

Canadian Nosocomial Infection Surveillance Program

2015-2017 Surveillance for *Clostridium difficile* infection (CDI)

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INTRODUCTION

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.

During the past decade, 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.

Despite progress being made in understanding the pathogenesis and epidemiology of healthcare-associated (HA)-CDI, the incidence and severity of CDI continues to increase in North America and Europe. It has been suggested the rise in reported CDI cases may be attributed to ones 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 recurs a second or third time after cessation of appropriate therapy. Identifying recurrent and CA-CDI cases represents a significant gap in the national surveillance of *C. difficile* in Canada.

Beginning in 2015, CNISP is proposing to conduct three years of surveillance for recurrent and CA-CDI in addition to the ongoing HA-CDI core surveillance. The purpose of the surveillance is 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.

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-, CA- and recurrent 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 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.

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 criteria¹ 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 AND the patient had been previously hospitalized at your healthcare facility and discharged within the previous 4 weeks.
- **Related to a previous healthcare exposure² 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 exposure² 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 exposure² at your facility within the previous 4 weeks.

Healthcare-associated (acquired in any other healthcare facility³) 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 facility³ 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 facility³ and discharged/transferred within the previous 4 weeks.
- **Related to a previous healthcare exposure² 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 exposure² at any other healthcare facility³ 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 exposure² at any other healthcare facility³ 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 facility³), but unable to determine to which facility the case is primarily attributable to.

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 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.

³ Any other healthcare facility which includes other acute-care, psychiatric, rehabilitation or long-term care facility

Community-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 exposure² 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 exposure² 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 exposure².

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) weeks⁴ 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) during 2015 to 2017. 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) and stool specimens (if available) will be forwarded to NML.

⁴ 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) and stool specimens (if available) will be forwarded 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. Stool samples for cases identified as recurrent episodes for both adult and pediatric patients 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 (Q17-Q24) in ‘Patient Questionnaire for Targeted surveillance’ using the same unique identifier (Appendix 4). Outside of this period, MDS maybe used. Please send stool samples to NML for cases identified as recurrent cases.

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). Whenever possible, stool samples must be submitted 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.

f) *Denominator data*

To obtain the necessary denominator information for the calculation of national CDI rates, each participating hospital will complete a CORE surveillance quarterly denominator data collection form (including patient admissions and patient days) and submit to the Agency or on-line at CNPHI (www.cnphi-rcrsp.ca) on a quarterly basis, 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
<ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> The patient had a healthcare exposure² at your facility within the previous 4 weeks 			
<ul style="list-style-type: none"> The patient had a healthcare² at any other facility within the previous 4 weeks 	Healthcare-associated CDI but unable to determine which facility		Healthcare-associated CDI but unable to determine which facility
<ul style="list-style-type: none"> No hospitalization or any other healthcare exposure² within the previous 12 weeks 	Community-associated CDI		Community-associated CDI
<ul style="list-style-type: none"> 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 exposure² 	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	<p style="text-align: center;">_____ 17 _____</p> <p style="text-align: center;">(CHEC site #) (year) (case number)</p>
<p>3. Date of birth</p> <p>If actual Date of Birth is unavailable, please indicate age at time of the first positive lab specimen</p>	<p style="text-align: center;">____ / ____ / ____</p> <p style="text-align: center;"><i>DD MM YYYY</i></p> <p>Age _____ years</p>
4. Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female
5. Was the patient an inpatient or an outpatient on the day the positive lab specimen was collected?	<input type="checkbox"/> Inpatient <ul style="list-style-type: none"> <input type="checkbox"/> Inpatient ward/unit <input type="checkbox"/> ER (admitted patients, awaiting inpatient bed) <p style="text-align: right;">Admission date: ____ / ____ / ____</p> <p style="text-align: center;"><i>DD MM YYYY</i></p> <input type="checkbox"/> Outpatient <ul style="list-style-type: none"> <input type="checkbox"/> Emergency department (non-admitted patients) <input type="checkbox"/> Outpatient area (excluding ER) <input type="checkbox"/> Outpatient but was subsequently admitted because of CDI <p style="text-align: right;">Admission date: ____ / ____ / ____</p> <p style="text-align: center;"><i>DD MM YYYY</i></p> <input type="checkbox"/> Other (please specify) _____
6. Date of admission or visit and if applicable most recent previous inpatient discharge date	<p>If CDI diagnosed <u>DURING</u> hospital stay, record date of admission:</p> <p>Current hospital admission date: ____ / ____ / ____</p> <p style="text-align: center;"><i>DD MM YYYY</i></p> <p>If CDI diagnosed during outpatient visit (ER or other outpatient setting) record date of visit</p> <p>Visit (ER/outpatient) date: ____ / ____ / ____</p> <p style="text-align: center;"><i>DD MM YYYY</i></p> <p>If CDI diagnosed within 12 weeks following a previous inpatient discharge, record most recent previous discharge date</p> <p>Previous inpatient discharge date: ____ / ____ / ____</p> <p style="text-align: center;"><i>DD MM YYYY</i></p>
7. Date of 1 st positive lab specimen for the current episode	<p style="text-align: center;">____ / ____ / ____</p> <p style="text-align: center;"><i>DD MM YYYY</i></p>

