AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Implementation Guide for the Surveillance of *Clostridioides difficile* Infection

August 2024

Published by the Australian Commission on Safety and Quality in Health Care

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ISBN: 978-1-922880-19-2 - *Implementation Guide for surveillance of Clostridioides difficile Infection 2020* (electronic format)

The Commission's preference is that you attribute this publication (and any material sourced from it) using the following citation:

> Australian Commission on Safety and Quality in Health Care. Implementation Guide for the Surveillance of *Clostridioides difficile* infection. Sydney: ACSQHC; 2020

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Version control

Date	Version	Comments
July 2020	Version 1.0	Original publication
March 2021	Version 1.1	Revision of Flowchart 3.1
January 2023	Version 1.2	Revision of Section 4, Updated Public health laboratory network CDI laboratory definition
August 2023	Version 1.3	Revision of reference list and intext referencing - ACIPC/ASID position Statement (2019) rescinded in August 2023
July 2024	Version 1.4	Update of Case definition, Criterion B1to include toxin gene(s). Addition of footnote for case definition, page 2.

1. Introduction

Clostridioides difficile infection* (CDI) is a serious gastrointestinal disease caused by toxins produced by the spore-forming bacterium *Clostridioides difficile*. CDI is associated with prolonged and unnecessary use of broad-spectrum antimicrobials, hospitalisation, advanced age and underlying morbidity.[1]

In the clinical setting, CDI is spread between individuals via the contact transmission route.[2] CDI produces symptoms ranging from mild diarrhoea to hyper-inflammation and necrosis of the gut lining.[1,2,3] Patients who acquire CDI may stay in hospital up to three times longer than a patient without CDI.[4] Approximately 20% of patients with an initial infection will have at least one recurrent episode of symptomatic infection, usually within 21 days of the initial episode.[5]

The implementation of standard and contact precautions, effective antimicrobial stewardship and infection surveillance systems may reduce the rate of CDI. Surveillance for CDI is well established in most Australian states and territories. The surveillance of hospital-identified CDI is not designed to be utilised as a hospital performance measure or to compare rates between hospitals; it is an indicator of the burden of CDI in the patient population presenting to a hospital, and captures both community and healthcare-associated events.

Continuous ongoing surveillance of CDI in hospitals is an important quality improvement activity that contributes to safer care for patients, and informs strategies to improve practice and minimise preventable CDI. *C. difficile* infections are included in the Hospital-Acquired Complications (HACs) list, which has been endorsed by all Australian Governments as part of a commitment to improving health outcomes for patients, and decreasing potentially avoidable demand for public hospital services.

Hospital-Acquired Complications data is utilised for the calculation of National Health Reform Agreement funding for states and territories. For more information on the national health reform funding, see www.publichospitalfunding.gov.au/public-hospital-funding/funding-formula.

This guide is intended to be used by Australian hospitals and health service organisations to support implementation of surveillance of hospital-identified CDI and national reporting.

This guide is not intended to replace clinical assessment of infection for patient management. This guide does not include any detail relating to transmission of infection within a hospital or outbreaks associated with CDI.

The target audience for this guide includes clinicians, health service organisations, infection control practitioners, and quality and safety managers who are responsible for CDI surveillance and infection prevention and control.

This guide supersedes the *2013 Implementation Guide for Surveillance of Clostridium difficile Infection*. The CDI case definition (Box 1) in this guide has been adapted from the 2020 US Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network Patient Safety Manual and the 2021 Public Health Laboratory Network (PHLN) *Clostridioides difficile* Infection Laboratory case definition.[6,7]

* *Clostridioides difficile*, previously known as *Clostridium difficile*. Also known as *C. difficile*, *C.diff*, CDI.

Box 1: Case definition for hospital-identified *Clostridioides difficile* infection

A hospital-identified CDI case is a case of CDI identified for a patient attending a hospital (including positive specimens obtained from admitted patients and those attending the emergency department and outpatient departments). This does not mean the case of CDI is attributed to or acquired at the hospital conducting the surveillance.

