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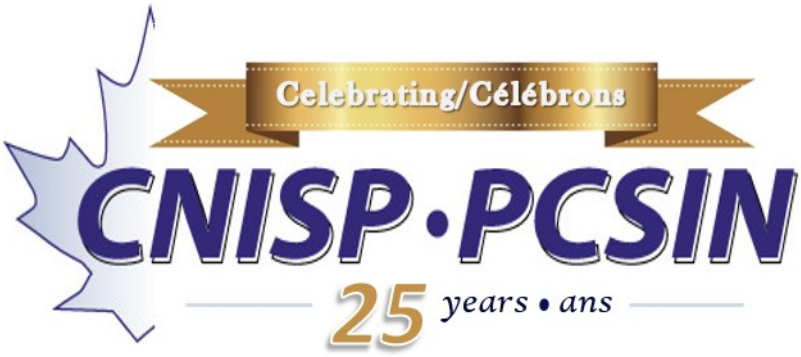

Canadian Nosocomial Infection Surveillance Program

Surveillance for *Clostridioides difficile* infection (CDI)

CDI Surveillance Protocol

Contact Information

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BACKGROUND

Clostridioides difficile is an anaerobic, spore-forming bacillus that is responsible for a spectrum of *C. difficile*-associated infection (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 is the most frequent cause of healthcare-associated infectious diarrhea in industrialized countries, affecting more than 300,000 hospitalized patients yearly in the United States.

Several hospitals in Canada have experienced dramatic increase in the incidence, severity, and number of recurrences associated with CDI. This situation prompted the establishment of a prospective surveillance system, initially limited to few hospitals participating in the Canadian Nosocomial Infection Surveillance Program (CNISP) network, and then broadened as a core CNISP surveillance project in 2007.

Due to improved understanding of the pathogenesis and epidemiology of healthcare-associated (HA)-CDI, the incidence and severity of CDI has steadily decreased in North America and Europe. It has been suggested that the rise in reported CDI cases may have been attributed to infections acquired in the community and recurrence of infection. Recent estimates report that 20 to 28% of CDI cases are community-associated (CA). In relation to recurrent CDI, estimates suggest that individuals infected with CDI, who initially respond to antimicrobial therapy, have a 15 to 35% chance of having a recurrence. About 50% of this group will experience a recurrence a second or third time after cessation of appropriate therapy.

Since 2015, CNISP has conducted surveillance for recurrent and CA-CDI in addition to the ongoing HA-CDI core surveillance. The purpose of this surveillance was to increase our understanding of the burden, risk factors, and outcomes of recurrent and CA-CDI in Canada, through a combination of genome sequencing and epidemiologic data collection. Based on a preliminary review of the data, CA-CDI comprises about 30% of all CDI cases. The proportion of patients with CDI who develop recurrent infection is about 10%. Identifying recurrent and CA-CDI cases represents a significant gap in the national surveillance of *C. difficile* in Canada. CNISP is proposing to continue with CA-CDI and recurrent infection (only epi data) surveillance to fill this identified gap.

OBJECTIVES

- To determine the incidence and burden of illness associated with both HA and CA-CDI (among admitted patients).
- To determine the proportion of patients with CDI who develop recurrent infection.
- To describe the epidemiology of HA-CDI, CA-CDI, and recurrent CDI (among admitted patients).
- To characterize susceptibility profiles of *C. difficile* strains.
- To characterize molecular subtypes of *C. difficile* strains in different provinces and correlate if certain strains are associated with different outcomes.
- To characterize *C. difficile* strains and to compare HA-and CA- strains using a combination of standard molecular subtyping and whole genome sequencing techniques.
- To determine the adverse outcomes (mortality and morbidity) associated with HA-, CA- and recurrent CDI.

METHODS

Eligibility

CDI surveillance is ongoing in all hospitals participating in CNISP. Routine surveillance collects basic clinical information whereas targeted surveillance collects severity markers, outcome, and lab data. Recurrence of CDI is determined by following patients with primary CDI occurring between March and April of each year.

Patient Population

Adult patients (≥18 years)

Aged 18 years and older

Routine Surveillance (clinical information only)	Targeted Surveillance (clinical and lab information)	Recurrent Surveillance (clinical information only)
• 10 months (Jan-Feb, May-Dec) • Complete Appendix 3 – Patient Questionnaire for Routine CDI Surveillance ***DO NOT submit stool specimens to NML*** *If unable to complete Appendix 3, you may participate in Minimum Dataset Submission by completing Appendix 8 – Patient Questionnaire for MDS CDI Surveillance	• 2 months (Mar-Apr) • Complete Appendix 4 – Patient Questionnaire for Targeted CDI Surveillance • Stool specimens will be forwarded to NML	• Any primary case collected between March 1st and April 30th of each year will be followed for up to 8 weeks from date of first positive diagnostic test to determine if recurrent CDI occurs • Recurrent CDI Surveillance (continuation of Targeted CDI surveillance patient questionnaire) ***DO NOT submit stool specimens to NML***

Pediatric patients (1≥ <18 years)
Aged between 1 year and less than 18 years old

Targeted Surveillance (clinical and lab information)	Recurrent Surveillance (clinical information only)
• Year-round • Complete Appendix 4 – Patient Questionnaire for Targeted CDI Surveillance • Stool specimens will be forwarded to NML	• Any primary case collected between March 1st and April 30th of each year will be followed for up to 8 weeks from date of first positive diagnostic test to determine if recurrent CDI occurs • Complete Recurrent CDI Surveillance (continuation of Targeted CDI surveillance patient questionnaire) ***DO NOT submit stool specimens to NML***

Surveillance period

The CDI surveillance period will begin January 1st and continue to December 31st of a given surveillance year.

	Routine Surveillance	Targeted Surveillance	Recurrent Surveillance
Adult (≥18 years)	10 months (Jan-Feb, May-Dec)	2 months (Mar 1st –Apr 30th)	2 months (Mar 1st –Apr 30th) Patients followed up for 8 weeks from **DDT** for the **primary episode** of CDI
Pediatric (1≥ <18 years)	N/A	12 months (Jan 1st – Dec 31st)	2 months (Mar 1st –Apr 30th) Patients followed up for 8 weeks from **DDT** for the **primary episode** of CDI

***DDT** = Date of Diagnostic Test*

Numerators

1. Primary CDI case definition

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

A patient is identified as having CDI if the patient meets one of the following criteria:

Criterion 1: has diarrhea[1] 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* toxin gene(s) (without reasonable evidence of another cause of diarrhea).

OR

Criterion 2: has a diagnosis of pseudomembranes on sigmoidoscopy or colonoscopy (or after colectomy) or histological/ pathological diagnosis of CDI.

OR

Criterion 3: is diagnosed with toxic megacolon (in adult patients only).

Exclusions

- Any patients under 1 year of age.
- Any pediatric patients (aged 1 year to less than 18 years) with alternate cause of diarrhea found (i.e. rotavirus, norovirus, enema or medication etc.) are excluded even if C. difficile diagnostic test result is positive.

Note: Starting in 2017, we will no longer accept asymptomatic cases identified only by laboratory confirmation of a positive toxin assay or PCR for C. difficile (i.e. A patient must have diarrhea or fever, abdominal pain and/or ileus AND a laboratory confirmation of a positive toxin assay or PCR for C. difficile to be identified as having CDI).