8. Where was the CDI acquired? (see definitions pages 3-5)

- Healthcare-associated (acquired in your facility)
- Healthcare-associated (acquired in any other healthcare facility³)
 - 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
- Indeterminate
- Information not available

<p>8. Where was the CDI acquired? (see definitions pages 3-5)</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Healthcare-associated (acquired in your facility) <input type="checkbox"/> Healthcare-associated (acquired in any other healthcare facility³) <ul style="list-style-type: none"> <input type="checkbox"/> Related to other acute-care facility <input type="checkbox"/> Related to a psychiatric facility <input type="checkbox"/> Related to a rehabilitation facility <input type="checkbox"/> Related to a LTCF <input type="checkbox"/> Unknown <input type="checkbox"/> Healthcare-associated but unable to determine which facility <input type="checkbox"/> Community-associated <ul style="list-style-type: none"> <input type="checkbox"/> Did the patient have a previous hospitalization in the previous 1 year? <ul style="list-style-type: none"> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Indeterminate <input type="checkbox"/> Information not available
<p>9. Date of CDI symptom onset <i>(if unable to determine data of onset, please indicate date of first positive lab specimen)</i></p>	<p style="text-align: center;">____ / ____ / ____ <i>DD MM YYYY</i></p>
<p>10. Date when CDI therapy was started</p>	<p style="text-align: center;">____ / ____ / ____ <i>DD MM YYYY</i></p>
<p>11. What was the initial medical treatment for CDI? (check all that apply)</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Metronidazole PO <input type="checkbox"/> Metronidazole IV <input type="checkbox"/> Vancomycin PO <input type="checkbox"/> Fidaxomicin PO <input type="checkbox"/> No treatment <input type="checkbox"/> Unknown <input type="checkbox"/> Other (please specify)

