator for healthcare facility CDI rates is the number of patientdays. If a facility notes an increase in the incidence of CDI from the baseline rate, or if the incidence is higher than in comparable institutions, surveillance data should be stratified by hospital location to identify particular wards or units where transmission is occurring more frequently, so that intensified control measures may be targeted. In addition, measures should be considered for tracking severe outcomes, such as colectomy, intensive care unit admission, or death, attributable to CDI. Comparison of incidence rates between hospitals in a given state or region could be more meaningful if rates are age-standardized (because the age distribution of inpatients may vary substantially between facilities) or are limited to specific age groups.

A current surveillance definition for community-associated CDI is as follows: disease in persons with no overnight stay in an inpatient healthcare facility in at least the 12 weeks prior to symptom onset.^{10,95} A reasonable denominator for community-associated CDI is the number of person-years for the population at risk.

Molecular typing. Molecular typing is an important tool for understanding a variety of aspects of the epidemiology of CDI. The molecular characterization of isolates is essential for understanding the modes of transmission and the settings where transmission occurs. As described above, molecular typing of strains can confirm a shift in the epidemiology of CDI. In addition, tracking certain strains and observing their clinical behavior has assisted investigators in determining the importance of antimicrobial resistance and virulence factors in outbreaks of epidemic CDI.

Current C. difficile typing measures depend on having access to isolates recovered from patient stool specimens. Because of the popularity of using nonculture methods to diagnose C. difficile infection, such isolates often are not available, and this may hinder our further understanding of the epidemiology of CDI. It is, therefore, imperative that culture for C. difficile be performed for toxin-positive stool samples during outbreaks or in settings where the epidemiology and/or severity of CDI is changing and is unexplained by the results of investigations in similar settings.96 Outbreaks of CDI in healthcare facilities are most often caused by transmission of a predominant strain; cessation of the outbreak is usually accompanied by a decrease in strain relatedness among C. difficile isolates. Because of the clonality of C. difficile in outbreaks and in settings with high rates of endemicity, it may be difficult to draw conclusions about some aspects of the epidemiology of C. difficile. For example, cases of recurrent disease caused by a strain that is prevalent in a given healthcare facility may just as likely represent reinfection as relapse.

C. difficile may be typed by a variety of methods. Current genetic methods for comparing strains include methods that examine polymorphisms after restriction endonuclease digestion of chromosomal DNA, PCR-based methods, and sequence-based methods. DNA polymorphism-based methods include restriction endonuclease analysis,97 PFGE,98 and toxinotyping.99 PCR-based methods include arbitrarily-primed PCR,100 repetitive element sequence PCR,101 and PCR ribotyping.102 Sequence-based techniques consist presently of multilocus sequence typing¹⁰³ and multilocus variable-number tandem-repeat analysis.104,105 A recent international comparative study of 7 different typing methods (multilocus sequence typing, multilocus variable-number tandem-repeat analysis, PFGE, restriction endonuclease analysis, PCR-ribotyping, amplified fragment-length polymorphism analysis, and surface layer protein A gene sequence typing) assessed the discriminatory ability and typeability of each technique, as well as the agreement among techniques in grouping isolates according to allele profiles defined by toxinotype, the presence of the binary toxin gene, and deletion in the tcdC gene.106 All the techniques were able to distinguish the current epidemic strain of C. difficile (NAP1/BI/027) from other strains. Restriction endonuclease analysis, surface layer protein A gene sequence typing, multilocus sequence typing, and PCR ribotyping all included isolates that were toxinotype III, positive for binary toxin, and positive for an 18-base pair deletion in *tcdC* (ie, the current epidemic strain profile) in a single group that excluded other allelic profiles.

II. WHAT IS THE BEST TESTING STRATEGY TO DIAGNOSE CDI IN THE CLINICAL LABORATORY AND WHAT ARE ACCEPTABLE OPTIONS?

Recommendations

5. Testing for C, *difficile* or its toxins should be performed only on diarrheal (unformed) stool, unless ileus due to C. *difficile* is suspected (B-II).

 Testing of stool from asymptomatic patients is not clinically useful, including use as a test of cure. It is not recommended, except for epidemiological studies (B-III).

7. Stool culture is the most sensitive test and is essential for epidemiological studies (A-II).

8. Although stool culture is not clinically practical because of its slow turnaround time, the sensitivity and specificity of stool culture followed by identification of a toxigenic isolate (ie, toxigenic culture), as performed by an experienced laboratory, provides the standard against which other clinical test results should be compared (**B-III**).

9. Enzyme immunoassay (EIA) testing for *C. difficile* toxin A and B is rapid but is less sensitive than the cell cytotoxin assay, and it is thus a suboptimal alternative approach for diagnosis (**B-II**).

10. Toxin testing is most important clinically, but is hampered by its lack of sensitivity. One potential strategy to overcome this problem is a 2-step method that uses EIA detection of glutamate dehydrogenase (GDH) as initial screening and then uses the cell cytotoxicity assay or toxigenic culture as the confirmatory test for GDH-positive stool specimens only. Results appear to differ based on the GDH kit used; therefore, until more data are available on the sensitivity of GDH testing, this approach remains an interim recommendation. (**B-II**)

11. Polymerase chain reaction (PCR) testing appears to be rapid, sensitive, and specific and may ultimately address testing concerns. More data on utility are necessary before this methodology can be recommended for routine testing. (B-II)

12. Repeat testing during the same episode of diarrhea is of limited value and should be discouraged (B-II).

Evidence Summary

Accurate diagnosis is crucial to the overall management of this nosocomial infection. Empirical therapy without diagnostic testing is inappropriate if diagnostic tests are available, because even in an epidemic environment, only approximately 30% of hospitalized patients who have antibiotic-associated diarrhea will have CDI.¹³ Efficiently and effectively making the diagnosis of CDI remains a challenge to the clinician and the microbiologist.

Since the original observations that C. difficile toxins are responsible for antibiotic-associated colitis, most diagnostic tests that have been developed detect the toxin B and/or toxin A produced by C. difficile. Using an animal model and isogenic mutants of C. difficile, toxin B was demonstrated to be the primary toxin responsible for CDL¹⁰⁷ Initial tests were performed using cell culture cytotoxicity assays for toxin B. Subsequent tests have used antigen detection with EIA. Tests detecting C. difficile common antigen (ie, GDH) have been improved using EIA, compared with the older latex agglutination assays.¹⁰⁸⁻¹¹⁰ Because of cost and turnaround time, the focus of diagnostic testing has been on antibody-based tests to identify the toxins. These tests are also easier to perform in the clinical laboratory. The sensitivity of these tests is suboptimal when compared with more time-intensive methodologies. Furthermore, toxin EIAs have suboptimal specificity, which means that, because the great majority of diagnostic samples will not have toxin present, the positive predictive value of the results can be unacceptably low.^{111,112} Culture followed by detection of a toxigenic isolate (ie, toxigenic culture) is considered the most sensitive methodology, but it routinely takes 2-3 days and could take up to 9 days to obtain results.¹¹³⁻¹¹⁵ Thus the optimal strategy to provide timely, cost-effective, and accurate results remains a subject of controversy.

Specimen collection and transport. The proper laboratory specimen for the diagnosis of *C. difficile* infection is a watery, loose, or unformed stool promptly submitted to the laboratory.^{116,117} Except in rare instances in which a patient has ileus without diarrhea, swab specimens are unacceptable, because toxin testing cannot be done reliably. Because 10% or more of hospitalized patients may be colonized with *C. difficile*,^{1,116} evaluating a formed stool for the presence of the organism or its toxins can decrease the specificity of the diagnosis of CDI. Processing a single specimen from a patient at the onset of a symptomatic episode usually is sufficient. Because of the low increase in yield and the possibility of false-positive results, routine testing of multiple stool specimens is not supported as a cost-effective diagnostic practice.¹¹⁸

Detection by cell cytotoxicity assay. Detection of neutralizable toxin activity in stools from patients with antibioticassociated colitis was the initial observation that led to the discovery that C. difficile is the causative agent of this infection.¹¹⁹ The presence or absence of the pathogenicity locus (PaLoc), a 19-kilobase area of the C. difficile genome that includes the genes for toxins A and B and surrounding regulatory genes, accounts for the fact that most strains of C. difficile produce either both toxins or neither toxin, although an increasing number of strains are found to lack production of toxin A.120 Numerous cell lines are satisfactory for detection of cytotoxin, but most laboratories use human foreskin fibroblast cells, on the basis of the fact that it is the most sensitive cell line for detecting toxin at low titer (1:160 or less).121

Using a combination of clinical and laboratory criteria to

establish the diagnosis of CDI, the sensitivity of cytotoxin detection as a single test for the laboratory diagnosis of this illness is reported to range from 67% to 100%.^{2,9,122}

Detection by EIA for toxin A or toxins A and B. Commercial EIA tests have been introduced that either detect toxin A only or detect both toxins A and B. Compared with diagnostic criteria that included a clinical definition of diarrhea and laboratory testing that included cytotoxin and culture, the sensitivity of these tests is 63%–94%, with a specificity of 75%–100%. These tests have been adopted by more than 90% of laboratories in the United States because of their ease of use and lower labor costs, compared with the cell cytotoxin assay. The toxin A/B assay is preferred because 1%–2% of strains in the United States are negative for toxin A.¹²³

Detection by culture. Along with cytotoxin detection, culture has been a mainstay in the laboratory diagnosis of CDI and is essential for the epidemiologic study of isolates. The description of a medium containing cycloserine, cefoxitin, and fructose (CCFA medium) provided laboratories with a selective culture system for recovery of C. difficile.124 Addition of taurocholate or lysozyme can enhance recovery of C. difficile, presumably because of increased germination of spores.125 Optimal results require that culture plates be reduced in an anaerobic environment prior to use. The strains produce flat, yellow, ground glass-appearing colonies with a surrounding yellow halo in the medium. The colonies have a typical odor and fluoresce with a Wood's lamp.¹¹⁵ Additionally, Gram stain of these colonies must show typical morphology (gram-positive or gram-variable bacilli) for C. difficile. Careful laboratory quality control of selective media for isolation of C. difficile is required, as there have been variations in the rates of recovery with media prepared by different manufacturers. With experience, visual inspection of bacterial colonies that demonstrate typical morphology on agar and confirmation by Gram stain usually is sufficient for a presumptive identification of C. difficile. Isolates not fitting these criteria can be further identified biochemically or by gas chromatography.

Detection by tests for C. difficile common antigen (GDH). The initial test developed to detect GDH was a latex agglutinin assay. It had a sensitivity of only 58%–68% and a specificity of 94%–98%.^{2,122} The latex test for *C. difficile*–associated antigen, therefore, is not sufficiently sensitive for the routine laboratory detection of CDI, even though it is rapid, relatively inexpensive, and specific. Use of this test provides no information regarding the toxigenicity of the isolate, nor does it yield the isolate itself, which would be useful for epidemiologic investigations.

Several assays for GDH have been developed using EIA methodology. These newer assays show a sensitivity of 85%–95% and a specificity of 89%–99%. Most importantly, these tests have a high negative predictive value, making them useful for rapid screening, if combined with another method that detects toxin.^{126,127} Several 2-step algorithms have been

Variable	Strength of recommendation	Reference(s)
Hand hygiene	A-II	
Contact precautions		
Glove use	A-I	Johnson et al ¹⁵⁰
Gowns	B-III	
Use of private rooms or cohorting	C-III	
Environmental cleaning, disinfection, or use of disposables		
Disinfection of patient rooms and environmental surfaces	В-П	
Disinfection of equipment between uses for patients	C-III	Brooks et al ⁷⁹
Elimination of use of rectal thermometers	В-П	Mayfield et al,76 Wilcox et al78
Use of hypochlorite (1,000 ppm available chlorine) for disinfection	В-Ш	Allerente Actions

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developed that are based on the use of this test. (10.115.126.128.129 They all use the GDH test for screening in which a stool sample with a negative assay result is considered negative for the pathogen but a positive assay result requires further testing to determine whether the C. difficile strain is toxigenic. The confirmatory test has primarily been a cell cytotoxin assay,110,115,129 It is also possible to use a toxin A/B EIA or culture with cytotoxin testing as the confirmatory test, although the limited sensitivity of the toxin EIA is problematic. One of the more recent studies performed 2-step testing of 5,887 specimens at 2 different hospitals. The GDH test result was positive for 16.2% of specimens at one hospital and 24.7% of specimens at the other. Therefore, 75%-85% of the samples did not require that a cell cytotoxin assay be performed, at a cost savings of between \$5,700 and \$18,100 per month.¹¹⁰ Another recent study tested 439 specimens using GDH screening with cell cytotoxicity assay for confirmation.130 The comparator test in this study was culture with cell cytotoxin assay. The GDH test identified all samples that were culture positive. The sensitivity of the 2-step algorithm was 77%, and the sensitivity of culture was 87%. Another recent study comparing GDH EIA with culture, PCR, and toxin EIA found that only 76% of specimens that were culture positive for C. difficile and only 32% of culture-positive specimens in which toxin genes were detected tested positive for GDH using an insensitive confirmatory toxin A assay.¹³⁰ Although most studies have shown a high negative predictive value for the GDH assay, some studies have questioned its sensitivity. PCR tests for toxigenic C. difficile in stool samples are now available commercially from several manufacturers. and this may be a more sensitive and more specific approach, but more data on utility are necessary before this methodology can be recommended for routine testing. Currently there is no testing strategy that is optimally sensitive and specific and, therefore, clinical suspicion and consideration of the patient risk factors are important in making clinical decisions about whom to treat.

Other test methodologies. Pseudomembranous colitis can only be diagnosed by direct visualization of pseudomembranes on lower gastrointestinal endoscopy (either sigmoidoscopy or colonoscopy) or by histopathologic examination. However, direct visualization using any of these techniques will detect pseudomembranes in only 51%–55% of CDI cases that are diagnosed by combined clinical and laboratory criteria that include both a culture positive for *C. difficile* and a positive stool cytotoxin test result.⁹ Pseudomembranous colitis has been used as a marker of severe disease, as has CT scanning. Abdominal CT scanning may facilitate the diagnosis of CDI but this methodology is neither sensitive nor specific.¹³

III. WHAT ARE THE MOST IMPORTANT

INFECTION CONTROL MEASURES

TO IMPLEMENT IN THE HOSPITAL

DURING AN OUTBREAK OF CDI?

A. Measures for Healthcare Workers, Patients, and Visitors

Recommendations

13. Healthcare workers and visitors must use gloves (A-I) and gowns (B-III) on entry to a room of a patient with CDI.

14. Emphasize compliance with the practice of hand hygiene (A-II).

15. In a setting in which there is an outbreak or an increased CDI rate, instruct visitors and healthcare workers to wash hands with soap (or antimicrobial soap) and water after caring for or contacting patients with CDI (**B-III**).

16. Accommodate patients with CDI in a private room with contact precautions (B-III). If single rooms are not available, cohort patients, providing a dedicated commode for each patient (C-III).

17. Maintain contact precautions for the duration of diarrhea (C-III).

18. Routine identification of asymptomatic carriers for infection control purposes is not recommended (A-III) and treatment of such identified patients is not effective (B-I).

Evidence Summary

Prevention of *C. difficile* acquisition can be categorized into 2 strategies: preventing horizontal transmission, to minimize

exposure; and decreasing the risk factors for patients to develop *C. difficile* infection, if exposure has occurred.¹³¹ This section will focus on prevention of horizontal transmission. There are 3 ways in which patients may be exposed to *C. difficile* in the hospital milieu: (1) by contact with a healthcare worker with transient hand colonization, (2) by contact with the contaminated environment, or (3) by direct contact with a patient with CDI. The rate of acquisition during hospitalization increases linearly with time and can be as high as 40% after 4 weeks of hospitalization.¹³² There may not be a single method that is effective in minimizing exposure to *C. difficile*, and a multifaceted approach is usually required.^{133 136} Different methods may be more or less effective in different institutions, depending on the local epidemiology and the available resources (Table 2).

Hand hygiene. Hand hygiene is considered to be one of the cornerstones of prevention of nosocomial transmission of C. difficile, as it is for most nosocomial infections. Several studies have documented the reduction of rates of hospitalacquired infection by improvement in the compliance with hand washing by healthcare workers between episodes of contact with patients.137 Unfortunately, many studies have also documented low rates of hand washing by healthcare workers.137,138 The advent of alcohol-based hand antiseptics was greeted with great optimism as a breakthrough for improving compliance with hand hygiene.139,140 These alcoholbased antiseptics are popular because of their effectiveness in reducing hand carriage of most vegetative bacteria and many viruses, their ease of use at the point of care, and their ability to overcome the relative inaccessibility of hand washing facilities in many institutions.

However, C. difficile, in its spore form, is also known to be highly resistant to killing by alcohol.141 Indeed, exposing stool samples to ethanol in the laboratory facilitates isolation of C. difficile from these specimens.142 Therefore, healthcare workers who decontaminate their hands with alcohol-based products may simply displace spores over the skin surface, as opposed to physically removing C. difficile spores by mechanical washing with soap and running water. This could potentially increase the risk of transferring this organism to patients under their care. Several studies have not demonstrated an association between the use of alcohol-based hand hygiene products and increased incidence of CDI. Gordin et al¹⁴³ assessed the impact of using an alcohol-based hand rub on rates of infection with methicillin-resistant Staphylococcus aureus, vancomycin-resistant Enterococcus, and CDI 3 years before and after implementation. After implementation, a 21% reduction was observed in the rate of methicillin-resistant S. aureus infection, and a 41% decrease in the rate of vancomycin-resistant Enterococcus infection. The incidence of CDI was essentially unchanged and did not increase with the implementation of alcohol-based hand rub.

A recent study compared use of alcohol-based products with other methods of hand hygiene.¹⁴⁴ This study assessed the efficacy of different hand washing methods for removal of a nontoxigenic strain of *C. difficile*. Although there is a theoretical potential for alcohol-based hand hygiene products to increase the incidence of CDI because of their relative ineffectiveness at eliminating spores from the hands, there has not been any clinical evidence to support this thus far.

McFarland et al' suggested that chlorhexidine containing antiseptic was more effective than plain soap for removing *C. difficile* from the hands of healthcare workers. They found that *C. difficile* persisted on the hands of 88% of personnel (14 of 16) who had washed with plain soap (as determined by culture). Washing with 4% chlorhexidine gluconate reduced the rate to 14% (1 of 7 personnel). Another study involving experimental hand seeding with *C. difficile* showed no difference between bland soap and chlorhexidine gluconate in removing *C. difficile* from hands.¹⁴⁵

Contact precautions. The use of additional isolation techniques (contact precautions, private rooms, and cohorting of patients with active CDI) has been employed for control of outbreaks, with varied success. 28,146-148 Contact precautions include the donning of gowns and gloves when caring for patients with CDI.149 These measures are based on the premise that patients with active CDI are the primary reservoir for spread of disease within the institution. There is ample evidence for the contamination of personnel's hands with C. difficile spores.^{1.66} Hence, the use of gloves in conjunction with hand hygiene should decrease the concentration of C. difficile organisms on the hands of healthcare personnel. A prospective controlled trial of vinyl glove use for handling body substances showed a significant decline in CDI rates, from 7.7 cases per 1,000 discharges before institution of glove use to 1.5 cases per 1,000 discharges after institution of glove use (P = .015).¹⁵⁰ In addition, the use of gowns has been promoted because of potential soiling and contamination of the uniforms of healthcare personnel with C. difficile. C. difficile has been detected on nursing uniforms, but a study found no evidence of the uniforms being a source of transmission to patients.151

Cartmill and colleagues¹³⁶ achieved a reduction in the number of new *C. difficile* cases by using an aggressive policy of increasing the number of diarrheal stools cultured for *C. difficile*, instituting contact precautions early, treating CDI patients with vancomycin, and disinfecting environmental surfaces with a hypochlorite solution. Placing the focus for control measures on clinically symptomatic patients with CDI was successful in this institution, which supports the hypothesis that patients with diarrhea, who are known to have the highest number of organisms in their stools and in their immediate hospital environment, are the most likely source of nosocomial transmission.

Facilities. Improving the hospital layout can enhance the effectiveness of infection control measures. In a cohort study of nosocomial acquisition of CDI, there were higher acquisition rates in double rooms than in single rooms (17% vs 7%; P = .08) and a significantly higher risk of acquisition after exposure to a roommate with a positive culture result.¹

The importance of adequate hospital facilities was highlighted in a study comparing CDI rates in 2 Norwegian hospitals.¹³² These 2 hospitals were comparable in size and had similar clinical departments. However, the hospitals differed in their physical infrastructure, bed occupancy rate, and antibiotic utilization pattern. The older hospital had fewer single rooms and a higher bed occupancy rate but a lower rate of use of broad-spectrum antibiotics, compared with the modern hospital. The incidence of CDI was lower in the modern hospital than in the older hospital. However, this study was limited by a lack of description of patient demographic characteristics and other risk factors that may impact CDI rates. Furthermore, there may have been a higher rate of case finding in the older institution than in the modern hospital, because the incidence of patient testing was consistently higher in the older hospital during the study period.

In a systematic review of the architecture of hospital facilities and nosocomial infection rates, there was a lack of compelling evidence that a reduction in nosocomial infections could be attributable to improvement in hospital patient rooms.¹⁵³ In 8 studies reviewed, 3 studies documented a statistically significant decrease in the incidence of nosocomial infections after the architectural intervention, whereas 5 studies showed no difference.¹⁵³ It is difficult to assess the effect of improvements in hospital design and renovation on the incidence of nosocomial infections. These studies are often nonrandomized, historical cohort studies that examine the incidence of specific nosocomial infections before and after the intervention. The American Institute of Architects recommends single-patient rooms in new construction, as well as in renovations.¹⁵⁴

Healthcare worker carriage. Cases of nosocomial acquisition of *C. difficile* by healthcare workers have been reported.^{155,156} Two prospective studies indicate, however, that *C. difficile* poses little risk to the healthcare worker. In a 1-year prospective case-control study in which 149 patients with CDI were identified, rectal swab specimens from 68 personnel (54 nurses and 14 physicians) revealed only 1 employee (1.5%) colonized with *C. difficile*.⁹ A colonization rate of 1.7% was found among medical house staff.¹⁵⁷ Therefore, it is rare that healthcare workers acquire *C. difficile*; nevertheless, they can serve as primary transmitters of *C. difficile* by way of transient hand contamination.

Identification and treatment of asymptomatic patient carriers. In institutions with higher rates of CDI (7.8–22.5 cases per 1,000 discharges), the number of asymptomatically colonized patients has been found to be considerably higher than the number with CDI.^{1,150,158} The rationale for identifying and treating these asymptomatic patients is that they potentially serve as a reservoir for horizontal spread of *C. difficile* to other patients, either by way of the environment or by way of the hands of medical personnel. Delmee et al¹⁵⁹ demonstrated a significant reduction in new *C. difficile* infections in a leukemia unit after institution of oral vancomycin treatment (500 mg 4 times daily for 7 days) for asymptomatically colonized patients, combined with extensive environmental renovation and cleaning. In contrast, metronidazole therapy was ineffective in reducing the incidence of CDI when administered to all *C. difficile* carriers in a chronic-care facility, even when contact precautions and antibiotic restriction were used concurrently.¹⁶⁰

One prospective trial showed no significant reduction in the incidence of *C. difficile* carriage after therapy with oral metronidazole, compared with placebo, whereas 9 of 10 patients treated with vancomycin became culture negative for *C. difficile* after treatment.¹⁶¹ On day 70 of follow-up, however, 4 of 6 patients who had initial clearance with vancomycin treatment were positive for *C. difficile* (including 1 patient who developed CDI), whereas only 1 of 9 placebo-treated patients remained positive for the pathogen (P < .05).

Thus, treatment of asymptomatic *C. difficile* carriers is effective when vancomycin is used, but patients treated with vancomycin may be at increased risk for reinfection or prolonged carriage after treatment is stopped. The efficacy of using vancomycin treatment for asymptomatic carriers as a control measure to interrupt hospital transmission has not been established. Similarly, it has been suggested that identification of asymptomatic carriers and institution of more stringent barrier precautions may be useful in interrupting an outbreak, but there are no available data to support such a measure.

B. Environmental Cleaning and Disinfection

Recommendations

19. Identification and removal of environmental sources of *C. difficile*, including replacement of electronic rectal thermometers with disposables, can reduce the incidence of CD1 (**B-II**).

20. Use chlorine-containing cleaning agents or other sporicidal agents to address environmental contamination in areas associated with increased rates of CDI (B-II).

21. Routine environmental screening for *C. difficile* is not recommended (C-III).

Evidence Summary

The true extent of the contribution of the healthcare environment to infection transmission remains controversial. However, for bacteria that resist desiccation, there is much evidence that the environment is an important source of nosocomial infection.¹⁶² *C. difficile* spores can survive in the environment for months or years and can be found on multiple surfaces in the healthcare setting.^{1.66,163,104} The rate of recovery of *C. difficile* from the environment is increased if media that encourage spore germination—for example, media containing lysozyme—are used.¹²⁵ Interestingly, epidemic strains of *C. difficile* have a greater sporulation capacity in vitro than do nonoutbreak strains.¹⁶⁵ Studies have found that the rate of environmental contamination by *C. difficile* increases according to the carriage and symptom status of the patient(s): it was lowest in rooms of culture-negative patients (fewer than 8% of rooms), intermediate in rooms of patients with asymptomatic *C. difficile* colonization (8%–30% of rooms), and highest in rooms of patients with CDI (9%–50% of rooms).^{1,164} Also, a study found that the incidence of *C. difficile* infection correlated significantly with the environmental prevalence of *C. difficile* on one hospital ward (r = 0.76; P < .05) but not another (r = 0.26; P > .05), possibly because of confounding factors.⁷⁷ Environmental contamination has been linked to the spread of *C. difficile* by way of contaminated commodes,^{1,25,27} blood pressure cuffs,¹⁶⁶ and oral and rectal thermometers.^{79,167,168} Replacement of electronic thermometers with single-use disposable thermometers has been associated with significant reductions in CDI incidence.^{79,167,168}

There is evidence that the environmental prevalence of C. difficile can affect the risk of CDI, and may not simply reflect the prevalence of symptomatic disease. Samore and colleagues75 showed that the environmental prevalence of C. difficile correlated with the extent of contamination of healthcare workers hands by this bacterium. Furthermore, there are several reports that interventions to reduce environmental contamination by C. difficile have decreased the incidence of infection.76.78 Kaatz and colleagues169 found that phosphate buffered hypochlorite (1,600 ppm available chlorine; pH, 7.6) was more effective than unbuffered hypochlorite (500 ppm available chlorine) at reducing environmental levels of C. difficile. Introduction of cleaning with a hypochlorite-based solution (5,000 ppm available chlorine) was also associated with reduced incidence of CDI in a bone marrow transplant unit where there was a relatively high infection rate.76 The incidence of CDI increased almost to the baseline level after the reintroduction of use of the original quaternary ammonium compound cleaning agent. However, the environmental prevalence of C. difficile was not measured in this study, and the results were not reproducible with patients on other units, possibly because of the low prevalence of infection. Wilcox et al78 used a 2-year crossover study design to demonstrate a significant correlation between the use of a cleaning agent containing chlorine (dichloroisocyanurate; 1,000 ppm available chlorine) and a reduction in the incidence of CDI on 1 of the 2 hospital wards that were examined. Although it is likely that higher concentrations of available chlorine within the range of 1,000-5,000 ppm are more reliably sporicidal than lower concentrations, the potential disadvantages (eg, causticity to surfaces, complaints from personnel about the odor, and possible hypersensitivity) should be balanced against the potential advantages in particular settings (eg, environmental cleaning interventions may have their greatest impact in settings with the highest baseline rates). Therefore, depending on such factors, the concentration of available chlorine should be at least 1,000 ppm and may ideally be 5,000 ppm. A recent report highlighted the use of vaporized hydrogen peroxide to reduce the level of environmental contamination by C. difficile. The prevalence of C. difficile was significantly reduced (to a recovery level of 0) after hydrogen

peroxide use, albeit from a low level (5%), possibly because of former hypochlorite based cleaning; the incidence of CDI decreased, although not significantly.¹⁷⁰ Unfortunately, practical considerations (the need to seal rooms and to have access to specialized equipment) and the cost limit the applicability of this approach to environmental decontamination.

A wide range of disinfectants suitable for decontamination of instruments (eg, endoscopes) or the environment have in vitro activity against C. difficile spores.141,165,171-173 With the exceptions noted above, comparative data on the in situ efficacy of these disinfection options are lacking. The efficacy of cleaning is critical to the success of decontamination in general, and thus user acceptability of disinfection regimens is a key issue. Endoscopes have not been implicated in the transmission of C. difficile, but spread by means of this mechanism is preventable by careful cleaning and disinfection with 2% alkaline glutaraldehyde.121 In vitro data show greater C. difficile sporicidal activity as the concentration of free chlorine increases with acidified bleach, but practical issues may limit the use of such products for routine cleaning. A study found that working-strength concentrations of 5 different cleaning agents inhibited growth of C. difficile cultures in vitro.165 However, only chlorine-based cleaning agents used at the recommended working concentrations were able to inactivate C. difficile spores. Also, in vitro exposure of epidemic C. difficile strains, including NAP1/BI/027, to subinhibitory concentrations of non-chlorine-based cleaning agents (detergent or hydrogen peroxide) significantly increased sporulation capacity; this effect was generally not seen with chlorine-based cleaning agents.^{125,167} These observations suggest the possibility that some cleaning agents, if allowed to come into contact with C. difficile in low concentrations, could promote sporulation and, therefore, the persistence of the bacterium in the environment.

Use of chlorine-containing cleaning products presents health and safety concerns, as well as compatibility challenges that need to be assessed for risk. However, current evidence supports the use of chlorine-containing cleaning agents (with at least 1,000 ppm available chlorine), particularly to address environmental contamination in areas associated with endemic or epidemic CDI. Routine bacteriological surveillance of the environment is generally unhelpful, largely because it has not been possible to establish threshold levels associated with increased risk of clinical infection, but it may be useful for ascertaining whether cleaning standards are suboptimal, notably in a setting experiencing an outbreak or where *C. difficile* is hyperendemic.

C. Antimicrobial Use Restrictions

Recommendations

22. Minimize the frequency and duration of antimicrobial therapy and the number of antimicrobial agents prescribed, to reduce CDI risk (A-II).

23. Implement an antimicrobial stewardship program

(A-II). Antimicrobials to be targeted should be based on the local epidemiology and the *C. difficile* strains present, but restricting the use of cephalosporin and clindamycin (except for surgical antibiotic prophylaxis) may be particularly useful (C-III).

Evidence Summary

Most studies have determined that the great majority of patients with CDI have had prior exposure to antimicrobial agents. In a recent study, 85% of patients with CDI had received antibacterial therapy within the 28 days prior to the onset of symptoms.¹⁷⁴ The widespread use of antimicrobial agents and the propensity for polypharmacy means that the accurate quantification of the CDI risk associated with specific antibiotics is very difficult. An greater number of antimicrobial agents administered, a greater number of doses, and a greater duration of administration have been associated with increased risk of CDL,9,89,158,175-177 Antibiotic risk studies and prescribing intervention studies frequently do not consider exposure to C. difficile when assessing outcomes. Thus, efforts to demonstrate the effects of restriction of antibiotics may be confounded by infection control interventions that affect the risk of acquiring C. difficile.

Limitation or restriction of use of antimicrobial agents that are found to be associated with increased CDI rates is an intuitively attractive approach to reducing infection rates. However, there are few sound studies that clearly demonstrate the successful implementation of antibiotic prescribing interventions, notably in terms of their effectiveness at reducing CDI. A recent Cochrane systematic review by Davey and colleagues178 examined the effectiveness of interventions to improve antibiotic prescribing practices for hospital inpatients. It analyzed relevant randomized and guasi-randomized controlled trials, controlled before-and-after studies, and interrupted time-series studies (with at least 3 data points before and after implementation of the intervention). Of 66 identified intervention studies that contained interpretable data, 5 (all interrupted time-series) reported outcome data regarding occurrence of CDI.¹⁷⁹⁻¹⁸³ Three of these found significant reductions in CDI incidence,179-181 and 2 interrupted time-series showed weak or nonsignificant evidence for a decrease in incidence.182,183

Climo et al¹⁸⁰ observed a sustained decrease in the incidence of CDI after the prescribing of clindamycin was restricted (11.5 cases per month prior to restriction, compared with 3.33 cases per month after restriction; P < .001). By contrast, the incidence of CDI was increasing by 2.9 cases per quarter before the restriction of clindamycin use. Similarly, Pear and colleagues¹⁷⁹ found that, before clindamycin restriction, the CDI rate was increasing (mean incidence, 7.7 cases per month; P < .001), and after restriction the incidence suddenly decreased (mean incidence, 3.68 cases per month (P = .041), and there was a sustained reduction averaging 0.32 cases per month (P = .134). Furthermore, regression analysis showed a significant relationship between the amount of clindamycin being prescribed per unit time and the incidence of CDI. Carling et al¹⁸¹ examined the effectiveness of an antimicrobial management team that focused on 3 interventions to alter prescribing patterns: choice, shorter duration of antibiotic therapy (ie, stop therapy after 2–3 days if there was no confirmed infection), and switching from intravenous to oral formulations. Prescribing of third-generation cephalosporins (and aztreonam) was targeted, and over 6 years it decreased from 24.7 to 6.2 defined daily doses per 1,000 patient-days (P < .0001). The multidisciplinary antibiotic stewardship program had no impact on the prevalence rates of vancomycin-resistant *Enterococcus* infection or methicillinresistant *S. aureus* infection but did significantly reduce the rates of CDI (P = .002) and antibiotic-resistant gram-negative bacterial infections (P = .02).

However, it is important to emphasize that, for a significant decrease in the incidence of CDI to be realized, reducing the use of antimicrobial agents that are associated with a high CDI risk is necessary, as opposed to simply making lowerrisk agents available on the formulary. One study found that introduction of piperacillin-tazobactam onto the formulary for a large Elderly Medicine unit was not associated with a significant reduction in the CDI rate.¹⁸⁴ However, once cefotaxime was replaced by piperacillin-tazobactam, CDI rates decreased in 4 of 5 wards and overall by 52% (P < .008). Unintentional restriction of piperacillin-tazobactam, consequent to manufacturing difficulties, led to a 5-fold rise in cefotaxime prescribing, and CDI rates increased from 2.2 to 5.1 cases per 100 admissions (P < .01). Similar observations that a piperacillin-tazobactam shortage led to increased prescribing of cephalosporins (ceftriaxone and cefotetan) and higher CDI rates have also been reported elsewhere.185

As reports of increasing incidence and more-severe CDI associated with the highly fluoroquinolone-resistant NAP1/ BI/027 strain continue to mount, several investigators have addressed the issue of antimicrobial restriction as a means of controlling this strain. A reduction in overall antimicrobial use has played a role in controlling at least 2 large institutional outbreaks caused by this strain.48,186 However, other outbreaks appear to have come under control through the application of infection control measures alone.25 There are limited data on whether restriction of a specific fluoroquinolone, or restriction of the entire class, can favorably impact increased rates of CDI due to NAP1/BI/027. In an early single-hospital outbreak caused by NAP1/BI/027 and reported by Gaynes et al,¹⁸⁷ it appeared that a switch from levofloxacin to gatifloxacin as the formulary drug of choice precipitated the outbreak; when the formulary drug of choice was switched back to levofloxacin, the outbreak ceased. Moreover, a case-control study showed an association between CDI and gatifloxacin exposure, leading the authors to propose that gatifloxacin is a higher-risk antimicrobial than levofloxacin. However, in a similar scenario in which an outbreak occurred following a formulary switch from levofloxacin to moxifloxacin as the drug of choice, reverting to levofloxacin was not associated with a decrease in CDL.¹⁸⁸ Given that the NAP1/BI/027 strain has increased resistance to fluoroquinolones as a class, rather than to one specific agent, it is unlikely that restricting the use of a specific fluoroquinolone would reduce CDI rates to the same level that could be achieved if use of all members of the class were restricted. Nonetheless, there is currently insufficient evidence to recommend restriction of use of a specific fluoroquinolone or the fluoroquinolone class for the control of CDI, other than as part of a reduction in overall antimicrobial use.¹⁸⁶

D. Use of Probiotics

Recommendation

24. Administration of currently available probiotics is not recommended to prevent primary CDI, as there are limited data to support this approach and there is a potential risk of bloodstream infection (C-III).

Evidence Summary

For many years, administration of probiotics has been advocated as a preventive measure for patients receiving antibiotics. Until recently, no individual study had shown probiotics to be effective in the prevention of CDI. It is doubtful whether meta-analyses are acceptable, given the diversity of probiotics used in various studies. Additional problems are the lack of standardization of such products, variations in the bacterial counts in such products according to the duration of storage, and the possibility of inducing bacteremia or fungemia. A recent randomized trial showed, for the first time, that ingestion of a specific brand of yogurt drink containing Lactobacillus casei, Lactobacillus bulgaricus, and Streptococcus thermophilus reduced the risk of CDI in patients more than 50 years of age who were prescribed antibiotics and were able to take food and drink orally.189 However, this conclusion was based on a small number of patients in a highly selected population that excluded patients receiving high-risk antibiotics. There was also an extraordinarily high rate of CDI among patients in the placebo group, who were given a milkshake in place of the yogurt drink (9 of 53 patients in the placebo group developed CDI, compared with 0 of 56 patients in the intervention group). The Expert Panel believes that larger trials are required before this practice can be recommended.

IV. DOES THE CHOICE OF DRUG FOR TREATMENT OF CDI MATTER AND, IF SO, WHICH PATIENTS SHOULD BE TREATED AND WITH WHICH AGENT?

Recommendations

25. Discontinue therapy with the inciting antimicrobial agent(s) as soon as possible, as this may influence the risk of CDI recurrence (A-II).

26. When severe or complicated CDI is suspected, ini-

tiate empirical treatment as soon as the diagnosis is suspected (C-III).

27. If the stool toxin assay result is negative, the decision to initiate, stop, or continue treatment must be individualized (C-III).

28. If possible, avoid use of antiperistaltic agents, as they may obscure symptoms and precipitate toxic megacolon (C-III).

29. Metronidazole is the drug of choice for the initial episode of mild-to-moderate CDI. The dosage is 500 mg orally 3 times per day for 10–14 days. (A-I)

30. Vancomycin is the drug of choice for an initial episode of severe CDI. The dosage is 125 mg orally 4 times per day for 10–14 days. (B-I)

31. Vancomycin administered orally (and per rectum, if ileus is present) with or without intravenously administered metronidazole is the regimen of choice for the treatment of severe, complicated CD1. The vancomycin dosage is 500 mg orally 4 times per day and 500 mg in approximately 100 mL normal saline per rectum every 6 hours as a retention enema, and the metronidazole dosage is 500 mg intravenously every 8 hours. (C-III)

32. Consider colectomy for severely ill patients. Monitoring the serum lactate level and the peripheral blood white blood cell count may be helpful in prompting a decision to operate, because a serum lactate level rising to 5 mmol/L and a white blood cell count rising to 50,000 cells per μ L have been associated with greatly increased perioperative mortality. If surgical management is necessary, perform subtotal colectomy with preservation of the rectum. (B-II)

33. Treatment of the first recurrence of CDI is usually with the same regimen as for the initial episode (A-II) but should be stratified by disease severity (mild-to-moderate, severe, or severe complicated), as is recommended for treatment of the initial CDI episode (C-III).

34. Do not use metronidazole beyond the first recurrence of CDI or for long-term therapy because of potential for cumulative neurotoxicity (**B-II**).

35. Treatment of the second or later recurrence of CDI with vancomycin therapy using a tapered and/or pulse regimen is the preferred next strategy (**B-III**).

36. No recommendations can be made regarding prevention of recurrent CDI in patients who require continued antimicrobial therapy for the underlying infection (C-III).

Evidence Summary

For 25 years, metronidazole and oral vancomycin have been the main antimicrobial agents used in the treatment of CDI. Two randomized controlled trials conducted in the 1980s and 1990s that compared metronidazole therapy and vancomycin therapy found no difference in outcomes but included fewer than 50 patients per study arm.^{190,191} Fusidic acid or bacitracin have not been widely adopted for treatment, partially because comparative studies showed a trend toward higher frequency of recurrence of CDI or lower efficacy.191,192 Treatment with teicoplanin is probably not inferior to treatment with metronidazole or vancomycin, but this drug remains unavailable in the United States.¹⁹³ Vancomycin is the only agent with an indication for CDI from the US Food and Drug Administration. The use of vancomycin for initial treatment of CDI markedly decreased following the 1995 Centers for Disease Control and Prevention's recommendation that the use of vancomycin in hospitals be reduced, to decrease the selection pressure for the emergence of vancomycin-resistant enterococci.194 Since then, metronidazole has generally been recommended for first-line treatment of CDI, with oral vancomycin being used mainly after metronidazole is found to be ineffective or if it is contraindicated or not well tolerated.13,14,195 Prospective trials of metronidazole (and vancomycin) therapy have not compared regimens with durations longer than 10 days. However, it is recognized that some patients may respond slowly to treatment and may require a longer course (eg, 14 days). The oral formulation of vancomycin is much more expensive than metronidazole, and to reduce costs, some hospitals use the generic intravenous formulation of vancomycin for oral administration. Some patients report a bad taste after taking this intravenous formulation by mouth.

Recent reports from Canada and the United States, in the context of the emergence of a hypervirulent strain of C. difficile, have prompted a reassessment of the comparative efficacy of metronidazole and vancomycin, especially when used to treat patients with severe CDI, primarily on the basis of studies done prior to the emergence of the epidemic strain. When administered orally, metronidazole is absorbed rapidly and almost completely, with only 6%-15% of the drug excreted in stool. Fecal concentrations of metronidazole likely reflect its secretion in the colon, and concentrations decrease rapidly after treatment of CDI is initiated: the mean concentration is 9.3 μ g/g in watery stools but only 1.2 μ g/g in formed stools.196 Metronidazole is undetectable in the stool of asymptomatic carriers of C. difficile.161 Consequently, there is little rationale for administration of courses of metronidazole longer than 14 days, particularly if diarrhea has resolved. In contrast, vancomycin is poorly absorbed, and fecal concentrations following oral administration (at a dosage of 125 mg 4 times per day) reach very high levels: 64-760 µg/g on day 2 and 152-880 µg/g on day 4.197 Doubling the dosage (250 mg 4 times per day) may result in higher fecal concentrations on day 2.198 Fecal levels of vancomycin are maintained throughout the duration of treatment. Given its poor absorption, orally administered vancomycin is relatively free of systemic toxicity.

Historically, metronidazole resistance in *C. difficile* has been rare; minimal inhibitory concentrations (MICs) of nearly all strains have been less than or equal to 2.0 mg/L.^{109 203} In a recent report from Spain, the MIC₉₀ of 415 isolates was 4.0 mg/L, and 6.3% of isolates had metronidazole MICs of 32 mg/L or higher.²⁰⁴ These levels of resistance have not been

reported elsewhere. In the United Kingdom, recently recovered isolates belonging to ribotype 001 had geometric mean MICs of 5.94 μ g/mL, compared with 1.03 μ g/mL for historic isolates (recovered before 2005) of the same ribotype.²⁰⁵ There is no evidence that the epidemic NAP1/B1/027 strain is more resistant to metronidazole than are nonepidemic strains or historic isolates.^{25,206} However, given the relatively low fecal concentrations achieved with metronidazole, even a modest decrease in susceptibility might be clinically relevant, and continued surveillance for metronidazole resistance will be important. The MIC₉₀ of vancomycin against *C. difficile* is $1.0-2.0 \ \mu$ g/mL, and the highest MIC ever reported is $16 \ \mu$ g/ mL,^{200-203,207} but considering the high fecal concentrations achieved with oral vancomycin, emergence of resistance is likely not a concern.

Three main outcomes should be considered when evaluating drugs used in the treatment of CDI: time to symptom resolution (or the proportion of patients who respond within 7–10 days); recurrences after initial symptom resolution; and the frequency of major complications, such as death within 30 days of diagnosis, hypovolemic or septic shock, megacolon, colonic perforation, emergency colectomy, or intensive care unit admission.

Treatment of a first episode of CDI. Three factors may indicate a severe or complicated course and should be considered when initiating treatment: age, peak white blood cell count (leukocytosis), and peak serum creatinine level.25,80 The influence of greater age probably reflects a senescence of the immune response against C. difficile and its toxins, and greater age has been consistently related to all adverse outcomes. Leukocytosis likely reflects the severity of colonic inflammation; complications are more common among patients who had leukocytosis with a white blood cell count of 15,000 cells/ μ L or higher than among patients with a normal white blood cell count, and the course of the disease is truly catastrophic in patients with a white blood cell count of 50,000 cells/µL or higher.208 An elevated serum creatinine level may indicate severe diarrhea with subsequent dehydration or inadequate renal perfusion.