A case of CDI implies that the patient has the relevant clinical manifestations and must meet either 1) **Criterion A** *and* either **Criterion B1 or B2**, or 2) **Criterion A** and **Criterion C**:

	A	B1	B2	C
Is a case of hospital-identified CDI	√	√		
	√		√	
	√			√
Not a case of hospital-identified CDI		√		
			√	
				√

Criterion A: Diarrhoea (usually defined as three or more loose stools in a 24-hour period) or, less commonly, ileus, toxic megacolon or pseudomembranous colitis (identified by colonoscopy).[7,8]

AND EITHER

Microbiological evidence of toxin-producing *C. difficile* from at least **one** of the following criteria:

Criterion B1: Positive laboratory test result for *C. difficile* toxin A and/or B or toxin gene(s)* tested on an unformed (diarrhoea) stool specimen.[6,7,8]

OR

Criterion B2: A toxin-producing *C. difficile* organism detected by culture or other laboratory means performed on an unformed stool sample.[6,7,8]

OR

Criterion C: Patient has evidence of pseudomembranous colitis on gross anatomic (includes endoscopic exams) or histopathologic exam.[6,7,8]

Exclusions:

- Cases where a known previous positive test has been obtained within the last eight weeks
- Patients less than two years old at date of admission.[8]

See **Appendix 1** for application of the case definition.

*CDI toxin refers to the actual toxic substance produced by *C. difficile*, which is responsible for causing damage and symptoms during infection.
Toxin gene refers to the DNA sequence that encodes for these toxins, providing the genetic instructions for their production.

2. Classification of *Clostridioides difficile* infection

2.1 Hospital-identified *Clostridioides difficile* infection

The hospital-identified CDI case definition reflects the burden of CDI disease identified at an individual hospital. This definition may include cases of CDI that are associated with care provided at another hospital or in the community. The number of cases captured by applying this definition will vary between hospitals, depending on referral patterns and the local epidemiology of CDI.

2.2 Optional Surveillance

Surveillance of attribution, exposure or severity should be considered by hospitals, healthcare organisations and state and territories according to priority, local risk assessment and the capacity to categorise cases with greater certainty. These programs will require individual patient review that may include clinical data such as history of symptom onset, or clinical risk factors for CDI. This can be time consuming, but will allow more detailed assessment and analysis of CDI rates.[6]

2.2.1 Healthcare-associated CDI

Healthcare-associated infections (HAI) are defined as infections that develop at least 48 hours after admission to or contact with a healthcare facility or within 48 hours of discharge or transfer to another facility. Cases of CDI can be associated with healthcare provided at the hospital where the specimen was collected or may occur in the community from an unknown source.[9] Hospitals and states and territories can perform more detailed healthcare-associated/community-associated case classification by collecting data on the time of symptom onset and specimen collection. This level of CDI case review will help to identify whether CDI cases are associated with healthcare provided at an individual hospital.

The origin of a hospital-identified CDI case can be further classified by where a patient may have been initially exposed to the infection. CDI case exposure classification surveillance is recommended if the hospital-identified CDI rate is comparatively high or is noted to be increasing. Alternatively, CDI case exposure classification surveillance could be conducted for a target period on a regular basis (for example, three months each year) as part of a surveillance plan.

2.2.1.1 CDI case exposure classification definitions

These definitions reflect international expert consensus on the categorisation of CDI cases associated with healthcare.[10] Review of an individual's clinical history is required to apply these definitions.

A. Healthcare-associated healthcare facility (HCF)-onset CDI:

A patient classified as having healthcare-associated HCF-onset CDI is a patient with CDI symptom onset (or date and time of stool specimen collection if a laboratory system is used) more than 48 hours after admission to a healthcare facility.

B. Healthcare-associated community-onset CDI:

A patient classified as having healthcare-associated community-onset CDI has CDI symptom onset (or date and time of stool specimen collection if a laboratory system is used) in the community, or within 48 hours of admission to a healthcare facility, provided that symptom onset was less than four weeks after the last discharge from a healthcare facility.

C. Community-associated CDI:

A patient classified as having community-associated CDI has CDI symptom onset (or date and time of stool specimen collection if a laboratory system is used) in the community or within 48 hours of admission to a healthcare facility, provided that symptom onset was more than 12 weeks after the last discharge from a healthcare facility.

