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Suggestions for the prevention of *Clostridioides difficile* spread within outpatient hemodialysis facilities

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Abstract

Clostridioides difficile infections (CDIs) cause substantial morbidity and mortality. Patients on maintenance hemodialysis are 2 to 2.5 times more likely to develop CDI, with mortality rates 2-fold higher than the general population. Hospitalizations due to CDI among the maintenance hemodialysis population are high, and the frequency of antibiotic exposures and hospitalizations may contribute to CDI risk. In this report, a panel of experts in clinical nephrology, infectious diseases, and infection prevention provide guidance, based on expert opinion and published literature, aimed at preventing the spread of CDI in outpatient hemodialysis facilities.

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Keywords

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Clostridioides difficile (previously *Clostridium difficile*) infections (CDIs) are associated with considerable morbidity and mortality. In the United States, *C difficile* is the most common cause of gastroenteritis-related deaths; and in 2017, it was responsible for almost half a million infections and >20,000 deaths.^{1,2} Not only has CDI become one of the most common hospital-acquired infections, but there is ongoing spread within the community setting, accounting for up to 42% of all CDIs.^{3,4} The main risk factor for CDI is exposure to antimicrobials. Other risk factors typically associated with an increased risk of CDI include advanced age, multiple comorbidities, and residing in a nursing home.^{2,4}

However, numerous studies have also identified chronic kidney disease and maintenance hemodialysis (MHD) as risk factors for CDI.^{5–7} Patients on MHD are 2 to 2.5 times more likely to develop CDI. Patients on hemodialysis have frequent antimicrobial exposures, with approximately one-third of patients receiving i.v. antibiotics each year, and rates of hospitalization for MHD patients are high, approaching 2.0 per year per patient.⁸ The frequency of antimicrobial exposures and hospitalizations may contribute to CDI risk in patients on hemodialysis. Risk factors for CDI specific to the outpatient hemodialysis population include a low albumin level (<3 g/dl) and a high Charlson Comorbidity Index score, reflecting a higher number of comorbidities.^{9,10}

Morbidity and mortality associated with CDI in patients on MHD is high. Using the Centers for Medicare & Medicaid Services data, Wetmore *et al.* showed that, from 2004 to 2013, hospitalization rates for CDI among prevalent MHD patients increased by 68%.¹¹ Lengths of hospitalizations related to CDI are longer for MHD patients compared with the general population.^{9,12,13} Mortality rates among the MHD population with CDI are 2-fold higher than those without CDI.¹⁴

The transmission dynamics of *C difficile* are similar to those of multidrug-resistant organisms (MDROs), including methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant enterococci, and multidrug-resistant gram-negative bacteria, with important exceptions.¹⁵ Similar to other MDROs, *C difficile* can be transferred to patients via health care personnel (HCP) who have touched a contaminated surface or item, or helped care for a patient with *C difficile* without performing hand hygiene. In contrast to most other MDROs, *C difficile* is an anaerobic spore-forming bacterium. These spores have prolonged survival on inanimate surfaces and are resistant to commonly used disinfectants targeting MDRO eradication.¹⁶ Environmental contamination within health care settings via inadequately cleaned and disinfected multiuse patient care items, such as blood pressure cuffs and thermometers, has been reported.^{17,18}

Although the Centers for Disease Control and Prevention has provided recommendations for preventing the transmission of select MDROs and other infectious pathogens in the outpatient dialysis setting, these do not specifically address CDI and the need for additional precautions.¹⁹ Outpatient hemodialysis facilities pose unique challenges for the containment

of CDI in that they typically have open floorplans with patients receiving hemodialysis in close proximity to one another, and routine environmental cleaning of dialysis stations between patients is completed by clinical staff typically under time constraints. Furthermore, dialysis facilities may lack isolation rooms for placement of patients with CDI and dedicated staff with infection prevention training and expertise.