The time to resolution of diarrhea might be shorter with vancomycin than with metronidazole therapy.²⁰⁹ A recent observational study showed that patients treated with vancomycin in the years 1991–2003 were less likely to develop complications or die within 30 days after diagnosis than were patients treated with metronidazole.⁸⁰ However, extension of this case series up through 2006 showed that for the years 2003–2006, when infection with the NAP1/BI/027 strain predominated, vancomycin no longer was superior to metronidazole therapy.²¹⁰ Thus, the potential superiority of vancomycin therapy in avoiding complications of CDI, especially among patients infected with the NAP1/BI/027 strain, requires further study.

A recent randomized controlled trial showed, for the first time, that vancomycin at a dosage of 125 mg 4 times per day was superior to metronidazole at a dosage of 250 mg 4 times per day in a subgroup of patients with severe disease, as assessed by a severity score incorporating 6 clinical variables.²¹¹ The patients were recruited in the years 1994–2002, probably before the emergence of the NAP1/BI/027 strain in the United States. A more recent study conducted since the emergence of the NAP1/BI/027 strain, reported in abstract form, confirms the superiority of vancomycin over metronidazole for treatment of severe CDL.²¹² There is no evidence to support administration of combination therapy to patients with uncomplicated CDI. Although hampered by its low statistical power, a recent trial did not show any trend toward better results when rifampin was added to a metronidazole regimen. There is no evidence to support use of a combination of oral metronidazole and oral vancomycin.

The criteria proposed in Table 3 for defining severe or complicated CDI are based on expert opinion. These criteria may need to be reviewed in the future, on publication of prospectively validated severity scores for patients with CDI.

Treatment of severe, complicated CDI. Ileus may impair the delivery of orally administered vancomycin to the colon, but intravenously administered metronidazole is likely to result in detectable concentrations in feces and an inflamed colon. Even though it is unclear whether a sufficient quantity of the drug reaches the right and the transverse colon, intracolonic administration of vancomycin seems useful in some cases.^{28,215} If colonic perforation is demonstrated or colectomy is imminent, it may be prudent to stop oral or rectal therapy with any antimicrobial agent, but, short of these complications, the emphasis should be on delivery of effective therapy to the colon. Despite the lack of data, it seems prudent to administer vancomycin by oral and rectal routes at higher dosages (eg, 500 mg) for patients with complicated CDI with ileus. Use of high doses of vancomycin is safe, but high serum concentrations have been noted with long courses of 2 g per day, with renal failure. It would be appropriate to obtain trough serum concentrations in this circumstance. Passive immunotherapy with intravenous immunoglobulins (150–400 mg/kg) has been used for some patients not responding to other therapies,²¹⁴ but no controlled trials have been performed.

Colectomy can be life-saving for selected patients.²⁰⁸ Colectomy has usually been performed for patients with megacolon, colonic perforation, or an acute abdomen, but the procedure is now also performed for patients with septic shock.^{208,215} Among patients with a lactate level of 5 mmol/L or greater, postoperative mortality is 75% or higher, when possible colectomy should be performed earlier.²⁰⁸

Treatment of recurrent CDI. The frequency of further episodes of CDI necessitating re-treatment remains a major concern. Historically, 6%-25% of patients treated for CDI have experienced at least 1 additional episode.28,216,217 Recurrences correspond to either relapse of infection the original strain or re-infection of patients who remained susceptible and are exposed to new strains.^{218,219} In clinical practice, it is impossible to distinguish these 2 mechanisms. Recent reports documented an increase in the frequency of recurrences after metronidazole therapy, especially in patients aged 65 years or more. More than half of patients aged 65 years or more in a Canadian center experienced at least 1 recurrence,²²⁰ while in Texas, half of patients treated with metronidazole either did not respond to the drug or experienced a recurrence.²⁰⁶ Other risk factors for a recurrence are the administration of other antimicrobials during or after initial treatment of CDI, and a defective immune response against toxin A.^{69,221}

Using either metronidazole or vancomycin treatment of a first recurrence does not alter the probability of a second recurrence,²²² but use of vancomycin is recommended for the first recurrence in patients with a white blood cell count of

Clinical definition	Supportive clinical data	Recommended treatment	Strength of recommendation
Initial episode, mild or moderate	Leukocytosis with a white blood cell count of 15,000 cells/ μ L or lower and a serum creatinine level less than 1.5 times the premorbid level	Metronidazole, 500 mg 3 times per day by mouth for 10–14 days	A-I
Initial episode, severe ^a	Leukocytosis with a white blood cell count of 15,000 cells/µL or higher or a serum creatinine level greater than or equal to 1.5 times the premorbid level	Vancomycin, 125 mg 4 times per day by mouth for 10–14 days	B-I
Initial episode, severe, complicated	Hypotension or shock, ileus, megacolon	Vancomycin, 500 mg 4 times per day by mouth or by nasogastric tube, plus metro- nidazole, 500 mg every 8 hours intrave- nously. If complete ileus, consider adding rectal instillation of vancomycin	C-111
First recurrence		Same as for initial episode	A-II
Second recurrence	nie.	Vancomycin in a tapered and/or pulsed regimen	B-III

TABLE 3. Recommendations for the Treatment of Clostridium difficile Infection (CDI)

The criteria proposed for defining severe or complicated CDI are based on expert opinion. These may need to be reviewed in the future upon publication of prospectively validated severity scores for patients with CDI. 15,000 cells/μL or higher (or a rising serum creatinine level), since they are at higher risk of developing complications.

A substantial proportion of patients with a second recurrence will be cured with a tapering and/or pulsed regimen of oral vancomycin. Metronidazole should not be used beyond the first recurrence or for long-term therapy because of the potential for cumulative neurotoxicity.223 Various regimens have been used and are similar to this one: after the usual dosage of 125 mg 4 times per day for 10-14 days, vancomycin is administered at 125 mg 2 times per day for a week, 125 mg once per day for a week, and then 125 mg every 2 or 3 days for 2-8 weeks, in the hope that C. difficile vegetative forms will be kept in check while allowing restoration of the normal flora. Management of patients who do not respond to this course of treatment or experience a further relapse is challenging. There is no evidence that adding cholestyramine or rifampin to the treatment regimen decreases the risk of a further recurrence.²²⁴ It should be noted that cholestyramine, colestipol, and other anion-exchange resins bind vancomycin, which make these a specific contraindication. A recent uncontrolled case series of patients with multiple recurrences of CDI documented that oral rifaximin therapy (400 mg 2 times per day for 2 weeks) cured 7 of 8 patients when it was started immediately following the last course of vancomycin and before symptom recurrence.225 Caution is recommended with use of rifaximin because of the potential for isolates to develop an increased MIC during treatment.225,226

Studies of the probiotic *Saccharomyces boulardii* have been inconclusive, but in a subset analysis of a randomized controlled trial, administration of *S. boulardii* in combination with a high dosage of vancomycin appeared to decrease the number of recurrences. Administration of *S. boulardii* has, however, been associated with fungemia in immunocompromised patients and in patients with central venous lines, and it should be avoided in critically ill patients.²²⁷ There is no compelling evidence that other probiotics are useful in the prevention or treatment of recurrent CDI.²²⁸

Considering that disruption of the indigenous fecal flora is likely a major risk for infection with *C. difficile* and, particularly, for recurrent infection, instillation of stool from a healthy donor has been used with a high degree of success in several uncontrolled case series.^{229,36} The availability of this treatment is limited, however. If "fecal transplant" is considered, the donor should be screened for transmissible agents, and logistic issues need to be considered, including the timing, the collection and processing of the specimen from the donor, the preparation of the recipient, and the route and means of administration (ie, by nasogastric tube or by enema).

Other potential options for treatment include alternative antimicrobial agents, such as nitazoxanide,⁷ intravenous immunoglobulins (150–400 mg/kg).²⁵⁰⁻²⁵³

Prevention of recurrent CDI in patients requiring antimicrobial therapy. Some patients need to receive other antimicrobials during or shortly after the end of CDI therapy, either to complete the treatment of the infection for which they had received the inciting antibiotics or to treat a new incidental infection. These patients are at high risk of a recurrence and its attendant complications.^{69,221} Many clinicians prolong the duration of treatment of CDI in such cases, until after the other antimicrobial regimens have been stopped. Whether this reduces the risk of CDI recurrence is unknown, and the Expert Panel offers no specific recommendation, but if the duration of CDI treatment is prolonged, oral vancomycin is the preferred agent, given the absence of therapeutic levels of metronidazole in the feces of patients who no longer have active colitis.

RESEARCH GAPS

The initial step in developing a rational clinical research agenda is the identification of gaps in information. The process of guideline development, as practiced by SHEA and the IDSA, serves as a natural means by which such gaps are identified. Thus, these guidelines identify important clinical questions and identify the quality of evidence supporting those recommendations. Clinical questions identified by the SHEA-IDSA Expert Panel and by members of the IDSA Research Committee that could inform a *C. difficile* research agenda are listed below.

Epidemiology

What is the epidemiology of CDI? What is the incubation period of *C. difficile*? What is the infectious dose of *C. difficile*? How should hospital rates be risk-adjusted for appropriate interhospital comparisons? Does administration of proton pump inhibitors increase the risk of CDI and, if so, what is the magnitude of risk? What are the sources for *C. difficile* transmission in the community? Is exposure to antimicrobials (or equivalent agents, such as chemotherapy drugs) required for susceptibility to CDI? What is the role of asymptomatic carriers in transmission of *C. difficile* in the healthcare setting? What are the validated clinical predictors of severe CDI? At what age and to what degree is *C. difficile* pathogenic among infants?

Diagnostics

Is GDH detection in stool sufficiently sensitive as a screening test for C. difficile colitis? How well does this method correlate with culture for toxigenic C. difficile and cell culture cytotoxicity assay? Which of these "gold standard" assays (culture for toxigenic C. difficile or cell culture cytotoxicity assay) is optimal as a reference test for diagnosis of CDI? Is screening by GDH test, coupled with confirmatory testing for toxigenic C. difficile by cell culture cytotoxicity assay or real time PCR for toxin B, as sensitive as primary testing of stool using realtime PCR? What is the best diagnostic method for hospital laboratories that do not have PCR technology available? Which commercial PCR assay for toxin B performs best, compared with culture for toxigenic C. difficile? Is PCR testing for toxin B too sensitive for clinical utility? How do individual laboratory-derived PCR assays for C. difficile compare with commercial PCR assays?

Is there any role for repeated C. difficile stool testing during the same episode of illness?

After initial diagnosis of CDI, should testing be repeated for any reason other than recurrence of symptoms following successful treatment?

Management

If a validated severity-of-illness tool for CDI is developed, how will treatment recommendations for primary CDI be modified?

What is the best treatment for recurrent CDI? What is the best way to restore colonization protection of intestinal microbiota? What is the role of fecal transplant? What is the role of administration of passive antibodies (immunoglobulins or monoclonal antibodies) or active immunization (with vaccines)?

What is the best approach to treatment of fulminant CDI? What are the criteria for colectomy in a patient with fulminant CDI? What is the role of treatment with vancomycin or other antibiotics alone or in combination in fulminant infection? What is the role of treatment with passive antibodies (immunoglobulin or monoclonal antibody therapy) in fulminant infection?

Prevention

What preventive measures can be taken to reduce the incidence of CDI? Can administration of probiotics or biotherapeutic agents effectively prevent CDI? What are the most effective antimicrobial stewardship strategies to prevent CDI? What are the most effective transmission prevention strategies (ie, environmental management and isolation) to prevent CDI in inpatient settings? What is the incremental impact of each? Can vaccination effectively prevent CDI, and what would be the composition of the vaccine and the route of administration? What are systemic or mucosal serologic markers that predict protection against CDI?

Basic Research

What is the biology of C. difficile spores that leads to clinical infection? What induces spore germination and where does it occur in the human gastrointestinal tract? How do spores interact with the human gastrointestinal immune system? What are the triggers for sporulation and germination of *C. difficile* in the human gastrointestinal tract? What is the role of sporulation in recurrent *C. difficile* disease?

What is the basic relationship of C. difficile to the human gut mucosa and immune system? Where in the gut do C. difficile organisms reside? What enables C. difficile to colonize patients? Is there a C. difficile biofilm in the gastrointestinal tract? Is mucosal adherence necessary for development of CDI? Is there a nutritional niche that allows *C. difficile* to establish colonization? What is the role of mucosal and systemic immunity in preventing clinical CDI? What causes *C. difficile* colonization to end? Do *C. difficile* toxins enter the circulation during infection?

PERFORMANCE MEASURES

Performance measures are tools to help guideline users measure both the extent and the effects of implementation of guidelines. Such tools or measures can be indicators of the process itself, outcomes, or both. Deviations from the recommendations are expected in a proportion of cases, and compliance in 80%–95% of cases is generally appropriate, depending on the measure.

- Infection control practices should be consistent with guideline recommendations, including compliance with recommended isolation precautions and adequacy of environmental cleaning. Data exist supporting the conclusion that use of these measures has led to control of outbreaks of CDI.
- Treatment of the initial episode of CDI should be consistent with the guidelines. In particular, patients with severe CDI (provisionally identified as leukocytosis with a white blood cell count greater than 15,000 cells/µL or an increase in the serum creatinine level to 1.5 times the premorbid level) should be treated with vancomycin. Evidence suggests treatment with this agent has significantly better outcomes than does treatment with metronidazole.
- Appropriate testing for the diagnosis of CDI includes submitting samples only of unformed stool. Additionally, no more than 1 stool sample should be obtained for routine testing during a diarrheal episode. Stool should not be submitted for test of cure.

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Pharmaceutical, Romark Laboratories, and Acambis, V.G.L. reports that she has served as a consultant for Genzyme, J.P. reports that he has served on advisory boards for Pfizer and Novartis; as an advisor for Viropharma, Acambis, Wyeth Pharmaceuticals, and Bayer; and as speaker for Wyeth Pharmaceuticals. C.P.K. reports that he has served as scientific advisor and consultant to Actelion, Cubist Pharm, MicroBiotix, Salix Pharm, Sanofi-Pasteur, ViroPharma, and Wyeth Pharm and has received research support from Actelion and MicroBiotix. M.H.W. and L.C.M. report no conflicts relevant to this guideline.

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It is important to realize that guidelines cannot always account for individual variation among patients. They are not intended to supplant physician judgment with respect to particular patients or special clinical situations. SHEA and the IDSA consider adherence to these guidelines to be voluntary, with the ultimate determination regarding their application to be made by the physician in the light of each patient's individual circumstances.

The findings and conclusions in this report are those of the author(s), writing on behalf of SHEA and the IDSA, and do not necessarily represent the views of the Centers for Disease Control and Prevention, or the United States Department of Veterans Affairs.

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The single most important action a healthcare worker, patient, or visitor to a healthcare facility can do to prevent the spread of infection is to practice proper hand hygiene. While this may seem overly simple, studies show that hand hygiene adherence rates are consistently too low, with some estimates showing adherence of less than 40% for healthcare workers.²³ The current literature describes a variety of reasons affecting adherence, some practical (such as lack of access to sanitizing agents), and some behavioral (such as a lack of acknowledgment for the importance of consistent hand hygiene practices). Additionally, difficulties presented by methods of monitoring can influence accurate measurement of adherence rates.

Barriers that affect hand hygiene compliance include experiencing dryness or discomfort from repeated use of harsh soaps and alcohol-based hand rubs, feeling too busy, inaccessible hand-sanitizing stations, lack of knowledge on how and when to wash hands and what kind of sanitizing agent is most appropriate in a given situation, and the belief that wearing gloves is a substitute for hand hygiene. Unfortunately, compliance has been shown to be worse in situations where it is most important: when intensity of patient care is high, during procedures where contamination risk is high, and in intensive-care units.²⁴ Performing proper hand hygiene in the healthcare environment is fundamentally a behavioral habit that must be ingrained. Habits can be hard to change, but when the safety of patients and staff is in question, healthcare facilities must work actively to address the barriers that prevent success.

Difficulties in monitoring can be attributed to multiple points where hand hygiene can occur, the amount of time needed to adequately monitor workers, the frequency of opportunities that must be observed, the fact that opportunities can occur any time of day or night throughout the year in both clinical and non-clinical environments, and the consideration of changes in behaviors when staff know they are being observed.²⁵ Accuracy is dependent on knowledgeable, trained observers, consistent practices, and acknowledgment of biases and confounding factors.

This section of the tool kit will review current guidelines and methods of monitoring, with the intention of highlighting the most current interventions and strategies for improvement. The focus will be on improving adherence and overcoming challenges, as well as consideration of hygiene technique in circumstances where *C. difficile* is present.



Ignaz Semmelweiss (1818-1865), a Hungarian physician, discovered that hand hygiene reduced the incidence of puerperal fever in 1847. His practices were not widely accepted until after his death and were dismissed for their simplicity.⁶⁵



THE GUIDELINES

The World Health Organization's Guidelines on Hand Hygiene in Healthcare reviewed in this tool kit were developed beginning in 2004, were published in 2009, and are expected to remain current through 2011. The guideline provides a comprehensive review of evidence-based practices to improve hand hygiene in healthcare workers as a means of reducing the spread of infectious organisms. The guidelines are intended to be adapted to local settings and resources while maintaining adherence to the recommendations.

Recommendations are ranked according to the CDC/HICPAC (Healthcare Infection Control Practices Advisory Committee) system, which is based on existing data, applicability, economic impact, and theory.

RANKING SYSTEM				
Category IA	Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.			
Category IB	Strongly recommended for implementation and supported by certain experimental, clinical, or epidemiologic studies, as well as a strong theoretical rationale.			
Category IC	Required for implementation, as mandated by federal or state regulation or standard.			
Category II	Suggested for implementation and supported by suggestive clinical or epidemiologic studies, or a theoretical rationale.			
No Recommendation	Unresolved issue. Practices for which insufficient evidence or no consensus regarding efficacy exist.			

The WHO Guidelines on Hand Hygiene in Health Care are presented here (adapted)¹³:

Indications for hand washing and hand antisepsis:

- 1. Wash hands with soap and water when visibly dirty or visibly soiled with blood or other body fluids (IB) or after using the toilet (II).
- 2. If exposure to potential spore-forming pathogens is strongly suspected or proven, including outbreaks of *Clostridium difficile*, hand washing with soap and water is the preferred means (IB).
- 3. Use an alcohol-based hand rub as the preferred means for routine hand antisepsis in all other clinical situations described in items (a) to (f) listed below if hands are not visibly soiled (IA). If alcohol-based hand rub is not obtainable, wash hands with soap and water (IB).
 - a. before and after touching the patient (IB);
 - b. before handling an invasive device for patient care, regardless of whether or not gloves are used (IB);
 - c. after contact with body fluids or excretions, mucous membranes, non-intact skin, or wound dressings (IA);
 - d. if moving from a contaminated body site to another body site during care of the same patient (IB);
 - e. after contact with inanimate surfaces and objects (including medical equipment) in the immediate vicinity of the patient (IB);
 - f. after removing sterile (II) or non-sterile gloves (IB).
- 4. Before handling medication or preparing food, perform hand hygiene using an alcohol-based hand rub or wash hands with either plain or antimicrobial soap and water (IB).
- 5. Soap and alcohol-based hand rub should not be used concomitantly (II).

Hand hygiene technique:

- 1. Apply a palmful of alcohol-based hand rub and cover all surfaces of the hands. Rub hands until dry (IB).
- 2. When washing hands with soap and water, wet hands with water and apply the amount of product necessary to cover all surfaces. Rinse hands with water and dry thoroughly with a single-use towel. Use clean, running water whenever possible. Avoid using hot water, as repeated exposure to hot water may increase the risk of dermatitis (IB).Use towel to turn off tap/faucet (IB). Dry hands thoroughly using a method that does not recontaminate hands. Make sure towels are not used multiple times or by multiple people (IB).
- 3. Liquid, bar, leaf, or powdered forms of soap are acceptable. When bar soap is used, small bars of soap in racks that facilitate drainage should be used to allow the bars to dry (II).

Use of gloves:

- 1. The use of gloves does not replace the need for hand hygiene by either hand rubbing or hand washing (IB).
- 2. Wear gloves when it can be reasonably anticipated that contact with blood or other potentially infectious materials, mucous membranes, or non-intact skin will occur (IC).
- 3. Remove gloves after caring for a patient. Do not wear the same pair of gloves for the care of more than one patient (IB).
- 4. When wearing gloves, change or remove gloves during patient care if moving from a contaminated body site to either another body site (including non-intact skin, mucous membrane, or medical device) within the same patient or to another environment (II).
- 5. The reuse of gloves is not recommended (IB). In the case of glove reuse, implement the safest reprocessing method (II).

Other aspects of hand hygiene:

- 1. Do not wear artificial fingernails or extenders when having direct contact with patients (IA).
- 2. Keep natural nails short (tips less than 0.5 cm long or approximately ¼ inch) (II).



HAND HYGIENE AND C. DIFFICILE: SPECIAL CONSIDERATIONS

With the introduction of alcohol-based hand sanitizers in the healthcare facility, overall hand hygiene compliance has improved with the relative ease of use and availability of these products. As the WHO/CDC guidelines recommend the use of alcohol-based hand rubs as an appropriate means of hand hygiene when hands are not visibly soiled, it is fair to assume that the use of these sanitizing agents has increased in recent years. Similarly, the incidence of CDI has also increased, leading some to draw associations between the two. While it has been shown that alcohol-based cleaners and hand sanitizers may not be an effective means of killing C. difficile spores, it has not been proven that the use of alcohol-based sanitizers have caused increased rates of CDI.17 Rather, several studies have shown that CDI rates remained the same or even decreased following alcohol-based hand-rub hygiene programs.²⁶⁻²⁸ At present, this question remains an issue of debate.

This section provides an overview of current guidelines and recommendations to assist infection-control practitioners in promoting proper hand hygiene in settings that involve patients with CDI. Current guidelines recommend following the standard CDC/WHO hand hygiene guidelines upon exiting a room as part of the basic practices for prevention under circumstances where there is no current outbreak of CDI.¹⁰ In other words, the use of alcohol-based hand sanitizers is sufficient if hands are not visibly soiled after glove removal, unless there is an outbreak of CDI at the facility. For facilities that are experiencing high CDI rates, special approaches to minimize transmission should be followed:

- 1. Intensify assessment of compliance with process measures (B-III).
 - a. Hand hygiene should be performed on entry and exit from patient rooms. When hand washing is performed, determine whether proper techniques are being used (e.g., hand washing for at least 15 seconds).
 - b. If hand hygiene compliance or techniques are not adequate, conduct interventions to improve hand hygiene compliance and techniques.
- 2. Perform hand hygiene with soap and water as the preferred method before exiting the room of a patient with CDI (B-III).
 - a. Ensure proper hand hygiene technique when using soap and water.
 - b. Be aware that hand hygiene adherence may decrease when soap and water is the preferred method.
 - i. Additional education may be necessary to remind healthcare workers that alcohol-based hand hygiene products are superior to hand washing for non-spore forming organisms (e.g., MRSA).

COLORADO INFECTION PREVENTION COLLABORATIVE

C. DIFFICILE INFECTIONS

FAQS: HAND HYGIENE AND THE SPREAD OF CLOSTRIDIUM DIFFICILE²

(adapted from WHO Guidelines)

The following information is intended to support healthcare workers and others in understanding and explaining the challenges presented by patients with *C. difficile* infection.

Can appropriate infection control practices help prevent and control *Clostridium difficile*?

Yes. It is recommended that gloves be worn and hands washed appropriately if exposure to potential spore-forming pathogens is strongly suspected or proven, including *C*. *difficile* outbreaks. The method of hand hygiene to be employed must be hand washing using soap and water. Even when gloves have been worn, hand washing is essential. It is important that the correct technique for hand washing is applied. In all other situations, the use of alcohol-based hand rubs are the preferred method.

What is the concern about healthcare workers using alcohol-based hand rubs at the point of care when patients have *C. difficile*?

Alcohol hand rubs are known to be less effective on soiled hands generally, as well as when there is *C. difficile* infection. Conveying simple messages to healthcare workers through routine training and updates, and reinforcing these during times of outbreak situations, will help to ensure that the correct methods for hand hygiene are applied at the correct moments.

Should we remove alcohol-based hand rubs from areas where there is a *Clostridium difficile* infection?

No, alcohol-based hand rubs are required at the point of care for a number of reasons:

- They are easy to use and are more likely to result in greater compliance for workers.
- They are proven effective in killing a range of pathogens and they reduce risk of patients acquiring a healthcare-associated infection.
- They are effective in killing non-spore forms of C. difficile
- Sinks for hand washing are not always readily available.
- Evidence-based research reinforces the need for the presence of these hand rubs to ensure maximum patient safety.

• There is no evidence to suggest that their use has been connected with increased CDI.

Are visibly clean hands still at risk for cross-transmission?

It is very unlikely. Hand washing with soap and water is recommended when exposure to potential spore-forming pathogens is strongly suspected or proven (including outbreaks of *C. difficile*); however, it is very unlikely that using alcohol-based hand rubs on visibly clean hands will put patients at risk of cross-infection. Appropriate glove use and the adoption of either type of hand hygiene on non-soiled hands will ensure clean, safe hands. The bottom line is that hands should be washed with soap and water when they are visibly dirty or soiled with blood or other bodily fluids.

How often will the spores be present when patients have *Clostridium difficile* infection?

When patients have *C. difficile* with severe diarrhea, large amounts of spores can be present. This is also true of specific strains of *C. difficile*, including those that are epidemic in certain countries. Effective hand hygiene at the point of care, together with other well-accepted control measures, helps to manage the problem.

Clostridium difficile figures are very high in some countries, and seem to have become worse. Is this because of alcoholbased hand rubs?

There is published evidence that the extensive use of alcoholbased hand rubs in hospitals has not led to an increase in *C. difficile*.

Does the promotion of alcohol-based hand rubs imply the "downgrading" of sinks and hand washing?

No. Guidance highlights the fact that hand washing is essential in specific situations. Although washing hands with soap and water remains an accepted method for routine hand antisepsis, alcohol-based hand rubs should be promoted as the gold standard for hand hygiene, considering their dramatic impact on improving compliance with hand hygiene and ensuring clean, safe hands.

MONITORING METHODS

The direct observation method is considered the gold standard for hand hygiene monitoring and is the recommended practice per current guidelines. This method involves visually monitoring staff for hand hygiene behavior and recording the results. Benefits include the ability to observe many facets of proper hand hygiene, such as appropriate time spent cleansing hands, fingernail length, and accessibility of necessary hand hygiene products. It allows for the observation of compliance between groups, such as certain wards or units that may need to work on improvements, time of day, and differences in compliance among staff members. The opportunity for immediate education and feedback is also available during the monitoring process.

Drawbacks are that it is time-consuming and labor intensive; it requires trainers to use and understand uniform definitions of compliance; it captures only a small number of opportunities; and those being observed may modify their behavior if they know they are being monitored. Nevertheless, this method is the only method available to assess adherence to detect all opportunities. The WHO guidelines recommend using a standardized form based on the five monitoring moments for hand hygiene. The organization has developed such a form, released in 2009, which has been validated for use in several studies. A modified version of this form, which was used electively by facilities participating in the Infection Prevention Collaborative, is included in your tool kit. Direct methods can also involve patient assessment and healthcare worker self report, though these are not always thought of as reliable.2,25

NEW AND NOTABLE

A new addition to the direct-monitoring process is the development of the iScrub application for iPhone, iPad, and iPod touch. The current application allows observers to record observations, along with the time, location, and job role of the healthcare worker being observed. Data can then be transferred to any computer via email and reviewed in an Excel spreadsheet. For more information visit: <u>https://compepi.cs.uiowa.edu/iscrub/home/</u> or <u>http://itunes.apple.com/us/app/iscrub-lite/id329764570?mt=8</u>.

Indirect methods involve measuring the use of products such as paper towels, soap dispensers, and alcohol-based sanitizers—and automated monitoring of the use of sinks and hand-rub dispensers. These methods may provide a less expensive way of estimating hand hygiene adherence, though they do not provide the accuracy or wealth of information that comes from direct-monitoring methods. It is debatable as to whether indirect monitoring can really serve as a proxy for hand hygiene adherence, and the issue deserves more study.

COLORADO INFECTION PREVENTION COLLABORATIVE

Hand Hygiene

DEVELOPING A STRATEGY FOR MONITORING

With the complexities of hand hygiene monitoring, The Joint Commission developed some guidance on how to develop a monitoring strategy as part of a monograph, "Measuring Hand Hygiene: Overcoming the Challenges," published in 2009. A web address to the full monograph is available at the end of the hand hygiene section.

Three questions that should be asked before beginning any hand hygiene monitoring process include²⁵:

1. Why does your organization want to measure hand hygiene adherence, and what are its goals in doing so?

The strategy that is used will depend on your organization's goals for monitoring. For example, you may wish to monitor certain individuals or high-risk patient populations or units within the facility. The goal may be to provide insight into a recent infectious-disease outbreak, to improve adherence throughout the facility, to comply with regulations, and to improve quality of care. You will also want to consider the format in which results will be presented and to whom, as well as the time period of data collection.

2. What elements of hand hygiene does your organization wish to measure?

Specifically determine what the trained observers will be monitoring. It is important to be clear and provide education to those who will be conducting the monitoring of exactly what they are looking for. The following items can be considered for monitoring:

- a) Components: supplies, type of healthcare worker, adequacy of cleansing
- b) Indications: All five moments of hand hygiene or only before and after patient contact, etc.
- c) Structural considerations: Product availability and accessibility, adequacy in placement of sinks and dispensers, functionality, use of dispensers
- d) Product use: volume used, the number of workers who use it, the type of worker who uses it
- e) Adherence to policy: e.g., whether jewelry is worn and fingernails are kept short
- f) Staff knowledge: Do staff have the knowledge needed to perform appropriate hand hygiene?

- g) Staff competence: When given the knowledge, is staff able to perform adequate hand hygiene, such as washing hands with appropriate technique?
- h) Perceptions and attitudes of healthcare workers
- i) Satisfaction of staff and patients with hand hygiene practices
- 3. How does your organization wish to measure hand hygiene?

Depending on what you have decided to measure, the next step is to decide whether you want to use direct or indirect observation. It is important to consider what is affordable and practical given your organization's staffing availability and the budget that feasibly may be allocated toward monitoring efforts.

Deciding which observations to measure will affect your overall adherence rates. For example, the decision to monitor all five moments of hand hygiene, or strictly before patient contact, will likely yield different adherence rates. The Joint Commission has outlined three measurement types that you may wish to consider in your monitoring plan. These include:

- 1. Item by item measures, such as only considering one of the five moments—e.g., only consider indications after contact with a patient.
- 2. Composite measurement, which may include multiple indications into a single adherence rate. For example, the number of indications before patient contact plus the number of indications after patient contact.
- 3. The all-or-none measurement method, which implies that either all or no indications for hand hygiene were performed.



DEVELOPING A STRATEGY FOR MONITORING CONT.

WHO AND HOW	PROS	CONS					
Infection Preventionists	Highly knowledgeableAble to intervene and teach in the momentAble to provide immediate feedback	 Recognized by staff, which can lead to the Hawthorne Effect—"behavior improves when staff know they are being observed" Prevents ownership by the unit 					
Unit Staff	 Allows for ownership by the unit Can be an "eye-opener" to see the true level of adherence Improves knowledge of guidelines 	 Potential biases in observing colleagues Potential for inaccuracies in reporting Observer training may be needed 					
Patients	 Best for assessing basic indications Demonstrates the hospital is committed to patient care 	 Ethical considerations of involving patients Indications must be performed in front of patient and not in other locations, such as outside the room 					
Overt	• Allows for immediate access to staff for feedback and education	• May result in "Hawthorne Effect"					
Covert	• Minimizes "Hawthorne Effect"	 Limits opportunities for immediate feedback and education May create lack of trust May limit observations that can be tracked 					



COLORADO INFECTION PREVENTION COLLABORATIVE
IMPROVING ADHERENCE

Healthcare workers know they need to wash their hands, but there are often many barriers, occurring at every point of care, that prevent proper hygiene. Addressing these barriers and changing the behavior of individuals requires a multifaceted approach, similar to the one developed by Ontario's Just Clean Your Hands campaign adapted below.²⁹



MULTIMODAL STRATEGY FOR IMPROVING ADHERENCE

For initial improvements and sustained change, it is imperative that engagement in activities take place from the patient level all the way to the senior management. Hospitals and long-term care facilities must do more than ensure the availability of supplies at the point of care: they must take a systems approach to change.

Taking a multidisciplinary approach requires a multidisciplinary team. Physician champions, environmental services staff, infection control, nurses, materials management, health-education staff, administration, and leadership are all key players in the campaign for hand hygiene. Drafting termination policies for not practicing appropriate hand hygiene at all times is one way of involving upper management and sending a clear message that the healthcare organization is serious in its efforts to promote good habits. This tactic has been useful for facilities in the collaborative when the hand hygiene compliance rates have become stagnant, and it can help boost rates into the 90 percentile ranges. A sample is provided in your tool kit.⁷⁴



COLORADO INFECTION PREVENTION COLLABORATIVE C. DIFFICILE INFECTIONS

Hand Hygiene

STAFF TRAINING AND EDUCATION

The maxim is "knowledge is power." If healthcare workers don't know when and how to clean their hands, there is very little chance they will be successful in doing so. Many healthcare workers do not have a clear understanding of the complex opportunities for hand hygiene.²⁵ Habits are more easily formed when a task is perceived as easy to accomplish and knowing what to do makes things easier.²³

Basic training should consist of a review of current guidelines, hygiene techniques, methods of transmission of pathogen via the hands, and the burden of healthcareacquired infections. There are several interactive training modules available for use online. For example, CDC has a hand hygiene training module that reviews key concepts and other standard precautions to prevent infections. For access, visit: <u>http://www.cdc.gov/handhygiene/training.html</u>. Addressing the "what-ifs" of hand hygiene can be a crucial component to a hand hygiene program. This is important for training staff on basic practices, as well as training those who are monitoring hand hygiene practices. Consider incorporating such questions into regular training or posting information about what to do when more complicated circumstances arise.

- What if a staff member performs hand hygiene, leaves a patient's room and goes directly into another room? Does hand sanitizing need to happen again?
- What if my hands are full? How do I perform hand hygiene?
- What if I am only sticking my hand into a patient's room? Do I need to perform hand hygiene?
- What if I sanitize outside a room so the observers can collect data? Shouldn't the patients be the ones to see me using the hand rub?
- What if I put gloves on when I entered the room and removed them before I left the room? Do I still need to sanitize?
- When do I use soap and when to I use hand sanitizer?
- What if the hand-sanitizing station is out of hand rub?

Consider installing a suggestion box where staff can anonymously insert questions they may have about hand hygiene practices. Then provide answers at a monthly meeting or through emails, newsletters, posters, or screensavers.

COLORADO INFECTION PREVENTION COLLABORATIVE

C. DIFFICILE INFECTIONS

PATIENT INVOLVEMENT AND EMPOWERMENT

Patients and families can have an influence on hand hygiene adherence in two ways. First, they can be taught and reminded how to perform hand hygiene themselves, reducing the risk of acquiring infections themselves and reducing the spread to the environment. Second, they can be taught to remind healthcare workers to sanitize their hands. It is critical to remember that it is always the healthcare worker who is ultimately responsible for performing this part of their job, and there should never be any added pressure or expectation put on a patient. Patients may be vulnerable and weakened from illness, and they should not be expected to participate in improving hand hygiene adherence of staff if they are unwilling or unable. In a recent study, 40% of patients surveyed indicated that they felt they should remind caregivers to wash their hands, but most reported they would not feel comfortable doing so. The main reasons they gave are: they felt that healthcare providers already know when to perform hand hygiene, they felt uncomfortable telling them to do so, and they did not feel it was their responsibility. The study also showed, however, that if patients were asked to remind healthcare workers to wash their hands, they were twice as likely to do so.²⁸ Additionally, patients are more confident about the care they receive when they see that the hospital makes a commitment to patient-care activities such as hand hygiene.25

The CDC has created patient admission videos in Spanish and English that teach patients the importance of hand hygiene in the hospital, pointing out that it is appropriate to ask or remind workers to

Several studies have shown that patients are more likely to ask healthcare workers to practice hand hygiene if they receive an invitation to do so.²⁷

practice hand hygiene. The video is included as part of the tool kit.

Patients must also be provided with the needed tools and education on performing hand hygiene. Provide patients with bottles of hand sanitizer for disinfection. If a patient has *C. difficile*, explain that washing hands with soap and water after using the bathroom and before eating food is the preferred method and that everyone needs to clean their hands before exiting the patient's room.¹⁵

COLORADO INFECTION PREVENTION COLLABORATIVE
C. DIFFICILE INFECTIONS

NOTABLE RESOURCES

The following organizations have developed quality guidance for implementation of hand hygiene-improvement programs and provide a wealth of tools and educational information.

- World Health Organization: The WHO's "SAVE LIVES: Clean Your Hands Campaign" advocates the need to improve and sustain hand hygiene practices of healthcare workers at the right time and in the right place. For access to a variety of tools, including costing tools, draft letters to management, and staff- and patient-education materials, visit: <u>http://www.who.int/gpsc/5may/en</u>.
- Centers for Disease Control and Prevention: "Hand Hygiene in Healthcare Settings" is intended to provide healthcare workers with access to all current guidelines, patient-oriented materials, an interactive training course, videos and podcasts, as well as links to many other resources. For access, visit: <u>http://www.cdc.gov/ handhygiene/index.html</u>.
- The Joint Commission developed a monograph in 2009 titled "Measuring Hand Hygiene: Overcoming the Challenges." The document was created in collaboration with other leaders in the healthcare field. The monograph can be described as "anything you want to you know about measurement of hand hygiene but were afraid to ask." For access, visit: <u>http://www.jointcommission.org/</u> <u>assets/1/18/hh_monograph.pdf</u>.
- Institute for Healthcare Improvement developed the how-to guide "Improving Hand Hygiene—A Guide for Improving Practices among Health Care Workers" in 2006 in collaboration with the CDC, APIC, and SHEA, with contributions from WHO. For access visit: <u>http://</u> www.ihi.org and search for "Hand Hygiene" to access.

- Association for Professionals in Infection Control and Epidemiology (APIC) has developed several brochures aimed at improving hand hygiene practices of healthcare workers and consumers, as well as tips on hand washing. Additionally, current guidelines for hand hygiene are posted on the site. Visit: <u>www.apic.org</u> and click "Education" or "Guidelines & Standards."
- Washing Hands Saves Lives is a hand hygiene campaign developed by Novant Health, a nonprofit health system. Their website offers a variety of free marketing materials, including stickers, screen savers, mirror decals, and posters, as well as a sample protocol and knowledge surveys. For access, visit: http://www.washinghandssaveslives.org/index.html.
- The Hand Hygiene Resource Center is a project of the St. Raphael Healthcare System and Dr. John Boyce to improve hand hygiene practices in healthcare settings. The site offers current information on hand hygiene practices, including monitoring tools, educational presentations, and guidance on selecting alcohol-based hand rubs. For access, visit <u>www.handhygiene.org</u>.

COLORADO INFECTION PREVENTION COLLABORATIVE

TOOL KIT ARTICLE ABSTRACTS

• The World Health Organization Guidelines on Hand Hygiene in Health Care and Their Consensus Recommendations

The article included in your tool kit, "The World Health Organization Guidelines on Hand Hygiene in Health Care and Their Consensus Recommendations," provides a concise synopsis of the most relevant portions of the WHO's extensive guidelines on hand hygiene published in 2009. Visual representations of the five moments for hand hygiene, as well as the appropriate techniques for hand washing and use of alcohol rub, are shown.

Pittet D, Allegranzi B, Boyce J, et al. The World Health Organization Guidelines on Hand Hygiene in Health Care and Their Consensus Recommendations. *Infect Control Hosp Epidemiol* 2009; 30:611–622. • Improving Adherence to Hand Hygiene Practice: A Multidisciplinary Approach

The article included in your tool kit, "Improving Adherence to Hand Hygiene Practice: A Multidisciplinary Approach," reviews barriers to appropriate hand hygiene as well as risk factors for noncompliance. The author also proposes strategies for improving compliance, highlighting the need for practical and behavioral approaches, and states the need for involvement from leadership.

Pittet D. Improving Adherence to Hand Hygiene Practice: A Multidisciplinary Approach. *Emerging Infectious Diseases* 2001; 7 (2): 234–240.

COLORADO INFECTION PREVENTION COLLABORATIVE

Terms

Alcohol Based Handrub

Alcohol-containing preparations designed for hand application to reduce the numbers of viable microorganisms on the hands

Antimicrobial Soap

Soap (i.e. detergent) containing an antiseptic agent

Decontaminate Hands

To reduce bacterial counts on hands by performing antiseptic handrub or antiseptic handwash

Hand Hygiene

A general term that applies to handwashing, antiseptic handwash, antiseptic handrub, or surgical hand antisepsis

Persistent Activity

Refers to the prolonged or extended antimicrobial activity that prevents or inhibits the growth or survival of microorganisms following application of the product

Plain soap

Detergents that do NOT contain antimicrobial agents or contain low concentrations of antimicrobial agents that are effective solely as preservatives

Proteinaceous

Any substance composed of proteins

Surgical Hand Antisepsis

Antiseptic handwash or antiseptic handrub performed preoperatively by surgical personnel to eliminate transient and reduce resident flora. Antiseptic detergent preparations often have persistent antimicrobial activity

Visibly Soiled Hands

Hands showing visible dirt or that are visibly contaminiated with proteinaceous material, blood, or other body fluids (e.g. fecal material or urine)

mportant Hand Hygiene Tips

- When washing hands, repeated use of HOT (vs warm) water may increase the risk of dermatitis.
- Liquid, bar leaflet or powdered soap is acceptable for handwashing with nonantimicrobial soap and water.
- Handwashing, NOT alcohol-based handrubs, should be used to clean hands contaminated by bacterial spores such as Clostridiium difficile or Bacillus anthracis (Anthrax).
- Choose alcohol handrubs containing 60-95% isopropanol, ethanol or n-propanol per CDC Hand Hygiene Guidelines.
- Choose alcohol handrubs with 1-3% glycerol or other emollients.
- Alcohol-based handrubs, rinses or gels containing emollients cause LESS skin irritation and dryness than soaps OR antimicrobial detergents tested.
- Alcohol-based handrubs, etc., should be stored away from high temperatures, flames, electrical outlets or oxygen receptacles, according to recommendations from the National Fire Protection Agency (NFPA).
- It is NOT necessary, or recommended, to routinely WASH hands after application of alcohol-based handrubs.
- Provide moisturizing skin care products or barrier creams for employee use. Ensure these products will not compromise glove barrier.
- Use of antimicrobial-impregnated wipes is considered equivalent to handwashing, but they are not considered a substitute for alcohol handrubs or antimicrobial soap.