2. Recurrent CDI case definition

A recurrent case of CDI is defined as an episode of CDI that occurs in a patient less than or equal to eight (8) weeks following the diagnostic test date of the primary episode of CDI, providing the patient was treated successfully for the primary episode and symptoms of CDI resolved completely.

NOTE: *A new episode of CDI that occurs after eight (8) weeks following the diagnostic test date of the primary episode of CDI is considered a new infection.*

Case Classification

Once a patient has been identified with CDI, the infection will be classified further based on the following criteria and the best clinical judgment of the healthcare and/or infection prevention and control practitioner (ICP).

1. Healthcare-associated acquired in your acute-care facility (HA-YAF)

Related to the current hospitalization

- The patient's CDI symptoms occur in your healthcare facility 3 or more days (or ≥72 hours) after admission.

Related to a previous hospitalization

- **Inpatient**: The patient's CDI symptoms occur less than 3 days after the current admission (or <72 hours) AND the patient had been previously hospitalized at your healthcare facility and discharged within the previous 4 weeks.
- **Outpatient**: The patient presents with CDI symptoms at your ER or outpatient location[2] AND the patient had been previously hospitalized at your healthcare facility and discharged within the previous 4 weeks.

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[1] Diarrhea is defined as one of the following:

✓ 6 or more watery/unformed stools in a 36-hour period

✓ 3 or more watery/ unformed stools in a 24-hour period and this is new or unusual for the patient (in adult patients only)

[2] This includes all of your outpatient clinics such as chemotherapy, radiation, dialysis, day surgery, day hospital, transfusion clinic, or interventional radiology, but may not be exhaustive.

Related to a previous healthcare exposure[3] at your facility

- **Inpatient**: The patient's CDI symptoms occur less than 3 days after the current admission (or <72 hours) AND the patient had a previous healthcare exposure[3] at your facility within the previous 4 weeks.
- **Outpatient**: The patient presents with CDI symptoms at your ER or outpatient location[2] AND the patient had a previous healthcare exposure[3] at your facility within the previous 4 weeks.

2. Healthcare-associated acquired in any other healthcare facility (HA-Other)

Related to a previous hospitalization at any other healthcare facility

- **Inpatient**: The patient's CDI symptoms occur less than 3 days after the current admission (or <72 hours) AND the patient is known to have been previously hospitalized at any other healthcare facility[4] and discharged/transferred within the previous 4 weeks.
- **Outpatient**: The patient presents with of CDI symptoms at your ER or outpatient location AND the patient is known to have been previously hospitalized at any other healthcare facility[4] and discharged/transferred within the previous 4 weeks.

Related to a previous healthcare exposure[3] at any other healthcare facility

- **Inpatient**: The patient's CDI symptoms occur less than 3 days after the current admission (or <72 hours) AND the patient is known to have a previous healthcare exposure[3] at any other healthcare facility[4] within the previous 4 weeks.
- **Outpatient**: The patient presents with of CDI symptoms at your ER or outpatient location AND the patient is known to have a previous healthcare exposure[3] at any other healthcare facility[4] within the previous 4 weeks.

3. Healthcare-associated unable to determine which facility (HA-Unknown)

- The patient with CDI meets both definitions of healthcare-associated (acquired in your facility) and healthcare-associated (acquired in any other healthcare facility[4]), but the facility which the case is primarily attributable to is unable to be determined.

4. Community-associated (CA)

- **Inpatient**: The patient's CDI symptoms occur less than 3 days (or <72 hours) after admission, with no history of hospitalization or any other healthcare exposure[3] within the previous 12 weeks.
- **Outpatient**: The patient presents with CDI symptoms at your ER or outpatient location with no history of hospitalization or any other healthcare exposure[3] within the previous 12 weeks.

5. Indeterminate

- The patient with CDI does NOT meet any of the definitions listed above for healthcare-associated or community-associated CDI**.** The symptom onset was more than 4 weeks but less than 12 weeks after the patient was discharged from any healthcare facility or after the patient had any other healthcare exposure[3].

Zero Reports for CDI include all inpatient case classifications. If you have Zero cases for one of the above classifications you must fill out a Zero report for that quarter (Zero report category "Unknown" accounts for HA-Unknown, Indeterminate and outpatient cases).

[3] Healthcare exposure: The patient had 2 or more interventions at any of the following locations: chemotherapy, 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 to 24 hours.

[4] Any other healthcare facility which includes: other acute-care, psychiatric, rehabilitation, or long-term care facility.

Denominators

To obtain the necessary denominator information for the calculation of national CDI rates, each participating hospital will complete a denominator (including patient admissions, patient days and the number of emergency and outpatient clinic visits) for pediatric and adult patients.

Patient Admissions
Patient Days
Outpatient Visits
ER Visits

Adult (≥18 years)
Pediatric (1≥ <18)
If possible, exclude patients less than 1 year of age

Data Submission

Cases

All patient questionnaire data are to be submitted online through the Canadian Network for Public Health Intelligence (CNPHI) at www.cnphi-rcrsp.ca. For technical assistance, questions or comments, please contact CNISP at phac.cnisp-pcsin.aspc@canada.ca

Cases are to be identified by a multiple-character number that includes the CHEC identification number (3-character alphanumeric number, e.g., 99Z), the surveillance year (19), and the CDI case sequential number (three-digit number starting from 001) and continuing on with each additional case. An example of the first case in an institution would be 9Z19001. An example of the thirty-fifth case would be 99Z19035, and so on.

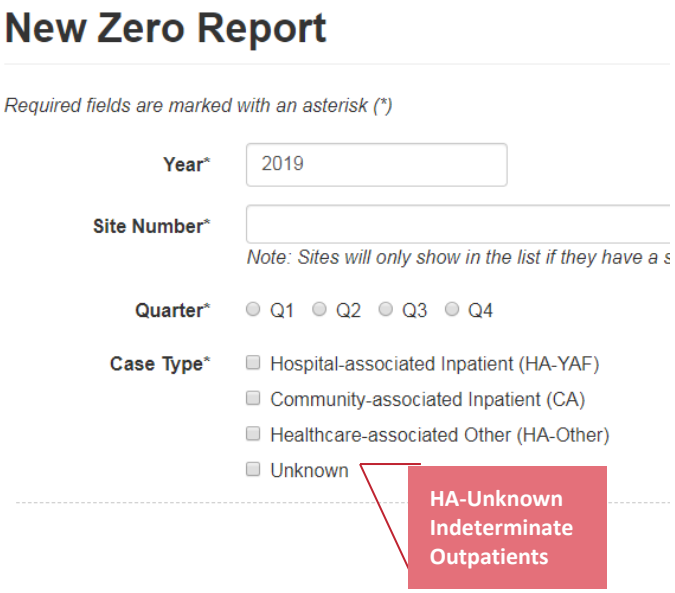
Zero Report

For any quarter with no cases at your site, a Zero Report must be made in the CNPHI CDI module so that quarters with zero counts can be differentiated from missing data. If no cases are submitted and you are missing zero reports for a surveillance year, your hospital data will not be included in the visual analytics.