<p>8. Where was the CDI acquired? (see definitions pages 3-5)</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Healthcare-associated (acquired in your facility) <input type="checkbox"/> Healthcare-associated (acquired in any other healthcare facility³) <ul style="list-style-type: none"> <input type="checkbox"/> Related to other acute-care facility <input type="checkbox"/> Related to a psychiatric facility <input type="checkbox"/> Related to a rehabilitation facility <input type="checkbox"/> Related to a LTCF <input type="checkbox"/> Unknown <input type="checkbox"/> Healthcare-associated but unable to determine which facility <input type="checkbox"/> Community-associated <ul style="list-style-type: none"> <input type="checkbox"/> Did the patient have a previous hospitalization in the previous 1 year? <ul style="list-style-type: none"> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Indeterminate <input type="checkbox"/> Information not available
<p>9. Date of CDI symptom onset <i>(if unable to determine data of onset, please indicate date of first positive lab specimen)</i></p>	<p style="text-align: center;">____ / ____ / ____ <i>DD MM YYYY</i></p>
<p>10. Date when CDI therapy was started</p>	<p style="text-align: center;">____ / ____ / ____ <i>DD MM YYYY</i></p>
<p>11. What was the initial medical treatment for CDI? (check all that apply)</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Metronidazole PO <input type="checkbox"/> Metronidazole IV <input type="checkbox"/> Vancomycin PO <input type="checkbox"/> Fidaxomicin PO <input type="checkbox"/> No treatment <input type="checkbox"/> Unknown <input type="checkbox"/> Other (please specify)
<p>Please skip to Q17 if this is an outpatient [Emergency department (non-admitted patient) or Outpatient area (excluding ER)] case, otherwise continue with Q12</p>	

<p>12. Selected severity markers at the time of diagnosis (toxin positive in stool OR positive histopathology)</p> <p style="text-align: center;"><i>Fill in values (+/- 48 hours, if same-day results not available)</i></p>	<p>Temp_{max} : _____ °C</p> <p>Serum albumin (lowest value): _____</p> <p>Serum creatinine (highest value): _____</p> <p>Total WBC count (highest value): _____</p> <p><input type="checkbox"/> Unknown</p>
<p>13. Did the patient require ICU admission for the initial CDI episode?</p>	<p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes admitted to ICU for complications of CDI</p> <p><input type="checkbox"/> Yes admitted to ICU, but for reasons other than CDI</p> <p><input type="checkbox"/> No, already in ICU</p> <p><input type="checkbox"/> Unknown</p>
<p>14. Did the patient require colectomy due to the initial CDI?</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Unknown</p>
<p>15a. What was the outcome of this patient at 30 days after the positive lab specimen?</p> <p><i>(check one response only)</i></p>	<p><input type="checkbox"/> Patient survived and discharged</p> <p><input type="checkbox"/> Patient alive, still in hospital</p> <p><input type="checkbox"/> Patient died</p> <p><input type="checkbox"/> Unknown</p>
<p>15b. If patient survived and was discharged or transferred, what was the date of the discharge or transfer?</p>	<p>____ / ____ / ____ DD MM YYYY</p>
<p>15c. If the patient died, what was the date of death?</p> <p><i>(as recorded on death record)</i></p>	<p>____ / ____ / ____ DD MM YYYY</p>
<p>16. If the patient died within 30 days after the positive lab specimen, please indicate the relationship of CDI to the death</p>	<p><input type="checkbox"/> CDI was the cause of death</p> <p><input type="checkbox"/> CDI contributed to death</p> <p><input type="checkbox"/> Death is unrelated to CDI</p> <p><input type="checkbox"/> Causality between CDI and death cannot be determined</p>

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.

However, please add an "R" for the **stool specimen** from a recurrent case at end of the Unique Patient Identifier (e.g. 99A17001R).

17. Did the patient have a recurrent episode of CDI within 8 weeks of the following the diagnostic test of the primary episode?	<input type="checkbox"/> Yes (if yes, complete Q19-24) <input type="checkbox"/> No
18. Date of the recurrence (ie onset of symptoms of CDI)	____ / ____ / ____ <i>DD MM YYYY</i>
19. Was the patient an inpatient or an outpatient on the day the positive lab specimen was collected for this recurrent episode of CDI?	<input type="checkbox"/> Inpatient <input type="checkbox"/> Inpatient ward/unit <input type="checkbox"/> ER (admitted patients, awaiting inpatient bed) Admission date: ____ / ____ / ____ <i>DD MM YYYY</i> <input type="checkbox"/> Outpatient <input type="checkbox"/> Emergency department (non-admitted patients) <input type="checkbox"/> Outpatient area (excluding ER) <input type="checkbox"/> Outpatient but was subsequently admitted because of recurrent CDI Admission date: ____ / ____ / ____ <i>DD MM YYYY</i> <input type="checkbox"/> Other (please specify) _____
20. What was the initial medical treatment for the recurrent CDI?	<input type="checkbox"/> Metronidazole PO <input type="checkbox"/> Metronidazole IV <input type="checkbox"/> Vancomycin PO <input type="checkbox"/> Fidaxomicin PO <input type="checkbox"/> No treatment <input type="checkbox"/> Unknown <input type="checkbox"/> Other (please specify) _____
<p>End of questions if Q19 is answered as either Emergency department (non-admitted patients) or Outpatient area (excluding ER), otherwise continue with Q21</p>	