Kimberly-Clark

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Adapted Fram: Boyce, J., Pittet, D. the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/ APIC/IDSA Hand HygieneTask Force. Guideline For Hand Hygiene in Health-Care Settings. MMWR, 2002, 51, RR-16



Hand Hygiene for Healthcare Workers



Background	Hand Hygiene Recommendations	Hand Hygiene Techniques
For over 150 years, scientists have associated decreased morbidity and mortality rates with the practice of cleaning one's hands. Studies show that hand hygiene contributes to reductions in healthcare-associated infections. Studies also reveal that the greater the need to clean hands, the LESS the adherence to proper hand hygiene.	 Wash Hands with Plain or Antimicrobial Soap. When visibly dirty When contaminated with proteinaceous material When contaminated with blood or body fluids Before eating or handling food After using the restroom 	 Handwashing with Plain or Antimicrobial Soap. Purpose: Physical removal of soil and transient microorganisms, including bacterial spores Wet hands with water. Apply soap to hands, according to manufacturer's directions. Rub hands vigorously together for at least 15 seconds. Cover all surfaces of hands and fingers.
Healthcare workers report various factors that contribute to poor compliance with hand hygiene, including, but not limited to: Working in an intensive care unit Wearing of gloves/belief that gloves eliminate the need Hand dryness or inritation nconvenient sink location Lack of soap/paper towels If hand hygiene is to improve, it is essential	 Decontaminate Hands with Alcohol Handrubs: When NOT visibly solled Before direct patient contact Before donning sterile gloves to insert central intravascular lines Before inserting urinary catheters, other IV catheters, OR invasive devices that do not require surgical placement After contact with muccous membranes or non-intact skin if hands are not visibly solled 	 Rinse hands well to remove soap residue. Dry with paper towel. Use towel to turn off faucet. Hand Hygiene with Alcohol-Based Handrub Purpose: Reduction of bacterial counts on hands when hands are NOT visibly soiled Apply product to palm of one hand. Rub hands together. Cover all surfaces of hands and fingers.
 to eliminate the barriers associated with these factors. Barriers include: Lack of knowledge that guidelines for hand hygiene exist Failure to recognize hand hygiene opportunities during the performance of one's duties 	 After removing gloves If moving from a contaminated body site to a clean body site during cares After contact with objects (including equipment) located in the patient's environment 	Surgical Hand Antisepsis with Antimicrobial Soap or Alcohol-Based Handrub Purpose: Elimination of transient microorganisms and reduction of resident hand flora, performed prior to surgical procedures, before donning sterile gloves
 Lack of awareness for the risk for cross- transmission of organisms On the average, studies reveal that it takes about 62 seconds to complete the cycle from finishing a patient task, to washing hands, to returning to patient care activities. 	A Note About Fingernails Thousands of pathogenic organisms can survive under and around fingernails. Clean areas under fingernails if they are visibly dirty, and pay special attention to these areas when you wash OR use	 Remove rings, watches, bracelets before beginning surgical hand scrub. Use a nail cleaner and running water to remove debris from under fingernails. When using antimicrobial soap, scrub for at least 2-6 minutes, or as recommended by the manufacturer.
Removing barriers requires efforts to make hand hygiene easily accessible, time saving, and contribute to improved skin condition. Use of the recommended 1-3 ml alcohol handrub solution takes about 25-30 seconds. You will save time using alcohol handrubs!	alcohol handrubs for cleaning hands. Freshly applied nail pollsh does not increase the numbers of germs present, but chipped nail polish may harbor bacteria. Persons with artificial nails are more likely to harbor higher bacterial counts than those who do not wear them. For this reason, healthcare personnel who work in high risk areas should not wear artificial nails.	 When using an alcohol-based surgical hand scrub product with persistent activity, prewash hands and forearms with a non- antimicrobial soap: 1. Dry hands and forearms completely. 2. Apply alcohol-based product as recommended. 3. Allow hands and forearms to dry completely.
		4. Don sterlle gloves.



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Reviewed by Rosie Fardo, RN, BSN, CIC

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improved hand hygiene practices

recommendations to promote

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JCAHO National Patient Safety

Goals

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www.jcaho.org/

http://

accredited+

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important infection control issues for healthcare To learn more about hand hygiene and other workers, visit www.apic.org or call APIC at 202/789-1890

moisturization products may help the skin...the use of moisturizing

general hand hygiene...skin

"All personnel should practice

Surgical Hand Antisepsis/Hand

Scrubs

Recommended

AORN 2004

Practices for

patient+safety/ organizations/

reduce bacterial shedding from

incorporated...into policies." products should be

#1 Occupational Illness: Skin Disorders Promote and maintain healthy skin. Infection Rates Have low irritancy potential. (HAIs/SSIs) skin wellness programs.

An Ounce of Prevention

other fluids. Improved adherence to patient outcomes and occupational A clinician's intact skin is his or her hand hygiene practices and skin wellness may significantly impact microorganisms, chemicals and first line of defense against nealth.

addressing skin dermatitis is a critical The Centers for Disease Control and has been a great deal of interest in nealthcare issue. As a result, there provides significant evidence that known to moisturize or otherwise Prevention's "Guideline for Hand Hygiene in Healthcare Settings" products that contain additives new glove products and other benefit the skin.

Causes of Irritation/Contact Dermatitis

Frequent occupational exposure to various soaps, detergents, disinfectants and other caustic chemicals

changes in the skin. known to cause

gloves, especially if Frequent donning not properly sized, which can cause and removal of



riction across the dorsum of the hand (knuckles).

- Age. The majority of practicing nurses are over 40 years old and this population is at greater risk for dry skin.
- -ow humidity; seasonal changes.
- Glove powder, especially among exam glove wearers.

dehydration, damage to barrier properties, Moisturizing with effective, clinically appropriate products can help prevent excessive skin cell shedding, and loss of lipids, as well as



clinically effective in helping to

prevent and treat irritant

contact dermatitis.

creams have been proven shown that regular use of

certain hand lotions or

ayer, Controlled studies have

capacity of the skin's keratin

restore the water-holding

that the use of emollients on the skin of health professionals may be protective Additionally, there is evidence against cross-infection.²

Employee Safety

- illness across all occupations, and cost Skin disorders are the #1 occupational \$1 billion annually.³
- that more than 4 out of 5 nurses reported reported symptoms or signs of dermatitis a history of skin problems, and 1 out of 4 One particular research study indicated at the time of the study.⁴

Patient Safety

- that moisturize the skin may help reduce contamination via the hands. Products 30 to 40% of healthcare-associated bacteria shedding from the skin. infections are related to cross-
- Compromised skin may harbor infectious. organisms on the hands of clinicians, compared to healthy skin.
 - increase length of stay by almost 11 days 3% of all surgeries result in site infection, at an extra cost of \$57/27 and increase and infections acquired during surgery the risk of death by 22%.5

The Role of Infection Control Professionals

evidence that addressing skin dermatitis is Prevention Guideline for Hand Hygiene in a critical healthcare issue. In light of this Guideline, infection control professionals Healthcare Settings provide significant The Centers for Disease Control and should insist on products that:

- Reduce transepidermal water loss.
- Increase skin hydration (moisturization).

products addresses only part of the issue. Clinician compliance with recommended key, and is a common weak link in many skin care and hygiene protocols is also Availability of appropriate hand hygiene

caregivers and encourage compliance Products such as gloves with prover emollients provide a convenient and effective way to improve the skin of with handwashing and antisepsis guidelines.

protocols and the impact on clinician and products can be easily justified by the ncreased adherence to handwashing The potential added cost of these oatient health and well-being.





asking those around you to practice

it as well.

restroom. Your healthcare provider especially after touching objects or before eating, and after using the every time they enter your room. You and your loved ones should should practice hand hygiene surfaces in the hospital room, clean your hands very often,

alcohol-based hand rub to kill the It only takes 15 seconds of using either soap and water or an either soap and water or an germs that cause infections.

can use an alcohol-based hand rub. hands look dirty; otherwise, you Use soap and water when your

You, your loved ones, and your healthcare providers should healthcare providers should practice hand hygiene.

www.cdc.gov/handhygiene or call 1-800-CDC-INFO For more information, please visit

CDC acknowledges the following partners in the development of the Hand Hygiene Saves Lives video: the Association for Professionals in Infection Control and Epidemiology and Safe Care Campaign.

This brochure was developed with support from the CDC Foundation and Kimberly-Clark Corporation.

and Hygiene

A Patient's Guide

hand hygiene

- Washing hands with soap and water.
 - Cleansing hands using an alcoholbased hand rub.
- of germs and infections. Preventing the spread



CDC

To prevent hospital

infections.

- In the United States, hospital patients get nearly 2 million infections each year. That's about 1 infection per 20 patients!
 Infections you get in the hospital can be
 - life-threatening and hard to treat.
 All patients are at risk for hospital infections.
- You can take action by asking both your healthcare providers and visitors to wash their hands.

Remember: Hand hygiene saves lives.

To make a difference in your own health.

 Hand hygiene is one of the most important ways to prevent the spread of infections, including the common cold, flu, and even hard-to-treat infections, such as methicillin-resistant Staphylococcus aureus, or MRSA.

When?

You should practice hand hygiene:

- Before preparing or eating food.
 Before touching your eyes, nose,
- or mouth. • Before and after changing wound dressings or bonderes
 - After using the restroom.
- After blowing your nose, coughing,
- or sneezing.
 After touching hospital surfaces such as bed rails, bedside tables, doorknobs, remote controls, or the phone.

Healthcare providers should practice hand hygiene:

- Every time they enter your room.*
 Before putting on gloves. Wearing
- Denote putting on gloves, wearing gloves alone is not enough to prevent the spread of infection.
 After removing gloves.
- Remember: Ask your doctors and nurses to clean their hands before

they examine you.

* If you already have an infection, your healthcare providers may take special measures (isolation precautions) to prevent the spread of your infection to others. They might enter your room wearing protective equipment (e.g., gloves, gown, mask). You do not need to ask them to clean their hands because they should have done so before they put on gloves.

How?

- With soap and water: 1. Wet your hands with warm water. Use liquid soap if possible. Apply a
 - nickel- or quarter-sized amount of soap to your hands. 2. Rub your hands together until soap
- forms a latter and then rub all over the top of your hands, in between your fingers and the area around and under the fingernails.
- 3. Continue rubbing your hands for 15 seconds. Need a timer? Imagine singing
 - the "Happy Birthday" song twice. 4. Rinse your hands well under running water.
- Dry your hands using a paper towel if possible. Then use your paper towel to turn off the faucet and to open the door if needed.

Remember: It only takes 15 seconds to protect yourself and others.

With an alcohol-based hand rub:

- Follow directions on the bottle for how much of the product to use.
- Rub hands together and then rub product all over the top of your hands, in between your fingers and the area
- around and under the fingernails. 3. Continue rubbing until your hands are dry. If enough rub was used to kill germs, it should take at least 15 seconds of rubbing before your hands feel dry. You should not rinse your hands

with water or dry them with a towel.

Which?

Use soap and water:

- When your hands look dirty.
- After you use the bathroom.
- Before you eat or prepare food.

Use an alcohol-based hand rub:

- When your hands do not look dirty.
 - If soap and water are not available.

Products that kill germs on the hands. Products that kill germs on the hands. Should contain 60% to 95% ethanol or isopropanol (types of alcohol). Are fast-acting and convenient.

Who?

You can make a difference in your own health:

- Healthcare providers know they should practice hand hygiene, but they sometimes forget. Most welcome your
- friendly reminder. • Ask healthcare providers to practice hand hygiene in a polite way — tell them that you know how easy it is for people to get infections in the hospital and that you don't want it to happen to you.

Remember: Take control of your health, practice hand hygiene.

<text><text><text><text><list-item><list-item>

- hygiene every time they enter your room.
- You and your visitors should clean your hands before eating, after using the restroom, and after touching surfaces in the hospital room.

For more information, please visit www.cdc.gov/handhygiene or call 1-800-CDC-INFO

CDC acknowledges the following partners in the development of the *Hand Hygiene Saves Lives* video: the Association for Professionals in Infection Control and Epidemiology and Safe Care Campaign.

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Your 5 Moments for Hand Hygiene



1	BEFORE TOUCHING	WHEN?	Clean your hands before touching a patient when approaching him/her.
	A PATIENT	WHY?	To protect the patient against harmful germs carried on your hands.
2	BEFORE CLEAN/	WHEN?	Clean your hands immediately before performing a clean/aseptic procedure.
	ASEPTIC PROCEDURE	WHY?	To protect the patient against harmful germs, including the patient's own, from entering his/her body.
3	AFTER BODY FLUID	WHEN?	Clean your hands immediately after an exposure risk to body fluids (and after glove removal).
	EXPOSURE RISK	WHY?	To protect yourself and the health-care environment from harmful patient germs.
4	AFTER TOUCHING	WHEN?	Clean your hands after touching a patient and her/his immediate surroundings, when leaving the patient's side.
	A PATIENT	WHY?	To protect yourself and the health-care environment from harmful patient germs.
5	AFTER TOUCHING PATIENT SURROUNDINGS	WHEN? WHY?	Clean your hands after touching any object or furniture in the patient's immediate surroundings, when leaving – even if the patient has not been touched. To protect yourself and the health-care environment from harmful patient germs.



Patient Safety

A World Alliance for Safer Health Care

SAVE LIVES Clean Your Hands

HAND HYGIENE (HH) AND CONTACT ISOLATION (CI) OBSERVATION TOOL

Unit (Room)	Position	ition HH "5 Moments" Opportunity (see key below)			HH Compliant?		Soap+Water (H20+) Or Waterless (EtOH)		CI Compliant before entering room?				
		1	2	3	4	5	Y	N	H2O+	ETOH	YES	NO	N/A
		1	2	3	4	5	Y	N	H2O+	ETOH	YES	NO	N/A
		1	2	3	4	5	Y	N	H2O+	ETOH	YES	NO	N/A
		1	2	3	4	5	Y	N	H2O+	ETOH	YES	NO	N/A
		1	2	3	4	5	Y	N	H2O+	ETOH	YES	NO	N/A
_	h	1	2	3	4	5	Y	N	H2O+	ETOH	YES	NO	N/A
		1	2	3	4	5	Y	N	H2O+	ETOH	YES	NO	N/A
	14	1	2	3	4	5	Y	N	H2O+	ETOH	YES	NO	N/A
		1	2	3	4	5	Y	N	H2O+	ETOH	YES	NO	N/A
		1	2	3	4	5	Y	Ν	H2O+	ETOH	YES	NO	N/A
		1	2	3	4	5	Y	N	H2O+	ETOH	YES	NO	N/A
		1	2	3	4	5	Y	N	H2O+	ETOH	YES	NO	N/A
		1	2	3	4	5	Y	N	H2O+	ETOH	YES	NO	N/A
		1	2	3	4	5	Y	Ν	H2O+	ETOH	YES	NO	N/A
		1	2	3	4	5	Y	N	H2O+	ETOH	YES	NO	N/A
		1	2	3	4	5	Y	N	H2O+	ETOH	YES	NO	N/A
		1	2	3	4	5	Y	N	H2O+	ETOH	YES	NO	N/A

5 Moments for Hand Hygiene http://www.who.int/gpsc/5may/background/5moments/en/index.html



FACTS ABOUT HEALTHCARE ASSOCIATED INFECTIONS

- Health-care associated infections result in almost 100,000 deaths in the U.S. annually and cost between \$5-6 billion dollars annually.
- Multi-drug resistant organisms are posing a crisis in public health because antibiotics are
 not being developed fast enough to keep up with the microbes ability to develop
 antibiotic resistance. More people die of MRSA infections in the U.S. than HIV/AIDS
 and tuberculosis combined. Only 2 new antibiotics have been approved in the past 3
 years.
- The most common mode of transmission in the hospital setting is by direct and indirect contact transmission by the hands of healthcare workers if hand hygiene is not performed and by patient care devices if not disinfected properly. Contaminated clothing is also a source for transmission to patients.
- The Centers for Disease Control and Prevention recommend donning gowns and gloves **upon entering the room** of a patient on contact isolation since the nature of the interaction with the patient cannot be predicted with certainty and because contaminated environmental surfaces are important sources for transmission of pathogens.

Given the above information, I understand that I must perform hand hygiene at the following times during patient care:

- Before touching a patient and/or before donning gloves when entering a patient room.
- Before performing a clean or aseptic procedure and when going from a dirty site to a clean site when caring for a patient.
- After touching a patient or after touching a patient's environment and when removing gloves upon exiting the patient room.
- After an exposure risk to body fluids.

I also understand that gowns and gloves are required when entering a contact isolation room when going beyond the wallaroo on the regular floors or beyond the cabinet in ICU.

I have read the above information and understand it. I understand that noncompliance with these expectations may result in dismissal.

Signature

Date

WHO GUIDELINE

The World Health Organization Guidelines on Hand Hygiene in Health Care and Their Consensus Recommendations

Didier Pittet, MD, MS; Benedetta Allegranzi, MD; John Boyce, MD; for the World Health Organization World Alliance for Patient Safety First Global Patient Safety Challenge Core Group of Experts

The World Health Organization's Guidelines on Hand Hygiene in Health Care have been issued by WHO Patient Safety on 5 May 2009 on the occasion of the launch of the Save Lives: Clean Your Hands initiative. The Guidelines represent the contribution of more than 100 international experts and provide a comprehensive overview of essential aspects of hand hygiene in health care, evidence- and consensusbased recommendations, and lessons learned from testing their Advanced Draft and related implementation tools.

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The World Health Organization (WHO) First Global Patient Safety Challenge, launched in October 20051 and aimed at reducing healthcare-associated infection worldwide, identified the promotion of hand hygiene practices in health care as a priority measure and the entry point to improve infection control in Member States.2 In April 2006, the WHO World Alliance for Patient Safety issued the Advanced Draft of the WHO Guidelines on Hand Hygiene in Health Care.' The document was developed with the contribution of more than 100 international experts with the objective of providing a comprehensive overview of essential aspects of hand hygiene in health care and evidence- and consensus-based recommendations for successful practice promotion. To achieve this objective, systematic reviews of the literature using PubMed, Ovid, MEDLINE, Embase, and the Cochrane Library were conducted, as well as referring to national and international guidelines and textbooks; task forces dedicated to specific topics were established; and three consultations of a core group of experts were held at WHO Headquarters.

In parallel to the production of the Advanced Draft, an implementation strategy (WHO Multimodal Hand Hygiene Improvement Strategy [http://www.who.int/gpsc/en/]) was developed, together with a wide range of tools (Pilot Implementation Pack) to help healthcare settings translate the guidelines into practice. A key element of the implementation strategy is a very innovative concept, "My five moments for hand hygiene" (Figure 1).⁴ It integrates the indications for hand hygiene in five essential moments during the sequence of healthcare delivery and facilitates understanding and ap-

propriate practice performance. According to WHO recommendations for guideline preparation, a test phase of the Advanced Draft guidelines was undertaken by using the implementation strategy and tools in eight pilot healthcare settings in seven countries representing all WHO regions worldwide. The objectives of this testing were: to provide local data on the resources required to carry out the recommendations; to generate information on feasibility, validity, reliability, and cost effectiveness of the interventions; and to adapt and refine proposed implementation strategies. Other healthcare settings around the world volunteered to participate autonomously in the test phase and provided WHO with feedback on implementation.

Starting in 2007, an update of the evidence through a review of the literature was performed up to June 2008. In 2008, an analysis of data and an evaluation of lessons learned from testing sites were conducted. The WHO Guidelines on Hand Hygiene in Health Care have now been finalized and include lessons learned from testing, updated evidence, and expert consensus through two further consultations. External and internal reviewers provided contributions and comments on both the Advanced Draft and the final Guidelines.

The WHO Guidelines on Hand Hygiene in Health Care provide healthcare workers (HCWs), hospital administrators, and health authorities with a thorough review of evidence on hand hygiene in health care and specific recommendations to improve practices and reduce the transmission of pathogenic microorganisms to patients and HCWs. They are intended to be implemented in any situation in which health

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FIGURE 1. The "My 5 moments for hand hygiene" concept (adapted from Sax et al.⁴).

care is delivered either to a patient or to a specific group in a population and in all settings where health care is permanently or occasionally performed, including home care by birth attendants.

In comparison with other international or national guidelines, the added values of the WHO guidelines are many: they bring a global perspective; they represent the challenge to bridge the gap between developing and developed countries, irrespective of resources available; and their feasibility has been tested in settings with different cultural backgrounds⁵ and development levels.⁶ Indeed, the WHO Guidelines explore many innovative aspects, such as religious and cultural aspects, promotion on a national scale, and social marketing. Attention has been paid to some critical topics, particularly safety issues, infrastructures required for hand hygiene, and strategies for improvement.

These Guidelines and the associated WHO Multimodal Hand Hygiene Improvement Strategy and Implementation Toolkit, updated and revised on the basis of data and lessons learned from testing, are designed to offer healthcare facilities in Member States a conceptual framework and practical tools for the application of recommendations in practice at the bedside.

Recommendations were formulated on the basis of the evidence described in the various sections and discussed in depth during the expert core group consultations. In addition to expert consensus, the criteria developed by the Healthcare Infection Control Practices Advisory Committee (HICPAC) of the United States Centers for Disease Control and Prevention (CDC) were used to categorize the consensus recommendations. It is anticipated that the recommendations in these Guidelines will remain valid until 2011, and the Patient Safety Department at WHO headquarters is committed to ensuring that the Guidelines are updated every two to three years.

The WHO Guidelines on Hand Hygiene in Health Care⁷ together with the Implementation Toolkit have been available since 5 May 2009 on the occasion of the launch of the "Save Lives: Clean Your Hands" initiative (http://www.who.int/gpsc/en/). Based on the promising success observed with the Advanced Draft, these Guidelines are expected to be adopted as the gold standard for hand hygiene in many countries and healthcare settings worldwide. While ensuring consistency with the Guidelines' recommendations, individual adaptation according to local regulations, settings, needs, and resources is desirable.

The Guidelines Consensus Recommendations and their ranking system for evidence are detailed below.

RANKING SYSTEM FOR EVIDENCE

The consensus recommendations listed below (Sections 1–9) are categorized according to the CDC/HICPAC system, adapted as follows:

- Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiological studies.
- Category IB. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiological studies and a strong theoretical rationale.
- Category IC. Required for implementation, as mandated by federal and/or state regulation or standard.
- Category II. Suggested for implementation and supported by suggestive clinical or epidemiological studies or a theoretical rationale or a consensus by a panel of experts.

RECOMMENDATIONS

- 1. Indications for hand hygiene
 - A. Wash hands with soap and water when visibly dirty or visibly soiled with blood or other body fluids (IB) or after using the toilet (II).^{8 18}
 - B. If exposure to potential spore-forming pathogens is strongly suspected or proven, including outbreaks of *Clostridium difficile*, handwashing with soap and water is the preferred means (IB).¹⁹⁻³²
 - C. Use an alcohol-based handrub as the preferred means for routine hand antisepsis in all other clinical situations described in items D(a) to D(f) listed below, if hands are not visibly soiled (IA).²³⁻³⁴ If alcohol-based handrub is not obtainable, wash hands with soap and water (IB).^{25,32,33}

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- D. Perform hand hygiene:
 - a) before and after touching the patient (IB);51-43
 - b) before handling an invasive device for patient care, regardless of whether or not gloves are used (IB); ⁴⁴
 - c) after contact with body fluids or excretions, mucous membranes, non-intact skin, or wound dressings (IA);^{8,40,42,45}
 - d) if moving from a contaminated body site to another body site during care of the same patient (IB);^{35,36,39,42,45}
 - e) after contact with inanimate surfaces and objects (including medical equipment) in the immediate vicinity of the patient (IB);^{45,39,41,42,45-49}
 - f) after removing sterile (II) or non-sterile (IB) gloves.^{35,50,53}

Indications for hand hygiene at the point of care are integrated in Figure 1 that illustrates the concept of "My five moments for hand hygiene".⁴

- E. Before handling medication or preparing food perform hand hygiene using an alcohol-based handrub or wash hands with either plain or antimicrobial soap and water (IB).¹¹⁻¹⁴
- F. Soap and alcohol-based handrub should not be used concomitantly (II).^{54,55}
- 2. Hand hygiene technique
 - A. Apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry (IB) (Figure 2A).^{36,57}
 - B. When washing hands with soap and water, wet hands with water and apply the amount of product necessary to cover all surfaces (Figure 2B). Rinse hands with water and dry thoroughly with a singleuse towel. Use clean, running water whenever possible. Avoid using hot water, as repeated exposure to hot water may increase the risk of dermatitis (IB).⁵⁸⁻⁶⁰ Use towel to turn off tap/faucet (IB).⁶¹⁻⁶⁵ Dry hands thoroughly using a method that does not recontaminate hands. Make sure towels are not used multiple times or by multiple people (IB).⁶⁶⁻⁶⁹
 - C. Liquid, bar, leaf or powdered forms of soap are acceptable. When bar soap is used, small bars of soap in racks that facilitate drainage should be used to allow the bars to dry (II).⁷⁰⁻⁷⁶
- 3. Recommendations for surgical hand preparation
 - A. Remove rings, wrist-watch, and bracelets before beginning surgical hand preparation (II).⁷⁷⁻⁰¹ Artificial nails are prohibited (IB).⁸²⁻⁸⁶

- B. Sinks should be designed to reduce the risk of splashes (II).^{87,88}
- C. If hands are visibly soiled, wash hands with plain soap before surgical hand preparation (II). Remove debris from underneath fingernails using a nail cleaner, preferably under running water (II).⁸⁹
- D. Brushes are not recommended for surgical hand preparation (1B).⁹⁰⁻⁹⁶
- E. Surgical hand antisepsis should be performed using either a suitable antimicrobial soap or suitable alcohol-based handrub, preferably with a product ensuring sustained activity, before donning sterile gloves (IB).^{45,97,103}
- F. If quality of water is not assured in the operating theatre, surgical hand antisepsis using an alcoholbased handrub is recommended before donning sterile gloves when performing surgical procedures (11).^{95,98,100,104}
- G. When performing surgical hand antisepsis using an antimicrobial soap, scrub hands and forearms for the length of time recommended by the manufacturer, typically 2–5 minutes. Long scrub times (e.g. 10 minutes) are not necessary (IB).^{97,105,105-111}
- H. When using an alcohol-based surgical handrub product with sustained activity, follow the manufacturer's instructions for application times. Apply the product to dry hands only (IB).^{112,113} Do not combine surgical hand scrub and surgical handrub with alcohol-based products sequentially (II).²⁴
- When using an alcohol-based handrub, use sufficient product to keep hands and forearms wet with the handrub throughout the surgical hand preparation procedure (IB).¹¹⁴⁻¹¹⁶
- J. After application of the alcohol-based handrub as recommended, allow hands and forearms to dry thoroughly before donning sterile gloves (IB).^{95,100}
- Selection and handling of hand hygiene agents
 - A. Provide HCWs with efficacious hand hygiene products that have low irritancy potential (IB).^{24,} 62,117-123
 - B. To maximize acceptance of hand hygiene products by HCWs, solicit their input regarding the skin tolerance, feel, and fragrance of any products under consideration (IB).^{23,24,120,124-129} Comparative evaluations may greatly help in this process.^{119,124, 129,130}
 - C. When selecting hand hygiene products
 - a) determine any known interaction between products used to clean hands, skin care products, and the types of glove used in the institution (II);^{131,132}



Hand Hygiene Technique with Alcohol-Based Formulation

Apply a palmfull of the product in a cupped hand and cover all surfaces.



Rub hands palm to palm



right palm over left dorsum with interlaced fingers and vice versa



palm to palm with fingers interlaced



backs of fingers to opposing palms with fingers interlocked











...once dry, your hands are safe.

FIGURE 2A. Hand hygiene technique with an alcohol-based formulation.3

- b) solicit information from manufacturers about the risk of product contamination (IB);¹³⁴⁻¹³⁵
- c) ensure that dispensers are accessible at the point of care (IB);^{28,136}
- d) ensure that dispensers function adequately and reliably and deliver an appropriate volume of the product (11);^{25,137}
- e) ensure that the dispenser system for alcoholbased handrubs is approved for flammable materials (IC);
- f) solicit and evaluate information from manufacturers regarding any effect that hand lo-

tions, creams, or alcohol-based handrubs may have on the effects of antimicrobial soaps being used in the institution (IB);^{131,138,139}

- g) cost comparisons should only be made for products that meet requirements for efficacy, skin tolerance, and acceptability (II).^{129,140}
- D. Do not add soap (IA) or alcohol-based formulations (II) to a partially empty soap dispenser. If soap dispensers are reused, follow recommended procedures for cleansing.^{141,142}

Handwashing Technique with Soap and Water



Wet hands with water



apply enough soap to cover all surfaces



rub hands palm to palm



right palm over left dorsum with interlaced fingers and vice versa



palm to palm with fingers interlaced



backs of fingers to opposing palms with fingers interlocked



rotational rubbing of left thumb clasped in right palm and vice versa



dry thoroughly with a single use towel



rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa



use towel to turn off faucet/tap



rinse hands with water



...and your hands are safe.

FIGURE 2B. Handwashing technique with soap and water."

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5. Skin care

- A. Include information regarding hand-care practices designed to reduce the risk of irritant contact dermatitis and other skin damage in education programmes for HCWs (IB).^{143,144}
- B. Provide alternative hand hygiene products for HCWs with confirmed allergies or adverse reactions to standard products used in the healthcare setting (II).
- C. Provide HCWs with hand lotions or creams to minimize the occurrence of irritant contact dermatitis associated with hand antisepsis or handwashing (IA).^{120,121,144-147}
- D. When alcohol-based handrub is available in the healthcare facility for hygienic hand antisepsis, the use of antimicrobial soap is not recommended (II).
- E. Soap and alcohol-based handrub should not be used concomitantly (II).⁵⁴
- 6. Use of gloves
 - A. The use of gloves does not replace the need for hand hygiene by either handrubbing or handwashing (IB).^{35,30-52,148-150}
 - B. Wear gloves when it can be reasonably anticipated that contact with blood or other potentially infectious materials, mucous membranes, or non-intact skin will occur (IC).¹³¹⁻¹⁵³
 - C. Remove gloves after caring for a patient. Do not wear the same pair of gloves for the care of more than one patient (1B).^{35,41,50-52,154,155}
 - D. When wearing gloves, change or remove gloves during patient care if moving from a contaminated body site to either another body site (including non-intact skin, mucous membrane or medical device) within the same patient or the environment (II).^{50,51,156}
 - E. The reuse of gloves is not recommended (IB).¹⁵⁷ In the case of glove reuse, implement the safest reprocessing method (II).¹⁵⁸
- 7. Other aspects of hand hygiene
 - A. Do not wear artificial fingernails or extenders when having direct contact with patients (ΙΛ).^{82, 86,159-162}
 - B. Keep natural nails short (tips less than 0.5 cm long or approximately 1/4 inch) (II).¹⁶⁰
- 8. Educational and motivational programmes for healthcare workers
 - A. In hand hygiene promotion programmes for

HCWs, focus specifically on factors currently found to have a significant influence on behaviour, and not solely on the type of hand hygiene products. The strategy should be multifaceted and multimodal and include education and senior executive support for implementation (IA).^{25,87,183–179}

- B. Educate HCWs about the type of patient-care activities that can result in hand contamination and about the advantages and disadvantages of various methods used to clean their hands (II).^{25,57,168,178-185}
- C. Monitor HCWs' adherence to recommended hand hygiene practices and provide them with performance feedback (IA).^{25,128,165,166,168,178,180-182,184,186,187}
- D. Encourage partnerships between patients, their families, and HCWs to promote hand hygiene in healthcare settings (II).^{188,190}
- 9. Governmental and institutional responsibilities
 - 9.1 For healthcare administrators
 - A. It is essential that administrators ensure conditions are conducive to the promotion of a multifaceted, multimodal hand hygiene strategy and an approach that promotes a patient safety culture by implementation of points B– 1 below.
 - B. Provide HCWs with access to a safe, continuous water supply at all outlets and access to the necessary facilities to perform handwashing (IB).^{178,191,192}
 - C. Provide HCWs with a readily accessible alcohol-based handrub at the point of patient care (IA).^{25,27,28,30,193–197}
 - D. Make improved hand hygiene adherence (compliance) an institutional priority and provide appropriate leadership, administrative support, financial resources, and support for hand hygiene and other infection prevention and control activities (IB).^{25,103,108,170, 198}
 - E. Ensure HCWs have dedicated time for infection control training, including sessions on hand hygiene (II).^{172,199}
 - F. Implement a multidisciplinary, multifaceted and multimodal programme designed to improve adherence of HCWs to recommended hand hygiene practices (IB).^{25,163,200}
 - G. With regard to hand hygiene, ensure that the water supply is physically separated from drainage and sewerage within the healthcare setting, and provide routine system monitoring and management (1B).²⁰¹
 - H. Provide strong leadership and support for

hand hygiene and other infection prevention and control activities (II).¹⁶³

- Alcohol-based handrub production and storage must adhere to the national safety guidelines and local legal requirements (II).
- 9.2 For national governments
 - A. Make improved hand hygiene adherence a national priority and consider provision of a funded, coordinated implementation programme, while ensuring monitoring and long-term sustainability (II).²⁰²⁻²⁰⁵
 - B. Support strengthening of infection control capacities within healthcare settings (II).^{199,206,207}
 - C. Promote hand hygiene at the community level to strengthen both self-protection and the protection of others (II).^{16-18,208-211}
 - D. Encourage healthcare settings to use hand hygiene as a quality indicator (Australia, Belgium, France, Scotland, USA) (II).^{185,212}

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Special Issue

Improving Adherence to Hand Hygiene Practice: A Multidisciplinary Approach

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Hand hygiene prevents cross-infection in hospitals, but health-care workers' adherence to guidelines is poor. Easy, timely access to both hand hygiene and skin protection is necessary for satisfactory hand hygiene behavior. Alcohol-based hand rubs may be better than traditional handwashing as they require less time, act faster, are less irritating, and contribute to sustained improvement in compliance associated with decreased infection rates. This article reviews barriers to appropriate hand hygiene and risk factors for noncompliance and proposes strategies for promoting hand hygiene.

Hand hygiene is the simplest, most effective measure for preventing nosocomial infections (1,2). Despite advances in infection control and hospital epidemiology, Semmelweis' message is not consistently translated into clinical practice (3,4), and health-care workers' adherence to recommended hand hygiene practices is unacceptably low (3,5-10). Average compliance with hand hygiene recommendations varies between hospital wards, among professional categories of health-care workers, and according to working conditions, as well as according to the definitions used in different studies. Compliance is usually estimated as <50% (Table 1).

Promotion of hand hygiene is a major challenge for infection control experts (3,19-21). In-service education, distribution of information leaflets, workshops and lectures, and performance feedback on compliance rates have been associated with transient improvement (3,6,13,22,23). No single intervention has consistently improved compliance with hand hygiene practices (24). This review summarizes factors influencing lack of adherence by health-care personnel to hand hygiene procedures and suggests strategies for improvement.

Definitions

Two major groups of microorganisms are found on the skin: organisms that normally reside on it (resident flora) and contaminants (transient flora) (25). Unless introduced into body tissues by trauma or medical devices such as intravenous catheters, the pathogenic potential of the resident flora is low (26). Transient flora, which are easily removed by handwashing, cause most hospital infections resulting from cross-transmission (27-29).

The term hand hygiene includes several actions intended to decrease colonization with transient flora. This objective can be achieved through handwashing or hand disinfection. Handwashing refers to washing hands with an unmedicated detergent and water or water alone. Its objective is to prevent cross-transmission by removing dirt and loose transient flora (10,30). Hygienic handwash refers to the same procedure

Table 1. Compliance with hand hygiene in differ	rent hospital settings
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Year	Setting	Average compliance	Author	Ref.
1981	Open ward	16%	Preston	11
	ICU	30%		
1981	ICUs	41%	Albert	5
	ICUs	28%		
1983	All wards	45%	Larson	12
1987	PICU	30%	Donowitz	13
1990	ICU	32%	Graham	6
1990	ICU	81%	Dubbert	14
1991	SICU	51%	Pettinger	15
1992	NICU/others	29%	Larson	16
1992	ICUs	40%	Doebbeling	7
1992	ICUs	40%	Zimakoff	17
1994	Emergency room	32%	Meengs	18
1999	All wards	48%	Pittet	9
	ICUs	36%		

ICUs = intensive care units; PICU = pediatric ICU; NICU = neonatal ICU.

when an antiseptic agent is added to the detergent. Hand disinfection refers to use of an antiseptic solution to clean hands, either medicated soap or alcohol. Some experts refer to the action of "degerming" as the use of detergent-based antiseptics or alcohol (21). Hygienic hand rub is rubbing hands with a small quantity (2 mL to 3 mL) of a highly effective, fast-acting antiseptic agent.

Hand Hygiene Agents

If hands are known to be or suspected of being contaminated, transient flora must be eliminated by washing or disinfecting the hands to render them safe for the next patient contact. Plain soap with water can physically remove a certain level of microbes, but antiseptic agents are necessary to kill microorganisms (10,31-33). Hand antiseptic agents are designed to rapidly eliminate most transient flora by their mechanical detergent effect and to exert an additional sustained antimicrobial activity on remaining flora. The multiplication of resident flora may be retarded as well, so that hand disinfection may be useful in situations in which microbiologically clean hands are required for extended periods.

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Rotter showed that hand hygiene with unmedicated soap and water removed some transient flora mechanically; preparations containing antiseptic or antimicrobial agents not only removed flora mechanically but also chemically killed contaminating and colonizing flora, with long-term residual activity (30,34). Alcohol-based preparations have more rapid action than products containing other antiseptics (e.g., chlorhexidine gluconate or povidone iodine) (30,31,35).

Semmelweis observed that normal handwashing did not always prevent the spread of fatal infection (1) and recommended hand disinfection in a solution of chlorinated water before each vaginal examination. Hand disinfection is substantially more efficient than standard handwashing with soap and water or water alone (2,30), particularly when contamination is heavy (14,36-40). Frequent handwashing may result in minimal reduction or even an increase in bacterial yield over baseline counts of clean hands (21,41).

Because alcohols have excellent activity and the most rapid bactericidal action of all antiseptics, they are the preferred agents for hygienic hand rubs, so-called "waterless hand disinfection." In addition, alcohols are more convenient than aqueous solutions for hygienic hand rubs because of their excellent spreading quality and rapid evaporation. At equal concentrations, n-propanol is the most effective alcohol and ethanol the least (30). Alcohol-based hand rubs are well suited for hygienic hand disinfection for the following reasons: optimal antimicrobial spectrum (active against all bacteria and most clinically important viruses, yeasts, and fungi); no wash basin necessary for use and easy availability at bedside; no microbial contamination of health-care workers' clothing; and rapidity of action. After extensive reduction following hand disinfection with an alcohol preparation, it takes the resident skin flora several hours to become completely restored (30). Since alcohol alone has no lasting effect, another compound with antiseptic activity may be added to the disinfection solution to prolong the effect. These antiseptics have recently been extensively reviewed by Rotter (30).

Prevention of bacterial contamination and subsequent infection requires timely hand cleansing. Guidelines have delineated indications for hand cleansing (10,32,42) but without reliance on evidence-based studies of microbiologic contamination acquired during routine patient care. To provide such evidence, we studied the dynamics of bacterial contamination of health-care workers' hands in daily hospital practice (43). Our findings should help identify patient-care situations associated with high contamination levels and improve hand cleansing practices.

Structured observations of patient care were conducted by trained external observers, who took an imprint of the fingertips of the health-care worker's dominant hand to quantify bacterial colony counts at the end of a defined period of patient care (43). Bacterial contamination on ungloved hands increased linearly during patient care (mean 16 CFU per minute, 95% confidence interval [CI] 11-21). Activities independently associated with higher contamination levels were direct patient contact, respiratory care, handling body fluids, and disruption in the sequence of patient care (all p<0.05). Contamination levels varied according to hospital location, with the medical rehabilitation ward having the highest levels (>49 CFU, p = 0.03). Both the duration and type of patient care influenced hand contamination. Furthermore, simple handwashing before patient care, without hand disinfection, was also associated with higher colony counts (>52 CFU, p = 0.03), which suggests that hand antisepsis is better than standard handwashing. These findings suggested that intervention trials should explore the role of systematic hand disinfection as a cornerstone of infection control to reduce cross-transmission in hospitals.

Factors Influencing Noncompliance with Hand Hygiene

Risk factors for noncompliance with hand hygiene have been determined objectively in several observational studies or interventions to improve compliance (3,14,20,24,44-47). Factors influencing reduced compliance, identified in observational studies of hand hygiene behavior, included being a physician or a nursing assistant rather than a nurse; being a nursing assistant rather than a nurse; being male; working in an intensive care unit (ICU); working during weekdays rather than the weekend; wearing gown and gloves; using an automated sink; performing activities with high risk for cross-transmission; and having many opportunities for hand hygiene per hour of patient care.

In the largest hospital-wide survey ever conducted (9), we also identified predictors of noncompliance with hand hygiene during routine patient care. Variables included professional category, hospital ward, time of day or week, and type and intensity of patient care, defined as the number of opportunities for hand hygiene per hour of patient care. In 2,834 observed opportunities for hand hygiene, average compliance was 48%. In multivariate analysis, compliance was highest during weekends and among nurses (odds ratio [OR] 0.6, 95% CI 0.4-0.8). Noncompliance was higher in ICUs than in internal medicine (OR 2.0, CI 1.3-3.1), during procedures with a high risk for bacterial contamination (OR 1.8, CI 1.4-2.4), and when intensity of patient care was high (21 to 40 opportunities [OR 1.3, CI 1.0-1.7], 41 to 60 opportunities [OR 2.1, CI 1.5-2.9], >60 opportunities [OR 2.1, CI9 1.3-3.5]) compared with a reference level of 0 to 20 opportunities. In other words, compliance with handwashing worsened when the demand for hand cleansing was high; on average, compliance decreased by 5% (±2%) per increment of 10 opportunities per hour when the intensity of patient care exceeded 10 opportunities per hour. Similarly, the lowest compliance rate (36%) was found in ICUs, where indications for handwashing were typically more frequent (on average, 20 opportunities per patient per hour). The highest compliance rate (59%) was observed in pediatrics, where the average activity index was low (on average, eight opportunities per patient per hour). This study confirmed modest levels of compliance with hand hygiene in a teaching institution and showed that compliance varied by hospital ward and type of health-care worker, thus suggesting that targeted educational programs may be useful. These results also suggested that full compliance with current guidelines may be unrealistic (9,20,48) and that facilitated access to hand hygiene could help improve compliance.

Perceived Barriers to Hand Hygiene

Several barriers to appropriate hand hygiene have been reported (9,14,24,44-47). Reasons reported by health-care workers for the lack of adherence with recommendations include skin irritation, inaccessible supplies, interference with worker-patient relation, patient needs perceived as priority, wearing gloves, forgetfulness, ignorance of guidelines, insufficient time, high workload and understaffing, and lack of scientific information demonstrating impact of improved hand hygiene on hospital infection rates.

Risk Factors for Noncompliance

Some of the perceived barriers for the lack of adherence with hand hygiene guidelines have been assessed or even quantified in observational studies (3,14,20,24,44-47). The most frequently reported reasons associated with poor compliance, in addition to those mentioned above, are inconveniently located or insufficient numbers of sinks; low risk for acquiring infection from patients; belief that glove use obviates need for hand hygiene; and ignorance of or disagreement with guidelines and protocols.

Skin irritation by hand hygiene agents is an important barrier to appropriate compliance (49). The superficial skin layers contain water to keep the skin soft and pliable and lipids to prevent dehydration of the corneocytes. Hand cleansing can increase skin pH, reduce lipid content, increase transepidermal water loss, and even increase microbial shedding. Soaps and detergents are damaging when applied to skin on a regular basis, and health-care workers need to be better informed about their effects. Lack of knowledge and education on this topic is a key barrier to motivation. Alcoholbased formulations for hand disinfection (whether isopropyl, ethyl, or n-propanol, in 60% to 90% vol/vol) are less irritating than antiseptic or nonantiseptic detergents. Alcohols with added emollients are at least as well tolerated and efficacious as detergents. Emollients are recommended and may protect against cross-infection by keeping the resident skin flora intact, and hand lotions help protect skin and may reduce microbial shedding (21).

The value of easy access to hand hygiene supplies, whether sink, soap, medicated detergent, or waterless alcohol-based hand rub solution, is self explanatory. Asking busy health-care workers to walk away from the patient bed to reach a wash basin or a hand antisepsis solution invites noncompliance with hand hygiene recommendations (9,48). Engineering controls could facilitate compliance, but hand hygiene behavior should be carefully monitored to identify negative effects of newly introduced devices (50).

Wearing gloves might represent a barrier for compliance with hand hygiene (8,51,52). Failure to remove gloves after patient contact or between dirty and clean body site care for the same patient constitutes noncompliance with hand hygiene recommendations (9). Washing and reusing gloves between patient contact is ineffective, and handwashing or disinfection should be strongly encouraged after glove removal. In a study involving artificial contamination, organisms were cultured from 4% to 100% of the gloves and observed counts were up to 4.7 log on hands after glove removal (53).

Additional barriers to hand hygiene compliance include lack of active participation in promotion at the individual or institutional level, of a role model for hand hygiene, of institutional priority assigned to hand hygiene, of administrative sanctions for noncompliance; and of an institutional climate encouraging safety (14,22,41,54,55). A system change may be necessary for improvement in hand hygiene practices by health-care workers.

Impact of Improved Hand Hygiene

Lack of scientific information on the definitive impact of improved hand hygiene on hospital infection rates has been reported as a possible barrier to adherence with recommendations. Hospital infections have been recognized for more than a century as a critical problem affecting the quality of patient care provided in hospitals. Studies have shown that at least one third of all hospital infections are preventable (56). A substantial proportion of infections results from crosscontamination, and transmission of microorganisms by the hands of health-care workers is recognized as the main route of spread (57). Seven quasi-experimental hospital-based studies of the impact of hand hygiene on the risk of hospital infections were published from 1977 to 1995 (Table 2) (7,22,58,60-63). Despite limitations, most reports showed a temporal relation between improved hand hygiene practices and reduced infection rates.

We recently reported the results of a successful hospitalwide hand hygiene promotion campaign, with emphasis on hand disinfection, which resulted in sustained improvement in compliance associated with a significant reduction in hospital infections and methicilllin-resistant *Staphylococcus aureus* cross-transmission rates over a 4-year period (63). The beneficial effects of hand hygiene promotion on the risk of cross-transmission have also been reported in surveys conducted in schools, day-care centers (64-68), and a community (69-71). Although additional scientific and causal evidence is needed for the impact of improved hand hygiene on infection rates, these results indicate that improvement in behavior reduces the risk of transmission of infectious pathogens.

