Provincial Surveillance Protocol for *Clostridium difficile* infection

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Background

Provincial Infection Control Newfoundland Labrador (PIC-NL), established in 2007, is the provincially recognized source for best practices in infection prevention and control (IPAC). One of the key areas of practice for IPAC is surveillance for healthcare-associated infections (HAIs). PIC-NL launched a surveillance program for HAIs in 2009 and methicillin-resistant *Staphylococcus aureus* and *Clostridium difficile* infections were identified for provincial reporting. PIC-NL provides a database for the storage of this data in the Regional Health Authorities (RHAs) that facilitates reporting to the province. Reports are provided to decision makers in the RHAs.

Clostridium difficile infection surveillance

Purpose: To monitor the incidence of CDI which provides valuable insight into the state of clinical practice and the burden of CDI in NL; to identify changing patterns of disease across NL as indicator of infection prevention and control program achievements; to provide valuable data on antimicrobial stewardship program impact and program development.

Impact of *Clostridium difficile* infection:

Clostridium difficile (C. difficile), the major cause of antibiotic-associated pseudomembranous colitis, is also the most frequently identified cause of hospital-acquired diarrhea. *C. difficile* is present asymptomatically as part of the bowel microbiota in up to half of all healthy neonates during the first year of life; the carriage rate decreases to the adult rate of ≤ 3% by the age of 2. Many antibiotics and anticancer drugs disrupt the bowel microbiota sufficiently for *C. difficile* to proliferate and precipitate disease. In addition, *C. difficile* may become problematic in patients with bowel stasis and those who had bowel surgery. The clinical manifestations of *C. difficile* associated diarrhea (CDAD) range from a self-limiting diarrheal disease that disappears when antibiotics are discontinued to fulminant presentations with characteristic pseudomembranes within the large intestine and progression to toxic megacolon, bowel perforation and death.[1]

Since 2000, *Clostridium difficile* infection (CDI) has been recognized as a serious nosocomial infectious complication in Canada.[2-3] In addition to the impact on the patient's quality of life, a conservative estimate of the cost of this disease in the United States exceeds $1.1 billion per year.[4] A study by the Canadian Nosocomial Infections Surveillance Program (CNISP) found the incidence of nosocomial CDI in Canada to be 5.9 cases per 1000 admissions.[5] However, rates of up to 25 cases per 1000 admissions have been reported from healthcare institutions in Quebec.[6] Miller et al., (2006) suggested a benchmark incidence rate of < 6 cases per 1000 admissions or < 0.6 per 1000 patient care days (excluding pediatric cases).[7] In 2007 the 49 hospitals participating in CNISP reported a mean incidence rate of 4.8 per 1000 admissions and 6.4 per 10,000 patient days for hospital acquired CDIs.[8] Simor et al., (2012) reported a rate of 0.1 per 100 inpatient days for Newfoundland and Labrador in a point prevalence study done in Canadian hospital in November 2010.[9] The prevalence rates reported for all provinces ranged from 0.1 in NL to 1.7 for British Columbia.[9]

Objectives:

- To monitor the incidence of CDIs and reinfections in acute and long term care facilities in all RHAs
- To identify healthcare-associated (not hospitalized) and community acquired cases of CDIs
- To establish a benchmark on CDIs among Regional Health Authorities (RHAs) in NL
- To detect and monitor outbreaks of CDI in RHA in NL

Definitions:

***Clostridium difficile* infection (CDI) case:** A confirmed CDI case includes clinical illness* and laboratory confirmation of infection:

- a positive *C. difficile* toxin assay (enzyme immunoassay, nucleic acid amplification test or toxigenic cell culture assay)[10] or
- diagnosis of pseudomembranes on signoidoscopy or colonoscopy, or histological/pathological diagnosis of *C. Difficile* infection

- *Clinical illness consists of diarrhea or fever, abdominal pain and/or ileus. Diarrhea is defined as one of the following:
    - Six watery stools in past 36 hours
    - Three unformed stools in 24 hours for at least 1 day
    - Eight unformed stools over 48 hours

- **Healthcare-associated nosocomial (hospital) acquired:** A case in which symptoms occur at least 72 hours or more after the current admission OR symptoms occur in a patient who has been hospitalized at your hospital and discharged within the previous 4 weeks.

