NHS National Services Scotland

Protocol for the surveillance of *Clostridioides difficile* infection

Version 5.0
September 2024

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Protocol for surveillance of *Clostridioides difficile* infection- Version 5.0.

ARHAI Scotland, 2024

Version history

Version	Date	Summary of key changes
V3.0	March 2009	Addition of the 15 to 64 age group.
V4.0	December 2016	Addition of Origin of Infection definitions.
V5.0	September 2024	Update to the Origin of Infection definitions and the data linkage methodology Update to reflect the SMVN testing algorithm published in 2024.

Approvals

Version	Date Approved	Group / Individual
V3.0	March 2009	Health Protection Scotland
V4.0	December 2016	Health Protection Scotland
V5.0	September 2024	ARHAI Scotland

Contents

1. Introduction

This protocol sets out the methodology for national surveillance of *Clostridioides difficile* infection (CDI) in Scotland.

Aims and Objectives

The **aim** of the national surveillance programme is to monitor *C. difficile* infection (CDI) and inform strategies for prevention and reduction within NHSScotland.

The **objectives** of the national surveillance programme are:

- To provide robust epidemiological data for CDI to monitor trends, support benchmarking and enable the identification of risk factors for infection.
- To provide expert epidemiological support for outbreaks and incidents in NHS boards.
- To monitor antimicrobial resistance and the emergence of new strains of *C. difficile* in collaboration with laboratory services.
- To provide a national expert role in epidemiology and to support the identification of quality improvement and reduction strategies.
- To support partner organisations and clinical networks in the development of national guidance and quality improvement tools for the reduction of CDI.

National and local surveillance

National and local surveillance serve different purposes:

- **National surveillance** identifies overall trends for 15 Scottish NHS boards and for Scotland overall (including community and healthcare associated cases). It is intended to support benchmarking, long-term planning and implementation of interventions, and monitor their impact.

- **Local surveillance** is intended to monitor the number of cases by ward, unit or other care setting, in real-time (i.e. daily or weekly at least) supporting outbreak detection and prompting immediate action when an increased number of cases or severe cases has been observed.

2. Obtaining specimens and testing for *C. difficile*

The national surveillance programme reports infection rates of CDI based on the number of *C. difficile* toxin positive specimens tested in accordance with the Scottish Microbiology and Virology Network (SMVN)- Review of *Clostridioides difficile* diagnostic testing in NHS Scotland: Best practice recommendations, and reported to Electronic Communication of Surveillance in Scotland (ECOSS).

The SMVN guidance sets out how stool specimens should be selected for testing. Only diarrhoeal specimens conforming to the shape of the container should be tested and there should be no clearance testing. A summary of the SMVN diagnostic testing guidance can be found in **Appendix A. Testing of C. difficile.**

3. Epidemiological case definitions

These are epidemiological case definitions for the purpose of surveillance and are **not** intended for clinical decision making.

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

Under the mandatory surveillance programme, only confirmed CDI cases aged 15 and above need to be reported to ARHAI Scotland via ECOSS. However, testing of patients aged 3-14 is recommended by the SMVN and these test results should be reported to ECOSS.[1]

CDI 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).

Diarrhoea

Diarrhoea is defined as the passage of three or more loose or liquid stools in a 24-hour period, or more frequently than is normal for the individual, and with no other underlying cause. For mild disease, diarrhoea is usually the only symptom. However, severe CDI is not always associated with diarrhoea, e.g. in the case of ileus.

New, repeat positive and recurrent cases

The **start date** of a CDI case is determined as the **date of specimen collection**.

Date of specimen collection is used as a proxy date for the date of onset of symptoms. If the specimen collection date is not available, the date on which the specimen was received by the laboratory will be used as the start date.

New CDI cases

A **new CDI case** occurs if an individual meets the CDI case definition **and** at least 28 days have elapsed since their last *C. difficile* toxin positive specimen. *i.e. SpecimenDate2 - SpecimenDate1 > 28 days.*

ARHAI Scotland carry out a deduplication process to ensure that only toxin positive specimens with at least **28 days between specimen collection dates** are included in surveillance reports.