CNPHI auto-generates the variable 'Case Type' for each CDI case entered. Please note that currently, only the inpatient cases are coded under the case type because the visual analytics is only designed to display inpatient data. Outpatient cases, indeterminate and unknown cases are currently coded as 'unknown', we hope to update this in the near future.

Denominators

Denominators must be submitted quarterly on CNPHI under "Profiles and Denominators".



One Zero report is required for each quarter

Each zero report (for each quarter) must include ALL case types for which there were ZERO cases

(check all that apply)

The "Unknown" case type in the Zero report includes: HA-Unknown, Indeterminate, and Outpatient cases

Analysis

Individual site-specific, regional and national rates (per 1,000 patient admissions and per 10,000 patient days) and proportions will be calculated each year by Agency staff.

While individual site-specific rates will be kept confidential and may only be disclosed to the site's authorized contacts, regional and national rates will be reported through CNISP reports, presentations, publications, and published on the Agency and AMMI website. The CDI rates will also be provided to individual provincial and/or territorial authorities upon request.

ETHICS

While this surveillance project is observational and does not involve any alteration in patient care, ethics approval may be sought at some hospital sites. Surveillance for healthcare-associated infections is a routine component of quality assurance and patient care in Canadian healthcare institutions and therefore, informed consent is not required. A unique identifier linked to patient name will only identify patients at the local CHEC site and is not transmitted to the Public Health Agency of Canada. All data submitted to the Public Health Agency of Canada is kept strictly confidential.

PRIVACY

There is current demand for public disclosure of hospital-associated infections. Any data released by CNISP will be in summary format and will not identify individual hospitals. Hospital administrators should be made aware that national reporting of aggregate data will occur.

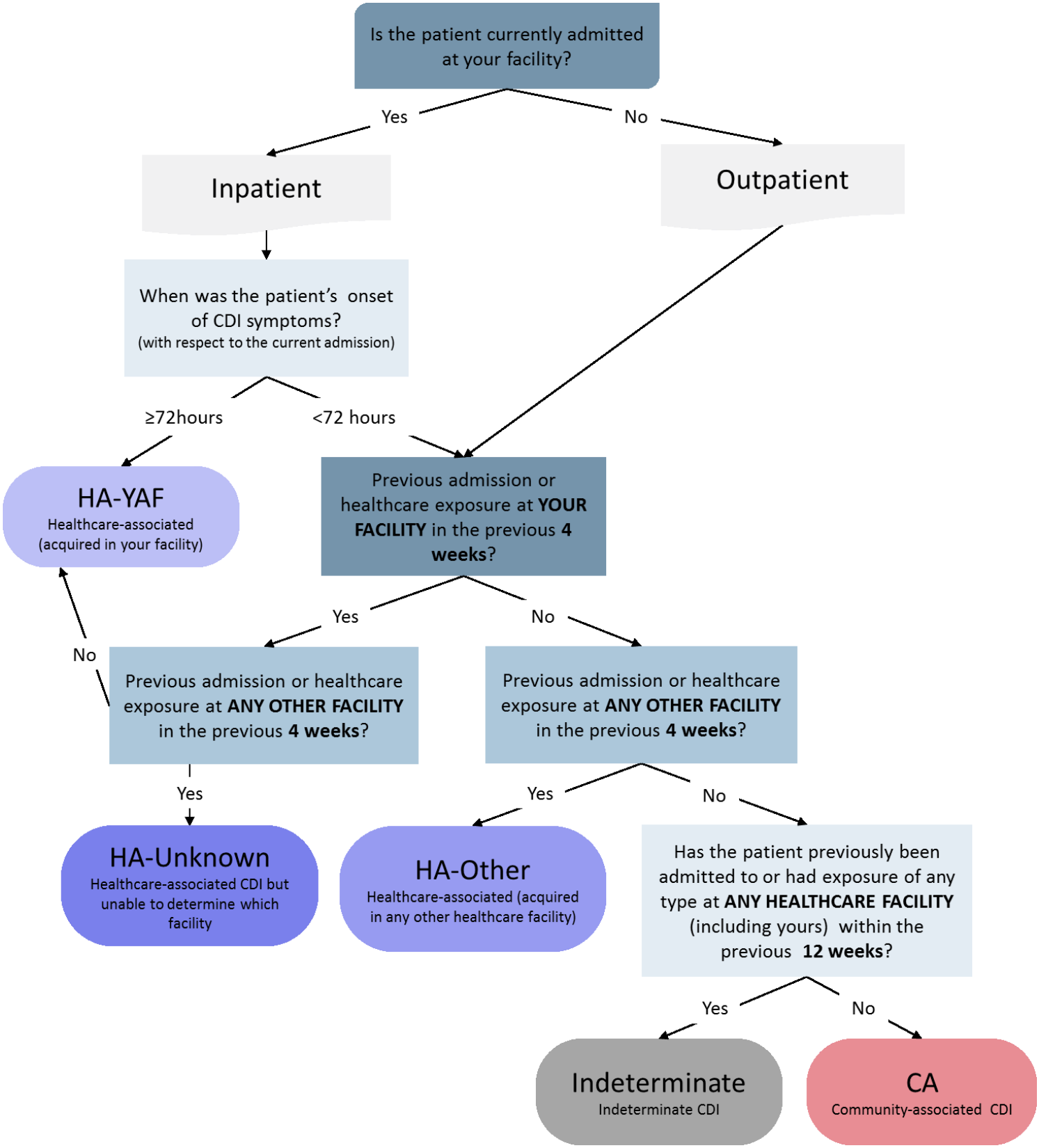
Appendix 1 – CDI Data Submission Table

Adult ≥18 years	**Cases**	Cases due by the end of the following quarter	Cases due by the end of the following quarter	Cases due by the end of the following quarter
	Lab	N/A	Lab samples due by July 31st of the **current** surveillance year	N/A
Pediatric 1≥ <18 years	**Cases**	N/A	Cases due by the end of the following quarter	Cases due by the end of the following quarter
	Lab	N/A	Lab samples due by the end of the following quarter All samples MUST be submitted to the lab by March 31st of the **following** surveillance year	N/A
Zero report		Zero reports must be filled out for each quarter. Zero reports are due by the end of the following quarter.		
Denominators		Denominators are required quarterly. Denominators are due by the end of the following quarter.		

