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Ontario

February 07, 2014

MEMORANDUM

To: Board of Health Chairs
Medical Officers of Health and Associate Medical Officers of Health

Re: Reissuance of the Provincial Case Definition (Appendix B) for Clostridium difficile Infection (CDI) outbreaks in public hospitals

I am writing to inform you of further updates made to the Provincial Case Definition (Appendix B) for *Clostridium difficile* Infection (CDI) outbreaks in public hospitals under the *Infectious Diseases Protocol*. As you may know, the Provincial Case definition for CDI was released on December 30, 2013 as part of a larger collection of updates made to disease-specific chapters of Appendix A and provincial case definitions of Appendix B of the *Infectious Diseases Protocol*.

A section of the Provincial Case Definition for CDI has been updated to reflect current best practices for laboratory diagnosis of *Clostridium difficile*. The changes are consistent with the recent Chief Medical Officer of Health approval of the ministry-led *Clostridium difficile* Infection Best Practices Laboratory Working Group (CDILWG) recommendations in December 2013 which can be found through Quality Management Program – Laboratory Services (QMP-LS) website at the following link:
http://www.qmpls.org/Portals/0/Knowledge%20Centre/CDI%20Lab%20Recommendations%20Final.pdf

Changes made to the Provincial Case Definition (Appendix B) for CDI outbreaks in public hospitals will come into effect on February 3, 2014.

A summary of these changes is included in the new *Document History* section that has been added to the provincial case definition of Appendix B. The document is attached for your reference and as of February 3, 2014 will be available through the OPHS website at the following link:
http://www.health.gov.on.ca/english/providers/program/pubhealth/oph_standards/ophs/infdispro.html

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I would like to express my thanks to you and your staff for your ongoing work in upholding the OPHS and Protocols to ensure the continued strength of the public health system in Ontario.

Original signed by

Arlene King, MD, MHSc, FRCPC
Chief Medical Officer of Health

c: Roselle Martino, Executive Director, Public Health Division and Office of the Chief Medical Officer of Health
Nina Arron, Director, Public Health Policy and Programs Branch
Sylvia Shedden, Director, Public Health Standards, Practice and Accountability Branch
Vivek Goel, Chief Executive Officer, Public Health Ontario
George Pasut, Vice President, Public Health Ontario
Lisa Fortuna, Director, Communicable Disease Prevention and Control, Public Health Ontario

Attachments:
Updated Provincial Case Definition (Appendix B) for *Clostridium difficile* Infection (CDI) outbreaks in public hospitals

Appendix B: Provincial Case Definitions for Reportable Diseases

Disease: *Clostridium difficile* Infection (CDI) outbreaks in public hospitals

[Known as *Clostridium difficile* associated disease (CDAD) in the regulations under the HPPA]

Revised February 2014

Ontario

Clostridium difficile Infection (CDI) outbreaks in public hospitals

1.0 Provincial Reporting

Confirmed outbreaks and outbreak-associated cases occurring in hospitals under the Public Hospitals Act

2.0 Type of Surveillance

Outbreak and case level data

3.0 Outbreak Classification

CDI outbreak definitions incorporate the concept of notification thresholds that optimally trigger action and dialogue between the local public health unit and the facility to determine if an outbreak is occurring.

Facilities should use the following CDI notification thresholds to assist them in determining the need for consultation with their local public health unit. Facilities with limited experience in managing CDI should consult with the local public health unit and/or with the local regional infection control network. These thresholds were developed by the Ministry of Health and Long-Term Care (the 'Ministry') and can also be found in the Provincial Infectious Diseases Advisory Committee's *Annex C: Testing, Surveillance and Management of Clostridum difficile in All Health Care Settings.*

3.1 Notification thresholds are defined as:

For wards/units with ≥20 beds, three (3) new cases of nosocomial CDI identified on one ward/unit within a seven-day period OR five (5) new cases of nosocomial CDI within a four-week period,

OR

For wards/units with <20 beds, two (2) new cases of nosocomial CDI identified on one ward/unit within a seven-day period OR four (4) new cases of nosocomial CDI within a four-week period,

OR

Facilities that have a facility nosocomial CDI rate that exceeds their annual nosocomial baseline rate for a period of two consecutive months. NOTE: This is not valid for a small community hospital, where a single case of nosocomial CDI can artificially elevate the facility rate.

It should be noted that exceeding a threshold does not necessarily imply that an outbreak will be declared. Following consultation between the facility and the local public health unit, decisions on the declaration of an outbreak will be made based on the following criteria:

- There has been a significant* (as determined by the facility and the local public health unit) increase in CDI numbers or rate compared to own baseline and/or that of comparator facilities.
- Recognized control measures are in place and are being used.

- There is epidemiologic evidence of ongoing nosocomial transmission on the ward/unit or facility.