Improving Adherence with Practices

In 1998, Kretzer and Larson (46) revisited hand hygiene behavioral theories in an attempt to better understand how to target more successful interventions. These researchers

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Year	Authors	Hospital setting	Results	Ref.
1977	Casewell and Philips	Adult ICU	Reduction in HI ^a due to endemic Klebsiella spp	58
1982	Maki and Hecht	Adult ICU	Reduction in HI rates	59
1984	Massanari and Heirholzer	Adult ICU	Reduction in NI rates	60
1990	Simmons et al.	Adult ICU	No effect	22
1992	Doebbeling et al.	Adult ICU	Significant difference in rates of HI between two different hand hygiene agents	7
1994	Webster et al.	NICU	Elimination of MRSA	61
1995	Zafar et al.	Newborn nursery	Elimination of MRSA	62
1999	Pittet et al.	Hospital-wide	Significant reduction in HI and MRSA cross-transmission rates	63

^aHI = hospital infection; ICU = intensive care unit; NICU = neonatal ICU; MRSA = methicillin-resistant Staphylococcus aureus.

proposed a hypothetical framework to enhance hand hygiene practices and stressed the importance of considering the complexity of individual and institutional factors in designing behavioral interventions. Behavioral theories and secondary interventions have primarily focused on the individual, which is insufficient to effect sustained change (46,72,73). Interventions aimed at improving compliance with hand hygiene must be based on the various levels of behavior interaction (20,46,74). Thus, the interdependence of individual factors, environmental constraints, and institutional climate should be considered in strategic planning and development of hand hygiene promotion campaigns. Factors associated with noncompliance with recommendations are related not only to the individual worker but also to the group to which he or she belongs and, by extension, to the parent institution. Factors influencing compliance at the group level include lack of education and performance feedback; working in critical care (high workload); downsizing and understaffing; and lack of encouragement or role models from key staff. Factors operating at the institutional level include lack of written guidelines; lack of appropriate hand hygiene agents; lack of skin care promotion and agents; lack of hand hygiene facilities; lack of atmosphere of compliance; and lack of administrative leadership, sanctions, rewards, and support. Interventions to promote hand hygiene in hospitals should take into account variables at all these levels.

The complex dynamic of behavioral change involves a combination of education, motivation, and system change. Various psychosocial parameters influencing hand hygiene behavior include intention, attitude toward the behavior, perceived social norms, perceived behavioral control, perceived risk of infection, habits of hand hygiene practices, perceived model roles, perceived knowledge, and motivation (46). Factors necessary for change include dissatisfaction with the current situation, perception of alternatives, and recognition, both at the individual and institutional level, of the ability and potential to change. While the last factor implies education and motivation, the former two necessitate primarily a system change.

Among reasons reported for poor adherence with hand hygiene recommendations, some that are clearly related to the institution (i.e., the system) include lack of institutional priority for hand hygiene, need for administrative sanctions for noncompliance or rewards for compliance, and lack of an institutional climate that encourages safety. Whereas all three reasons would require a system change in most institutions, the last would also involve management commitment, visible safety programs, an acceptable level of work stress, a tolerant and supportive attitude toward reported problems, and belief in the efficacy of preventive strategies (20,46,73,75).

Strategies for Improvement

Improvement in infection control practices requires questioning basic beliefs, continuous assessment of the stage of behavioral change, interventions with an appropriate process of change, and supporting individual and group creativity (46). Because of the complexity of the process of change, single interventions often fail, and a multimodal, multidisciplinary strategy is necessary.

A framework for change should include parameters to be considered for hand hygiene promotion, together with the level at which each change must be applied: education, motivation, or system (Table 3). Some parameters are based on epidemiologic evidence and others on the authors' and other investigators' experience and review of current knowledge. Some parameters may be unnecessary in certain circumstances and helpful in others. In particular, changing the hand hygiene agent could be beneficial in institutions or hospital wards with a high workload and a high demand for hand hygiene when waterless hand rub is not available (9,61,62,76). However, a change in the recommended hand hygiene agent could be deleterious if introduced during winter, when skin is more easily irritated.

Several parameters that could potentially be associated with successful promotion of hand hygiene would require a system change (Table 3). Enhancing individual and institutional self-efficacy (the judgment of one's capacity to organize and execute actions to reach the objective), obtaining active participation at both levels, and promoting an institutional safety climate represent major challenges that exceed the current perception of the infection control practitioner's role.

More research is needed to determine whether education, individual reinforcement technique, appropriate rewarding, administrative sanction, enhanced self-participation, active involvement of a larger number of organizational leaders,

Table 3. Strategies for successful promotion of hand hygiene in hospitals

Parameter	Tool for change	Selected ref. ^a
Education	E ^a (M, S)	14,23,63,74,76
Routine observation and feedback	S (E, M)	6,14,23,63,74,76
Engineering controls	S	63
Make hand hygiene easy, convenient	S	63,74,77,78
Make available alcohol- based hand rub	S	63
Alcohol-based hand rub available in high- demand situations	S	63,78
Patient education	S(M)	79
Reminders in the workplace	S	52,63
Administrative sanctions, rewards	S	3,20
Change in hand hygiene agent	S (E)	21,80
Promote, facilitate skin care for HCW hands	S (E)	17,21,47,63
Obtain active participation at individual and institutional levels	E, M, S	46,63
Ensure institutional safety climate	S (M)	46,63
Enhance individual and institutional self-efficacy	S (E, M)	46,63
Avoid overcrowding, understaffing, excessive workload	s	9,15,63,81,82
Combination of above strategies	E, M, S	14,23,46,63,74

 $^{\circ}E$ = education; M = motivation; S = system; HCW = health-care worker

^bOnly selected references are listed; refer to more extensive reviews (10,30,46) for exhaustive reference lists.

enhanced perception of health threat, self-efficacy, and perceived social pressure (20,46,83,84), or combinations of these factors would improve health-care workers' adherence to recommendations. Ultimately, compliance with hand hygiene could become part of a culture of patient safety in which a set of interdependent elements interact to achieve a shared objective (85).

More readily achievable than major system change, easy and timely access to hand hygiene in a timely fashion and the availability, free of charge, of skin care lotion both appear to be necessary prerequisites for appropriate hand hygiene behavior. In particular, in high-demand situations, such as in critical care units, in high-stress working conditions, and at times of overcrowding or understaffing, having health-care workers use a hand rub with an alcohol-based solution appears as the best method for achieving and maintaining a higher level of compliance with hand hygiene. Alcohol-based hand rub, compared with traditional handwashing with unmedicated soap and water or medicated hand antiseptic agents, may be better because it requires less time (48), acts faster (30), and irritates hands less often (21,30). This method was used in the only program that reported a sustained improvement in hand hygiene compliance associated with decreased infection rates (63).

Finally, strategies to improve compliance with hand hygiene practices should be multimodal and multidisciplinary (Table 3). It is important to note, however, that the proposed framework for such strategies needs further research before implementation.

Future Research

Among key questions regarding the practices of hand hygiene in the health-care setting today, the following need to be addressed in controlled studies: What are the key determinants of hand hygiene behavior and promotion? Should hand disinfection replace conventional handwashing? What are the best hand hygiene agents? Should hand hygiene solution include a long-lasting compound? What are the most suitable skin emollients to include in hand hygiene solution? How can skin irritation and dryness from hand hygiene agents be reduced? How does skin care protection with hand cream affect the microbiologic efficacy of hand hygiene agents? and What are the key components of hand hygiene agent acceptability by health-care workers? Additional research questions include- How can researchers generate more definitive scientific evidence for the impact of improved compliance with hand hygiene on infection rates? What is the acceptable level of compliance with hand hygiene (i.e., What percentage increase in hand hygiene results in a predictable risk reduction in infection rates?) and To what extent should the use of gloves be encouraged or discouraged? Finally, recognizing that individual and institutional factors are interdependent in terms of behavioral changes in health-care settings, what is the best way to obtain top management support for hand hygiene promotion? These questions are addressed to infection control practitioners, laboratory research scientists, and behavioral epidemiologists.

The challenge of hand hygiene promotion could be summarized in one question: How can health-care workers' behavior be changed? Tools for change are known; some have been tested, and others need to be tested. Some may prove irrelevant in the future; others have worked in some institutions and need to be tested in others. Infection control professionals should promote and conduct outstanding research and provide solutions to improve health-care worker adherence with hand hygiene and enhance patient safety.

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Main Causes of Failure to Clean Hands (across all participating hospitals)



- Fineffective placement of dispensers or sinks
- Hand hygiene compliance data are not collected or reported accurately or frequently
- Lack of accountability and just-in-time coaching
- Safety culture does not stress hand hygiene at all levels
- Ineffective or insufficient education
- Hands full
- Wearing gloves interferes with process
- Perception that hand hygiene is not needed if wearing gloves
- F Health care workers forget
- Distractions

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(across all participating hospitals)	A	в	C	Ð	E	F	G	н
Ineffective placement of dispensers or sinks		×		×	×		×	,
Hand hygiene compliance data are not collected or reported accurately or frequently	x	×		×	×			*
Lack of accountability and just-in-time coaching		x	×	×	×		×	,
Safety culture does not stress hand hygiene at all levels			×	x	×	x		,
Ineffective or insufficient education		x	×	x	x		×	
Hands full	×	×	×	×	×		×	
Wearing gloves interferes with process	×	×	×	×			×	
Perception that hand hygiene is not needed if wearing gloves	×		×	×	×		×	
Health care workers forget	×	×	1	×			×	
Distractions	×	×				x	×	

Note that not all of the main causes of failure appear in every hospital. The chart above represe the validation of the root causes across hospitals. This underscores the importance of understanding hospital-specific root causes so that appropriate solutions can be targeted.

		com	plian	ce.	
Your Ros	-		-	-	
Your Unit	2041	RGENCY	16 9 7 a		N = 33
	1		_		
Check all that apply	e the rea	sonsr	-	$\overline{}$	
	Agree	Disagree	N/A	% Agree	Recommendations
Hands full	20	13		61%	Requires further reasearch
Empty gel dispenser	19	14	1	56%	Develop replenishment mechanisms that ensure availability - surveyed ED 41 total dispensers (8 kids track all full) 8 empty ones
Wearing gloves	18	15		55%	Short education session about wearing gloves
I forgot	12	20	1	36%	Education - what-ifs / scenario training
Empty soap dispenser	11	22		33%	Develop replenishment mechanisms that ensure availability
Distracted	11	23		32%	
Dry/cracked hands	10	23	-	30%	
Inconvenient dispenser location	8	25	1		Inside room vs outside of room
Current requirement is excessive	6	28			
Too busy	6	28	_	6	
Too time consuming	1	33	1	3%	
Unclear when necessary to do hand hygiene GREAT SURVEY RE	= =SP	ONS	E	0%	POSITIVE ATTITUDE



- What if: I sanitize outside. This allows the secret observer to collect data. "Shouldn't our patients be the ones to observe us washing our hands?"
- What if: I am only "sticking my head into the room, but not touching anything"?
- What if: I am going out of a room directly into the next room. Do I have to sanitize? "My hands are still wet"
- What if: Patients are in the hallways during peak times. Do I need to wash my hands between patients?
- What if: "My hands are full". How do I do hand hygiene?















Hand Hygiene Recommendations/ Implementation

Dept Changes

- Relocate / increase hand hygiene stations
- Hand Gel Clips
- Increase lotion
- · Gel to foam

Education

- · Elevator speech
- Poster presentation
- Staff huddles
- Culture Board
- Buttons
- Increased signage

Hand Hygiene Goals

- · ED Goal / Incentive
- July 2010 @ 75% = Café certificate
- October 2010 @ 85%
 = Barbeque
- December 2010 @ 90
 % = ?????







The ED Hand Hygiene Team

Fred Yates Beth Strimpel Judy Gorham Jean Schuppe Danielle Claflin Amy Grace Lisa Funk Julia Dyson Iris Kang









Summary of ED Environmental Cultures

- Winner of the most growth the phone.
- Close second EKG machine, which not only had a significant amount of growth, but also grew organisms originating from fecal matter. Eeeew...
- Of note, every surface had MRSA and/or MSSA, (Staph.)
- Goal is to promote an awareness of what a difference hand hygiene can make, and how we can protect ourselves, our coworkers, our patients and families by having an awareness of what we touch and where we might be spreading germs
- We can take ownership of our workspace by taking the initiative to get involved in keeping our ED clean and by washing our hands!
- Conclusion? WASH-IN, WASH-OUT!!!















A PICTURE IS WORTH A THOUSAND WORDS WASH IN ... WASH OUT



Fred Yates, RN; Mari Compton EMT, ED Tech (ELMC); Beth Strimpel, RN; Judy Gorham, RN; Jean Schuppe, RN; Danielle Claftin EMT, ED Tech; Lisa Funk, RN; Amy Grace, RN; Julia Dyson, EMT, ED Tech; Iris Kang, RN; Todd Bickford, MD

PROBLEM STATEMENT

Hand washing compliance at Exempla Good Samaritan Medical Center (EGSMC) has been consistently below the desired 90% compliance for the past year.

In addition, hand washing compliance in the Emergency Department has been in the 50-60% range for the past year.

BACKGROUND

Exempla Healthcare established a corporate wide benchmark metric of 90% for Best In The Nation (BITN) performance for hand hygien compliance. In order to achieve BITN performance each institution must achieve 90% compliance for 9 months. EGSMC was not meeting this metric, in part due to low scores by some departments, the ED being and of those departments. In spile of routine education and random observation audits by "secret observes" the ED scores computed to approach this process with a EAN event, using EXEME ED monogement decided to approach this process with a EAN event, using Exempla Lutheran Medical Center resources to assist in this process.

AIM STATEMENT

EGSMC Emergency Department will improve hand washing compliance. Measure of success will be an improvement of observed hand washing audit scores from 50% to 90% by December 2010. Implementation will take place in May. Increment scores will show an improvement to 75% by July, 85% by October and 90% by December 2010. This improvement will have a positive impact on EGSMC overall hand washing scores as reported on the EXEMPLA REPORT CARD.

CURRENT STATE

System	Feb 2010 2 Hospital at Min	Mar 2010 2 Hospital at Min	Apr 2010 2 Hospital at Min	May 2010 2 Hospital at Min	2 Hospital at Mi
ELMC	Feb 2010 11 Months at 90%	12 Months of 90%	Api 2010 11 Months of 90%	May 2010 11 Months of 90%	11 Months of 90
ESJH	5 Months at 90%	Mar 2010 6 Months at 90%	Apr 2010 7 Months at 90%	May 2010 8 Months at 90%	9 Morths at 903
EGSMC	Feb 2010 O Months of 90%	0 Months at 90%	Apr 2010 0 Months at 90%	Moy 2010 O Months at 90%	Jun 2010 1 Months at 903





(ng this links experiment waan't to gross strong of them you putationally already how, and inclusing partial and the commander of and inclusing partial and the commander of the provide and how we com- grigate commons of all how we com- grigate common of how we com- net we buch and where we might be too we buch and where we might be and working an head hor we com- gate and where an emighting and any working an head hor we com- any working an head hor we com- go why working an head hor we com- tain we compared and hor we com- tain any and working any bulk we com- gate and any and any any any any any any any any any any working any emission.
Our purpose for conducting you out or not to remit yo that is we work in or hole the othe that is the horn, but backer on sick. In hort, our goal hear is ack in hort, our goal hear is tratter to unrelive, our cowe by being continuem. The parceding continuem.

take ownership of our workspace by taking the initiative to get involved in keeping our ED chan and by washing our hands, in and out of every patient care area.

not only had a significant mount of growth, but dog growth, and all of the opposite organization organization that were found on the EG mount in the left of the growth organization or the left or the channel or growth. Not had the set of the channel or growth, and had the rest of the left of t for the most growth was the phone, YUK a second was the EKG machine, which Coming in at a close tot only had a signifi

Conclusion ... ? WASH IN WASH OUTIN

Special thanks to Susan Young from the Lab for all her help with this project.



Large spreading gray colon; Bacillus spi Environmental organisms ubiquitous in nature (spores that travel with dirt and dust particles)

Medium white or yellow colonies or small dry looking colonies

Medium while or yellow colonies may be beto hemolytic Stophylococcus sp: Colonizers of vorious kin and mucosal surfaces includes both Staph areas (MRSA) and MSSA) and Staph to, not aureus, Microsotras to, and Stamtaooccus ynebacterium sp: onizers of various skin and mucosal

Gray colonies that can be alpha, beta, or non hemolytic colonies itroptococcus sp: Colonizars of various skin and mucosal whoces

Gray, non hemolytic colonie Gray Spreading colonies Enterococcus sp: Normal Rora, usually of the human gastrointestinal tract or other mucous membranes

Evaluate progress – resurvey
 Give feedback to staff
 Celebrate success
 Determine hard wiring strategies

June 2010

Proteus sp: Normal Rora, usually of the human gastrointestinal tract Member of the Enterobacteriaceae Group





Proposed Interventions May 2010

- Implement Lean Methodology and tools Spaghetti diagrams Cause and effect diagram

Co the Bits. Staff hyddes • Staff hyddes • Nak me obord hand washing Buttoris • Nak me obord hand washing Buttoris • Nak me obord hand • Elevitar in a Staff for a summanu they • Elevitar in a buttori of the staff and • Elevitar in a buttori of the staff • Elevitar in a buttori of the staf

- Volue stream map
 Select appropriate team members that will be Owners · Select

Establish incentives

- Remetry For Exemplo Lutheron Medical Center
 Les expert from Exemplo Lutheron Medical Center Energency Department
 Los arreys with our address observers (Judi did nol beiner sector observer medical beiner sector medical beiner sector medical bei

- Analysis/Evaluation
 - Use of survey tools
 Share survey results

Pictures, important
 Why this is important
 Pican roll out end go live date (sam rask)
 Piccess in daily houlding.
 Elevator speak
 Hand washing buttans.

- Subsequent Action
 - Mano v Mano competitio Re-survey
 Timely feedback

Plan For Sustaining Change

 Evaluate progress – resurvey
 Give feedback to staff
 Make adjustments as needed **Actions Taken**

July 2010

Celebrate success

feam selection

- Ranoe Barries
 Sanitzer location
 Hand gel doring bo much goo
 Hand suit home group into the room
 Counter hops are full of suit
 Supplies hore to leave the room to get suif
 Eutocion

 - Choose team members who were informal and formal leaders: Cowners vs. Renters
 Choose Subject Matter Expert, Mari Compton, EM, ED
 Ech ren EUMC. Mari vos key to the success of EUMC ED's hand washing efforts.
 - Need signs to remind us and patients Lack of hard wring
 Lack of buy in, We don't have a problem
 Distraction—just forget
 - - Right Tools
 - Resurvey & Give Feedback Have Funl Dispenser sizues • Survey of staff regarding gel/foram preference • Survey of staff regarding and Reparaers • Varke vith School Offleer to determine regulations for gel/foram immedions • Relaccation of dispensers • Increase number and oralidality of dispensers • Store research articles.

Successes



ding barriers to hand washing

Observed work flow

ew staff

(aizen in department



- in it for them Remove the barriers when possible Constant and timely feedback Listen to the team Make it fun

A picture is worth a thousand words

 Methoday and a second se Staff observations for hand hygiene compliance

All team members were educated on use of survey tool
and expectation to participate in random audits. Staff education: Why this project is important, what is in it for them? Cavi wipe container Singh, corynebacterium and Bacill





5/10/14

- Monitor Buttons& Navigation Wheel (room 4) Stoph, corynebocterium







Cleaning can be defined as the physical action of scrubbing surfaces or objects with a detergent or other cleansing agent followed by rinsing with water to remove microorganisms, salts, and other visible dirt in order to render the surface safe to handle or touch.³¹ Cleaning in healthcare facilities refers to the cleaning and disinfection of environmental surfaces, patient care devices, and medical equipment. Although the primary means by which microorganisms come into contact with patients is via the hands of healthcare workers, adequate cleaning and disinfection of the environment is a fundamental aspect in reducing the spread of healthcare-acquired infections. Organisms may spread to patients from the patient touching a contaminated surface or from a healthcare provider touching this surface and not performing appropriate hand hygiene to eradicate the organisms prior to touching the patient.³²

Clostridium difficile can exist in two forms, as a vegetative cell and as a spore. In its vegetative state, *C. difficile* does not survive in the environment for more than 15 minutes on dry surfaces or more than 6 hours on moist surfaces.³³ However, in its spore form, *C. difficile* has been known to persist on surfaces for at least 5 months and is known to be highly resistant to chemical agents and other means of cleaning. In fact, cleaning agents that are non-chlorine-based have been shown to increase spore production.³⁴

In one study, 49% of rooms occupied by patients with symptomatic CDI were found to be contaminated, while 29% of the rooms occupied by asymptomatic carriers were found to be contaminated.³⁵ Positive correlations have been shown to exist between the amount of contamination on the hands of healthcare workers and the level of contamination that exists in the healthcare environment.³³ Patients admitted to rooms previously occupied by patients with *C. difficile* have a higher risk of contracting the infection.³³ The rate of surface contamination is thought to be proportional to the severity of symptoms in *C. difficile* patients, the level of incontinence of patients, and the number of patients with symptomatic infection. Fortunately, adequate cleaning and disinfection of patient rooms has been shown to reduce rates of infection.³³

Any surface area in a patient's room has the potential for becoming a source of disease transmission. This includes furnishings such as overbed tables, bed rails, chairs, sinks, and toilets. Frequently touched areas, known as "high touch" areas are thought to be more highly contaminated and may need more frequent cleaning and disinfection. These areas may include doorknobs, IV fluid pumps, nurse call buttons, the phone, and light switches.^{10,17,22,36} Carpeted rooms have been shown to be more highly contaminated than noncarpeted rooms.³⁴ A minimal amount of spores are thought to significantly contaminate areas outside of patient rooms.⁹

<u>The guidelines</u>

There are currently two guidelines produced by CDC/HICPAC that should serve as the basis for institutional policies on environmental cleaning practices. These include Guidelines for Environmental Infection Control in Healthcare Facilities (2003) and Guidelines for Disinfection and Sterilization in Healthcare Facilities (2008). The 2003 guideline is a compilation of recommendations for prevention and control of infectious diseases associated with healthcare environments. The 2008 guideline provides detailed recommendations on the preferred methods for cleaning, disinfection, and sterilization of patient-care medical devices and for the cleaning and disinfection of the healthcare environment. The full text for either guideline can be accessed at: http://www.cdc.gov/hicpac/pubs.html.

The following is adapted from the 2003 guideline and provides specific recommendations on the prevention and control of *C. difficile* in the healthcare environment. In general, the guideline recommends "meticulous cleaning followed by disinfection using hypochlorite-based germicides as appropriate."

The ranking categories are as follows³¹:

	RANKING SYSTEM
Category IA	Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.
Category IB	Strongly recommended for implementation and supported by certain experimental, clinical, or epidemiologic studies, as well as a strong theoretical rationale.
Category IC	Required for implementation, as mandated by federal or state regulation or standard.
Category II	Suggested for implementation and supported by suggestive clinical or epidemiologic studies, or a theoretical rationale.
Unresolved Issue	No recommendation is offered. No consensus or insufficient evidence exists regarding efficacy.



RECOMMENDATIONS—ENVIRONMENTAL SERVICES (ADAPTED)

I. Cleaning and Disinfecting Strategies for Environmental Surfaces in Patient-Care Areas

- A. Select EPA-registered disinfectants, if available, and use them in accordance with the manufacturer's instructions (IB, IC).
- B. Do not use high-level disinfectants and/or liquid chemical sterilants for disinfection of either noncritical instrument/ devices or environmental surfaces; such use is counter to label instructions for these toxic chemicals (IB, IC).
- C. Follow manufacturers' instructions for cleaning and maintaining noncritical medical equipment (II).
- D. In the absence of a manufacturer's cleaning instructions, follow certain procedures.
 - 1. Clean noncritical medical equipment surfaces with a detergent/disinfectant. This may be followed with an application of an EPA-registered hospital disinfectant with or without a tuberculocidal claim (depending on the nature of the surface and the degree of contamination), in accordance with disinfectant label instructions (II).
 - 2. Do not use alcohol to disinfect large environmental surfaces (II).
 - 3. Use protective-barrier coverings as appropriate for noncritical equipment surfaces that are 1) touched frequently with gloved hands during the delivery of patient care; 2) likely to become contaminated with blood or bodily substances; or 3) difficult to clean (e.g., computer keyboards) (II).

- E. Keep housekeeping surfaces (e.g., floors, walls, and tabletops) visibly clean on a regular basis and clean up spills promptly (II).
 - 1. Use a one-step process and an EPA-registered hospital disinfectant/detergent designed for general housekeeping purposes in patient-care areas when 1) uncertainty exists as to the nature of the soil on these surfaces (e.g., blood or bodily fluid versus routine dust or dirt); or 2) uncertainty exists regarding the presence or absence of multi-drug resistant organisms on such surfaces (II).
 - 2. Detergent and water are adequate for cleaning surfaces in nonpatient-care areas—e.g., administrative offices (II).
 - 3. Clean and disinfect high-touch surfaces (e.g., doorknobs, bed rails, light switches, and surfaces in and around toilets in patients' rooms) on a more frequent schedule than minimal-touch housekeeping surfaces (II).
 - 4. Clean walls, blinds, and window curtains in patientcare areas when they are visibly dusty or soiled (II).
- F. Do not perform disinfectant fogging in patient-care areas (IB).
- G. Avoid large-surface cleaning methods that produce mists or aerosols, or disperse dust in patient-care areas (IB).
- H. Follow proper procedures for effective use of mops, cloths, and solutions (II).
 - 1. Prepare cleaning solutions daily or as needed; replace with fresh solution frequently, according to facility policies and procedures (II).
 - 2. Change the mophead at the beginning of the day and also as required by facility policy, or after cleaning up large spills of blood or other bodily substances (II).
 - 3. Clean mops and cloths after use and allow to dry before reuse; or use single-use, disposable mopheads and cloths (II).



RECOMMENDATIONS—ENVIRONMENTAL SERVICES (ADAPTED)

I. After the last surgical procedure of the day or night, wet vacuum or mop operating-room floors with a single-use mop and an EPA-registered hospital disinfectant (II).

- J. Do not use mats with tacky surfaces at the entrance to operating rooms or infection-control suites (IB).
- K. Use appropriate dusting methods for patient-care areas designated for immunocompromised patients (IB).
 - 1. Wet-dust horizontal surfaces daily by moistening a cloth with a small amount of an EPA-registered hospital detergent/disinfectant (IB).
 - 2. Avoid dusting methods that disperse dust (e.g., feather-dusting) (IB).
- L. Keep vacuums in good repair, and equip vacuums with HEPA filters for use in areas with patients at risk (IB).
- M. Close the doors of immunocompromised patients' rooms when vacuuming, waxing, or buffing corridor floors to minimize exposure to airborne dust (IB).

- N. When performing low- or intermediate-level disinfection of environmental surfaces in nurseries and neonatal units, avoid unnecessary exposure of neonates to disinfectant residues on environmental surfaces by using EPAregistered disinfectants in accordance with manufacturers' instructions and safety advisories (IB, IC).
 - 1. Do not use phenolics or any other chemical germicide to disinfect bassinets or incubators during an infant's stay (IB).
 - 2. Rinse disinfectant-treated surfaces, especially those treated with phenolics, with water (IB).
- O. When using phenolic disinfectants in neonatal units, prepare solutions to correct concentrations in accordance with manufacturers' instructions, or use premixed formulations (IB, IC).

RECOMMENDATIONS SPECIAL PATHOGENS—INCLUDES C. DIFFICILE CONT.

- A. Use appropriate hand hygiene, PPE (e.g., gloves), and isolation precautions during cleaning and disinfecting procedures (IB).
- B. Use standard cleaning and disinfection protocols to control environmental contamination with antibioticresistant gram-positive cocci (e.g., methicillin-resistant Staphylococcus aureus, vancomycin-intermediateresistant Staphylococcus aureus, or vancomycin-resistant Enterococcus [VRE]) (IB).
 - 1. Pay close attention to cleaning disinfecting hightouch surfaces in patient-care areas (e.g., bed rails, carts, bedside commodes, doorknobs, or faucet handles) (IB).
 - 2. Ensure compliance by housekeeping staff with cleaning and disinfection procedures (IB).
 - 3. Use EPA-registered hospital disinfectants appropriate for the surface to be disinfected (e.g., either low- or intermediate-level disinfection) as specified by the manufacturers' instructions (IB, IC).
 - 4. When contact precautions are indicated for patient care, use disposable patient-care items (e.g., blood-pressure cuffs) whenever possible to minimize cross-contamination with multiple-resistant microorganisms (IB).
 - 5. Follow these same surface cleaning and disinfecting measures for managing the environment of MRSA patients (II).
- C. Thoroughly clean and disinfect environmental and medical equipment surfaces on a regular basis using EPA-registered disinfectants in accordance with manufacturers' instructions (IB, IC).

- D. Advise families, visitors, and patients about the importance of hand hygiene to minimize the spread of body-substance contamination (e.g., respiratory secretions or fecal matter) to surfaces (II).
- E. Do not use high-level disinfectants (i.e., liquid chemical sterilants) on environmental surfaces; such use is inconsistent with label instructions (IC).
- F. Because no EPA-registered products are specific for inactivating *Clostridium difficile* spores, use hypochlorite-based products for disinfecting environmental surfaces in those patient-care areas where surveillance and epidemiology indicate ongoing transmission of *C. difficile* (II).
- G. No recommendation is offered regarding the use of specific EPA-registered hospital disinfectants with respect to environmental control of *C. difficile* (Unresolved Issue).
- H. Apply standard cleaning and disinfection procedures to control environmental contamination with respiratory and enteric viruses in pediatric-care units and care areas for immunocompromised patients (IC).
- I. Clean surfaces that have been contaminated with bodily substances; perform low- to intermediate-level disinfection on cleaned surfaces with an EPA-registered disinfectant in accordance with the manufacturer's instructions (IC).
- J. Use disposable barrier coverings as appropriate to minimize surface contamination (II).



RECOMMENDATIONS SPECIAL PATHOGENS-INCLUDES C. DIFFICILE CONT.

- K. Develop and maintain cleaning and disinfection procedures to control environmental contamination with agents of Creutzfeldt-Jakob disease (CJD), for which no EPA-registered product exists (II).
 - 1. In the absence of contamination with centralnervous-system tissue, extraordinary measures (e.g., use of 2N sodium hydroxide [NaOH] or applying full-strength sodium hypochlorite) are not needed for routine cleaning or terminal disinfection of a room housing a confirmed or suspected CJD patient (II).
 - 2. After removing gross tissue from the surface, use either 1N NaOH or a sodium-hypochlorite solution containing approximately 10,000–20,000 ppm available chlorine (dilutions of 1:5 to 1:3 v/v, respectively, of U.S. household chlorine bleach; contact the manufacturers of commercially available sodium-hypochlorite products for advice) to decontaminate operating-room or autopsy surfaces with central-nervous-system or cerebral-spinal-fluid contamination from a diagnosed or suspected CJD patient (II).
 - a. The contact time for the chemical used during this process should be 30 minutes–1 hour.
 - b. Blot up the chemical with absorbent material and rinse the treated surface thoroughly with water.
 - c. Discard the used, absorbent material into appropriate waste containment.
 - 3. Use disposable, impervious covers to minimize body-substance contamination to autopsy tables and surfaces (IB).

- M. Use standard procedures for containment, cleaning, and decontamination of blood spills on surfaces as previously described (IC).
 - 1. Wear PPE appropriate for a surface decontamination and cleaning tasks (IC).
 - 2. Discard used PPE by using routine disposal procedures or decontaminate reusable PPE as appropriate (IC).



SELECTION OF CLEANING PRODUCTS/METHODS

Current data are conflicting on whether the cleaning agent used must inactivate or "kill" *C. difficile* spores in order to prevent transmission.⁴ Regardless, there are currently no EPA-registered products that can claim to effectively eliminate these spores from the hospital environment. For routine cleaning of *C. difficile* patient rooms in hospital settings where there is currently no outbreak or increased activity, the use of EPA-registered disinfectant products that are more routinely used in the hospital setting are suitable. Although not effective in eliminating spores of *C. difficile*, the physical motion of cleaning and routine use of germicides remove and dilute the concentration of spores effectively enough in endemic situations.¹⁵

RECOMMENDATIONS ON CLEANING SOLUTIONS FOR *C. DIFFICILE*³⁴

According to CDC's Guideline for Disinfection and Sterilization, healthcare facilities that are experiencing outbreak levels of *C. difficile* or where ongoing transmission is occurring, the recommendation is to use dilution solutions of 5.25% to 6.15% sodium-hypochlorite solutions (such as a 1:10 dilution of household bleach), along with additional prevention and control measures (II).

If chlorine solutions are not prepared fresh daily, it can be stored at room temperature for up to 30 days in a capped, opaque plastic bottle with a 50% reduction in chlorine concentration after 30 days of storage (e.g., 1000 ppm chlorine [approximately a 1:50 dilution] at day 0 decreases to 500 ppm by day 30) (IB).

An EPA-registered sodium-hypochlorite product is preferred, but if such products are not available, a generic version of sodium hypochlorite solutions (e.g., household chlorine bleach) can be used (II).

Common disinfectants used in healthcare settings that may be used for routine cleaning of *C. difficile* rooms in the absence of an outbreak include quaternary ammoniums, phenolics and other EPA-approved germicides.

FACTORS TO CONSIDER WHEN CHOOSING A CLEANING AGENT³¹:

- Costs and safety of the product
- Product—surface compatibility and contact time needed for product activation
- User acceptability
- Sporicidal activity of cleaning agent
- Hypochlorite solutions can cause damage (corrosion and pitting) to equipment and aggravate respiratory problems¹⁵
- The adequacy of the cleaning process in highcontamination situations versus the adequacy of the product or the need to change products³⁷



COLORADO INFECTION PREVENTION COLLABORATIVE

C. DIFFICILE INFECTIONS

ADVANTAGES AND DISADVANTAGES OF LOW-LEVEL DISINFECTANTS APPROVED FOR USE IN HEALTHCARE FACILITIES FOR SURFACE-AREA CLEANING^{31,34,37}

CLEANING Method	ADVANTAGES	DISADVANTAGES
Sodium hypochlorite	 1:10 dilution active against <i>C. difficile</i> spores Inexpensive Fast-acting Widely available Broad spectrum of antimicrobial activity Does not leave toxic residues Unaffected by water hardness Removes dried or fixed organisms surfaces Low incidence of serious toxicity 	 Odor can be irritating Corrosive to metals in high concentrations Inactivated by organic material May discolor fabrics Inactivation by organic matter discoloring or "bleaching" of fabrics Release of toxic chlorine gas when mixed with ammonia or acid
Quaternary ammonia compounds	 Not too expensive Widely available Effective cleaning agent Widely used as disinfectants Generally fungicidal, bactericidal, and virucidal against lipophilic (enveloped) viruses Commonly used in ordinary environmental sanitation of noncritical surfaces, such as floors, furniture, and walls EPA-registered quaternary ammonium compounds are appropriate to use for disinfecting medical equipment that contacts intact skin (e.g., blood-pressure cuffs) 	 Not effective against spores Healthcare-associated infections have been reported from contaminated quaternary ammonium compounds used to disinfect patient-care supplies or equipment High water hardness⁴³ and materials such as cotton and gauze pads can make them less microbicidal because of insoluble precipitates or active ingredient absorption, respectively
Phenolics	 Widely available Many phenolic germicides are EPA registered as disinfectants for use on environmental surfaces (e.g., bedside tables, bed rails, and laboratory surfaces) and noncritical medical devices Bactericidal, fungicidal, virucidal, and tuberculocidal 	 May be toxic to infants—use of phenolics in nurseries has been questioned because of hyperbilirubinemia in infants placed in bassinets where phenolic detergents were used Phenolics are absorbed by porous materials, and the residual disinfectant can irritate tissue Poor activity against bacterial spores
Ethyl or isopropyl alcohol	 Inexpensive Widely available Rapidly effective Rapidly bactericidal, rather than bacteriostatic, against vegetative forms of bacteria; they also are tuberculocidal, fungicidal, and virucidal Alcohols have been used effectively to disinfect oral and rectal thermometers, hospital pagers, scissors and stethoscopes 	 Not active against <i>C. difficile</i> spores Fatal postoperative wound infections with Clostridium have occurred when alcohols were used to sterilize surgical instruments contaminated with bacterial spores Alcohols have been used to disinfect fiber-optic endoscopes but failure of this disinfectant has lead to infection May cause damage to surfaces over time Rapid evaporation makes adequate exposure time difficult to achieve unless the items are immersed
Iodophor germicidal solutions	 Used for disinfecting blood culture bottles and medical equipment, such as hydrotherapy tanks, thermometers, and endoscopes This product and other iodophors retain the germicidal efficacy of iodine but, unlike iodine, generally are nonstaining and relatively free of toxicity and irritancy 	• Antiseptic iodophors are not suitable for use as hard- surface disinfectants



NOVEL APPROACHES TO ROOM DECONTAMINATION

In light of the fact that there are no EPA-recommended products that can claim to kill *C. difficile* spores and only 50% of rooms are cleaned effectively following terminal clean at patient discharge, some novel approaches have recently been introduced in an effort to improve terminal room cleaning and disinfection of *C. difficile* patient rooms. Two are discussed briefly here.

Hydrogen peroxide vapor (HPV) room-decontamination systems inject liquid hydrogen peroxide into sealed rooms where the gaseous vapor is allowed to cover and disinfect objects and surfaces in the room following terminal cleaning. Vapor is released until the appropriate amount of hydrogen peroxide is in the room, a process which generally takes 2-4 hours for one room and up to 12 hours for an entire ward. The process allows for high levels of penetration of the cleaning agent; is noncorrosive to surfaces and compatible with hospital surfaces; and is less toxic to the environment, patients and staff than traditional cleaning methods. Most important, this method has been shown to be highly effective against eradicating C. difficile and MRSA from the patientcare environment. Boyce et al. found that they were able to reduce the incidence of CDAD by 53% following use of the decontamination system.³⁹ However, more studies need to be conducted before it is recommended for routine use and may only be warranted in healthcare facilities where high rates of infection persist despite adherence to preventive measures due to higher costs and slow room turnaround times.

A second method, ultraviolet light systems, may be used following terminal cleaning to more completely eradicate pathogens from patient rooms. These systems target areas for cleaning and deliver the appropriate dose of UV energy into the room for the appropriate length of time. In one study, this type of system was successful in eradicating 99.9% of vegetative bacteria and 99.8% of C. difficile spores in less than one hour.⁴⁰ These systems have also been effective in significantly reducing MRSA and VRE contamination in rooms. Additional benefits to this method include the fact that it is environmentally friendly, rapidly decontaminates a variety of organisms and does not require the sealing off of ventilation systems. Drawbacks are that initial capital costs can be high; however, there is no need to purchase additional supplies on a regular basis. Patients and staff may need to leave the area, and the room may still require cleaning of other visually unappealing elements that are important to patients and families, such as dust and stains.

MONITORING CLEANING PRACTICES

Surfaces that are in close proximity to the patient, or likely to be frequently touched by patients or healthcare workers, are known as "high-touch areas." The recommendation provided by CDC's 2003 guideline for environmental cleaning advises that hospitals "clean and disinfect high-touch surfaces" more frequently than other surfaces (category IB). Current estimates on the adequacy of room cleaning are suboptimal at best, with some estimating that about only half of these high-touch surfaces are effectively cleaned by housekeeping following patient discharge.⁴⁰ These high-touch areas may include the tray table, light switches, bathroom doorknob, telephone, and bed rails. In a study that analyzed data of high-touch areas in 36 acute-care hospitals in the United States, only 48% were found to be appropriately cleaned. The areas that had the highest rate of being cleaned included the sink, tray table, and toilet. The areas with the worst rate, with less than 30% being adequately cleaned, included light switches, doorknobs, bathroom handholds and bedpan cleaners.⁴¹ Clearly, there are substantial opportunities that exist for improving compliance with environmental cleaning guidelines.

CDC/HICPAC's 2006 Guideline for the Management of Multi-Drug-Resistant Organisms states that "monitoring for adherence to recommended environmental cleaning practices is an important determinant for success in controlling transmission for MDROs and other pathogens in the environment." The guideline strongly recommends (a category IB ranking) that "hospitals monitor (clean and inspect) cleaning performance to ensure consistent cleaning and disinfection of surfaces in close proximity to the patient and likely to be touched by the patient and healthcare professionals." With these data and recommendations in mind, the CDC in collaboration with the Environmental Evaluation Workgroup has developed *Options for Evaluating Environmental Cleaning* that focuses on monitoring cleanliness of these high-touch areas. Although there is a lack of standardized recommendations for the monitoring of environmental cleaning, this document provides a starting point for healthcare facilities to begin the basic practices of monitoring then to progress to more advanced levels. Additional related resources, including an evaluation worksheet and monitoring form, are available at <u>http://www.cdc.gov/HAI/toolkits/Evaluating-Environmental-Cleaning.html</u>.

The tool kit also offers recommendations for providing education to environmental services staff to promote effective cleaning. A survey conducted in 2009 by APIC and the American Society for Healthcare Environmental Services (ASHES) found the top three challenges to adequate environmental cleaning were too much pressure to turn the room over in a timely manner, lack of assignment to cleaning non-stationary objects, and high hospital occupancy. Consider how these factors may affect adequate cleaning in your own institution. A close relationship with environmental services and clear role assignments were key factors in successful improvement initiatives.⁴²

ENVIRONMENTAL CLEANING EDUCATION USING FLUORESCENT MARKER OR POWDER

The use of objective systems of monitoring, such as the use of fluorescent gel markers or ATP bioluminescence, provide a useful tool for education for all staff and may be particularly helpful when a staff member's first language is not English. Once placed on an object, these materials are invisible to the naked eye, yet can be removed with cleaning agents, light pressure, and a damp cloth. The solution dries rapidly and can persist on surfaces for several weeks, making it possible to monitor immediately after cleaning has been conducted or up to several weeks. Several products on the market can be used, including GloGerm products and Black Light World's Cleaning Detective Kit.

Learning Objective: To educate environmental services staff on high-touch areas that require cleaning, and to demonstrate whether staff are effectively cleaning these areas.

Step 1: Identify high-touch areas or other locations within patient rooms that will be targeted for education and monitoring. Utilize an environmental cleaning checklist to ensure consistency in monitoring, and modify this checklist for training purposes if needed.

Step 2: Determine how often monitoring will take place and which rooms or staff members will be monitored.

Step 3: Educate staff on the monitoring process and expectations for cleaning patient care areas. Be sure to provide specific information on staff roles and processes for adequate cleaning.

Step 4: Work with environmental services managers and staff to determine a method for notifying infection control staff when the room is available for placement of the fluorescent gel markings.

Step 5: Place one dot of fluorescent gel on each high-touch area or other surface selected for monitoring.

Step 6: Following cleaning, return to the room and use a black light to highlight the areas marked with fluorescent gel to determine where cleaning may be insufficient.

Step 7: Conduct follow-up education on the spot by returning to the room with EVS staff, or develop follow-up presentations for a group. If cleaning is inadequate, revisit the protocol and find out where gaps in knowledge continue to exist.

Options for Evaluating Environmental Cleaning

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Introduction:

In view of the evidence that transmission of many healthcare acquired pathogens (HAPs) is related to contamination of near-patient surfaces and equipment, all hospitals are encouraged to develop programs to optimize the thoroughness of high touch surface cleaning as part of terminal room cleaning at the time of discharge or transfer of patients. Since dedicated resources to implement objective monitoring programs may need to be developed, hospitals can initially implement a basic or Level I program, the elements of which are outlined below. Some hospitals should consider implementing the advanced or Level II program from the start, particularly those with increased rates of infection caused by healthcare acquired pathogens (e.g., high *Clostridium difficile* infection rate). All hospitals that have successfully achieved a Level I program should advance to Level II.

At present, the objective monitoring of the cleaning process of certain high touch surfaces (e.g., the curtain that separates patient beds) beyond those outlined in the attached checklist is not well defined. Additionally, there is no standard method for measuring actual cleanliness of surfaces or the achievement of certain cleaning parameters (e.g., adequate contact time of disinfectant) or for defining the level of microbial contamination that correlates with good or poor environmental hygienic practices. As our understanding of these issues evolve and a standardization of assessment in these respective areas can be developed and practically implemented, hospitals that have obtained a high compliance rate with surface cleaning as outlined in the Level II program are encouraged to advance their efforts in optimizing environmental hygienic practices.