Appendix 2.1 – CDI Case Classification Table

<table>
<tr><th></th><th></th><th>Outpatient</th><th colspan="2">Inpatient</th></tr>
<tr><th>Risk factors</th><th>Symptom onset</th><td>CDI symptoms in ER or other outpatient location</td><td>CDI symptoms <72 hours after current admission</td><td>CDI symptoms ≥72 hours after current admission</td></tr>
<tr><td>The patient had been hospitalized at your healthcare facility and discharged</td><td rowspan="4">Previous 4 weeks</td><td colspan="2" rowspan="2">Healthcare-associated (acquired in your facility) CDI
HA-YAF</td><td rowspan="5">Healthcare-associated (acquired in your facility) CDI
HA-YAF</td></tr>
<tr><td>The patient had a healthcare exposure[3] at your facility</td></tr>
<tr><td>The patient had been hospitalized at any other healthcare facility[4] and discharged/transferred</td><td colspan="2" rowspan="2">Healthcare-associated (acquired in any other healthcare facility[4])CDI
HA-Other</td></tr>
<tr><td>The patient had a healthcare exposure[3]at any other facility</td></tr>
<tr><td>The patient had been hospitalized both at your facility and any other healthcare facility[4] and discharged/transferred</td><td colspan="2">Healthcare-associated CDI but unable to determine which facility
HA-Unknown</td></tr>
<tr><td>No hospitalization or any other healthcare exposure[3]</td><td>Previous 12 weeks</td><td colspan="2">Community-associated CDI
CA</td></tr>
<tr><td>The patient DOES NOT meet any of definitions for healthcare-associated or community-associated CDI. The symptom onset was more than 4 weeks but less than 12 weeks after the patient was discharged from any healthcare facility OR after the patient had any healthcare exposure[3]</td><td>Previous 4 to 12 weeks</td><td colspan="2">Indeterminate CDI
Indeterminate</td></tr>
</table>

Appendix 2.2 – CDI Case Classification Algorithm



Appendix 3 – Patient Questionnaire for Routine CDI Surveillance

Instructions

Please complete for all adult cases of CDI that occur from January 1 to Feb 28/29 and May 1 to December 31 of each year. Please see data dictionary for definitions and notes (Appendix 5). Summary of Laboratory Requirements: NO isolates are to be sent to the NML.

1.	CHEC Site: _____
2.	Unique Patient ID _____ YY _____(e.g. 99Z19001) *(CHEC site #) (year) (case number)*
3.	Age in years (please provide round down age) _____ years
4.	Postal code (first 3 digits) _____
5.	Sex ☐ Male ☐ Female
6.	Was the patient an inpatient or an outpatient on the day the positive lab specimen was collected? Please provide admission or visit (ER/outpatient) date For outpatient but was subsequently admitted because of CDI, please provide both admission and visit (ER/outpatient) dates ☐ **Inpatient** **Admission date**: **_____ / _____ / _____** DD MMM YYYY ☐ Inpatient ward/unit ☐ ER (admitted patients, awaiting inpatient bed) ☐ **Outpatient** **Visit date** : **_____ / _____ / _____** DD MMM YYYY ☐ Emergency department (non-admitted patients) ☐ Outpatient area (excluding ER)[2] ☐ Outpatient but was subsequently admitted because of CDI **Admission date**: **_____ / _____ / _____** DD MMM YYYY ☐ **Other** (please specify) _____ **Visit date**: **_____ / _____ / _____** **AND/OR** **Admission date**: **_____ / _____ / _____** DD MMM YYYY DD MMM YYYY
7.	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 Previous inpatient discharge date : **_____ / _____ / _____** DD MMM YYYY

8.	Date of 1st positive lab specimen for the current episode _____ / _____ / _____ DD MMM YYYY
9.	Where was the CDI acquired? (see Case Classifications) ☐ Healthcare-associated (acquired in your facility) ☐ Inpatient ☐ Outpatient with healthcare exposure[3] ☐ Unknown ☐ Healthcare-associated (acquired in any other healthcare facility[4]) ☐ Related to other acute-care facility ☐ Related to a psychiatric facility ☐ Related to a rehabilitation facility ☐ Related to a LTCF ☐ Unknown ☐ Healthcare-associated but unable to determine which facility ☐ Community-associated ☐ Did the patient have a previous hospitalization in the previous 1 year (between the previous 13 to 52 weeks)? ☐ Yes ☐ No ☐ Unknown ☐ Indeterminate ☐ Information not available
10.	Date of CDI symptom onset *(if unable to determine data of onset, please indicate date of first positive lab specimen)* _____ / _____ / _____ DD MMM YYYY
11.	Date when CDI therapy was started _____ / _____ / _____ DD MMM YYYY
12.	a. What was the initial medical treatment for CDI? (check all that apply) ☐ Metronidazole PO ☐ No treatment ☐ Metronidazole IV ☐ Unknown ☐ Vancomycin PO ☐ Other (please specify) _____ ☐ Fidaxomicin PO
	b. Has the patient been referred for Fecal Microbiota Transplantation (FMT) therapy for this episode of CDI? ☐ Yes ☐ No ☐ Unknown

Appendix 4 – Patient Questionnaire for Targeted CDI Surveillance

Instructions

Please complete for all adult cases of CDI that occur from March 1st to April 30th of each year and for pediatric cases (year-round). All stool specimens must be sent to NML.

1.	CHEC Site: _____
2.	Unique Patient ID _____ YY _____(e.g. 99Z19001) *(CHEC site #) (year) (case number)*
3.	Age in years (please provide round down age) _____ years
4.	Postal code (first 3 digits) _____
5.	Sex ☐ Male ☐ Female
6.	Was the patient an inpatient or an outpatient on the day the positive lab specimen was collected? Please provide admission or visit (ER/outpatient) date For outpatient but was subsequently admitted because of CDI, please provide both admission and visit (ER/outpatient) dates ☐ **Inpatient** **Admission date**: **_____ / _____ / _____** DD MMM YYYY ☐ Inpatient ward/unit ☐ ER (admitted patients, awaiting inpatient bed) ☐ **Outpatient** **Visit date** : **_____ / _____ / _____** DD MMM YYYY ☐ Emergency department (non-admitted patients) ☐ Outpatient area (excluding ER)[2] ☐ Outpatient but was subsequently admitted because of CDI **Admission date**: **_____ / _____ / _____** DD MMM YYYY ☐ **Other** (please specify) _____ **Visit date**: **_____ / _____ / _____** **AND/OR** **Admission date**: **_____ / _____ / _____** DD MMM YYYY DD MMM YYYY
7.	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 Previous inpatient discharge date : **_____ / _____ / _____** DD MMM YYYY

8.	Date of 1st positive lab specimen for the current episode _____ / _____ / _____ DD MMM YYYY
9.	Where was the CDI acquired? (see Case Classifications) ☐ Healthcare-associated (acquired in your facility) ☐ Inpatient ☐ Outpatient with healthcare exposure[3] ☐ Unknown ☐ Healthcare-associated (acquired in any other healthcare facility[4]) ☐ Related to other acute-care facility ☐ Related to a psychiatric facility ☐ Related to a rehabilitation facility ☐ Related to a LTCF ☐ Unknown ☐ Healthcare-associated but unable to determine which facility ☐ Community-associated ☐ Did the patient have a previous hospitalization in the previous 1 year (between the previous 13 to 52 weeks)? ☐ Yes ☐ No ☐ Unknown ☐ Indeterminate ☐ Information not available
10.	Date of CDI symptom onset *(if unable to determine data of onset, please indicate date of first positive lab specimen)* _____ / _____ / _____ DD MMM YYYY
11.	Date when CDI therapy was started _____ / _____ / _____ DD MMM YYYY
12.	a. What was the initial medical treatment for CDI? (check all that apply) ☐ Metronidazole PO ☐ No treatment ☐ Metronidazole IV ☐ Unknown ☐ Vancomycin PO ☐ Other (please specify) _____ ☐ Fidaxomicin PO
	b. Has the patient been referred for Fecal Microbiota Transplantation (FMT) therapy for this episode of CDI? ☐ Yes ☐ No ☐ Unknown
	Please skip to Q18 if this is an outpatient [Emergency department (non-admitted patient) or Outpatient area (excluding ER)] case, otherwise continue with Q13