Because there is a paucity of data pertaining to C difficile transmission in outpatient hemodialysis facilities, the goal of this document is to provide US HCP with expert opinion-based answers to commonly asked questions pertaining to the prevention and control of CDI among MHD patients. Recommendations follow the current 2017 clinical practice guidelines for CDI prevention in other health care settings, provided by the Infectious Diseases Society of America (IDSA) and the Society of Healthcare Epidemiology of America (SHEA).²⁰ Where relevant, these recommendations are modified for the MHD population and the dialysis setting based on the expert opinion of the authors and the available literature. Further support for the recommendations can be found from the IDSA/SHEA guidelines and reviews.^{20,21} Diagnosis and treatment recommendations are not addressed but can be found in the IDSA/SHEA guidelines and apply to the MHD population.²⁰ The recommendations in this report are directed at adult outpatient hemodialysis facilities and apply to MHD patients with active signs and symptoms of CDI (suspected infection), as well as those with laboratory confirmation of disease and ongoing signs and symptoms of active infection (confirmed infection). As with any recommendations, those provided in this report should not substitute for individual clinical judgment.

The author panel was composed of nephrology and infectious disease physicians, clinical nephrology nurse specialists, clinical managers of dialysis facilities, public health experts, and infection preventionists. The American Society of Nephrology's Nephrologists Transforming Dialysis Safety initiative supported the development of this document, aiming to provide practical strategies and guidance for managing CDI in outpatient dialysis facilities.²² A summary is provided in Table 1.

1. What infection prevention and control resources/activities should outpatient hemodialysis facilities have in place for the prevention of CDI transmission and care of patients with CDI?

Nurses, patient care technicians, and others who work in dialysis facilities face the difficult task of managing the complex conditions affecting their patients while simultaneously reducing the risk of infection. A successful infection prevention program is critical to support their efforts to decrease infections in patients. Those with primary oversight of the facility must ensure sufficient human and fiscal resources are available to develop, support, and maintain infection prevention efforts. The individual with authority over infection prevention should be empowered and supported to ensure effectiveness of the infection prevention and control (IPC) program. The 2008 Centers for Medicare & Medicaid Services End Stage Renal Disease Conditions for Coverage require outpatient dialysis facilities to

include IPC as a formal piece of their Quality Assessment and Performance Improvement program. $^{\rm 23}$

Given the high risk of *C difficile* spread and the frequent, close contact between patients and HCP in dialysis facilities, the potential for widespread transmission of *C difficile* exists. Monitoring rates of CDI can inform prevention efforts, especially when a higher rate of infection is identified (i.e., outbreak). Outbreaks of CDI among MHD patients have been reported in the literature.^{24,25} In a Michigan outpatient dialysis facility between October 2012 and March 2013, 8 of 37 patients (21.6%) and 1 HCP developed CDI.²⁴ Compliance audits revealed several deficiencies in practice, including inadequate hand hygiene, insufficient wet contact times of bleach on surfaces, and patients without CDI were being dialyzed at designated CDI-only stations. After implementation of control measures, including designating 3 dialysis stations for CDI patients, donning gloves and isolation gowns, using soap and water for hand hygiene, and using a 1:10 dilution of bleach to disinfect dialysis stations used by CDI patients, the outbreak ended.²⁴

Ongoing patient education and HCP training are critical for ensuring infection prevention policies are understood and followed. Patients should be educated regarding how *C difficile* is transmitted and methods of preventing spread; they should be instructed to notify their dialysis providers if they have diarrhea or a CDI diagnosis. Demonstration of HCP competence is essential to optimize performance of a procedure, and measuring performance at intervals is critical to ensure procedures continue to be performed in the recommended manner. Verification of competence for CDI prevention is done through the use of knowledge-based testing and direct observation. The Centers for Disease Control and Prevention, IDSA, SHEA, and the Association for Professionals in Infection Control and Epidemiology provide numerous guidelines and toolkits, which can be found at their respective websites.^{20,26–28}

Antimicrobial exposure is one of the main risk factors for CDI. Some antimicrobials prescribed in dialysis facilities may not be indicated, up to 30% in one study.²⁹ Antimicrobial stewardship programs implemented in dialysis facilities have been shown to reduce the rate of inappropriate antimicrobial prescribing.³⁰ Furthermore, a decision analytic model of a nationwide dialysis facility's antimicrobial stewardship program estimated 4.8% fewer infections caused by MDRO and *C difficile*, 4.6% fewer infection-related deaths associated with these pathogens, and a cost saving of 5% per year.³¹

