

Public Reporting of Clostridium difficile (*C.difficile*) Frequently Asked Questions – Revised January 2010

The following FAQs, which were originally circulated to all Ontario hospitals in July 2008, have been updated to reflect the recent publication of the Ministry of Health and Long-Term Care's "Control of Clostridium difficile Infection (CDI) Outbreaks in Hospitals, A Guide for Hospital and Health Unit Staff".

A: Background Information

1. What is Clostridium difficile (*C.difficile*)?

C.difficile is a spore-forming bacteria that is present in the environment and can colonize up to 3-5% of adults in the community without causing symptoms. *C.difficile* has been a known cause of healthcare-associated diarrhea for about 30 years. Its spores are resistant to eradication by many environmental influences, including standard cleaning agents used in hospitals.

The case definition for *C.difficile* infection (CDI), formally known as Clostridium difficile Associated Disease (CDAD) can be found in Appendix A.

2. What causes *C. difficile*?

C. difficile can be picked up on the hands from exposure in the environment, and can get into the stomach once the mouth is touched, or if food is handled and then swallowed. Once in the stomach, the bacteria usually will not cause any problems unless the other bowel bacteria are disturbed, which can happen when antibiotics are taken. Without the presence of the typical bowel bacteria, the *C. difficile* bacteria may start to grow and produce a toxin that will cause illness. The spread of *C.difficile* occurs due to inadequate hand hygiene and environmental cleaning.

3. What are the risk factors for CDI?

Certain people are at increased risk for acquiring CDI. These risk factors include:

- History of antibiotic usage
- Bowel surgery
- Chemotherapy
- Prolonged hospitalization
- Being elderly
- Serious underlying illness or debilitation

B: Public Reporting Process and Requirements

4. Does public reporting of CDI apply to all hospitals or just all acute hospitals?

The requirement to report to the public on CDI applies to **all Ontario public hospitals**. Public reporting of CDI in Ontario hospitals began on September 30, 2008 and is required monthly.

The reporting process has two streams:

- Patient Safety Indicator Reporting of monthly CDI rates. Hospitals will post rates of CDI and case counts acquired in their facility on their website each month, and will also report their data to the MOHLTC through an online template captured by the Web Enabled Reporting System (WERS).
- Reporting of CDI outbreaks. Hospitals are required under the *Health Protection and Promotion Act* to report CDI outbreak associated cases of CDI to their local public health unit when the definition of an outbreak is met in their facility (see Section C for information on outbreak reporting).

5. What are the expectations for the public reporting of *C.difficile*?

On the last day of each month, all Ontario hospitals are required to publicly report on their own websites the:

- **rates** of new nosocomial CDI cases associated with the reporting facility, separately for each hospital site; and
- **number** of new nosocomial CDI cases associated with the reporting facility (count) separately for each hospital site.

Hospitals can identify this information through their existing infection prevention and control surveillance programs

Before reporting the data on the hospital website, hospitals are required to send their CDI data to the MOHLTC using the Web Enabled Reporting System (WERS) database by the 15th of every month to meet monthly posting requirements.

Hospitals are strongly encouraged to post information on their public website when:

- They are actively in an outbreak*;
- A ward/unit or the entire facility is affected;
- The outbreak is declared over.

**Outbreak definitions have been revised. The new notification thresholds are outlined in Section C. Hospitals are encouraged to post outbreak information on their websites using the new notification thresholds beginning February 26 2010.*

The MOHLTC will also report on its own website: http://www.health.gov.on.ca/patient_safety/

- the nosocomial CDI **rate** for each hospital site, and
- the **number** of new CDI cases associated with the reporting facility (count) for each hospital site.

The MOHLTC will calculate the rates using the hospital's data, and will forward its calculated rate to the hospital. Hospitals whose calculated rates differ from the MOHLTC's calculated rate, should contact the MOHLTC to discuss. The MOHLTC will post its calculated rate. It is the

MOHLTC's recommendation that hospitals wait to post the monthly rate until they have received the results of the MOHLTC's calculations

The MOHLTC also posts on its website, hospitals that have been in outbreak for the previous month. The public will be encouraged to contact the hospital directly for additional information.

