How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for CDI. In it, you’ll find:

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Executive Summary

The Problem
Annually, Clostridioides difficile infection (CDI) impacts an estimated 500,000 Americans with approximately 29,000 associated deaths (Mada et al., 2019). Globally, its incidence rate hovers around 2.24 per 1000 admissions annually (Balsells, et al., 2018). CDIs could be entirely eliminated with protocols already available and affordable in healthcare settings, including frequent hand hygiene and isolation precautions.

The Cost
The average total cost for a single inpatient CDI infection is an estimated $35,000 and the estimated annual cost burden of CDI on the healthcare system exceeds $6 billion (APIC, 2013). Investment in low-cost preventive measures, such as implementation of a CDI bundle, could save lives and entirely eliminate the significant financial burden.

The Solution
Many healthcare organizations have successfully implemented and sustained improvements and reduced death from CDI. These organizations have focused on projects that included judicious use of antimicrobials, frequent and routine environmental cleaning, and early identification and treatment of CDI.

This document provides a blueprint that outlines the actionable steps organizations should take to successfully reduce and improve CDI prevention compliance and summarizes the available evidence-based practice protocols. This document is revised annually and is always available free of charge on our website. Hospitals who make a formal commitment to improve CDI compliance rates and share their successes on the PSMF website have access to an additional level of consulting services.
Leadership Checklist

On a monthly basis, or more frequently if a problem exists, the executive team should review the outcomes of patients with CDI. Use this checklist as a guide to determine whether current evidence-based guidelines are being followed in your organization:

- Measure and report CDI prevention compliance monthly (Number of healthcare associated CDI based on [CDC NHSN definitions](https://www.cdc.gov/nhsn/pdfs/dfa/dfa_nhsn_definitions.pdf) / total number of patient days based on [CDC NHSN definitions](https://www.cdc.gov/nhsn/pdfs/dfa/dfa_nhsn_definitions.pdf)). Note trends in areas with low compliance and high CDI incidence. Routinely reassess outcomes.

- If CDI incidence rates indicate room for improvement, initiate a PI (performance improvement) project. If a problem is not indicated, routinely reassess to identify gaps, and ensure integrity of the data collected.

- Ensure frontline involvement in CDI improvement activities. Maintain their engagement and remove barriers to progress.

- If a PI plan is put in place, measure the associated process outcomes.

- Ensure that CDI prevention protocols are embedded into [clinical workflows](https://www.cdc.gov/nhsn/pdfs/dfa/dfa_nhsn_definitions.pdf), whether electronic or paper.

- Ensure there are enough staff to effectively manage necessary preventive care.

- Ensure adequate training and documentation of CDI prevention competencies and skills.

- Eliminate barriers to making rapid changes to documentation templates and order sets.

- Debrief on a regular basis to solicit team feedback about barriers to sustained compliance. Adjust the plan quickly and nimbly as needed.

- Hold staff accountable for providing the standard of care and reward success.

- Ensure that leaders have a simple process to oversee CDI prevention improvement work while also considering how it aligns with other initiatives across the organization.
To meet patient needs, the care team should coordinate the preparation of the patient and bring together all necessary resources to guide the patient through their recovery. The patient requires close monitoring of their performance and readiness to discharge. The family members and caregivers should receive thorough and engaged education regarding the care plan before discharge.

Communication
- Update the patient on the next day. The care team will coordinate the communication with the family members and the nursing staff.
- The hospital environment is patient-centered, and all measures are taken to ensure a comfortable and safe recovery. Keeping up-to-date with patient feedback and concerns is vital.
- The care team establishes effective communication with the patient and the family members.
- Maintain the utmost personal and professional conduct.

TREATMENT
- For patients with a confirmed Clostridioides difficile infection, the care team follows the latest treatment protocols. Antibiotics are prescribed as per the CDI prescription guidelines.
- The care team closely monitors patients for any signs of recurrence and ensures a smooth transition back to their daily routine.

PREVENTION
- Establish thorough infection control practices and policies, including hand hygiene and appropriate isolation measures.
- The care team follows the latest CDC guidelines and recommendations for preventing CDI in healthcare settings.
- The care team closely monitors patients for any signs of recurrence and ensures a smooth transition back to their daily routine.
Performance Improvement Plan
Follow this checklist if the leadership team has determined that a performance improvement project is necessary:

☐ **Gather the right project team.** Be sure to involve the right people on the team. You’ll want two teams: an oversight team that is broad in scope, has 10-15 members, and includes the executive sponsor to validate outcomes, remove barriers, and facilitate spread. The actual project team consists of 5-7 representatives who are most impacted by the process. Whether a discipline should be on the advisory team or the project team depends upon the needs of the organization. Patients and family members should be involved in all improvement projects, as there are many ways they can contribute to safer care.