Level I Program

Elements of the program:

- The program will be an infection preventionist/hospital epidemiologist infection prevention & control (IPC) based program internally coordinated and maintained through environmental services (ES) management level participation. The goal should be seen as a joint (IPC/ES), team effort during planning implementation and ongoing follow-up phases.
- 2. Each program will be hospital-specific and based on a joint (IC/ES) definition of institutional expectations consistent with the CDC standards^{1,2} and the attached check list. The responsibilities of ES staff and other hospital personnel for cleaning high touch surfaces (e.g., equipment in ICU rooms) will be clearly defined.
- 3. Structured education of the ES staff to define programmatic and institutional expectations will be carried out and the proportion of ES staff who participate

will be monitored (see Elements of the Educational Intervention – Appendix A).

- 4. Development of measures for monitoring along with methods and identified staff for carrying out monitoring will be undertaken by the IPC/ES team. Monitoring measures may include competency evaluation of ES staff by ES management, IPC staff or, preferably, both. Teams are also encouraged to utilize patient satisfaction survey results in developing measures. Regular ongoing structured monitoring of the program will be performed and documented.
- 5 Interventions to optimize the thoroughness of terminal room cleaning and disinfection will be a standing agenda item for the Infection Control Committee (ICC) or Quality Committee as appropriate for the facility.
- 6. Consideration of the feasibility of moving to the Level II program will be discussed by the ICC and documented in the committee minutes.

Reporting:

Results should be reported to the ICC and facility leadership.

Level II Program

Elements of the Program

- The program will be an infection preventionist/hospital epidemiologist infection prevention & control (IPC) based program internally coordinated and maintained through environmental services (ES) management level participation. The goal should be seen as a joint (IPC/ES), team effort during planning implementation and ongoing follow-up phases.
- 2. Each program will be hospital-specific and based on a joint (IC/ES) definition of institutional expectations consistent with the CDC standards^{1,2} and the attached check list. The responsibilities of ES staff and other hospital personnel for cleaning high touch surfaces (e.g., equipment in ICU rooms) will be clearly defined.
- 3. Either covertly or in conjunction with ES staff, an objective assessment of the terminal room thoroughness of surface disinfection cleaning will be done using one or more of the methods discussed below (see Objective Methods for

Evaluating Environmental Hygiene - Appendix B) to document the preintervention thoroughness of disinfection cleaning (generally referred to as the "TDC Score" calculated as # of objects cleaned / total # of objects evaluated X 100). Such results will be maintained by the institution and used internally to optimize programmatic and educational interventions.

- 4. Structured education of the ES staff to define programmatic and institutional expectations will be carried out and the proportion of ES staff who participate will be monitored. It would be expected that the results of the pre-intervention objective evaluation of disinfection cleaning be incorporated into the ES educational activity in a non-punitive manner (see Elements of the Educational Intervention Appendix A).
- 5. Scheduled ongoing monitoring of the TDC cleaning using one or more of the objective monitoring approaches discussed in Appendix B will be performed at least three times a year. The monitoring will use a projected sample size based on the previous level of TDC in order to detect a 10-20% change in performance (see Sample Size Determination Appendix C). The results will be recorded in an excel spreadsheet to calculate aggregate TDC scores (see Appendix D).
- 6. The results of the objective monitoring program and the objectively developed TDC scores will be used in ongoing educational activity and feedback to the ES staff following each cycle of evaluation. It is recommended that such results be shared more widely within and beyond the institution as useful and appropriate.
- 7. Results of the objective monitoring program and interventions to optimize the thoroughness of terminal room cleaning and disinfection will be a standing agenda item for the Infection Control Committee (ICC).

Reporting:

Results should be reported to the ICC and facility leadership and could be reported to the state health department through the state prevention collaborative coordinator by various mechanisms (e.g., NHSN template), depending on infrastructure.

¹ Guidelines for Environmental Infection Control in Healthcare Facilities, 2003 (http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf)

² Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection Nov 2008.pdf)

Appendices to the Conceptual Program Model for Environmental Evaluation

APPENDIX A

Elements of the Educational Intervention

Environmental Services Line Personnel – A presentation should be developed for all line staff involved in terminal room cleaning and should:

- A. Provide an overview of the importance of HAIs in a manner commensurate with their educational level using as many pictorial illustrations as is feasible.
- B. Explain their role in improving patient safety through optimized hygienic practice.
- C. Review specific terminal room cleaning practice expectations.
- D. Discuss the manner in which their practice will be evaluated. For Level II programs, a participatory demonstration of the monitoring method is very useful.
- E. Provide them with information from the baseline evaluation emphasizing or possibly exclusively showing them results for those objects which have been most thoroughly cleaned (Level II).
- F. Stress the non-punitive nature of the program.
- G. Inform them that their good performance will be broadly recognized (i.e., beyond their department) and highlighted within their department for others to emulate. (Level II)
- H. Repeatedly reinforce the importance of their work, and how it directly relates to the hospital's goals and mission and how it is appreciated by patients and plays a major role in a patient's satisfaction with the hospital.

Many hospitals have provided a small (possibly ES staff-language specific) pictorial booklet to the environmental services personnel at the conclusion of the presentation which is often developed to be language skill appropriate.

ES managers – As senior managers will be actively involved in the design and implementation of either Level I or Level II programs, educational interventions for them will need to be customized. While many of these individuals have an excellent understanding of the basic policies and procedures involved in terminal room cleaning, most will benefit from focused educational interventions related to our evolving understanding of the role of the environment in healthcare-associated pathogen (HAP) transmission. Evaluation of mid-level managers also needs to be customized. Most importantly, the impact of the program on mid-level ES managers needs to be monitored since additional formal and informal education is frequently needed for those individuals who are somewhat unsure of the importance of developing programmatic approaches to optimize terminal room cleaning.

Other groups – Given the overall importance of optimizing the thoroughness of hygienic practice in healthcare settings, hospital specific educational interventions graphically illustrating the impact of the program should be considered for both Level I and Level II programs. Such communications should be developed for a range of audiences within the hospital including the senior hospital administration, the medical staff, nursing personnel on the units, executive nursing and medical staff committees and the hospital's board of managers or directors.

APPENDIX B

Objective Methods for Evaluating Environmental Hygiene

In considering implementation of a Level II program, the advantages and limitations of various monitoring approaches must be considered carefully. The factors which distinguish each approach to Level II monitoring are discussed below and summarized in Fig.1. With any method or methods used it is important that neither the system itself (fluorescent marker) nor its use (precleaning cultures or ATP measurements) induce a Hawthorne type effect.

Direct Practice Observation – Covert monitoring of disinfection cleaning can provide an objective assessment of individual ES staff performance and compliance with cleaning protocols. This approach has been used to objectively evaluate and improve ICU environmental hygiene in one hospital.¹ While conceptually feasible, logistical issues related to maintaining such a program outside a research setting could limit adaptation of this form of Level II monitoring. Furthermore, the complexity of monitoring cleaning practice in individual patient rooms without the evaluator being recognized as such might represent a difficult confounding issue.

Swab Cultures – While several outbreak intervention studies have associated decreased environmental contamination by target organisms as a result of modified cleaning practice leading to decreased acquisition of targeted pathogens, none of the reports specifically note if serial environmental culture results were actually used to provide practice feedback to the ES staff. Although swab cultures are easy to use, the cost of processing, including isolate identification, the delay in analyzing results, the need to determine pre-cleaning levels of contamination for each object evaluated in order to accurately assess cleaning practice, and the limited feasibility of monitoring multiple surfaces in multiple patient rooms as part of an ongoing Level II monitoring program represent issues which could limit the broad application of this system.

Agar Slide Cultures – Agar coated glass slides with finger holds were developed to simplify quantitative cultures of liquids. The slides have been adopted for use in environmental surface monitoring in healthcare settings.² These studies have used agar

coated slide systems to evaluate cleaning practice by quantifying aerobic colony counts (ACCs) per cm.^{2,3} While studies have measured aggregate ACCs before and after cleaning, no studies to date have evaluated the actual thoroughness of cleaning of the same objects to determine if objects with relatively high ACCs were either poorly cleaned or actually overlooked by the ES staff. Although some difficulties have been encountered in utilizing the agar slide cultures on other than large, flat surfaces, they potentially provide an easy method for quantifying viable microbial surface contamination. There is a need, similar to that noted above for swab cultures, to determine pre-cleaning levels of contamination for each object evaluated in order to accurately assess cleaning practice. Agar coated slides and dedicated incubation systems are commercially available.

Fluorescent Markers – The fluorescent gel is a substantially invisible transparent gel which dries on surfaces following application and resists abrasion. A monitoring system using this gel was developed specifically to evaluate the thoroughness of environmental cleaning in healthcare settings. Several studies have demonstrated the accuracy of the system in objectively evaluating cleaning practice and quantifying the favorable impact of interventions on such cleaning.^{4,5} The system is commercially available for use in acute care hospitals on a subscription basis.

While fluorescent powders and lotions can be used to mark high touch objects just prior to room cleaning as part of educational interventions, there is little or no published experience in using these markers as a monitoring system, and distinct limitations may be inherent in their use for measuring cleaning practice over time. These limitations may include their overt visibility (lotions and powders), ease with which they can be disturbed (powders), or difficulty with their easy removal (lotions if allowed to dry completely).

ATP Bioluminesence – The measurement of organic ATP on surfaces using a luciferase assay and luminometer has been used to evaluate cleanliness of food preparation surfaces for more than thirty years. A specialized swab is used to sample a standardized surface area which is then analyzed using a portable handheld luminometer. The total amount of ATP, both microbial and non-microbial, is quantified and expressed as relative light units. Although readout scales vary more than 10 fold and sensitivity varies between commercially available systems, very low readings are typically associated with low aerobic colony counts (ACCs).⁶ Very high readings may represent either a viable bioburden, organic debris including dead bacteria or a combination of both. An independent study in 2007 by the U.K. National Health Service evaluating the potential role of the ATP tool in assessing cleaning practice,⁷ while noting several limitations in the ATP system, concluded that the tool could potentially be used effectively for ES education. Although it is likely that part of the lack of correlation between ATP readings and ACCs noted in the preceding studies relates to the fact that ATP systems measure organic debris as well as viable bacterial counts, several studies have noted additional

environmental factors which may increase or decrease ATP readings. Additional logistical challenges related to the use of the ATP tool include the need to develop precleaning values for each object and the need to evaluate a surface within a few minutes of cleaning as well as the inability to use the system when a bleach based disinfectant is being used for cleaning. Despite these limitations, the ATP system has been used to broadly document significant improvement in the daily cleaning in two studies at the same facility.^{8,9} Luminometers and specimen collection swabs are available from several commercial sources.

Final Points

No matter which of the Level II monitoring approaches is chosen by the hospital, it is important that the monitoring be performed by hospital epidemiologists, infection preventionists or their designees who are not part of the actual ES cleaning program. Such an approach assures the validity of the information collected and provides an opportunity for the Infection Control and Prevention Department to independently champion the value of well performed disinfection cleaning.

A more detailed and fully referenced discussion of the above noted approaches to Level II monitoring of terminal room cleaning, may be found in the article **Evaluating Hygienic Cleaning in Healthcare Settings: What You Don't Know Can Harm Your Patients** by P.C. Carling and J.M. Bartley in the June, 2010 supplement to the American Journal of Infection Control

http://www.ajicjournal.org/issues/contents?issue_key=S0196-6553(10)X0005-0

APPENDIX C

Sample Size Determination

Logistical issues must also be considered as part of planning for the implementation of an enhanced program. Before a decision has been made to use one of the Level II methods to objectively monitor cleaning practice, it is important to determine the number of surfaces to be evaluated for establishing baseline level of thoroughness of cleaning and the number of data points which must be monitored on a regular basis to accurately assess improvement or deterioration in practice. While it would be ideal to be able to identify small fluctuations in practice accurately (e.g., 10% relative change), such an approach would be highly labor intensive. Instead, a meaningful change in cleaning practice (e.g., 20% relative change) can be detected without having to evaluate a substantial number of surfaces. Previous experience suggests that conducting a baseline evaluation of all available surfaces (listed in the checklist) in a 10-15% sample of representative patient rooms is reasonable in a hospital with \geq 150 beds. When hospitals have achieved a thoroughness of cleaning rate of >80%, the number of surfaces to be monitored can be decreased to those available in a 5% sample of rooms per evaluation cycle unless there is a deterioration in practice. In hospitals with less than 150 beds, all available surfaces (listed in the checklist) in a minimum of 15 rooms may be monitored for baseline and ongoing evaluation.

APPENDIX D

Calculation of Aggregate Thoroughness of Disinfection Cleaning (TDC) Score

The results of the evaluation of each object listed on the check list can be recorded in the attached excel spreadsheet template. The percentage of individual surfaces cleaned across multiple patient rooms will be automatically calculated by the excel spreadsheet. Because it has been found that cleaning practice within an institution is more likely to vary between types of objects than by patient units, the high touch surfaces listed in the check list have been grouped into 5 categories for calculating aggregate TDC scores: High Touch I, High Touch II, High Touch III, Bathroom Surfaces, and Equipment Surfaces. The aggregate TDC scores for each category of objects can be reported to the HAI prevention collaborative coordinator by various mechanisms (e.g., NHSN), depending on infrastructure.

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Figure 1

Evalua	ting Pat	ient Zone	Environn	nental Hy	giene
Method	Ease of Use	ldentifies Pathogens	Useful for Individual Teaching	Directly Evaluates Cleaning	Published Use in Programmatic Improvement
Direct Practice Observation	Low	No	Yes	Yes	1 Hospital
Swab cultures	High	Yes	Not Studied	Potentially	1 Hospital
Agar slide cultures	Good	Limited	Not Studied	Potentially	1 Hospital
Fluorescent gel	High	No	Yes	Yes	49 Hospitals
ATP system	High	No	Yes	Potentially	2 Hospitals

INSTRUCTIONS FOR EVALUATING THE CLEANING OF OBJECTS IN THE PATIENT ZONE

The group of objects on the checklist was chosen on the basis of information regarding the contamination of these surfaces with healthcare-associated pathogens (HAPs) as well as a consideration of the likelihood they would be touched during routine care by healthcare personnel without changing gloves or performing hand hygiene prior to using these items.

The following descriptions and suggestions should be used to standardize, to the degree feasible, the manner in which the thoroughness of cleaning can be most consistently evaluated. If the evaluation system utilizes a fluorescent gel targeting system, the targets should generally be placed very near but not in/on the area of the object touched in routine use (as noted in the outline below) in order to avoid disturbing the target during actual use of the object. If one of the direct evaluation systems (one of the two culture methods or the ATP method as described in the Appendix) is being used, the primary hand touch area of each object should be evaluated as noted in the outline below, taking particular care to evaluate exactly the same area of the object before and after cleaning.

All available objects noted below should be marked in each room.

Patient Area

Bed rails – If the bed rail incorporates bed controls, evaluate the control area (on the patient side) slightly away from the control buttons. If the rails do not contain the new style control areas, the rails are best evaluated on the smooth inner surface in an area easily accessible to cleaning.

Tray table - The top of the tray table should be evaluated in one corner.

Call boxes – Evaluation is done on the back mid portion of the call box in an area easily accessible to cleaning. If tiny call buttons are used, mark the separate TV control box instead if feasible.

Telephones – Evaluation is best done on the back side of the hand-held portion of the telephone near the top of the phone, away from the end that is attached to the phone wire.

Bedside tables - The drawer pull is evaluated.

Patient chair – Evaluation is done in the center of the seat of the chair close to the rear of the cushion. If the cushion is covered in textured fabric, evaluate the arm of the chair.

IV pole – For hanging IV poles, the shaft of the pole just above the textured grab area should be evaluated. For standing IV poles, the chest-high portion where hand contact is most common should be evaluated.

Toilet Area

Sinks – If using a targeting system, the best place to mark the sink rim is towards the rear in order to avoid water splash interference with evaluation of the target. If direct evaluation is used, the faucet handle should be evaluated.

Bathroom and patient room light switches – When using a targeting method, a target is placed on the plate portion of the light switch. When using a direct evaluation system, the switch or plate should be evaluated because of its relatively large surface area.

Door knobs and door levers – The inside door knob or lever is marked for each bathroom door and each patient room door. If using a targeting system on a round door knob, the mark is best placed as close to the middle of the face of the door knob as possible. If the knob has a locking mechanism, place the target on the circular door plate that surrounds the handle. Lever-type handles are marked on any easily cleanable surface somewhat away from the end of the lever where direct hand contact would be most frequent. Similarly, when using a fluorescent system, door push plates are marked in the middle of the smooth part of the plate. When using direct evaluation systems, the most frequently contacted portion of the door knob, lever or push plate should be evaluated.

Toilet area hand holds (bathroom handrails) – Evaluate the most accessible surface of the hand hold just off the edge of the textured surface at the curve where the hand hold goes towards the wall. If there are two hand holds, mark the one most likely to be touched by a patient using the toilet.

Toilet seats – When using a targeting method, the target is placed on the back of the toilet seat just below the outside edge of the seat in an area readily accessible to cleaning activities. When using a direct evaluation method, the surface of the toilet seat should be evaluated, being sure to evaluate the same area before and after cleaning.

Toilet handles – When using a targeting method, the target is placed on top of the handle approximately two thirds away from the end of the handle.

Bed pan cleaning equipment – Two types of bed pan cleaning equipment designed as part of toilet units are in general use in hospitals.

<u>Hinged pipe type cleaner</u> - The most commonly used bed pan cleaner consists of a pipe with a small shower head type device that is lowered over the toilet bowl by the user. When the arm is lowered, the toilet flush water is sprayed in a stream through the cleaner head. This device is best targeted by marking the spray head (the most common area which would be touched by users).

<u>Spray hoses</u> – Some toilets have a spray hose with a lever-type trigger on the handle which is depressed to activate the spray head. Evaluate the handle itself.

Where Applicable

IV Pump control panel – Evaluate an area that is just adjacent to the portion of the panel that is most frequently touched by healthcare providers.

Monitor control panel – When using a targeting method, the control panel should be evaluated in an area immediately adjacent to a part of the panel which is directly contacted by caregivers' hands. When using a direct method, the control area itself is evaluated.

Monitor touch screen – The touch screen should be evaluated in the lower right hand corner in an area easily accessible to cleaning.

Monitor cables - Evaluate the junction box area.

Ventilator control panel – Evaluate an area immediately adjacent to a part of the panel which is most frequently touched by healthcare provider.

TARGET PLACMENT ON HIGH TOUCH OBJECTS

















CDC Environmental Checklist for Monitoring Terminal Cleaning¹

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 Swab cultures

Fluorescent gel ATP system

Agar slide cultures

¹Selection of detergents and disinfectants should be according to institutional policies and procedures ²Hospitals may choose to include identifiers of individual environmental services staff for feedback purposes.

³Sites most frequently contaminated and touched by patients and/or healthcare workers

National Center for Emerging and Zoonotic Infectious Diseases Division of Healthcare Quality Promotion



Colorado Clostridium difficile Collaborative Environmental Cleaning Checklist

Observe at least 5 ROUTINE cleanings and 1 TERMINAL cleaning per month

Date:

Instruction	Component	Yes	No	N/A
Put on PPE		1		1.
Thoroughly disinfect high	Door knobs			1
touch surfaces	Door surface			1
	Light switches			-
	Window sills			
	Medical equipment (iv controls and buttons)		1	
	Bed rails		1	
	Call button	-		1
	Phone			
	Over bed table			1+
	Countertop and other misc horizontal surfaces	1	1	
	Patient chair arms	-	1	
	Patient chair seat			
Spot clean with disinfectant	Wall surfaces to 6 feet		1	
cloth	Blood Pressure cuffs			
	Furniture		1	1
Damp Dust	Overhead light		1	
	TV and stand			
Thoroughly disinfect	Bathroom door knob			
bathroom surfaces	Mirror	1		
	Tub/ shower			
	Faucets (sink)			
	Bathroom handrails	1		
	Sink	· · · · ·	-	
	Toilet lever/flush	1		
	Toilet horizontal surfaces/seat	1	1	
Clean Floor	Dust mop tile (routine)	1	1	1.
	Wet mop tile (terminal)	1		
Additional steps for Terminal	Bed Frame	1		
Cleaning:	Mattress covers			
Damp Dust	Pillows		1	
2 3 JP - 7 A20	Remove unused linen, send curtains for cleaning	-		1
	Discard unused disposable items	1		
After cleaning is complete	Remove trash, mops, soiled curtains, discard wipes/cloths, etc			
	Dispose of gloves, gown before exiting room			1
	Change mop head			
	Perform hand hygiene			

*For monitoring using a fluorescent marker: place 1 dol on each high touch and bathroom surface. Record as YES if marker is eliminated (or smeared) when viewed under black light.

% COMPLIANCE SCORE= (# YES/ # YES+NO)*100











SUMMARY

- EVS invites collaboration with *IP*, the collaboration had helped managers to target staff education
- *IP* is currently working to transfer the Germ Juice project to *EVS*
- *IP* will randomly observe compliance on planned days with *EVS* manager
- The *CDI* collaboration along with other *CDC* recommended efforts has helped Denver Health to decrease the numbers of *CDI* cases



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Environmental Services Terminal Cleaning Procedure for Clostridium Difficile(CDI)

The Environment plays a key role in supporting the spread of infections.

Process:

- Wash hands with soap and water.
- Put on PPE with gown and gloves
- Use new rags and solutions to begin
- Remove cubicle curtains, sheets, pillows
- · Begin horizontal to vertical
- Cleaning will be done with germicidal solution
- Common touched surfaces shall be rinsed clear water and a clean rag.
- PDI Sani-Cloth 1:10 bleach wipe high touch surface
- One minute is required for proper "kill" time
- Once room is completed the bed and cubicle curtains are reapplied and the floor is mopped with germicide
- Gloves and gown are removed and hands are washed with soap and water
- Supervisor notifies nursing once the room is complete

IP will begin random observations of EVS routine and terminal cleaning and disinfection of pt rooms. Monitor 5 routine cleaning of pt rooms Monitor one terminal cleaning monthly Orange sign with the wording **"wash your hands with soap and water"** is attached to the green contact sign is posted on the door, this means Cdiff precautions should be followed when doing a routine or terminal clean.

Nursing/clerical places indicator in Nava-Care. Notifying EVS of CDI terminal clean needed. New unit is notified of CDI patient. New unit follows CDI process. Nursing pages Bell-boy pager #248 for terminal Cdiff room

Hand Hygiene With Soap and water

Contact precautions Gown and glove for Cdiff pts

Monitor EVS adherence to terminal process



COLORADO INFECTION PREVENTION COLLABORATIVE C.DIFFICILE INFECTIONS







The use of protective barrier measures, including standardand transmissions-based precautions, are recommended by the CDC for the prevention and control of infectious agents with special clinical and epidemiologic significance, including C. difficile and multi-drug resistant organisms.43 Standard precautions imply the use of proper hand hygiene technique and include the use of gloves, masks, gowns, respirators, and face shields in circumstances when contact with blood, bodily fluids, or other infectious agents may occur. Transmission-based precautions are indicated for use when patients are suspected or known to be colonized with an infectious agent. There are three distinct categories, including contact, droplet, and airborne precautions, and these are always used in addition to standard precautions. Selection of the precautionary method to be used depends on the likely mode of transmission of the infectious agent. Contact precautions are recommended for use in preventing the spread of C. difficile and other agents that are spread through contact with the patient-care environment.44

When contact precautions are in place, healthcare workers are required to wear gown and gloves upon entering the patient's room and to remove this protective equipment upon exiting the patient's room. Proper hand hygiene should always be performed following the removal of gloves. Ideally, patients placed under contact precautions should be isolated in their own rooms, or at least cohorted with other patients with the same infection. When neither option is available, the appropriate staff should be consulted to determine the best location for the patient that will minimize the spread of infection to others. These measures are intended to prevent the spread of infectious agents through the environment and on the hands of healthcare workers.⁴⁴ Patients with active symptoms of infection are thought to a be primary source of spread for CDAD; thus, measures to reduce contamination of their surrounding environment are crucial for prevention.

Gloves are crucial in protecting healthcare workers and patients from infectious agents that can be spread through the environment via their hands. In a prospective controlled trial that implemented a glove-use policy-and included educational elements and increased availability of supplies-CDI rates were significantly lowered to 1.5 cases per 1,000 patients discharged, from an initial rate of 7.7 per 1,000 discharges.⁴⁵ Gloves are particularly useful in light of the fact that hand hygiene compliance rates are typically quite low, and that pathogens may remain on the hands even after hand washing is performed.³⁶ Staff must be educated on performing hand hygiene following the removal of gloves, as the use of this protective equipment is not a substitute for hand hygiene but rather an extra precautionary measure. Gloves should be made readily available, as their selection is dependent on hand size, latex allergies, tasks performed, and chemical or infectious agents that may be contacted.

Although the spread of C. difficile has not been shown to occur as a result of contamination on clothing and staff uniforms, the use of gowns is still a warranted measure to protect exposed areas of the body and clothing.¹⁷ Workers who wear protective gowns are also more likely to practice proper hand hygiene or glove use. Gowns are also more visible to staff who may be monitoring compliance with contact precautions, and thus may serve as a proxy for measuring appropriate glove use.⁴⁶ Gowns should be put on before entering the patient's room and worn in anticipation of any interaction with a patient or contaminated equipment and environment, including all instances for patients that are placed under contact precautions. Gowns should be available in varying sizes to ensure staff is properly protected from the neck to mid-thigh or lower. Care should be taken when removing the gown to ensure the contaminated side is rolled into a bundle and thrown away.44

continued >



COLORADO INFECTION PREVENTION COLLABORATIVE

It is recommended that contact precautions for *C. difficile* be put in place in as timely a fashion as possible to minimize the risk of spread through the patient-care environment. A positive lab test should be communicated to the appropriate infection prevention and patient-care staff to ensure isolation occurs as promptly as possible. Use of a laboratory-based alert system is a method of providing this immediate notification. A lab-alert tracking tool is included in your tool kit to assist in gauging whether timely notifications are taking place. In healthcare facilities experiencing unacceptably high rates of CDI despite adherence to best practices, contact precautions may be instituted based on provider suspicion and the onset of symptoms, such as uncontrolled diarrhea.¹⁰

The decision on when to discontinue contact precautions and patient isolation is not well defined. Recommendations by the CDC specify that precautions should remain in place for the duration of a patient's illness or until the patient no longer has diarrhea. Some experts have recommended precautions remain in place for up to 48 hours after a patient's symptoms resolve, which may be considered in facilities where rates are high despite adherence to preventive measures.¹⁰ Yet others have stated a patient should remain in isolation until they are discharged from the facility. This ambivalence comes from the thought that patients may still contaminate their surroundings even if non-symptomatic. In general, the patient with active symptoms is the main source of transmission for nosocomial C. difficile; therefore, discontinuation that coincides with the patient becoming asymptomatic is reasonable and recommended.17,36



THE GUIDELINES

In 2007, CDC/HICPAC released the "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings."⁴⁴ The recommendations presented are intended for use by a variety of healthcare facilities, including hospitals and long-term care, ambulatory care, home care, and hospice facilities. The guideline provides updates and expands on information in the preceding guideline published in 1996, emphasizing new concerns with hospital-acquired infections. The following is an adaptation of these guidelines that applies to patients with *C. difficile*. For the full document, visit: <u>http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf</u>.

RECOMMENDATIONS

These recommendations are designed to prevent transmission of infectious agents among patients and healthcare personnel in all settings where healthcare is delivered. The CDC/HICPAC system for categorizing recommendations is as follows:

	RANKING SYSTEM
Category IA	Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.
Category IB	Strongly recommended for implementation and supported by certain experimental, clinical, or epidemiologic studies, as well as a strong theoretical rationale.
Category IC	Required for implementation, as mandated by federal or state regulation or standard.
Category II	Suggested for implementation and supported by suggestive clinical or epidemiologic studies, or a theoretical rationale.
Unresolved Issue	No recommendation is offered. No consensus or insufficient evidence exists regarding efficacy.

TRANSMISSION-BASED PRECAUTIONS

I. General Principles

In addition to standard Precautions, use transmission-based precautions for patients with documented or suspected infection or colonization with highly transmissible or epidemiologically important pathogens for which additional precautions are needed to prevent transmission (IA).

Extend duration of transmission-based precautions (e.g., droplet, contact) for immunosuppressed patients with viral infections due to prolonged shedding of viral agents that may be transmitted to others (IA).

II. Contact Precautions

Use contact precautions as recommended in Appendix A for patients with known or suspected infections or evidence of syndromes that represent an increased risk for contact transmission. For specific recommendations for use of contact precautions for colonization or infection with MDROs, go to the MDRO guideline: <u>www.cdc.gov/ncidod/dhqp/pdf/ar/</u> <u>mdroGuideline2006.pdf</u>.

III. Patient Placement

In acute care hospitals, place patients who require contact precautions in a single-patient room when available (IB).

When single-patient rooms are in short supply, apply the following principles for making decisions on patient placement: prioritize patients with conditions that may facilitate transmission (e.g., uncontained drainage, stool incontinence) for single-patient room placement (II).

Place together in the same room (cohort) patients who are infected or colonized with the same pathogen and are suitable roommates (IB).

continued >



COLORADO INFECTION PREVENTION COLLABORATIVE C. DIFFICILE INFECTIONS

THE GUIDELINES

If it becomes necessary to place a patient who requires contact precautions in a room with a patient who is not infected or colonized with the same infectious agent:

- Avoid placing patients on contact precautions in the same room with patients who have conditions that may increase the risk of adverse outcome from infection or that may facilitate transmission (e.g., those who are immunocompromised, have open wounds, or have anticipated prolonged lengths of stay) (II).
- Ensure that patients are physically separated (i.e., more than 3 feet apart) from each other. Draw the privacy curtain between beds to minimize opportunities for direct contact (II).
- Change protective attire and perform hand hygiene between contact with patients in the same room, regardless of whether one or both patients are on contact precautions (IB).

In long-term-care and other residential settings, make decisions regarding patient placement on a case-by-case basis, balancing infection risks to other patients in the room, the presence of risk factors that increase the likelihood of transmission, and the potential adverse psychological impact on the infected or colonized patient (II).

In ambulatory settings, place patients who require contact precautions in an examination room or cubicle as soon as possible (II).

IV. Use of Personal Protective Equipment

Gloves

Wear gloves whenever touching the patient's intact skin or surfaces and articles in close proximity to the patient (e.g., medical equipment, bed rails). Don gloves upon entry into the room or cubicle (IB).

Gowns

Wear a gown whenever clothing will have direct contact with the patient or potentially contaminated environmental surfaces or equipment in close proximity to the patient. Don gown upon entry into the room or cubicle. Remove gown and observe hand hygiene before leaving the patient-care environment (IB).

After gown removal, ensure that clothing and skin do not contact potentially contaminated environmental surfaces that could result in the possible transfer of microorganism to other patients or environmental surfaces (II).

V. Patient Transport

In acute care hospitals, long-term care hospitals and other residential settings, limit transport and movement of patients outside of the room to medically necessary purposes (II).

When transport or movement in any healthcare setting is necessary, ensure that infected or colonized areas of the patient's body are contained and covered (II).

Remove and dispose of contaminated PPE and perform hand hygiene prior to transporting patients on contact precautions (II).

Don clean PPE to handle the patient at the transport destination (II).

VI. Patient-care equipment and instruments/devices

Handle patient-care equipment and instruments/devices according to Standard Precautions (IB/IC).

In acute care hospitals, long-term care hospitals and other residential settings, use disposable noncritical patientcare equipment (e.g., blood pressure cuffs) or implement patient-dedicated use of such equipment. If common use of equipment for multiple patients is unavoidable, clean and disinfect such equipment before use on another patient (IB).

continued >



COLORADO INFECTION PREVENTION COLLABORATIVE C. DIFFICILE INFECTIONS

THE GUIDELINES

VII. In home-care settings

Limit the amount of nondisposable patient care equipment brought into the home of patients on contact precautions. Whenever possible, leave patient-care equipment in the home until discharge from home-care services (II).

If noncritical patient-care equipment (e.g., stethoscope) cannot remain in the home, clean and disinfect items before taking them from the home using a low- to intermediate-level disinfectant. Alternatively, place contaminated reusable items in a plastic bag for transport and subsequent cleaning and disinfection (II).

In ambulatory settings, place contaminated reusable noncritical patient-care equipment in a plastic bag for transport to a soiled utility area for reprocessing (II).

VIII. Environmental Measures

Ensure that rooms of patients on contact precautions are prioritized for frequent cleaning and disinfection (at least daily) with a focus on frequently touched surfaces (e.g., bed rails, overbed table, bedside commode, lavatory surfaces in patient bathrooms, doorknobs) and equipment in the immediate vicinity of the patient (IB).

Discontinue contact precautions after signs and symptoms of the infection have resolved or according to pathogen-specific recommendations in Appendix A (IB).

TYPE AND DURATION	A OF PRECAUTIONS RECOM	PPENDIX A: AMENDED FOR SELECTED IN	FECTIONS AND CONDITIONS
INFECTION	ТҮРЕ	DURATION	PRECAUTIONS
Gastroenteritis	Standard precautions		• Use contact precautions for diapered or incontinent persons for the duration of illness or to control institutional outbreaks for gastroenteritis caused by <i>C</i> . <i>difficile</i>
C. difficile	Contact precautions	Duration of illness	 Discontinue antibiotics if appropriate. Do not share electronic thermometers; ensure consistent environmental cleaning and disinfection. Hypochlorite solutions may be required for cleaning if transmission continues. Hand washing with soap and water is preferred because of the absence of sporicidal activity of alcohol in waterless antiseptic hand rubs.

COLORADO INFECTION PREVENTION COLLABORATIVE

C. DIFFICILE INFECTIONS

STAFF COMPLIANCE AND TRAINING

Strict adherence to contact precautions by healthcare staff is a significant factor in reducing the spread of hospitalacquired infections. As with basic hand hygiene practices, adherence to contact precautions has room for improvement. An observational study conducted in a 900-bed hospital for 11 months assessed adherence to the donning of gowns upon entry to patient rooms under contact precautions and found an overall compliance rate of 73%. In this study, female staff members had better adherence compared with male staff, which has also similarly been demonstrated in studies of hand hygiene. Among types of healthcare workers, physicians were shown to have the worst adherence (67%), followed by nursing staff (78%); physical therapists and respiratory therapists were among the best, with 90% and 96% compliance, respectively.46 Clock et al. measured the adherence to contact precautions more broadly and estimated a 67% adherence rate for wearing gown and gloves upon room entry, 63.5% adherence to proper glove disposal, and 77.1% adherence to proper gown disposal upon exiting a patient room. The most frequently observed violation was the failure to dispose of contaminated gloves upon exit from the room.47

A study conducted in 2001 surveyed 2,000 randomly sampled healthcare workers about their knowledge and attitudes toward adhering to contact precautions. The study found the most important reason for not following current guidelines was a lack of knowledge (47%), followed by lack of time (41%), and finally a lack of means to engage in the appropriate behavior, such as availability of supplies (29%).⁴⁸ Rather than reviewing guidelines, healthcare workers were more likely to contact infection prevention staff with questions and requests for specific information. Education of staff in combination with the availability of supplies is necessary to improving adherence to contact precautions compliance. The Centers for Disease Control and Prevention and the National Center for Infectious Diseases has developed a 12-minute video that demonstrates these techniques and can be used for training staff. Posters describing the proper procedures for donning and removal of gowns and gloves are included in your tool kit. The video and posters are available for purchase from the CDC and are available at <u>http://www.cdc.gov/HAI/prevent/ppe.</u> <u>html</u>. This website also features a presentation slide set for infection control practitioners to help train other staff on the appropriate selection and use of personal protective equipment.





COLORADO INFECTION PREVENTION COLLABORATIVE

ADVERSE EFFECTS OF PATIENT ISOLATION

Current guidelines recommend single-patient rooms with private bathrooms as the preferred method of isolation for patients with *C. difficile* However, this type of isolation may not always be possible given hospital infrastructure and bed occupancy. Patients may have higher rates of infection when admitted to double-occupancy rooms compared to singleoccupancy rooms.¹⁷ Ben-Abraham et al. noted a reduction in the average number of hospital-acquired infections per patient in a cohort study of pediatric ICU patients following the introduction of single isolation rooms.⁴⁹ Other studies have demonstrated that being in the same room as an infected patient is not always a risk factor for transmission; rather consideration of each patient on a case-by-case basis, given local infrastructure, is warranted.⁴⁴

Once a decision has been made that patient isolation is warranted, additional steps may be taken to ensure that the comfort and well-being of the patient are considered during treatment. A study published in 2003 evaluated depression and anxiety levels in patients isolated for MRSA or VRE infection and found that isolation negatively affects mood and raises anxiety levels.⁵⁰ Patients with more severe illness who have been placed in isolation similarly report feelings of helplessness.⁵⁰ The most significant deprivation noted was a lack of human touch.⁵¹ Loss of companionship, boredom, reduced movement, lack of interaction, and a lack of information about the infection and reasons for isolation may lead to frustration, anger, and feelings of neglect. Some patients may interpret reduced interaction with nurses as a fear of contracting infection, rather than nurses having lack of time or the lack of practicality inherent in the gownand-glove process. Patients' feelings of being unclean, dirty, and infected can create stigma and worsen any feelings of depression.52

Tips to Improve Care for Patients in Isolation⁵²

- Place patients in rooms with windows or a view to the ward when possible.
- Provide books, magazines, television and other activities if the patient is well enough.
- Educate patients and family to help alleviate the stress and anxiety that may occur with being placed in isolation.
- Ensure isolated patients are visited by healthcare staff, even though it may be more time-consuming and difficult.

Quality of care may be compromised for patients placed in isolation. It has been estimated that healthcare workers are half as likely to enter a patient's room when the patient is in isolation.⁵³ While this may seem unavoidable, given the physical barriers and limitations placed on staff when isolation procedures are put in place, efforts should be made to ensure that patients are receiving quality care. A strong relationship has been demonstrated between patient isolation and reduced patient satisfaction and standard of care, and these patients may be twice as likely to experience preventable adverse events such as pressure ulcers and falls.⁵⁴ Satisfaction was compromised as isolated patients had negative perceptions of treatment, reduced access to staff, and felt a lack of communication.



COLORADO INFECTION PREVENTION COLLABORATIVE

ISOLATION SIGNS

The timeliness of placing a patient under transmissionsbased precautions and isolation is a key factor in breaking the spread of *C. difficile* or other organisms throughout the patient-care environment. Once the decision for contact precautions or isolation has been made, an isolation sign should be placed on the patient's door or other area in order to notify staff and visitors of the need for any necessary precautions.

In 2010, the Colorado Hospital Association, in collaboration with various hospital infection preventionists (IPs), worked to develop standardized colors for isolation signs to quickly identify isolation precautions. Standardized colors help healthcare workers avoid confusion and aid in quick identification of precautions to be used. As part of this project, the following colors were assigned to each isolation sign:

- Magenta—contact precautions
- Brown—contact enteric precautions
- Orange—droplet precautions
- Blue—airborne precautions

These signs are available for order from CHA and have been printed on special paper, which can cling to most surfaces yet is non-adhesive and reusable. A sample of the isolation sign that could be used outside a *C. difficile* patient's room has been included in your tool kit. If you would like more information about these signs or would like to order, please contact CHA directly or use the order form provided in your tool kit.

Additionally, supplies must be readily and easily available for staff and visitors in order for the use of contact precautions to be an effective strategy in preventing the spread of infection. Consider creating isolation kits that contain the appropriate sign, gowns, gloves and dedicated equipment, such as disposable blood pressure cuffs and stethoscopes, to be used while the patient is in isolation. Include patienteducation pamphlets that provide information about the infectious agent and reasons for isolation. Assigning responsibility for ensuring the continued availability of supplies on an isolation cart placed outside of the room will reduce the chance of supplies running low.

COLORADO INFECTION PREVENTION COLLABORATIVE

C. DIFFICILE INFECTIONS

DEDICATED EQUIPMENT

CDC's 2007 "Guideline for Isolation Precautions" recommends the use of disposable noncritical patient-care equipment or of dedicated equipment for patients under contact precautions. This recommendation garners a level IB ranking. When this is not possible, cleaning and disinfection of patient-care equipment between patients is mandatory.⁴⁴

In particular, the replacement of electronic rectal thermometers with disposables, or oral or tympanic thermometers, has been shown to significantly reduce CDI infection rates.^{17,55} Other commonly used patient-care items such as blood-pressure cuffs and stethoscopes have also been shown as potential means of spreading organisms through the environment.^{56,57}

STETHOSCOPES

Only 22% of healthcare workers state that they regularly clean their stethoscopes, and some providers do not like to use disposable stethoscopes due to their inferior quality.⁵² Cleaning with alcohol wipes could minimize the chance of spreading infection; however, there are no studies demonstrating that this has been effective in reducing the spread of *C. difficile*. Using dedicated or disposable equipment is ideal for preventing the spread of *C. difficile*. Consider making disposable stethoscope diaphragm covers available to improve compliance and reduce the spread of infection.

Stethoscope shields are inexpensive and easy-to-use disposable protective covers that are placed on the stethoscope's diaphragm. The shields can be placed on contact isolation carts or next to examination-glove dispensers and are discarded following use on the patient.

	MANUFACTURERS	
STETHOCAP	SCOPESHIELD	STETHGUARD
www.stethocap.com or call 866-691-4181	www.scopeshield.com or call 888-364-5720	www.stethguard.com

TOOL KIT ARTICLE ABSTRACT

Proposed Checklist of Hospital Interventions to Decrease the Incidence of Healthcare-Associated Clostridium difficile Infection

The article included in your tool kit, "Proposed Checklist of Hospital Interventions to Decrease the Incidence of Healthcare-Associated *Clostridium difficile* Infection," describes a bundle approach used by one hospital to reduce outbreak levels of *C. difficile*. This bundle emphasizes timely lab-alert systems and the use of contact precautions posters, as well as the fostering of communication among staff, to ensure appropriate action is taken when needed.

Abbett SK, Yokoe DS, Lipsitz SR, et al. Proposed Checklist of Hospital Interventions to Decrease the Incidence of Healthcare-Associated *Clostridium difficile* Infection. Infection Control and Hospital Epidemiology 2009; 30: 1062–1069.



