INTERIM GUIDANCE

Policy Statement: *Clostridium difficile* Laboratory Diagnosis
Georgia Healthcare Associated Infections Advisory Committee Policy Statement
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Introduction:

The primary method to determine if a patient may have *Clostridium difficile* infection (CDI) is a clinical evaluation. Clinical evaluation is used to determine if laboratory testing for CDI is appropriate. There is no consensus among authorities on which laboratory test method is best. We have summarized prevailing methods and related evidence. We anticipate updating these recommendations in the future when authorities release new guidelines.

Recommendations:

Based on current evidence, we recommend that facilities:

1. Develop a written *Clostridium difficile* diagnostic stewardship policy to include appropriate patient selection, specimen, ordering, and testing practices. The policy will include:
   a. Only test patients who are clinically likely to have CDI. These are patients who have 3 or more unformed, diarrheal stools in a 24-hour period without an underlying condition (inflammatory colitis, constipation with overflow diarrhea) or therapy (stool softeners/laxatives, chemotherapy, enteral feeding, oral contrast) [1-4].
   b. Only perform diagnostic tests on diarrheal stool specimens. Diarrheal stools are those that take the shape of the container [1-6].
   c. Discourage repeat testing during the same episode of diarrhea, particularly when a nucleic acid amplification test (NAAT) such as polymerase chain reaction (PCR) is used [4-6].
   d. Do not perform test of cure as the assay may be positive after clinical cure [1-5].
   e. Consult a pediatric specialist before testing children under 2 years of age [3, 5].
2. Combine laboratory test use with an effective diagnostic stewardship policy. (See #1 above and page 2 of this document for sample diagnostic stewardship algorithms.)
   a. Recommended laboratory tests:
      i. NAAT, which can be performed as a stand-alone test. Reliance on NAAT results without consideration of clinical symptoms can result in over diagnosis of disease [2, 8].
      or
      ii. Multi-step testing:
         1. Two-step testing can consist of EIA GDH or NAAT to screen samples, followed by EIA toxin A/B if the screening test is positive [2, 4-5].
         2. Three-step testing can consist of enzyme immunoassay (EIA) for glutamate dehydrogenase (GDH) and toxins A and B, followed by NAAT for discrepant results [2, 4-5].
   b. Non-recommended laboratory test: EIA toxin A/B as a stand-alone test due to low sensitivity [4-6].
3. Create a multidisciplinary committee to address all aspects of *Clostridium difficile* disease. Committee membership depends on the care setting and may include representation from clinicians including GI, and infectious disease, infection control, nursing, gastroenterology, microbiology, pharmacy, environmental services, building management, and administration [2].
4. Consider using laboratory results indicating colonization to inform infection prevention strategies, such as contact precautions. Colonized patients are those who have tested positive for the *Clostridium difficile* organism or genome, but do not have clinical symptoms. These patients may have a role in *Clostridium difficile* transmission [5-8].

FURTHER READING

CDI Diagnostic Stewardship Resources and CDI Management Guidelines:

- Duke Center for Antimicrobial Stewardship and Infection Prevention. Diagnosis of *C. difficile* Infection (CDI) at Duke Health. Published July 2016. https://sites.duke.edu/micu/files/2016/07/CDI-testing-FAQs.pdf
- Duke Center for Antimicrobial Stewardship and Infection Prevention. Diagnostic Testing for Clostridium difficile Infection. Published June 2015. https://dicon.medicine.duke.edu/sites/default/files/june_2015_dason_newsletter_diagnostic_testing_for_clostridium_difficile_infection_final.pdf
- University of Michigan, Michigan Medicine. *Clostridium difficile* Infection in Adults and Children. Published December 2016. http://www.med.umich.edu/1info/FHP/practiceguides/InptCDiff/C-Diff.pdf%20
- The Ohio State University, Wexler Medical Center. Prevention and Management of *Clostridium difficile* Infection (CDI). Published June 2016. https://evidencebasedpractice.osumc.edu/Documents/Guidelines/Cdifficile.pdf
- Vanderbilt University Medical Center. Guidance to Providers: Testing for *C. difficile* Infection. Published August 2011. http://www.mc.vanderbilt.edu/documents/infectioncontrol/files/Guidance%20for%20Providers%20FINAL%202011.pdf
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- Shane, AL, Mody RK, Crump JA et al. 2017 Infectious Diseases Society of America Clinical Practice Guidelines for the Diagnosis and Management of Infectious Diarrhea. Clin Infect Dis. 2017 Nov 29;65(12):1963-1973. https://academic.oup.com/cid/article/65/12/1963/4655039
- Polage CR, Solnick JV, and Cohen SH. Nosocomial Diarrhea: Evaluation and Treatment of Causes Other Than *Clostridium difficile*. Clinical Infectious Diseases. 2012;55(7):982-989

Long-Term Care Settings:

- Georgia Department of Public Health. Guidance on C. difficile testing for long-term care providers. Published October 2017. https://dph.georgia.gov/sites/dph.georgia.gov/files/related_files/site_page/C%20diff%20testing%20guidance%20for%20LTC_v1%20%282%29.pdf
- Minnesota Department of Health. Algorithms for Prevention and Management of *Clostridium difficile* Infections in Long-term Care Facilities. Published November 2014; Revised November 2017. http://www.health.state.mn.us/divs/idepc/diseases/cdiff/hcp/ltcalgorithms.pdf

Citations:

1. Avila MB, Avila NP, and Dupont AW. Recent Advances in the Diagnosis and Treatment of *Clostridium difficile* Infection. F1000Research. 2016; 5(118): 1-8.
2. Brecher SM, Novak-Weekley SM, Nagy E; Laboratory Diagnosis of *Clostridium difficile* Infections: There Is Light at the End of the Colon. Clinical Infectious Diseases. 2013; 57(8): 1175–1181.
3. Schutze GE and Willoughby RE. *Clostridium difficile* Infection in infants and children. Pediatrics. 2013; 131:196-200.
4. Suawicz CM, Brandt LI, Binion DG, et al. Guidelines for diagnosis, treatment, and prevention of *Clostridium difficile* Infections. American Journal of Gastroenterology. 2013; 108(4): 478-98
5. Crobach MJ, Planche T, Eckert C, Barbut F, Terveer EM, Dekkers OM, Wilcox MH, Kuijper EJ. European Society of Clinical Microbiology and Infectious Diseases: update of the diagnostic guidance document for *Clostridium difficile* infection. Clin Microbiol Infect. 2016 Aug;22 Suppl 4:S63-81.
6. Association for Professionals in Infection Control and Epidemiology. Guide to Preventing *Clostridium difficile* Infections. 2013.
7. Donskey CJ, Kundrapu S, Deshpande A. Colonization Versus Carriage of *Clostridium difficile.* Infectious Disease Clinics of North America. 2015; 29: 13–28
8. Fang FC, Polage CR, Wilcox MH. 2017. Point-Counterpoint: What is the optimal approach for detection of *Clostridium difficile* infection? J Clin Microbiol 55:670–680.