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Public Health Agency of Canada | Agence de la santé publique du Canada

Canadian Nosocomial Infection Surveillance Program (CNISP)

Surveillance for *Clostridium difficile* infection (CDI)

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BACKGROUND

Clostridium 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 the 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 an identified gap regarding recurrent CDI and CDI cases in the community.

GOALS AND OBJECTIVES

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

METHODOLOGY

a) *Surveillance case definition for primary episodes of CDI*

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 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 of another cause of diarrhea).

OR

- the patient has a diagnosis of pseudomembranes on sigmoidoscopy or colonoscopy (or after colectomy) or histological/pathological diagnosis of CDI.

OR

- the patient is diagnosed with toxic megacolon (in adult patients only).

*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).

Exclusion

- 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.

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). CDI case classification.

Once a patient has been identified with CDI, the infection will be classified further based on the following criteria[1] and the *best clinical judgment* of the healthcare and/or infection prevention and control practitioner (ICP).

***Healthcare-associated (acquired in your facility)* CDI case definition**

- **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.
- **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 at your facility within the previous 4 weeks.
  - **Outpatient**: The patient presents with CDI symptoms at your ER or outpatient location AND the patient had a previous healthcare exposure[3] at your facility within the previous 4 weeks.

***Healthcare-associated (acquired in any other healthcare facility[4])* CDI case definition**

- **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 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 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 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 within the previous 4 weeks.

Healthcare-associated CDI but unable to determine which facility

- The patient with CDI **DOES** meet both definitions of healthcare-associated (acquired in your facility) and healthcare-associated (acquired in any other healthcare facility), but unable to determine to which facility the case is primarily attributable to.

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[1] Adapted from SHEA/IDSA practice recommendations 'Strategies to Prevent *Clostridium difficile* Infections in Acute Care Hospitals: 2014 Update '– available at URL http://www.jstor.org/stable/10.1086/676023?origin=JSTOR-pdf

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

[3] Healthcare exposure: 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.

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

C***ommunity-associated*** **CDI case definition**

- **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.

Indeterminate **CDI case definition**

- 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.

b) *Surveillance case definition for* recurrent CDI

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[5] 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.

c) *Surveillance design*

CDI surveillance is ongoing in all hospitals participating in CNISP. Information on patients with HA- and CA-CDI will be collected year round (January to December). Information on recurrent CDI will be collected from patients with the primary diagnostic test date falling in March and April of each year.

Adult patients (aged 18 years and older)

Ten-month clinical surveillance of HA- and CA-CDI, including medical treatment information, excluding outcome and stool analyses (known as "*Routine CDI surveillance*") for **adult patients** (aged 18 years and older). "Routine" surveillance will run from January 1st to February 28/29th and May 1st to December 31st of each year. A detailed questionnaire will be completed on all adult patients with HA- or CA-CDI (Appendix 2 or 3). Stool specimens will NOT be submitted to NML.

Two-month combined clinical/laboratory surveillance of HA-and CA-CDI (known as *"Targeted CDI surveillance"*) including patient outcomes and laboratory characterization of *C. difficile* isolates for **adult patients** (aged 18 years and older). During March 1st to April 30th of each year, a detailed patient questionnaire will be completed, which will include an assessment of all adult patients with CDI who died (Appendix 4). Stool specimens will be forwarded to NML.

Two-month recurrent surveillance for the primary episode of CDI in **adult patients** with the positive diagnostic test collected between March 1st and April 30th of each year, will be followed through lab surveillance for up to 8 weeks to determine if recurrent CDI occurs. A detailed patient questionnaire will be completed (Appendix 4). **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.

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[5] Some hospitals may define a CDI case (successfully treated and symptoms resolved) that occurs ≤ 8 weeks after a previous case as a 'relapse' however for CNISP CDI surveillance this is defined as a 'recurrent' CDI case.

Pediatric patients (aged between one year and less than 18 years old)

Year round combined clinical/laboratory surveillance of HA- and CA-CDI (known as *"Targeted CDI surveillance"*) for patient outcomes, selected severity variables, and laboratory characterization of *C. difficile* isolates for **pediatric patients** (aged between 1 year and less than 18 years old). A detailed questionnaire will be completed year-round and will include an assessment of all pediatric patients with CDI who died (Appendix 2 or 4). Stool specimens will be forwarded to NML.

