Guidance on Prevention and Control of *Clostridium difficile* Infection (CDI) in Care Settings in Scotland

Health Protection Network
Scottish Guidance

Revised October 2014
(Version 2.1)
# Document Amendment Log

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The Health Protection Network (HPN) is a network of existing professional organisations and networks in the health protection community across Scotland. It aims to promote, sustain, and coordinate good practice. The HPN supports a systematic approach to development, appraisal and adaptation of guidelines, seeking excellence in health protection practice.


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Designed and typeset by:
Graphics Team, Health Protection Scotland
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Comments on the published guidance

Comments on this guidance should be sent to the HPN Steering Group via its national coordinator or administration, submitting the form available at http://www.hps.scot.nhs.uk/about/guidancedevelopment.aspx, to the following email address NSS.HPN@nhs.net. A copy of this form is also available in Appendix I on page 52.

Sometimes a comment after publication may highlight a potential error in a clinical guidance. This might be in either the interpretation or the presentation of the evidence considered by the GDG. In these cases the Chair of the Health Protection Network and the advisors they approach will consider whether the potential error:

- may result in harm to patients / the population;
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Comments or new evidence that are not an error but should be considered at the time when review of the document is due, will be collated and taken into consideration in due course.
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<th>Description</th>
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<tr>
<td>AMT</td>
<td>Antimicrobial management team</td>
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<td>CDI</td>
<td><em>Clostridium difficile</em> infection</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>ESCMID</td>
<td>European Society of Clinical Microbiology and Infectious Diseases</td>
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<td>ESGCD</td>
<td>European Study Group on <em>Clostridium difficile</em></td>
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<td>GDG</td>
<td>Guidance Development Group</td>
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<td>GDH</td>
<td>Glutamate dehydrogenase</td>
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<td>HAI</td>
<td>Healthcare Associated Infections</td>
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<td>HICPAC</td>
<td>Healthcare Infection Control Practices Advisory Committee</td>
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<td>HIIAT</td>
<td>Hospital Infection Incident Assessment Tool</td>
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<td>HPN</td>
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<td>ICU</td>
<td>Intensive Care Unit</td>
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<td>ITU</td>
<td>Intensive Treatment/Therapy Unit</td>
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<td>i.v.</td>
<td>Intravenous</td>
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<td>NES</td>
<td>National Education for Scotland</td>
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<td>NIP&amp;C</td>
<td>National Infection Prevention &amp; Control (Manual)</td>
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<td>PPM</td>
<td>Parts per million</td>
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<td>PCR</td>
<td>Polymerase chain reaction</td>
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<td>PHE</td>
<td>Public Health England</td>
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<td>PMC</td>
<td>Pseudomembranous colitis</td>
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<td>QoE</td>
<td>Quality of Evidence</td>
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<td>RCA</td>
<td>Root cause analysis</td>
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<td>RIDDOR</td>
<td>Reporting of Infections, Diseases and Dangerous Occurences Regulations</td>
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<td>SAPG</td>
<td>Scottish Antimicrobial Prescribing Group</td>
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<td>SICPs</td>
<td>Standard Infection Control Precautions</td>
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<td>SIGN</td>
<td>Scottish Intercollegiate Guidelines Network</td>
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<tr>
<td>SoR</td>
<td>Strength of recommendation</td>
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<tr>
<td>SPC</td>
<td>Statistical Process Control</td>
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<tr>
<td>TBP$s$</td>
<td>Transmission Based Precautions</td>
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<tr>
<td>US</td>
<td>United States</td>
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<td>WBC</td>
<td>White blood cells</td>
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1. Introduction

This guidance is a revised version of the ‘Guidance on Prevention and Control of Clostridium difficile Infection (CDI) in Healthcare Settings in Scotland’ issued in September 2009, and provides easily accessible advice covering key aspects of prevention and control of CDI.

A multidisciplinary group (Appendix F on page 47) was convened in Scotland in 2013 for the purpose of reviewing current guidance. Under the auspices of the Health Protection Network (HPN), the group followed a systematic development framework proposed by the HPN, which is available at: http://www.hps.scot.nhs.uk/about/hpn.aspx.

The recommendations that follow are based on a systematic literature review produced by the European Study Group on Clostridium difficile (ESGCD) in 2008 [1] and recently updated guidance on the treatment of CDI published by the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) [2], Public Health England (PHE) [3] and practice guidelines published in the American Journal of Gastroenterology [4] (see section 2.3 on page 24). A rapid literature review was undertaken to evaluate any new evidence within the areas of infection prevention and control, and outbreak management. In areas where insufficient evidence exists, advice is based on expert consensus.

The level of evidence for the key recommendations was graded in the literature review by the ESGCD and categories for implementation in clinical practice were generated based on the Healthcare Infection Control Practices Advisory Committee (HICPAC) Guidelines (the Centers for Disease Control and Prevention (CDC)) (Appendix A on page 39). The recommendations listed in this document (as bullet points) are followed by categories for implementation in clinical practice (IA, IB, IC or II), where IA is the strongest recommendation.