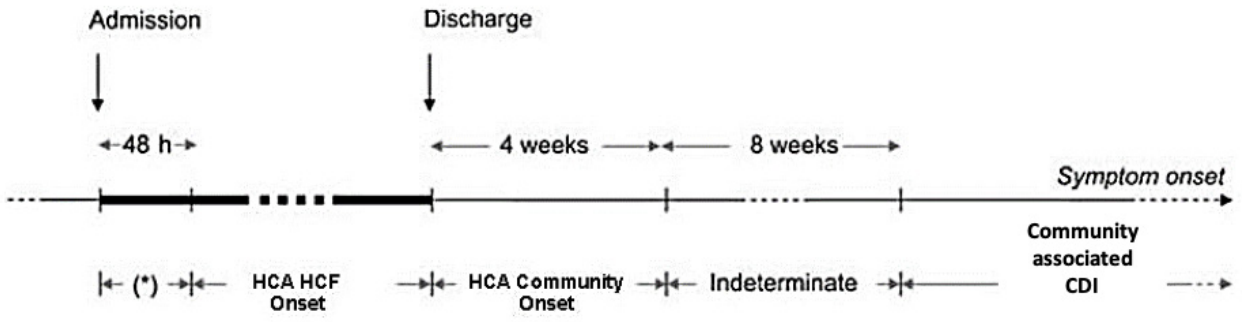
D. Indeterminate onset CDI:

A patient classified as having indeterminate onset of CDI exposure is defined as a patient that does not fit any of the above criteria for exposure setting (for example, onset in the community but within four and 12 weeks of discharge from a healthcare facility).

E. Unknown:

Exposure setting cannot be determined because of a lack of data.

Figure 1: Timeline for onset of *Clostridioides difficile* infection*



* Adapted from European Centre for Disease Prevention and Control. European Surveillance of *Clostridium difficile* infections. Surveillance protocol version 2.3. Stockholm: ECDC; 2017

Figure 1 shows the application of definitions in relation to the timing of the onset of symptoms and or timing of stool specimen collection.

Facilities that use the CDI case exposure classification definitions should define whether healthcare exposure will be limited to only the healthcare facility that is performing the surveillance or will include other healthcare facilities from which patients may be admitted, such as other acute care hospitals or residential care facilities. This information should be clearly stated when events and rates are reported. Rates should be calculated and tracked independently for each onset type.

2.2.2 Severe disease surveillance

Surveillance and reporting of severe CDI may be included as part of optional CDI surveillance. This information may help to identify changes in the characteristics of at risk patient groups or the evolution of different strains of *C. difficile*.[7,8] If there is evidence of hypervirulent or epidemic strains of *C. difficile*, surveillance of severe CDI is recommended for hospitals and at the jurisdictional level. Detection and monitoring of cases of severe CDI is an important prevention and control strategy that enables early detection of such strains.

For surveillance, a case of severe CDI is defined as a patient with CDI who meets any of the following criteria within 30 days of symptom onset:

- History of admission to an intensive care unit for complications associated with CDI (for example, shock that requires vasopressor therapy)
- History of surgery (for example, colectomy) for toxic megacolon, perforation or refractory colitis
- Death caused by CDI within 30 days after symptom onset.

Implementation of severe disease surveillance will require individual case review at 30 days and/or reliable linkages with the intensive care unit and surgical staff. The decision to investigate and report on severe disease should be made at a local level, based on the local experience with severe CDI.

2.2.3 Recurrent CDI

Recurrent CDI is defined as an episode of CDI that occurs within eight weeks or less after the onset of the initial CDI episode, regardless of whether the initial episode resolved with or without therapy.

A recurrent case should not be included in the hospital-identified CDI case definition and calculation; only the initial episode should be reported. Reporting and investigation of recurrent CDI will require individual case review of each reported positive CDI result to identify if the patient has recurrent disease. The decision to investigate and report on recurrent disease should be made at a local level based on the local experience with recurrent CDI.