Two-month recurrent surveillance for the primary episode of CDI in **pediatric patients** with the positive diagnostic test collected between March 1st and April 30th of each year, will be followed through lab surveillance for up to 8 weeks to determine if recurrent CDI occurs. A detailed patient questionnaire will be completed (Appendix 4). **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.

d) ***Data collection and submission***

Patients with CDI (inpatients and if possible at your facility emergency department and outpatients – both admitted and not admitted) are identified through review of toxin- or PCR-positive stool samples from the microbiology laboratory analysis, and then a chart (health record) review is conducted to determine if the patient meets the criteria for the surveillance case definition of CDI. For each CDI case identified a patient questionnaire is completed by directly entering or uploading into CNPHI. Stool samples are collected during the targeted surveillance for adult (March– April) and all-year-round for pediatric patients and are submitted to the NML for culture and further analyses.

Minimum dataset (MDS) CDI surveillance

If participating only in MDS surveillance (NOT participating in any adult or pediatric targeted surveillance or recurrent CDI surveillance) from January 1 – December 31 of each year, please complete the 'Patient Questionnaire for MDS Surveillance' (Appendix 2) only. Please send CDI stool samples to NML for any adult case that occurs March 1st to April 30th of each year and for all pediatric cases (year-round).

If participating in recurrent CDI surveillance (adults and pediatric), you must complete the 'Patient Questionnaire for Targeted Surveillance' (Appendix 4) for the primary CDI episode that occurs from March 1 to April 30 of each year. Please complete recurrent CDI questions (Q18-Q25) in 'Patient Questionnaire for Targeted surveillance' using the same unique identifier (Appendix 4). Outside of this period, MDS may be used. Please **DO NOT** send stool samples to NML for cases identified as recurrent CDI.

Routine CDI Surveillance

For each adult case of CDI that occurs from January 1 to Feb 28/29 and May 1 to December 31 of each year, please complete the 'Patient Questionnaire for Routine Surveillance' (Appendix 3) only. No stool samples are to be sent to the NML.

Targeted CDI Surveillance

For each adult case of CDI that occurs during March 1st to April 30th of each year and all pediatric cases (year-round) please complete the 'Patient Questionnaire for Targeted surveillance' (Appendix 4). Whenever possible, stool samples must be submitted to NML.

Severe outcome information will be collected on all patients with CDI during the targeted surveillance. Severe outcome is defined as a patient who is admitted to the intensive care unit for complications related to CDI,

underwent colectomy, or died. All cases of death within 30 days after the diagnostic test of CDI will be assessed by the CHEC member or a designated physician to determine if the death was attributable to CDI. Cause of death will be determined by the following criteria: 1) CDI was directly related to the death of the patient; that is, the patient had no other underlying condition that would have caused death during this hospitalization; or 2) CDI was indirectly related to death; that is, the CDI contributed to the patient's death but was not the primary cause; or 3) the patient died with CDI but CDI was not related to death. The death attribution may be done by the CHEC member, a designated physician, or by ICP judgment.

NOTE: if the patient dies after discharge, they will be considered discharged alive.