Suggestions for IPC resources/activities in outpatient hemodialysis facilities aimed at minimizing CDI transmission and improving the care of patients with CDI are as follows: (i) Develop and maintain a robust IPC program that is integrated within the Quality Assessment and Performance Improvement program and assure at least one individual with training in IPC is regularly available to the facility. (ii) Have a written policy detailing infection control precautions specifically designed to prevent the transmission of pathogenic bacteria, such as *C difficile*, among patients and staff. The policy should be based on the most current recommendations and research, meet regulatory requirements, be tailored to the facility, and be reassessed on a regular basis (e.g., annually).²⁰ (iii) Provide education and training to all HCP on the basic principles and practices for preventing the spread of

infections, including CDI, on initial employment and repeated regularly (e.g., annually), including any time policies are updated or revised. Furthermore, dialysis units should consider conducting competency assessments on initial employment at the facility and regularly (e.g., annually), including any time policies or procedures are updated or revised. Competency should be documented. (iv) Provide CDI education to patients, including signs

and symptoms of infection and the importance of reporting symptoms and/or recurrence of symptoms to the dialysis care team. (v) Conduct regular surveillance for CDI, calculate facility rates, and share results with front-line clinical staff. (vi) Encourage judicious use of antimicrobials through implementation of antimicrobial stewardship activities. (vii) Ensure open communication with other health care facilities (e.g., acute-care hospitals) to facilitate timely notification of laboratory results, such as CDI testing results. (viii) Contact local or state health department if an outbreak or cluster is detected or if transmission is identified within the facility.

2. What are the preferred hand hygiene measures for HCP when caring for a patient with suspected or confirmed CDI?

Although hand hygiene should always be performed at key moments during patient care, such as the 5 moments of hand hygiene, the recommendations above are specific to CDI, taking into account the mode of transmission. Transmission of *C difficile* in health care settings often occurs via the hands of HCP and therefore gloves should always be used when providing care to patients with CDI.³² Hand hygiene should always be performed after removal of gloves and between patients, because contamination of hands can occur either through small holes in gloves or when removing gloves.

Hand hygiene with soap and water substantially reduces *C difficile* spores by approximately $1 \log_{10}$.³³ In contrast, alcohol-based sanitizers do not effectively reduce spores.^{34,35} However, several studies have shown that rates of CDI do not increase when alcohol-based sanitizers are used.^{36–38} Given the greater compliance with use of alcohol-based sanitizers versus soap and water, alcohol-based sanitizers are an alternative hand hygiene measure, although soap and water is always preferred. However, during CDI outbreaks or when there is concern for spread of CDI within the facility, soap and water should be used in preference to alcohol-based sanitizers, throughout the entire facility.

Suggestions for hand hygiene measures, specific to caring for a patient with suspected or confirmed CDI, are as follows: (i) Wear gloves when caring for patients with CDI to reduce hand contamination. (ii) Perform hand hygiene before donning gloves and after removing gloves. Handwashing with soap and water is preferred; however, use of an alcohol-based hand rub before and after contact with a patient with CDI is acceptable, unless there is an outbreak or concern for horizontal transmission within the facility. (iii) Perform handwashing with soap and water if there has been direct contact with feces or an area where fecal contamination is likely. (iv) Encourage patients to perform hand hygiene and increase personal hygiene measures to reduce the number of spores on the skin, before their dialysis session. (v) Audit HCP hand hygiene compliance and provide feedback.

3. What personal protective equipment should be worn when caring for a patient with suspected or confirmed CDI?

Patients with CDI can spread spores to health care workers and the surrounding environment.³⁹ In an investigation of an outpatient dialysis facility CDI outbreak, both epidemiological and laboratory data implied transmission to a health care worker from an infected patient.²⁴ The use of personal protective equipment (PPE) helps prevent transmission. A study by Johnson *et al.* demonstrated that use of gloves significantly decreased the rate of CDI at discharge from 7.7 cases per 1000 discharges to 1.5 cases after glove use was implemented.³² Transmission of *C difficile* in health care settings often occurs via the hands of HCP, and gloves should always be used when providing care to patients with CDI.³² Hand hygiene should always be performed before donning gloves, after removal of gloves, and between patients because contamination of hands can occur either through small holes in gloves or when removing gloves.