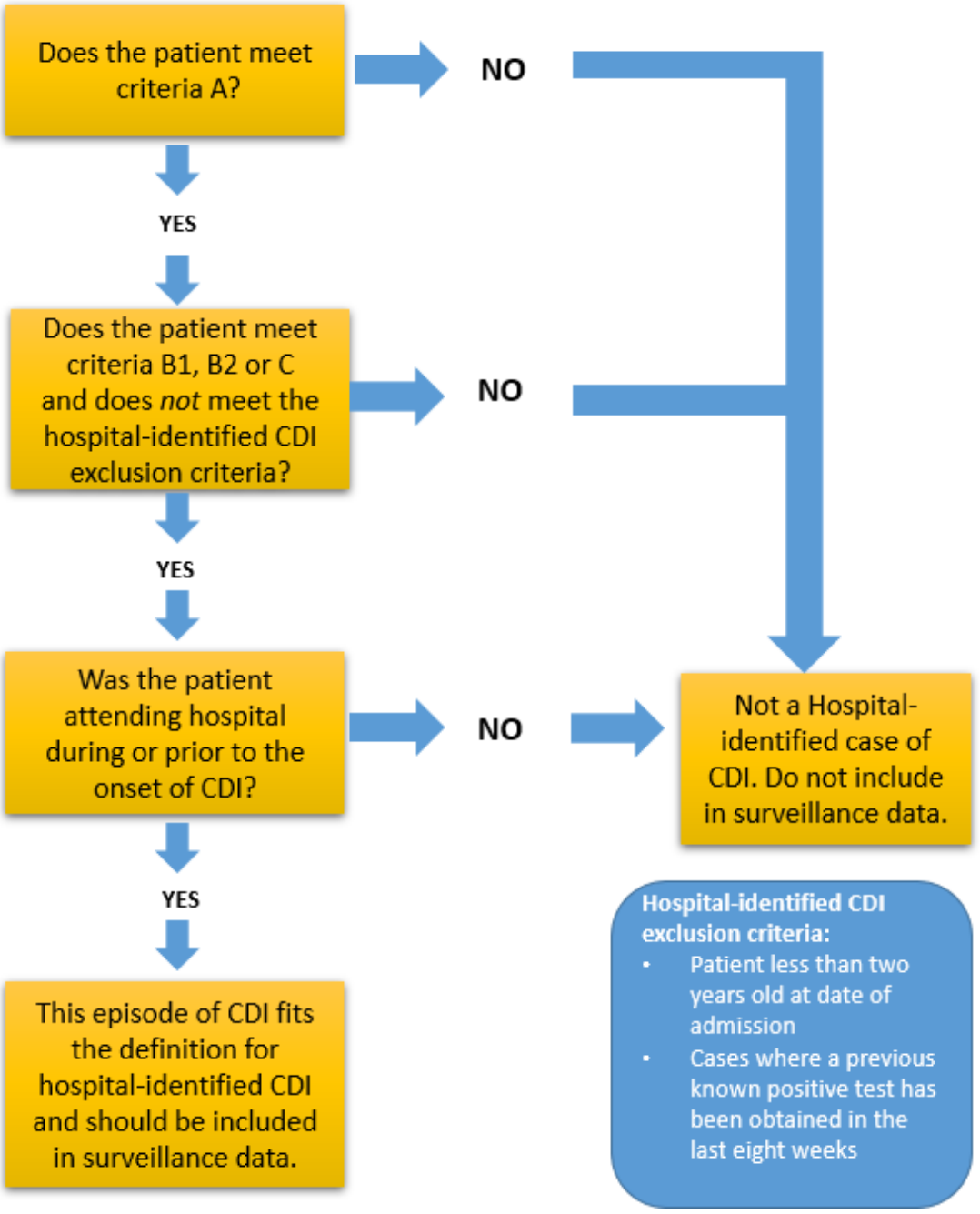
To exclude recurrent CDI, there should be an eight week delay in finalising case numbers and rates for the reporting period.

3. Application of the CDI case definition

3.1 Flowchart for determining a hospital-identified CDI case

New text to include in guide above flow chart

This flow chart has been developed to assist staff undertaking HAI surveillance to identify potential Hospital Identified-CDI (HI-CDI) cases. In the hospital setting, a laboratory notification of a positive *C. difficile* result is often the first alert that staff undertaking HAI surveillance receive about a new case of CDI. The HI-CDI case definition should be applied to determine if the case should be included in local surveillance data.



3.2 Exclusions from the CDI case definition

Patients under two years of age.

The exclusion of patients under two years of age from testing for *C. difficile* is consistent with the Public Health Laboratory Network (PHLN) guidance[7] and international CDI surveillance recommendations.[9] These recommendations reflect the common asymptomatic carriage of *C. difficile* in infants. While *C. difficile* can be a cause of disease in this age group, and may require treatment, such cases should not be included in surveillance programs.[7]

Duplicate positive tests within eight weeks.

Repeat testing within the same episode of CDI is of limited value, and repeat testing within 4 weeks of a positive test is not recommended.[9] Repeat testing generally occurs if patients present to multiple healthcare providers.

