

Australian Commission on Safety and Quality in Health Care

Implementation Guide for Surveillance of *Clostridium difficile* Infection

Consultation Edition



Acknowledgement

Members of the HAI Technical Working Group for the SAB Guide:

Helen Van Gessel –Western Australia

Rebecca McCann – Western Australia

Allison Peterson – Western Australia

Christine Cope – South Australia

Irene Wilkinson – South Australia

Brett Mitchell – Tasmania

Annie Wells –Tasmania

Bernadette Kennedy – Victoria

Lisa Hall – Queensland

Julie Gallard – Infection Prevention and Control Professional

Rosie Lee – Infection Prevention and Control Professional

Louise Cooley – Public Health Laboratory Network

Marilyn Cruickshank – ACSQHC

Sue Greig – ACSQHC

Elizabeth Hanley –ACSQHC

Kylie Willows – ACSQHC

Neville Board – ACSQHC

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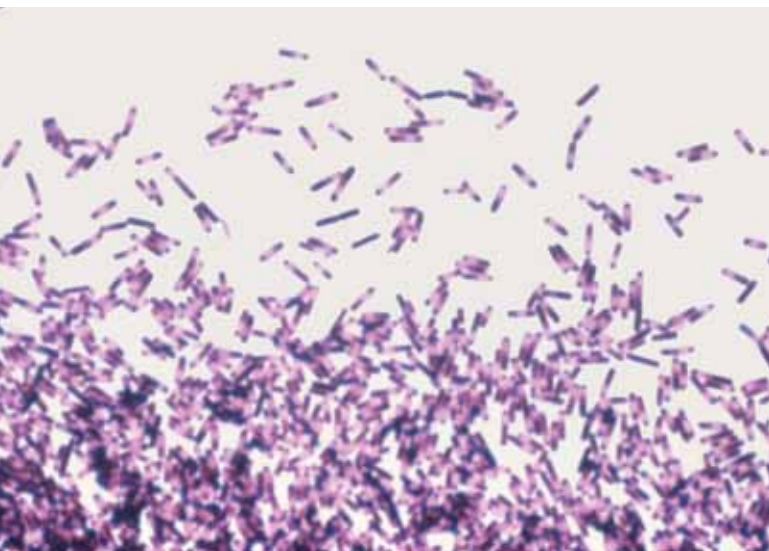
Introduction

Implementation Guide for Hospital Surveillance of *Clostridium difficile* Infection

The Implementation Guide for hospital surveillance of *Clostridium difficile* infection (CDI) has been produced by the Healthcare Associated Infection (HAI) Technical Working Group of the Australian Commission on Safety and Quality in Health Care (ACSQHC), and endorsed by the HAI Advisory Group. State jurisdictions and the ACSQHC have representatives on the Technical Working Group, and have had input into this document. (See acknowledgements on inside front cover)

The Guide is intended to be used by Australian hospitals and organisations to support the implementation of hospital-identified *Clostridium difficile* infection (CDI) surveillance using the endorsed case definition in the box below. **It has been produced to support consistency of surveillance activities and is not intended to replace clinical assessment of infection for patient management.**

As this is a Consultation Edition of the Guide, you are encouraged to provide comments or ask questions about the Guide. Please send your comments and questions to the email address provided and all comments and questions received will be responded to (See Appendix 3).



Case definition



hospital identified *Clostridium difficile* Infection

A CDI case is defined as a case of diarrhoea that meets the following criteria

- the stool sample yields a positive result in a laboratory assay for *C. difficile* toxin A and/or B, or
- a toxin-producing *C. difficile* organism is detected in the stool sample by culture or other means.

A hospital identified CDI case is:

- a CDI case diagnosed in a patient attending a hospital (that is, it includes positive specimens obtained from admitted patients and those attending the Emergency Department, and outpatient departments).

Exclusions

- Cases where a known previous positive test has been obtained within the last 8 weeks (that is, only include cases once in an 8 week period).
- Patients less than two years old at date of admission.

