Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

hpsc

Enhanced Surveillance of *Clostridium difficile* Infection in Ireland

Protocol for Completion of

Enhanced Surveillance Information

Version 3.5 , July 2014

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Background

Clostridium difficile infection (CDI) or *C. difficile*-associated disease (CDI) has been a notifiable disease in Ireland since May 2008. Prior to 2012, only new cases of CDI were notifiable. The case definition for this disease has been revised and since 1st January 2012 both new and recurrent cases are notifiable. Weekly reports from notifiable data are published by the HPSC at: http://www.hpsc.ie/hpsc/NotifiableDiseases/WeeklyIDReports/.

Whilst this has given important preliminary information on the burden of CDI in Ireland, it does not capture enhanced information on the origin, onset or severity of cases. With this in mind, from 1st August 2009 the HPSC began collecting enhanced surveillance data on all CDI cases from acute hospitals on a voluntary basis. Participating hospitals are provided with individual quarterly feedback reports and a national report is compiled and made available at the end of each quarter on the HPSC website at http://www.hpsc.ie/hpsc/A-Z/Gastroenteric/Clostridiumdifficile/CdifficileSurveillance/CdifficileEnhancedSurveillance/Reports/

At present, there are two parallel national surveillance systems capturing data on C*. difficile* infections in Ireland: (i) **Surveillance of statutory notifications** under the infectious diseases regulations, which captures new (since May 2008) and recurrent cases (since January 2012) on CIDR and (ii) **the Enhanced surveillance system** which hospitals complete on a voluntary basis and submit to HPSC quarterly. It is the responsibility of the reporting healthcare facility to ensure that all CDI cases that meet the case definition are being reported to both surveillance systems to ensure consistency and accuracy across these databases.

Methodology

Which Patients are Under Surveillance?

Enhanced surveillance data should be collected on **all patients** who meet the case definition for a CDI (new or recurrent) (See description of case definition below). This includes the following patients:

1. inpatients,
2. patients seen at outpatient departments (e.g. dialysis patients),
3. patients in the emergency room,
4. day patients,
5. samples from patients sent in from other non-acute healthcare facilities (e.g. nursing homes) or
6. samples from GPs in the community

All positive *C. difficile* laboratory results should be discussed with the clinician responsible for the patient to ascertain that the patient with the positive laboratory test result for *C. difficile* meets the CDI case definition.

Case Definition of CDI:

A confirmed *C. difficile* associated disease (CDI) case is a patient two years or older, to whom one or more of the following criteria applies:

- Diarrhoeal* stools or toxic megacolon, with either a positive laboratory assay for *C. difficile* toxin A (TcdA) and / or toxin B (TcdB) in stools or a toxin-producing *C. difficile* organism detected in stool via culture or other means.
- Pseudomembranous colitis (PMC) revealed by lower gastrointestinal endoscopy.
- Colonic histopathology characteristic of *C. difficile* infection (with or without diarrhoea) on a specimen obtained du*ring endosco*py, colectomy or autopsy.

*** Diarrhoea is defined as three or more loose/watery bowel movements that take up the shape of their container (which are unusual or different for the patient) in a 24 hour period.**

How is the Data Collected?

The enhanced surveillance data can be collected in one of three ways:

1. **Manually on forms** (See Appendix 1). When completed, the form should be transcribed into an Excel database provided at: http://www.hpsc.ie/hpsc/A-Z/Gastroenteric/Clostridiumdifficile/CdifficileSurveillance/CdifficileEnhancedSurveillance/ProtocolsandForms/

OR

2. **Data can be entered directly into the Excel database** (see link above) OR
3. **Complete teleform forms** (See Appendix 1 and 2 or download teleform form from link above) and scan forms using a teleform scanner directly into a local database. This information can then be transferred to the Excel database (see link above).

- Participants should complete enhanced surveillance details for each episosde of CDI per patient that meets the case definition (both new and recurrent cases) and these records should be securely filed for reference.

- The Excel database should be regularly updated with available information and submitted **quarterly** via e-mail to the following HPSC e-mail address: fionamary.roche@hse.ie. **Please only send the current quarter's data to the HPSC each quarter.**

- **Please encrypt all data that is sent via email using either Private File, Axcrypt or Winzip.** Contact fionamary.roche@hse.ie at the HPSC for further information if required.