*Significance may be determined by reviewing:
- number of new nosocomial cases associated with the reporting ward/unit or facility
- historic level of CDI activity of the ward/unit or facility
- current trend in ward/unit CDI activity or facility rate
- location of current cases and possible epidemiologic links between cases

3.2 Confirmed Case Definition

- Diarrhea* with laboratory confirmation of toxin A or B for *C. difficile* (Refer to 4.0 Laboratory Evidence);

  OR

- Visualization of pseudomembranes on sigmoidoscopy or colonoscopy;

  OR

- Histological/pathological diagnosis of pseudomembranous colitis;

  OR

- Diagnosis of toxic megacolon.

*Diarrhea is defined as:

- loose/watery bowel movements (conform to the shape of the container), and
- the bowel movements are unusual or different for the patient, and
- there is no other recognized etiology for the diarrhea (for example, laxative use).

For the purpose of defining a case of CDI, there should be three or more episodes of diarrhea within a 24-hour period.

The following definitions are from Ontario's mandatory patient safety reporting program and can be used to determine whether the case attribution is nosocomial:

3.2.1 CDI Attributable to Your Facility

The symptoms of CDI were not present on admission (i.e. onset of symptoms >72 hours after admission) or the infection is present at the time of admission but is related to a previous admission to your facility within the last four weeks.

3.2.2 CDI Not Attributable to Your Facility

- The symptoms of CDI were present on admission or <72 hours after admission and there was no admission to your facility within the last four weeks.

  OR

- The symptoms of CDI recur within two months of the last infection (relapse).

4.0 Laboratory Evidence

4.1 Laboratory Confirmation

Any of the following will constitute a confirmed case of CDI:

- Laboratory confirmation by validated methods
- Visualization of pseudomembranes on sigmoidoscopy or colonoscopy
- Histological/pathological diagnosis of pseudomembranous colitis
- Diagnosis of toxic megacolon

4.2 Approved/Validated Tests

- *Clostridium difficile* (*C. difficile*) enzyme immunoassay (EIA) for glutamate dehydrogenase (GDH) followed by EIA for toxin (A and/or B)
- Molecular testing nucleic acid amplification test (NAAT)/polymerase chain reaction (PCR) for *C. difficile* toxin genes (A and/or B) with or without GDH.
- *C. difficile* cytotoxicity assay

4.3 Indications and Limitations

- Laboratory testing for CDI requires the identification of toxin A or B, or the genes related to cytotoxin production. Cultures for *C. difficile* are not routinely performed, and require confirmation of toxin A and/or B or the related genes.
- Stool specimen collection should occur as soon as possible after the onset of symptoms.
- Testing for *C. difficile* should not be done in children under 12 months of age as the presence of *C. difficile* in stool is normal in this age group.
- Quick turnaround time for *C. difficile* testing is essential and should be pre-arranged with the microbiology laboratory serving the facility.
- A single negative EIA should not be relied on to rule out *C. difficile*. If a single EIA is negative, a second specimen should be sent and the specimen should be tested using a more sensitive method such as molecular testing (NAAT/PCR).
- Testing by molecular methods such as NAAT/PCR is more sensitive and if the first test is negative, a second test is not necessary. Some laboratories employ a two-step method, with detection of *C. difficile* GDH antigen followed by a molecular test if GDH is positive.
- Alternatively, some laboratories may employ a two-step method of a GDH test followed by EIA. If the results between these tests are discordant, the specimen should sent for confirmatory testing by NAAT/PCR.
- Molecular testing is now considered the testing method of choice.
- Testing can detect *C. difficile* colonization or disease. Results of laboratory testing must be correlated with the clinical condition of the patient. If the patient does not meet the case definition for CDI, he/she should not be counted as a case of CDI.
- *C.difficile* toxin testing is not recommended as a test of cure. Toxin and toxin genes may be detected long after clinical symptoms have resolved.
- Formed stool specimens will be rejected for testing. If CDI is still suspected, contact the testing laboratory to arrange testing.

5.0 Clinical Evidence

Clinically compatible signs and symptoms are characterized by the following:

- Diarrhea (as defined above)
- Fever
- Loss of appetite
- Nausea and
- Abdominal pain or tenderness

C.difficile infection can lead to diseases ranging from mild diarrhea to toxic megacolon and death.

6.0 ICD Code(s)

6.1 ICD-10 Code(s)

J22a

7.0 Comments

- It should be noted that exceeding a threshold does not necessarily imply that an outbreak will be declared. Declaration of an outbreak can be made by either the institution or the medical officer of health (MOH).
- In the event of a disagreement between the institution and the MOH, the MOH has the authority to determine if an outbreak of a communicable disease exists, for purposes of exercising statutory powers under the *Health Protection and Promotion Act*. Once an outbreak is declared it is reported to the Ministry through integrated Public Health Information System (iPHIS).
- The hospital may declare an outbreak over and shall consult with the MOH in doing so. Criteria for declaring an outbreak over can be found in the Provincial Infectious Diseases Advisory Committee's *Annex C: Testing, Surveillance and Management of Clostridum difficile in All Health Care Settings*. Rationale for declaring or not declaring an outbreak, and declaring an outbreak over should be documented.