An additional positive test obtained from a specimen collected from the same patient more than 8 weeks since the last positive test is regarded as a new case.

This definition was recommended by the ACSQHC HAI Advisory Committee in 2009, and endorsed by jurisdictions in 2009 and 2010. It is also reflected in the HAI Data Set Specification developed by ACSQHC.

NOTE: The surveillance of hospital identified CDI is not designed as a hospital performance indicator but a measure of the burden of CDI in the patient population and has not been designed as a measure of performance or comparison between hospitals.

1. General background for CDI surveillance

- The national CDI case definition and calculation provided (see box above and Appendix 1) was developed by the HAI Advisory Committee of the ASQHC and was endorsed by all Australian Health Ministers in 2009.
- The case definition and calculation of hospital-identified CDI rates is primarily intended to apply to hospitals in jurisdictions across Australia as an indicator of the hospital burden of CDI disease.
- The case definition and hospital-identified CDI rate is intended to be able to be calculated from laboratory reports, and does not require individual patient review by a clinician.
- The decision to perform CDI surveillance over and above this minimum requirement (e.g. rates of CDI associated with healthcare, or calculation of rates of severe disease) should be considered by hospitals, organisations and jurisdictions according to priority, local risk assessment and the capacity to categorise cases correctly. Such programs will require individual patient review that may be time consuming, but will allow more detailed assessment and analysis of CDI rates. Criteria to support this additional monitoring are also contained in the document (see Appendix 2).
- As with all hospital-based infection surveillance, the responsibility for collection, analysis and reporting generally rests with hospital infection control teams. In many states, jurisdictional surveillance units provide support for these activities for at least some hospitals, and relevant manuals and material from such units should be used where appropriate.
- If inter-facility comparisons are to be made, they should be made using comparable case definitions. Differences in case mix, antibiotic usage, adherence to infection prevention and control recommendations, laboratory testing protocols and data quality will all impact on hospital-level CDI rates.

2. Application of the CDI case definition

2.1 Appropriate specimens for CDI testing and specimen description

When applying the definition for a case of diarrhoea, diarrhoeal stool is a specimen that “takes the shape of the specimen container”. This may require liaison with laboratories to establish correct interpretation of the varied specimen descriptions that are in local use. If the local laboratory only tests stool that matches this description, then all positive toxin tests will fulfil criteria for classification of a case as CDI.

While it is recommended that formed stools are **not** tested for *C. difficile*, laboratory practices vary, and on occasions, a formed stool will be tested. In this case, a positive toxin detection test will not fulfil the case definition.

If positive tests from formed stools are included as CDI cases, then CDI rates may be overestimated.

2.2. Diagnostic laboratory testing methods

For detail regarding diagnostic test use, interpretation and performance, readers are referred to the Australasian Society for Infectious Diseases (ASID) Position Paper on diagnosis and management of CDI (MJA 2011; 194 (7): 353–358).⁹ A variety of methods are in use in Australian laboratories for routine detection of CDI, with varying levels of sensitivity and specificity.

Accurate laboratory diagnosis of CDI ensures that patients receive appropriate treatment and correct infection control measures are put in place.¹⁰ Inaccurate testing has implications for patients and the hospital. False-positive results lead to unnecessary treatment and isolation. False-negative results may lead to cross-infection to other patients.

Inaccurate testing will also potentially lead to poor quality surveillance data. Individuals with accountability for interpretation of CDI rates, particularly if using for comparison of rates over time or between facilities, should be aware of the performance characteristics of tests in local use.

If tests that are in local use have suboptimal sensitivity, then CDI rates may be underestimated.

2. Application of the CDI case definition (continued)

2.3. The implications of varying laboratory *C. difficile* test selection policies for CDI surveillance

There are variations in hospital specimen collection and laboratory test selection protocols that will also influence CDI surveillance results.