- ALL cases of *C. difficile* –associated disease (CDI) that meet the case definition are notifiable. Please ensure that ALL CDI cases reported in the enhanced surveillance system have been notified to Public Health. Please use the same identifiers and dates when reporting a case to Public Health and to the Enhanced System to ensure these cases can be linked in the databases at a later stage.

What Enhanced Information is Reported?

The following outlines the information to be collected on the enhanced surveillance form (see link to form on page 14).

Section 1 - Patient Details

Hospital Code	This identifier (sent to you in advance) is unique to your hospital and should be documented on all your forms. If using teleform, you can edit the form on Teleform Designer to prefill this field with your hospital code.
Patient ID	This identifier can be decided upon by the participant but must be unique for a patient and be a valid identifier within the hospital LIMS. If the patient is an inpatient, this identifier would generally be the hospital MRN number. If you are reporting a second or subsequent CDI case for the same patient, please ensure to use the same patient identifier as the previous case. This will ensure that these patients can be linked in the database.
Age	The age of the patient at time of sampling. This information is calculated automatically in the Excel tool as soon as the 'Date of birth' and 'Date of Specimen' are entered. If the 'Date of Specimen' cannot be provided, the 'Date of Onset' is used as a surrogate. However, data providers are always encouraged to provide the 'Date of Specimen' if the information is available.
Sex	Male/Female/Unknown
Date of birth	Please use the format DD/MM/YYYY
Was the patient admitted to hospital?	Yes, No or No information available
Date of admission	If patient was admitted to hospital, please specify the date.

Section 2 - Case Type

Case Type	Patients that meet the CDI case definition should then be further classified as either a **new case**, a **recurrent case** or an unknown case of CDI. **** Please use the Specimen date when calculating the number of weeks since a previous positive result **** **See Appendix 3 for algorithm**

How to determine the case type of CDI:

If the case definition is met, it important to establish whether this is a first positive *C. difficile* test result or whether the patient has previously had a positive *C. difficile* test result:

a. if a first positive result then this is a notifiable **new case of CDI**

b. if the patient has previously had a positive result

i. more than eight weeks prior and symptoms had resolved* then this is a notifiable **new case of CDI.**

ii. Less than eight weeks prior and symptoms had resolved* then this is a notifiable **recurrent case of CDI**

iii. and symptoms have not resolved then this is a repeat positive specimen from the same CDI episode and is **not notifiable.**

If the case definition is not met, the laboratory result is not notifiable.

Please use the Specimen date when calculating the number of weeks since a previous positive result

* The definition of a resolved case is that the patient has had no diarrohea for at least 48 hours and has had a formed or normal stool for that patient.

Note: Both new and recurrent cases of *C. difficile* –associated disease (CDI) that meet the case definition are notifiable. Please ensure that ALL CDI cases reported in the enhanced surveillance system have been notified to Public Health

Section 3 - Isolate Details

Specimen ID	Enter your laboratory ID of the sample sent for testing. ** Please ensure the same identifier is used when reporting a case to CIDR and to the enhanced surveillance system **
Specimen date	Please enter date specimen was taken
Origin of Specimen	Please enter where the CDI specimen was sent in from: • GP practice; • Nursing home/LTCF; • This hospital; (reporting hospital) • Other hospital; (another acute hospital) • Other; (non-acute HCF that is not a LTCF) • No information available.

'Other hospital' refers to another acute hospital. Community hospitals are classified as LTCFs if the patient case mix is >80% long term care. If not, these hospitals should be classified as 'Other'.

Section 4 - Onset of CDI Infection

Onset of CDI	Onset of CDI refers to the location of the patient when symptoms of CDI first started. Please specify the onset of CDI according to the following definition: • **Healthcare onset** » Symptoms start during a stay in a healthcare facility (HCF). This includes nursing homes and LTCFs. • **Community onset** » Symptoms start in a community setting, outside health care facilities • **No information available** » If no information was available on onset of symptoms

Onset Facility (if in a HCF)	Please answer this question **ONLY** if the onset of CDI is known to be in a healthcare facility. Note the facility the onset of symptoms were in: • **This hospital:** Please select if onset of symptoms were in the reporting hospital. • **Other hospital:** Please select if onset of symptoms were in another acute hospital to the reporting hospital (i.e. a transferred patient). • **Nursing home/LTCF:** Please select if the onset of symptoms were in a nursing home or other long term care facility. • **Other:** Please select if the onset of symptoms were in a HCF that is non-acute and not a LTCF • **No information available**
Date of Onset	Date of onset of symptoms.