<p>21. Did the patient require ICU admission for the recurrent CDI?</p>	<p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes admitted to ICU for complications of recurrent CDI</p> <p><input type="checkbox"/> Yes admitted to ICU, but for reasons other than recurrent CDI</p> <p><input type="checkbox"/> No, already in ICU</p> <p><input type="checkbox"/> Unknown</p>
<p>22. Did the patient require colectomy due to the recurrent CDI?</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Unknown</p>
<p>23a. What was the outcome of this patient at 30 days after the positive lab specimen of the recurrent CDI</p> <p><i>(check one response only)</i></p>	<p><input type="checkbox"/> Patient survived and discharged</p> <p><input type="checkbox"/> Patient alive, still in hospital</p> <p><input type="checkbox"/> Patient died</p> <p><input type="checkbox"/> Unknown</p>
<p>23b. If patient survived and was discharged or transferred, what was the date of the discharge or transfer?</p>	<p>____ / ____ / ____</p> <p style="text-align: center;"><i>DD MM YYYY</i></p>
<p>23c. If the patient died, what was the date of death?</p> <p><i>(as recorded on death record)</i></p>	<p>____ / ____ / ____</p> <p style="text-align: center;"><i>DD MM YYYY</i></p>
<p>24. If the patient died, please indicate the relationship of recurrent CDI to the death</p>	<p><input type="checkbox"/> Recurrent CDI was the cause of death</p> <p><input type="checkbox"/> Recurrent CDI contributed to death</p> <p><input type="checkbox"/> Death is unrelated to recurrent CDI</p> <p><input type="checkbox"/> Causality between CDI and death cannot be determined</p>

APPENDIX 5 – Data Dictionary for all CDI patient questionnaires

Please note:

Questions 1 through 8 represent the MDS CDI questionnaire

Questions 1 through 11 represent the Routine CDI questionnaire

Questions 1 through 16 represent the targeted CDI questionnaire

Questions 1 through 24 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.

For submitting a stool from a recurrent case, please add an “R” and the recurrent sample number to the end of the CHEC ID number (e.g. 99A16001R)

3. Date of Birth

Please enter Day (##), Month (May) and Year (1973) in this order. If the date of birth is not available 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. Gender

Check male or female gender as appropriate.

5. Status of hospital admission

Please indicate whether the patient was an inpatient or an outpatient on the day the stool sample was collected, if the diagnostic test result is positive for *C.difficile*?

- 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).

- 6. 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 diagnosed during outpatient visit (ER or other outpatient setting) record date of visit
 - If CDI diagnosed within **12 weeks** following a most recent previous inpatient discharge, record date of discharge
- 7. Date of first positive laboratory specimen or positive histopathology specimen**
Please indicate when the first lab or histopathology specimen tested positive
- 8. 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
- 9. Date of CDI symptom onset**
Please indicate the date of CDI symptom onset.
- 10. Date when CDI therapy started**
Please indicate the date when CDI treatment was initiated.
- 11. Initial medical treatment on the day of diagnosis**
Please indicate the initial medical treatment on the day of diagnosis.
- 12. 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.
- 13. ICU admission**
Please indicate if the patient required admission to the ICU for this episode of CDI.
- 14. Colectomy**
Please indicate if the patient required a colectomy due to CDI.
- 15a. 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.
- 15b. Date of discharge or transfer**
If the patient survived, please indicate the date of discharge or transfer.