8.0 Sources

Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. Annex C – testing, surveillance and management of *Clostridium difficile*. Annexed to: routine practices and additional precautions in all health care settings. Toronto, ON: Queen's Printer for Ontario; 2013 [cited 2013 Aug 27]. Available from: http://www.publichealthontario.ca/en/eRepository/PIDAC-IPC_Annex_C_Testing_SurveillanceManage_C_difficile_2013.pdf

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Labstract. *Clostridium difficile* toxin testing: specimen acceptance criteria. Toronto, ON: Queen's Printer for Ontario; 2008 [cited 2013 Aug 27]. Available from: http://www.publichealthontario.ca/en/eRepository/LAB_SD_002_Clostridium_difficile_toxin_acceptance_criteria.pdf

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Labstract. *Clostridium difficile*: specimen acceptance and testing during outbreaks. Toronto, ON: Queen's Printer for Ontario; 2008 [cited 2013 Aug 27]. Available from: http://web.archive.org/web/20110827183143/http://www.oahpp.ca/resources/documents/labstracts/LAB-SD-045-000_C_diff_outbreaks_with_revisions_drp2.pdf

Health Canada; Public Health Agency of Canada. C. difficile (Clostridium difficile). It's Your Health. Ottawa, ON: Her Majesty the Queen in Right of Canada, represented by the Minister of Health; 2006 [cited 2013 Aug 27].

Dallal RM, Harbrecht BG, Boujoukas AJ, Sirio CA, Farkas LM, Lee KK, et al. Fulminant *Clostridium difficile*: an Underappreciated and increasing cause of death and complications. Ann Surg. 2002 [cited 2013 Aug 27];235(3):363-72. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1422442/pdf/20020300s00008p363.pdf

9.0 Document History

Table 1: History of Revisions

Revision Date	Document Section	Description of Revisions
February 2014	General	Specific references have been made to PIDAC *Annex C: Testing, Surveillance and Management of Clostridum difficile in All Health Care Settings* in section 3.0 Outbreak Classification and 7.0 Comments.
February 2014	4.0 Laboratory Evidence	4.2 Approved/Validated Tests have been revised. Additions to 4.3 Indications and Limitations and further clarifications to this subsection have been made in bullets three, five, six, and seven.
January 2014	General	New template. Sections 9.0 Document History Added.

Revision Date	Document Section	Description of Revisions
January 2014	3.0 Outbreak Classification	Changed from "CDI outbreak definitions have been revised to incorporate the concept of notification thresholds, which are more sensitive than outbreak definitions" to "CDI outbreak definitions incorporate the concept of notification thresholds that optimally trigger action and dialogue between the local public health unit and the facility to determine if an outbreak is occurring. Facilities should use the following CDI notification thresholds to assist them in determining the need for consultation with their local public health unit. Facilities with limited experience in managing CDI should consult with the local public health unit and/or with the local regional infection control network. These thresholds were developed by the Ministry of Health and Long-Term Care (the 'Ministry')".

Revision Date	Document Section	Description of Revisions
January 2014	3.1 Notification Thresholds are defined as:	First paragraph changed from "...3 cases of nosocomial CDI..." to "...three (3) **new** cases of nosocomial CDI..." and from "...5 cases within a..." to "...five (5) **new** cases of nosocomial CDI within a...". Second paragraph changed from "...2 cases of nosocomial CDI..." to "...two (2) **new** cases of nosocomial CDI..." and from "...or 4 cases within a 4 week period..." to "...four (4) **new** cases of nosocomial CDI within a four-week period...". Third paragraph changed from "Hospitals that have a baseline CDI rate for two months that is at or above the 80th percentile for comparator hospitals" to "Facilities that have a facility nosocomial CDI rate that exceeds their annual nosocomial baseline rate for a period of two consecutive months. NOTE: This is not valid for a small community hospital, where a single case of nosocomial CDI can artificially elevate the facility rate." "Hospitals that have a facility rate that is greater than or equal to 2 standard deviations above their baseline" deleted. "Hospitals that have a facility rate that is greater than or equal to 2 standard deviations above their baseline" added to the fourth paragraph. Second bullet point, "recognized control measures are in place and are being used" added to fourth paragraph.
January 2014	3.2 Confirmed Case Definition	PCR replace with nucleic acid amplification testing (NAAT) in first bullet point. "For the purpose of defining a case of CDI, there should be three or more episodes of diarrhea within a 24-hour period" added. Definitions to be used to determine whether the case is nosocomial revised.

Revision Date	Document Section	Description of Revisions
January 2014	4.2 Approved/ Validated Tests	PCR replaced with NAAT in second bullet point.
January 2014	4.3 Indications and Limitations	Fourth bullet point changed from "Quick turnaround time for C. difficile cytotoxin and PCR testing is essential…" to "Quick turnaround time for C. difficile testing is essential…". "The role of repeating a PCR test is not known, and is not routinely recommended" deleted from fifth bullet point. Sixth and seventh bullet points added.
January 2014	8.0 Sources	Updated.