NHS National Services Scotland

Protocol for the Scottish Surveillance Programme for *Clostridium difficile* infection.

User manual.

Version 4.0
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Health Protection Scotland

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This is the fourth revised version of the CDI surveillance protocol (version 4.0). If you have any comments or questions, or would like further information please send an email to NSS.HPSenquiries@nhs.net.

This document can be downloaded from:
http://www.hps.scot.nhs.uk/haiic/sshaip/guidelines.aspx#cdiff.

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1. Introduction

Mandatory surveillance for CDI currently includes all patients aged 15 and above in all healthcare settings who present with diarrhoea not attributable to any other cause.

In 2016, the Scottish Microbiology and Virology Network (SMVN) in collaboration with HPS and the Scottish Salmonella, Shigella and *Clostridium difficile* Reference Laboratory (SSSCDRL) published a revised version of the 'Recommended Protocol for Testing for *Clostridium difficile* and Subsequent Culture'. This version (which supersedes the former) is available from: http://www.hps.scot.nhs.uk/haiic/sshaip/resourcedetail.aspx?id=690.

The revised testing guidance recommends testing stools in patients aged 3 or above; however, the mandatory surveillance of CDI remains limited to those patients aged 15 or above. Therefore, other than for submissions to the *C. difficile* Reference Laboratory for ribotyping, the following surveillance protocol only applies to those aged 15 or above.

2. Data Management

2.1 Data definitions

Case definition

A case of CDI is someone in whose stool *C. difficile* toxin has been identified at the same time as they have experienced diarrhoea not attributable to any other cause, or from whose stool *C. difficile* has been cultured at the same time as they have been diagnosed with pseudomembranous colitis (PMC).

Definition of an outbreak

An outbreak of CDI occurs when more cases of CDI than would normally be expected occur in a clinical unit, ward or hospital.

Definition of community-associated CDI (CA-CDI)

This is a CDI case patient with onset of symptoms while outside a healthcare facility, and without discharge from a healthcare facility within the previous 12 weeks (community-onset, community-associated (CO-CA)) or with onset of symptoms within 48 hrs following admission to a healthcare facility without residence in a healthcare facility within the previous 12 weeks (healthcare-onset, community-associated (HO-CA)).

Definition of healthcare-associated CDI (HA-CDI)

This is a CDI case patient with onset of symptoms at least 48 hrs (>48 hrs) following admission to a healthcare facility; with onset within 48 hrs of admission to a healthcare facility and within 4 weeks following discharge from a healthcare facility (both classed as healthcare-onset, healthcare-associated (HO-HA)); or with onset of symptoms in the community within 4 weeks following discharge from a healthcare facility (community-onset, healthcare-associated (CO-HA)).

Definition of an unknown CDI (U-CDI)

This is a CDI case patient who was discharged from a healthcare facility 4–12 weeks before the onset of symptoms. These may be either community onset (CO-U) or hospital onset (HO-U).

Definition of a healthcare facility

A healthcare facility relates to hospitals (acute and non-acute).

2.2 Data capture

Guidance on when to obtain specimens for CDI testing

A faecal specimen should be obtained from any patient (aged 15 or over) with diarrhoea (defined as the passage of 3 or more loose or liquid stools per day, or more frequently than is normal for the individual), and with no other underlying cause. Only diarrhoeal specimens should be tested. Screening of symptom-free patients is not recommended. When symptoms have resolved clearance testing is not recommended.

Definition of a diarrhoeal specimen

A diarrhoeal specimen is a specimen of faeces that conforms to the shape of its container.

The above definition of diarrhoea can be used to discard faecal specimens in the laboratory that have been collected mistakenly from symptom-free patients.

Guidance for obtaining faecal specimens from patients with diarrhoea may be accessed from: http://www.hps.scot.nhs.uk/haiic/sshaip/guidelinedetail.aspx?id=40364.

Toxin testing

Laboratories should test all diarrhoeal specimens received from patients in the healthcare setting (including general practices, acute and non-acute hospitals), aged 15 or over, for *C. difficile* toxin following the SMVN, SSSCDRL and HPS 'Recommended Protocol for Testing for *Clostridium difficile* and Subsequent Culture' which can be accessed from: http://www.hps.scot.nhs.uk/haiic/sshaip/guidelinedetail.aspx?id=53536.