13.	Selected severity markers at the time of diagnosis (toxin positive in stool OR positive histopathology) *Fill in values (+/- 48 hours, if same-day results not available, if unknown, please enter 9999)* $Temp_{max}$:_____ ^{o}C Serum albumin (lowest value): _____g/L Serum creatinine (highest value): _____ µmol/L Total WBC count (highest value): _____ x 10^9 cells/L □ Unknown
14.	Did the patient require ICU admission for the initial CDI episode within the 30 days following the positive lab specimen? □ No □ Yes admitted to ICU for complications of CDI □ Yes admitted to ICU, but for reasons other than CDI □ No, already in ICU □ Unknown
15.	a. Did the patient require colectomy due to the initial CDI within the 30 days following the positive lab specimen? □ Yes □ No □ Unknown
	b. Did the patient require loop ileostomy due to the initial CDI within the 30 days following the positive lab specimen? □ Yes □ No □ Unknown
16.	a. What was the outcome of this patient at 30 days after the positive lab specimen? *(check one response only)* □ Patient survived and discharged □ Patient alive, still in hospital □ Patient died □ Unknown
	b. If patient survived and was discharged or transferred, what was the date of the discharge or transfer? **_____ / _____ / _____** DD MMM YYYY
	c. If the patient died, what was the date of death? *(as recorded on death record)* **_____ / _____ / _____** DD MMM YYYY
17.	If the patient died within 30 days after the positive lab specimen, please indicate the relationship of CDI to the death □ CDI was the cause of death □ Death is unrelated to CDI □ CDI contributed to death □ Causality between CDI and death cannot be determined

Recurrent CDI Surveillance (continuation of Targeted CDI surveillance patient questionnaire)

The following questions are only to be filled in if your site is participating in the collection of recurrent CDI cases

All cases of CDI in both adult and pediatric patients identified between March 1st and April 30th of each year will be followed prospectively for up to eight (8) weeks following diagnostic test date of the primary CDI episode to determine if recurrent CDI occurs. Please do not create another Unique Patient Identifier for the recurrent CDI case but use the same Unique Patient Identifier as the primary case to respond to questions related to recurrent CDI.

NOTE: Please DO NOT send recurrent CDI stool samples to NML. The collection of these specimens has been discontinued.

18. Did the patient have a recurrent episode of CDI within 8 weeks of the following the diagnostic test of the primary episode?

- ☐ Yes (if yes, complete Q19-25)
- ☐ No (end of questionnaire)

19. Date of the recurrence (i.e. onset of symptoms of CDI)

_____ / _____ / _____
DD MMM YYYY

20. Was the patient an inpatient or an outpatient on the day the positive lab specimen was collected for this recurrent episode of CDI? Please provide admission or visit (ER/outpatient) date

For outpatient but was subsequently admitted because of recurrent CDI, please provide both admission and visit (ER/outpatient) dates

☐ **Inpatient** **Admission date**: _____ / _____ / _____
DD MMM YYYY

- ☐ Inpatient ward/unit
- ☐ ER (admitted patients, awaiting inpatient bed)

☐ **Outpatient** **Visit date** : _____ / _____ / _____
DD MMM YYYY

- ☐ Emergency department (non-admitted patients)
- ☐ Outpatient area (excluding ER)[2]
- ☐ Outpatient but was subsequently admitted because of CDI **Admission date**: _____ / _____ / _____
DD MMM YYYY

☐ **Other** (please specify) _____

Visit date: _____ / _____ / _____ **AND/OR** **Admission date**: _____ / _____ / _____
DD MMM YYYY DD MMM YYYY

21.	a. What was the initial medical treatment for the recurrent CDI*? (Check all that apply)* ☐ Metronidazole PO ☐ No treatment ☐ Metronidazole IV ☐ Unknown ☐ Vancomycin PO ☐ Other (please specify) _____ ☐ Fidaxomicin PO
	b. Has the patient referred for Fecal Microbiota Transplantation (FMT) therapy for this episode of recurrent CDI? ☐ Yes ☐ No ☐ Unknown
	End of questions. If Q20 is answered as either Emergency department (non-admitted patients) or Outpatient area (excluding ER), otherwise continue with Q22
22.	Did the patient require ICU admission for the recurrent CDI within the 30 days following the positive lab specimen for recurrent CDI? □ No □ Yes admitted to ICU for complications of recurrent CDI □ Yes admitted to ICU, but for reasons other than recurrent CDI □ No, already in ICU □ Unknown
23.	a. Did the patient require colectomy due to the recurrent CDI within the 30 days following the positive recurrent CDI lab specimen? ☐ Yes ☐ No ☐ Unknown
	b. Did the patient require loop ileostomy due to the recurrent CDI within the 30 days following the positive recurrent CDI lab specimen? ☐ Yes ☐ No ☐ Unknown
24.	a. What was the outcome of this patient at 30 days after the positive lab specimen of the recurrent CDI? *(check one response only)* □ Patient survived and discharged □ Patient alive, still in hospital □ Patient died □ Unknown
	b. If patient survived and was discharged or transferred, what was the date of the discharge or transfer? _____ / _____ / _____ DD MMM YYYY
	c. If the patient died, what was the date of death? *(as recorded on death record)* _____ / _____ / _____ DD MMM YYYY
25.	If the patient died, please indicate the relationship of recurrent CDI to the death ☐ Recurrent CDI was the cause of death ☐ Death is unrelated to recurrent CDI ☐ Recurrent CDI contributed to death ☐ Causality between CDI and death cannot be determined

Appendix 5 – Data Dictionary

Definitions and notes for Patient Questionnaire

1. CHEC Site

This will be the 3-character alphanumeric number assigned to your institution. It will always begin with the two digit number assigned to your CHEC member e.g., 99, a letter assigned by the CHEC member for that specific institution e.g., A, B, C, etc. The CHEC site # for each institution should always be the same for all the CHEC/CNISP surveillance projects and will always have all three alphanumeric digits reported as the CHEC site #, e.g., 99Z.

2. Unique patient identifier

This number should never be longer than 10 characters. The 10 characters should consist of the 3 character CHEC site # (e.g., 99Z), the surveillance year the infection occurred in (e.g., 19), and a consecutive number starting at 001 and continuing on with each additional case. An example of the first case in an institution would be 99Z19001. An example of the thirty-fifth case would be 99Z19035, and so on.

DO NOT create a new Unique Patient Identifier for recurrent CDI cases*. For a recurrent case, please use the same Unique Patient Identifier created for the primary episode. Once Q18 under the Unique Patient Identifier to report the primary episode is answered as "Yes", CNPHI will automatically populate Q19-Q25 to collect information on recurrent CDI cases.*

3. Age in years

Please enter the patient's age (in years), rounded down, at the time of positive culture; e.g. if the patient is 17 years and 11 months of age, indicate 17 years.

4. Postal code (first 3 digits)

Please indicate patient's residential first 3 digit postal code.

5. Sex

Check male or female.

6. Status of hospital admission and respective dates

Please indicate whether the patient was an inpatient or an outpatient on the date the lab specimen was collected, if the diagnostic test result is positive for C. difficile.

Please provide admission or visit (ER/outpatient) date. For outpatient but was subsequently admitted because of CDI, please provide both admission and visit (ER/outpatient) dates.