Section 5 - Origin of CDI

Origin of CDI	Please specify the origin of the CDI episode according to the definition below: (See Appendix 4 for algorithm)

- **Healthcare-associated case (also must answer 'Origin Facility' below)**

»This is a CDI case with either:

- Onset of symptoms at least 48 hours following admission to a healthcare facility* (i.e. Infection arising day 3 on-wards – where date of admission = day 1) (healthcare-onset, healthcare-associated).

OR

- With onset of symptoms in the community within 4 weeks following discharge from a healthcare facility (community-onset, healthcare-associated).

- **Community-associated case**

»This is a CDI case patient with either:

- Onset of symptoms while outside a healthcare facility and without discharge from a healthcare facility within the previous 12 weeks (community-onset, community-associated).

OR

- With onset of symptoms within 48 hours following admission to a healthcare facility (i.e. symptom onset on day 1 or day 2 of admission) without residence in a healthcare facility within the previous 12 weeks (healthcare-onset, community-associated).

- **Discharged 4 – 12 weeks from a healthcare facility**

»This is a CDI case patient with either:

- Onset of symptoms while outside a healthcare facility but who was discharged from a healthcare facility 4-12 weeks before the onset of symptoms

OR

- With onset of symptoms within 48 hours following admission to a healthcare facility (i.e. symptom onset on day 1 or day 2 of admission) but who was discharged from a healthcare facility 4-12 weeks before the onset of symptoms

- **No information available**

» If no information was available on a CDI case patient regarding origin of infection

* A healthcare facility is any acute care, long-term care, long-term acute care, or other facility in which skilled nursing care is provided and patients/residents are admitted at least overnight. This includes hospitals and nursing homes.

**** Please see the following to help identify the origin of infection for your CDI case:**

- **See the algorithms in Appendix 4 on how to determine the origin of infection using the onset of symptoms as the starting point**
- **See the Case Studies in Appendix 5 on sample CDI cases and how the origin is defined**

Origin Facility (if in a HCF)	Please answer this question **ONLY** if the case was known to be healthcare-associated. Please note the facility the CDI case originated in: • **This hospital:** Please select if CDI case is associated with the reporting hospital. • **Other hospital:** Please select if CDI case is associated with another acute hospital to the reporting hospital (i.e. a transferred patient). • **Nursing home/LTCF:** Please select if CDI case is associated with a nursing home or other long term care facility. • **Other:** Please select if CDI case is associated with a HCF that is non-acute and not a LTCF • **No information available**

Section 6 - Severity

Severity	The definition of a severe CDI is if the patient was either: (i) **admitted to ICU** for **treatment of CDI or its complications?** (e.g. for shock requiring vasopresser therapy), OR (ii) the patient received **surgery as a consequence of CDI complications**? (e.g. surgery for toxic megacolon (colectomy), perforation or refractory colitis). Please answer 'Yes', if the patient meets this definition, or 'No' if they do not. Or please indicate if 'No information available'.

Section 7 - Ribotype

Ribotype	Please enter the ribotype data if available. • Only include the actual ribotype code. Do not include additional text. • Also, please only report the ribotype if that particular sample was ribotyped. Please do not report the ribotype associated with a previous sample from that patient that was ribotyped. ** If the ribotype data for a particular quarter is not available when returning your quarterly data, then please forward this on when available and highlight this in your email **

Section 8 - Treatment

Treatment	Please record if a patient was prescribed one of the following antibiotics as a first line of treatment for the *C. difficile* infection specifically: (i) metronidazole, (ii) vancomycin, or (iii) fidaxomycin.

NOTE: Ribotype and treatment information is not found on the enhanced surveillance form. Please enter this data directly into the Excel database.

Additional Information

Laboratory Testing Method Used:

There are a variety of test methods available to laboratories for the diagnosis of CDI. These include EIAs for toxins A and B, EIAs for GDH, Cell cytotoxicity assay (CCTA), toxigenic culture and NAAT for toxin genes. The diagnosis of CDI is a rapidly evolving situation. To aid in the interpretation of both local and national CDI trends, information is being collected quarterly on the testing method used. If using the Excel data collection tool, a drop down box is provided in the 'Hospital Data' worksheet. Please select the test method used by your laboratory each quarter.

