QUALITY IMPROVEMENT COMMITTEE

Clostridium difficile INFECTION CLINICAL QUALITY MEASURE WORKGROUP OVERVIEW

BACKGROUND

In February 2018, IDSA published the *Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA)*. Understanding the importance of promoting best practices for the treatment of patient with *Clostridium difficile* infections (CDI), the Quality Improvement Committee (QIC) sanctioned a workgroup to be composed to QIC members and CDI clinical practice guideline panel members to review the 2017 CDI clinical practice guidelines and identify candidate clinical quality measure (CQM) concepts. The *Clostridium difficile* Infection (CDI) Clinical Quality Measure (CQM) workgroup began their work in April 2018.

Clostridium difficile INFECTION CLINICAL QUALITY MEASURE WORKGROUP

The goal of the CDI CQM workgroup was to develop CQMs to facilitate the use of evidenced based, best practices for the improvement of health outcomes of patients with *Clostridium difficile* infections with the following objectives:

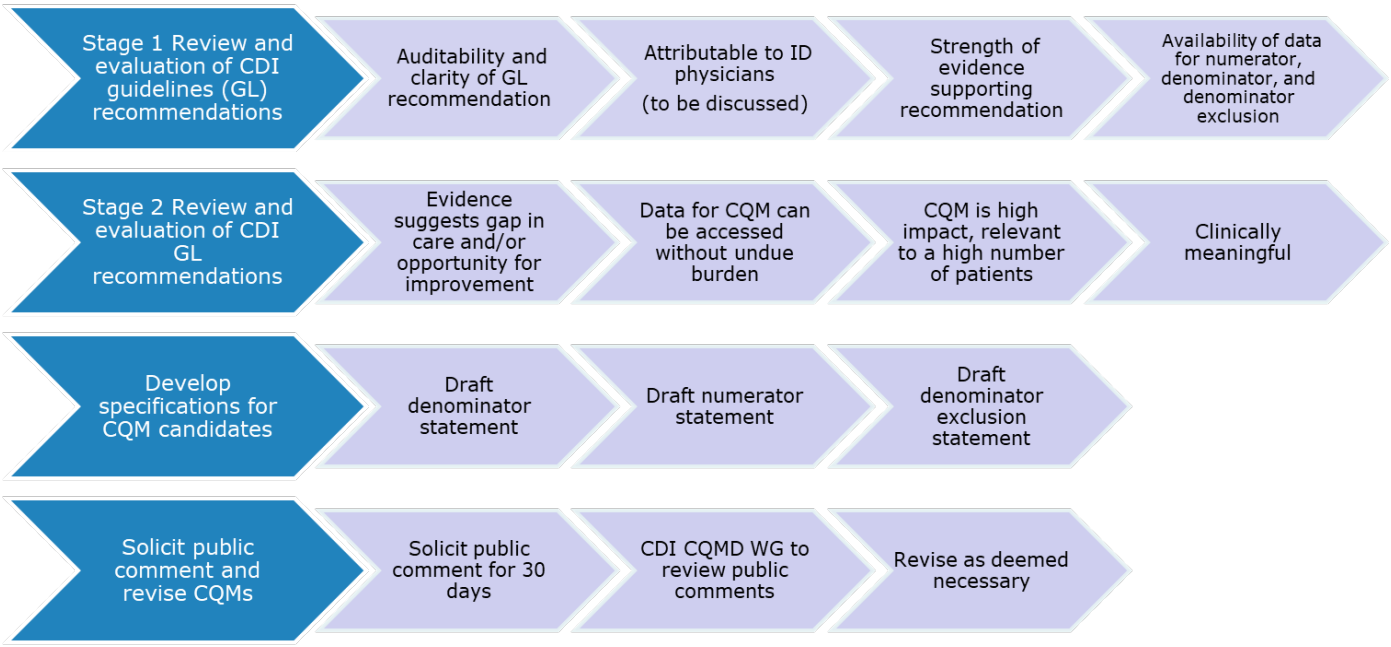
- Review CDI guideline to assess the feasibility of developing CQMs from the recommendations
- Develop CQMs specification statements for the medical intervention (numerator), patient population (denominator), patient exclusion
- Solicit public comment from stakeholders regarding CQMs
- Review public comment and revise CQMs as the WG deems necessary

The CDI CQM workgroup was composed of four total members, two representatives from the QIC and two representatives from the CDI clinical practice guidelines panel.