Inpatient: a patient who has been admitted to hospital or in the emergency department (awaiting inpatient bed).

Outpatient: a patient seen in the emergency department, other outpatient areas OR a patient was in an outpatient setting on the day the stool sample was collected (the test result positive for C. difficile) but the patient was subsequently admitted to hospital because of CDI (example: A patient seen in an outpatient clinic and tested for C. difficile, sent home and came back next day with worsening symptoms and was admitted.

7. Date of current admission or visit, and if applicable, most recent previous inpatient discharge date

- If CDI was diagnosed during the hospital stay, please indicate the date when the patient was admitted to the hospital.
- If CDI was diagnosed during outpatient visit (ER or other outpatient setting), record date of visit.
- If CDI was diagnosed within 12 weeks following a most recent previous inpatient discharge, record date of discharge.

8. Date of first positive laboratory specimen or positive histopathology specimen

Please indicate when the first lab or histopathology specimen tested positive.

9. Where was the CDI acquired

Using the case definitions supplied in the protocol (pages 3-5), please indicate whether the CDI was HA (acquired in your facility), HA (acquired in any other healthcare facility), HA but unable to determine which facility, CA, Indeterminate or Information not available.

Interpretation and example of CDI case definition

A patient is admitted 1000 hrs March 1 2016 = Day of admission = Day 1

- after 1000 hrs March 2 2016 = 1st day after day of admission
- after 1000 hrs March 3 2016 = 2nd day after day of admission
- after 1000 hrs March 4 2016 = 3rd day after day of admission

Therefore the infection would be considered HA if CDI symptoms occur any time after 1000 hrs on March 4 – This works out to (approximately in hours) CDI being HA if the patient has been admitted ≥ 72 hrs versus CA if admitted <72 hrs.

10. Date of CDI symptom onset

Please indicate the date of CDI symptom onset.

11. Date when CDI therapy started

Please indicate the date when CDI treatment was initiated.

12. a. Initial medical treatment on the day of diagnosis

Please indicate the initial medical treatment on the day of diagnosis.

b. Fecal Microbiota Transplantation (FMT) therapy

Please indicate if the patient was referred to a FMT therapy for this episode of CDI.

13. Severity markers at the time of positive diagnosis

Please complete the values (maximum temperature, serum albumin, serum creatinine and total WBC count) at the time of positive diagnosis (toxin positive in stool OR positive histopathology). If same day results are not available, please use results +/- 48 hours. If results are not available, please indicate as unknown.

14. ICU admission

Please indicate if the patient required admission to the ICU for this episode of CDI.

15. a. Colectomy due to CDI

Please indicate if the patient required a colectomy due to CDI.

b. Loop ileostomy due to CDI

Please indicate if patient required loop ileostomy due to CDI.

16. a. Outcome within 30 days after the positive lab specimen

At thirty days after the date of positive diagnostic test, please select one of the outcome options available.

b. Date of discharge or transfer

If the patient survived, please indicate the date of discharge or transfer.

c. Date of death

If the patient died, please indicate the date of death.

17. Relationship of CDI to death

If the patient died, please indicate if CDI was the cause of death (i.e. the patient had no other condition that would have cause death during the admission); CDI contributed to death (i.e. CDI exacerbated an existing condition that led to the patient's death), CDI was unrelated to death or unable to determine the causality between CDI and death.

18. Did the patient have recurrent CDI

A recurrent case of CDI is defined as an episode of CDI that occurs in a patient less than or equal to eight (8) weeks following the diagnostic test date of the primary CDI episode, providing the patient was treated successfully for the primary episode and symptoms of CDI resolved completely.

19. Date of recurrence

Please indicate when the first lab or histopathology specimen tested positive for the recurrent infection.

20. Status of hospital admission for the recurrent episode of CDI

Please indicate whether the patient was an inpatient or an outpatient on the date the lab specimen was collected for this recurrent episode of CDI, if the diagnostic test result is positive for C. difficile.

Please provide admission or visit (ER/outpatient) date. For outpatient but was subsequently admitted because of recurrent CDI, please provide both admission and visit (ER/outpatient) dates.

21. a. Initial medical treatment for the recurrent CDI

Please indicate the initial medical treatment on the day of diagnosis of the recurrent infection.

b. Fecal Microbiota Transplantation (FMT) therapy referred for the recurrent CDI

Please indicate if the patient was referred for a FMT therapy for this episode of recurrent CDI.

22. ICU admission required for the recurrent CDI episode

Please indicate if the patient required admission to the ICU for this recurrent episode of CDI.

23. a. Colectomy due to the recurrent CDI

Please indicate if the patient required a colectomy due to recurrent CDI.

b. Loop ileostomy due to the recurrent CDI

Please indicate if patient required loop ileostomy due to the recurrent CDI.

24. a. Outcome within 30 days after the positive lab specimen of the recurrent CDI episode

At 30 days after the date of positive diagnostic test of the recurrent CDI episode, please select one of the outcome options available.

b. Date of discharge or transfer

If the patient survived from the recurrent CDI, please indicate the date of discharge or transfer.

c. Date of death

If the patient died with the recurrent CDI, please indicate the date of death.

25. Relationship of CDI to death

If the patient died with the recurrent CDI, please indicate if CDI was the cause of death (i.e. the patient had no other condition that would have cause death during the admission); CDI contributed to death (i.e. CDI exacerbated an existing condition that led to the patient's death), CDI was unrelated to death or unable to determine the causality between CDI and death.

Appendix 6 – Stool Storage & Submission Protocol

Targeted CDI Laboratory Surveillance

Adult – Targeted: All cases of CDI in adult patients (aged 18 years and older) identified between March 1st and April 30th of each year.

Pediatric – Targeted: All cases of CDI in pediatric patients (aged between one year and less than 18 years old) identified between January 1st and December 31st of each year.

Unique patient identifier
The assigned CHEC ID must correspond to the unique identifier on the patient questionnaire.

Stools submitted for which there is no corresponding patient epidemiological information entered/uploaded to CNPHI or sent to Ottawa, will not be processed by the NML.

Materials Provided by the NML

Each CHEC site laboratory will be sent:

1) 2 ml cryovials in storage boxes for the collection of the CDI stool samples.
2) Sheet(s) of peel-off labels with ***partial CHEC ID #s***.

   i.e. the first 2 numbers defining the site (e.g. 99), followed by a space for the site/sub-site letter (e.g. A, B, C, etc…), followed by the alphanumeric value of the study year (e.g 19), followed by space for the isolate number (e.g. 001).

Note: If you require additional cryovials and/or labels, please contact Romeo Hizon at (204) 789-5000 or email: romeo.hizon@canada.ca.

Methodology

1) Each CHEC site laboratory will use their current laboratory procedures to diagnose stools from diarrhetic patients (potentially CDI) for the presence *C. difficile* toxin(s).

2) Potential CDI stools should be held at 4°C degrees for no longer than 48 h while the confirmatory tests are conducted.

3) Once a stool specimen is confirmed as positive for *C. difficile* toxin(s), remove a cryovial from the supplied box (can be stored on the bench) and dispense 2 ml of the watery stool into the vial.

4) Using a pen/marker with indelible ink, fill-out the rest of a label within the appropriate spaces, using the correct CHEC ID format, and affix the label to the cryovial.