- 15c. Date of death**
If the patient died, please indicate the date of death.
- 16. 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.
- 17. 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.
- 18. Date of the recurrence**
Please indicate when the first lab or histopathology specimen tested positive for the recurrent infection.
- 19. Status of hospital admission for the recurrent episode of CDI**
Please indicate whether the patient was an inpatient or an outpatient on the day the stool sample was collected for this recurrent episode of CDI, if the diagnostic test result is positive for *C.difficile*?
- 20. Initial medical treatment for the recurrent CDI**
Please indicate the initial medical treatment on the day of diagnosis of the recurrent infection.
- 21. ICU admission required for the recurrent CDI episode**
Please indicate if the patient required admission to the ICU for this recurrent episode of CDI.
- 22. Colectomy due to the recurrent CDI?**
Please indicate if the patient required a colectomy due to recurrent CDI
- 23a. 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.
- 23b. Date of discharge or transfer**
If the patient survived from the recurrent CDI, please indicate the date of discharge or transfer.
- 23c. Date of death**
If the patient died with the recurrent CDI, please indicate the date of death.
- 24. 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 2015-2017 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.

Recurrent – Targeted: All cases of CDI in both 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.

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	Recurrent – Targeted
<u> 17 </u> (CHEC site #) (year) (case number)	<u> 17 R </u> (CHEC site #) (year) (case number) (sample number)

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., 17), 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-17-001. An example of the thirty-fifth case would be 99A-17-035, and so on.

If the stool is from a recurrent case, please add an “R” and the recurrent sample number to the end of the CHEC ID number (e.g. 99A17001R).

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 (17), followed by space for the isolate number (e.g. 001). Add an “R” and the recurrent sample number to the end of the CHEC ID number, if required.

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

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°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 **CNISP CDI standardized shipping form (Appendix 7)**. You may include your Laboratory Identification Number (LIN) if there is one.

Note: *The LIN 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)** and the **CDI standardized shipping form** 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: 2299-8435-7

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, quarterly denominator data and CDI isolates 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 2017	Jun 30 2017
Apr 1 – Jun 30 2017	Sep 30 2017
Jul 1 – Sep 30 2017	Dec 31 2017
Oct 1 – Dec 31 2017	Mar 31 2018

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

Table 2

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

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@phac-aspc.gc.ca
National Microbiology Laboratory
Winnipeg, MB

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

APPENDIX 7 CNISP CDI 2015-2017 Surveillance: Standardized Laboratory Shipping Form

Dr. GEORGE GOLDING
 National Microbiology Laboratory
 1015 Arlington St., Winnipeg, Manitoba R3E 3R2
 Tel: 204-784-8096
 Use FedEx billing number: 2299-8435-7