Consensus recommendations from Australian experts⁹ are generally consistent with European recommendations² and support the following:

- CDI testing of the stool of all patients with potential infective diarrhoea that lasts longer than 48 hours and negative tests for common enteropathogens
- CDI testing of the stool of all patients with diarrhoea who have been hospitalised for longer than 72 hours, irrespective of physician's request.

Actual practice varies widely (e.g. the rate of CDI testing of inpatient stools varied from 20% to 88% in Western Australia in 2006³) and varying compliance with the above recommendations is likely to continue.

Hospitals or jurisdictions in which a higher proportion of patients at risk receive CDI testing will potentially report higher CDI rates than those in which few patients are tested.

3. Hospital identified CDI case classification

- The case definition is congruent with that used in international CDI surveillance programs.
- The case definition does not require cases to be investigated to ascertain whether they are healthcare associated or not.
- Admitted patients or those attending the emergency department and outpatients departments at the time a specimen is collected will be included as a hospital identified CDI case according to this definition. This reflects the limitations of some laboratory information systems, better reflects the burden of CDI disease on a hospital, removes the need for individual case review, and for allocating CDI cases to other hospitals.
- While the majority of these CDI cases will be associated with healthcare provided at the hospital performing the testing, the "hospital identified CDI case" definition will include some cases that are associated with care provided at another hospital or in the community. The size of this effect is likely to vary between hospitals depending on referral patterns, but less so between jurisdictions.
- Hospitals and jurisdictions could evaluate the magnitude of this effect by performing more detailed healthcare associated / community associated case classification as described below and by ensuring data on the location of specimen collection is obtained.

Hospitals or jurisdictions in which a higher proportion of hospital identified CDI cases are not associated with healthcare provided at those hospitals or jurisdictions, will potentially report higher CDI rates. The size of this effect is likely to be small (less than 5% of cases).



4. Exclusions from the CDI case definition

4.1 Patients under 2 years of age

- Exclusion of patients under 2 years of age is consistent with international CDI surveillance recommendations, and reflects 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.
- Further information is contained in the ASID position paper.⁹

4.2 Duplicate positive tests within 8 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 However, repeat testing does occur, particularly if patients present to multiple healthcare providers.

The extent of look-back to previous positive tests for the same patient within 8 weeks should be determined by the jurisdictions and hospitals according to their infrastructure and resources. The process of identifying and resolving duplicates in the situation where more than one laboratory may perform tests should extend as far as possible and practical, however the following recommendations apply:

- As a minimum, each hospital should have reliable systems in place to ensure that recurrent positive tests tested at their major referral laboratory from the same patient are not included multiple times within an 8 week period. This may be able to be done automatically by the laboratory.
- If coordinating surveillance organisations (e.g. jurisdictional surveillance units) can collect raw data direct from some / all private and public microbiology laboratories serving a population, they should apply exclusion criteria to the entire available data set.

Example

Consider the scenario below. Dates provided are all collection dates of all positive samples from the same patient collected at two hospitals. **The hospitals have applied the exclusion criteria based on their own testing results and had submitted data (in bold) to the jurisdiction.**

- **Hospital A** – 1st Jan, 3rd Feb, 10th April
- **Hospital B** – 25th Feb, 2nd April

Cases actually reported to jurisdiction:

- 1st Jan (hospital A), 25th Feb (hospital B), 10th April (hospital A)

If the jurisdiction did not remove duplicate cases, they would count three CDI events. However, with access to the entire testing history of this patient, with positive tests on 1st Jan, 3rd Feb, 25th Feb, 2nd April, 10th April, only the 1st Jan should be included i.e. one event.

Therefore de-duplicating at the jurisdictional level in general will reduce over-reporting.

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

- Where a coordinating surveillance organisation collects data from multiple hospitals who have applied exclusion criteria only at the level of a single hospital, such units should take all practical steps to exclude duplicates by for example collecting patient identifying information.