COLORADO INFECTION PREVENTION COLLABORATIVE C. DIFFICILE INFECTIONS

Colorado Clostridium difficile Collaborative Audit of Laboratory-based Alert System

Location of <i>Clostridium difficile</i> positive Patient	Date (Time) specimen SUBMITTED	Date (Time) patient ISOLATED	Time (hours) between SUBMITTED and ISOLATED

If time (hours) between SUBMITTED and ISOLATED is consistently > than 24 hours, consider presumptive isolation strategies

SECUENCIA PARA PONERSE EL EQUIPO DE PROTECCIÓN PERSONAL (PPE)	El tipo de PPE que se debe utilizar depende del nivel de precaución que sea necesario; por ejemplo, equipo Estándar y de Contacto o de Aislamiento de infecciones transportadas por gotas o por aire.	 1. BATA 1. BATA 1. BATA 1. Cubra con la bata todo el torso desde el cuello hasta las rodillas, los brazos hasta la muñeca y dóblela alrededor de la espalda 1. Átesela por detrás a la altura del cuello y la cintura 	 2. MÁSCARA O RESPIRADOR 2. MÁSCARA O RESPIRADOR Asegúrese los cordones o la banda elástica en la mitad de la cabeza y en el cuello Ajústese la banda flexible en el puente de la nariz Acomódesela en la cara y por debajo del mentón Verifique el ajuste del respirador 	 3. GAFAS PROTECTORAS O CARETAS 3. GAFAS PROTECTORAS O CARETAS Colóquesela sobre la cara y los ojos y ajústela 4. GUANTES Extienda los guantes para que cubran la parte del puño en la bata de aislamiento 	UTILICE PRÁCTICAS DE TRABAJO SEGURAS PARA PROTEGERSE USTED MISMO Y LIMITAR LA PROPAGACIÓN DE LA CONTAMINACIÓN	 Mantenga las manos alejadas de la cara Limite el contacto con superficies Cambie los guantes si se rompen o están demasiado contaminados Realice la higiene de las manos
SEQUENCE FOR DONNING PERSONAL PROTECTIVE EQUIPMENT (PPE)	The type of PPE used will vary based on the level of precautions required; e.g., Standard and Contact, Droplet or Airborne Infection Isolation.	 1. GOWN Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back Fasten in back of neck and waist 	 2. MASK OR RESPIRATOR Secure ties or elastic bands at middle of head and neck Fit flexible band to nose bridge Fit snug to face and below chin Fit-check respirator 	 3. GOGGLES OR FACE SHIELD Place over face and eyes and adjust to fit 4. GLOVES Extend to cover wrist of isolation gown 	USE SAFE WORK PRACTICES TO PROTECT YOURSELF AND LIMIT THE SPREAD OF CONTAMINATION	 Keep hands away from face Limit surfaces touched Change gloves when torn or heavily contaminated Perform hand hygiene

SEQUENCE FOR REMOVING PERSOI PROTECTIVE EQUIPMENT (PPE)	NAL	SECI	JENCIA PARA QUITARSE EL EQUIPO E PROTECCIÓN PERSONAL (PPE)	
pirator, remove PPE at doorway or in anteroom. Remove at room and closing door.	e respirator after	Con la excepción del Quítese el respirador	respirador, quítese el PPE en la entrada de la puerta o en la antesala. después de salir de la habitación del paciente y de cerrar la puerta.	
f gloves is contaminated! side of glove with opposite gloved hand; peel off oved glove in gloved hand ers of ungloved hand under remaining glove at wrist off over first glovet oves in waste container			 GUANTES ¡El exterior de los guantes está contaminado! Agarre la parte exterior del guante con la mano opuesta en la que todavia tiene puesto el guante y quíteselo Sostenga el guante que se quitó con la mano enguantada Deslice los dedos de la mano sin guante por debajo del otro guante que no se ha quitado todavía a la altura de la muñeca Quítese el auante de manera que acabe cubriendo el primer 	
OR FACE SHIELD f goggles or face shield is contaminated! v, handle by head band or ear pieces esignated receptacle for reprocessing or in tainer			guante Arroje los guantes en el recipiente de deshechos 2. GAFAS PROTECTORAS O CARETA i jEl exterior de las gafas protectoras o de la careta está contaminado!	
nt and sleeves are contaminated! ies			cabeza o de las piezas de las orejas Colóquelas en el recipiente designado para reprocesar materiales o de materiales de deshecho	
from neck and shoulders, touching inside of gown onl i inside out Il into a bundle and discard		je starter and the second seco	 3. BATA i.la parte delantera de la bata y las mangas están contaminadas! Desate los cordones Tocondo solamente el interior de la bata pásela por envinado 	
RESPIRATOR ask/respirator is contaminated — DO NOT TOUCH! tom, then top ties or elastics and remove			 del cuello y de los hombros Voltee la bata al revés Dóblela o enróllela y deséchela 	
waste container			 4. MÁSCARA O RESPIRADOR La parte delantera de la máscara o respirador está contaminada — iNO LA TOQUE! Primero agarre la parte de abajo, luego los cordones o banda elástica de arriba y por último quítese la máscara o respirador Arrójela en el recipiente de deshechos 	
RFORM HAND HYGIENE IMMEDIATELY AFTER REMOVING	ALL PPE	EFECTÚE LA HI	IGIENE DE LAS MANOS INMEDIATAMENTE DESPUÉS DE QUITARSE	

Except for respirator, remove PPE at do leaving patient room and closing door.

1. GLOVES

- Outside of gloves is contaminated
- Grasp outside of glove with oppos
- Hold removed glove in gloved han
 Slide fingers of ungloved hand und
 - Peel glove off over first glovet
- Discard gloves in waste container .

2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield
 To remove, handle by head band
- Place in designated receptacle for waste container

3. GOWN

- Gown front and sleeves are contait
 - Unfasten ties
- Pull away from neck and shoulder

 - Turn gown inside out Fold or roll into a bundle and disc È

4. MASK OR RESPIRATOR

- Front of mask/respirator is contam
 - Grasp bottom, then top ties or elast
 - Discard in waste container





CUALQUIER EQUIPO DE PROTECCIÓN PERSONAL

Special Precautions (Contact Precautions)

Everyone **must** perform hand hygiene upon entering the patient's room. Everyone **must** wash their hands with soap and water upon exiting the room. Do **not** use waterless hand rub when exiting the room.

Gown



¡Vea las fotos abajo! Favor de usar el siguiente equipo antes de entrar a la habitación

Please put on the following items before entering the room:



• Gloves



Use dedicated equipment



Mask Precautions (Droplet Precautions)

Everyone <u>must</u> wash hands or use an alcohol-based hand rub when entering or leaving the patient's room.

¡Vea las fotos abajo! Favor de usar el siguiente equipo antes de entrar a la habitación

Please put on the following item before entering the room:



Surgical Mask

Closed Door and Special Mask Precautions (Arborne Precautions)

Everyone <u>must</u> wash hands or use an alcohol-based hand rub when entering or leaving the patient's room.

¡Vea las fotos abajo! Favor de usar el siguiente equipo antes de entrar a la habitación

Please put on the following item before entering the room:



 N95 Respirator Mask or PAPR



Keep door closed

This patient needs to be placed in a negative airflow pressure room. This patient must wear a surgical mask during transport.



Everyone **must** wash hands or use an alcohol-based hand rub when entering or leaving the patient's room.

¡Vea las fotos abajo! Favor de usar el siguiente equipo antes de entrar a la habitación

Please put on the following items before entering the room:



Gloves



• Gown





Use dedicated equipment

Isolation Sign Order Form

Facility Name:	
Shipping Address:	
Contact Person:	
Phone Number:	

LANDSCAPE			PORTRAIT				
Poster	Quantity	Price/Sheet	Subtotal	Poster	Quantity	Price/Sheet	Subtotal
Cristen Door and Special March Princ Suttions Vers las foton abolo Marchanter States about Marchanter		\$0.95				\$0.95	
A series of the		\$0.95				\$0.95	
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Subtotal							

Subtotal (Landscape)	
Subtotal (Portrait)	
GRAND TOTAL	

Complete the order form and send it along with a check payable to *Colorado Hospital Association* to 7335 E. Orchard Road, Greenwood Village, CO 80111, Attn: Crystal Berumen

Isolation Precautions: Preventing Infection

A Guide for Patients

What are isolation precautions?

Isolation precautions means you are placed in a protective environment and healthcare workers must wear protective equipment to prevent the spread of germs to others. Being placed under isolation will help keep you and other patients safe and protected from germs. Your healthcare provider has placed you under 'Isolation Precautions' to help keep everyone safe and help you recover.

Isolation means:

- ✓ You may be placed in a private room during your stay at the hospital.
- ✓ A sign will be placed outside your door describing the type of isolation you are under. The sign is there to notify staff that they must follow special procedures before entering and leaving your room. Your privacy is always protected and the type of illness you have is *not* displayed on your door.
- ✓ You should remain in your room to prevent the spread of infection. If you need to leave your room please ask a staff member to assist you because you may need to follow special instructions.

Are there different types of isolation?

Yes, there are several types depending on the type of germ and how the germ is spread to others. Your healthcare provider should explain your illness to you and be sure you understand what precautions are necessary. If you do not see your healthcare provider using protective clothing or washing their hands, it is okay to remind them to do so.

Contact Isolation: If you are placed under contact precautions, the germ you have may be spread to others by touching other people or objects in your room. To prevent the germ from spreading, anyone who enters your room should:

- ✓ Wear gowns and gloves and throw them away before they leave the room.
- ✓ Wash hands with soap and water or use a hand sanitizer after gloves are removed.

Droplet Isolation: If you are placed under droplet precautions, the germ you have may be spread to others by sneezing and coughing. To prevent the germ from spreading, anyone who enters your room should:

- ✓ Wear a mask and throw it away before they leave the room.
- ✓ Wash hands with soap and water or use a hand sanitizer before entering the room and after removing the mask.

Respiratory/Airborne Isolation: If you are placed under airborne precautions, the germ you have may be spread to others through the air. To prevent the germ from spreading, anyone entering your room should:

- ✓ Wear a special respirator mask and throw this mask away after leaving your room.
- Wash hands with soap and water or use a hand sanitizer before entering the room and after removing the mask.

What do I do if I need to leave the room?

You should remain in your room as much as possible. If you need to leave for a medical test or to walk in the hallway, please ask one of your healthcare provider for assistance. You may need to wear protective clothing. Always wash your hands before you leave your room.

Do my friends and family need to follow these rules?

Yes, anyone who enters your room should follow these rules. Friends and family should always wash their hands with soap and water or use a hand sanitizer for at least 15 seconds to protect themselves and prevent the spread of germs. If your visitors feel sick they should not come to visit so you are able to get better.

What can patients and hospital visitors do to help prevent the spread of germs?

The most important thing patients and visitors can do is wash hands thoroughly and wash them often. You should wash your hands with soap and water or a hand sanitizer for at least 15 seconds before you eat, after using the bathroom, before you leave your hospital room, after sneezing or coughing, or if you touch any of your body fluids.

It may be difficult for you and your family or other visitors to follow the isolation precautions, but your effort is needed to protect those around you and ensure you have a speedy recovery.

Remind your healthcare providers to wash their hands or wear protective equipment if you do not seem them doing so. Hospitals can be busy and healthcare workers sometimes need to be reminded.



The information on this handout has been adapted from Langone Medical Center's *Patient and Visitor's Guide to Isolation* and the Ohio State University Medical Center's *Isolation Precautions: To Prevent the Spread of Infection*.

ORIGINAL ARTICLE

Proposed Checklist of Hospital Interventions to Decrease the Incidence of Healthcare-Associated *Clostridium difficile* Infection

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BACKGROUND. The incidence and severity of *Clostridium difficile* infection (CDI) are increasing, and previously described interventions for controlling the spread of CDI are not easily generalized to multiple healthcare institutions.

OBJECTIVE. We tested prevention and treatment bundles to decrease the incidence of CDI and the mortality associated with CDI at our hospital.

DESIGN. Observational before-after study of adult patients admitted to a tertiary care, university-affiliated hospital during the period from January 2004 through December 2008.

METHODS. In January 2006, we launched an educational campaign and introduced a prevention bundle—a series of specific processes aimed at preventing the transmission of *C. difficile* among hospitalized patients, including enhanced isolation practices, laboratory notification procedures, and steps coordinating infection control and environmental services activities. In April 2006, we implemented a treatment bundle—a set of hospital-wide treatment practices aimed at minimizing the risk of serious CDI complications. We tracked quarterly incidence rates and case-fatality rates for healthcare-associated CDI cases at our hospital. Our main outcome was the healthcare-associated CDI incidence rate, measured as the number of healthcare-associated cases of CDI per 1,000 patient-days.

RESULTS. We followed patients for a total of 1,047,849 patient-days. The healthcare-associated CDI incidence rates fell from an average of 1.10 cases per 1,000 patient-days before intervention to 0.66 cases per 1,000 patient-days after intervention. This statistically significant decrease amounts to a 40% reduction in incidence after the intervention.

CONCLUSIONS. Our intervention was successful in reducing the incidence of CDI at our hospital. On the basis of our experience, we propose the use of a checklist of hospital interventions to decrease the incidence of healthcare-associated CDI.

Infect Control Hosp Epidemiol 2009; 30:1062-1069

The incidence and severity of Clostridium difficile infection (CDI) are increasing.12 The number of hospitalized patients in the United States for whom CDI was listed as a discharge diagnosis more than doubled during the period from 2000 through 2005 (ie, from 134,361 to 291,303 patients),3 and CDI-associated mortality rates are estimated to have more than quadrupled during the period from 1999 through 2004 (ie, from 5.7 to 23.7 cases per million population in the United States).4 This increasing severity has been linked to the emergence of a new strain of C. difficile that has been observed in the United States and in an increasing number of other countries.57 There is substantial financial burden associated with this changing epidemiology.8 A recent study9 estimates CDI-related hospital costs to be as much as \$6,326 per hospitalization. Because of the increasing incidence, severity, and costs associated with CDI, there is a substantial need for efforts to prevent exposure to and transmission of CDI, as well as to improve the treatment for patients who received a diagnosis of CDI.

Although antimicrobial use is viewed as the primary risk factor for developing CDI¹⁰ (with targeted antimicrobial use preferred),¹¹ widespread infection prevention efforts are also necessary for reducing the spread of CDI in a healthcare setting. Recently, the Society for Healthcare Epidemiology of America and the Infectious Diseases Society of America published recommendations for preventing CDIs in hospitals.¹² These guidelines described recommended strategies for acute care hospitals, including using contact precautions; cleaning and disinfecting equipment and the environment; implementing laboratory-based alert systems to notify infection prevention and control personnel about new diagnoses of CDI; conducting CDI surveillance; analyzing and reporting CDI data; educating healthcare personnel, housekeeping personnel, hospital administrators, as well as patients and their

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families about CDI; and measuring compliance with the hand-hygiene and contact-precaution recommendations of the Centers for Disease Control and Prevention or the World Health Organization. In addition, special approaches were described that can be considered by hospitals when the transmission of *C. difficile* continues despite implementation of basic practices. These special approaches include the use of hypochlorite-based environmental cleaning agents for cleaning of rooms once occupied by patients with CDI, the preferential use of soap and water (rather than alcohol-based hand disinfectant) for routine hand hygiene after contact with patients known or suspected to have CDI, and the initiation of antimicrobial stewardship programs.

These interventions are complex and involve changes in practices and policies that require difficult behavioral changes on the part of healthcare workers at multiple points in care. The guidelines did not specify methods for successful implementation. For this reason, they have proven difficult to implement for the entire hospital population.^{11,13,14} For quality improvement, the grouping of practices in bundles and in checklists has proven to be a highly successful strategy in multiple medical domains.^{15,17} The principle is to identify for teams of healthcare workers the critical actions that must be performed daily, assigning specific responsibilities to individual personnel and ensuring that the information contained in the guidelines is translated into behavioral changes.

In late 2005, routine infection control surveillance for CDI at our hospital revealed an upward trend in CDI rates, and an additional investigation demonstrated an increase in the number of patients with severe infection necessitating colectomy or intensive care as well as an increase in the number of deaths attributable to CDI complications. Therefore, in January of 2006, we initiated an intervention that involved the implementation of an educational campaign, a prevention bundle, and a treatment bundle all aimed at decreasing the incidence and severity of CDI at our hospital.

METHODS

Baseline Condition

Brigham and Women's Hospital is a 750-bed tertiary care, university-affiliated teaching hospital in Boston, Massachusetts. Prior to the intervention, its hospital-wide infection control policies for patients with diarrhea due to CDI were consistent with the Centers for Disease Control and Prevention recommendations and included the use of contact precautions (ie, single-patient rooms, alcohol-based hand hygiene, and the donning of gowns and gloves prior to patient contact). Positive *C. difficile* toxin test results were communicated to patient-care staff by the hospital's microbiology laboratory staff, and the threshold for suspecting and initiating workup for CDI was variable, depending on the judgment of individual clinicians. Surveillance for all incident cases of healthcare-associated CDI was performed routinely by the hospital's infection preventionists. A case of healthcare-associated CDI was defined as a hospitalized patient whose first positive *C. difficile* toxin test result was at least 3 days after hospital admission or within 4 weeks of a previous discharge from the hospital, unless there were intervening hospitalizations at other healthcare facilities. Healthcare-associated CDI rates were calculated using a denominator of patient-days, excluding patient-days attributed to newborns in the neonatal intensive care unit. At baseline, there was no set of treatment guidelines implemented, no mechanism to confirm adherence to prevention guidelines, and no specific expectation for soap-based hand washing or for cleaning of rooms with a hypochlorite-based disinfectant.

Intervention

Our intervention included 3 components: an educational campaign, a prevention bundle, and a treatment bundle. By use of this intervention, we aimed to increase prevention adherence and add enhanced infection prevention practices—including washing hands with soap and water after patient contact and cleaning patient rooms with a hypochlorite-based disinfectant—for all patients with clinically suspected CDI, in addition to all patients with laboratory-confirmed CDI. We also implemented basic treatment guidelines for the first time. The prevention and treatment bundles assigned specific responsibilities to individual healthcare personnel.

Educational Campaign

When introducing our prevention bundle, we initiated an educational outreach campaign designed to teach nurses, physicians, physician assistants, environmental services personnel, and hospital leaders about the increasing incidence and severity of CDI in our hospital and to encourage them to increase their level of suspicion for this diagnosis and to promptly initiate appropriate diagnostic testing, isolation precautions, and treatment. In addition, we emphasized the importance of consistent adherence to hand hygiene and isolation precautions when caring for patients with presumed or confirmed CDI.

Prevention Bundle

We designed a CDI prevention bundle that specified individual responsibilities for physicians, physician assistants, nurse practitioners, floor nurses, microbiology staff, infection control practitioners, and environmental services personnel. This prevention bundle included specific infection control practices, laboratory notification procedures, and steps to be taken in coordinating infection control and environmental services that aimed to decrease the transmission of *C. difficile* between patients (ie, a prevention checklist; Figure 1). The bundle begins with "provider suspicion," which is defined as the ordering of a stool *C. difficile* toxin test (Figure 1).

Because of the increase in the incidence of CDI at Brigham and Women's Hospital and reports of the increasing severity of the disease, we elected to incorporate some infection pre-

Clostridium difficile Infection (CDI) Checklist

Hospital interventions to decrease the incidence and mortality of healthcare-associated C. difficile infections

Prevention Checklist	Treatment Checklist
 When an MD, PA, NP, or RN suspects a patient has CDI: Physician, Physician Assistant, or Nurse Practitioner: Initiate Contact Precautions Plus Order stool C. difficile toxin testing Discontinue non-essential antimicrobials Discontinue all anti-peristaltic medications Registered Nurse: Obtain stool sample for C. difficile toxin test Place patient in single-patient room Place Contact Precautions Plus sign on patient's door Ensure that gloves and gowns are easily accessible from patient's room 	 When an MD, PA, or NP diagnoses mild CDI: All of the following criteria are present: diarhea (<6 BM/day), no fever, WBC<15,000, no peritoneal signs, and no avidence of sepsis Physician, Physician Assistant, or Nurse Practitioner: Initiate oral metronidazole at dose 500mg every 8 hours If no clinical improvement by 48-72 hours after diagnosis, treat patient as moderate CDI Continue therapy for at least 14 days total and at least 10 days after symptoms have abated
 Place dedicated stethoscope in patient's room Remind staff to wash hands with soap and water following patient contact Microbiology Laboratory Staff Person: Call relevant patient floor with positive <i>C. difficile</i> toxin test result Provide daily list of positive test results for Infection Control Infection Control Practitioner: Check microbiology results daily for positive <i>C. difficile</i> toxin results Call relevant floor to confirm that patient with positive <i>C. difficile</i> toxin results Call relevant floor to confirm that patient with positive <i>C. difficile</i> toxin results is in a single-patient room and that the <i>Contact Precautions Plus</i> sign is on the patient's door Flag the patient's <i>C. difficile</i> status in the hospital's clinical information system or in the patient is on <i>Contact Precautions Plus</i> Environmental Services Staff Person: Prior to discharge cleaning, check for <i>Contact Precautions Plus</i> sign on the patient's door If <i>Contact Precautions Plus</i> sign is on the door, clean the room with a bleach-based cleaning agent Confirm for supervisor that bleach-based cleaning agent was used for discharge cleaning for every patient on <i>Contact Precautions Plus</i> 	 When an MD, PA, or NP diagnoses moderate CDI: At least one of the following criterie is present: diarrhea (6-12 BM/day), Tever 37.5-38.5°C, WBC 15,000-25,000, or frankly visible stable lower gastrointestinal bleading Physician, Physician Assistant, or Nurse Practitioner: Initiate oral vancomycin at dose 250mg every 6 hours If no clinical improvement by 48 hours, add IV metronidazole at dose 500mg every 8 hours Consider obtaining infectious disease consultation Consider obtaining abdominal CT scan Continue therapy for at least 14 days total and at least 10 days after symptoms have abated When an MD, PA, or NP diagnoses severe CDI: At least 10 days after symptoms have abated When an MD, PA, or NP diagnoses severe CDI: At least 10 days after symptoms have abated Physician, Physician Assistant, or Nurse Physician, Physician Assistant, or Nurse Practitioner: Obtain immediate infectious disease consultation Obtain immediate general surgery consultation Obtain abdominal CT scan Initiate oral vancomycin at dose 250mg every 6 hours together with IV metronidazole at dose 500mg every 6 hours Following consultation with general surgery regarding its use, consider rectal vancomycin

Abbreviations. MD=medical doctor, PA=physician assistant, NP=nurse practitioner, RN=registered nurse, BM=bowet movement, WBC=white blood cell count, CT=computed tomography, (V=intravenous

FIGURE 1. Clostridium difficile infection checklist at Brigham and Women's Hospital.

vention practices recommended for outbreak settings into special and more stringent isolation precautions that we termed "contact precautions plus" (CPP), including cleaning rooms with a hypochlorite-based disinfectant after patient is discharged from hospital and emphasizing hand hygiene with soap and water after contact with patients with CDI. The CPP signs were brightly colored, facilitating both staff awareness and compliance (Figure 2).

The infection control practices in the prevention bundle were initiated when a provider suspected that a patient may


FIGURE 2. Contact precautions plus sign, as developed at Brigham and Women's Hospital for healthcare workers caring for patients with *Clostridium difficile* infection.

have CDI. Providers were then encouraged to start CPP, to order a *C. difficile* toxin test, and to discontinue all nonessential antimicrobials as well as all antiperistaltic medications.

The patient's nurse was responsible for obtaining a stool specimen for *C. difficile* toxin testing, for moving the patient to a single-patient room, and for placing a CPP sign outside the doors of the patient's room. In keeping with the CPP requirements, the nurse must ensure that adequate supplies of gloves and gowns are easily accessible outside of the patient's room, must place a stethoscope inside the patient's room for the patient's use only, and must urge all staff to wash their hands with soap and water after having had contact with the patient with suspected or confirmed CDI.

The next set of practices in the prevention bundle involved clinical laboratory notification procedures. The microbiology laboratory staff were responsible for calling the relevant hospital floor to notify the patient's nurse verbally after each positive *C. difficile* toxin test result. In addition, a list of positive *C. difficile* toxin test results was generated each day from the clinical microbiology database and automatically sent to the hospital's infection preventionists.

The infection preventionists were responsible for checking all microbiology results for positive *C. difficile* test results each weekday. Once informed of a patient's positive test result, the infection preventionist must contact the patient's floor to verify that the patient is in a single-patient room and that the CPP sign is posted on the patient's door. The preventionist then must activate a *C. difficile* flag in the electronic medical record to alert anyone accessing the patient's clinical information to the patient's CDI status. In addition, the preventionist must notify environmental services management each day about all patients on CPP. As a final step, environmental services personnel are trained to look for the CPP sign prior to cleaning a room after the patient is discharged from the hospital and to use a hypochlorite-based cleaning agent to clean rooms that have a CPP sign posted.

Treatment Bundle

A CDI treatment bundle (Figure 1) was created to standardize the treatment of patients with severe CDI at our institution and to provide guidelines for when to consider consulting the surgery department regarding a patient's need for a colectomy. The guidelines contained in the treatment bundle were the result of a multidisciplinary effort involving infectious disease physicians, general surgeons, infection control preventionists, and pharmacy staff. These guidelines recommended the specific actions for physicians, physician assistants, and nurse practitioners to take based on categories of CDI (including mild, moderate, and severe disease) determined by clinical and laboratory information. In particular, for patients meeting the criteria for severe CDI, the guidelines urged providers to obtain immediate consultations with the departments of infectious diseases and general surgery. The overall goal of these guidelines was to encourage timely and effective medical treatment and prompt surgical treatment, if appropriate, based on consultation with the surgery department, as a means of reducing the risk for serious complications and mortality resulting from CDI.

Implementation

We launched our educational campaign and prevention bundle in January 2006. The treatment bundle was introduced in April 2006.

Statistical Methods

We analyzed the aggregate number of cases of CDI and the aggregate number of patient-days over 20 different 3-month time periods. We defined 2 study time periods: the preintervention period (from January 2004 through March 2006) and the postintervention period (from April 2006 through December 2008). We analyzed the data for differences in outcomes between the pre- and postintervention periods. Our primary outcome was the rate of healthcare-associated CDI (estimated as the number of cases of healthcare-associated CDI per 1,000 patient-days) over each of the 20 different 3month time periods. Our secondary outcome was the CDI case-fatality rate (estimated as the number of deaths due to healthcare-associated CDI divided by the number of cases of healthcare-associated CDI, times 100) over each of the 20 different 3-month time periods. By means of Poisson regression analysis, log-linear models were used to determine the rates over time, as proposed by Holford18 and Laird and Olivier.19 In the log-linear models, we tested for trends over time and for changes before and after implementation of the checklists using Wald statistics, We also controlled for the possible confounding effects of an aggregate Charlson score (as a proxy for severity of illness) during the time period. A

Quarter	No. of cases of healthcare- associated CDI	No. of patient-days	Incidence rate, cases per 1,000 patient-days	No. of healthcare- associated deaths due to CDI	Case-fatality rate," %
2004					
Jan-Mar	40	48,647	0.82	0	0.00
Apr-Jun	35	44,639	0.78	0	0.00
Jul-Sep	69	41,279	1.67	1	1.45
Oct-Dec	42	54,121	0.78	0	0.00
2005					
Jan-Mar	50	49,988	1.00	1	2.00
Apr-Jun	52	45,370	1.15	4	1.92
Jul-Sep	52	41,060	1.27	3	5.77
Oct-Dec	57	54,713	1.04	3	5.26
2006					
Jan-Mar	79	51,447	1.54	3	3.80
Apr-Jun	48	47,320	1.01	1	2.08
Jul-Sep	36	56,796	0.63	1	2.78
Oct-Dec	38	55,036	0.69	1	2.63
2007					
Jan-Mar	44	55,482	0.79	2	4.55
Apr-Jun	41	56,159	0.73	0	0.00
Jul-Sep	31	56,599	0.55	2	6.45
Oct-Dec	27	56,368	0.48	1	3.70
2008					
Jan-Mar	36	57,371	0.63	1	2.78
Apr-Jun	31	57,606	0.54	0	0.00
Jul-Sep	37	58,412	0.63	0	0.00
Oct-Dec	36	59,436	0.61	0	0.00

TABLE 1. Incidence Rates and Case-Fatality Probability Rates for Healthcare-Associated Clostridium difficile Infection (CDI), by Quarter, at Brigham and Women's Hospital

* Estimated as the no. of deaths due to healthcare-associated CDI divided by the no. of cases of healthcareassociated CDI, times 100.

P value of less than .05 was considered to be statistically significant. All tests were 2-sided.

period included 431,264 patient-days, and the postintervention period included 616,585 patient-days.

RESULTS

The surveillance data encompassed 1,047,849 patient-days, from January 2004 to December 2008. The preintervention

The incidence rate of healthcare-associated CDI decreased from an average of 1.10 cases per 1,000 patient-days (95% confidence interval [CI], 1.00–1.21) during the preintervention period to 0.66 cases per 1,000 patient-days (95% CI,



FIGURE 3. Incidence rates of healthcare-associated *Clostridium difficile* infection (CDI) among patients hospitalized at Brigham and Women's Hospital (excluding newborns in the neonatal intensive care unit).

TABLE 2. Rates of *Clostridium difficile* Toxin Testing, by Quarter, at Brigham and Women's Hospital

		Rates tests pe			
Quarter	2004	2005	2006	2007	2008
Jan-Mar	21.6	30.2	32.1	35.8	29.9
Apr-Jun	22.3	34.7	40.4	33.0	28,6
Jul-Sep	25.7	34.7	30.2	32.5	29.6
Oct-Dec	23.7	28.2	33.2	31.7	30.4

0.60–0.72) during the postintervention period. This reduction was sustained for 21 months and amounted to a 40% decrease in the rate of healthcare-associated CDI (incidence rate ratio, 0.60 [95% CI, 0.52–0.68]; P < .001) after the implementation of the prevention bundle (Table 1 and Figure 3).

During the course of our study, the number of *C. difficile* toxin tests sent to the microbiology laboratory increased significantly from the preintervention period (rate, 28.0 tests per 1,000 patient-days [95% CI, 27.5–28.5]) to the postintervention period (rate, 32.1 tests per 1,000 patient-days [95% CI, 31.7–32.6]). There was a 15% increase in the rate of *C. difficile* toxin testing (testing rate ratio, 1.15 [95% CI, 1.12–1.17]; P < .001) after the implementation of the prevention bundle (Table 2).

Among patients with CDI, there was no statistically significant decrease in the probability of dying from CDI (Table 1). The case-fatality rate was 2.52% (95% CI, 1.44%–4.39%) before the prevention bundle was introduced and 2.22% (95% CI, 1.16%–4.21%) after the prevention bundle was introduced. The relative risk of dying from CDI during the postintervention period, compared with the preintervention period, was 0.88 (95% CI, 0.37–2.11; P = .77). Because of the small number of deaths due to healthcare-associated CDI, we would have had adequate power to detect a statistically significant difference only if there had been a relative risk of 0.1 or less in the probability of dying from CDI during the postintervention period, compared with during the preintervention period.

During the course of our study, the medical acuity of our hospitalized patients' CDI increased, as reflected by the aggregate Charlson scores over time (Table 3). There was a significant increase in the aggregate Charlson score over time. The Spearman rank correlation between time period and Charlson score was $\rho = 0.959$ (P < .001 for trend). In addition, on the basis of Poisson regression analysis, the aggregate Charlson score was not a statistically significant predictor of CDI over time (P = .455) (Table 3).

DISCUSSION

In our study, the implementation of our CDI educational campaign, prevention bundle, and treatment bundle was associated with a statistically significant, approximately 2-year decrease in the incidence rate of healthcare-associated CDI. This decrease occurred despite an increase in patient acuity among hospitalized patients at our institution, as reflected by the upward trend in aggregate Charlson scores over time. There were no major changes in CDI-related infection control practices other than the ones included in our intervention.

We did not observe a significant decrease in CDI-related mortality. However, the number of CDI-related deaths was small, and we were underpowered to detect a statistically significant difference.

Although our educational programs included a discussion about exposure to antimicrobials as a major risk factor for CDI, we did not seek to restrict the use of high-risk antimicrobials because of the intensity of resources that this would have required. A number of CDI prevention efforts reported in the literature have required inclusion of antimicrobial restriction as a component of the intervention, to demonstrate improvement in outcomes.^{13,20-23} Antimicrobial stewardship programs are resource intensive,²⁴ particularly when restricting the commonly used antimicrobials that are associated with increased risk for CDI, such as fluoroquinolones. An intervention such as ours that does not require antimicrobial restriction has the advantage of requiring fewer institutional resources.

Our intervention relied on increasing provider suspicion for CDI. The significant increase in *C. difficile* toxin testing that we observed after the intervention suggests that the educational campaign and prevention bundle effectively lowered the threshold for hospital providers to suspect the diagnosis of CDI among patients with diarrhea and to consider diagnostic testing.

Under pressure from payers who may no longer reimburse for cases of CDI and other healthcare-associated infections, providers may be pushed to limit toxin testing and other documentation of CDI. It is important to emphasize, however, that there is potentially a dangerously high cost to be paid—both in lives lost and money wasted—in decreasing documentation of healthcare-associated CDI and, therefore, foregoing the opportunity to decrease the spread of this serious infection. We believe that there is a substantial benefit associated with increasing provider suspicion and *C. difficile* toxin testing and with confirming cases of CDI. We urge hospital administrators to adopt a more active and transparent approach to reducing the incidence and severity of

TABLE 3. Aggregate Charlson Scores for Hospitalized Population, by Quarter, at Brigham and Women's Hospital

		Aggreg	ate Charlson	n scores	
Quarter	2004	2005	2006	2007	2008
Jan-Mar	1.53	1,54	1.74	1.8	1.85
Apr-Jun	1.53	1.57	1.7	1.83	1.86
Jul-Sep	1.51	1.54	1.71	1.81	1.83
Oct-Dec	1.56	1.69	1.73	1.82	1.86

NOTE. The data exclude all patients admitted to the observation unit, all newborns, and all patients in the special care nursery.

CDI by introducing this hospital-wide prevention and treatment intervention.

There were a number of limitations to our study, including its observational before-after design. The decrease in incidence of healthcare-associated CDI, however, was temporally related to the implementation of the intervention, took place during a period of continued increasing incidence of CDI based on national data,¹⁰ and was sustained over 21 months. The decreasing rates of CDI that we noted after the implementation of our intervention are even more striking because of the more complete ascertainment of cases of CDI that would be expected with an increased frequency of *C. difficile* toxin testing.

An additional limitation was our inability to correlate compliance with specific practices with the decrease in CDI rates, because we did not formally monitor adherence to the components of the bundles. We did, however, as indicated above, achieve a statistically significant increase in *C. difficile* toxin testing after implementation of the intervention. Future work regarding measurement of compliance with specific practices in the bundles is warranted.

Further research to evaluate the cost-effectiveness of our prevention and treatment bundles would be useful. We did not gather specific cost data for the cases of CDI included in our study, although we would suspect that the cost of preventive equipment such as gowns and gloves would be small relative to the cost savings from the decrease in incidence. The use of more single-patient rooms may represent an opportunity cost.

Our findings suggest that the guidelines from the Society for Healthcare Epidemiology of America and the Infectious Diseases Society of America can be effectively implemented as prevention and treatment bundles and can help to substantially reduce the incidence of CDI. We recognize that adherence to the practices included in our bundles could be improved, and one approach to do so is to distribute these bundles as a checklist (Figure 1), with individual sections for specific healthcare workers. Checklists offer a convenient method for confirmation that necessary actions have been performed by the teams of healthcare workers. One means of implementing the CDI checklist and tracking compliance with its steps is to print the checklist on stickers that are checked off by physicians, physician assistants, nurse practitioners, or registered nurses, as appropriate, and placed in the patient's medical chart. The microbiology, infection control, and environmental services portions of the checklist could be printed on posters that hang in the relevant hospital departments where they could be confirmed daily. Alternatively, the portions of the prevention and treatment checklists aimed at providers could be built directly into electronic ordering systems, creating systems-based forcing functions that directly improve quality of care.

Our CDI checklist, which combines critical multidisciplinary and systems-oriented approaches,¹⁴ is a simple tool to aid hospitals in tackling the devastating problem of CDI. This tool should be tested on a larger scale to evaluate its generalizability.

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OLATION ROU	NDS DATE 1	0/15/10			
CONTACT	REASON	SIGN	GLOVES	GOWN	HANE
215	C. DIFF	у	Y	N	Y
			Y	Y	Y
			Y	N	N
			Y	Y	N
512	MRSA	Y	Y	Y	
OPLET			-		
AIRBORNE				2	



How are we doing?

Signage – 100% Bleach Cleaning of C Diff Rooms – 100% Hand Washing – 91% PPE Availability – 100% Use of gloves – 100% Use of gowns – opportunity for improvement



Labor Intensive Staff change behavior when you are around - they momentarily improve so they won't have to endure the 'teaching moment' Miss the 'real behavior' - what really happens when staff go into the rooms when you aren't there You have to leave all of the data input and responses to everyone's request for data for a later time - you actually have to leave your office or cube

Closing

There is no 'right' or 'wrong' way to monitor

There is only what works for you & your facility.

Make sure all factors are monitored

□Hand washing

PPE Availability

PPE Usage

Signage

Environmental Cleaning



COLORADO INFECTION PREVENTION COLLABORATIVE C.DIFFICILE INFECTIONS







Case Study: A 75-year-old woman was admitted to her local hospital presenting with urinary symptoms consistent with a urinary-tract infection (UTI). Her emergency-room physician decided empirically to begin treatment with ciprofloxacin, as was his standard practice since medical school. The patient was admitted for observation the same day but was released as her symptoms began to resolve. Unfortunately, following discharge from the hospital the patient began to develop new symptoms, including frequent, loose, malodorous bowel movements and abdominal pain. She returned to the hospital and was readmitted with presumptive *C. difficile* infection (CDI).

The physician who previously treated the patient for the UTI had known that antibiotics were a risk factor for CDI, but he also knew the patient was symptomatic and needed an antibiotic for treatment. He wasn't sure what else he could have done in the situation. He decided to consult with the

hospital's infectious-disease specialist to find out if he could have handled things differently. He discovered that based on local epidemiology, the hospital's protocol for empirical treatment of a UTI was not to treat with ciprofloxacin but instead to use a different class of drug that was less likely to promote the onset of *C. difficile* in hospitalized patients and would still have successfully treated the bacteria causing the urinary-tract infection.

This scenario provides an example of how using antibiotics appropriately, or practicing antibiotic stewardship, can serve to improve patient outcomes, as well as to avoid the significant costs that are incurred when treating a patient who has *C. difficile*. Antibiotic stewardship means engaging in the most cost-effective therapy for treating patients while reducing adverse effects such as antimicrobial resistance.

COLORADO INFECTION PREVENTION COLLABORATIVE C. DIFFICILE INFECTIONS

ANTIBIOTIC STEWARDSHIP AND C. DIFFICILE

Exposure to antibiotics is an important risk factor for the development of disease. In one study, 97% of patients diagnosed with CDI had received an antibiotic treatment regimen in the 60 days prior to the onset of symptoms.⁵⁹ The use of an antimicrobial agent causes disruption of the normal bacterial flora in the gut, providing ample opportunity for *C. difficile* to attach to available receptors in the colon. Exposure to a toxin-producing strain of the bacteria in combination with ingestion of an antibiotic places the patient at risk for development of symptomatic disease.^{15,22}

Antimicrobial agents that have specifically been shown to be associated with an increased risk of developing CDI include clindamycin, ampicillin, amoxicillin, beta lactam/ beta lactamase inhibitors and cephalosporins.³⁶ Additionally, fluoroquinolones are thought to be more strongly linked to the development of disease compared with other antimicrobial agents, and may have a particular role to play in disease associated with hypervirulent NAP1 strains.²² However, any antibiotic has the ability to alter the normal gut flora in a patient and thus any antibiotic also has the ability to create a favorable environment for the onset of *C. difficile* infection.

The term "collateral damage" is given to describe the negative effects caused by antibiotic therapy, such as toxicity and the selection of pathogenic organisms to cause disease.⁶⁰ In the case of *C. difficile*, collateral damage refers to the ability of an antibiotic treatment regimen to influence and change the gut bacteria in a patient, making the gut a more hospitable place for *C. difficile* bacteria to flourish. Factors that may influence the amount of collateral damage include the dose, spectrum of activity, route of admission, treatment duration, and the amount of antibiotic that reaches the colon.¹⁵

Since the use of antibiotics for treatment of infections is necessary and warranted in the inpatient hospital environment, efforts must be made to reduce the level of collateral damage that may occur from their use. This can best be achieved by the use of antibiotic-stewardship programs that focus on selection of the most appropriate choice of antibiotic, provided at the correct dose and duration, and delivered by the ideal route for the infection being treated. There are two main goals to any antibiotic-stewardship program, the first of which involves optimizing patient outcomes and reducing the unintended consequences of antibiotic use. The second goal is reducing healthcare costs while focusing on the quality of care.⁵⁸

Efforts to improve antibiotic prescribing have been demonstrated to reduce the rate of CDI. During an outbreak of CDI that occurred in a Veterans hospital in Arizona, clindamycin was identified as an antibiotic associated with increased rates of infection. Prior to the outbreak, an increased use in clindamycin was noted, and patients who developed CDI were three to nine times more likely to have received this antibiotic compared with another agent. Clindamycin was then restricted for use and removed from the hospital formulary, resulting in a prompt end to the outbreak levels of infection, from 15.8 per 1,000 discharges to 1.9 per 1,000 discharges.⁶¹ Similarly, Climo et al. observed a significant reduction in CDI cases per month, from 11.7 to 5.7, six months after the use of clindamycin was restricted. Stewardship efforts resulted in a net savings for the hospital due to significantly fewer patients requiring the costly treatment that can be associated with CDI in addition to the reduced need for initiating isolation and contact precautions.62

Stewardship efforts may be successful in significantly reducing *C.diff* infection rates where more traditional approaches to infection control fall short, even when those efforts are intensive. Development of local guidelines and pocket guides detailing recommended treatment to infections commonly treated in inpatients can be beneficial.⁵⁹



COLORADO INFECTION PREVENTION COLLABORATIVE C. DIFFICILE INFECTIONS

THE GUIDELINES

In 2007, the Infectious Disease Society of America (IDSA) and the Society for Healthcare Epidemiology of American (SHEA) published Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship that provides evidencebased recommendations for developing a program to enhance stewardship in the hospital setting. The full version of these guidelines is also available at: http://www.journals.uchicago.edu/doi/pdf/10.1086/510393.

The guideline promotes the use of two core strategies that should provide the foundation for an effective antibiotic-stewardship program. These strategies and additional supplemental elements are ranked according to the following system⁵⁸:

CATEGORY/GRADE	DEFINITION			
STRENGTH OF RECOMMENDATION				
А	Good evidence to support a recommendation for use			
В	Moderate evidence to support a recommendation for use			
С	Poor evidence to support a recommendation for use			
QUALITY OF EVIDENCE				
Ι	Evidence from one or more properly randomized controlled trials			
II	Evidence from one or more well-designed clinical trials, without randomization; from cohort or case-control analytic studies (preferably from more than one center); drawn from multiple time series; or from dramatic results from uncontrolled experiments			
III	Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees			

Adapted from the Canadian Task Force on the Periodic Health Examination.¹²



COLORADO INFECTION PREVENTION COLLABORATIVE

THE GUIDELINES

- 1. Prospective audit of antimicrobial use with intervention and feedback to the prescriber, performed by either an infectious-disease physician or a clinical pharmacist with infectious-disease training (AI).
- 2. Antibiotic stewardship (through formulary restriction and preauthorization requirements):
 - a. Has led to significant and immediate reductions in antimicrobial use and costs (AII).
 - b. Has been shown to be a beneficial component of a multifaceted response to nosocomial outbreaks (BII).
 - c. Has not yet clearly been proven effective in controlling antimicrobial resistance in the long term, as in some circumstances use may shift to another agent resulting in increased resistance (BII).
 - d. Necessitates the monitoring of overall trends in antimicrobial use to assess and respond to shifts in use (BIII).

SUPPLEMENTAL ELEMENTS:

- A) Education is considered an essential element of any program designed to influence prescribing behavior; it can provide a foundation of knowledge that will enhance and increase the acceptance of stewardship strategies (AIII). However, education when used alone, without incorporation of active intervention, is only marginally effective in changing antimicrobial-prescribing practices and has not demonstrated sustained impact (BII).
- B) Multidisciplinary development of evidence-basedpractice guidelines incorporating local microbiology and resistance patterns can improve antimicrobial utilization (AI). Guideline implementation can be facilitated through provider education and feedback on antimicrobial use and patient outcomes (AIII).
- C) There are insufficient data to recommend the routine use of antimicrobial cycling as a means of preventing or reducing antimicrobial resistance over time (CII).

- D) Antimicrobial order forms are an effective component of stewardship and can facilitate implementation of practice guidelines (BII).
- E) Combination therapy to prevent the emergence of resistance is based on insufficient data (CII).
 Combination therapy does have a role in certain clinical contexts, including use for critically ill patients at risk of infection with MDROs, to increase the breadth of coverage and likelihood of adequate initial therapy (AII).
- F) Streamlining or de-escalation of empirical antimicrobial therapy on the basis of culture results and elimination of redundant combination therapy can more effectively target the causative pathogen, resulting in decreased antimicrobial exposure and substantial cost savings (AII).
- G) Dose optimization based on individual patient characteristics, causative organism, site of infection, and pharmacokinetic and pharmacodynamic characteristics of the drug are an important part of stewardship (AII). A systematic plan for parenteral to oral conversion if antimicrobials with excellent bioavailability, when the patient's condition allows, can decrease length of stay and healthcare costs (AI).
- H) Development of clinical criteria and guidelines allowing conversion to oral agents can facilitate implementation at the institutional level (AIII).

Additionally, the use of electronic medical-records systems, computer-based surveillance methods, and involvement of the microbiology lab in providing patient-specific data to clinicians and assisting infection control with surveillance duties have all been shown to be effective elements.

COLORADO INFECTION PREVENTION COLLABORATIVE C. DIFFICILE INFECTIONS

PRACTICAL APPLICATION

Following the publication of their 2007 guidelines, SHEA and IDSA conducted a follow-up survey in 2008 to determine the prevalence of antibiotic-stewardship programs in U.S. hospitals. Three hundred fifty-seven practitioners responded to the survey, which found⁶⁴:

- 52% stated their facility did not currently have an antibiotic-stewardship program.
- 61% of practitioners surveyed at facilities that did have a formal stewardship program stated the program had existed for more than 2 years, 11% for 1 to 2 years, and 28% for less than 1 year.
- The most frequently used strategy of the two core strategies recommended in the guideline was prospective monitoring and feedback (66%) compared with restriction or preauthorization (38%).
- Many facilities that claim to not have a formal stewardship program in place do make use of the suggested supplemental strategies, such as having an IV to oral conversion protocol, closed formularies, and providing education to staff and providers.

Survey respondents who did not have a stewardship program in place indicated the following as barriers to implementation:

- Personnel shortages (55%)
- Financial considerations (36%)
- Higher priority clinical initiatives (34%)
- Opposition from prescribers (27%)
- Resistance from administration (14%)

Authors of the survey concluded that more practical strategies and resources are needed to aid hospitals and other healthcare facilities in implementing the guidelines. As part of this effort, the CDC has launched a "Get Smart for Healthcare" campaign focused on improving antimicrobial use in inpatient healthcare settings, including acute- and long-term-care facilities, through antibiotic-stewardship programs.