Hospital Laboratory Number	Assigned CHEC ID _____ 17 _____ (CHEC site #) (year) (case #) e.g. 01C-17-001	Please indicate if sample is for Adult targeted (Mar 1 – Apr 30) or all year Pediatric surveillance Please check ONE box only	Date Specimen Obtained Please use this date format dd-mmm-yyyy 26 – Apr - 2017	Optional Notes from Submitting Lab Indicate if the sample is not available, or provide any important information about the sample
		<input type="checkbox"/> Adult targeted (Mar1-Apr 30) <input type="checkbox"/> Peds all year (Jan 1– Dec 31)		
		<input type="checkbox"/> Adult targeted (Mar1-Apr 30) <input type="checkbox"/> Peds all year (Jan 1– Dec 31)		
		<input type="checkbox"/> Adult targeted (Mar1-Apr 30) <input type="checkbox"/> Peds all year (Jan 1– Dec 31)		
		<input type="checkbox"/> Adult targeted (Mar1-Apr 30) <input type="checkbox"/> Peds all year (Jan 1– Dec 31)		
		<input type="checkbox"/> Adult targeted (Mar1-Apr 30) <input type="checkbox"/> Peds all year (Jan 1– Dec 31)		
		<input type="checkbox"/> Adult targeted (Mar1-Apr 30) <input type="checkbox"/> Peds all year (Jan 1– Dec 31)		
		<input type="checkbox"/> Adult targeted (Mar1-Apr 30) <input type="checkbox"/> Peds all year (Jan 1– Dec 31)		
		<input type="checkbox"/> Adult targeted (Mar1-Apr 30) <input type="checkbox"/> Peds all year (Jan 1– Dec 31)		
		<input type="checkbox"/> Adult targeted (Mar1-Apr 30) <input type="checkbox"/> Peds all year (Jan 1– Dec 31)		
		<input type="checkbox"/> Adult targeted (Mar1-Apr 30) <input type="checkbox"/> Peds all year (Jan 1– Dec 31)		
		<input type="checkbox"/> Adult targeted (Mar1-Apr 30) <input type="checkbox"/> Peds all year (Jan 1– Dec 31)		
		<input type="checkbox"/> Adult targeted (Mar1-Apr 30) <input type="checkbox"/> Peds all year (Jan 1– Dec 31)		
		<input type="checkbox"/> Adult targeted (Mar1-Apr 30) <input type="checkbox"/> Peds all year (Jan 1– Dec 31)		

Please ensure that this form is included in your shipment

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 <ul style="list-style-type: none">• 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 <i>C. difficile</i> diagnostic test result is positive.

Revised Dec 23, 2016

	<ul style="list-style-type: none"> 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 <p><u>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 <i>C. difficile</i>. (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 <i>C. difficile</i> to be identified as having CDI).</u></p>
Methodology - CDI case classification	<p>CDI classification revised:</p> <ul style="list-style-type: none"> 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	<p>Q5-Responses revised to:</p> <p><input type="checkbox"/> Inpatient</p> <p style="margin-left: 20px;"><input type="checkbox"/> Inpatient ward/unit</p> <p style="margin-left: 20px;"><input type="checkbox"/> ER (admitted patients, awaiting inpatient bed)</p> <p style="margin-left: 20px;">Admission date: ___ / ___ / ___</p> <p style="margin-left: 40px; text-align: center;"><i>DD MM YYYY</i></p> <p><input type="checkbox"/> Outpatient</p> <p style="margin-left: 20px;"><input type="checkbox"/> Emergency department (non-admitted patients)</p> <p style="margin-left: 20px;"><input type="checkbox"/> Outpatient area (excluding ER)</p>
Appendix 2,3 and 4	<p>Q8-Responses revised to:</p> <p><input type="checkbox"/> Healthcare-associated (acquired in any other healthcare facility³)</p> <p style="margin-left: 20px;"><input type="checkbox"/> Related to other acute-care facility</p> <p style="margin-left: 20px;"><input type="checkbox"/> Related to a psychiatric facility</p> <p style="margin-left: 20px;"><input type="checkbox"/> Related to a rehabilitation facility</p> <p style="margin-left: 20px;"><input type="checkbox"/> Related to a LTCF</p> <p style="margin-left: 20px;"><input type="checkbox"/> Unknown</p> <p><input type="checkbox"/> Healthcare-associated but unable to determine which facility</p> <p><input type="checkbox"/> Community-associated</p> <p style="margin-left: 20px;"><input type="checkbox"/> Did the patient have a previous hospitalization in the previous 1 year?</p> <p style="margin-left: 40px;"><input type="checkbox"/> Yes</p> <p style="margin-left: 40px;"><input type="checkbox"/> No</p> <p style="margin-left: 40px;"><input type="checkbox"/> Unknown</p>
Appendix 2,3 and 4	<p>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?)</p>

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	<ul style="list-style-type: none"> • Diagnostic test date is used as a reference date to determine the severe outcomes or recurrent CDI status • Other minor wording changes for clarification