Only those stool samples which are positive in both the initial screening test and the subsequent toxin test are eligible for reporting under mandatory surveillance of CDI. Equivocal test results do not need to be reported.

The current testing protocol recommends testing of diarrhoeal stool samples in patients aged 3 and above; however, only confirmed CDI cases in patients aged 15 and above need to be reported to HPS under the mandatory surveillance programme. CDI cases from patients aged <15 years may still be submitted via the Electronic Communication of Surveillance in Scotland (ECOSS) at the discretion of the NHS boards.

Culturing and ribotyping

Laboratories should culture faecal specimens for *C. difficile* from cases of severe disease and suspected outbreaks according to agreed criteria outlined below (see page 8).

In addition, specimens should be cultured in line with the *Clostridium difficile* representative typing surveillance (snapshot programme).

The protocol for the programme is available at: http://www.hps.scot.nhs.uk/haiic/sshaip/guidelinedetail.aspx?id=46879.

Isolates should be submitted in cooked meat broth (Robertson's) and accompanied by a completed request form giving relevant clinical and demographic details and reason for submission to:

Scottish *Clostridium difficile* Reference Service
Scottish *Salmonella*, *Shigella* and *Clostridium difficile* Reference Laboratory
5th Floor
New Lister Building
10-16 Alexandra Parade
Glasgow Royal Infirmary
GLASGOW
G31 2ER

Further forms and full details of the service can be found at: http://www.nhsggc.org.uk/content/default.asp?page=s162.

Criteria for mandatory submission of *C. difficile* isolates

Isolates of *C. difficile* should be submitted to SSSCDRL in the case of:

1) Severe cases

- Admission to a healthcare facility for treatment of community associated CDI.
- Admission to ITU for treatment of CDI or its complications.
- Endoscopic diagnosis of PMC (with or without toxin confirmation).
- Surgery for the complications of CDI (toxic megacolon, perforation or refractory colitis).
- Death within 30 days following a diagnosis of CDI where it is either the primary or a major contributory factor.
- Persisting CDI where the patient has remained symptomatic and toxin positive despite 2 courses of appropriate therapy.

2) Suspected outbreaks

When an outbreak is suspected and stools are positive for *Clostridium difficile* toxin (see definition of outbreak on page 4).

3) As part of the "*Clostridium difficile* Snapshot Programme"

Laboratories should submit a defined number of consecutive isolates on a quarterly basis with request forms clearly labelled "snapshot".

Details on submission criteria are available at: http://www.hps.scot.nhs.uk/haiic/sshaip/guidelinedetail.aspx?id=46879.

Other molecular typing technologies

Ribotyping may not be sufficiently discriminatory for the purposes of an investigation, and it may be necessary to use alternative techniques to provide better resolution, e.g. multilocus variable number of tandem repeat analysis (MLVA) and whole genome sequencing. Any further requirements should be discussed with both SSSCDRL and HPS.

Guidance on storage of toxin positive faecal specimens

In order to preserve the opportunity of investigating a problem with *C. difficile* retrospectively, it is recommended that toxin positive faecal specimens are stored routinely at –20°C for a period of three months. Faecal specimens can be stored in their original containers or smaller aliquots can be saved. No additional broth is needed. *C. difficile* survive in frozen specimens and can be cultured upon thawing.

2.3 Data transfer

De-duplication procedures at HPS

The results of all positive tests for *C. difficile* toxin and culture positive stools for *C. difficile* meeting the case definition shall be sent to HPS (see Toxin testing section).

De-duplication will be carried out at HPS. Only persons that have not been diagnosed with CDI within the previous 28 days are counted as new cases.

It is important that laboratories submit all toxin positive cases to HPS since all cases including the deleted duplicate cases are used to estimate the gap between two positive tests. De-duplication procedures are done on a continuous basis, which sometimes results in comparing duplicates from two different quarters.

Dating of episodes at HPS

In order to identify individual episodes of CDI, a starting date of each episode must be determined which should reflect, as near as possible, the date on which the faecal specimen was taken from the patient.