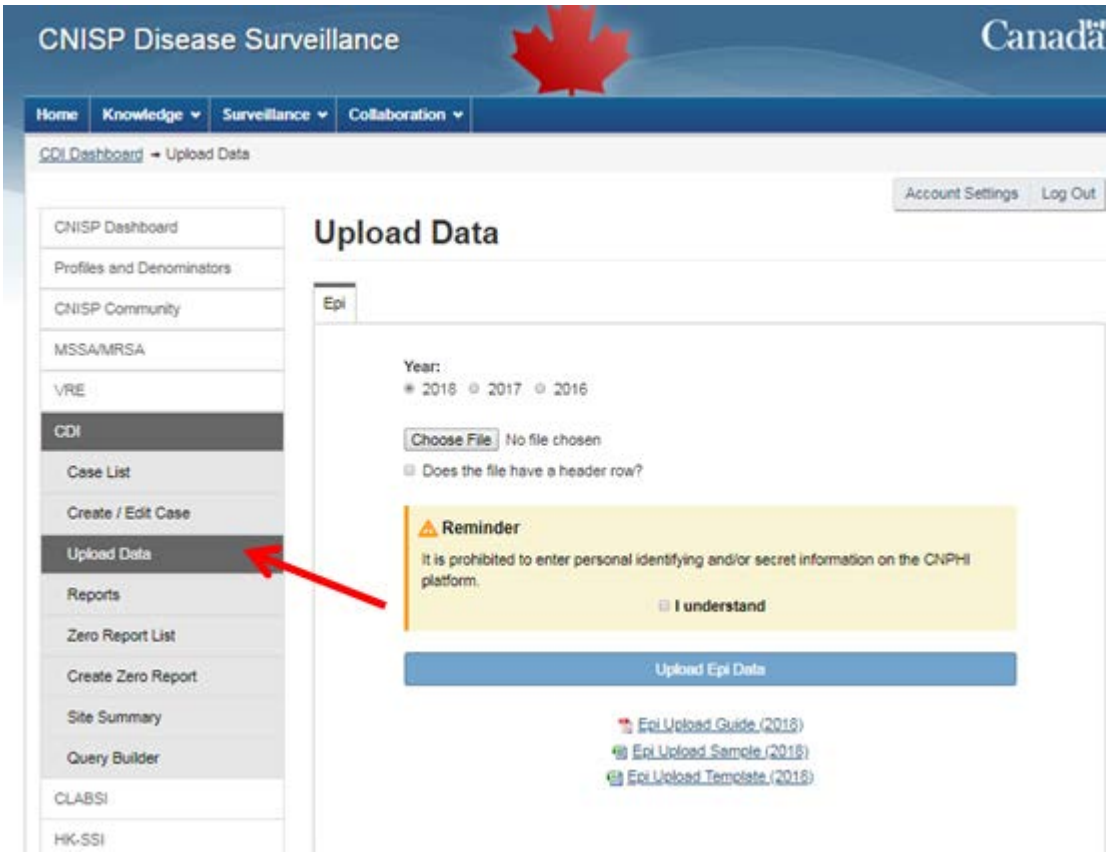
Recurrent CDI Surveillance

All cases of CDI in adult and pediatric patients identified (based on the diagnostic test date of CDI) between March 1st and April 30th of each year will be followed prospectively for up to eight (8) weeks following the diagnostic test date of the primary CDI episode to determine if recurrent CDI occurs. Please complete 'Recurrent section' in 'Patient Questionnaire for Targeted surveillance' using the same unique identifier (Appendix 4). No recurrent isolates are to be sent to NML.