<table>
<thead>
<tr>
<th>RECOMMENDED CDI IMPROVEMENT TEAM</th>
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</thead>
<tbody>
<tr>
<td>- Environmental service staff members</td>
</tr>
<tr>
<td>- Infection preventionists</td>
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<tr>
<td>- Laboratorians</td>
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<tr>
<td>- Pharmacists</td>
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<td>- Nurses</td>
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<tr>
<td>- Physicians</td>
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<tr>
<td>- Admitting and registration staff</td>
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<tr>
<td>- Quality and safety specialists</td>
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*Table 1: Understanding the necessary disciplines for a CDI prevention improvement team*

☐ **Understand what is currently happening and why.** Reviewing objective data and trends is a good place to start to understand the current state, and teams should spend a good amount of time analyzing data (and validating the sources), but the most important action here is to go to the point of care and observe. Even if team members work in the area daily, examining existing processes from every angle is generally an eye-opening experience. The team should ask questions of the frontline during the observations that allow them to understand each step in the process and identify the people, supplies, or other resources needed to improve patient outcomes.

<table>
<thead>
<tr>
<th>CDI PROCESSES TO CONSIDER ASSESSING</th>
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<tbody>
<tr>
<td>- Antimicrobial use</td>
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<tr>
<td>- Time between suspicion and ordered laboratory testing</td>
</tr>
<tr>
<td>- Time between laboratory results and communication to the appropriate teams (infection control, unit nurse, etc.)</td>
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<tr>
<td>- Use of soap versus alcohol-based rub</td>
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<tr>
<td>- Number of laboratory retests for the same patient</td>
</tr>
<tr>
<td>- Time between suspicion and isolation precaution initiation</td>
</tr>
<tr>
<td>- Auditing of antimicrobial therapy appropriateness and duration</td>
</tr>
<tr>
<td>- Use of single-use equipment for CDI positive patients</td>
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<tr>
<td>- Disinfection of equipment that is not intended for single-use</td>
</tr>
<tr>
<td>- Hand hygiene</td>
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</tbody>
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*Table 2: Consider assessing these processes to understand where the barriers contributing to CDI may be in your organization*

Complete this Lean Improvement Activity: Conduct a [SIPOC](#) analysis to understand current state and scope of the problem. A SIPOC is a lean improvement tool that helps leaders to carefully consider everyone who may be touched by a process, and therefore, should have input on future process design.

Create a [process map](#) once the workflows are well understood that illustrates each step and the best practice gaps the team has identified ([IHI, 2015](#)). Brainstorm with the advisory team to understand why the gaps exist, using whichever [root cause analysis tool](#) your organization is accustomed to ([IHI, 2019](#)). Review the map with the advisory team and invite the frontline to validate accuracy.
Prioritize the gaps to be addressed and develop an action plan. Consider the cost effectiveness, time, potential outcomes, and realistic possibilities of each gap identified. Determine which are a priority for the organization to focus on. Be sure that the advisory team supports moving forward with the project plan so they can continue to remove barriers. Design an experiment to be trialed in one small area for a short period of time and create an action plan for implementation.

Typical Gaps Identified in CDI

- Frequent retesting
- Inadequate sterilization of rooms and equipment
- Poor hand hygiene
- Lack of adequate antimicrobial therapy auditing and reporting systems
- Poor communication with visitors of the importance of hand hygiene
- Poor discharge planning and patient education

Table 3: By identifying the gaps in CDI prevention compliance, organizations can tailor their project improvement efforts more effectively.

Evaluate outcomes, celebrate wins, and adjust the plan when necessary. Measure both process and outcome metrics. Outcome metrics include the rates outlined in the leadership checklist. Process metrics will depend upon the workflow you are trying to improve and are generally expressed in terms of compliance with workflow changes. Compare your outcomes against other related metrics your organization is tracking. Routinely review all metrics and trends with both the advisory and project teams and discuss what is going well and what is not. Identify barriers to completion of action plans, and adjust the plan if necessary. Once you have the desired outcomes in the trial area, consider spreading to other areas (IHI, 2006).

It is important to be nimble and move quickly to keep team momentum going, and so that people can see the results of their labor. At the same time, don’t move so quickly that you don’t consider the larger, organizational ramifications of a change in your plan. Be sure to have a good understanding of the other, similar improvement projects that are taking place so that your efforts are not duplicated or inefficient.