Quality Improvement Committee Members	
Clare Gentry, MD, MS	Private Practice Physician Houston Methodist Hospital Baylor St. Luke's Medical Center
Michael Lane, MD, MPH, MSc	Assistant Professor of Medicine Washington University School of Medicine
CDI Guidelines Panel Members	
Erik Dubberke, MD, MSPH, FIDSA, FSHEA	Associate Professor of Medicine Director, Section of Transplant ID Washington University School of Medicine
Dale Gerding, MD, FACP, FIDSA, FSHEA	Professor of Medicine of ID Loyola University Chicago Stritch School of Medicine Research Physician Hines VA Hospital

MEASURE DEVELOPMENT PROCESS

The workgroup completed a measure development process that involved a two-stage review of the IDSA CDI guidelines, drafting of measure specifications, and soliciting public feedback regarding the draft of the measure specifications. The following graphic provides an overview of the steps involved in each phase of measure development process.



Stage 1 review and evaluation of CDI guideline recommendations sought to identify strong candidate measures based on the evaluation criteria specified in the graphic above. Stage 1 resulted in three guideline recommendations that were identified as strong candidate measures, nine guideline recommendations that needed further workgroup discussion to determine if the recommendations would make for good candidates, and two guideline recommendations that were poor measure candidates. The three strong candidates were:

1. Do not perform repeat testing (within 7 days) during the same episode of diarrhea and do not test stool from asymptomatic patients, except for epidemiological studies.
2. Either vancomycin or fidaxomicin is recommended over metronidazole for an initial episode of CDI. The dosage is vancomycin 125 mg orally 4 times per day or fidaxomicin 200 mg twice daily for 10 days.
3. If surgical management is necessary for severely ill patients, perform subtotal colectomy with preservation of the rectum.

After deliberating, the workgroup determined that the recommendation *Either vancomycin or fidaxomicin is recommended over metronidazole for an initial episode of CDI. The dosage is vancomycin 125 mg orally 4 times per day or fidaxomicin 200 mg twice daily for 10 days* was the only feasible candidate for specification.

During Stage 2 review and evaluation, the workgroup reviewed the results of a medical literature search with abstracts that demonstrated the opportunity for improvement (gap in care), relevance to high number of patients, and clinical meaningfulness for the candidate measure.

After completion of Stage 2, the workgroup drafted specifications for the candidate measure in preparation for a 30-day public comment period. The 30-day public comment period opened on February 3, 2019 and closed on March 5, 2019. A total of 71 respondents viewed the survey while 39 persons provided feedback on the draft of the measure specifications. Majority of the respondents approved of the measure title and the numerator. A slight majority indicated conditional support for the denominator and denominator exclusions with

modifications. To reach majority consensus on which public comments to take into consideration for amending the measure specifications, the workgroup reviewed 40 public comments and indicated which comments they "approved" or "rejected." A total of 18 comments received majority approval from the workgroup and were considered to for revision. After several rounds of drafting, the workgroup completed the development of Guideline Recommended Treatment of Clostridioides difficile Infection (CDI) clinical quality measure concept.

GUIDELINE RECOMMENDED TREATMENT OF Clostridioides difficile INFECTION (CDI) MEASURE CONCEPT SPECIFICATIONS

Guideline Recommended Treatment of *Clostridioides difficile* Infection (CDI)

Measure Description	
Percentage of patients with an episode of non-fulminant *Clostridioides, formerly Clostridium, difficile* infection (CDI) able to take medications by mouth or per tube that are prescribed oral vancomycin or fidaxomicin, and not metronidazole, either by itself or in combination with vancomycin or fidaxomicin.	
Measure Components	
Numerator Statement	Number of denominator eligible patients who are treated with oral vancomycin or fidaxomicin and not metronidazole, either by itself or in combination with vancomycin or fidaxomicin.
Denominator Statement	Inpatients age 18 years or older diagnosed with an episode of *non-severe OR severe Clostridioides difficile* infection (CDI) requiring treatment. **Definitions:** *Clostridium difficile infection*: 1. Centers for Disease Control and Prevention National Healthcare Safety Network *Clostridium difficile* Infection LabID Definition: a. A positive laboratory test result for *C. difficile* toxin A and/or B, (includes toxin assays) tested on an unformed stool specimen (must conform to the container) OR b. A toxin-producing *C. difficile* organism detected by culture or other laboratory means (molecular assays [PCR]) performed on an unformed stool sample (must conform to the container) c. Note: When using a multi-testing methodology for CD identification, the final result of the last test finding which is placed onto the patient medical record will determine if the CDI positive laboratory assay definition is met 2. Patients with either non-severe or severe CDI a. Non-severe CDI: Leukocytosis with a white blood cell count of ≤15 000 cells/mL and a serum creatinine level <1.5 mg/dl b. Severe CDI: Leukocytosis with a white blood cell count of >15 000 cells/mL or a serum creatinine level >=1.5 mg/dl
Denominator Exclusion	- Patients who die, are transferred to another facility, or who are discharged prior to when results of *C. difficile* testing is known. - Fulminant CDI (hypotension or shock, ileus or megacolon) o Definitions:

	▪ Hypotension or Shock: Systolic blood pressure of < 80 mm Hg at the time of diagnosis within 24 hours of positive test for CDI ▪ Unable to take medications per mouth or tube (ileus) ▪ Megacolon: Colonic dilatation > 6 cm - Patients who are NPO for reasons other than CDI and unable to tolerate oral medication - Patients who have documented allergy to vancomycin **AND** fidaxomicin - Patients receiving metronidazole for infections other than CDI.
Denominator Exception	NA
Rationale for the Measure	The below references demonstrate that the measure concept addresses a national health goal or priority - healthcare associated infections, affects a large number of patients, is a leading cause of morbidity and mortality for diarrheal disease, and is a high resource use condition. The Centers for Disease Control and Prevention's Antibiotic Resistance Threats in the United States 2013 report prioritized *Clostridium difficile* as one of the highest bacterial threats that requires immediate public health attention and action [1]. Additionally, the President's Council of Advisors on Science and Technology's (PCAST) National Action Plan for Combating Antibiotic-Resistant Bacteria states that slowing the emergence of resistance bacteria and prevent the spread of resistant infections as their number one goal [2]. The priorities of the Centers for Medicare and Medicaid Services (CMS) aligns with the CDC and PCAST as their Meaningful Measures Initiative identifies Healthcare Associated Infections as one of the highest priorities for quality measure and improvement [3]. In 2011, the U.S. burden of CDI was estimated to be 500,000 infections annually and, depending on the model of attribution, CDI has been associated with 15,000 – 30,000 U.S. deaths [4]. In an analysis of 2008 data, which was the best available at the time, Dubberke and Olsen found that CDI may have resulted in as much as $4.8 billion in excess healthcare costs in acute-care facilities alone [5]. In an analysis of deaths among patients with gastroenteritis, Hall et al found that 83% of deaths were among adults 65 years and older. *C.* difficile was the predominant cause of gastroenteritis during this study period [6]. 1. U.S. Department of Health and Human Services, The Centers for Disease Control and Prevention. Antibiotic Resistance Threats in the United States, 2013. https://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf#page=5. Accessed: July 2018 2. President's Council of Advisors on Science and Technology (PCAST). National Action Plan for Combating Antibiotic-Resistant Bacteria. March 2015. https://www.cdc.gov/drugresistance/pdf/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf. Accessed: July 2018 3. The Centers for Medicaid and Medicare Services. Meaningful Measures Framework. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html. Accessed: July 2018