6. How does the hospital send the *C.difficile* data to the MOHLTC?

On the 15th of every month, hospitals will be required to provide CDI data using the Web Enabled Reporting System (WERS) database to the MOHLTC.

7. How are CDI rates calculated?

CDI counts: the number of new cases of *C.difficile* infection by month.

The counts will be broken down into: (see definitions in Appendix A)

- a) Number of new nosocomial cases of CDI associated with reporting facility
- b) Number of new nosocomial cases of CDI associated with other health care facilities
- c) Number or new cases of CDI associated with a source other than a health care facility or unknown/indeterminate source

The rate of CDI is calculated as follows:

$$\frac{\text{Number of new nosocomial cases of CDI associated with the reporting facility} \times 1000}{\text{Number of patient days}}$$

This rate represents the incidence rate of nosocomial CDI associated with the reporting facility per 1000 patient days.

Exclusion criteria for data: children under one year should be excluded from the numerator and denominator. All other patients (eg: mental health, rehab) should be included.

8. Will CDI data collection be retrospective or prospective?

Hospitals will be required to report through WERS on a retrospective basis. For January 30th reporting for example, hospitals will report in WERS CDI data by January 15th for data collected between December 1 – 31st

At the end of each month, hospitals will report the previous month's data on their website by hospital site including:

- (i). the number of new nosocomial CDI cases **totaling 10 or more** associated with that hospital site; and
- (ii). the nosocomial CDI rate

NOTE: if (i). above is less than 10 cases, then hospitals should post "**< 10 cases**" as their result.

9. Who is responsible for calculating the C.difficile rate?

Hospitals are responsible for calculating their own CDI rate and for posting its rate on its own website by the last day of every month. This will be one of the data fields in WERS, which is forwarded to the MOHLTC. Once the MOHLTC receives the information on the WERS form, it will calculate the rates using the hospital's data, and will forward its calculated rate to the hospital.

While the MOHLTC recognizes that hospitals may choose to post rates throughout the month, it is the MOHLTC's recommendation that hospitals wait to post the monthly rate until they have received the results of the MOHLTC's calculations to ensure accuracy and consistency.

10. Who is responsible for collecting the data and who is responsible for entering the data in WERS?

Each facility should currently be conducting surveillance for CDI. PIDAC's "Best Practices for Surveillance of Health Care- Associated Infections in Patient and Resident Populations (2008)," can assist with surveillance program.

Those collecting the data should be managed by trained and experienced professionals skilled in data collection procedures like your hospital's Infection Control practitioner/team. Once the data has been collected, it is important that the hospital determine who, in each facility and/or site, is responsible for entering the data into WERS.

11. Once the Ministry receives the CDI data from WERS, how does this data become public?

On the 15th of every month, the hospital will submit the CDI data through WERS to the MOHLTC.

The WERS form that is forwarded to the MOHLTC includes a row for the hospital to list the CDI cases, patient days, and CDI rate that it has calculated. The MOHLTC will receive the information on the WERS form, calculate the rates using the hospital's data, and will then forward its calculated rate to the hospital. The MOHLTC will forward its calculated rate to the hospital before the 30th of every month. The MOHLTC is performing this function to ensure consistency between theirs and the hospitals' calculations.

Hospitals whose rates differ from the MOHLTC rates should contact the MOHLTC to discuss them. When the MOHLTC forwards its calculated rate to the hospital, a MOHLTC contact name will be provided in the event that there are discrepancies in rates.

The Ministry will post its calculated rate.

The hospital is responsible for calculating its own rates and for posting rates on its own website by the last day of every month. The MOHLTC recognizes that hospitals may choose to post rates throughout the month; however it is the MOHLTC's recommendation that hospitals wait to post the monthly rate until they have received the results of the MOHLTC's calculations to ensure accuracy and consistency.