CDI Comparative Outcomes

- Hand hygiene
- Length of stay
- Antimicrobial use
- Number of isolation rooms in use

Table 4: Consider evaluating related metrics to better understand CDI presence and contributing factors.
What We Know About Clostridioides difficile Infection (CDI)

Clostridioides difficile Infection (CDI)

Clostridioides difficile (CDI) is a bacterium that can cause symptoms ranging from diarrhea to life-threatening swelling of the colon (CDC, 2012). C. diff is a spore-forming, Gram-positive anaerobic bacillus bacteria that produces two exotoxins: toxin A and toxin B (CDC, 2012).

Patients can become infected with a CDI if they touch items or surfaces that are contaminated with feces and then touch their mouth or other mucous membranes. In healthcare settings, spores are primarily spread to patients by the hands of healthcare staff who have touched a contaminated surface or item. These spores are not killed by alcohol-based hand rubs, therefore, soap and water must be used (Oughton et al., 2009; Jabbar et al., 2010).

There is a difference between Clostridioides difficile colonization and infection. Clostridioides difficile colonization is defined by a lack of apparent clinical symptoms with positive patient tests for C. diff organism or its toxin. Patients with Clostridioides difficile infection show clinical symptoms and test positive for the C. diff organism or its toxin.

Symptoms of CDI include (CDC, n.d.):
- Watery diarrhea
- Fever
- Dehydration
- Loss of appetite
- Serious intestinal conditions, i.e. toxic megacolon
- Nausea
- Abdominal pain and tenderness

Diagnosis

Doctors use laboratory tests to diagnose CDIs, including:
- Stool cultures
- Molecular tests
- Antigen detection for C. diff
- Toxin testing:
  - Tissue culture cytotoxicity assay
  - Enzyme immunoassay

The toxin is very unstable and degrades at room temperature. It may be undetectable within two hours after collection of a stool specimen. False-negative results can happen when specimens are not quickly tested or kept refrigerated until testing can be done.

Clinical Implications

Annually, CDI impacts an estimated 500,000 Americans with approximately 29,000 associated deaths (Mada et al., 2019). In the EU, there are approximately 125,000 CDI cases and, with a 3% mortality rate, approximately 3,700 deaths per year (European Centre for Disease Prevention and Control). It has been suggested that approximately 40,000 cases are underdiagnosed in Europe each year (Balsells et al., 2020). Once a patient has been infected, the recurrence of CDIs is estimated to occur in 20-30% of cases (Banawas, 2018). Due to its significant prevalence and unique challenges, CDI is projected to become the most common healthcare-associated gastrointestinal infection in the US and Europe (Banawas, 2018).

CDI, if left untreated, can lead to other complications, including:
- Pseudomembranous colitis (PMC)
- Toxic megacolon
- Perforations of the colon
- Sepsis
- Death

Financial Implications

The average total cost for a single inpatient CDI infection is an estimated $35,000 and the estimated annual cost burden of CDI on the healthcare system exceeds $6 billion (APIC, 2013), requiring approximately 2.4 million hospital days (Zhang et al., 2016).
The cost of healthcare-associated CDI ranges in the general population from $6,893 to $90,202. However, in high risk groups, such as congestive heart failure patients and renal impairment patients, the cost hovers around $7,332 and $122,318, respectively (Zhang et al., 2016).

Prevention and Treatment
Prevention of CDI for all patients requires a commitment to improvement from all individuals within the hospital. The below outline provides a high-level overview of the components that should be included to improve patient safety as it pertains to CDI:

- **Early identification of suspected CDI patients:**
  - **Symptoms:** Nurses should be trained to recognize the signs and symptoms of CDI, using tools like Bristol Stool Chart. Only watery or loose stool should be collected and tested in a clean watertight container (APIC, 2013).
  - **Testing:** In the case of suspected CDI, laboratory tests should be performed to confirm the presence of CDI. Laboratories should reject formed stool samples and should limit retesting of patients. After treatment, research suggests that repeat testing is not recommended if the patient’s symptoms have gone away because they may remain colonized with the bacterium. Additionally, asymptomatic patients should not be tested. Diagnostic tests include the GDH, toxin A&B EIA, or nucleic acid amplification tests (Vogelzang et al., 2020).
  - **Communication:** Test results should be communicated promptly back to the care team, including the provider and infection preventionist.

- **Isolation precautions:** Initiate contact precautions for all symptomatic patients (diarrhea of an unknown origin, 3 or more unformed stools in one day). If laboratory testing reveals a negative result, discontinue isolation unless suspicion remains (APIC, 2013). CDI patients should be placed in a single room with a bathroom used only by that patient. Single use equipment should be used whenever possible. Communicate isolation precautions properly through EMR, signage on the door, and verbally upon transferring the patient. Remove patient from isolation room only when CDI symptoms resolve (when the patient has less than three unformed stools within 24 hours).

