PROVINCIAL SURVEILLANCE PROTOCOL FOR *CLOSTRIDIUM DIFFICILE* INFECTION

Provincial Infection Control-NL
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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 (MRSA) and Clostridium difficile (C. difficile)* infections were identified for provincial reporting. In 2012 the Accreditation Canada Standards for Infection Prevention and Control required organizations to monitor trends in infections and to track safety indicators for healthcare-associated (nosocomial) infections: MRSA and *C. difficile*. In 2019 definitions for *C. difficile* were revised to align with Canadian Nosocomial Infection Surveillance Program (CNISP).

Clostridium difficile Surveillance

Clostridium *difficile* is an anaerobic, spore-forming bacillus (bacteria) that is present asymptomatically as part of the bowel microbial 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. C. *difficile* is responsible for a spectrum of C. *difficile* associated infections (CDI), including uncomplicated diarrhea, pseudo-membranous colitis (PMC), and toxic megacolon, which can, in some instances, lead to bowel perforation, septic shock, and subsequent death. CDI has been reported as the most frequent cause of Health Care Associated Infection (HAIs) in Canada.[1]

Drugs such as antibiotics, chemotherapy agents, and protein pump inhibitors may disrupt the bowel microbiota sufficiently for C. *difficile* to proliferate and precipitate disease.[2] A major risk factor for the development of CDI is the use of antibiotics for unrelated infections; 85% of CDI cases have an antibiotic history.[3] Certain antibiotics have been more strongly associated with CDIs; clindamycin, broad spectrum cephalosporins and fluoroquinolones.[4]

Interventions such as antimicrobial stewardship practice may help to reduce the incidence of CDI. Infection prevention and control strategies may also help prevent the acquisition of C. *difficile* during hospitalization and most importantly prevent the spread of C. *difficile* spores from infected patients to non-infected patients.

Purpose

The purpose of this protocol is to provide a consistent approach for surveillance of Clostridium *difficile* infections in Newfoundland and Labrador.

Objectives

- To monitor the incidence of CDIs in the community, and acute and long-term care facilities in Newfoundland and Labrador.
- To help identify at risk population, inform health departments in trends and to evaluate the effectiveness of infection prevention and control programs.
- To provide valuable data on antimicrobial stewardship program impact and program development.

Definitions

Clostridium *difficile* infection inclusion criteria:
A confirmed CDI case includes clinical illness and laboratory confirmation of infection.

A case is identified as having CDI if:
The case has diarrhea or fever, abdominal pain and/or ileus **AND** a laboratory confirmation of a positive toxin assay or positive polymerase chain reaction (PCR) for C. *difficile* (without reasonable evidence or another cause of diarrhea).

OR
The case has a diagnosis of pseudomembranous on sigmoidoscopy or colonoscopy (or after colectomy) or histological/pathological diagnosis of CDI.

OR
The case is diagnosed with toxic megacolon (adult patients only).

C. *difficile* exclusion criteria:
- Less than one year of age.
- Recurrent CDI.

Diarrhea:
- Six (6) or more watery/unformed stools in a 36-hour period.
- Three (3) or more watery/unformed stools in a 24-hour period and is new or unusual for the patient (adult patients only).

Primary episode: (CDI):
A "primary 'episode of CDI is defined as either the first episode of CDI ever experienced by the patient/client/resident or a new episode which occurs **greater than eight (8**) **weeks** after the diagnosis of a previous episode in the same patient.

Recurrent CDI:
An episode that occurs in a case less than or equal to eight (8) weeks* following the diagnostic test date of the primary episode of CDI, providing the case was treated successfully for the primary episode and symptoms of CID resolved completely.

Infected cases:
Once a case has been identified with a CDI, they will be classified based on the following criteria and the ***best clinical judgement*** of the healthcare and/or infection prevention and control practitioner (IPC).

Healthcare associated CDI case definition:
A case in which symptoms occur three (3) or more days (or greater than or equal to 72 hours) after the current acute care admission.

OR
Occur in a case less than three (3) days after the current admission and had been previously hospitalized at your healthcare region and discharged within the previous 4 weeks.

OR
Occur in a case less than three (3) days after the current admission (or less than 72 hours) **AND** the patient had a previous healthcare exposure** within the previous 4 weeks.

Healthcare associated Long Term Care (LTC):
A case in which the symptoms occur at least three (3) or more days **(**or ≥72 hours) after the admission to LTC.

Healthcare associated Other:
Outpatient
The case presents with symptoms, is not admitted but has had a previous health care exposure within the last **4** weeks.

OR
Previously hospitalized at your Region and discharged within the previous **four (4)** weeks.