12. How frequently will hospitals have to publicly report on CDI?

Hospitals will be reporting their CDI data for every calendar month.

13. We are a multi-site hospital. Are we required to report CDI data by corporation or by site?

Hospitals with multi-sites should be measuring, collecting, and reporting data for each site rather than providing an overall rate as these can vary widely between sites.

The MOHLTC website will report on hospitals by individual sites; hospitals are requested to post their CDI rates by hospital site.

14. What should hospitals be doing if their CDI rates are high?

Hospitals that identify a high rate of CDI should review their infection prevention and control practice to ensure that it aligns with what has been provided to them, including the PIDAC documents, “Best Practices for the Management of *Clostridium difficile* in all health care settings (revised January 2009)”, “Best Practices for Hand Hygiene in all health care settings” and the MOHLTC’s “*Just Clean Your Hands*” program.

Hospitals should also refer to the 2009 publication of “Control of Clostridium difficile Infection (CDI) Outbreaks in Hospitals, A Guide for Hospital and Health Unit Staff” to manage CDI outbreaks. The recommendations contained in this document support the management of CDI outbreaks by:

- Defining the roles of the hospital and public health staff in outbreak control processes;
- Providing specific guidance for CDI outbreak control; and
- Providing a compilation of tools and resources for the management of CDI outbreaks

In addition, hospitals should review their environmental cleaning practices to ensure that they are following the PIDAC *C.difficile* best practice document. Hospitals should also consult with their local Public Health Unit to identify any further action that may be required to improve cleaning practices in their organization.

15. Will hospitals be required to report on the number of deaths caused by CDI?

Reporting deaths caused by CDI is a complicated matter. At this time, there is no requirement for hospitals to publicly report on the number of deaths caused by CDI. Deaths related to outbreaks should be reported to the Public Health Unit.

C: Outbreak Reporting Process and Requirements

16. How is a CDI outbreak declared?

The following CDI notification thresholds replace the existing outbreak definitions that were issued on September 1, 2008. These thresholds come into effect January 1, 2010 and hospitals are encouraged to post outbreak information on their websites using the new notification thresholds beginning February 26, 2010.

Outbreak definitions have been redefined to incorporate notification thresholds that optimally trigger action and dialogue between public health and hospitals to determine if an outbreak is occurring. Notification thresholds are more sensitive than outbreak definitions and are defined as:

1. For wards/units with ≥ 20 beds, 3 cases of nosocomial CDI identified on one ward/unit within a seven day period or 5 cases within a 4 week period; OR
2. For wards/units with < 20 beds, 2 cases of nosocomial CDI identified on one ward/unit within a seven day period or 4 cases within a 4 week period; OR
3. Hospitals that have a baseline CDI rate for two months that is at or above the 80th percentile for comparator hospitals; OR
4. Hospitals that have a facility rate that is greater than or equal to 2 standard deviations above their baseline. Note: This does not apply to small hospitals with a single case of nosocomial CDI which artificially elevates the facility rate

Hospitals will be able to use the comparator data on the public website for outbreak determination when provincial baselines are established after several months of data reporting. Facilities that are under the 80th percentile for their category but have experienced a doubling of their new nosocomial cases of CDAD for two consecutive months should also trigger an investigation and notify public health.

It should be noted that exceeding a threshold does not necessarily imply that an outbreak will be declared.

17. How does a hospital declare an outbreak?

Following consultation between the institution and the Medical Officer of Health (MOH), decisions on the declaration of an outbreak will be made based on the following two criteria:

- Significant* (as determined by the facility and health unit) increase in CDI numbers or rate compared to own baseline and/or that of comparator institutions
- Epidemiologic evidence of ongoing nosocomial transmission within 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;
- Current control measures (and evidence that they are being implemented);

Declaration of an outbreak can be made by either the institution or the MOH.

18. What happens in the event of a disagreement between the hospital and the MOH regarding the declaration of an outbreak?