Information on Frequency of Testing:

To adjust for differences in the frequency of *C. difficile* testing across hospitals, information is captured on the number of faecal specimens tested for toxigenic *C. difficile* in your laboratory for your hospital each quarter. Please record this number in the 'Hospital Data' worksheet in the relevant quarter period.

HPSC Contact Details

We welcome comments and feedback on any aspect of this project. Please contact either Dr. Fidelma Fitzpatrick, Dr Karen Burns, or Ms. Fiona Roche by phone or e mail as follows:

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Appendices

Appendix 1: Enhanced Surveillance Form

See pages 16 and 17 of this protocol for a printable pdf version of the enhanced surveillance form. The pdf version of the form is also available for download at:

http://www.hpsc.ie/hpsc/A-Z/Gastroenteric/Clostridiumdifficile/EnhancedSurveillance

If you would like a copy of the form in **teleform format**, please contact **fionamary.roche@hse.ie.**

Appendix 2: How to Fill-in Teleform Survey Forms

It is important when filling in these forms to follow the points outlined below to ensure a valid and accurate scanning process.

- Use a dark ink pen or biro. Avoid light coloured pens, e.g. green.
- Place cross (not tick) in appropriate box, i.e. ☒
- Mistakes can be rectified.

  If an incorrect response is chosen, blot out the incorrect response, ● and choose correct response by placing a cross in the appropriate box, ☒. The person scanning will interpret the correct response.
- Be thorough in completion

  Write from left to right (starting at the first box)

  Write clearly

  Write within the boxes

  - If you make a mistake - cross out the error and write the correct character in the box.
  - If it is not possible to fit a character in a box write directly above or below the relevant box
  - do not leave gaps
- Avoid damaging form. Do not staple or tape forms together.
- The four-locator blocks (black boxes in the corners of forms) are essential for correct reading, do not write or draw around these locator blocks.
- Do not write on an area designated for a serial number.

- **DO NOT PHOTOCOPY BLANK FORMS**

  Each form contains unique identification elements and is intended for single use.

  You may photocopy completed forms for your own personal use.

Appendix 3: Algorithm to Determine CDI Case Type

See Algorithm on page 18 of this protocol to help determine the case type of a CDI case when filling out the enhanced surveillance data.

Appendix 4: Algorithms to Determine Origin of Infection

See Algorithms on pages 19 and 20 of this protocol to help determine the origin of infection of a CDI case when filling out the enhanced surveillance data. The starting point of these algorithms is “Where did the onset of symptoms start?”

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National *Clostridium difficile* Enhanced Surveillance Form, v3
Clinical Details

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

1. Patient Details:

Hospital Code: | | | | |

Patient ID: | | | | | | | | | | |

Age: | | |

Sex: M ☐ F ☐ Unk ☐

Date of birth: ☐☐ / ☐☐ / ☐☐☐☐

Was the patient admitted to hospital? ☐ Yes ☐ No ☐ Unknown →

If admitted please give date of admission: ☐☐ / ☐☐ / 2 0 ☐☐

2. Case Type:

☐ New ☐ Recurrent **Please refer to page two for new and recurrent case definitions.**

3. Isolate Details:

Specimen ID: | | | | | | | | |

Specimen date: ☐☐ / ☐☐ / 2 0 ☐☐

Origin of Specimen:

☐ This hospital ☐ Other hospital ☐ Nursing home/LTCF ☐ GP practice ☐ Other ☐ No information available

4. Onset of *C difficile* Infection (CDAD):

☐ Healthcare onset >> Symptoms start during a stay in a healthcare facility (HCF)

☐ Community onset >> Symptoms start in a community setting, outside healthcare facilities.

☐ No information available

Date of onset: ☐☐ / ☐☐ / 2 0 ☐☐

If patients onset of CDAD was within a health care facility, please specify in which facility this occurred:

☐ This hospital ☐ Other hospital ☐ Nursing home/LTCF ☐ Other ☐ No information available

5. Origin of *C difficile* Infection (CDAD):

☐ Healthcare-associated

>> This is a CDAD case with either:
Onset of symptoms at least 48 hours following admission to a HCF (healthcare-onset, healthcare-associated)
or
Onset of symptoms in the community within 4 weeks following discharge from a HCF (community-onset, healthcare-associated)