- **Long Term Care acquired:** A case in which symptoms occur at least 72 hours after the admission and the resident has not had a hospital admission within the last 4 weeks.

- **Recurrent CDI:** Recurrence of diarrhea within four weeks of a previous *C difficile* infection episode. A recurrent infection is to be considered a continuation of the previous episode and not a new infection.

- **Reinfection:** A case in which symptoms started greater than four weeks from a previous *C difficile* infection episode.

- **Episode:** The time from the start of the symptoms until the symptoms resolve.

- **Healthcare-associated - Other:** A case that does not meet the definition for healthcare-associated (hospitalized), healthcare-associated (long term care) or community-associated infection.

- **Community-associated CDI**: A case with symptom onset in the community or three calendar days or less after admission to a healthcare facility, provided that symptoms onset was more than four weeks after the last discharge from a healthcare facility.

- **Unknown:** A patient does not fit any of the above criteria

Roles, Responsibilities & Reporting

Laboratory

Specimen collection:

- Rapid turnaround time for *C difficile* testing and reporting is essential and should be pre-arranged with the microbiology laboratory [11]
- Testing indicated only for hospitalized, or institutionalized individuals with diarrhea, or community patients with demonstrated current or recent antibiotic exposure
- Stool sample collection should occur as soon as possible after the onset of diarrhea
    - Stool specimen should be collected in Cary-Blair screw cap collection container
    - 5 ml of stool required
    - Testing should not be carried out on formed stool, unless toxic megacolon is suspected

- A negative test cannot be used to exclude CDAD. If clinical signs, symptoms and risk factors are inconsistent with result consider submission of repeat specimen.
- If a patient has been found positive for CDI no follow up testing indicated for 14 days – testing cannot be used to determine treatment success.
- If a patient with suspected CDI yields ≥3 negative tests in the preceding 7 days an alternative diagnosis should be considered. Further testing for CDI not indicated.

Sites for testing:

Stool testing for CDI should be performed such that a rapid turn around-time can be assured. If an RHA does not have capacity to perform CDI testing specimens may be submitted to the PHL for testing.

Laboratory reporting:

- RHA microbiology laboratories are required to forward all positive stool specimens to the PHL for surveillance and monitoring.
- RHA microbiology laboratories are required to report weekly aggregate data to the PHL employing the NESP reporting tool in MicroLabNet on CNPHI.
- *C. difficile* infection is considered a critical result and therefore immediate reporting using the fastest means possible to the attending physician is essential.
- As an infection prevention and control significant finding all positive *C. difficile* results should be reported to the infection control practitioner in the healthcare facility where the patient resides.
- As a provincial notifiable disease all positive *C. difficile* results are required to be reported as weekly aggregate data to the Regional Medical Officer of Health (RMOH)/designate.

Infection Prevention and Control

All cases of *Clostridium difficile infection* will be reviewed by the Infection Control Practitioner (ICP). If necessary the ICP will collaborate with the Communicable Disease Control Nurse (CDCN) and/or the Environmental Health Officer to collect the data. Information may be obtained from the admission log, patient's hospital chart, ward rounds, laboratory reports and nursing/medical staff to enhance data collection. The ICP will complete the data collection form on each CDI case (form available in Appendix A). An ACCESS® database is available in each RHA for data entry.