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 HPPA. Once an outbreak is declared it is reported to the Ministry of Health and Long Term Care through integrated Public Health Information System (iPHIS).

An Infection Control Resource Team (ICRT) review can be requested by the MOH or by the facility Chief Executive Officer through the MOH at any time during the threshold investigation or for outbreak control. The hospital may declare an outbreak over and shall consult with the MOH

in doing so. Rationale for declaring or not declaring an outbreak, and declaring an outbreak over should be documented.

19. When a hospital has an outbreak of CDI, what are reporting and outbreak management requirements?

As of September 1, 2008, hospitals are required under the *Health Protection and Promotion Act* (HPPA) to report CDI outbreaks and outbreak associated cases to the local medical officer of health. Reporting requirements for hospitals and public health units are defined under the *Public Hospitals Act* and the HPPA.

CDI outbreaks and outbreak-associated cases in public hospitals are designated as per regulations under the *HPPA* as follows:

- O. Reg. 558/91, includes outbreaks of CDI in hospitals on the list of communicable diseases in Ontario;
- O. Reg. 559/91, includes outbreaks of CDI in hospitals on the list of reportable diseases in Ontario; and
- O. Reg. 569, which includes the specific data elements for outbreaks of CDI which hospitals must provide to their local medical officers of health.

The MOHLTC also posts on its website, hospitals that have been in outbreak for the previous month. The public will be encouraged to contact the hospital directly for additional information.

Hospitals are strongly encouraged to post information on their public website when:

- They are actively in an outbreak;
- A ward/unit or the entire facility is affected;
- The outbreak is declared over.

Hospitals are encouraged to refer to MOHLTC's "Control of Clostridium difficile Infection (CDI) Outbreaks in Hospitals, A Guide for Hospital and Health Unit Staff" (December 2009) for steps to follow during a CDI outbreak.

The Guide can be accessed at

http://www.health.gov.on.ca/patient_safety/pro/cdad/pro_resource/guide_cdi_infect_control.pdf

20. What happens to outbreaks that were declared under the old outbreak definitions?

Outbreaks declared under the old definitions will continue until they are declared over. All new outbreaks will be based on the new threshold and outbreak criteria (see question 16 above)

22. Will the MOHLTC be providing the 80th percentile for comparator groups?

The MOHLTC will be providing the 80th percentile for hospital comparator groups to the public health units on a monthly basis (i.e. preliminary and final CDI case counts and rates). The OHA will continue to provide hospitals who have been identified as having either a high case count or rate for preliminary data on a monthly basis.

Appendix A Definitions

***Clostridium difficile* associated disease (CDI):**

Diarrhea* with laboratory confirmation of a positive toxin assay (A/B) for *C. difficile*; OR visualization of pseudomembranes on sigmoidoscopy or colonoscopy; OR histological/pathological diagnosis of pseudomembranous colitis.

***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).

New nosocomial case of CDI associated with reporting facility:

A case that meets the case definition for CDI; AND CDI was not present on admission (i.e., onset of symptoms >72 hours after admission); OR the infection was present at time of admission but was related to a previous admission to the same facility within the last 4 weeks; AND the case has not had CDI in the past 8 weeks.

NOTE: in the event of a ward/unit outbreak, it is important to determine the length of time the CDI case has been a patient on the outbreak unit

New nosocomial case of CDI associated with other health care facilities:

A case that meets the case definition for CDI; AND CDI was present on admission; OR the case had symptom onset <72 hours after admission; AND the case was exposed to any other health care facility (including LTC) other than the reporting facility within the last 4 weeks; AND the case has not had CDI in the past 8 weeks.

New case of CDI associated with source other than a health care facility or indeterminate source:

A case that meets the case definition for CDI; AND CDI was present on admission; OR the case had symptom onset <72 hours after admission; AND there was no exposure to any health care facility within the last 4 weeks; OR the source of infection cannot be determined; AND the case has not had CDI in the past 8 weeks.