It is important that laboratories submit **all** *C. difficile* toxin positive stool results to ECOSS in line with current SMVN guidance. The dates of all *C. difficile* toxin positive stool specimens are reviewed to determine whether they should be counted as a new CDI case, recurrent CDI or excluded as a duplicate.

Recurrent CDI cases

New CDI cases with a *C. difficile* toxin positive stool specimen **more than four weeks (>28 days) and less than eight weeks (<56 days)** of the last toxin positive specimen are considered **recurrent cases**.

All new cases, including recurrent CDI, are counted within the total CDI case numbers for reporting by ARHAI Scotland.

Repeat Positives

Repeat positives are *C. difficile* toxin positive stool specimens taken within 28 days of the last *C. difficile* toxin positive specimen. These are considered duplicate episodes and are not reported as new cases.

It should be noted that the SMVN guidance does not recommend clearance testing as individuals can remain toxin positive for weeks after symptoms have settled. The SMVN guidance recommends that repeat testing in confirmed positive cases should only be undertaken where symptoms have recurred after initial successful treatment.[1]

See Appendix B: Illustration of epidemiological case definitions of CDI with examples of new cases, repeat positive specimens and recurrent cases.

Origin of infection definitions

CDI cases are defined as community associated infection (CAI), healthcare associated infection (HCAI) or unknown origin (UNK) according to date of CDI onset in relation to hospital admission and discharge dates.

Note: If information on the date of onset of symptoms is unavailable, then the date of the first toxin positive specimen collection should be used as a proxy date.

Community associated CDI

A CDI case with onset of symptoms while outside of hospital **and** without discharge from a hospital within the previous 12 weeks,

OR,

A CDI case with onset of symptoms within 48 hours (≤48 hours) following admission to a hospital **and** without residence in a hospital within the previous 12 weeks.

Healthcare associated CDI

Healthcare associated CDI are sub-categorised as Hospital acquired CDI (HAI) and Other HCAI:

Hospital acquired CDI (HAI)

A CDI case with onset of symptoms at least 48 hours (> 48 hours) following admission to a hospital

Other HCAI

A CDI case with onset of symptoms within 48 hours (≤48 hours) following admission to a hospital **and** within 4 weeks following discharge from a hospital

OR,

A CDI case with onset of symptoms in the community within 4 weeks following discharge from a hospital.