Dates of episodes are extracted directly from the electronic reports (via ECOSS) based on the date of collection of specimen.

The following hierarchy will be used to identify the date of which the episode of CDI began:

(a) “date specimen collected” will be used if available; (b) if this is not available “date specimen received at the laboratory” will be used; or (c) If neither of these dates are available the “date specimen reported to HPS” will be recorded as the start date of the episode.

2.4 Data analysis

Data analysis will consist of calculating rates for NHS boards. The numerator is the number of cases of CDI (not the number of identifications of *C. difficile*) and the denominators will be per 100 000 occupied bed days.

The number of recurrent cases will calculated based on the date of collection. Recurrent CDI cases are patients who meet the CDI case definition with an episode of CDI (return of diarrhoeal stools with a positive laboratory test after the end of treatment) more than two weeks and less than eight weeks following the onset of a previous episode (no matter where that previous episode occurred). See also the ECDC CDI surveillance protocol: http://ecdc.europa.eu/en/publications/_layouts/forms/Publication_DispForm.aspx?List=4f55ad51-4aed-4d32-b960-af70113dbb90&ID=1402.

Once a year, incidence rates by CA-CDI and HA-CDI will also be calculated using population and occupied bed days as the denominators, respectively, and the results published in an annual report.

2.5 Information output

HPS will post reports on its web site http://www.hps.scot.nhs.uk/ quarterly and annually. Reports will be provided to users and stakeholders.

The reports present the incidence rates of CDI and their rates for each NHS board area in Scotland. They will also include data on ribotyping from both the clinical and snapshot surveillance.

Annual reports will also be produced with more in-depth interpretation of the data (including reporting of CDI outcome data and incidence rates for CA-CDI and HA-CDI).

2.6 Database specification

The minimum dataset for cases are specified under the ECOSS protocol:

The minimum dataset

- Reporting laboratory
- Date specimen collected
- Date specimen received at the laboratory
- Date of reporting to HPS
- Surname
- Forename
- Age in years
- Sample type (always faeces in this dataset)
- Organism (always *C. difficile* in this data set)
- Whether toxin positive or culture positive
- Culture subtype (if culture positive)

European surveillance of *Clostridium difficile* infections

ECDC has published a surveillance protocol to introduce and improve standardisation of surveillance of CDI in Europe.[1] The Scottish CDI surveillance programme has aligned to the European protocol where necessary, and this has resulted in the added need to include collection of further data items including:

- Number of stool specimens tested;
- Number of stool specimens that tested positive for CDI; and
- Algorithm used for CDI diagnosis.

HPS will carry out surveys of the laboratories to collect this information on a routine (6-month or annual) basis.

Databases at HPS

Once a quarter, an export procedure will be carried out for data analysis. Initial analysis will include identifying duplicate reports within a 28-day period.

Typographical errors, for example where a patient's name has been typed differently on two occasions, are also identified.

The latest quarter's data will then be merged with all the previous quarters to create a new working database.

3. Quality Assurance

Local quality assurance

Local systems of quality control vary. Many laboratories check their reports to HPS against their own computerised records on a weekly basis prior to sending them. They also receive copies of the final data from HPS relating to themselves in order to check for any inconsistencies.

Quality assurance at HPS

At the end of each quarter, HPS will send out a de-duplicated local dataset to each reporting laboratory. Each laboratory is requested to validate the local datasets by comparing the HPS records to their own records. If inconsistencies between the records of HPS and a reporting laboratory are found, these cases must be investigated further and revised until an agreed, validated dataset for each laboratory has been produced.

Pre-publication access to the quarterly and annual reports will be available in the five working days prior to the publication date to allow for any serious errors to be corrected.

4. Notes

This protocol describes how HPS coordinates the surveillance of CDI in Scotland with the essential cooperation of colleagues in clinical diagnostic microbiology laboratories.

The programme does not (and cannot) provide a completely accurate picture of CDI in the healthcare setting. No surveillance programme can have complete sensitivity (the ability to identify all true cases) or specificity (the ability to ensure all cases identified are true). The consistency required in a surveillance programme means that some accuracy must be sacrificed for the sake of consistency.