LTC Resident:
The CDI symptoms occur less than three (3) days (or <_72 hours) after the LTC admission, with a history of hospitalization or any other health care exposure within the previous **four (4)** weeks.

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****** Healthcare exposure: The patient had two or more visits at any of the following locations (oncology [including chemotherapy or radiation]. Dialysis, day surgery, day hospital, transfusion clinic, interventional radiology or emergency department) **OR** had a single visit to the emergency department for more than or equal to24 hours

Community-associated CDI case definition:

Inpatient

- The CDI symptoms occur less than three (3) days (or < 72 hours) after acute care admission, with no history of hospitalization or other healthcare exposure in the previous **twelve (12)** weeks.

Outpatient

- The patient presents with CDI symptoms at your ER or outpatient location with no history of hospitalization or hospitalization or any other healthcare exposure within the previous **twelve (12)** weeks.

LTC Resident

- The residents CDI symptoms occur less than three (3) days (or <72 hours) after LTC admission, with no history of hospitalization or any other healthcare exposure within the previous **12** weeks.

Indeterminate CDI case definition:

The case with CDI does not meet any of the definitions listed above for healthcare associated or community associated CDI. The symptom onset was more **than four (4) weeks but less than twelve (12) weeks** after the patient was discharged from any healthcare facility or after the patient had any other healthcare exposure.

Alternate causes of Diarrhea:

Any case with an alternative cause of diarrhea (i.e., rotavirus, norovirus, enema, medication, etc.) **and a positive toxin** C. *difficile* diagnostic test and meets the case definition of CDI should be counted and classified using the CDI case classification.

Roles, Responsibilities & Reporting

Specimen Collection:

- Stool sample collection should occur as soon as possible after the onset of diarrhea.
- Rapid turnaround time for C. *difficle* testing and reporting is essential and should be pre-arranged with the microbiology laboratory.
- Only liquid/unformed stool specimens are to be referred to the Public Health Microbiology Laboratory (PHML) for gastrointestinal molecular multiplex testing (GI MPx) for C. *difficle* PCR testing on stool samples, unless toxic megacolon or ileus is suspected in which case Microbiologist on call should be consulted for test approval.

Different stool transport media are available for use across the province. It is advised to check with the local laboratory staff to ensure the correct medium is chosen and properly shipped. If stool specimens CANNOT be immediately shipped to PHML, please store at 2-8°C if delivery will be delayed or take over 72 hours.

Laboratory

Laboratory testing:

All Regional Health Authority (RHA) microbiology laboratory sites will offer onsite rapid same day C. *difficle* toxin testing for inpatients with suspected CDI.

The RHA microbiology laboratories are required to forward all stool specimens to the PHML for subsequent molecular testing and surveillance purposes.

Laboratory Reporting:

The Public Health Laboratory reports all positive samples to the referring microbiology laboratory and to the Regional Medical Officer of Health (RMOH).

The staff in the RHA microbiology laboratory report all confirmed cases to:

- Attending physician – C. *difficle* is considered a critical result.
- Infection Control Practitioner responsible for the healthcare facility where the patient/client resides.
- As weekly aggregate data to RMOH/delegate.

Infection Prevention and Control

All identified cases of C. *difficile* will be reviewed by an Infection Control Practitioner (ICP). The ICP will determine if the case meets the criteria in the definitions section. The ICP will collaborate with the Communicable Disease Control Nurse (CDCN) and/or the Environmental Health Office to collect the data if necessary. Information may also be obtained from the admission log, patient's hospital chart, ward rounds, laboratory reports and nursing/medical staff to enhance data collection.

- A data collection form (Appendix A) can be used to collect the data.

- Data will be entered into the HAI excel database.
- On a quarterly basis the ICP/designate, responsible for regional CDI surveillance will submit data from the excel file to the provincial office.

Medical Officer of Health

- Review the quarterly reports.
- Determine any actions necessary as indicated by the incidence of CDI.

Provincial Epidemiologist

- Compile regional CDI reports into a yearly provincial HAI report.
- Support regional representatives in data extract, analysis, and reporting from HAI excel file.
- Provide surveillance advice and expertise, as needed.

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 yearly provincial report.
- Review the report with the manager of Public Health.
- Liaise with PIC-NL on the CDI report and determine the actions required to reduce disease occurrence.

Data Analysis

The data will be used to meet the objectives. 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.

All CDIs will be identified and classified according to the definitions.

The numerator will be the number of CDIs.
Acute care inpatient care days and resident care days will be used to calculate denominator data the rates of CDI in acute care facilities and long-term care facilities, respectively.