	4. F. C. Lessa, et al., "Burden of Clostridium difficile Infection in the United States," New England Journal of Medicine, 372 (2015): 825–34. 5. E. R. Dubberke, M.A. Olsen. "Burden of Clostridium difficile on the healthcare system," Clin Infect Dis 2012; 55(Suppl 2):S88–92. 6. A. J. Hall, A. T. Curns, L. C. McDonald, U. D. Parashar, B. A. Lopman. The roles of Clostridium difficile and norovirus among gastroenteritis-associated deaths in the United States, 1999–2007. Clin Infect Dis 2012; 55:216–23.
Supporting Guideline & Other Evidence	"Either vancomycin or fidaxomicin is recommended over metronidazole for an initial episode of CDI. The dosage is vancomycin 125 mg orally 4 times per day or fidaxomicin 200 mg twice daily for 10 days (strong recommendation, high quality of evidence)" 1. McDonald LC, Gerding DN, Johnson S, et al.; Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA), Clinical Infectious Diseases, Volume 66, Issue 7, 19 March 2018, Pages e1–e48, https://doi.org/10.1093/cid/cix1085
Measure Importance	
Relationship to Desired Outcome	As CDI is a severe diarrheal disease, the desired outcome is the resolution of CDI-related diarrhea after appropriate treatment (drug, dose, duration). Randomized controlled trials conducted by Louie et al and Cornely et al respectively concluded that oral fidaxomicin and vancomycin are similarly efficacious in resolving CDI diarrhea at the end of 10 day treatment [1]. 1. McDonald LC, Gerding DN, Johnson S, et al.; Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA), Clinical Infectious Diseases, Volume 66, Issue 7, 19 March 2018, Pages e1–e48, https://doi.org/10.1093/cid/cix1085
Gap in Care/ Opportunity for Improvement	To highlight a gap in care and/or opportunity for improvement, citations related to the burden of CDI – mortality, cost, morbidity – have been included. These high-level outcomes suggest that less-than-optimal performance is occurring at the provider level e.g. suboptimal prescribing of less effective antibiotics. In 2011, the U.S. burden of CDI was estimated to be 500,000 infections annually and, depending on the model of attribution, CDI has been associated with 15,000 – 30,000 U.S. deaths [1, 2]. Reported mortality rates attributed to CDI since 2000 have been higher during both endemic and epidemic periods, where mortality ranged from 4.5 to 5.7 percent and 6.9 to 16.7 percent, respectively [3]. In an analysis of 2008 data, which was the best available at the time, Dubberke and Olsen found that CDI may have resulted in as much as $4.8 billion in excess healthcare costs in acute-care facilities alone [4]. Regarding morbidity, up to 30 percent of patients with CDI have been found to experience a recurrence [5, 6]. Furthermore, Olsen et al. concluded that recurrent CDI is associated with significantly increased mortality, with more than a third of recurrent CDI patients dying within 6 months after completing initial CDI treatment [7]. In concert, these data on outcomes indicate the urgent need for this measure.

	1. F. C. Lessa, et al., “Burden of Clostridium difficile Infection in the United States,” New England Journal of Medicine, 372 (2015): 825–34. 2. A. J. Hall, et al., “The Roles of Clostridium difficile and Norovirus among Gastroenteritis-associated Deaths in the United States, 1999–2007,” Clinical Infectious Diseases, 55 (2012): 216–23. 3. J. H. Kwon, M. A. Olsen, and E. R. Dubberke, “The Morbidity, Mortality, and Costs Associated with Clostridium difficile Infection,” Infectious Disease Clinics of North America, 29 (2015): 123–34. 4. E. R. Dubberke, M.A. Olsen. “Burden of Clostridium difficile on the healthcare system,” Clin Infect Dis 2012; 55(Suppl 2):S88–92. 5. K.W. Garey, S. Sethi, Y. Yadav, H. L. Dupont. “Meta-analysis to assess risk factors for recurrent Clostridium difficile infection,” J Hosp Infect. 2008; 70: 298–304 6. S. Johnson, et al. “Recurrent Clostridium difficile infection: a review of risk factors, treatments, and outcomes,” J Infect. 2009; 58: 403–410. 7. M. A. Olsen, et al. “Recurrent Clostridium difficile infection is associated with increased mortality,” Clin Microbiol Infect 2015; 21:164–70.
Exception Justification	NA

Measure Designation	
Measure Purpose	• ☒Quality improvement • ☒Accountability • ☐MOC
Type of Measure	• ☒Process • ☐Outcome • ☐Structure
National Quality Strategy Priority/CMS Measure Domain	• ☒Clinical Process-Effectiveness • ☐Patient Safety • ☐Patient Experience • ☐Care Coordination • ☐Efficiency: Overuse • ☐Efficiency: Cost • ☐Population & Community Health
Level of Measurement	• ☒Individual clinicians • ☒Clinician groups • ☐Hospitals Outpatient/ED
Care setting	• ☐Emergency Departments • ☐Urgent Care • ☐Physician Office Based Measures • ☒Hospital Inpatient Measures
Data source	• ☒Electronic Health Record (EHR) data • ☒Administrative Data/Claims (inpatient, outpatient, or multiple-source claims) • ☐Paper medical record/chart abstracted • ☐Registry