☐ Community-associated

>> This is a CDAD case with either:
Onset of symptoms while outside a healthcare facility, and without discharge from a HCF within the previous 12 weeks (community-onset, community-associated).
or
Onset of symptoms within 48 hours following admission to a healthcare facility without residence in a HCF within the previous 12 weeks (healthcare-onset,community-associated)

☐ Discharged 4-12 wks from HCF

>> This is a CDAD case who was discharged from a healthcare facility 4-12 weeks before the onset of symptoms

☐ No information available

>> No information was available on this CDAD case

If patients origin of CDAD was within a health care facility, please specify in which facility this occurred:

☐ This hospital ☐ Other hospital ☐ Nursing home/LTCF ☐ Other ☐ No information available

6. Severity: *(If applicable)*

ICU Admission for CDAD treatment or its complications ☐ Yes ☐ No ☐ No information available

Surgery (colectomy) for toxic megacolon, perforation or refractory colitis. ☐ Yes ☐ No ☐ No information available

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Definitions of *Clostridium difficile* Infection:

***A confirmed Clostridium difficile* - associated disease (CDAD) case is a patient two years or older, to whom one or more of the following criteria applies:**

- Diarrhoeal* stools or toxic megacolon, with either a positive laboratory assay for C. difficile toxin A (TcdA) and/or toxin B (TcdB) in stools or a toxin-producing C. difficile organism detected in stool via culture or other means.

- Pseudomembranous colitis (PMC) revealed by lower gastrointestinal edoscopy.

- Colonic histopathology characteristic of C. difficile infection (with or without diarrhoea) on a specimen obtained during endoscopy, colectomy or autopsy.

*** Diarrhoea is defined as three or more loose/watery bowel movements (which are unusual or different for the patient) in a 24 hour period**

Case Type:

New Case of CDAD:

A new of case of CDAD is either:

A. The first episode of CDAD

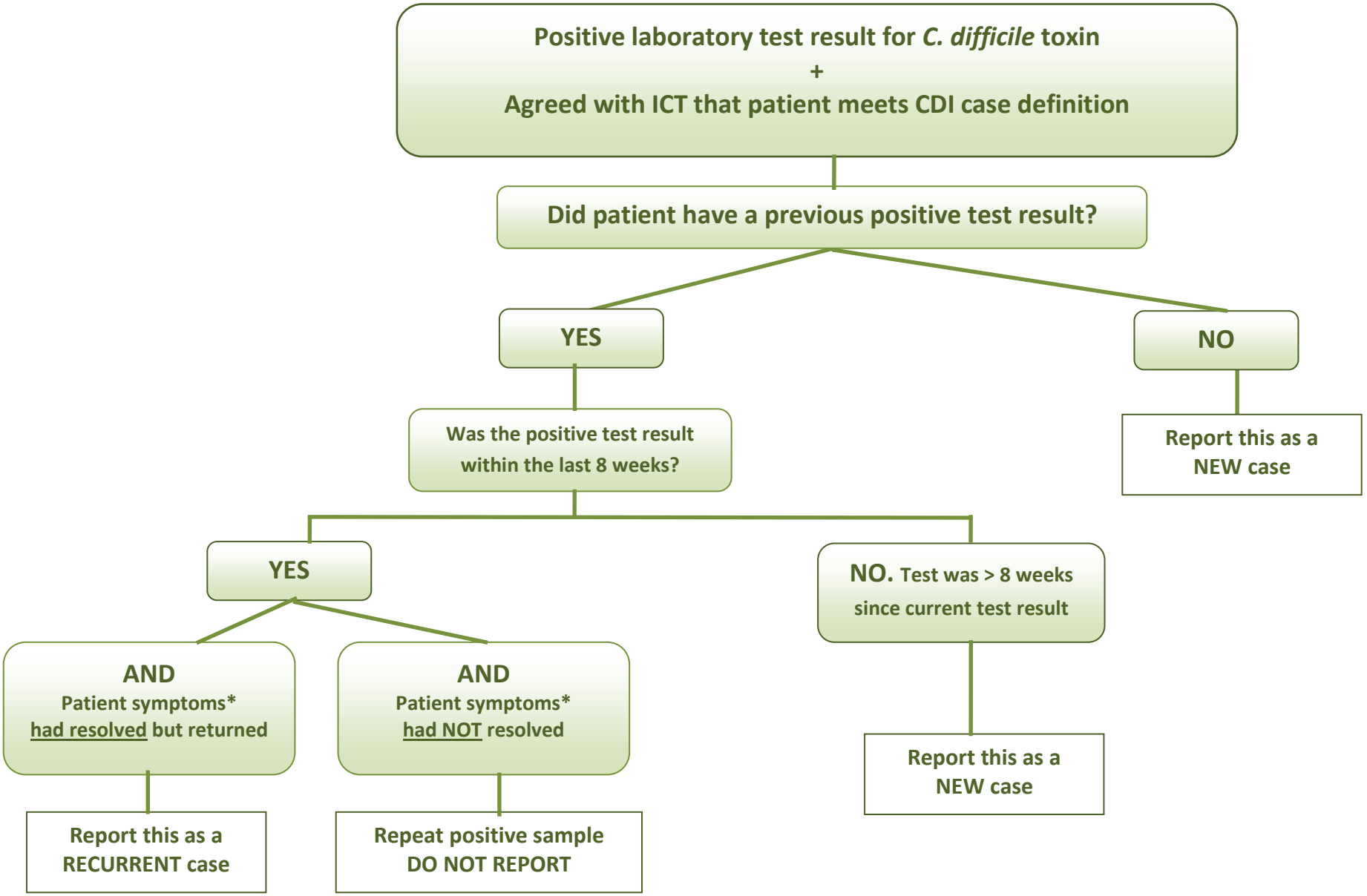
OR

B. A subsequent episode of CDAD with onset of symptoms **more than 8 weeks** after the onset of a previous episode.

Recurrent Case of CDAD:

A recurrent case of CDAD is a patient with an episode