Hospitals and jurisdictions that cannot reliably exclude duplicate specimens may report higher CDI rates. The process of identifying and resolving duplicates in situations where more than one laboratory may perform tests should extend as far back as possible and practical, taking into account local infrastructure and resources. The following factors should also be considered:

- Each hospital, as a minimum, should have reliable systems in place to ensure that recurrent positive tests for the same patient by their major referral laboratory are not reported multiple times within an eight week period. This may be able to be done automatically by the laboratory
- Each coordinating surveillance organisation (such as state or territory surveillance units), should collect raw data directly from some/all private and public microbiology laboratories serving a population, exclusion criteria should be applied to the entire available dataset
- Where a coordinating surveillance organisation collects data from multiple hospitals that have applied exclusion criteria only at the level of a single hospital, they should take all practical steps to exclude duplicates; for example, by collecting patient identifying information.

Appendix 2 provides further examples on how to identify and remove duplicate positive CDI results for the same patient.

3.3 Application of healthcare- associated community-onset case definition

Surveillance of healthcare-associated community-onset CDI cases should only be performed in addition to reporting of healthcare-associated healthcare facility onset CDI cases.

Healthcare-associated community-onset cases should:

- Be attributed to the reporting period during which the case patient was discharged from the healthcare facility before CDI symptom onset. For example, if a patient was discharged on 28 May and was readmitted with CDI on 10 June, the case should be assigned to the month of May
- Include cases where CDI symptom onset occurred in the community or within 48 hours of admission to a healthcare facility, with the last discharge from a healthcare facility being less than four weeks ago. In this case, the CDI could be attributed to the healthcare facility from which the patient was last discharged, providing the patient was an inpatient of that healthcare facility for more than 48 hours.[10]

Cases of healthcare-associated community-onset CDI may also include cases where a person has developed CDI secondary to antimicrobial treatment as an outpatient. If the CDI is found to be attributed to care received in a non-inpatient setting, it should be reported as such.

For example, outpatient renal dialysis or community health service. This would not include patients who develop CDI more than 12 weeks after the last discharge from a healthcare facility (this would be considered community associated CDI). This level of surveillance will require individual case review to determine the correct case classification.

4. Specimen collection and testing

4.1 Appropriate specimens for CDI testing and specimen description

The PHLN recommends unformed faecal specimens, rectal swab or intestinal contents as suitable specimens for *C. difficile* testing.[7] Liaison with local laboratories may be required to establish correct interpretation of this description. If the local laboratory only tests stool that matches this description, all positive toxin or gene tests will fulfil the criteria for classification as a case of CDI.

While it is recommended that formed stools should not be tested for *C. difficile*, laboratory practices do vary and on occasion, a formed stool may be tested. In this case, a positive toxin or gene detection test will not fulfil the case definition and CDI rates may be overestimated.

The use of rectal swabs or intestinal contents for CDI testing should be considered in the context of the individual patient. The decision to use these types of specimens for CDI testing should be made with both medical and laboratory input.[7]

4.2 Diagnostic laboratory testing methods

The PHLN provides standardised guidance on testing methods for *C. difficile* detection.[7] The PHLN laboratory case definition for CDI recommends that CDI diagnosis be based on a combination of rapid tests for the detection of both toxins A and B, and toxigenic culture to identify strain types for extended surveillance purposes.[7] Laboratories should refer to local clinical practice guidelines for CDI diagnosis and laboratory results should be interpreted together with a patient's clinical symptoms.[7]

Accurate laboratory diagnosis of CDI ensures that patients receive appropriate treatment and correct infection prevention and control measures are put in place. Inaccurate testing has implications for the patient and the hospital. False-positive results lead to unnecessary treatment and isolation. False-negative results may lead to cross-infection of other patients.

Inaccurate testing will also potentially lead to poor quality surveillance data. Individuals with accountability for the interpretation of CDI rates, particularly for comparison of rates over time, should be aware of the performance characteristics of tests that are used locally.