The campaign outlines four keys to success⁶⁵:

- 1. Engage a physician champion to lend legitimacy and gain buy-in from other prescribers.
- 2. Garner leadership support to ensure funding, and show a visible commitment from key administrators.
- 3. Tailor interventions to local problems, and address local issues to increase buy-in.
- 4. Measurement and selection of outcomes that are important to key groups is critical to success and continued participation.



COLORADO INFECTION PREVENTION COLLABORATIVE

C. DIFFICILE INFECTIONS

CREATING A CORE STEWARDSHIP TEAM^{58, 63}

The creation of a stewardship team is an essential preliminary step to any successful program. A good place to start is by having informal discussions with potential members to gauge their interest and ability to make a commitment. The diagram below displays recommended core members of an antibiotic-stewardship team and a brief description of their roles. It is imperative that this team receive support of hospital administration, medical staff leadership, and local providers.

INFECTIOUS-DISEASE PHYSICIAN AND/OR CLINICAL PHARMACIST

If there is no physician on staff with training in infectious diseases, another champion may be selected who demonstrates the following qualities:

- Basic knowledge of antibiotics
- A demonstrated interest in leadership roles in their community
- Respected by peers
- Good interpersonal skills
- Good team player
- Basic understanding of human factors and culture transformation

Physician champions and other leaders of the stewardship team should be compensated for their efforts as an incentive to provide the level of consistent participation that is needed for a successful program.

Physician champions lend legitimacy to the stewardship effort.

\checkmark	\checkmark	\checkmark	\checkmark
CLINICAL Microbiologist	INFORMATION-SYSTEM Specialist	INFECTION-CONTROL Professional	HOSPITAL Epidemiologist
Provides expert information about interpretation and use of susceptibility panels and guidance on use and interpretation of antibiograms.	Advises the stewardship team on potential uses of available technology.	Provides information on current infection-prevention and control efforts and the relationship these may have with stewardship efforts.	Advises the stewardship team on surveillance and research methods to use in order to evaluate the program.



COLORADO INFECTION PREVENTION COLLABORATIVE

C. DIFFICILE INFECTIONS

THREE SIMPLE STEPS TO STEWARDSHIP

There are many different steps that healthcare facilities can take to improve the use of antibiotics and enhance patient safety. According to the CDC's "Get Smart for Healthcare" campaign, the following three simple steps provide a starting point any facility can employ to improve antibiotic use⁶⁴:

Step 1: All antibiotic orders should have three key pieces of information.

These include:

- 1. Dosage
- 2. Duration
- 3. Indication

When patients are cared for by multiple practitioners in the inpatient environment, it is easy for clinicians to be uniformed about the reasons an antibiotic was started and how long the patient should take the medication. Having the appropriate data available will ensure antibiotics are discontinued appropriately and new medications can be started if needed.

Step 2: Ordering microbiology cultures when prescribing an antibiotic.

Empiric treatment for an infection may begin before any information is known about the causative agent. Ordering microbiology cultures when prescribing an antibiotic will help ensure this information becomes readily available. Once susceptibility data of the infectious organisms are obtained, the most appropriate agent can be prescribed. The CDC has a "Clinician Guide" available on its website with recommendations for obtaining accurate culture results. For access, visit: <u>http://www.cdc.gov/getsmart/healthcare/</u> improve-efforts/resources/clinician-guide.html.

Step 3: Take an antibiotic "time-out."

When culture results become available, take a moment to reassess the patient's needs. Consider the following questions based on culture results:

- 1. Is the antibiotic still warranted?
- 2. Is the antibiotic still effective against the organism?
- 3. If not, should the antibiotic therapy be narrowed or discontinued?

The development of hospital-specific antibiotic-treatment protocols and guidebooks can assist clinicians in their efforts to improve appropriate antibiotic-prescribing habits.



COLORADO INFECTION PREVENTION COLLABORATIVE

NOTABLE RESOURCES

- The Joint Commission developed a tool kit in 2009, "What Every Healthcare Executive Should Know: The Cost of Antibiotic Resistance," aimed at educating hospital CEOs and leadership teams about the issue. The tool kit provides information and tools needed to sustain an effective multi-drug resistant organism prevention program. The information may be useful to facilities of any size and may also be tailored to the unique needs of different organizations. A section on antibiotic stewardship provides useful tools, including an antibiogram template, a summary of proactive strategies and an antibiotic use audit form among others. The tool kit is available at no charge and may be accessed at: http://www.jcrinc.com/MDRO-Toolkit/.
- The CDC's "Get Smart for Healthcare" campaign is focused on improving antibiotic use in inpatient healthcare facilities, including hospitals and long-termcare facilities, by focusing on strategies to assist in the implementation of interventions to improve antibiotic use. The site provides a variety of resources, including a sample business plan, success stories of other facilities, clinician guides for obtaining cultures, antibiotic-approval forms, and order sets. The site is worth checking often for updated information and can be accessed at: <u>http://www. cdc.gov/getsmart/healthcare/index.html</u>.
- Johns Hopkins Medicine posts its high-quality antibiotic guidelines online for others to view. This document should be used as an example only, as hospitals and long-term-care facilities should develop their own guidance based on local trends and epidemiology. To access the guidelines or for more information about the stewardship program at Johns Hopkins, visit: http://www.hopkinsmedicine.org/amp/.

- The American Society for Health System Pharmacists developed an initiative, "Antimicrobial Practice Improvement in Hospitals: Implementing Antimicrobial Stewardship" as a means of providing expert assistance to pharmacists and other professionals in implementing or augmenting antibiotic-stewardship programs. The website offers access to live webinars from experts, available at no charge. Additional resources include "A Hospital Pharmacist's Guide to Antimicrobial Stewardship Program" and other practical information. For access to the website, visit: www.ashpadvantage.com/stewardship.
- The Nebraska Medical Center developed an institutional antibiotic-stewardship program in 1994 with a mission to optimize the use of antimicrobial agents in order to realize improved patient outcomes, a positive effect on antimicrobial resistance, and have an economic benefit. This program acts as an example to other facilities interested in developing similar programs and provides a wealth of resources. To access the site, visit: <u>http://www.nebraskamed.com/careers/education/asp/</u>.
- The University of Pennsylvania Health System developed a website for its "Antimicrobial Management Program" that provides more-technical resources, such as guidelines for antimicrobial therapy, current susceptibility data for the UPHS system, information on dose adjustments and infection-control procedures. For access to the site, visit: http://www.uphs.upenn.edu/bugdrug/.
- Making a Difference in Infectious Diseases Pharmacotherapy offers an Antimicrobial Stewardship Certificate Program designed for pharmacist practitioners who already have residency training and are currently planning to or already are pursuing antimicrobialstewardship efforts. The program has three components, including an internet learning module, live online lessons including teleconferences with expert faculty, and a practical component. Upon completion, a certificate of completion is awarded, along with 19 hours of ACPE credit. For more information, visit: <u>http://www.mad-id. org/asp/asp_index.htm</u>.



COLORADO INFECTION PREVENTION COLLABORATIVE C. DIFFICILE INFECTIONS

NOTABLE RESOURCES CONT.

- The Society for Healthcare Epidemiology of America (SHEA)'s mission is preventing and controlling healthcare-associated infections and advancing the field of healthcare epidemiology. As part of this effort, SHEA produces guidelines and resources on the topic of antibiotic stewardship. Resources posted include current guidelines, sample business plans, antibiotic approval forms, and links to educational events. To access SHEA's and other related resources, visit: <u>http://www.shea-online.org/news/stewardship.cfm</u>.
- The Infectious Disease Society of America (IDSA) provides clinical practice guidelines to assist practitioners in providing appropriate care for their patients. Additionally, the Society produces select guidelines in the form of user-friendly pocket cards, which can act as quick reference tools to assist practitioners in selecting the appropriate treatment of specific infections, including *C*. *difficile*. The cards may be viewed for free and ordered in spiral bound or multifold cards. Check the site in winter 2011 for a new "Prevention of Healthcare-Associated Infections" pocket card. For more information, visit: http://www.idsociety.org/Content.aspx?id=15733.
- The Sanford Guide has provided up-to-date guidelines and recommendations for the treatment of infectious disease for the last 40 years. The comprehensive content is provided in a user-friendly format and provides recommendations for treatment and prevention of bacterial, fungal, viral, parasitic and mycobacterial infections, surgical prophylaxis, and ancillary information covering pharmacology, adverse effects, drug-drug interactions, and dose adjustments, all supported by commentary and references. The 2010 "Guide to Antimicrobial Therapy" is available for order and provides an invaluable reference for clinicians. For more information visit: http://www.sanfordguide.com/ Sanford Guide/Home.html.

COLORADO INFECTION PREVENTION COLLABORATIVE

TOOL KIT ARTICLE ABSTRACTS

Antimicrobial Stewardship Programs: How to Start and Steer a Successful Program

The article included in your tool kit, "Antimicrobial Stewardship Programs: How to Start and Steer a Successful Program," provides a summary of the importance of instituting a stewardship program and an overview of strategies that may be used by healthcare facilities to promote judicious use of antibiotics. While these strategies have been previously described in the SHEA/IDSA's "Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship," this article provides a more readable, practical discussion of a multifaceted approach to stewardship.

Drew RH. Antimicrobial Stewardship Programs: How to Start and Steer a Successful Program. *J Manag Care Pharm.* 2009; 15(2) (Suppl): S18–S23.

• A Hospital Pharmacist's Guide to Antimicrobial Stewardship Programs

"A Hospital Pharmacist's Guide to Antimicrobial Stewardship Programs" provides valuable information to any healthcare professional, not strictly a pharmacist, interested in implementing and improving antibioticstewardship programs in their healthcare facilities. The guide provides an overview of strategies discussed previously in the SHEA/IDSA guideline from 2007, as well as ideas for the bundling of evidence-based practices, insight into development of teams, and potential strategies for health professionals to improve education on stewardship.

American Society of Health-System Pharmacists. A Hospital Pharmacist's Guide to Antimicrobial Stewardship Programs, Published June 1, 2010. Available at: http://www.ashpadvantage.com/docs/stewardshipwhite-paper.pdf.

COLORADO INFECTION PREVENTION COLLABORATIVE C. DIFFICILE INFECTIONS

Can antibiotics sometimes be harmful?

helpful in fighting disease, but there are Antibiotics are generally safe and very actually be harmful. These are some certain cases where antibiotics can things to watch for while taking antibiotics:

Side effects of the antibiotics .

and stomach pain. Sometimes these antibiotics include nausea, diarrhea symptoms can lead to dehydration your doctor has told you about side effects. It is very important to notify and other problems. Be sure that your doctor if you have any side Some common side effects of effects from your antibiotics.

Allergic reaction .

difficulty breathing. Tell your doctor about any drug allergies you have Some people may experience an allergic reaction characterized by rash, itching and in severe cases nad in the past

incorrectly, you increase your chance antibiotic is not able to kill the germs of getting an illness someday that is time you take an antibiotic when you very big problem in the world today. Antibiotic resistance has become a causing the infection. Your infection getting better you get worse. Every inappropriately for viral infections. really don't need it or if you take it antibiotics are used too often or When resistance develops, the may last longer, and instead of Resistance may result when resistant to antibiotics.

Antibiotic issues specific to women

discharge. Antibiotics may cause birth control pills treatment. Some antibiotics may be passed on to This happens because antibiotics kill the normal bacteria in the vagina and this causes yeast to a fetus and cause harm. Because of this, it is Antibiotics can lead to vaginal yeast infections. tching, burning, pain during sex, and vaginal Include one or all of the following symptoms: to be less effective. Another method of birth grow rapidly. Symptoms of a yeast infection important to let your doctor know if you are control may be needed during antibiotic pregnant or nursing.

Resources

Centers for Disease Control & Prevention American Academy of Family Physicians Medem—The Nation's Medical Society www.aafp.org www.cdc.gov

Food & Drug Administration

National Institutes of Health

Alliance for the Prudent Use of Antibiotics www.nih.gov

Georgia-Pacific Health Smart Institute www.gphealthsmart.com

original manuscript, and to Arlene Potts, BA, MPH, CIC, Kathy Brooks, RN, PhD, CIC, and Lianne Delaney, RN, Copyright © 2005 by The Association for Professionals Special thanks to Rhonda Harsch, RN, for writing the MPH, CIC for reviewing the brochure.

in Infection Control and Epidemiology (APIC). www.apic.org

Antibiotic Safety



Appropriate Antibiotic Use – Saves lives, saves money, makes sense.

Get Smart About Antibiotics Week Wednesday, November 17, 2010



Did you know?

- Antibiotic resistance is one of the world's most pressing public health threats.
- Antibiotics are the most important tool we have to combat lifethreatening bacterial diseases.
- Increased antibiotic resistance is compromising the effectiveness of antibiotics.
- Patients, healthcare providers, hospital administrators, and policy makers must work together to employ effective strategies for improving appropriate antibiotic use – ultimately saving lives.

Cost of the Problem

- Antibiotic resistance increases the economic burden on the entire healthcare system.
- Resistant infections cost more to treat and can prolong healthcare use.
- In one study, the cost of 188 cases of antibiotic-resistant infections was \$15 million.
- More than \$1.1 billion is spent annually on unnecessary antibiotic prescriptions for respiratory infections in adults.

U.S. antibiotic-resistant infections are responsible for:

- \$20 billion in excess healthcare costs
- \$35 billion in societal costs
- 8 million additional hospital days

Why we must act now

- Antibiotics are a shared resource and becoming a scarce resource. We must make better use of existing antibiotics through appropriate antibiotic use.
- Appropriate use of existing antibiotics can limit the spread of antibiotic resistance, preserving antibiotics for the future.
- Antibiotic resistance is not just a problem for the person with the infection. Some resistant bacteria have the potential to spread to others – promoting antibiotic-resistant infections.



Hospital administrators and payers can help

- We must enhance efforts to get healthcare administrators to recognize the importance of antibiotic stewardship and provide resources to do it.
- Interventions to improve antibiotic use can be done in any setting.
- Every facility regardless of setting and hospital size – should emphasize and implement antibiotic stewardship.
 - Antibiotic stewardship helps improve patient care and shorten hospital stays, thus benefiting patients as well as the hospitals.
 - Antibiotic stewardship programs are a "win-win" for all involved.
- Reducing unnecessary antibiotic use can decrease resistance, *Clostridium difficile* infections, costs, and improve patient outcomes.
- Improving antibiotic use improves patient outcomes while saving healthcare dollars.
 - Community education campaigns make a difference. A four-month local media campaign in Colorado focusing on appropriate antibiotic use saved two managed care organizations \$815,000 in prescription and visit costs.
 - Inpatient antibiotic stewardship programs have consistently demonstrated annual savings of \$200,000 to \$400,000.
- Payers should monitor Healthcare Effectiveness Data and Information Set (HEDIS®) performance measures on pharyngitis, upper respiratory infection, acute bronchitis, and antibiotic utilization.
- Make appropriate antibiotic use a quality improvement and patient safety priority.

Steps to starting an Antimicrobial Resistance Stewardship Program:

- 1) Ensure all orders have dose, duration, and indications
- 2) Get cultures before starting antibiotics
- 3) Take an "antibiotic time-out," reassessing antibiotics after 48-72 hours

U.S. ANTIBIOTIC-RESISTANT INFECTIONS ARE RESPONSIBLE FOR:





Centers for Disease Control and Prevention For more information, please contact Centers for Disease Control and Prevention 1600 Clifton Road NE, Atlanta, GA 30333 Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-63548 E-mail: cdcinfo@cdc.gov Web: http://www.cdc.gov/getsmart/

Antimicrobial Stewardship Programs: How to Start and Steer a Successful Program

Richard H. Drew, PharmD, MS, BCPS

ABSTRACT

BACKGROUND: Antimicrobial stewardship programs (ASPs) promote the appropriate use of antimicrobials by selecting the appropriate dose, duration, and route of administration. The appropriate use of antimicrobials has the potential to improve efficacy, reduce treatment-related costs, minimize drug-related adverse events, and limit the potential for emergence of antimicrobial resistance.

OBJECTIVE: To summarize ASP tactics that can improve the appropriate use of antimicrobials in the hospital setting. Several measures can be used to implement such programs and gain multidisciplinary support while addressing common barriers.

SUMMARY: Implementation of an ASP requires a multidisciplinary approach with an infectious diseases physician and a clinical pharmacist with infectious diseases training as its core team members. As identified by recently published guidelines, 2 proactive strategies for promoting antimicrobial stewardship include: (1) formulary restriction and pre-authorization, and (2) prospective audit with intervention and feedback. Other supplemental strategies involve education, guidelines and clinical pathways, antimicrobial order forms, de-escalation of therapy, intravenous-to-oral (IV-to-PO) switch therapy, and dose optimization. Several barriers exist to successful implementation of ASPs. These include obtaining adequate administrative support and compensation for team members. Gaining physician acceptance can also be challenging if there is a perceived loss of autonomy in clinical decision making.

CONCLUSION: ASPs have the potential to reduce antimicrobial resistance, health care costs, and drug-related adverse events while improving clinical outcomes. The efforts and expense required to implement and maintain ASPs are more than justified given their potential benefits to both the hospital and the patient.

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Justification for ASPs

Though it is difficult to establish causal relationships (because multiple factors contribute to the development and persistence of antimicrobial resistance), ASPs have the potential to limit the emergence and spread of resistant pathogens. A number of observations have suggested an association between antimicrobial use and the emergence of resistance. First, in vivo selection of resistance during antimicrobial therapy can cause de novo resistance, which can quickly spread to other patients in the setting of poor infection control measures (i.e., improper hand hygiene techniques or environmental contamination). Second, patients harboring a resistant organism (when transferred to a particular unit) may introduce the resistant strain. Third, resistance genes can also be transferred between organisms to create new resistant organisms. Fourth, ASPs attempt to reduce antimicrobial pressures that have been shown to promote resistance development.35 For example, several studies have reported parallel changes in antimicrobial use and the prevalence of resistance.6.9 Prior antimicrobial use is common in patients with health careassociated infections caused by resistant strains.10 Areas within hospitals with higher rates of antimicrobial resistance also tend to have higher rates of antimicrobial use.9 Increasing the duration of antimicrobials also increases the risk for colonization with resistant organisms.

Antimicrobial stewardship aims to promote the appropriate use of antimicrobials—the right selection, duration, dose, and route of administration. Promoting the appropriate use of antimicrobials is intended to improve clinical outcomes by reducing the emergence of resistance, limiting drug-related adverse events, and minimizing the risk of unintentional consequences associated with antimicrobial use (such as an increased risk of *Clostridium difficile* infection).^{3,10,12}

ASPs also have the potential to reduce antimicrobial costs by limiting the overuse and inappropriate use of these agents and by promoting active intravenous-to-oral (IV-to-PO) switch therapy. By reducing the unnecessary use of antimicrobials, a well-designed ASP has the additional advantages of reducing (a) the risk of drug-related adverse events and their associated costs, and (b) the emergence of resistance and, hence, minimizing infections caused by resistant pathogens. Infections caused by resistant organisms are associated with poorer clinical outcomes, prolonged hospital length of stay (LOS), and higher overall costs compared to infections caused by susceptible organisms.¹¹⁻¹⁵ Therefore, by promoting the appropriate use of antimicrobials, ASPs can have a broad impact on improving clinical outcomes while reducing overall health care costs.





Stewardship Tactics

The Infectious Diseases Society of America/Society for Healthcare Epidemiology of America (IDSA/SHEA) guidelines³ identify 2 core proactive evidence-based strategies for promoting antimicrobial stewardship: (1) formulary restriction and pre-authorization, and (2) prospective audit with intervention and feedback.

Formulary Restriction and Pre-Authorization. The strategy of formulary restriction and pre-authorization involves limiting the use of specified antimicrobials to certain approved indications. An antimicrobial committee creates guidelines pertaining to the approved use of agents. If necessary, designated personnel are made available for the approval process. The strategy leads to direct control over antimicrobial use at an institution and educational opportunities for prescribers when a request is made. The major disadvantage of this strategy is that prescribers can have a perceived loss of autonomy when making clinical decisions. Personnel also need to be available for consultation at all times. As with many ASP tactics, there is an initial cost to implement and monitor the effectiveness of such programs.

Formulary restrictions have been proven to impact antimicrobial use.^{16,17} One intervention at the University of Kentucky Chandler Medical Center in 1999 involved multiple aspects: (a) the removal of ceftazidime and cefotaxime from the formulary, (b) the restriction of ceftriaxone and carbapenem use to only approved indications, (c) the addition of cefepime to the formulary, (d) the replacement of ciprofloxacin with levofloxacin on the formulary, and (e) a 72-hour stop order on all vancomycin requests.¹⁶ Follow-up analysis evaluated antimicrobial use and resistance rates in selected organisms. In 2000, antimicrobial expenditures decreased by over \$200,000 (despite an increase in inpatient days) and further declined by \$600,000 as of 2002 (when compared to 1998 expenditures). Not surprisingly, ceftazidime, cefotaxime, and ceftriaxone use decreased by nearly 80% by 2002. Another benefit of the ASP has been a decrease in resistance rates of several important pathogens, including multidrugresistant *P. aeruginosa* and methicillin-resistant *Staphylococcus aureus* (MRSA; Figures 1a and 1b). The benefits from implementing this program have shown to be persistent.

Prospective Audit With Intervention and Feedback. A strategy of prospective audit with intervention and feedback involves a daily review of targeted agents for appropriateness. Follow-up intervention, if necessary, involves contacting the prescriber to recommend alternative agents. This tactic requires an antimicrobial committee to develop guidelines for appropriate use of targeted agents, and personnel (usually clinical pharmacists) are needed to perform the reviews and follow-up communication on a daily basis. The advantage of this strategy is that prescribers do not experience any perceived loss of autonomy, particularly if suggested changes by the reviewers are voluntary. This tactic also allows opportunity for educating prescribers through follow-up.

When utilized in a medium-sized community teaching hospital in Boston, this strategy resulted in significant reductions in inappropriate use of broad-spectrum intravenous agents, particularly third-generation cephalosporins.¹⁸ An antimicrobial management team (consisting of an infectious diseases physician and an infectious diseases-trained pharmacist) reviewed antimicrobial orders for all patients receiving parenteral thirdgeneration cephalosporins, aztreonam, parenteral fluoroquinolones, or imipenem. The recommendations of the antimicrobial management team were communicated to the prescribers via nonpermanent chart notes. Following the implementation of the program, parenteral antimicrobial use decreased steadily from



^aSource: Reprinted with permission from Carling P, Fung T, Killion A, Terrin N. Barza M. Favorable impact of a multidisciplinary antibiotic management program conducted during 7 years. Infect Control Hosp Epidemiol. 2003;24(9):699-706.¹⁸ Published by University of Chicago Press; ©2003 The University of Chicago Press. All rights reserved. IV = intravenous.

1994 to 1998 while costs of parenteral antimicrobials decreased by nearly 30% (Figure 2), despite a 15% increase in the Medicare Case Mix Index and a 56% increase in ICU patient-days. The effect of this strategy on resistance and nosocomial infections was less clear. The rate of *Clostridium difficile* infection showed an initial decrease in 1993 and remained fairly steady after this (Figures 3a and 3b).¹⁸ Similarly, the number of infections caused by ceftazidime-resistant Enterobacteriaceae decreased following implementation of the program, followed by a steady rate until 1996 and then a decrease again in 1997 and 1998. However, vancomycin-resistant enterococci (VRE) were first isolated in 1995 and their number grew dramatically in 1996. MRSA rates did not seem to be affected by the program and grew steadily.¹⁸

Supplemental Strategies. Other supplemental strategies can also play a pivotal role in ASPs.³ These include education, guide-lines and clinical pathways, antimicrobial order forms, streamlining or de-escalation, dose optimization, and IV-to-PO switch.

Education is essential for any program that is designed to influence prescribing behaviors. Programs are needed to disperse information in an accurate and timely fashion. Since personnel can change over time, it is also important that the message be repeated routinely. Effective implementation of ASPs will incorporate education along with active strategies, such as prospective audit and intervention.¹⁹

Guidelines and clinical pathways can improve antimicrobial utilization by multidisciplinary development of evidence-based guidelines that incorporate local microbiology and resistance pat-



"Source: Carling et al.¹⁰ Published by University of Chicago Press. All rights reserved.

terns.³ However, it is important to note that antimicrobial selection is only one component of these recommendations. Diagnosis and testing, admission criteria, nursing care, conversion to oral medication, and discharge planning can also impact quality of care and resource utilization.³ One study that incorporated a critical pathway at 20 hospitals for patients with CAP showed an 18% decrease in admissions for low-risk patients and significantly lower LOS and duration of IV therapy when compared to conventional therapy, resulting in significant cost savings.²⁰

Antimicrobial order forms can be an effective tactic to decrease antimicrobial consumption by implementing automatic stop orders and/or requiring physicians to justify antimicrobial use.²¹ However, prescribers may view the process of filling out these forms as inconvenient and time consuming. The transition to computerized data entry systems at institutions may improve the use and convenience of such strategies.

Streamlining or de-escalation can decrease antimicrobial exposure and save costs when empiric therapy involves a combination of agents to ensure broad-spectrum coverage. Once culture results identify the pathogen, a planned removal of antimicrobials that are not necessary or that provide redundant coverage is initiated to provide more targeted therapy. For example, if vancomycin is initially included in the treatment regimen but culture results show an absence of MRSA, vancomycin can then be removed. This approach can lead to substantial cost savings without affecting clinical outcomes.^{22,23}

Dose optimization, an important part of antimicrobial stewardship, takes into account factors such as the pharmacokinetics and pharmacodynamics of the agent, patient and pathogen





"Source: Reprinted with permission from Carling P, Fung T, Killion A, Terrin N, Barza M. Favorable impact of a multidisciplinary antibiotic management program conducted during 7 years. Infect Control Hosp Epidemiol. 2003;24(9):699-706.¹⁸ Published by University of Chicago Press; ©2003 The University of Chicago Press. All rights reserved.

characteristics, and the site of infection when selecting the most appropriate antimicrobial regimen. Dose optimization strategies may include prolonged infusion of β -lactams, extended dosing intervals of aminoglycosides, or higher doses of fluoroquinolones to ensure that pharmacokinetic-pharmacodynamic targets are met.^{24,26}

IV-to-PO switch, discussed in the article by Dr. Nicolau in this supplement, is an effective factic to decrease the LOS and health care costs.

The role of *antimicrobial cycling* in antimicrobial stewardship is not clear; insufficient data are available to recommend this strategy for routine use. Antimicrobial cycling involves the deliberate scheduled removal and substitution of specific antimicrobials or classes of antimicrobials within an institution to avoid or reverse the emergence of antimicrobial resistance.²⁷ As the scheduled antimicrobial is changed on a regular basis, adherence can be difficult with these programs mainly because prescribers may be unaware of the current scheduled antimicrobial.²⁸

The routine use of combination therapy is not recommended given a lack of data supporting its impact on preventing resistance development or improving outcomes.²⁹ However, empiric combination therapy can be important when treating severely ill patients to ensure early adequate coverage of potential pathogens.³⁰ Once culture results are available, de-escalation of therapy is recommended to provide targeted therapy and reduce antimicrobial exposure.^{3,30}



"Source: MacDougait C, Polk RE: Animicrobial stewardship programs in health care systems. Clin Microbiol Rev. 2005;18(4):638-56.³¹ Reproduced with permission from American Society for Microbiology. ©2005 American Society for Microbiology. All rights reserved.

Stewardship Tactics at Various Stages of Patient Management

Stewardship tactics can be used at the various stages of managing a patient with an infectious disease (Figure 4).³¹ During patient evaluation, clinician education as well as management guidelines can aid in the proper diagnosis and the further actions needed (admission, laboratory testing, etc). Selecting the initial antimicrobial can also be impacted by education and the implementation of guidelines, as well as any formulary restriction and preauthorization policies. Computer-assisted strategies can be useful during the stage of antimicrobial selection, while a review and feedback strategy can help provide additional educational opportunities to the prescriber and offer a chance to adjust therapy and amend prescribing practices.

Impact of ASPs

Though more data are needed to demonstrate the benefits of the programs, ASPs have the potential to reduce resistance, health care costs, and drug-related adverse events while improving clinical outcomes. The impact of ASPs on bacterial resistance can be difficult to assess due to the multiple factors that can influence resistance development and spread. Optimized antimicrobial use is thought to help reduce the emergence of resistance, though few prospective randomized trials have attempted to analyze this.³² Other studies that have attempted to assess various strategies to minimize resistance development usually have multiple confounding variables that can make it difficult to attribute any impact to one tactic. However, as discussed earlier, given an apparent association between antimicrobial use and the emergence of resistance. ASPs that reduce the inappropriate use of antimicrobials will decrease the selection pressure for the emergence of resistance.

The IDSA/SHEA guidelines report that comprehensive programs can lead to a reduction in antimicrobial use by 22%-36%, resulting in significant cost savings.³ The study by Martin et al., presented earlier, demonstrated how a policy of formulary restriction and pre-authorization can result in substantial pharmacy cost savings.¹⁶ These programs can provide substantial economic benefits irrespective of the size of the institution.

The impact of ASPs on clinical outcomes and adverse events can also be difficult to measure given the multifactorial nature of these issues. In one example of prospective audit and feedback, the rate of *C. difficile* infections decreased and remained stable after implementation of the program.¹⁸ ASPs that reduce overall antimicrobial usage by minimizing the inappropriate use of these agents will have the potential to decrease the risk of drug-related adverse events and unintended consequences.

Implementing an ASP

The rationale, design, and implementation of ASPs have been described extensively in the medical literature.^{3,31,33-35}

Creating an ASP involves multiple steps.32 Baseline information should be obtained pertaining to antimicrobial use, expenditure, and institutional bacterial susceptibilities derived from the hospital antibiogram. This can help identify recurrent problems with antimicrobial use at the institution, such as overuse of a particular class or failure to switch from IV-to-PO when appropriate. An antimicrobial management strategy should be formulated, and an antimicrobial stewardship team with welldefined responsibilities formed. A multidisciplinary approach should be considered when selecting the ASP team members. The IDSA/SHEA guidelines recommend that the 2 core members of the team should include an infectious diseases physician and a clinical pharmacist with infectious diseases training.¹ Other critical members of the team can include a clinical microbiologist, a hospital epidemiologist, an infection control professional, and an information system specialist.

It is important to obtain support from the hospital administration as well as build relationships within the institution to help gain acceptance of the program once implemented. The hospital administration should give core team members the authority to enforce stewardship tactics. The ASP team members should also be fairly compensated for the additional time and effort needed to implement the ASP. One survey of infectious diseases consultants identified lack of compensation as a major barrier to implementing ASPs.³⁶ Prior to implementation of a program, the ASP team should negotiate the expected outcomes with hospital administration, which should be measurable and attainable.

Physician acceptance is extremely important during the design and implementation of an ASP. Adherence to ASPs should be monitored on a regular basis in order to identify ways in which physicians may try to circumvent ASP policies. One study described the experience at the University of Pennsylvania, where requests for restricted antimicrobials from 8:00 a.m. to 10:00 p.m. must be approved by an infectious diseases-trained pharmacist or infectious diseases fellow.37 However, outside of these active ASP hours, restricted antimicrobials may be ordered without prior approval, though all orders still require approval by the ASP for continuation of treatment. The study evaluated whether prescribers were waiting until after the approval period ended (10:00 p.m.) for ordering restricted antimicrobials. Antimicrobial orders over a 3-month period were compared from one hour before (9:00-9:59 p.m.) and one hour after (10:00-10:59 p.m.) the ASP approval period. A greater proportion of antimicrobials ordered after the ASP approval period was for restricted antimicrobials (57% vs. 49.9%, P=0.02). Furthermore, once the ASP evaluated new antimicrobial orders for continuation of therapy, a significantly higher percentage of orders made after the ASP approval period was discontinued. The difference was most profound for orders originating from the surgical unit. This study suggests that physicians were more likely to wait until after the ASP approval period ended to order restricted antimicrobials without prior approval. These orders were more often found to be in conflict with guidelines or were unnecessary and hence discontinued. Finally, prescribers should receive positive feedback on a regular basis, and audits should be conducted routinely to monitor the effectiveness of the program.

Barriers to ASPs

Despite the many benefits of ASPs in improving antimicrobial use and clinical outcomes while reducing costs, several barriers exist that may hinder their implementation. Foremost is finding the appropriate personnel who are willing to devote the extra time and effort towards developing and enforcing ASPs. This barrier is further exacerbated by the fact the few clinicians receive additional compensation for the added responsibility. A survey by the Emerging Infectious Diseases Network found that only 18% of respondents were compensated for added responsibility.³⁶ Hospital administration may be hesitant to fund such programs without a guarantee of future pharmacy savings.

Implementing tactics for an effective ASP will require funding to compensate those involved in the planning and monitoring of such programs. Further study is needed to understand the economic impact of ASPs as current reports are limited to single-center, longitudinal studies.^{17,18,38,44} However, these reports consistently show a decrease in antimicrobial use ranging from 22% to 36% and annual cost savings of \$200,000 to \$900,000 at both large academic medical centers^{17,18,38,39} and smaller community hospitals.^{40,41} These savings should more than offset any additional cost in implementing an ASP.

Another barrier is that ASP team members may not want to antagonize colleagues in other specialties as this can damage relationships and the potential for future consultations. This barrier may be circumvented by using a prospective audit with feedback tactic that makes any recommendation voluntary rather than mandatory and allows for educational opportunities. Other barriers for acceptance of ASPs may include a loss of physician autonomy pertaining to clinical decision making, a shortage of infectious diseases-trained pharmacists, restriction policies that can be onerous to adopt, and the continued need to assess the success of a program in order to sustain efforts.

Future Direction of Antimicrobial Stewardship

The IDSA/SHEA guidelines provide institutions with information needed when considering implementing an ASP. With more and more institutions implementing ASPs, it is anticipated that a growing number of studies will become available to better assess their impact—particularly, how the appropriate use of antimicrobials may impact the emergence of bacterial resistance. With the growing use of computerized order-entry and decision-support systems, ASPs may also become easier to implement and enforce while still providing opportunities to discuss with clinicians the appropriate use of antimicrobials. The greatest challenge may be in finding qualified personnel willing and able to direct such programs at each institution.

DISCLOSURES

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A Hospital Pharmacist's Guide to Antimicrobial Stewardship Programs



For more information on antimicrobial stewardship, please visit this initiative's website at **www.ashpadvantage.com/stewardship**

Developed by the American Society of Health-System Pharmacists and sponsored by Ortho-McNeil, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.







Executive Summary

he development of new antibiotics led to marked improvements in the health of Americans beginning in the mid 20th century. However, in recent years antimicrobial resistance has become a major public health problem in the United States. Antimicrobial resistance often is attributed to inappropriate antibiotic use, which is common in U.S. hospitals. Hospital-acquired infections (HAI), increased morbidity and mortality, prolonged hospital lengths of stay, and increased health care costs are among the potential consequences of inappropriate antimicrobial use and antimicrobial resistance. Pathogens that are resistant to all currently available antibiotics have emerged. To make matters worse, the research and development pipeline for antimicrobial agents is essentially empty, lending urgency to the need to use currently available effective agents wisely.

Antimicrobial stewardship—the appropriate selection, dosing, route of administration, and duration of antimicrobial therapy—in conjunction with infection prevention and control measures prevents or slows the emergence of antimicrobial resistance and transmission of antimicrobialresistant pathogens. Various strategies are used in antimicrobial stewardship programs (ASPs) to improve the quality of antimicrobial therapy, minimize antimicrobial resistance, and optimize clinical outcomes. Reducing health care costs without adversely affecting the quality of care is a secondary goal of ASPs. Pharmacists should assume a prominent role in antimicrobial stewardship because of their knowledge of and influence over antimicrobial use and membership on multidisciplinary committees in hospitals.

Developing and implementing an ASP in the hospital setting can present a challenge, with pitfalls to avoid and barriers to overcome. The process involves developing a proposal to obtain institutional support for the ASP, assembling and leading the ASP core team, analyzing current institutional practices, developing processes to meet ASP goals, analyzing and reporting data demonstrating the impact of ASP processes, and developing and implementing outreach plans directed to key hospital staff. A multidisciplinary effort with the support of hospital administration is essential to success in the process.

PURPOSE

This document is intended as an information resource on implementing antimicrobial stewardship programs for health system pharmacists and other professionals. This document is not intended to provide a comprehensive review of the appropriate use of antimicrobial agents or of the implementation of antimicrobial stewardship programs. Rather, it has been developed to generate ideas that health practitioners can use in their institutions.

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2 ANTIMICROBIAL STEWARDSHIP PROGRAMS
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A Hospital Pharmacist's Guide to Antimicrobial Stewardship Programs

Introduction

he use of antimicrobial agents has increased in hospitalized Americans over the past several decades.¹ By some estimates, half of patients hospitalized in the United States receive antibiotics, and up to half of antimicrobial use may be inappropriate.^{1,2} Problems with the excessive and inappropriate use of antimicrobial agents in the United States have been widely recognized for a long time.³

The potential consequences of inappropriate antimicrobial use include toxicity, the emergence of antimicrobial resistance, *Clostridium difficile (C. difficile)* and other hospital-acquired infections (HAI), increased morbidity and mortality, prolonged hospital lengths of stay, and increased health care costs.⁴⁻⁷ In 2002, approximately 1.7 million HAI occurred in U.S. hospitals, resulting in nearly 99,000 deaths.⁸ Estimates of the overall annual direct medical costs of HAI in U.S. hospitals ranges from \$28 billion to \$45 billion in 2007 dollars.⁹ Hospital-acquired infections caused by gramnegative bacteria are particularly problematic.¹⁰

There is a causal relationship between inappropriate antimicrobial use and resistance; changes in antimicrobial use lead to parallel changes in the prevalence of resistance.¹¹ Antimicrobial resistance is a serious public health concern because of the emergence of multidrug-resistant and extremely drug-resistant microbial species for which there is no effective antimicrobial agent and the paucity of new antimicrobial agents in the research and development pipeline.^{3,12,13}

The ESKAPE pathogens—Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae (K. pneumoniae), Acinetobacter



FIGURE 1

Centers for Disease Control and Prevention Campaign to Prevent Antimicrobial Resistance in Healthcare Settings

baumannii, *Pseudomonas aeruginosa*, and *Enterobacter* species—are the most troublesome bacterial pathogens in hospitals because they often are resistant to (i.e., escape the effects of) currently available antimicrobial agents and cause HAI.⁵ Surgical site infections are a common postoperative complication and account for 14% to 16% of HAI.¹⁴ Resistance rates are high among ESKAPE pathogens associated with surgical site infections.⁵

Antimicrobial resistance is the result of a variety of mechanisms (e.g., producing enzymes that inactivate or destroy the antibiotic, altering the antibiotic target site to prevent the drug from binding, changing the permeability of the cell wall to preventing antibiotic access to the

TABLE 1

Infection Prevention and Control Methods for Controlling Antimicrobial Resistance in Hospitals²¹

- Hand hygiene
- Contact (i.e., barrier) precautions
- Active surveillance for and decolonization (i.e., eradication) of multidrug-resistant organisms
- Perioperative antimicrobial prophylaxis
- Implementation of best practices for invasive procedures and devices (e.g., removal of unnecessary central catheters, oral disinfection with chlorhexidine for patients on ventilators)
- Disinfection and sterilization of medical devices
- Environmental cleaning

target site, actively pumping the antibiotic from the cell).3,10,15 The antimicrobial agents to which ESKAPE pathogens are resistant have changed over the years as a result of selective pressure and various mechanisms for resistance (e.g., production of extended-spectrum B-lactamases [ESBLs] by Klebsiella pneumoniae [K. pneumoniae], Escherichia coli [E. coli], and other gram-negative pathogens to circumvent effective killing by cephalosporins, monobactams, and penicillins).15 The mechanisms for resistance of ESKAPE pathogens often confer resistance to more than one agent (i.e., multidrug resistance).5 A change in the ESKAPE acronym to ESCAPE, with C for C. difficile instead of K for K. pneumoniae and E for Enterobacteriaceae (which includes Enterobacter species, K. pneumoniae, Klebsiella oxytoca, E. coli, and Proteus mirabilis) instead of Enterobacter species, recently was suggested because of increases in antimicrobial resistance among and the impact of HAI caused by these organisms.16 The emergence of K. pneumoniae carbapenemase (KPC)-producing strains of K. pneumoniae and other Enterobacteriaceae currently is a major public health concern.17 Plasmid-mediated transfer of genes that encode KPCs and other ESBLs severely limits the available options for treating serious infections in criticallyill patients.10

To address the lack of antimicrobial agents in the research and development pipeline, the Infectious Diseases Society of America (IDSA) and several other organizations recently launched the "10 x '20 initiative," a call to action to develop 10 new antimicrobial drugs by the year 2020.¹⁸ Federal legislation—the Strategies to Address Antimicrobial Resistance Act (H.R. 2400 known as STAAR)—was introduced in May 2009 to encourage the development of new antimicrobial agents as well as strengthen federal antimicrobial resistance surveillance, prevention and control, and research efforts.¹⁹

Preventing antimicrobial resistance requires weighing the needs of the individual patient and those of the larger society. Inadequate empiric antibiotic therapy in critically ill patients is associated with increased morbidity and mortality, but indiscriminate use of antibiotics promotes resistance that can affect the entire patient population.⁶ Antimicrobial stewardship is a means for achieving balance between providing appropriate care for the individual and protecting public health.

Antimicrobial Stewardship

Antimicrobial stewardship involves the appropriate selection, dosing, route of administration, and duration of antimicrobial therapy (i.e., the prudent use of antibiotics).11 The wise use of antimicrobial agents is a key strategy in the Centers for Disease Control and Prevention Campaign to Prevent Antimicrobial Resistance in Healthcare Settings (Figure 1).20 Use of antimicrobial stewardship in combination with infection prevention and control efforts limits the emergence and transmission of antimicrobial-resistant pathogens.^{3,4,11} Table 1 lists infection control methods for preventing the emergence and spread of antimicrobial resistance in hospitals.21 Compliance with hand hygiene and other infection prevention and control measures in hospitals typically is poor.²¹

The primary goal of antimicrobial stewardship is to optimize clinical outcomes while minimizing the unintended consequences of antimicrobial use (e.g., toxicity, selection of pathogenic organisms, emergence of resistance).¹¹ Reducing health care costs without adversely affecting the quality of care is a secondary goal of antimicrobial stewardship.¹¹

In 2007, IDSA and the Society for Healthcare Epidemiology of America (SHEA) released guidelines for developing an institutional program to enhance antimicrobial stewardship.¹¹ The American Society of Health-System Pharmacists (ASHP) provided input into the development of and endorsed the guidelines. According to IDSA and SHEA, effective antimicrobial stewardship programs (ASPs) are evidence-based and can improve patient care and be financially selfsupporting.¹¹

Core Strategies

Two proactive core strategies form the foundation of an ASP, with various supplemental elements depending on local practice patterns and resource availability, according to IDSA/SHEA guidelines. The potential advantages and disadvantages of these core strategies and supplemental elements are listed in Table 2.