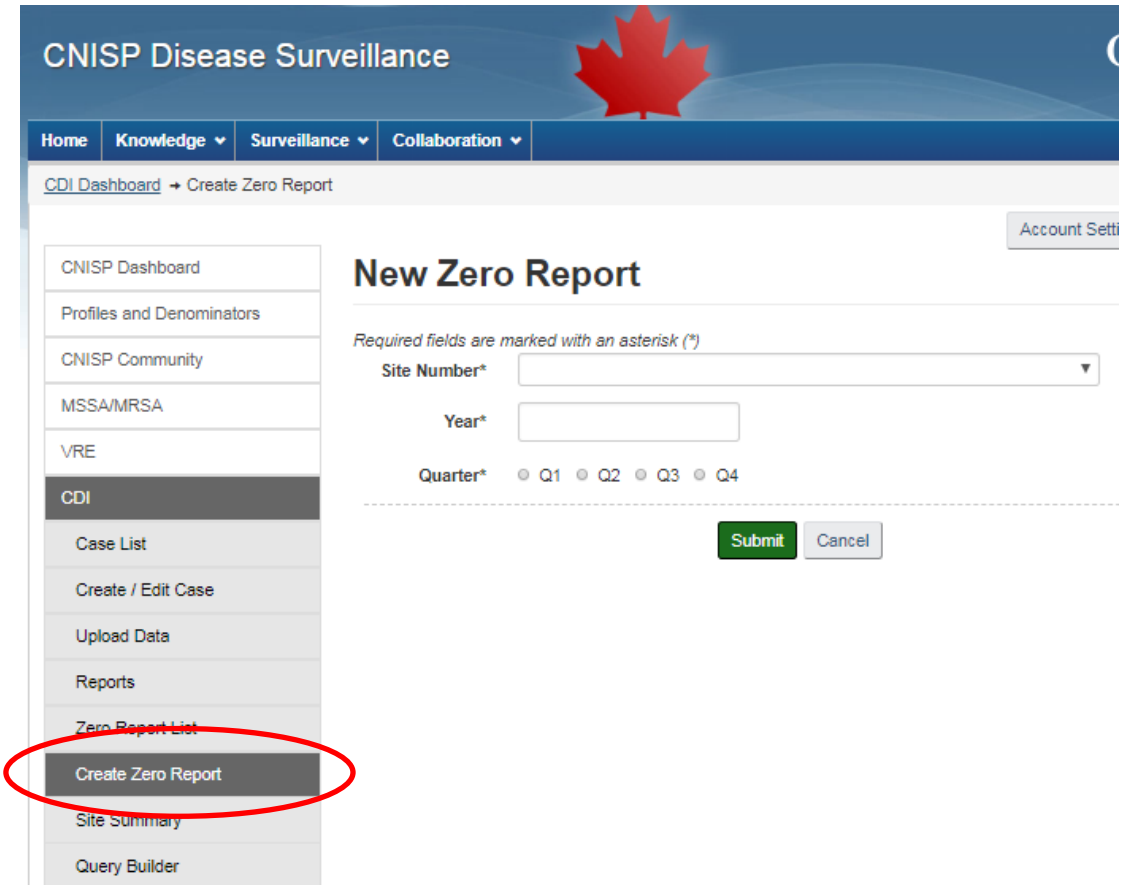
e) *Electronic Data Entry*

All patient questionnaire data should 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 cnisp.pcsin@phac-aspc.gc.ca.

Data can also be entered using the uploader tool available on CNPHI (www.cnphi-rcrsp.ca) under the "Upload Data"



For any quarter wth no cases at your site, a Zero Report must be made in the CNPHI CDI module so tha tquarters with zero counts can be differentiated from missing data.



f) *Denominator data*

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) data collection form on a quarterly basis and submit to the Agency through CNPHI (www.cnphi-rcrsp.ca) no later than the end of the following quarter.

Pediatric denominator (aged between 1 year and less than 18 years old) data are also required.

DATA 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.

Attached Appendices:

Appendix 1 CNISP CDI case classification
Appendix 2 Patient Questionnaire for MDS CDI surveillance
Appendix 3 Patient Questionnaire for Routine CDI surveillance
Appendix 4 Patient Questionnaire for Targeted CDI surveillance
Appendix 5 Data Dictionary for all CDI patient questionnaires
Appendix 6 Stool Storage/Submission Protocol
Appendix 7 Standardized shipping form

APPENDIX 1 – CDI Classification

Risk factors	Inpatient		Outpatient
	The patient's CDI symptoms occur <72 hours after current admission	**The patient's CDI symptoms occur ≥72 hours after current admission**	**Patient presents with CDI symptoms to ER outpatient location**
• The patient had been hospitalized at your healthcare facility and discharged within the previous 4 weeks	Healthcare-associated (acquired in your facility) CDI	Healthcare-associated (acquired in your facility) CDI	Healthcare-associated (acquired in your facility) CDI
• The patient had a healthcare exposure at your facility within the previous 4 weeks			
• The patient had been hospitalized at any other healthcare facility and discharged/transferred within the previous 4 weeks	Healthcare-associated (acquired in any other healthcare facility) CDI		Healthcare-associated (acquired in any other healthcare facility)CDI
• The patient had a healthcare exposureat any other facility within the previous 4 weeks			
• The patient had been hospitalized both at your facility and any other healthcare facility and discharged/transferred within the previous 4 weeks	Healthcare-associated CDI but unable to determine which facility		Healthcare-associated CDI but unable to determine which facility
• No hospitalization or any other healthcare exposure[3] within the previous 12 weeks	Community-associated CDI		Community-associated CDI
• 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	Indeterminate CDI		Indeterminate CDI