Suggestions for PPE when caring for a patient with suspected or confirmed CDI are as follows: (i) Wear gloves when caring for CDI patients and remove and immediately discard gloves when finished interacting with the CDI patient. (ii) Wear a new gown over usual clothing during high-contact patient care activities that provide opportunities for transfer of pathogens to HCP hands and PPE, such as initiating and terminating dialysis treatment, manipulating access needles or catheters, helping the patient into and out of the station, and cleaning and disinfecting of patient care equipment and the dialysis station. The gown should be immediately discarded after each use. Disposable gowns should not be reused. When using reusable gowns, they should be appropriately reprocessed between uses. (iii) Use disposable face shields for each interaction that warrants face protection and immediately discard after each use. If disposable face shields are not available, reusable face shields should be dedicated to the patient and remain in the treatment station during care of the patient with CDI. When the patient's treatment is complete, and the patient has left the facility, reusable face shields should be appropriately cleaned and disinfected or discarded. A new, clean face mask for any patient care activity requiring a face mask should be worn and immediately discarded after each use. Face masks should not be reused. (iv) Remove PPE slowly and deliberately in a sequence that prevents self-contamination.

4. What is the preferred placement for dialysis treatment for patients with CDI?

In the hospital setting, patients with CDI are placed in a single room to avoid transmission to other patients.²⁰ A study by Teltsch *et al.* showed a 43% decrease in acquisition rate of *C difficile* when use of private rooms was instituted in a 25-bed intensive care unit.⁴⁰

Dialysis facilities use open floor plans; therefore, providing care in a single room may be difficult. Additional infection control precautions should be considered during treatment of patients who are at increased risk for transmitting pathogens to other patients. Dialyze these patients at a station with as few adjacent stations as possible (e.g., at the end or corner of the unit).¹⁹ Another option is to use isolation rooms, if available. These isolation rooms

there are no hepatitis B–positive patients requiring the isolation room on the dialysis facility patient census, or if an additional room is available and not used for hepatitis B isolation, these rooms can be used for patients with CDI, after appropriate terminal environmental cleaning.⁴¹

Suggestions for the preferred placement for dialysis treatment for patients with CDI, primarily based on expert opinion, are as follows: (i) Assess patients for signs and symptoms of CDI before their entry to the treatment area. (ii) Provide dialysis during sessions with the fewest number of other patients or minimal number of adjacent stations as possible (e.g., at the end or corner of the facility). (iii) Consider using isolation room if there are no hepatitis B–infected patients being cared for in the facility and the room has been terminally cleaned. (iv) The dialysis station or isolation room should be thoroughly cleaned with *C difficile*–active disinfectants after dialysis of patients with CDI.

5. What bathroom facilities should be provided to dialysis patients with

CDI?

Given the shedding of *C difficile* spores in fecal material, additional measures to prevent spread are necessary during toileting. The suggestions provided are based on expert opinion from the author panel. (i) Allow patients with CDI to use the bathroom facilities available to all patients within the facility. These facilities should be thoroughly cleaned with Cdifficile-approved disinfectants after use by a patient with CDI. Caution should be taken to ensure other patients do not use the bathroom facilities until cleaning and disinfection of the bathroom is completed. (ii) Assess the patient before entering the treatment floor to determine if the patient is having active diarrhea or incontinence. If present, the patient should be placed closer to the restroom or in a more private space, or steps should be taken to reduce likelihood of incontinence incidents or having to stop treatment due to toileting needs. (iii) Limit use of bedpans and bedside commodes in the treatment floor. Use of these items is strongly discouraged due to significant concerns about contamination of the patient care environment. In rare circumstances, if an incontinence event occurs or use of a disposable bedpan is necessary, items contaminated with stool should be discarded at point of use into leak-proof, puncture-resistant bags and disposed of appropriately. Promptly clean and disinfect the affected area, as outlined below. (iv) Bedside commodes can be an alternative to bedpans. HCP must use appropriate PPE and empty waste at the nearest dirty utility room hopper or bathroom toilet in a manner that prevents splashing. If waste is emptied in a bathroom toilet, caution should be taken to ensure that other patients (and staff) do not use the bathroom facilities until cleaning and disinfection is completed. The commode and receptacle used to dispose of waste must also be cleaned using C difficile-approved disinfectants after waste is discarded, before use by another patient. (v) If roll-out screens are used for privacy during toileting, these screens should be nonporous and immediately cleaned and disinfected with C difficile-approved disinfectants after use. Screens should not be used for another patient until they have been appropriately cleaned. (vi) Change and discard all PPE, including gloves, gowns, and face masks, and perform hand hygiene with soap and water, immediately after assisting the patient with