5) Immediately store the cryovial, containing the stool sample, at -20°C degrees in a similar storage box (supplied by the NML).

It is extremely important to freeze the sample as soon as possible. The viability of C. difficile decreases over time in stool even when stored at 4°C. It may become difficult to isolate a C. difficile from a stool which has been held longer than 48 h at 4°C.

6) When shipping stools to the NML, each lab must use the CDI standardized laboratory shipping form (Appendix 7, available in MS Excel format). You may include your Hospital Laboratory Number (HLN) if there is one.

The HLN and/or CHEC ID# will be used to match this specimen with the corresponding patient information collected by the hospital infection control team. It is imperative that the number you record can be cross-referenced to the patient number i.e. CHEC ID number.

7) Ship the **boxes (stools)** to the NML ***on DRY ICE*** to the address below:

Dr. George Golding
National Microbiology Laboratory
1015 Arlington St.
Winnipeg, Manitoba
R3E 3R2
Tel: 204-784-8096
Use FedEx billing number: 6327-8173-3

8) Include the shipping form with the shipment AND email an electronic copy to the NML at phac.nml.ARNI-RAIN.lnm.aspc@canada.ca.

The samples MUST be shipped on DRY ICE to avoid thawing during transport and the shipment should be made on a Monday or Tuesday to ensure the specimens are not held in transit over a weekend.

Laboratory (NML) Contacts:

Dr. George Golding
Phone: (204) 784-8096
Email: George.Golding@canada.ca

Romeo Hizon
Phone: (204) 789-5000
Email: Romeo.Hizon@canada.ca

Appendix 7 – CDI Standardized Laboratory Shipping Form

Include the following form with the shipment **AND** email to the NML address provided.

Send CDI samples to:
Dr. George Golding
National Microbiology Laboratory
1015 Arlington St., Winnipeg, Manitoba R3E 3R2
Tel: 204 784 8096
Use FedEx billing number: 6327-8173-3

In addition, email the shipping form to
phac.nml.ARNI-RAIN.lnm.aspc@canada.ca

Please click on the icon below to access the excel shipping form:

Appendix 7_CDI
Standardized Shippin

Appendix 8 – Patient Questionnaire for MDS CDI Surveillance

Instructions

Please complete for all cases of CDI that occur from January 1 to Feb 28/29 and May 1 to December 31 of each year if also participating in targeted surveillance. Please see data dictionary for definitions and notes (Appendix 5). Summary of Laboratory Requirements: NO isolates are to be sent to the NML – however if please send isolates during targeted period (March 1 – April 30) and pediatric isolates all year.

1.	CHEC Site: _____
2.	Unique Patient ID _____ YY _____(e.g. 99Z19001) *(CHEC site #) (year) (case number)*
3.	Age in years (please provide round down age) _____ years
4.	Postal code (first 3 digits) _____
5.	Sex ☐ Male ☐ Female
6.	Was the patient an inpatient or an outpatient on the day the positive lab specimen was collected? Please provide admission or visit (ER/outpatient) date For outpatient but was subsequently admitted because of CDI, please provide both admission and visit (ER/outpatient) dates ☐ **Inpatient** **Admission date**: **_____ / _____ / _____** DD MMM YYYY ☐ Inpatient ward/unit ☐ ER (admitted patients, awaiting inpatient bed) ☐ **Outpatient** **Visit date** : **_____ / _____ / _____** DD MMM YYYY ☐ Emergency department (non-admitted patients) ☐ Outpatient area (excluding ER)[2] ☐ Outpatient but was subsequently admitted because of CDI **Admission date**: **_____ / _____ / _____** DD MMM YYYY ☐ **Other** (please specify) _____ **Visit date**: **_____ / _____ / _____** DD MMM YYYY **AND/OR** **Admission date**: **_____ / _____ / _____** DD MMM YYYY

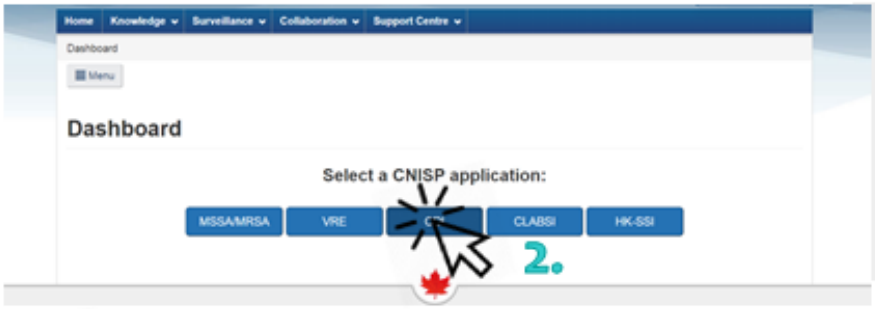
7.	Most recent previous inpatient discharge date if applicable If CDI diagnosed within **12 weeks** following a previous inpatient discharge, record most recent previous discharge date Previous inpatient discharge date : **_____ / _____ / _____** DD MMM YYYY
8.	Date of 1st positive lab specimen for the current episode **_____ / _____ / _____** DD MMM YYYY
9.	Where was the CDI acquired? (see Case Classifications) ☐ Healthcare-associated (acquired in your facility) ☐ Inpatient ☐ Outpatient with healthcare exposure[3] ☐ Unknown ☐ Healthcare-associated (acquired in any other healthcare facility[4]) ☐ Related to other acute-care facility ☐ Related to a psychiatric facility ☐ Related to a rehabilitation facility ☐ Related to a LTCF ☐ Unknown ☐ Healthcare-associated but unable to determine which facility ☐ Community-associated ☐ Did the patient have a previous hospitalization in the previous 1 year (between the previous 13 to 52 weeks)? ☐ Yes ☐ No ☐ Unknown ☐ Indeterminate ☐ Information not available