Example: Hospital A supplies a jurisdiction with CDI data excluding duplicates within 8 weeks within a single laboratory. The jurisdictional surveillance body should develop a system to review whether the same patient has had a positive sample identified in a different hospital within 8 weeks of the sample being identified by Hospital A. If so, the case should be removed.

Hospitals or jurisdictions that cannot reliably exclude duplicate specimens may report higher CDI rates. The size of this effect is likely to be small (less than 10% of cases).

5. Surveillance of severe CDI

The issue of hypervirulent /epidemic *C. difficile* strains in Australia is discussed further in the Australasian Society for Infectious Diseases' Position Paper on diagnosis and management of CDI.⁹ Microbiology laboratories and surveillance groups should keep up to date with evolving CDI epidemiology locally and internationally, and have protocols to access *C. difficile* typing where appropriate to confirm strain type. Hospitals, organisations and jurisdictions should have agreed protocols for identification and response to increases in local incidence and severity of CDI. This should include outbreak investigation procedures, protocols to guide referrals for strain typing, and processes to communicate with associated healthcare facilities and relevant jurisdictional bodies as required.

CDI disease severity is known to vary from mild to severe and life threatening. Where hypervirulent / epidemic strains such as NAP1 / O27 / BI have emerged, in general there have been increases in CDI rates and in the proportion of CDI cases that are severe. Detection and monitoring of cases of severe CDI is therefore an important prevention and control strategy that is recommended to allow early detection of such strains. While there are clinical

criteria for severity of CDI (see Appendix 2) that are intended to act as a guide to management for clinicians, the three surveillance criteria for severe CDI below are appropriate for continuous monitoring within an ongoing HAI surveillance program.

Hospital identified *C. difficile* case definition does not require differentiation between severe and non-severe cases. However, surveillance of severe CDI is recommended for hospitals and jurisdictions.

For surveillance, a severe case is defined as a CDI case patient 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 (e.g. for shock that requires vasopressor therapy)
- history of surgery (e.g. colectomy) for toxic megacolon, perforation or refractory colitis
- death caused by CDI within 30 days after symptom onset.

Implementation of such surveillance will require individual case review at 30 days and / or reliable linkages with ICU and surgical staff.

Calculation of incidence of severe disease

For hospitals monitoring severe disease, this should be expressed as the proportion of total CDI cases in the reporting period that were severe, against the total number of CDI cases in the reporting period.⁴ The raw numbers as well as the proportion should be reported to aid interpretation.

The proportion should be calculated each reporting period for each hospital as follows:

Numerator: $\frac{\text{Patient episodes of hospital identified CDI - severe disease}}{\text{Patient episodes of hospital identified CDI (total hospital CDI cases)}}$

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

The hospital-identified CDI rate reflects the per day patient risk of CDI. The rate will therefore be expected to vary with the proportion of the patients with CDI risk factors, the effectiveness of transmission prevention and control strategies including antibiotic stewardship and the characteristics of laboratory testing and de-duplication protocols described above.

6. Calculation and interpretation of hospital identified CDI rates

Principles of *Clostridium difficile* infection prevention include antibiotic stewardship, monitoring of incidence and outbreaks, appropriate use of contact precautions, accurate identification of infected patients, consistent hand hygiene and improved environmental cleaning.

The rate of CDI is an important indicator of safety and quality, and CDI is the object of national surveillance. Recently published international recommendations and a national definition support implementation of an appropriate surveillance program in Australia.

The following information will be used to calculate the rates of *C. difficile* infection (CDI) in each Australian hospital with acute inpatient beds:

Numerator

Patient episodes of hospital identified CDI (total hospital CDI cases)

Denominator

Total patient days (including same day admissions)

Exclusions

Cases where a known previous positive test has been obtained within the last 8 weeks (that is, only include cases once in an 8 week period).

Patients under 2 years old at date of admission in both numerator and denominator.