of CDAD that occurs **within 8 weeks** following the onset of a previous episode **provided that CDAD symptoms from the earlier episode resolved with or without therapy.**

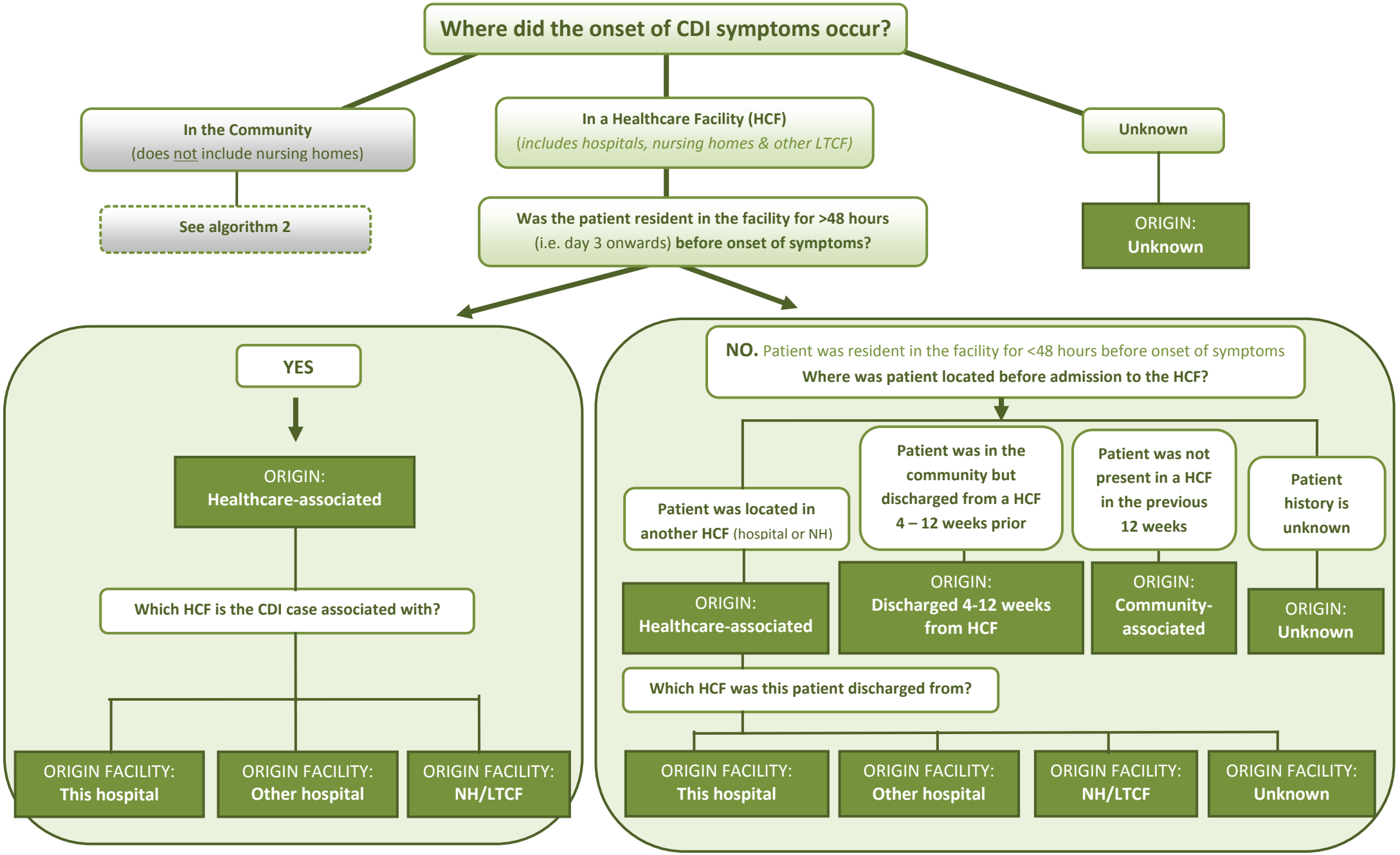
APPENDIX 3: HOW TO WORK OUT THE CDI CASE TYPE?