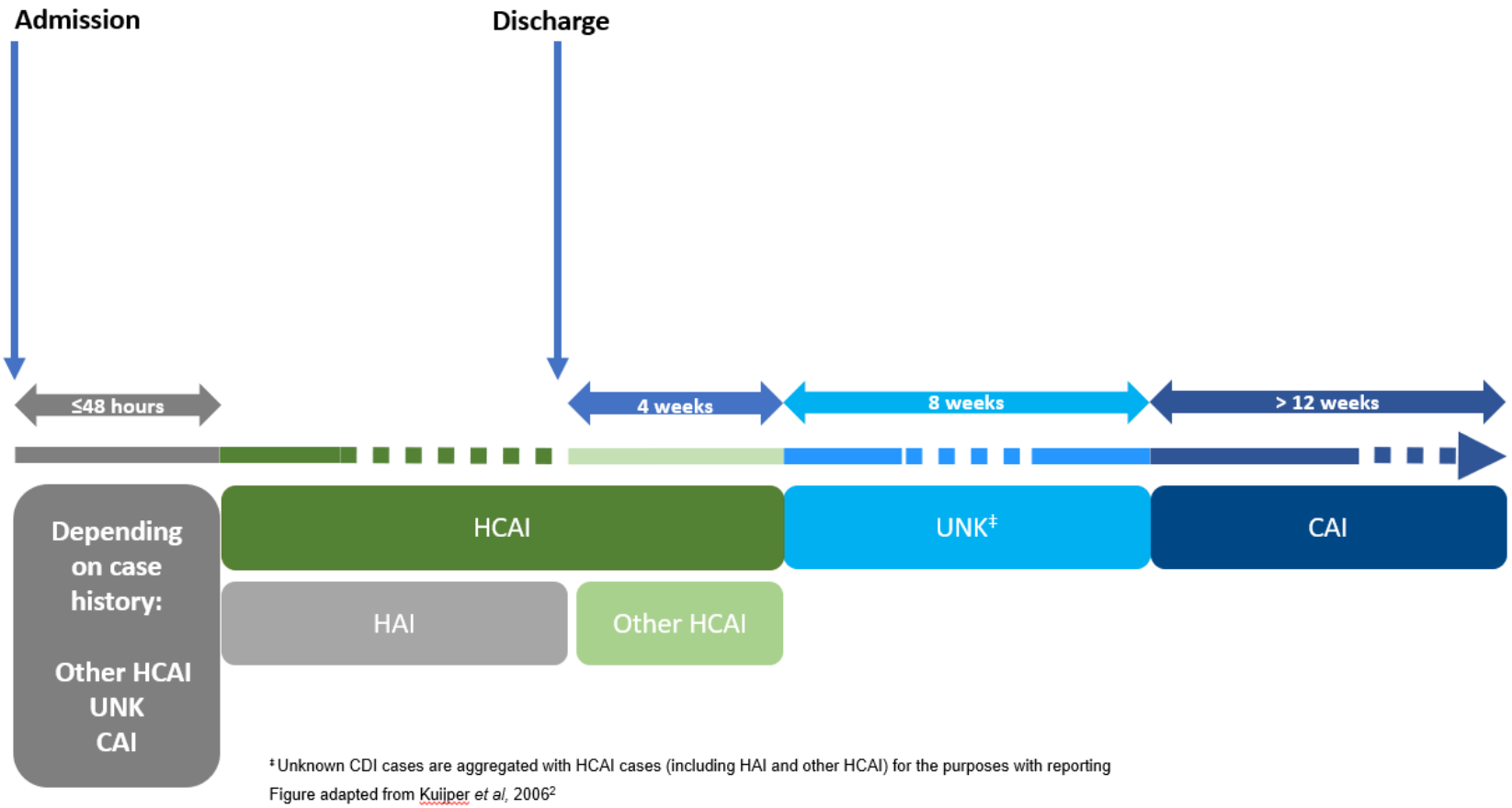
Unknown CDI

This is a CDI case who was discharged from a hospital 4–12 weeks before the onset of symptoms.

> Unknown CDI cases are cases for which the origin of infection is indeterminate. **For the purposes of national reporting and benchmarking, 'Unknown' CDI cases are aggregated with HCAI cases (including HAI and Other HCAI).**

The epidemiological definitions described above are summarised in Figure 1.

Figure 1: Summary of the CDI epidemiological definitions for origin of infection.



‡ Unknown CDI cases are aggregated with HCAI cases (including HAI and other HCAI) for the purposes with reporting

Figure adapted from Kuijper *et al*, 2006[2]

4. National epidemiological reporting

CDI case validation and assigning origin of infection

Each quarter, ARHAI Scotland extract a list of CDI cases from ECOSS and send it to the NHS boards for validation. The validation process requires individual NHS boards to:

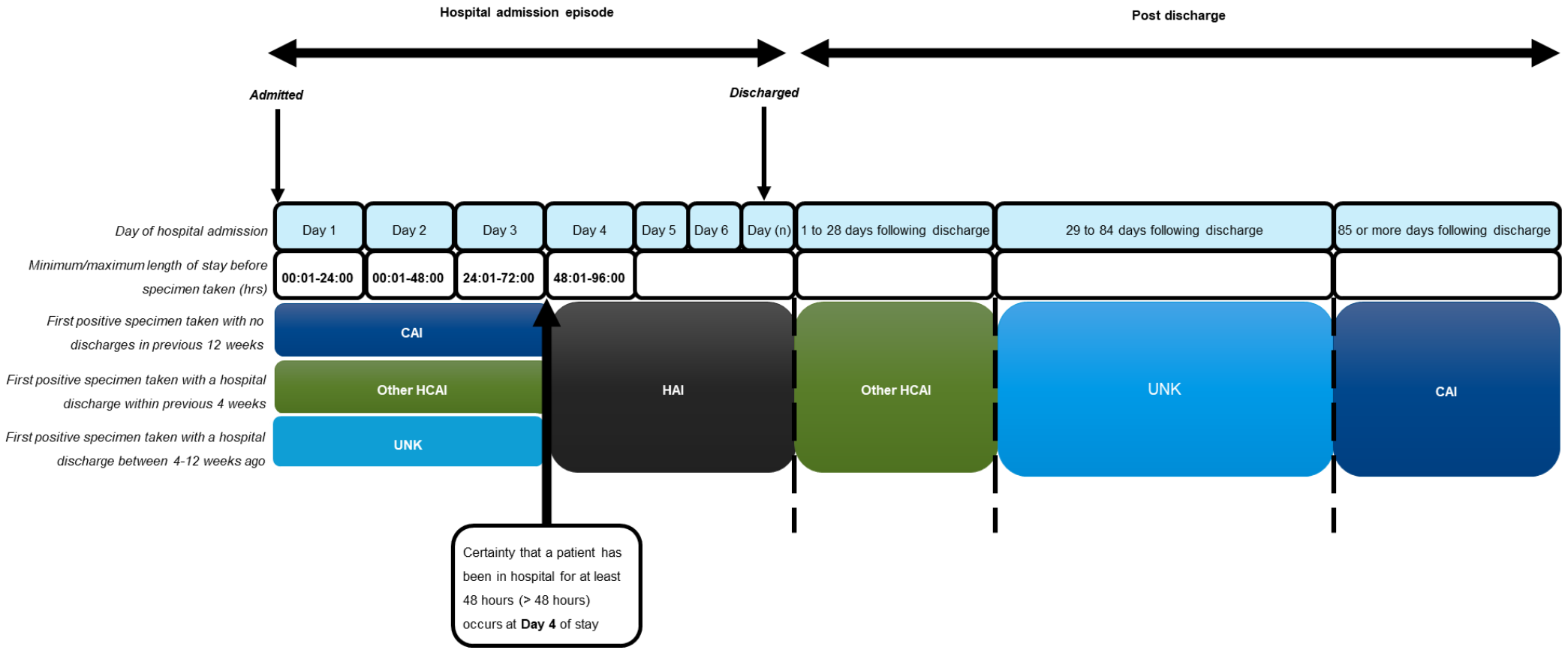
1. Confirm the list of CDI cases.
2. Provide details of any additional CDI cases that may have not been reported via ECOSS prior to the data extraction.
3. Provide a reason for excluding any cases that do not meet the case definition.
4. Provide the origin of infection according to the epidemiological case definitions for each of the cases listed.
5. Return validated CDI case lists and origin of infections to ARHAI Scotland.

Following validation, ARHAI Scotland link confirmed CDI cases with national healthcare datasets to identify any relevant hospital admissions/discharges and maximise ascertainment of HAI and other HCAI cases. This linkage aims to detect hospital discharges from any NHS board in Scotland within 12 weeks prior to specimen collection.

Since only the dates of patient admission and discharge are captured within the national healthcare datasets the time components of the origin of infection definitions are adapted for the linkage process. Calendar dates are used in the linkage process to determine how long a patient has been in hospital prior to specimen collection.

To ensure that there has been a hospital stay of ***at least* 48 hours** prior to specimen collection, cases will be assigned **HAI** where specimen collection date is on **day 4** of admission or later. The rationale for this is illustrated in **Figure 2**.

Figure 2: Rationale for assigning origin of infection using data linkage based on date of first positive specimen in relation to date of hospital admission and discharge.



To ensure that all healthcare associated CDI are captured, data from NHS board validation and linkage are combined, and the hierarchy in **Figure 3** is applied. Examples of how the infection hierarchy is applied is shown in **Table 1**.

Figure 3: The hierarchy of origin of infection subcategories assigned to CDI cases.

Table 1: Examples of assigning reported origin of infection to CDI cases.