toileting activities due to the high risk of contamination from assisting patients with toileting activities.

6. What is the appropriate length of time to maintain precautions?

Evidence to support the duration of maintaining contact precautions is limited. Guidelines from IDSA and Public Health England recommend continuing contact precautions for at least 48 hours after diarrhea has resolved.^{20,42} IDSA recommends prolonged contact precautions until discharge if CDI rates are high despite implementation of standard precautions for CDI. A prospective study of 52 patients, which demonstrated skin contamination and environmental shedding of *C difficile* after resolution of diarrhea and 1 to 4 weeks after therapy, supports IDSA recommendation for prolonged contact precautions.³⁷ However, there are no studies demonstrating that extending contact precautions results in reductions in CDI incidence.^{20,42,43}

The author panel provides the following suggestions for the length of time to maintain precautions: (i) CDI-specific precautions should be continued for at least 48 hours after the diarrhea has ceased.^{20,42} If signs and symptoms of CDI recur after precautions have been discontinued, CDI-specific precautions should be resumed. (ii) CDI-specific precautions beyond 48 hours should be considered if CDI rates remain high despite implementation of CDI IPC measures.

7. What are the optimal measures for environmental disinfection?

The environment is frequently contaminated by *C difficile* spores, and the extent of contamination correlates with the degree of patient symptoms.^{44,45} These spores can survive for several months on inanimate surfaces and are resistant to a variety of disinfectants, including the quaternary ammonium compounds typically used in hospital settings.^{34,35} Thus, specific agents registered by the Environmental Protective Agency against *C difficile* are necessary. A list can be found at its website.⁴⁶

Environmental disinfection should also follow Centers for Disease Control and Prevention's recommendations for routine disinfection of the hemodialysis station, including removing all supplies from the station and prime bucket emptying, ensuring the station is empty (patient and his/her belongings are not in the station) before cleaning and applying disinfectant to all surfaces and making sure all surfaces are visibly wet.⁴⁷

Suggestions for *C difficile* environmental disinfection are as follows: (i) Thoroughly clean and disinfect the station (including computer charting terminal, machine, chair, and other environmental surfaces that are in close proximity to the patient) after the patient with CDI completes his/her dialysis treatment and exits the station. (ii) Use disinfectants from the Environmental Protection Agency's Registered Antimicrobial Products Effective against the spores of *C difficile* (list K agents, https://www.epa.gov/pesticide-registration/list-k-epas-registered-antimicrobial-products-effective-against-clostridium).⁴⁶ The manufacturers' instructions should be followed, and include ensuring that all surfaces of the dialysis station are visibly wet with disinfectant and allowed to air dry when performing cleaning and disinfection. If visible soil (e.g., organic or inorganic material) is present, a cleaning step

before disinfection is warranted. (iii) Limit multiuse items and dedicate patient care items that are typically multiuse to the care of the patient with CDI. When the patient's treatment is complete, and the patient has left the facility, these multiuse items should be appropriately cleaned and disinfected before being returned to a common area or used on another patient. Some examples include thermometers, stethoscopes, blood pressure cuffs, glucose monitors, and wheelchairs. If an item cannot be cleaned and disinfected, it should be discarded. (iv) Audit staff practices to ensure effective environmental disinfection is occurring and provide feedback.