4.3 Implications of varying laboratory testing methods for *C. difficile*

Surveillance results for CDI will be affected where there are variations in hospital specimen collection and laboratory test selection protocols. Hospitals, states and territories in which a higher proportion of patients at risk receive *C. difficile* testing will potentially report higher CDI rates than those in which few patients are tested. The following actions are recommended to improve the validity of surveillance data:

- *C. difficile* testing of the stool of all patients with potential infective diarrhoea that lasts longer than 48 hours and tests negative for common enteropathogens
- *C. difficile* testing of the stool of all patients with diarrhoea who have been hospitalised for longer than 72 hours, irrespective of physician's request
- Any patient who has three episodes of diarrhoea within 24 hours should be tested for CDI.[7,8]

5. Calculation of CDI Rates

The surveillance of hospital-identified CDI will enable healthcare facilities to identify episodes of infection, identify local problems and implement strategies and interventions to improve patient care.[11]

5.1 Denominator

The recommended denominator for calculating rates of healthcare-associated infections in Australian healthcare facilities is patient days. Reporting periods can vary from monthly to quarterly or annually, depending on local incidence and reporting requirements. Patient days are calculated by counting the total patient days of those patients separated during the specified period, including those admitted before the specified period. Patient days of those patients admitted during the specified period who did not separate until the following reference period are not counted.[12] For example, Patient A is admitted on 20 January and discharged on 20 February. Patient A generates zero patient days in the hospital's January record, and 31 patient days for February (11 days from the January period of the separation, and 20 days in February).

5.2 Calculation of hospital- identified CDI rate

The calculation of the hospital-identified CDI rate is as follows:

Numerator:	Patient episodes of hospital-identified CDI	X 10,000
Denominator:	Patient days at the hospital (including same-day admissions)	

It is acknowledged that when rates of events are calculated the denominator would normally be representative of the population from which the numerator is collected. In the case of hospital-identified CDI surveillance, this is not strictly the case. All cases of CDI presenting to hospitals are reported (including those originating in the community) while the denominator used is patient days (see Appendix 3 for examples on how to calculate rates of CDI).

The hospital-identified CDI rate should not be seen as rates of healthcare-associated CDI but can be used to compare CDI rates broadly over time and to identify local outbreaks of disease. This is an important assumption underpinning CDI surveillance.

The rate calculation can also be applied to wards, units, hospitals, districts, regions or jurisdictional levels as desired, and the numerator and denominator can be adjusted to aid analysis and interpretation as appropriate for specific settings (for example, to calculate rate for medical or surgical patients only, rates for teaching hospitals only etc.).

Hospitals and jurisdictions should calculate and monitor their CDI rates over time in line with their HAI surveillance plans. Reporting periods could vary from monthly to quarterly or annually depending on local incidence and reporting requirements. Appendix 3 provides an example of how to calculate hospital-identified CDI rates.

5.3 Calculation of the proportion of severe disease

For hospitals monitoring severe disease, the total CDI cases in the reporting period that were severe should be expressed as a proportion of the total number of CDI cases in same reporting period.[8] The proportion of severe disease is calculated as follows:

Numerator:	Patient episodes of hospital-identified CDI with severe disease
Denominator:	Patient episodes of hospital-identified CDI (total hospital CDI cases)

This proportion can be measured over years, months, weeks or days for a healthcare facility (see Appendix 3 for examples on how to calculate rates of severe disease). This information may be useful to monitor the local epidemiology of CDI.

Appendix 1: Application of hospital-identified CDI definition

A hospital-identified CDI case is a case of CDI identified for a patient attending a hospital (including positive specimens obtained from admitted patients and those attending the emergency department, and outpatient departments). This does not mean the case of CDI is attributed to or acquired at the hospital conducting the surveillance.

A case of CDI implies that the patient has the relevant clinical manifestations and must meet either 1) **Criterion A** *and* either **Criterion B1 or B2**, or 2) **Criterion A and Criterion C**:

Criterion A: Diarrhoea (usually defined as three or more loose stools in a 24 hour period) or, less commonly, ileus, toxic megacolon or pseudomembranous colitis (identified by colonoscopy).

AND EITHER:

Microbiological evidence of toxin-producing *C. difficile* from at least **one** of the following criteria:

> **Criterion B1**: Positive laboratory test result for *C. difficile* toxin A and/or B or toxin gene(s) tested on an unformed (diarrhoea) stool specimen
>
> ***OR***
>
> **Criterion B2**: A toxin-producing *C. difficile* organism detected by culture or other laboratory means performed on an unformed stool sample
>
> ***OR***
>
> **Criterion C**: Patient has evidence of pseudomembranous colitis on gross anatomic (includes endoscopic exams) or histopathologic exam.

Examples of CDI diagnosis that meet HI-CDI definition

A patient **must** meet Criterion A and either Criterion B1, B2 or C to meet the definition of HI-CDI.