Notes for calculation and interpretation of hospital identified CDI rates:

1. 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.
2. However, the rate calculation can be applied to wards, units, hospitals, groups of hospitals or jurisdictions as desired, and the numerator and denominator can be adjusted to aid analysis and interpretation as appropriate for this analysis (e.g. calculate rate for medical or surgical patients only, rates for teaching hospitals only etc.).
3. 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 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. These rates, therefore, should not be seen as rates of healthcare associated CDI but can be used to compare broadly over time and to identify local outbreaks of disease – an important element of CDI surveillance.

This will be calculated as cases / 10,000 patient days for each hospital as follows:

Numerator: $\frac{\text{Patient episodes of hospital identified CDI (total hospital CDI cases)}}{10,000}$

Denominator: Patient days at the hospital (including same day admissions)

6. Calculation and interpretation of hospital identified CDI rates (continued)

6.1 Patient days

The recommended denominator for calculating monthly rates of HAI in Australian healthcare facilities is patient days.

Patient days is a national standard (<http://meteor.aihw.gov.au/content/index.phtml/itemId/181162>) defined in the national health data dictionary and used for national reporting. Occupied bed days is a term commonly used by some states to express a similar concept to patient days. However, there is no national standard for calculating occupied bed 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 January 20 and discharged February 20. Patient A generates 0 patient days in the hospital's January record, and 31 patient days for February (11 from the January period of the separation, and 20 in February).

The yearly variance between calculations of patient days and occupied bed days is minimal (less than 1%); however the monthly variation can be quite significant for smaller hospitals.

Contract patient days are included in the count of total patient days. If it is a requirement to distinguish contract patient days from other patient days, they can be calculated by using the rules contained in the data element: total contract patient days.

7. CDI case exposure classification – optional surveillance

The following classification reflects international expert consensus on categorisation of CDI cases associated with healthcare.⁴ Case review of individual cases is required to apply these definitions. These are optional for Australian hospitals to use as part of a comprehensive *Clostridium difficile* infection (CDI) surveillance program. Their use is particularly recommended if the hospital-identified CDI rate is comparatively high or increasing. Alternatively, this more intensive surveillance could be applied for a target period on a regular basis (e.g. 3 months each year) as part of a surveillance plan.

Note that the international nomenclature of “health care facility (HCF)” is used here to ensure consistency with the reference documents. Notes are provided at the end of this section that explains what is regarded by these authors as a HCF within these definitions. It may be appropriate and pragmatic for Australian facilities or jurisdictions to vary this operational definition (for example, not to include residential care facilities as a HCF) but this local interpretation of what a “HCF” is, should be clearly stipulated when events and rates are subsequently reported.

Further information including detailed background and rationale for reporting healthcare associated health care facility and community onset is provided in reference 4, and this should be referred to as a guide for consideration and use.

CDI case patients can be further classified by their exposure as follows:

A. Health Care Associated – Health care facility^{Note 1} (HCF) onset

A patient classified as having HCF-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 hour after admission to a health care facility.

B. Health Care Associated (HCA), community onset^{Note 2}

A patient classified as having HCA-associated community-onset CDI is defined as a patient with 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 health care facility, provided that symptom onset was less than 4 weeks after the last discharge from a health care facility.

7. CDI case exposure classification – optional surveillance (continued)

C. Community associated

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 health care facility, provided that symptom onset was more than 12 weeks after the last discharge from a health care facility. ^{Note 1}

D. Indeterminate onset

A patient classified as having indeterminate disease exposure is defined as a CDI case patient that does not fit any of the above criteria for exposure setting (e.g. onset in community but within 4 and 12 weeks of discharge from a health care facility).

E. Unknown

Exposure setting can not be determined because of a lack of data.