The Data will be entered into an excel database and analyzed with the help of the Provincial Epidemiologist. At minimum the analysis will include:

- Rate of healthcare-associated – (hospitalized) CDI incidence per 10,000 patient care days
- Rate of healthcare-associated – long term care CDI incidence per 10,000 resident care days

- Number of cases of healthcare-associated CDI: other
- Number of community associated cases

Surveillance Period

The calendar quarter will be used for reporting purposes. A calendar quarter is a period of three (3) consecutive months starting on the first day of January, April, July, or October. The start date for the first quarter reporting will be January 1 of each year.

References

1. Jawa, RS, & Mercer D, (2012). *Clostridium difficile*–associated infection: a disease of varying severity. The American Journal of Surgery, 204(6), 836-42.

2. Loo VG, Libman MD, Miller MA, et al. (2004). *Clostridium difficle*: a formidable foe. CMAJ, 171(1), 47-48.

3. Miller M. (2006). *C difficile*-associated disease (CDAD)-what we know, what we still don't know and what we learned from the Quebec epidemic. CHICA-Canada Conference, May 19, 2006, London, Ontario.

4. Public Health Agency of Canada (2018). Canadian Nosocomial Infection Surveillance Program: (CNISP) 2018 Surveillance for *Clostridium difficile* infection (CDI)

5. Department of Health and Wellness (2015) Healthcare associated Clostridium difficile Infection surveillance for acute care hospitals in Nova Scotia.

APPENDIX A

INSTRUCTIONS

Please complete for all cases that meet ***Clostridium difficile* infection definition**

1. Unique Identifier Code	
2. Community of residence	
3. Date of birth	____/_____/_____ DD MMM YYYY
4. Gender	☐ Male ☐ Other ☐ Female
5. Date of Current Admission (hospitalized acute care patient)	____/_____/_____ DD MMM YYYY
6. Type of care	☐ Acute ☐ Outpatient ☐ LTC
7. Facility Name	
8. Type of patient care unit	☐ Medical ☐ Surgical ☐ Combined/ med Surg ☐ Critical care ☐ Obstetrical unit ☐ Outpatient ☐ LTC ☐ Other (specify) _____
9. Most recent previous inpatient discharge date if applicable	If CDI diagnosed within **12 weeks** <u>following a previous inpatient discharge</u>, record most recent previous discharge date: ____/_____/_____ DD MMM YYYY

10. Date of specimen collection for the current episode	____/_____/_____ DD MMM YYYY
11. Alternate causes of diarrhea (Ages 1-17yrs)	☐ Medication ☐ Lab confirmed Co-Infection
12. Where was the CDI acquired? (page 3-5)	☐ Healthcare-associated ☐ acute care ☐ LTC ☐ Other ☐ Community-associated ☐ Indeterminate ☐ Out of RHA
13. Date when CDI therapy was started	____/_____/_____ DD MMM YYYY
14 . What was the initial medical treatment for CDI? (check all that apply)	☐ Metronidazole PO ☐ Metronidazole IV ☐ Vancomycin PO ☐ Fidaxomicin PO ☐ No treatment ☐ Unknown ☐ Other (please specify)_____
15. Did the patient receive Fecal Microbiota Transplantation (FMT) therapy for this episode of CDI?	☐ Yes ☐ No ☐ Unknown
16. Did patient require ICU admission for initial CDI episode?	☐ No ☐ Yes, admitted to ICU for complications of CDI ☐ Yes, admitted to ICU, but for reasons other than CDI ☐ No, already in ICU ☐ Unknown

Appendix B: Data Dictionary Clostridium difficile infection surveillance form

1. **Patient unique reference number**: such as MCP/ chart number.

2. **Community of Residence:** Please choose from drop down box if applicable**.** These communities are listed- Conne River, Nain, Natuashish, Hopedale Postville, Makkovik, Rigolet and Sheshatshiu.

3. **Date of Birth:** Enter day (##), month (e.g., May) and year (2008) in this order.

4. **Gender:** Check gender as appropriate.

5. **Date of Current Admission**: Enter day (##), month (e.g., May) and year (e.g., 2008) in this order.

6. **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.

7. **Facility** Name – 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.

8. **Type of patient Care Unit**: 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.

9. **Most Previous inpatient discharge date**: Enter day (##), month (e.g., May) and year (e.g., 2008) in this order.

10. **Date of specimen collection for the current episode**: Enter day (##), month (e.g., May), and year (e.g., 2007).

11. **Alternate causes of diarrhea**: Choose from the options given.

12. **Where was the CDI acquired?** Choose one of the options given.

13. **Date CDI therapy started**: Enter day (##), month (e.g., May) and year (e.g., 2008) in this order.

14. **What was the initial medical treatment for CDI?**: Choose from the opinions, check all that apply.

15. **Did the patient receive FTM**: Choose from options provided?

16. **Did the patient require ICU admission for initial CDI episode?** Choose from options provided.