Conclusion

This document provides dialysis providers and other HCP guidance on preventing the transmission of *C difficile* within outpatient hemodialysis facilities. These recommendations follow the same principles outlined by the Centers for Disease Control and Prevention, SHEA, and IDSA in preventing *C difficile* spread, but are extended to consider the unique setting of the dialysis facility. Further research is needed to gain a better understanding of *C difficile* epidemiology, transmission, and the most effective infection prevention strategies in the outpatient dialysis setting.

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Questions	Suggestions
 What IPC resources/activities should outpatient hemodialysis facilities have in place for the prevention of CDI transmission and care of patients with CDI? 	 Develop and maintain a robust IPC program that is integrated within the QAPI program. Assure at least one individual with training in IPC is regularly available to the facility. Have a written policy detailing IPC precautions specifically designed to prevent the transmission of <i>C difficile</i>. Provide education and training to all HCP on the basic principles and practices for preventing the spread of CDI. Provide coll education to patients. Conduct regular surveillance for CDI, calculate facility rates, and share results with fron-line clinical staff. Encourage judicious use of antimicrobial sthrough implementation of antimicrobial stewardship activities. Ensure open communication with other health care facilities. Contact local or state health department if an outbreak or cluster is detected or if transmission is identified within the facility.
 What are the preferred hand hygiene measures for HCP when caring for a patient with suspected or confirmed CDI? 	 Wear gloves when caring for patients with CDI to reduce hand contamination. Perform hand hygiene before doming gloves and after removing gloves. Soap and water are preferred; however, use of an alcohol-based hand rub is acceptable unless there is an outbreak or concern for horizontal transmission within the facility. Perform handwaking with soap and water if there has been direct contact with feces or an area where fecal contamination is likely. Encourage patients to perform hand hygiene and increase personal hygiene measures before their dialysis session. Audit HCP hand hygiene compliance and provide feedback.
 What PPE should be worn when caring for a patient with suspected or confirmed CDI? 	 Wear gloves when caring for CDI patients and remove and immediately discard gloves when finished. Wear a new gown over usual clothing during high-contact patient care activities. Use disposable face shields for each interaction that warrants face protection and immediately discard after each use. Remove PPE slowly and deliberately in a sequence that prevents self-contamination.
 What is the preferred placement for dialysis treatment for patients with CDI? 	 Assess patients for signs and symptoms of CDI before their entry to the treatment area. Provide dialysis during sessions with the fewest number of other patients or minimal number of adjacent stations as possible. Consider using isolation room if there are no hepatitis B-infected patients being cared for in the facility and the room has been terminally cleaned. The dialysis station or isolation room should be thoroughly cleaned with <i>C difficile</i>-active disinfectants after dialysis of patients with CDI.
 What bathroom facilities should be provided to dialysis patients with CDI? 	 Bathroom facilities should be thoroughly cleaned with <i>C difficile</i>-approved disinfectants after use by a patient with CDI. Assess the patient before entering the treatment floor to determine if he/she is having active diarrhea or incontinence. Limit use of bedpans and bedside commodes in the treatment floor. Roll-out screens, if used for toileting privacy, should be nonporous and immediately cleaned and disinfected with <i>C difficile</i>-approved disinfectants after use. Change and discard all PPE and perform hand hygiene with scap and water, immediately after assisting the patient with toileting activities.
6. What is the appropriate length of time to maintain precautions?	 CDI-specific precautions should be continued for at least 48 hours after the diarrhea has ceased. If signs and symptoms of CDI recur after precautions have been discontinued, CDI-specific precautions should be resumed. CDI-specific precautions beyond 48 hours should be considered if CDI rates remain high despite implementation of CDI PC measures.
 What are the optimal measures for environmental disinfection? 	 Thoroughly clean and disinfect the station after the patient with CDI completes his/her dialysis treatment and exits the station. Use disinfectants from the EPA's Registered Antimicrobial Products Effective against the spores of <i>C difficile</i> (list K). Limit multiuse items and dedicate patient care items that are typically multiuse to the care of the patient with CDI. Audit staff practices to ensure effective environmental disinfection is occurring and provide feedback.

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