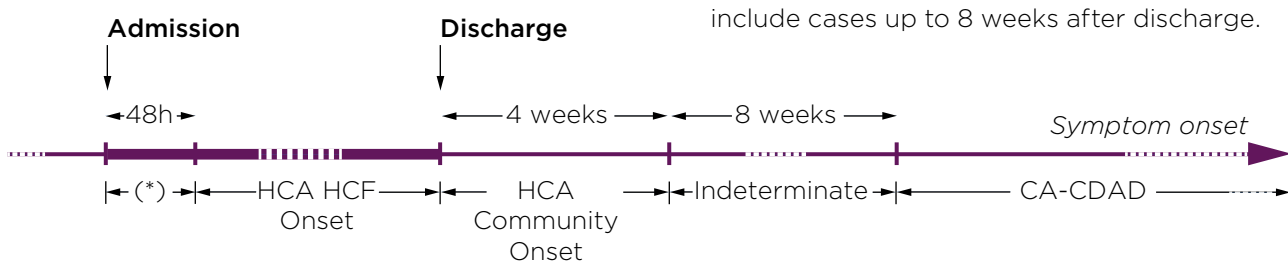
Recurrent CDI case patients can also be identified using the following definition:

Recurrent CDI case is an episode of CDI that occurs within 8 weeks or less after the onset of a previous CDI episode, provided that CDI symptoms from the earlier episode resolved with or without therapy.



Photo: Professor Thomas Riley, University of Western Australia

Recurrent cases are not included in the hospital identified CDI case definition and calculation.



Notes for CDI case exposure classification – optional surveillance

Note 1

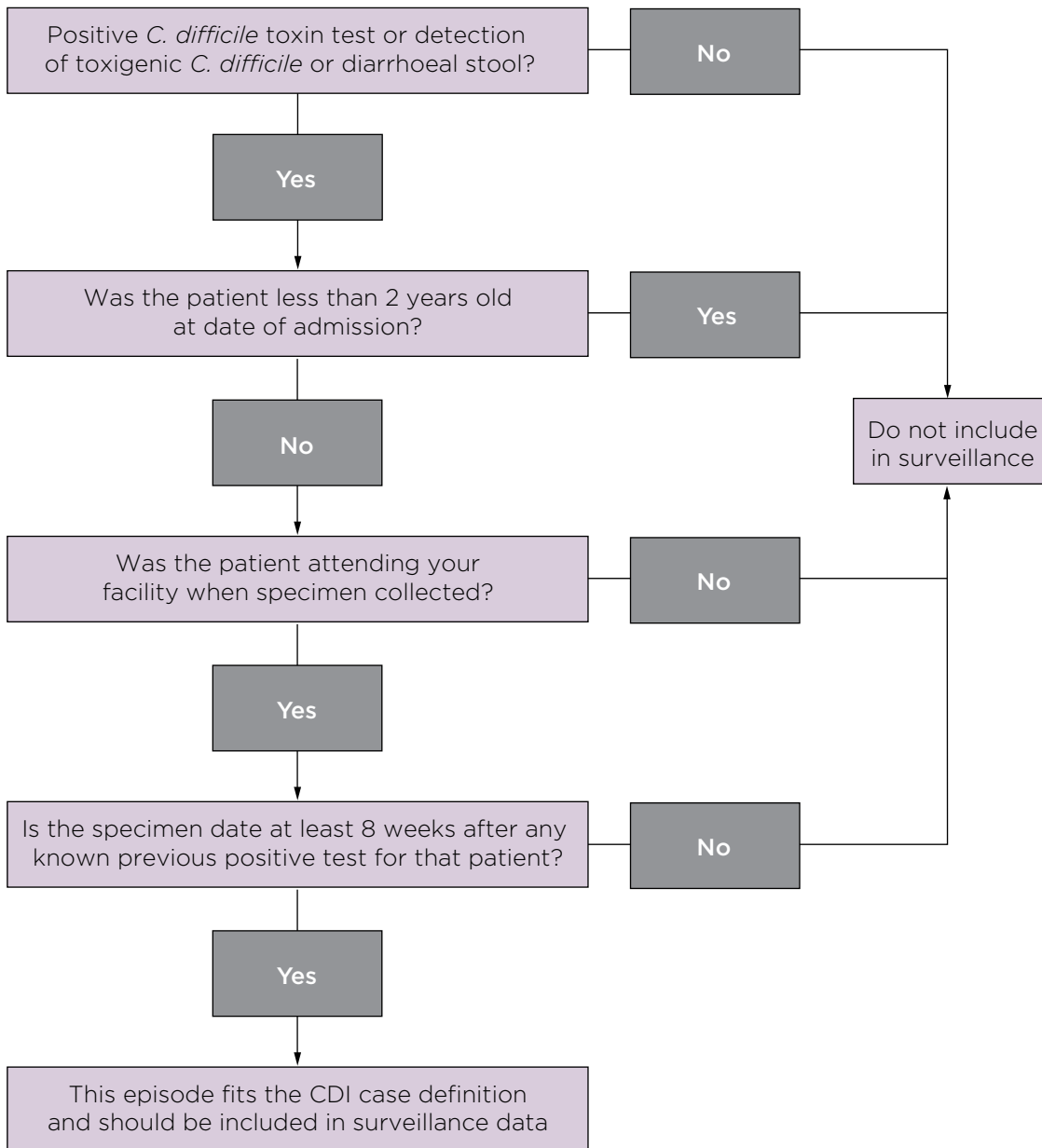
International recommendations define “health care facility” as any acute care, long-term care, long-term acute care, or other facility in which skilled nursing care is provided and patients are admitted at least overnight. This may not be appropriate to an Australian context, and the facilities using such a classification system should carefully define whether healthcare exposure is confined to the same hospital as reporting, to other acute care hospitals or whether residential care facilities are also included, and this information provided in any reports of rates.