* If a patient's symptoms are not available then if the specimen collected date is ≤14 days of a previously notified specimen collection date, treat this as a repeat positive specimen.

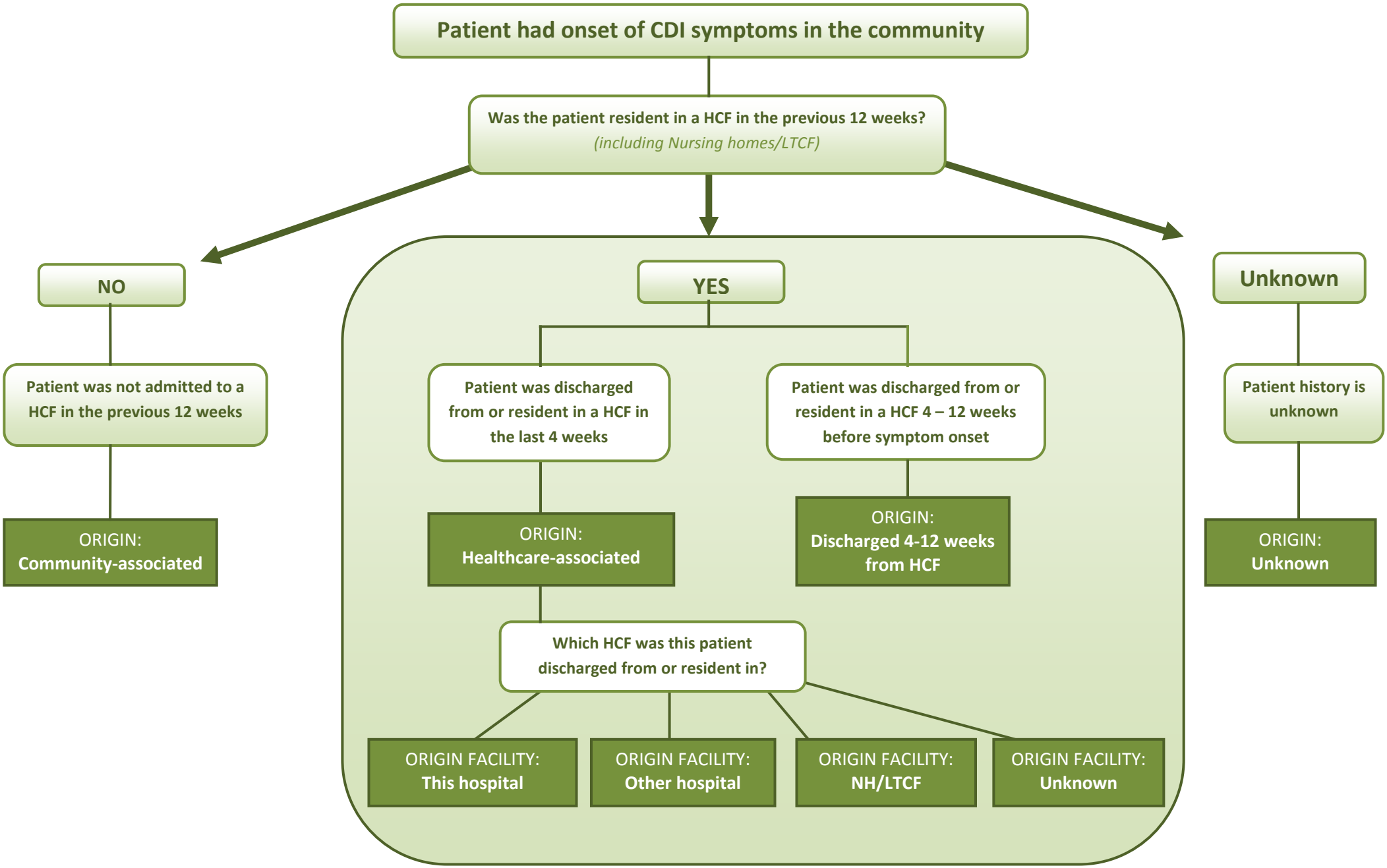
APPENDIX 4: HOW TO WORK OUT THE ORIGIN OF CDI INFECTION

This algorithm is designed to be used by the hospital infection control team participating in the Enhanced CDI Surveillance Project.



APPENDIX 4: HOW TO WORK OUT ORIGIN OF CDI INFECTION WHEN SYMPTOM ONSET IS IN THE COMMUNITY?

This algorithm is designed to be used by the hospital infection control team participating in the Enhanced CDI Surveillance Project.



Appendix 5: Case Studies for Enhanced CDI Surveillance

Case	Case description and answer
1	A patient was admitted to your hospital on 15/03/2014. On the 20/03/2014 the patient had onset of diarrhoea. A sample was taken and laboratory tests came back positive for toxin-producing *C. difficile* . **ONSET:** Healthcare onset, This hospital **ORIGIN:** Healthcare-associated, This hospital
2	A nursing home resident suffered from abdominal pain and had several bouts of diarrhoea. A sample was taken on 12/03/2014 and was sent to the laboratory for testing. Test results were positive for toxin-producing *C. difficile* . The patient had not been admitted to a hospital in the previous year. **ONSET:** Healthcare onset, Nursing home/LTCF **ORIGIN:** Healthcare-associated, Nursing home/LTCF
3	A patient was discharged from your hospital on 05/01/2014. On 16/02/2014, the patient visited their GP suffering from diarrhoea and abdominal pain. Results confirmed the presence of toxin-producing *C. difficile* . **ONSET:** Community onset **ORIGIN:** Discharged 4-12 wks from healthcare facility
4	A patient was admitted to hospital A through A&E on 08/02/2014. On 10/02/2014 at 12.30pm they were transferred to your hospital for surgery. On the morning of the 11/02/2014 the patient had onset of diarrhoea that continued throughout the day. A sample was sent to the lab for testing and results confirmed the present of toxin-producing *C. difficile.* **ONSET:** Healthcare onset, This hospital **ORIGIN:** Healthcare-associated, Other hospital

5	A nursing home resident was admitted to your hospital for surgery on 15/01/2014 and on the 03/02/2014, they were discharged back to the nursing home. On 20/03/2014 the resident had onset of diarrhoea and tested positive for *C. difficile* . **ONSET:** Healthcare onset, Nursing home/LTCF **ORIGIN:** Healthcare-associated, Nursing home/LTCF
6	A nursing home resident was admitted to your hospital on 06/03/2014 for the treatment of an infection. They were discharged on the 12/03/2014 and transferred back to the nursing home. On the 6/04/2014 the resident had onset of diarrhoea and tested positive for toxin producing *C. difficile* . There were two other cases of *C. difficile* infection in the nursing home at the same time. **ONSET:** Healthcare onset, Nursing home/LTCF **ORIGIN:** Healthcare-associated, Nursing home/LTCF
7	A nursing home resident was admitted to your hospital on 13/02/2014 for surgery. They were discharged on 20/02/2014. Two weeks later the resident had onset of diarrhoea and tested positive for toxin positive *C. difficile* . Upon review of this case, you were made aware of two other cases of CDI that were accommodated in the same surgical ward of the hospital as the nursing home resident. **ONSET:** Healthcare onset, Nursing home/LTCF **ORIGIN:** Healthcare-associated, Nursing home/LTCF