APPENDIX 2 - 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 Identifier Code	_____ YY _____ (e.g. 99A19001) *(CHEC site #) (Surveillance year) (case number)*
3. Age in years (Please provide round down age – refer to the Appendix 5)	Age _____ years
4. Postal code (first 3 digit)	
5. Gender	☐ 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 ☐ 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) 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
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 definitions pages 3-5)	☐ Healthcare-associated (acquired in your facility) ☐ Inpatient ☐ Outpatient with healthcare exposure ☐ Unknown ☐ Healthcare-associated (acquired in any other healthcare facility) ☐ 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 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 Identifier Code	_____ YY _____ (e.g. 99A19001) *(CHEC site #) (Surveillance year) (case number)*
3. Age in years (Please provide round down age – refer to the Appendix 5)	Age _____ years
4. Postal code (first 3 digit)	
5. Gender	☐ 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 ☐ 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) 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
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 definitions pages 3-5)	☐ Healthcare-associated (acquired in your facility) ☐ Inpatient ☐ Outpatient with healthcare exposure ☐ Unknown ☐ Healthcare-associated (acquired in any other healthcare facility) ☐ 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
11Date when CDI therapy was started	_____ dd-mmm-yyyy
12a. 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)
12b. Did the patient receive 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 of each year and for pediatric cases (year-round). All stool specimens must be sent to NML.**	
1. CHEC Site #	
2. Unique Patient Identifier	_____ YY _____ (e.g. 99A19001) *(CHEC site #) (Surveillance year) (case number)*
3. Age in years (Please provide round down age – refer to the Appendix 5)	Age _____ years
4. Postal code (first 3 digit)	
5. Gender	☐ 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 ☐ 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) 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
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 definitions pages 3-5)	☐ Healthcare-associated (acquired in your facility) ☐ Inpatient ☐ Outpatient with healthcare exposure ☐ Unknown ☐ Healthcare-associated (acquired in any other healthcare facility) ☐ 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
12a. 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)
12b. Did the patient receive 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)*	$Temp_{max}$:_____ ^{o}C Serum albumin (lowest value): _____ Serum creatinine (highest value): _____ Total WBC count (highest value): _____ ☐ Unknown
14. Did the patient require ICU admission for the 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
15a. Did the patient require colectomy due to the initial CDI?	☐ Yes ☐ No ☐ Unknown
15b. Did the patient require loop ileostomy due to the initial CDI?	☐ Yes ☐ No ☐ Unknown
16a. 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
16b. If patient survived and was discharged or transferred, what was the date of the discharge or transfer?	☐ dd-mmm-yyyy
16c. 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 ☐ CDI contributed to death ☐ Death is unrelated to CDI ☐ Causality between CDI and death cannot be determined

RECURRENT CDI

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. Stool specimen collection for cases identified as recurrent CDI has been discontinued. Please DO NOT forward stool samples from recurrent CDI cases to NML.

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
19. Date of the recurrence (ie 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 ☐ 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) Visit (ER/outpatient) date: ☐☐☐☐☐☐☐☐☐ dd-mmm-yyyy ☐ Outpatient but was subsequently admitted because of recurrent 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
21a. What was the initial medical treatment for the recurrent CDI? (check all that apply)	☐ Metronidazole PO ☐ Metronidazole IV ☐ Vancomycin PO ☐ Fidaxomicin PO ☐ No treatment ☐ Unknown ☐ Other (please specify)

21b. Did the patient receive 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?	☐ 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
23a. Did the patient require colectomy due to the recurrent CDI?	☐ Yes ☐ No ☐ Unknown
23b. Did the patient require loop ileostomy due to the recurrent CDI?	☐ Yes ☐ No ☐ Unknown
24a. 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
24b. If patient survived and was discharged or transferred, what was the date of the discharge or transfer?	☐ dd-mmm-yyyy
24c. 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 ☐ Recurrent CDI contributed to death ☐ Death is unrelated to recurrent CDI ☐ Causality between CDI and death cannot be determined

APPENDIX 5 – Data Dictionary for all CDI patient questionnaires

Please note:
Questions 1 through 9 represent the MDS CDI questionnaire
Questions 1 through 12 represent the Routine CDI questionnaire
Questions 1 through 17 represent the targeted CDI questionnaire
Questions 1 through 25 represent the targeted plus recurrent CDI 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., 99A.