Example	NHS board origin subcategory	Linkage origin subcategory	Assigned Origin subcategory[1]	Grouped Reported origin category[2]
1	CAI	HAI	HAI	HCAI
2	HAI	CAI	HAI	HCAI
3	Other HCAI	UNK	Other HCAI	HCAI
4	Other HCAI	HAI	HAI	HCAI
5	UNK	CAI	UNK	HCAI
6	UNK	Other HCAI	Other HCAI	HCAI
7	CAI	CAI	CAI	CAI

1. See Origin of infection definitions for details on each subcategory.
2. Grouped reported origin HCAI includes HAI, Other HCAI and UNK subcategories.

The national surveillance process is summarised in Appendix C: Summary of the surveillance process.

Assigning CDI cases to an NHS board

For the purpose of analysis and reporting CDI cases are assigned to an NHS board based on the criteria set out in the Quarterly Epidemiological Commentary for the Surveillance of Healthcare Associated Infections In Scotland Method Caveats.

Healthcare associated infection

Assigned to the NHS board of **specimen collection**, or if this is not available, the NHS board of laboratory.

Community associated infection

Assigned to the **NHS board of residence** for the case. If the case is not a resident of Scotland, the NHS board of laboratory is used.

Calculation of incidence rates

Incidence rates are calculated as follows for NHSScotland or individual NHS boards. Further details are available in the following document: Quarterly Epidemiological Commentary for the Surveillance of Healthcare Associated Infections In Scotland Method Caveats

Healthcare associated incidence rates per 100,000 total occupied bed days (TOBDs) are calculated using:

$$Healthcare\ associated\ rate = \left(\frac{Number\ of\ healthcare\ associated\ CDI\ cases}{TOBDs}\right) \times 100{,}000$$

Community associated incidence rates per 100,000 population are calculated using:

$$Community\ associated\ rate = \left(\frac{Number\ of\ community\ associated\ CDI\ cases}{midyear\ Scottish\ population}\right) \times \left(\frac{number\ of\ days\ in\ year}{number\ of\ days\ in\ period}\right) \times 100{,}000$$

Outputs

Data reported for mandatory surveillance are routinely reported in the ARHAI Quarterly Epidemiological Commentary for the Surveillance of Healthcare Associated Infections in Scotland and ARHAI Scotland Annual Report which are published on the NSS ARHAI website.

NHSScotland staff can also view their data on NHS Discovery dashboards:

- NSS Discovery Level 1 Healthcare Associated Infections: Quarterly Trend - Tableau Server (scot.nhs.uk)
- NSS Discovery Level 1 *C.difficile* Infection Surveillance: Contents Page - Tableau Server (scot.nhs.uk)

Please contact ARHAI Scotland for guidance on how to access Discovery.

5. Exception Reporting

Following quarterly analyses of CDI rates by ARHAI Scotland, NHS boards may be identified as exceptions. The exception reporting process is carried out in line with the Production of Quarterly Exception Reports SOP and methodologies published in the ARHAI Quarterly Epidemiological Commentary for the Surveillance of Healthcare Associated Infections in Scotland.

ARHAI Scotland will notify the NHS board of their CDI exception and the NHS board will be required to complete and return an action plan.

6. Culture and typing of *C. difficile* isolates

National CDI surveillance is supported by the clinical typing scheme which requires isolates of *C. difficile* to be submitted to the Scottish Microbiology Reference Laboratories (SMiRL), Enteric Bacterial Infections Service (EBIS) in the case of severe cases and suspected outbreaks.

Isolates meeting the criteria for mandatory submission should be sent to EBIS for ribotyping and accompanied by a completed EBIS Request Form. Laboratories

should culture faecal specimens for *C. difficile* from cases of severe disease and suspected outbreaks, according to agreed criteria below.

Criteria for mandatory submission of *C. difficile* isolates

Isolates of *C. difficile* should be submitted to SMiRL, EBIS 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 two courses of appropriate therapy.

2. Suspected outbreaks

When an outbreak is suspected and stools are positive for *C. difficile* toxin, an outbreak is defined as per Chapter 3 of the National infection Prevention and Control Manual.[3]

3. *Clostridioides difficile* Snapshot Programme

As part of the *Clostridioides difficile* Snapshot Programme (representative typing surveillance) laboratories should submit a defined number of consecutive isolates from CDI cases on a quarterly basis with request forms clearly labelled “snapshot”. Details on submission criteria are outlined in the protocol.