Appendix

See the 'Recommended Protocol for Testing for *Clostridium difficile* and Subsequent Culture' for full details. http://www.hps.scot.nhs.uk/haiic/sshaip/resourcedetail.aspx?id=690.

Figure 1: Testing Algorithm 1

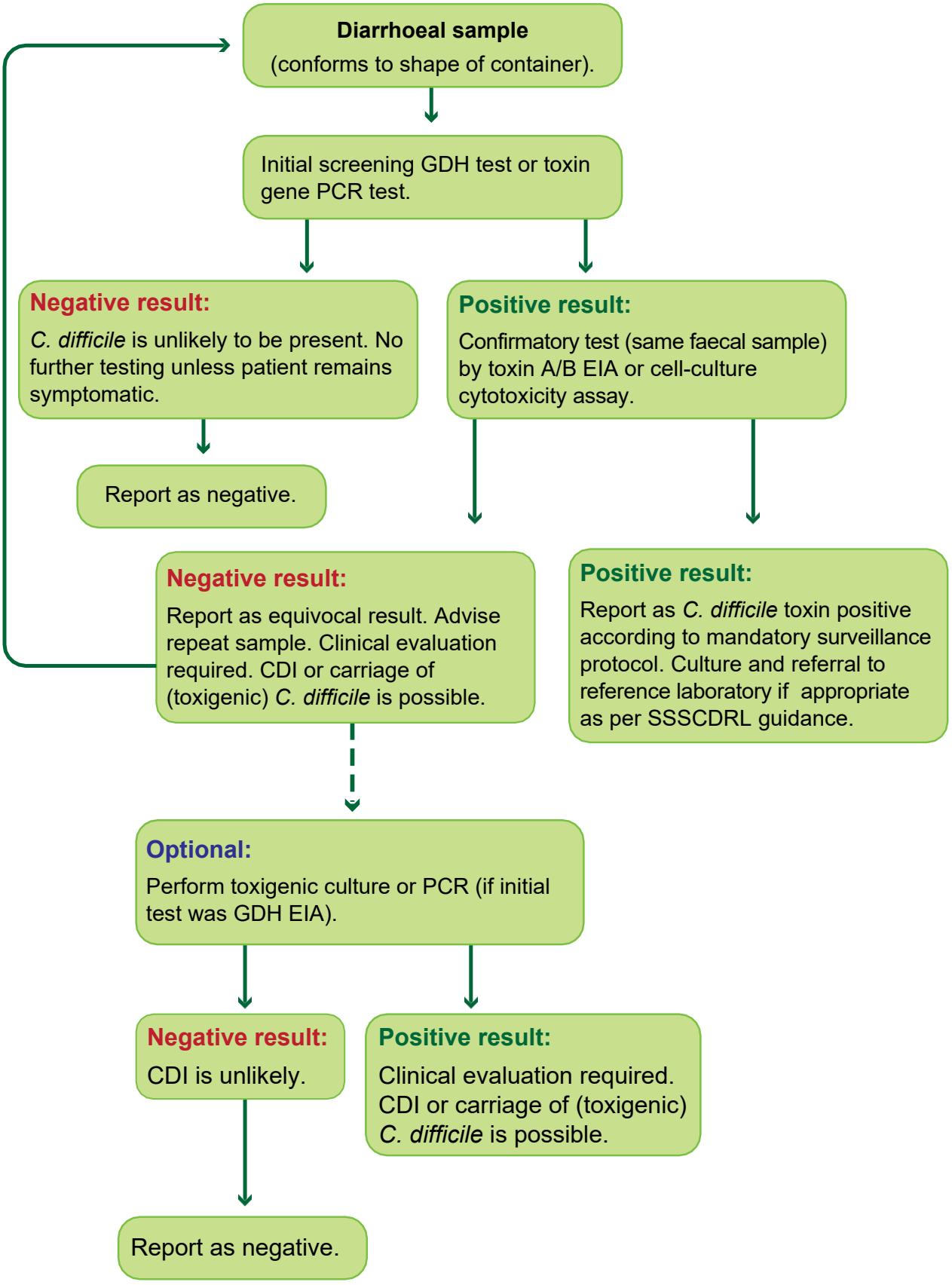