For example:

1. The patient has had a history of three episodes of diarrhoea in a 24 hour period (**Criterion A**)

   and

   The stool (diarrhoea) specimen is positive for *C. difficile* toxin A (**Criterion B1**)

2. The patient has had more than eight episodes of diarrhoea in 2 days (**Criterion A**)

   and

   The patient has had a colonoscopy which showed evidence of pseudomembranous colitis (**Criterion C**)

Examples of CDI that do *not* meet the HI-CDI definition

1. The stool specimen is positive for *C. difficile* toxin A (**Criterion B1**) but the patient has had no diarrhoea
2. Patient has had diarrhoea (**Criterion 1**) but laboratory specimen is negative for toxin A and B and negative for toxin gene(s).

Appendix 2: Identifying and removing duplicated positive CDI results for the same patient

a) A patient has had positive *C. difficile* specimens collected at two separate hospitals on the following dates. Each hospital has applied the exclusion criteria based on their own testing results and had submitted data (in bold) to the jurisdiction:

- Hospital A – **1 January**, 3 February, **10 April**
- Hospital B – **25 February**, 2 April

Cases reported to the state were from 1 January (Hospital A), 25 February (Hospital B), and 10 April (Hospital A). If the jurisdiction did not remove duplicate cases, they would count three cases of CDI. However, with access to the entire testing history of this patient, with positive tests on 1 January, 3 February, 25 February, 2 April, and 10 April, only the 1 January result should be included – that is, only one event.

b) When a jurisdiction examining an entire data set from multiple laboratories identifies a sample from the same patient within eight weeks of a previous sample (even if the samples are identified in different hospitals/laboratories), the duplicate sample will be excluded.

c) Hospital A supplies a jurisdiction with CDI data, excluding duplicates within eight weeks from a single laboratory. The jurisdiction's surveillance body should develop a system to review whether the same patient has had a positive sample identified in a different hospital within eight weeks of the sample being identified by Hospital A. If so, the case should be removed.

Appendix 3: Examples of calculations for CDI surveillance

Example 1: Calculation of hospital-identified CDI

Numerator: patient episodes of hospital-identified CDI (total hospital CDI cases) x 10,000

Denominator: Total patient days (including same day admissions)

Numerator: 7 X 10,000

Denominator: 10,750

= rate of hospital-identified CDI of 6.5 cases per 10,000 patient days

Example 2: Calculation of the proportion of severe disease

Numerator: Patient episodes of hospital-identified CDI-severe disease

Denominator: Patient episodes of hospital-identified CDI (total hospital cases)

Numerator: 3

Denominator: 7

Proportion of total CDI cases with severe disease = 0.4

Glossary

Term	Definition
Clostridioides difficile	Gram-positive species of spore forming bacteria that can produce diarrhoea symptoms.[7]
Diarrhoea	Loose, watery stools that occur more frequently than usual. [7]
Healthcare-associated infection (HAI)	Healthcare-associated infections (HAIs) are infections that develop at least 48 hours after admission to or contact with a healthcare facility or within 48 hours of discharge or transfer to another facility.
Hospital-acquired complication (HACs)	Hospital-acquired complications (HACs) are adverse healthcare events that have been identified as originating during the patient's hospital stay and are not present when the patient is admitted. A HAC refers to a complication for which clinical risk mitigation strategies may reduce (but not necessarily eliminate) the risk of that complication occurring.
Hypervirulent strain	A variation in the strain of disease that increases in incidence, severity and morbidity or mortality. This may also include resistance to current or common treatment modalities. The variation may occur in binary toxin production, biofilm production, germination or sporulation.[7]
Patient days	Patient days are calculated by counting the total patient days of those patients separated during the specified period, including those admitted before the specified period. Patient days of those patients admitted during the specified period who did not separate until the following reference period are not counted. For example, Patient A is admitted on 20 January and discharged on 20 February. Patient A generates 0 patient days in the hospital's January record, and 31 patient days for February (11 days from the January period of the separation, and 20 days in February).
Pseudomembranous colitis	Inflammation of the large intestines secondary to bacterial infection with *Clostridioides difficile*.
Toxin	Chemical produced by the bacteria that causes damage to cellular structures causing systemic inflammation and damage to cells and body tissue.[7]
Unformed stool	Stool that takes the shape of a container (diarrhoea)[7]

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