Other molecular typing technologies

Ribotyping may not be sufficiently discriminatory for the purposes of an investigation, and it may be necessary to use whole genome sequencing. Any further requirements should be discussed with EBIS.

7. Useful documents/links

- SMVN Review of *Clostridioides difficile* diagnostic testing in NHS Scotland: Best practice recommendations
- Protocol for the *Clostridioides difficile* snapshot programme
- ARHAI Quarterly Epidemiological Commentary for the Surveillance of Healthcare Associated Infections in Scotland,
- Quarterly Epidemiological Commentary for the Surveillance of Healthcare Associated Infections in Scotland Method Caveats.
- Scottish Microbiology Reference Laboratories - Enteric Bacterial Infections Service
- European surveillance of *Clostridioides (Clostridium) difficile* infections - surveillance protocol version 2.4

8. References

1. Scottish Microbiology and Virology Network (2024). Review of *Clostridioides difficile* diagnostic testing in NHS Scotland: Best practice recommendations. Available at: https://www.nn.nhs.scot/smvn/professional/smvn-guidelines (Accessed: 27/08/2024)

2. Kuijper EJ, Coignard B, Tull P, ESCMID Study Group for *Clostridium difficile*, EU Member States, European Centre for Disease Prevention and Control (ECDC). Emergence of *Clostridium difficile*-associated disease in North America and Europe. Clin Microbiol Infect. 2006 Oct;12 Suppl 6:2-18. [1].

3. NHSScotland (2023). National infection Prevention and Control Manual. Available at: https://www.nipcm.scot.nhs.uk/ (Accessed: 29/05/2024)