Prospective audit with direct intervention and feedback to the prescriber involves evaluating the appropriateness of orders for antimicrobial agents, contacting the prescriber if the order is inappropriate, and recommending alternative therapy.^{11,22} Feedback to prescribers may be oral or written. Failure to follow written recommendations may raise legal concerns; providing oral feedback without permanent documentation in the patient medical record may avoid these concerns.²³ Prospective audit with intervention and feedback may be adapted to the practice setting, with a limited scope and frequency of interventions (e.g., Monday through Friday instead of 7 days/week) at institutions with limited resources.²⁶

Formulary restriction and preauthorization requirements involves limiting the use of certain antimicrobial agents to specific indications, durations of therapy, physician services, prescribers, or patient populations.^{22,24} The nature of the restriction often depends on institutional antimicrobial resistance patterns and patient safety issues related to antimicrobial agents. Formulary restriction and preauthorization can serve an educational purpose.²² In some institutions, preauthorization requirements are used primarily for educational purposes, and the requirements are not strictly enforced.²⁴ In these institutions,

TABLE 2

Potential Advantages and Disadvantages of IDSA/SHEA Core Strategies and Supplemental Elements of Antimicrobial Stewardship Programs^{11,22-25}

Core Strategies	Advantages	Disadvantages	
Prospective audit with direct intervention and feedback	 May reduce inappropriate antimicrobial use May serve an educational purpose to modify future prescribing Allows prescribers to maintain autonomy 	 Difficulty identifying patients with inappropriate therapy and commu- nicating with prescribers 	
Formulary restriction and preauthorization requirements	 May result in immediate and sub- stantial reductions in antimicrobial use and costs 	 May increase staffing requirement May delay order implementation while approval is obtained from an authorized prescriber, with the potential for adverse patient outcomes 	
		 May increase use of and resistance to alternative antimicrobial agents Perceived loss of prescriber 	
		autonomy (Continued next page)	

TABLE 2 (Continued)

Supplemental Elements	Advantages	Disadvantages		
Education	 May influence prescribing behavior and promote acceptance of ASP strategies 	 Only marginally effective in modify- ing prescribing behavior when used without active intervention 		
Evidence-based guidelines and clinical pathways	May improve antimicrobial use and eliminate practice variations	Adherence may be poor		
Antimicrobial cycling ^a	 May minimize resistance by providing diversity in antimicrobial use 	 Insufficient data available demon- strating long-term effectiveness in reducing antimicrobial resistance 		
		Many patients excluded because of drug allergies, toxicity, or other concerns		
		 Potential for nonadherence due to prescriber lack of awareness of currently scheduled agent 		
		May increase antibiotic costs		
Antimicrobial order forms	 May reduce inappropriate antimicrobial use 	 Potential for inappropriate interruption in therapy due to 		
	May facilitate implementation of guidelines and clinical pathways	automatic stop orders		
Combination therapy ^a	 May improve clinical outcomes and provent registrance in contain types 	Often redundant and unnecessary		
	of patients and situations	 Insufficient data available demon- strating improved clinical outcome and prevention of resistance 		
Streamlining or de-escalation of therapy	 Reduces antimicrobial exposure, selection of resistant pathogens, and health care costs 	Prescriber reluctance to de- escalate therapy when cultures are negative and clinical improvement has been observed		
Dose optimization	 Tailors therapy to patient character- istics, causative organism, site of infection, and pharmacokinetic and pharmacodynamic characteristics of the antimicrobial agent 	 Nursing staff concerns about incompatibilities when prolonged infusions are used based on pharmacokinetic considerations 		
Parenteral-to-oral conversion	May decrease length of hospital stay and health care costs	 Difficulty identifying patients in whom conversion is appropriate 		
	 May reduce the risk of complica- tions from intravenous access 			

* Not routinely recommended in IDSA/SHEA guidelines

requests for restricted agents trigger an infectious diseases consultation, which serves as an opportunity to provide education, improves antimicrobial use, and reduces resistance and health care costs. Formulary restriction and preauthorization and prospective audit with intervention and feedback are not mutually exclusive.

Whether formulary restriction and preauthorization reduces antimicrobial resistance in the institution is unclear because this strategy may increase the use of and resistance to an alternative antimicrobial agent, a phenomenon known as "squeezing the balloon".^{11,24} The effectiveness of preauthorization requirements may depend on the education, training, and skills of the authorized prescribers.¹¹

Supplemental Elements

Education is the most commonly used supplemental element.¹¹ However, active intervention (e.g., prospective audit and intervention) is required with education because passive education alone (e.g., provision of seminars and written guidelines) is only marginally effective in modifying prescribing behavior.¹¹ Repeated education is needed because of changes over time in antimicrobial resistance patterns and staff turnover.²²

Evidence-based guidelines and clinical pathways

that take into consideration the institutional formulary and local microbiology and antimicrobial resistance patterns may improve antimicrobial use and eliminate practice variations.¹¹ These guidelines and clinical pathways should be developed with multidisciplinary input. Adherence to national guidelines typically is poor because of their lack of local applicability.24 Tailoring guidelines and clinical pathways to address local microbiology and resistance patterns improves the likelihood of adherence.11 Education and feedback should be provided to prescribers on antimicrobial use and patient outcomes to facilitate implementation of guidelines and clinical pathways.11,27 Guidelines and clinical pathways should be updated periodically.28

Antimicrobial cycling is the scheduled substitution of a specific antimicrobial agent or class for another agent or class to prevent or reverse antimicrobial resistance.¹¹ Cycling provides heterogeneity (i.e., diversity) in antimicrobial use, which may minimize the selection pressure that leads to resistance.^{11,29} This selection pressure is low during periods when the use of an agent or class is low.²⁴ However, there are insufficient data about the long-term effectiveness of antimicrobial cycling for preventing or reversing antimicrobial resistance, so this practice is not routinely recommended in the IDSA/SHEA guidelines.¹¹ The cost of antimicrobial agents could increase during cycling if use is insufficient to meet minimum quantities needed to obtain favorable contract prices.²³

Antimicrobial order forms with automatic stop orders and requirements for the prescriber to justify antibiotic use can prevent excessively long and other inappropriate antimicrobial therapy. Paper or electronic forms may be developed. Incorporation of antimicrobial order forms into computerized physician order entry (CPOE) systems minimizes the time required to complete forms.²² Staff access to paper antimicrobial order forms is a consideration in institutions without CPOE systems. Order renewal requirements should be explained to prescribers to avoid inappropriate interruption in therapy from the use of automatic stop orders.¹¹

Combination therapy in theory may improve clinical outcomes and prevent resistance in certain types of patients and situations. For example, critically-ill patients with serious infections suspected to be caused by multidrug-resistant pathogens may respond better to empiric therapy with a broad spectrum of coverage (e.g., a broad-spectrum β-lactam antibiotic, an aminoglycoside or fluoroquinolone, and an agent to which methicillin-resistant Staphylococcus aureus is susceptible) than to monotherapy with a more narrow spectrum of activity.11 However, combination therapy often is redundant and unnecessary, and there are insufficient data supporting its use to improve clinical outcomes or prevent resistance. Therefore, combination therapy is not routinely recommended to prevent the emergence of resistance in the IDSA/ SHEA guidelines.¹¹

Streamlining or de-escalation of therapy involves the discontinuation of inappropriate or redundant empiric antimicrobial therapy based on culture and antimicrobial susceptibility data usually obtained on the third day of empiric antibiotic therapy (e.g., discontinuing broad-spectrum

therapy and initiating targeted therapy with a more narrow spectrum of activity suited to the isolated pathogen).

Dose optimization is a strategy that takes into consideration patient characteristics (e.g., age, weight, renal function), the causative organism, site of infection (e.g., bone), and pharmacokinetic and pharmacodynamic characteristics of the antimicrobial agent.¹¹ The pharmacokinetic and pharmacodynamic considerations enter into antimicrobial use guidelines.

Parenteral-to-oral conversion for antimicrobial agents with excellent bioavailability when the patient's condition permits can decrease the length of hospital stay and health care costs.¹¹ Developing institutional guidelines with clinical criteria for conversion can facilitate use of this strategy.

Various combinations of the core strategies and supplemental elements listed in Table 2 are used in hospitals. De-escalation of therapy on the third day of empiric antibiotic use is widely used with prospective audit with intervention and feedback.

Care Bundles

Care bundles are groups of evidence-based best practices that improve care, with a greater improvement achieved when the practices are used as a group within a specific time frame than when each practice is used alone.³⁰ Care bundles involve practices (usually three or four) that are necessary and sufficient to improve quality (i.e., lack of any one practice diminishes the likelihood of success in improving quality).³¹ Measurement of compliance with the bundle is straightforward and dichotomous (i.e., all or nothing, with yes/no determinations at various checkpoints).^{30,31}

Care bundles can provide education and clinical decision support and facilitate documentation of decisions. ³⁰ The use of care bundles ensures a systematic approach so that the delivery of care is consistent for all patients based on established local evidence-based guidelines.³⁰ Auditing compliance with care bundles serves as a means for performance monitoring of processes of care that can lead to quality improvement.³⁰ Care bundles have been used successfully to reduce HAI by the Institute for Healthcare Improvement in its 100,000 Lives Campaign, a national initiative with a

TABLE 3

Proposed Care Bundles for Antibiotic Prescribing³⁰

Acute care: initiation of therapy

- Document clinical rationale for antibiotic initiation
- Collect and send appropriate specimens to microbiology laboratory
- Select antibiotic therapy according to local policies (i.e., local antimicrobial susceptibilities) and risk group (exclude drug allergy)
- Consider removal of foreign body/drainage of pus/surgical intervention

Acute care: continuation of therapy

- On a daily basis, consider de-escalation, parenteral-to-oral conversion, or discontinuation of antibiotic therapy based on clinical signs and symptoms and laboratory test results
- Monitor serum antibiotic concentrations in accordance with local policies

Surgical prophylaxis

- Select antibiotic therapy based on local guidelines (i.e., local antimicrobial susceptibilities) and type of surgery (exclude drug allergy)
- Give first dose within guideline-defined time before incision
- Discontinue antibiotic therapy within guidelinedefined time after first preoperative dose or surgical end time.

goal of saving 100,000 lives in hospitalized patients through improvements in the safety and effective-ness of health care.³²

The use of care bundles has been suggested for antimicrobial stewardship in the acute care and surgical settings (Table 3), with input from local microbiologists and pharmacists and adaptation of the care bundle to meet institutional needs.³⁰ The primary goals of an acute care antibiotic bundle are to select the antibiotic most likely to cure the patient while simultaneously minimizing the risk of side effects, resistance to the antibiotic, and *C. difficile* infection (CDI).³⁰ The primary goals of a surgical antibiotic prophylaxis bundle are to decrease the incidence of surgical site infections, while simultaneously reducing the risk of side effects and resistance to the antibiotic.³⁰

At a tertiary care center, improved compliance with quality indicators was associated with implementation of an antibiotic care bundle for internal medicine and surgery patients receiving an antipseudomonal β -lactam antibiotic, vancomycin, fluoroquinolone, linezolid, or aminoglycoside.³³ The quality indicators included documentation of treatment rationale, collection of appropriate culture specimens, appropriate empiric antibiotic selection, and de-escalation of antibiotic therapy. Clinical outcomes were not assessed.

Pulcini and colleagues identified four key process measures for the reassessment of inpatient empiric antibiotic use after approximately 3 days of treatment based on published literature.34 These measures include presence of an antibiotic plan (drug, dose, route of administration, dosing interval, and planned duration), a review of the diagnosis, adjustment of the antibiotic therapy (e.g., streamlining, discontinuation) based on positive microbiological results if available, and documented consideration of parenteral-to-oral conversion if therapy was initiated using the intravenous (i.v.) route. These four measures were grouped to form a care bundle as a fifth measure. Compliance with this day 3 bundle required completion of all four process measures. The feasibility of using the five measures of care was evaluated over a 15-week period. The investigators judged the measures suitable for reassessing empiric antibiotic use after 3 days, with data collection that was sustainable over the 15-week period. Full (100%) compliance with the care bundle was achieved after 15 weeks. Clinical outcomes were not assessed.

Additional experience with antibiotic care bundles is needed. Methodologic flaws limit the validity of published reports of studies evaluating the impact of interventions to improve hospital antibiotic use.^{35,36}

Information Technology

The information technology infrastructure at a hospital often dictates which of the core strategies and supplemental elements in Table 2 can be used. This infrastructure may comprise a CPOE system

and electronic clinical decision support system, with electronic alerts (e.g., warnings about the need to reassess empiric antibiotic therapy after 3 days). Systems with the capability for obtaining comprehensive data on a real-time basis are valuable for conducting ASP activities. Many of the core strategies and supplemental elements listed in Table 2 (e.g., automatic stops as part of standardized antimicrobial orders) may be incorporated into CPOE systems. In the future, interfaces between the clinical laboratory and the CPOE system will facilitate the use of evidence-based guidelines and clinical pathways based on culture and antimicrobial susceptibility data and renal and hepatic function test results by providing guidance in antibiotic selection and dosing.

Information technology may be used to gather, sort, and analyze antimicrobial drug use data to create databases and identify, prioritize, and target problems with prescribing that involve specific physician services, types of patients, hospital units, or antimicrobial agents.¹¹ Information technology also can streamline the analysis of data pertaining to antimicrobial resistance to yield meaningful information about the impact of ASP activities. A lack of information technology often is the biggest barrier to implementing an ASP, although an extensive database and sophisticated information system are not necessarily required for a successful ASP.

Role of the Pharmacist in Antimicrobial Stewardship

A statement about the pharmacist's role in antimicrobial stewardship and infection prevention and control recently was released by ASHP.37 Promoting optimal use of antimicrobial agents (Table 4), reducing the transmission of infections, and educating health professionals, patients, and the public about antimicrobial stewardship and infection prevention and control are key pharmacist responsibilities. Pharmacist efforts to promote optimal use of antimicrobial agents and contributions to the success of ASPs are well documented.^{2,38-40} According to ASHP, pharmacists should assume a prominent role in antimicrobial stewardship because of their knowledge of and influence over antimicrobial use and membership on multidisciplinary committees in the institution.37

TABLE 4

Pharmacist Functions that Promote Optimal Use of Antimicrobial Agents³⁷

- Promoting multidisciplinary collaboration in the institution to ensure optimal patient outcomes from prophylactic, empiric, and therapeutic uses of antimicrobial agents
- Making recommendations for appropriate antimicrobial agent selection, dose optimization, timely initiation of therapy, therapeutic monitoring, and de-escalation of therapy
- Working with the pharmacy and therapeutics committee or its equivalent to develop policies and procedures for restricted antimicrobial use and therapeutic interchange, treatment guidelines, and clinical care plans
- Generating and analyzing quantitative data on antimicrobial drug use for use in performing analyses of clinical and economic outcomes
- Collaborating with microbiology laboratory and infectious diseases personnel to ensure the timely reporting of microbial susceptibility test results for individuals and hospital-wide and unit-specific microbial susceptibility data to prescribers
- Using information technology for surveillance of antimicrobial resistance, preparation of reports on antimicrobial use and outcomes, and developing clinical decision support tools
- Encouraging safe medication management practices for antimicrobial agents using efficient and effective systems to reduce the risk for errors and adverse effects

Pharmacist involvement in the pharmacy and therapeutics (P & T) committee is instrumental in providing antimicrobial stewardship because this committee has the authority to manage antibiotic use in the institution. Pharmacists also should participate in the infection prevention and control committee; this involvement is critical to the success of antimicrobial stewardship efforts.³⁷ Antimicrobial stewardship efforts are unlikely to succeed without effective infection prevention and control measures.

Current IDSA/SHEA guidelines call for a clinical pharmacist with infectious diseases training and an infectious diseases physician to serve as core members of a multidisciplinary antimicrobial stewardship team.11 The team often is directed by these two core members. The current IDSA/SHEA guidelines reflect a change from previous guidelines in which pharmacists played a smaller role and were expected to defer requests for therapeutic information and recommendations to physicians.41 The prominent role for pharmacists in antimicrobial stewardship called for in current IDSA/SHEA guidelines represents an opportunity for pharmacists to assume an expanded role in and responsibility for collaborative drug therapy management based on their knowledge of pharmacokinetics and pharmacodynamics. The director of pharmacy should make a commitment to antimicrobial stewardship and assume a leadership role in promoting the role of pharmacists as antibiotic use experts in the institution when interacting with other department heads and hospital administration. The director of pharmacy in collaboration with an infectious diseases leader or other medical staff champion also should lead the effort to formally introduce antimicrobial stewardship to the organization.

According to IDSA/SHEA guidelines, the pharmacist who serves as a core member of the antimicrobial stewardship team should be knowledgeable about the appropriate use of antimicrobial agents and receive appropriate training to achieve and maintain this expertise.11 In a joint opinion published in 2009, the Society of Infectious Diseases Pharmacists (SIDP) and the Infectious Diseases Practice and Research Network (ID PRN) of the American College of Clinical Pharmacy (ACCP) recommended completion of a postgraduate year (PGY) 1 residency and a PGY2 residency in infectious diseases, board certification as a pharmacotherapy specialist, and assembly of a portfolio of educational experiences to maintain qualifications for pharmacists who wish to practice in infectious diseases.42 These two organizations encourage infectious diseases training programs to seek accreditation and advocate the development of a certification examination in infectious diseases.42 Until a certification examination in infectious diseases becomes available, SIDP and the ACCP ID PRN suggest that board-certified pharmacotherapy specialists seek added qualifications in infectious diseases from the Board of Pharmaceutical Specialties. Some PGY2 residency training programs in infectious diseases are accredited by ASHP. The SIDP maintains online listings of infectious diseases fellowships, residency training programs, continuing education programs, and other educational resources (www. sidp.org). Many fellowships in infectious diseases have a strong research focus, with less emphasis on clinical training in a patient care setting.⁴²

The limited availability of and substantial time investment required to complete infectious diseases fellowships and residency training programs have limited the number of pharmacists with these credentials. Recruiting pharmacists with infectious diseases training can be difficult for institutions with budgetary constraints because of competition for qualified candidates from the private sector with greater financial resources.

The burden for providing antimicrobial stewardship falls on pharmacists without infectious diseases training in many institutions, and a lack of specialized training should not be viewed as an insurmountable barrier to implementation of an ASP.36 A need for pharmacists without infectious diseases training to assume responsibility for antimicrobial stewardship because of a lack of sufficient numbers of pharmacists with such training in the United States is acknowledged by ASHP in its statement on the pharmacist's role in antimicrobial stewardship and infection prevention and control.37 Pharmacists without specialized training in infectious diseases often can contribute to antimicrobial stewardship through medication order review and detection of orders for restricted antimicrobial agents, without proper authorization, or inconsistent with clinical pathways or protocols. However, time constraints and discomfort due to a lack of training may limit the contribution of these individuals.24 In many hospitals without infectious diseases pharmacists, routine pharmacy services take priority over antimicrobial stewardship activities, compromising the success of antimicrobial stewardship efforts. Consistent antimicrobial stewardship efforts by pharmacists whose time and responsibilities are devoted to these efforts are needed for program success. The success of antimicrobial stewardship efforts relies heavily on the cooperation of pharmacists without

TABLE 5

Informal ID Educational Opportunities for Hospital Pharmacists

- Identify a mentor with ID expertise for case discussions
- Attend rounds with an ID physician
- "Shadow" a clinical microbiologist
- Join ID professional organizations
- Attend ID professional meetings
- Participate in ID-related continuing education programs
- Subscribe to ID list-servs
- Sign up for electronic alerts with tables of contents for ID-related periodicals
- Read basic primers, review articles, and practice guidelines on ID topics
- Conduct or participate in an ID journal club
- Attend ID-related morbidity and mortality case reviews
- ID = infectious diseases

infectious diseases training, even in hospitals with pharmacists who have such training.

Pharmacists may use a variety of methods to improve their knowledge of microbiology and infectious diseases pharmacotherapy without making the large time investment associated with infectious diseases fellowships and residencies. A certificate program in antimicrobial stewardship, with Web-based, live, and practical workplace components, is available from MAD-ID Making a Difference in Infectious Diseases Pharmacotherapy (www.mad-id.org/), a not-forprofit foundation for continuing education in infectious diseases pharmacotherapy.

The SIDP currently is developing a certificate program for pharmacists that will be available online and for which continuing education credit will be available. The certificate program is intended to supplement not supplant infectious diseases fellowships and residency training programs.

Pharmacists might augment their infectious diseases knowledge by identifying a pharmacist or physician mentor with infectious diseases expertise, attending rounds with infectious diseases physicians, and arranging to work alongside a clinical microbiologist on a short-term basis in their workplace (Table 5). Discussing patient cases with a mentor can be a good learning experience for the pharmacist. Attending infectious diseases-related professional meetings and participating in infectious diseases-related continuing education programs also can be helpful. Obtaining basic references (e.g., the Clinical and Laboratory Standards Institute Performance Standards for Antimicrobial Disk Susceptibility Tests) and readings in the published literature (e.g., basic primers, review articles, practice guidelines from authoritative sources) are other cost-effective ways of preparing pharmacists to participate in antimicrobial stewardship.43 The resource center at ASHP's Antimicrobial Practice Improvement Program in Hospitals Web site (www.ashpadvantage.com/stewardship/) provides links to useful Web-based resources.

Developing and Implementing an ASP

The development and implementation of an ASP in the hospital setting is a potentially daunting task, with many potential pitfalls to avoid and barriers to overcome. Developing a proposal to obtain institutional support for the ASP, assembling and leading the ASP core team, analyzing current institutional practices, and developing processes to meet ASP goals are key steps in the implementation process. Other steps include analyzing and reporting data demonstrating the impact of ASP processes, and developing and implementing outreach plans directed to key hospital staff. Because pharmacists serve as core members of antimicrobial stewardship teams and other multidisciplinary committees and have considerable knowledge of antimicrobial use in the institution, they might spearhead the development and implementation of an ASP.

Developing a Proposal to Obtain Institutional Support for an ASP

Obtaining approval from administration for an ASP is difficult in most hospitals because of competition for limited resources, so a strong business case and strategic plan for the ASP are vital to gaining support. Proposals must be compelling and based on sound arguments and solid data.

The proposal should provide justification for the program based on the institutional costs and consequences of inappropriate antimicrobial use (i.e., adverse effects, resistance, morbidity, mortality, and HAI). An evidence-based toolkit for estimating the cost of HAI and antimicrobial resistance, *What Every Health Care Executive Should Know: The Cost of Antibiotic Resistance*, is available from the Joint Commission at no charge to health care organizations, executives, and clinicians. Published estimates of the costs of HAI also are available.⁴⁴

Although an ASP may reduce the hospital length of stay, it is best not to use the savings associated with reductions in length of stay as part of the cost justification for an ASP because multiple factors affect length of stay.⁴⁵ The relationship between antibiotic use and length of stay is complex, and it often is difficult to demonstrate a direct cause-and-effect relationship between antimicrobial stewardship and length of stay.

The proposal should demonstrate the need for the ASP by providing examples from the published literature and selected institutional data on the prevalence of HAI caused by resistant organisms, bacterial susceptibilities to antimicrobial agents from antibiograms, and antimicrobial use patterns and costs that illustrate problems. Antibiograms are reports compiled by the clinical microbiology department that indicate the susceptibility of various pathogens to different antibiotics, and these reports may be obtained for specific hospital locations where unique resistance patterns often develop (e.g., surgical and medical intensive care units) as well as the overall institution. Problems with HAI caused by resistant organisms (e.g., methicillin-resistant Staphylococcus aureus) and antimicrobial use that can lead to resistance or increase costs (e.g., an excessive duration of use, especially involving the unnecessary use of the parenteral route once the oral route becomes

an alternative) and the implications of failure to address the problems should be described in the proposal.

Guidelines and recommendations for establishing an ASP from authoritative groups, especially IDSA and SHEA, should be outlined in the proposal. The SHEA recently called for efforts to achieve a goal of zero HAI, and this goal could provide impetus for the implementation of an ASP.⁴⁶

The financial implications for the hospital of Centers for Medicare & Medicaid Services (CMS) reimbursement policies for infection-related "never events" also should be addressed in the proposal because they provide justification for ASP implementation. In an effort to improve the quality of care in hospitals, CMS discontinued payment for never events—preventable medical errors that result in serious consequences for the patient—beginning in October 2008.⁴⁷ The agency considers certain HAI avoidable never events.⁴⁸

The impact on institutional image of publiclyreported infection-related national quality indicators should be mentioned in the proposal to strengthen the argument for ASP implementation. The Joint Commission and National Quality Forum require reporting by hospitals of various core performance measures (e.g., appropriate antibiotic section and timely administration for pneumonia) to facilitate quality comparisons among hospitals.49 The Joint Commission's National Patient Safety Goal 7 to reduce the risk of HAI provides added impetus for ASP implementation because it requires the implementation of evidence-based practices to prevent HAI due to multidrug-resistant organisms (NPSG.07.03.01) and surgical site infections (NPSG.07.05.01), with elements of performance that address prophylactic antimicrobial use in surgical patients.⁵⁰ Failure to meet NPSGs could affect Joint Commission accreditation decisions.

The Surgical Care Improvement Project (SCIP) is a national initiative developed by CMS, the Centers for Disease Control and Prevention, and various organizations to improve the safety of surgical care by reducing postoperative complications by 25% before 2010.⁵¹ Because surgical site infections are a common complication and account for 14% to 16% of HAI, several SCIP performance measures address the appropriate selection, time of initiation, and time of discontinuation of prophylactic antibiotic therapy in surgical patients.¹⁴ The need for these SCIP performance measures to provide a favorable impression of the institution lend support to proposals for ASP implementation.

The proposal should outline the goals of the ASP based on the scope of the problems identified and available resources. The ASP should be tailored to meet institutional needs, but the goals should be realistic. Short- and long-term goals should be identified through a formal strategic planning process. The "low-hanging fruit" might be targeted initially to maximize results from limited resources. This approach involves focusing first on activities that are easy or inexpensive to implement or associated with proven benefits and goals that are readily achieved. Initial efforts might focus on only one or a few antibiotics or types of infections. Pharmacists at many small institutions perform effective antimicrobial stewardship activities despite the lack of a formal, well-funded program.

In preparing the proposal, an attempt should be made to quantify the resource requirements and associated costs for the ASP. These costs can be substantial, especially for personnel (e.g., physician compensation) and information technology. As with other requests for funding, it may be wiseto request a larger amount than the minimum required to implement and conduct the ASP, with the expectation that a smaller amount of funding will be provided.

The costs of the ASP should be presented in the context of the potential for improved patient safety and clinical outcomes from the investment. The potential net cost savings or costs avoided (e.g., avoiding continuation of a recent trend of increasing costs) from an ASP also should be quantified, if possible.²³ The hospital finance department can be helpful in providing cost figures for the proposal.

The proposal for an ASP might call for pilot testing activities on a limited basis, with plans for hospital-wide expansion at a later date if success is demonstrated with pilot testing. The proposal might specify a target cost savings from the pilot program and stipulate that savings realized at the end of the pilot program will be used to fund salaries for new staff dedicated to the ASP. Future growth and needs (e.g., personnel, equipment) of the ASP should be anticipated.

The director of pharmacy and an infectious diseases physician should play instrumental roles in developing the proposal and negotiating with hospital administration for the ASP. The proposal should seek adequate authority as well as financial support from administration for the ASP. A commitment from hospital administration for the ASP is critical to the success of the program; financial support alone does not suffice.24 A survey of infectious diseases pharmacists at North American hospitals with an ASP revealed uncertainty about program effectiveness in improving patient outcomes, controlling antimicrobial resistance, and decreasing medication costs, and these perceptions were attributed to a lack of institutional support for the ASP.52

Assembling and Leading the ASP Core Team

A clinical pharmacist with infectious diseases training, infectious diseases physician, and ideally a clinical microbiologist, infection control professional, information system specialist, and hospital epidemiologist should be designated for the ASP core team, according to IDSA/SHEA guidelines.¹¹ The infectious diseases physician member of the core team plays a vital role in lending legitimacy to the ASP.²⁴ Other influential "key opinion leaders" (i.e., champions) among the medical staff should be identified, and their early buy-in and support for the ASP should be sought.

The need for physician compensation for ASP efforts as incentive for participation on the ASP team may need to be addressed because lack of compensation can be a barrier to participation.²² In most hospitals, physicians are compensated for services rendered to individual patients through consultation fees in contrast to hospital personnel who receive salaries.²³ The large time commitment required for participation in ASP activities can deter physician involvement.²⁴ A volunteer (i.e., uncompensated) physician core team member may not be available as consistently as one who is compensated. In institutions without an infectious diseases physician, an enthusiastic physician champion should serve as a core team member.

The clinical microbiologist member of the core team provides expert input about the use of microbiology susceptibility test panels (especially new assays for rapid diagnosis) and options for sorting among susceptibility data to generate meaningful antibiograms (i.e., without distortion from inappropriate data selection methods). These antibiograms may be based on unit-specific or hospital-wide data on appropriate pathogens and antibiotics for an entire year or a shorter period. Providing guidance in interpreting institutional antibiograms taking into consideration the limitations of the reports (e.g., the inability to draw conclusions from or extrapolate data based on small numbers of isolates) is another contribution of the clinical microbiologist. This input is essential for devising guidelines and clinical pathways for antimicrobial use to prevent or treat infections.

Infection control professionals are integral members of the ASP core team because of the close relationship between antimicrobial stewardship and infection prevention and control efforts. For example, infection control professionals monitor HAI rates, including CDI rates, which reflect resistance patterns.²⁴

The information system specialist member of the ASP core team can be instrumental in advising the team about optimal uses of available technology. Hospital epidemiologists have expertise in and can advise the ASP core team about infection surveillance and research methods to use in evaluating the impact of ASP activities.²⁴

A lack of personnel to serve on an ASP core team is a potential barrier in some facilities, especially small or rural hospitals. Some facilities lack an infectious diseases physician, often because of a lack of compensation. A physician with a strong interest in infectious diseases should be sought for the ASP core team in these facilities. Although pharmacists have led antimicrobial stewardship efforts in some facilities without infectious diseases physicians, ideally antimicrobial stewardship is a coordinated and equal partnership involving pharmacy and medicine. In institutions without a pharmacist with infectious diseases training, a clinical pharmacist with an interest in but no credentials in infectious diseases or the director of pharmacy could serve as a core team member.

Communication channels should be established to facilitate collaboration between members of the ASP core team and members of the infection control, P & T, medical executive, and other multidisciplinary committees. Networking can promote cooperation and may be mutually beneficial. For example, the clinical microbiology department may be able to use ASP data to justify the addition of new staff and equipment.

Establishing an ASP core team does not preclude the involvement of additional staff in planning and implementing ASP activities. For example, members of the pharmacy staff should be involved in the development of guidelines and policies for antibiotic use. Environmental services staff often participate in infection control efforts related to ASP goals. Other stakeholders (e.g., surgeon, pediatrician) should be involved as needed.²³ Input should be obtained from representatives of hospital departments that will be affected by and involved in ASP activities (e.g., emergency department personnel). Early involvement of these staff can forestall resistance to the ASP.²³

Analyzing Current Institutional Practices

Problems with current institutional practices for the diagnosis and treatment of infections should be identified by compiling and analyzing data on antimicrobial use and costs for common HAI (e.g., ventilator-associated pneumonia, catheter-associated bloodstream infections) and bacterial susceptibilities to antimicrobial agents from unit-specific and hospital-wide antibiograms. Infection-related national quality indicator data also should be evaluated.

Antibiograms from a 5- or 10-year period might be used to identify trends. Antibiograms are helpful for making decisions about empiric antibiotic therapy because they reflect local microbiology and resistance patterns. However, antibiograms should be interpreted with caution and they should not be used alone to make clinical decisions because of their limitations.⁵³ Antibiograms may provide misleading information if they are based on small numbers of or duplicate isolates, isolates cultured at a hospital outpatient clinic as well as from inpatients, or isolates that reflect resistance patterns that are subject to rapid change.⁵³ Patient-specific factors, including the type and severity of infection and prior infections and antibiotic use, should be taken into consideration when prescribing antibiotics.⁵³

Obtaining antibiograms is difficult at some institutions because of inadequate microbiology laboratory services. Proposals for ASPs should provide funding for these services to optimize the effectiveness of the program. When robust data pertaining to antimicrobial use and susceptibilities are not available, it may be helpful to consult with infectious diseases physicians about their perceptions of problems at the institution.

Goals for the ASP should be refined to address problems with current institutional practices identified through analysis of antibiograms and antimicrobial use and cost data for common HAI. Infection-related national quality indicator data also should be taken into consideration in establishing ASP goals.

Developing Processes to Meet ASP Goals

The antimicrobial stewardship core strategies and supplemental elements in Table 2 can be applied in various steps in the antimicrobial prescribing process. For example, education, guidelines, and clinical pathways may be used at the time of patient evaluation. When antimicrobial agents are selected, formulary restriction, preauthorization requirements, and prospective audit with direct intervention and feedback may be used as well as education, guidelines, and clinical pathways. Prospective audit with direct intervention and feedback also is used in antibiotic dispensing. Computer-assisted strategies (e.g., antimicrobial order forms integrated into CPOE systems) may be used in selecting and ordering antimicrobial agents. A strategic plan should be devised to implement these strategies and elements as part of institutional processes so that ASP goals are met.

Policies and procedures for antimicrobial prescribing should be revised to accommodate ASP goals and activities, with multidisciplinary input from all stakeholders. In small hospitals and other institutions with limited resources, the hours of operation for ASP activities may be limited. Providing these activities after hours may need to be addressed in policies and procedures.

Analyzing and Reporting Data Demonstrating the Impact of ASP Activities

Documentation and analysis of data are needed to demonstrate a favorable impact of ASP activities on clinical outcomes, antimicrobial resistance, and health care costs. The appropriate types and sufficient amounts of data must be documented and accessible for an analysis to yield meaningful information.³⁶

Data on antimicrobial use and costs, bacterial susceptibilities to antimicrobial agents from unitspecific and hospital-wide antibiograms, surgical site infection and other HAI rates, and infectionrelated quality indicators should be compared before and after ASP implementation and over time to document the impact of ASP activities and identify trends. Institutional data also should be compared with bench mark data from local hospitals and the published literature.

Antibiograms may be useful as an outcome measure of the success of ASP activities.⁵³ Guidance in preparing antibiograms is available from the Clinical and Laboratory Standards Institute (*Antibiograms: Developing Cumulative Reports for Your Clinicians Quick Guide*, M39-A3 QG, available at www.clsi.org).

Various process measures (Table 6) and adherence to institutional guidelines, care bundles, and policies and procedures also should be used to evaluate the impact of ASP activities. Antimicrobial resistance rates should not be relied on exclusively to judge the success of the ASP because they may also reflect the impact of infection prevention and control measures and the transfer from long-term-care facilities or other hospitals of patients previously infected or colonized with antimicrobial-resistant pathogens.^{21,24}

Cost analyses should take into consideration the costs associated with antimicrobial resistance (e.g., the use of isolation to prevent transmission of multidrug-resistant infection among hospitalized patients) and HAI as well as drug acquisition costs. Aggressive empiric use of high-cost antibiotic therapy can decrease the duration of treatment, hospital length of stay, and hospital costs despite an increase in drug acquisition costs.⁴⁵

TABLE 6

Process Measures for Use in Evaluating ASP Impact

- Justification for antibiotic use
- Empiric
- Therapeutic
- Appropriateness of antibiotic drug choice/ avoidance of unnecessary combination therapy
 - Based on spectrum of activity and susceptibility of suspected or documented pathogen
 - Based on drug allergies and potential for toxicity
 - Based on cost
- Appropriateness of antibiotic drug regimen (dose, dosing interval, and route of administration) based on pharmacokinetics and pharmacodynamics
- Appropriateness of time of initiation of antibiotic therapy
 - With respect to time of surgery for prophylactic use
 - With respect to time of cultures for therapeutic use
- Appropriateness of duration of antibiotic therapy/ avoidance of unnecessarily prolonged therapy
- Rate of acceptance of ASP recommendations
- Rate of adherence to institutional guidelines, care bundles, and policies and procedures for antibiotic use
- ASP = antimicrobial stewardship program

The results of the data analysis should be reported to hospital administration, the P & T and infection control committees, and other stakeholders to obtain support for program continuation or expansion. An annual report describing ASP activities and outcomes might be prepared. The results of the data analysis also should be used to revise ASP strategies as needed to improve efficacy of the ASP and quality of care (i.e. the ASP data analysis should be integrated with institutional continuous quality improvement efforts).³⁶ Publication of the results of the data analysis should be explored.

Developing and Implementing Outreach Plans Directed to Key Hospital Staff

Misperceptions about a lack of prescriber autonomy are a major potential barrier to ASP implementation. Physicians may view the ASP as a "cookbook approach" to medicine that eliminates clinical judgment and represents a cost-driven bureaucratic effort by hospital administration or the pharmacy department. In some instances, prescribers have been known to find ways to work around ASP requirements (e.g., wait until after hours to order restricted antibiotics in hospitals with limited hours of operation for the ASP).²³

Outreach plans should be devised to anticipate and avoid or overcome these problems. The plan should market and build buy-in for the ASP before it is launched by providing education about its rationale, goals, and components.³⁶ The education can take a variety of forms, including grand rounds, morbidity and mortality conferences, newsletter stories, and a concise one-on-one "elevator pitch." An emphasis on patient safety should be used to dispel misperceptions.¹¹ The use of guidelines and clinical pathways that reflect published literature, institutional microbiology and resistance patterns, and local practitioner input as the basis for the ASP should be explained to defuse concerns about a lack of autonomy.

All staff who are impacted by the ASP program, including supervisors, should be educated about the rationale, goals, and components of the program in a way that is relevant and meaningful to them to promote adherence to ASP requirements. For example, nursing staff need to understand that the ASP is designed to reduce the need for isolation of patients with HAI due to multidrug-resistant pathogens, which is laborintensive and time-consuming for nurses as well as costly for the institution. Nursing staff also require an understanding of antibiotic pharmacokinetics and pharmacodynamics because of the impact of continuous infusions on the use of i.v. tubing for other purposes. Pharmacists are uniquely qualified to provide this education because of their education. Staff education about ASP goals and requirements should be provided frequently

(at least annually for house officers) for all departments to accommodate new staff. When annual antibiograms become available, education should be provided about the implications for affected staff, including physicians, nurses, and hospital administrators.

Creating a "brand" for the ASP with a slogan and logo can unify and build recognition among hospital staff for various components of the ASP. This branding should be applied to all communications (e.g., memoranda, posters, newsletters, electronic mail), order forms, and computer interfaces (e.g., CPOE screens) used for the ASP. A Web site for the ASP might be established to provide a comprehensive, convenient source of program information for hospital staff.

A one-on-one intervention may be needed to address problems with individual prescribers who appear to undermine or sabotage ASP efforts. Political savvy and diplomacy may be needed to cope with recalcitrant persons. The support of hospital administration in enforcing ASP requirements can be helpful. In some cases, inappropriate prescribing practices reflect long-established habits that are difficult to change. Many prescribers fail to appreciate the urgency of the problem with multidrug resistance, potential for collateral damage (i.e., the selection of resistant pathogens arising from the unnecessary use of broad-spectrum antibiotics), need to reserve effective agents for use only when truly needed, and the impact of prescribing for an individual patient on resistance in the local flora.

Conclusion

Inappropriate antimicrobial use and antimicrobial resistance are major problems in U.S. hospitals that can be addressed through ASPs. Pharmacists play a vital role in leading the development and implementation process and ensuring the success of ASPs. The commitment of hospital administration and a multidisciplinary effort are required for successful ASP implementation. An awareness of the potential pitfalls in and barriers to implementation of an ASP can facilitate the process and lead to success.

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Antibiotic Stewardship and Clostridium difficile infection in the Hospital Setting

Colorado Infection Prevention Collaborative June 9, 2011

> Tim Jenkins, MD Director, Antibiotic Stewardship Program Division of Infectious Diseases Denver Health Medical Center



















Impact of antibiotic resistance Does it matter?

Multiple studies have shown:

- Increased morbidity and mortality
- Increased length of hospitalization
- Increased hospital costs

 when compared with infections due to susceptible organisms

Impact of antibiotic resistance Towards a post-antibiotic era?

 2 cases of *Klebsiella pneumoniae* infection resistant to all antibiotics ("pan-resistant") in a New York City Hospital

Elemam A. CID 2009; 49:271-4













Pathogenesis of CDI

At least 3 events must occur in the pathogenesis of *C. difficile* diarrhea:

- 1) alteration of the normal fecal flora
- colonic colonization with toxigenic C. difficile
- 3) organism growth with elaboration of toxins

Antibiotics alter normal gut flora to predispose to CDI

- 84 outpatients with laboratory-confirmed CDI
 - 85% diagnosed within 30 days of hospital discharge
 - 92% received antimicrobials during a prior hospitalization
 - -65% received antimicrobials both as inpatient and outpatient

Chang H. ICHE 2007; 28:926-31







Antibiotic stewardship programs

Primary goal:

Optimize antibiotic use to maximize the likelihood
 of a favorable clinical outcome for patients

Secondary:

- Minimize the likelihood of antibiotic-related adverse events
- Minimize the selective pressure for resistant organisms
- Limit infection-related costs
- Educate providers





Interventions to improve antibiotic use at the hospital level

- Prospective audit with provider feedback
- Formulary restriction/preauthorization
- Clinical practice guidelines or algorithms
- Short-course therapy
- Rapid diagnostic testing
- · Biomarker-guided antibiotic prescribing
- Antibiotic cycling
- Provider education
- Intravenous to oral conversion
- Computerized provider order entry and decision support



Prospective audit with feedback A randomized trial

Grady Memorial Hospital

 12 medicine teams randomized to intervention vs. standard of care

 Intervention: prescriptions for vancomycin, levofloxacin, and piperacillin/tazobactam reviewed by an ID physician or ID pharmacist with verbal recommendations to team

 ID physician blinded to intervention allocation determined "appropriateness" of therapy according to specific criteria

Camins B. ICHE 2009; 20:931-8

Prospective audit with feedback A randomized trial

TABLE 2. Appropriateness of Antibiotic Use in Randomized Controlled Trial of Impact of Antimicrobial Utilization Teams

	Proportion (%) of prescriptions			P
Variable	Intervention Control group group		Risk ratio (95% CI)	
Antibiotic use deemed appropriate	1.1.1.1.1.1		1.2.2	
Initial (<72 hours)	305/390 (78)	229/394 (58)	1.35 (1.22-1.49)	<.001
Empirical	242/294 (82)	211/291 (73)	1.14 (1.04-1.24)	.005
Definitive	92/112 (82)	60/138 (43)	1.89 (1.53-2.33)	<.001
Appropriate cultures obtained	188/270 (70)	193/286 (67)	1.03 (0.92-1.15)	.59
Changed to recommended antibiotics"	168/186 (90)	85/199 (43)	2.11 (1.79-2.50)	<.001
Appropriate end antimicrobial usage	367/390 (94)	277/394 (70)	1.34 (1.25-1.43)	<.001

NOTE. CI, confidence interval.

In the control group, a blinded assessment of the appropriateness of the antimicrobial therapy was still made by the medical director of the antimicrobial utilization program. However, any recommendations for optimization of therapy were only recorded and never conveyed to the control group physicians.

Camins B. ICHE 2009; 20:931-8




































Procalcitonin (PCT)

 Multicenter, randomized trial of antibiotic prescribing based on a PCT algorithm vs standard guidelines for lower respiratory tract infections, defined as:

-Community-acquired pneumonia (CAP)

- -COPD exacerbation
- -Acute bronchitis

Schuetz P. JAMA 2009; 302:1059-66



Antibiotic exposure and outcomes with procalcitonin-guided therapy

	Procalcitonin N = 671	Standard N = 688	Р
Mean antibiotic duration	5.7 days	8.7 days	<.05
CAP	7.2 days	10.7 days	<.05
COPD exacerbation	2.5 days	5.1 days	<.05
Acute bronchitis	1.0 days	2.8 days	<.05
Antibiotic-related adverse events	19.8%	28.1%	<.05
Adverse outcomes*	15.4%	18.9%	NS

*death or ICU admission due to any cause, disease-specific complications, recurrence within 30 days

Adapted from Schuetz P. JAMA 2009; 302:1059-66



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Systematic review of antibiotic cycling trials:

- only 4 studies suitable for review
- 3 showed decrease in antibiotic resistance to drugs withdrawn
- rates of resistance returned to baseline levels when drugs re-instated
- lack of standardization and multiple methodological flaws

→ No meaningful conclusions could be drawn

Brown E and Nathwani D. J Antimicrob Chemo 2005; 55:6-9









SHEA-IDSA antibiotic stewardship recommendations to prevent CDI

C. Antimicrobial Use Restrictions

22. Minimize the frequency and duration of antimicrobial therapy and the number of antimicrobial agents prescribed, to reduce CDI risk (A-II).

23. Implement an antimicrobial stewardship program (A-II). Antimicrobials to be targeted should be based on the local epidemiology and the *C. difficile* strains present, but restricting the use of cephalosporin and clindamycin (except for surgical antibiotic prophylaxis) may be particularly useful (C-III).

Cohen S et al. ICHE 2010; 31:431-55

national scale		
Organization	Initiative	
IDSA	Antimicrobial Availability Task Force	
	Bad Bugs, Need Drugs campaign	
	10 x '20 advocacy campaign	
CDC	Get Smart for Healthcare	
NIH	Funding for clinical trials to reduce antibiotic use	
	Use of ACTG infrastructure for studies of common	

Conclusions

- Antibiotic stewardship programs can utilize a number of interventions to improve antibiotic use
- Interventions targeted to specific antibiotics may decrease CDI, particularly in an outbreak setting
- Interventions to promote narrower spectrum agents and decrease overall antibiotic use may decrease CDI
- Antibiotic stewardship programs are a critical component of CDI control measures



COLORADO INFECTION PREVENTION COLLABORATIVE C.DIFFICILE INFECTIONS







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C. DIFFICILE INFECTIONS

COLORADO INFECTION PREVENTION COLLABORATIVE



COLORADO INFECTION PREVENTION COLLABORATIVE C.DIFFICILE INFECTIONS







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COLORADO INFECTION PREVENTION COLLABORATIVE

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