Note 2 – Application of Healthcare Associated Community-onset Case Definition

Application of healthcare associated community-onset cases should:

- be attributed to the reporting period during which the case patient was discharged from the health care facility before CDI symptom onset. For example, if a patient was discharged on the 28th May and was readmitted with CDI on the 10th June, the case should be assigned to May.
- be attributed to the health care facility from which the patient was last discharged, providing the patient was an inpatient of that health care facility for more than 48 hours.
- only be performed in addition to reporting of healthcare associated health care facility onset.
- have rates calculated and tracked independently for each type of classification.
- allow for surveillance systems measuring community onset cases of healthcare associated CDI to have a 1-2 month delay in finalising case numbers and rates for the reporting period because of the need to include cases up to 8 weeks after discharge.

Appendix 1: Flow chart for determining whether the *C.difficile* infection meets the case definition for hospital identified CDI



Source: SA Health.

Appendix 2: Clinical criteria for severe cases

There are a number of clinical criteria that have been associated with severe CDI^{5,6,7,8}

- age over 60 years of age
- temperature greater than 38.3°C
- serum albumin less than 25 g/L
- peripheral white blood cell count greater than 15,000 cells/microL
- deteriorating renal function
- elevated serum lactate
- endoscopic evidence of pseudomembranous colitis or treatment in the intensive care unit
- subtotal colectomy performed
- toxic megacolon diagnosed

CDI management is discussed in detail in the ASID position paper⁹

(available at http://www.asid.net.au/hicsigwiki/index.php?title=Infection_control_C._difficile).



Photo: Professor Thomas Riley, University of Western Australia

Appendix 3: Comments and feedback on the surveillance of *C.difficile* infection

Send feedback or comment on the Surveillance of CDI Guide to:

HAI@safetyandquality.gov.au



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**Australian Commission on
Safety and Quality in Health Care**

Level 7
1 Oxford Street
Darlinghurst NSW 2010

GPO Box 5480
Sydney NSW 2001

Phone: (02) 9126 3600
Fax: (02) 9126 3613

Email: mail@safetyandquality.gov.au

www.safetyandquality.gov.au