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., 99A), the surveillance year the infection occurred in (e.g., 15), 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 99A-15-001. An example of the thirty-fifth case would be 99A-15-035, and so on.

NOTE: Please **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 digit)**

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

5. **Gender**

Check male or female gender as appropriate.

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

12. b. **Fecal Microbiota Transplantation (FMT) therapy**

Please indicate if the patient received 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.

15. b. Loop ileostomy due to the recurrent CDI

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

16. b. Date of discharge or transfer

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

16. 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 the 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.

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

Please indicate if the patient received 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.

23. 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.

24. b. Date of discharge or transfer

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

24. 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

HA- and CA- 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.

CHEC ID Formats:

The assigned CHEC ID # **must** correspond to the Unique Identifier on the patient questionnaire whether submitted on-line (www.cnphi-rcrsp.ca) or by email (cnisp.pcsin@phac-aspc.gc.ca).

Adult or Pediatric – Targeted
_____ YY _____ eg. 99A19001 *(CHEC site #) (Surveillance year) (case number)*

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^{o}C*** degrees in a similar storage box (supplied by the NML).

Note: *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^{o}C. It may become difficult to isolate a C. difficile from a stool which has been held longer than 48 h at 4^{o}C.*

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

Note: *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.*

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7) Ship the **boxes (stools)** and the **CDI standardized laboratory shipping form (Appendix 7)** 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: 6636-8403-5

8) Email an electronic copy of the completed **CDI standardized laboratory shipping form (Appendix 7)** to the NML at phac.nml.ARNI-RAIN.lnm.aspc@canada.ca.

Note: *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.*

Case forms (Epi data) and Laboratory Submission Deadlines:

All case forms and quarterly denominator data are due to be submitted by the end of the following quarter - See table below for submission deadlines.

Table 1

Surveillance period	Data submission deadline
Jan 1 – Mar 31	Jun 30
Apr 1 – Jun 30	Sep 30
Jul 1 – Sep 30	Dec 31
Oct 1 – Dec 31	Mar 31

The **ABSOLUTE FINAL** deadline for submission of **CDI samples** to the NML is as follows

Table 2

Adult – Targeted	Pediatric – Targeted
July 31st of each surveillance year	March 31st of the next year for previous years surveillance

NOTE: CDI isolates not received by the deadlines outlined in Table 2 will NOT be processed and therefore will NOT be included in that surveillance year data or subsequent reports.

Every effort should be made to ship the stools and accompanying documentation (standardized shipping form) to the NML **as early as possible after the end of the sample collection period** to facilitate rapid laboratory testing and analysis.

Laboratory (NML) Contacts:

Dr. George Golding
Phone: (204) 784-8096
Email: George.Golding@canada.ca
National Microbiology Laboratory
Winnipeg, MB

Romeo Hizon
Phone: (204) 789-5000
Email: Romeo.Hizon@canada.ca
National Microbiology Laboratory
Winnipeg, MB

APPENDIX 7 CNISP CDI Surveillance: Standardized Laboratory Shipping Form

Appendix 7 must be included with the shipment **AND** emailed to the NML at **phac.nml.ARNI-RAIN.lnm.aspc@canada.ca**

Send isolates and Appendix 7 to:

Dr. George
Microbiology Laboratory
1015 Arlington St., Winnipeg, Manitoba R3E 3R2
Tel: 204-789-2133
Use FedEx billing number: 6636-8403-5
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(

Revision History

October 26, 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 16, 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.

Nov-Dec, 2016

Document Section	Summary of revisions
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 facility) ☐ 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

Oct 2017 – CNISP 2018 CDI protocol

Document Section	Summary of revisions
Cover page	The CDI Working group list is updated
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) 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