- **Antimicrobial stewardship:** A lack of judicious use of antibiotics increases the risk for CDIs and over 50% of hospitalized patients receive an antibiotic during their stay, 30-50% of which are prescribed unnecessarily or inappropriately (Mada et al., 2019). Implementation of an antimicrobial stewardship program is key to prevention. Hospitals should have a process to audit antimicrobial therapy for appropriateness and duration with an associated reporting system to the prescriber. See APSS #3B: Antimicrobial Stewardship.

- **Surveillance:** Adoption of a laboratory-based alert system will facilitate immediate notification of all CDI positive test results. This real-time monitoring of antimicrobial prescribing behaviors can be used to highlight the relationship between CDI and antimicrobial use.

- **Hand hygiene:** In healthcare settings, spores are primarily spread to patients by the hands of healthcare staff who have touched a contaminated surface or item. These spores are not killed by alcohol-based hand rubs (Oughton et al., 2009; Jabbar et al., 2010). It has been shown that nearly one-quarter of clinicians have hands contaminated with spores after routine care of patients with CDIs (Landell et al., 2014). It has also been suggested that the execution of thorough and frequent hand hygiene is inconsistent due to staffing shortages and workload demands (Legenza et al., 2018). All healthcare providers, patients, and family members should be encouraged to practice proper and frequent hand hygiene. See APSS #2A: Hand Hygiene.
  - No agent, including alcohol-based hand rubs, is effective against C. diff spores.

- **Environmental precautions:** Technologies, such as healthcare-certified bleach germicidal wipes and UV light disinfection systems, ensure the utmost cleanliness to prevent the spread of CDI. Equipment such as blood pressure cuffs and pulse oximeters can be vehicles for the spread of CDI and should be frequency cleaned between patients.
Resources

- CDC: C. diff Guidelines and Prevention Resources
- CDC: CDI Implementation Guide.
- APIC: Guide to Preventing Clostridium difficile Infections.
- Guidelines for Diagnosis, Treatment, and Prevention of Clostridium difficile Infections
- Minnesota Hospital Association: Road Map to a Comprehensive Clostridium difficile Infection (CDI) Prevention Program

Resources for patients and family members:

- CDC: What is C. diff?
- Patient education: Antibiotic-associated diarrhea caused by Clostridiodes difficile
- UWHealth: What you need to know about CDI
- CDC: The Progression of CDI infographic

For hospital project improvement teams for general improvement:

- CMS: Hospital Improvement Innovation Networks.
- IHI: A Framework for the Spread of Innovation
- The Joint Commission: Leaders Facilitating Change Workshop
- IHI: Quality Improvement Essentials Toolkit
- SIPOC Example and Template for Download
- SIPOC Description and Example
Education for Patients and Family Members

The outline below illustrates all of the information that should be conveyed to the patient and family members by someone on the care team in a consistent and understandable manner.

**Explain why CDI prevention is important.** A member of the healthcare team should elaborate on the risk factors for CDI and include information about the signs and symptoms that may indicate CDI. The healthcare professional should help the family understand if and how their loved one may be at increased risk for CDI. For example, the risk factors, including recent antibiotic use, recent hospitalization, older age, weakened immune systems, and inflammatory bowel disease should be conveyed.

**Indicate what to watch out for.** Family members can serve as an extra pair of eyes and ears and can alert medical staff if something might be wrong. Family members should have an understanding of what to look for that may indicate deterioration, such as abnormal vital signs and watery stool. Additionally, family members should know exactly when to call for help, where to go for help, and with whom they should speak. In order to adequately welcome patients and family members into the care team, it is not enough to explain “what” patients and family members should look for or “what” is going to happen in their care. The “what” must always be followed with a “why” to aid in genuine understanding. Instead of employing a directive conversation style, an active, engaging conversation should take place, leaving capacity for questions and repeat-back strategies. When patients and family members understand the signs and symptoms that could be indicative of a problem, they are able to serve as an extra set of eyes in order to elevate this concern as early as possible.

**Explain what is expected of them during their care.** By giving patients and family members a “job” while they are in the hospital, they can be immersed fully in the routine care, can hold other team members accountable, can feel more confident voicing their concerns or opinions, and can serve as an extra set of informed and vigilant eyes to improve early recognition of sepsis. This team involvement can also reduce their anxiety by transforming concern into proactive action. Patients and family members can:

- Remain vigilant for hand hygiene for all entering into the room.
- Help the patient wash their hands.
- Report any symptoms that may indicate CDI.
- Keep a record of all medications and antibiotics the patient is taking and ask questions when a new therapy or medication is recommended.
- Ensure the room is being properly sanitized.
- Disclose if the patient is taking PPIs and why.