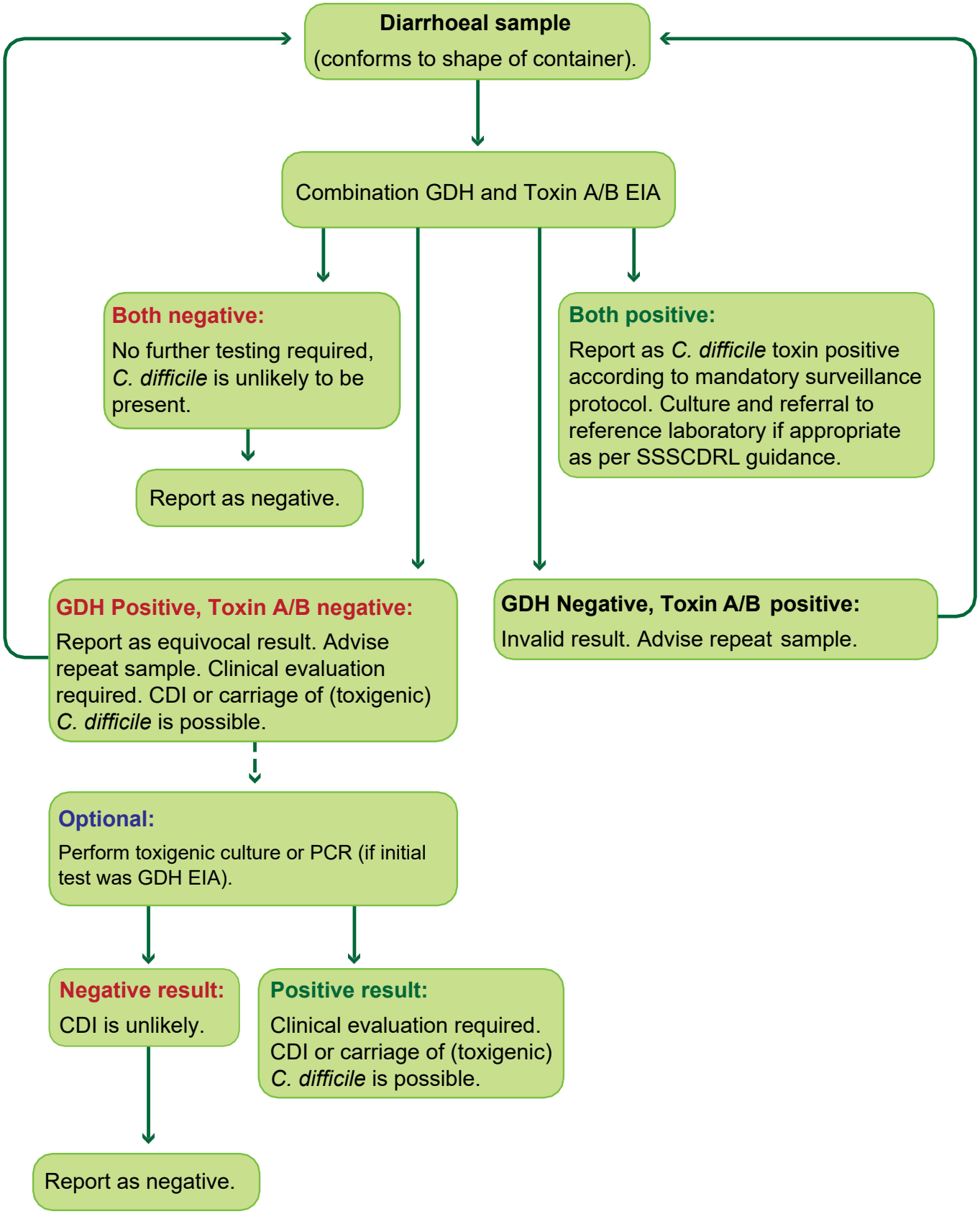


Figure 2: Testing Algorithm 2



Reference

1. ECDC, 2016. European surveillance of *Clostridium difficile* infections. Version 2.2. http://ecdc.europa.eu/en/publications/_layouts/forms/Publication_DispForm.aspx?List=4f55ad51-4aed-4d32-b960-af70113dbb90&ID=1402.