Public Health reporting:

On a quarterly basis the ICP/designate, responsible for regional CDI surveillance, will extract a report from the database based on the sample CDI reporting form (Appendix C)

- This report will be sent to the Regional Medical Officer of Health (RMOH) and the provincial epidemiologist

Medical Officer of Health

- Review the quarterly reports
- Determine actions necessary as indicated by burden of disease

Provincial Epidemiologist

- Provide ongoing training and non-technical support to regional users
- Provide ad hoc orientation sessions for new HAI database users, as requested
- Compile regional CDI reports into a quarterly, provincial HAI report
- Report to be provided to Provincial Infection Control Nurse Specialist for distribution to stakeholders
- Support regional representatives in data extract, analysis, and reporting from HAI database
- Provide surveillance advise and expertise, as needed

Public Health Information and Surveillance

- Provide ongoing training and non-technical support to regional users
- Provide ad hoc orientation sessions for new HAI database users, as requested
- Data extract, analysis, and reporting from HAI database

Provincial Infection Control Nurse Specialist

- Update the protocol for CDI surveillance as necessary
- Provide input on the clinical requirements for the database
- Review the quarterly reports from the RHAs
- Coordinate the development of a quarterly and provincial report
- Review the report with the Director of Disease Control
- Lease with PIC-NL on the CDI report and determine the actions required to reduce disease occurrence

Ethics

Specific ethics approval is not required for surveillance for diseases of importance to public health; however, all data collected will be governed by the privacy policies within the Regional Health Authorities (RHAs) and the Provincial Department of Health and Community Services. The database will be the responsibility of the Regional Health Authority. Only aggregate data will be submitted to the provincial Disease Control Division.

Data Analysis

The data will be used to meet the objectives of the program. The province will collect aggregate data from each RHA and no facility will be defined nominally. Additionally RHAs will be able to use their own data as they feel appropriate and may want to collect additional data to support their internal infection control programs.

The numerator will be the number of CDIs. Acute care inpatient days and resident care days will be used to calculate the CDI rates for acute care and long term care cases.

The data will be entered into an ACCESS® database and analyzed with the help of an epidemiologist. At a minimum the analysis will include:

- Incidence rate of nosocomial CDIs per 10,000 patient care days
- Incidence rate of nosocomial CDIs per 10,000 resident care days
- Number of cases of healthcare-associated infections

- Number of CDI reinfections
- Number of CDI community cases

Calendar Quarter

The calendar quarter will be used for reporting purposes. A calendar quarter is a period of three consecutive months starting on the first day of January, April, July or October. The start date for the first quarter reporting will be January 01 of each year.

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Appendices

Appendix A: CDI Surveillance Form

1	Patient unique number	
2	Chart # (if applicable)	
3	a) Type of Care (Acute, LTC, Other)	
	b) Facility (Name)	
4	Patient Care Unit in Facility	
5	Type of patient care unit	☐ Surgical Unit ☐ Critical Care Unit ☐ Medical Unit ☐ Obstetrical Unit ☐ Combined (med/surg) Unit ☐ Other; specify _____
6	Date of Birth	____/____/____ DD MMM YYYY Month = (ie., May)
7	Date of Admission	____/____/____ DD MMM YYYY
8	Reason for Admission	
9	Date of Discharge	____/____/____ DD MMM YYYY
10	Sex	☐Male ☐Female
11	Date of current positive lab test?	____/____/____ DD MMM YYYY
12	Why was the specimen collected?	☐ clinical signs and symptoms ☐ other _____
13	Has the patient ever had CDI before?	☐ No ☐ Yes, less than 2 months ago ☐ Yes, more than 2 months ago ☐ Unknown
14	Where was the CDI acquired? (Check one answer only)	☐ Same as treatment facility (#3b) – nosocomial ☐ If not acquired in the same facility as #3b ☐ Another Acute Care (AC) in region _____ ☐ Another LTC in region _____ ☐ An exposure outside the region _____ ☐ Healthcare associated ☐ Community-associated ☐ Unknown
15	Did patient require ICU admission for this episode?	☐ No ☐ Yes, admitted to ICU for complications of CDI
16	Treatment for CDI	☐ Metronidazole ☐ x 1 ☐ x 2 ☐ Vancomycin ☐ x 1 ☐ x 2 ☐ No antibiotic ☐ Other
17	Patient disposition at 30 days after diagnosis	☐ Alive, in hospital due to CDI ☐ Alive, in hospital for another reasons ☐ Alive, in a LTC facility ☐ Discharged from hospital prior to 30 days ☐ Deceased ☐Unknown☐Other_____