**Explore next steps.** Planning for life after the hospital, whether in assisted living, returning home, or another option, should begin as early as possible between the healthcare providers and the patient and family.

- Patients and family members should understand what can be anticipated in the patient after discharge regarding both physical and cognitive functioning.
  - Try to understand what specific barriers that patient as an individual may face upon discharge.
- Have a discussion with the patient and family around end of life care and advanced directives.
  - Make an attempt to thoroughly understand the religious or cultural nuances in any of the patient’s or family members’ decisions or questions.
- Ensure thorough explanation of necessary post-discharge appointments, therapies, medications, and potential complications.
  - Assess for patient preference in time and location of follow-up appointments, if possible.
  - Convey any changes in PPI therapy, if applicable.
- Provide patients and family members resources, including direct contact phone numbers, to the hospital for post-discharge questions.
  - If any care or maintenance is required post-discharge, set aside time with the patient and family members more than once to ensure their understanding and confidence.

Patients and family members should understand that, although all clinicians in the hospital do their best, no one is ultimately coordinating their care. Patients and family members should understand that they are the managers of their care and as such, should demand to be an active part of the care team including conversations and decisions.
Measuring Outcomes

Topic

Healthcare-associated Clostridioides Difficile Infection (CDI) Rate
Rate of patients with a healthcare associated CDI per 1,000 patient days

Outcome measure formula
Numerator: Number of healthcare associated CDI based on CDC National Healthcare Safety Network (NHSN) definitions
Denominator: Total number of patient days based on CDC NHSN definitions
* Rate is typically displayed as Infections/1000 Patient Days

Metric recommendations
Direct Impact:
All hospitalized patients
Lives Spared Harm:
\[ \text{Lives Spared Harm} = (\text{CDI Rate}_{\text{baseline}} - \text{CDI Rate}_{\text{measurement}}) \times \text{Patient Days}_{\text{baseline}} \]
Lives Saved:
\[ \text{Lives Saved} = \text{Spared Harm} \times \text{Mortality Rate} \]

Notes:
To meet the NHSN definitions, infections must be validated using the hospital acquired infection (HAI) standards (CDC, 2016). Infection rates can be stratified by unit types further defined by CDC. Infections that were present on admission (POA) are not considered HAs and not counted.

Data collection
C. diff and patient days can be collected through surveillance (at least once per month) or gathered through electronic documentation. Infections must be monitored according to NHSN surveillance definitions. Denominators documented electronically must match manual counts (+/- 5%) for a 3 month validation period.

Settings
Infection Surveillance will occur in any inpatient location where denominator data can be collected, which may include critical/ intensive care units, specialty care areas, step-down units, wards, and chronic care units. Surveillance will NOT be performed in Neonatal Intensive Care Units, Specialty Care Nurseries, babies in Labor, Delivery, Recovery and Postpartum (LDRP) room, or well-baby nurseries. If LDRP locations are being monitored, baby counts must be removed.

Mortality (will be calculated by the Patient Safety Movement Foundation):
The PSMF, when available, will use the mortality rates associated with Hospital Acquired Conditions targeted in the Partnership for Patient’s grant funded Hospital Engagement Networks (HEN). The program targeted 10 hospital acquired conditions to reduce medical harm and costs of care. “At the outset of the Partnership for Patients (PfP) initiative, the Department of Human Health Services agencies contributed their expertise to developing a measurement strategy by which to track national progress in patient safety—both in general and specifically related to the preventable Hospital-acquired Conditions (HACs) being addressed by the PfP. In conjunction with CMS's overall leadership of the PfP, AHRQ has helped coordinate development and use of the national measurement strategy. The results using this national measurement strategy have been referred to as the “AHRQ National Scorecard,” which provides summary data on the national HAC rate (AHRQ, 2019). CDI was included in this work, under the “All Other HACs” definition, with published metric specifications. This is the most current and comprehensive study to date. Based on these data the estimated additional inpatient mortality for CDI is 0.045 (45 per 1000 events).
Endnotes

Conflicts of Interest Disclosure

The Patient Safety Movement Foundation partners with as many stakeholders as possible to focus on how to address patient safety challenges. The recommendations in the APSS are developed by workgroups that may include patient safety experts, healthcare technology professionals, hospital leaders, patient advocates, and medical technology industry volunteers. Workgroup members are required to disclose any potential conflicts of interest.

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