Appendix 9 – Data Uploader on CNPHI

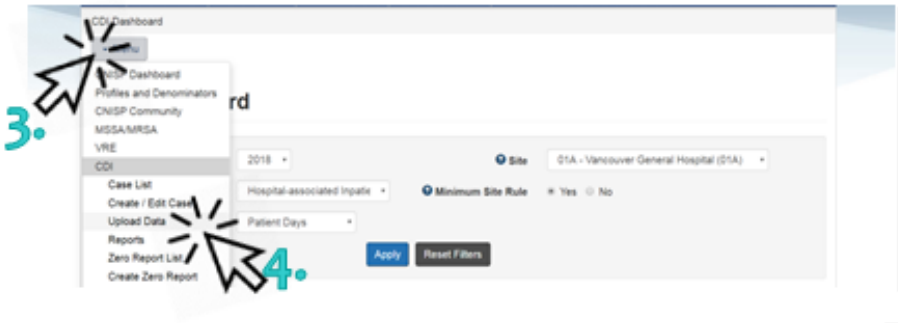
CNPHI – UPLOAD DATA FILES

How to submit data using the uploader on CNPHI

Step 1.
Surveillance
Canadian Nosocomial Infection Surveillance Program



Step 2.
Choose an application



Step 3.
Menu

Step 4.
Upload Data

***Select surveillance year**
***Choose your file**

Step 5.
Upload Epi Data

Revision History

Date	Revisions Made
October 2015	CDI classification has been modified. Examples for healthcare-associated (acquired in any other healthcare facility or setting is given in the foot note #3. "Information not available" has been added as an option. Page 4, ≥72 hours has been added for clarification "3 or more days after admission with day of admission being day 1" NEW!! • Q5 was created to ask whether the patient was an inpatient or an outpatient in preparation to create jumping rules. Description on inpatient, outpatient and outpatient, but the patient was subsequently admitted is given in the footnote. • Q8 – options have changed to have a consistency with other CNISP surveillance system. Examples are given in the footnote. An option for "Information not available" was added. • Q9b – option for "Any other healthcare facility or setting" was added. We have noticed that sites chose "Other" and entered "Other healthcare setting" or "LTC" for HA (acquired in another health care facility) cases as none of the previous options were applicable. An option for "Unknown" was also added. • Q23 – option for "No treatment" and "Unknown" were added. • Skipping rules have been created after Q12 and after Q21 in Appendix 3 – patient questionnaire for Targeted CDI surveillance. Skipping rules are designed for outpatient cases where information may not be available to answer all of the mandatory questions.
January 2016	Footnote for Healthcare-associated (acquired in any other healthcare facility or setting) has changed from 'in the previous 12 weeks' to 'in the previous 4 weeks' throughout the protocol. Now it reads as, Healthcare- associated (acquired in any other healthcare facility or setting) = Exposure to any healthcare setting (including other acute-care, long-term care, psychiatric, or rehabilitation facility or clinic (i.e. dialysis, outpatient) in the previous 4 weeks. Consideration should be given to the frequency and nature of exposure to a healthcare setting. For example, pediatric patients with clinic visits for otitis media, asthma, well-baby etc. in the previous 4 weeks may or may not be considered as HA while pediatric patients with clinic visits that involved invasive procedures or day surgery may be more likely to be considered HA.
December 2016	Cover page: The CDI Working group list is updated Methodology – Surveillance case definition for primary episodes of CDI: A new exclusion criteria created. Any patients age less than 1 year. Any pediatric patients (aged 1 year to less than 18 years) with alternate cause of diarrhea found (i.e. rotavirus, norovirus, enema or medication etc.) are excluded even if C. difficile diagnostic test result is positive. Note below from the previous protocol removed: (Note: If the information about the frequency and consistency of diarrhea is not available, a toxin-positive stool or positive PCR will be considered as a case).

	A new statement added as below Please note that starting in 2017, we will no longer accept an asymptomatic case identified only by a laboratory confirmation of a positive toxin assay or PCR for C. difficile. (i.e., a patient must have diarrhea or fever, abdominal pain and/or ileus AND a laboratory confirmation of a positive toxin assay or PCR for C. difficile to be identified as having CDI). Methodology - CDI case classification: CDI classification revised: Revision made to the healthcare exposure as 'The patient had 2 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 to 24 hours.' A revision made to the 'Any other healthcare facility' which now includes other acute-care, psychiatric, rehabilitation or long-term care facility Created a new category of 'Healthcare-associated but unable to determine which facility' Appendix 1 – CDI classification A CDI classification chart was created to summarize CDI cases Appendix 2,3 and 4 Q5-Responses revised to: □ Inpatient □ Inpatient ward/unit □ ER (admitted patients, awaiting inpatient bed) Admission date: _____ /_____ /_____ D D M M Y Y Y Y □ Outpatient □ Emergency department (non-admitted patients) □ Outpatient area (excluding ER) Appendix 2,3 and 4 Q8-Responses revised to: □ Healthcare-associated (acquired in any other healthcare facility4) □ Related to other acute-care facility □ Related to a psychiatric facility □ Related to a rehabilitation facility □ Related to a LTCF □ Unknown □ Healthcare-associated but unable to determine which facility □ Community-associated □ Did the patient have a previous hospitalization in the previous 1 year? □ Yes □ No □ Unknown Appendix 2,3 and 4 Q9a and Q9b from CDI 2016 protocol removed (Q9a. What ward/unit was the patient in at the time of positive culture for CDI was obtained? And Q9b. Where (ward/unit/community) was the patient at the time of presumed CDI acquisition? Appendix 3 and 4 Q11. A response 'Check all that apply' added to allow more than one answer options Appendix 4 Q13, Q14, Q15 Q20, Q21, Q22, Q23a. A response 'Unknown' added

	Entire document Diagnostic test date is used as a reference date to determine the severe outcomes or recurrent CDI status Other minor wording changes for clarification
October 2017	Goals and Objectives: Characterization of C. difficile strains for recurrent CDI is discontinued. Methodology - C) Surveillance design Any information related to collecting stool sample from recurrent CDI cases is removed. New note added "Note. Stool specimen collection for cases identified as recurrent CDI has been discontinued. Please DO NOT forward stool samples from recurrent CDI cases to NML." Appendix 1 – CDI classification A CDI classification chart was created to summarize CDI cases Appendix 2,3 and 4 Q5-Responses revised to indicate the respective date for each response option to match CNPHI interface □ Inpatient □ Inpatient ward/unit Admission date: dd-mmm-yyyy □ ER (admitted patients, awaiting inpatient bed) Admission date: : dd-mmm-yyyy □ Outpatient □ Emergency department (non-admitted patients) Visit (ER/outpatient) date : dd-mmm-yyyy □ Outpatient area (excluding ER)2 Visit (ER/outpatient) date: dd-mmm-yyyy □ Outpatient but was subsequently admitted because of CDI Visit (ER/outpatient) date: dd-mmm-yyyy AND Admission date: dd-mmm-yyyy □ Other (please specify) _____ Visit (ER/outpatient) date: dd-mmm-yyyy AND/OR Admission date: dd-mmm-yyyy Appendix 2,3 and 4 Q8 - More options added under the Healthcare associated (acquired in your facility) further clarify the question □ Healthcare-associated (acquired in your facility) □ Inpatient □ Outpatient exposure □ Unknown Q8- Time frame of previous 13 to 52 weeks is added for clarification □ Community-associated □ Did the patient have a previous hospitalization in the previous 1 year (between the previous 13 to 52 weeks)? □ Yes □ No

	Appendix 3 and 4 Q11b and Q20b. Did the patient receive Fecal Microbiota Transplantation (FMT) therapy for this episode of this episode of CDI / recurrent CDI? □ Yes □ No □ Unknown Q14b. and Q22b. Did the patient require loop ileostomy due to this episode of CDI/the recurrent CDI? □ Yes □ No □ Unknown Entire document: Other minor wording changes for clarification
July 2018	Appendix 2, 3 and 4 ○ Removed "Date of birth". ○ Added "Postal code (first 3 digits)" to capture the distribution/representation of CNISP data as patients from remote/rural/northern area access CNISP hospitals
October 2018	Created Appendix 7. CNISP CDI Surveillance: Standardized laboratory shipping Form guiding sites to email an electronic copy of the completed excel shipping form to phac.nml.ARNI-RAIN.lnm.aspc@canada.ca
November 2019	Standardization of all protocols ○ Added Appendix 1 ○ Added Appendix 2.2 Algorithm ○ Moved MDS form to end of Appendices ○ Restructured CDI Classifications ○ Updated Patient Population (only change was the removal of MDS, only use if cannot complete Appendix 3) ○ Added Surveillance period