Appendix B: Data Dictionary

***Clostridium difficile infection* surveillance form**

1. Patient unique reference number such as MCP

2. Chart number for those facilities that use a chart number as a patient identifier

3. a) Type of care – Placement (is the person in hospital or living at home) of the patient at the time of the positive culture; identify if it was acute care, long term care, or other. Other = living in the community or living in a personal care home at the time of the positive culture.

   b) Facility – If applicable, identify the name of the acute care facility or the long term care facility where patient resided when the positive culture was identified. The facilities can be identified from the drop down tab.

4. Name of patient care unit in the facility in question 3 eg., H4N, 3B.

5. If the patient was in a facility when laboratory confirmation was known, indicate the type of service provided on that Unit: medical, surgical, and critical care units. The ICP should use best judgment to determine to which unit the transmission is associated.

6. Date of Birth: Enter day (##), month (eg., May) and year (2008) in this order.

7. Date of Admission: Enter day (##), month (eg., May) and year (2008) in this order.

8. Reason for Admission: why is the person in the facility?

9. Date of Discharge: Enter day (##), month (eg., May) and year (2008) in this order.
   Not applicable – for example, if the person is a resident of LTC

10. Gender: Check male or female

11. What was the date of this patient's newly identified CDI culture? Enter day (##), month (eg., May), and year (2007) in this order, from the most recent diagnosed episode of CDI.

12. Identify the reason for the CDI testing.

13. Assess if the person has had previous testing for CDI and determine if this is a recurrence of CDI or a reinfection.

14. Where was the CDI acquired? - Use the definitions to guide making this decision.

    - *Same as treatment facility* – This applies to CDIs which have been acquired in the treatment facility identified in # 3b. If the CDI has not been acquired in the treatment facility identified in # 3b choose an option in the **type of care box**:
      - Acute Care
      - Long Term Care
      - Other

- In **the facility box –** choose either the acute care of long term care facility or choose one of the following options: outside your health region, healthcare associated, community-associated, or personal care home.

15. Outcome: Did the patient require an ICU admission due to CDI?

16. What antibiotics were prescribed for CDI? How many courses of the antibiotic were required to treat the person? X1 = one course of antibiotic; X2 = two courses of antibiotic; Other – indicate the type of antibiotic used and if one, two or more courses were required.

17. Disposition: At 30 days post CDI diagnosis, where was the person?

18. Comments - for personal use not for entry into the database.

Appendix C: Sample Public Health Reporting Form for CDI

Region: _____ Month: _____ Date: _____

1. Numerator Data

Table 1**:** Number of CDIs in Acute Care

Facility	A. Total number of infections	B. Total number of reinfections
Acute Care Facility 1		
Acute Care Facility 2		
Total		

Total infections for Acute Care Facilities for region = A + B

Table 2**:** Number of CDIs in Long Term Care

Facility	A. Total number of infections	B. Total number of reinfections
Long Term Care Facility 1		
Long Term Care Facility 2		
Total		

Total infections for Long Term Care for region = A + B

2. Denominator Data

Table 3

Facility	Patient Care Days	Number of admissions
Acute Care Facility 1		
Acute Care Facility 2		
Total		

Table 4

	Resident Care Days
Long Term Care Facility 1	
Long Term Care Facility 2	
Total	

3. Number of cases of community-associated CDI infections

Table 5.

Region	Number of Cases