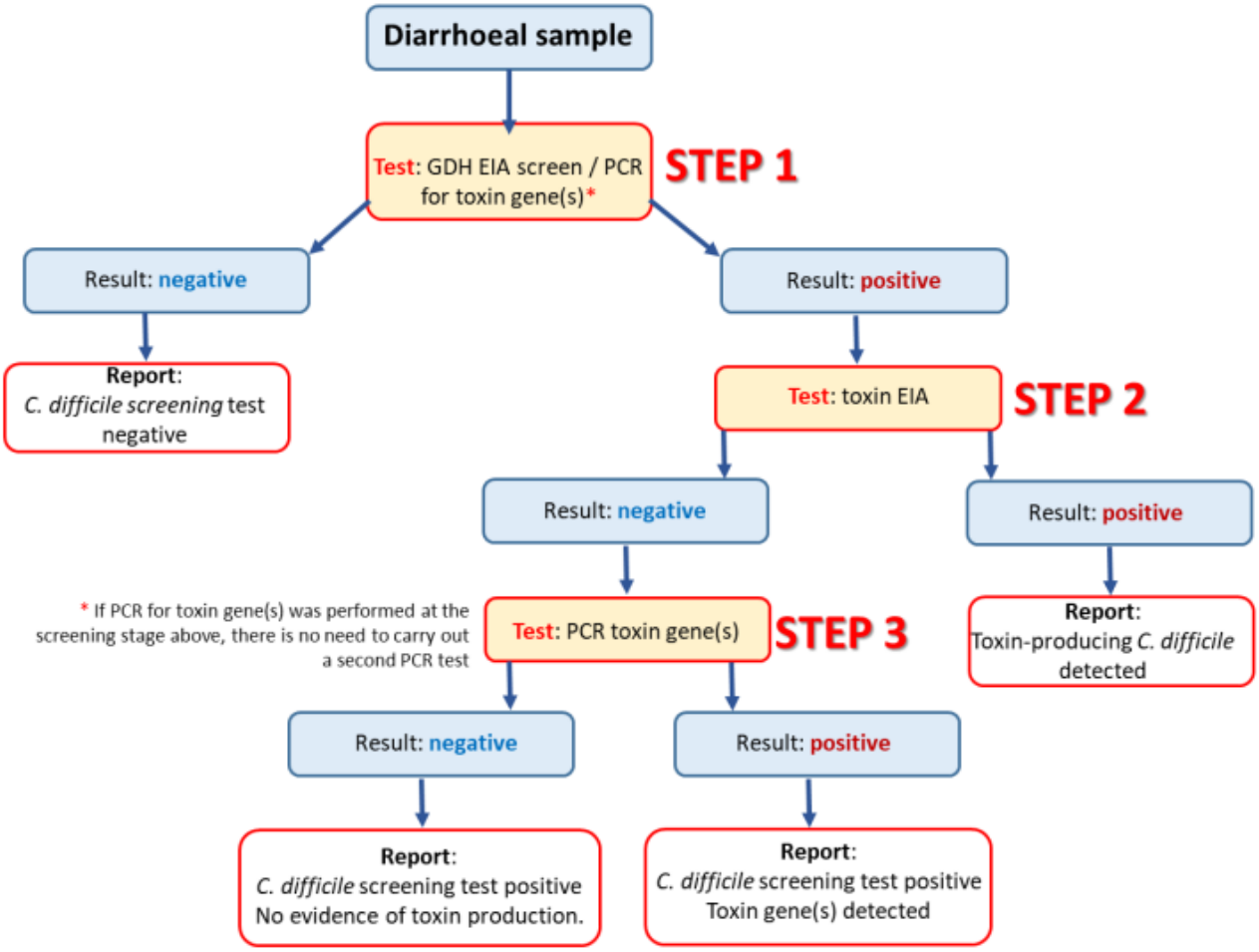
Appendices

Appendix A. Testing of *C. difficile*

Current guidance for specimen selection and testing are detailed in the Scottish Microbiology and Virology Network (SMVN) Review of Clostridioides difficile diagnostic testing in NHS Scotland: best practice recommendation. Testing and reporting should be in line with the SMVN recommendations. Any reports of '**Toxin-producing *C. difficile* detected**' following the first two steps of the algorithm must be submitted to ECOSS.

The SMVN has recently updated its testing algorithm as shown in **Figure 4**.

Figure 4: *C. difficile* laboratory testing / reporting algorithm 2024[1]



Appendix B: Illustration of epidemiological case definitions of CDI with examples of new cases, repeat positive specimens and recurrent cases.

Patient	Laboratory record	Specimen Date	Days between positive tests	Case type	Inclusion in reporting	Rationale for reporting
1	1	01/01/2024	-	New	Yes	First positive specimen date, reported as a CDI case.
1	2	30/01/2024	29	Recurrent	Yes	>4 weeks (>28 days) and less than eight weeks (<56 days) between the first and second positive specimen results. Reported as a CDI case.
1	3	10/02/2024	11	Repeat positive	No	<28 days between the second and third positive specimen results. Removed during the deduplication process, not reported as a CDI case.
2	1	01/01/2024	-	New	Yes	First positive specimen date, reported as a CDI case.
2	2	15/01/2024	14	Repeat positive	No	<28 days between the first and second positive specimen results, removed during the deduplication process, not reported as a CDI case.
3	1	01/01/2024	-	New	Yes	First positive specimen date, reported as a CDI case.
3	2	17/01/2024	16	Repeat positive	No	<28 days between the first and second positive specimen results. Removed during the deduplication process, not reported as a CDI case.

Patient	Laboratory record	Specimen Date	Days between positive tests	Case type	Inclusion in reporting	Rationale for reporting
3	3	29/01/2024	12	Repeat positive	No	<28 days between the second and third positive specimen results, removed during the deduplication process, not reported as a CDI case.
3	4	27/02/2024	29	Recurrent	Yes	>4 weeks (>28 days) and less than eight weeks (<56 days) between the third and fourth positive specimen results, reported as a CDI case.
4	1	01/01/2024	-	New	Yes	First positive specimen date, reported as a CDI case.
4	2	29/01/2024	28	Repeat positive	No	Exactly 28 days between the first and second positive specimen results, removed during the deduplication process and not reported as a CDI case.
5	1	01/01/2024	-	New	Yes	First positive specimen date, reported as a CDI case.
5	2	07/03/2024	66	New	Yes	>28 days between the first and second positive specimen results, reported as a new CDI case.

Appendix C: Summary of the surveillance process