This guidance is intended for use in all care settings in Scotland; i.e. acute and non-acute hospitals, care homes and care at home. It is acknowledged that not all of the information/recommendations contained in this guidance will apply to those working in the care home and/or care at home setting. The use of the word ‘persons’ can be used instead of ‘patients’ when using this document in a non-hospital setting.

The guidance should also be used alongside methods of the Scottish Patient Safety Programme of work (where applicable), which provide a standardised approach to implementation of the recommendations of this guidance.
1.1. Aims and scope

This guidance provides a standardised evidence-based approach to diagnosis, prevention and control, and treatment of CDI to enable staff to deliver safe care and support the reduction of CDI in their organisations.

Organisations and staff providing care have a key role in preventing and controlling CDI and other healthcare associated infections (HAI).

The guidance aims to:

- Outline roles and responsibilities;
- Aid the application of knowledge in preventing transmission of *C. difficile* in all care settings;
- Share best practice on antimicrobial treatment of CDI;
- Improve patient safety in relation to the acquisition and management of patients with CDI; and
- Reduce morbidity, mortality and service disruption as a result of CDI.

The guidance should be used as a framework to ensure the relevant policies are in place, to examine the currency of policy content where policies are already in place, or to inform local policy development.

1.2. Background

For a detailed overview of the epidemiology of CDI in Scotland (including quarterly and annual surveillance reports) please refer to the CDI website at: [http://www.hps.scot.nhs.uk/haic/sshaip/clostridiumdifficile.aspx](http://www.hps.scot.nhs.uk/haic/sshaip/clostridiumdifficile.aspx).

**Transmission of *C. difficile***

Since *C. difficile* is an anaerobic bacterium, viable bacteria will quickly die when exposed to air. However, *C. difficile* produces hardy spores that can tolerate air, heat and resist various detergents and disinfectants, and are able to survive for extended periods in the environment.

*C. difficile* is transmitted via these spores that are picked up either by direct contact with an infected (or colonised) person or by indirect contact with a contaminated surface and then swallowed. The ability of these spores to survive in the environment, even when disinfectants are used, has contributed to the widespread spread of *C. difficile* in care facilities [5, 6].

Direct and indirect contact (i.e. with an infected person or contact with a contaminated surface) followed by swallowing represent the main routes of transmission of *C. difficile*. 
Symptomatic CDI patients shed spores via their faeces into the environment at a high rate and these patients are considered the main source of contamination of the environment of care facilities [7].

Toilets, commodes and the environment of CDI patients (including frequently touched surfaces around toilets and beds) are likely to be contaminated. This is the reason why increased environmental cleaning is of paramount importance to decrease the risk of environmental cross contamination. The hands of care staff are also likely to be contaminated, and if hand hygiene is not optimal C. difficile will spread to other persons or the environment. Alcohol-based hand rubs are not effective in removing C. difficile spores from hands and should not be used alone when caring for patients with CDI – hand washing with liquid soap and water is necessary to remove spores and prevent their spread.

Some people carry C. difficile in their gut without having any symptoms, and sometimes people who have been treated and recovered from CDI will still be carrying C. difficile in their gut.

In a US study, it was found that up to 50% of patients in a long-term care facility were asymptomatic carriers of C. difficile [8]. These carriers were shedding spores into the environment although at lower concentrations than observed in patients with diarrhoea. Further studies have since been published on the role of asymptomatic carriers in the transmission of C. difficile, but there is currently insufficient evidence on which to base any recommendations. Special contact precautions (or other interventions) are not recommended for asymptomatic carriers.
2. Recommendations

The recommendations that follow (see sections 2.2.1 on page 10 to 2.2.10 on page 23) are adapted from a systematic review carried out by Vonberg et al. [1], which provides evidence-based guidance to limit the spread of *C. difficile* in care settings.

Prevention and control of CDI depends on ten key areas that cover: early diagnosis (see section 2.2.1 on page 10), implementation of surveillance (see section 2.2.2 on page 12), education (see section 2.2.3 on page 17), patient placement/isolation precautions (see section 2.2.4 on page 18), hand hygiene (see section 2.2.5 on page 19), protective equipment (see section 2.2.6 on page 19), environmental decontamination (see section 2.2.7 on page 20), management of care equipment (see section 2.2.8 on page 21), antimicrobial stewardship (see section 2.2.9 on page 21) and specific measures during outbreaks (see section 2.2.10 on page 23).

Standard Infection Control Precautions (SICPs) are the basic infection prevention and control measures necessary to reduce the risk of transmission of microorganisms from recognised and unrecognised sources of infection. Transmission Based Precautions (TBPs) are used in addition to SICPs to prevent cross transmission of specific infectious agents such as *C. difficile*. SICPs and TBPs form the basis of the recommendations found in sections 2.2.4 on page 18 to 2.2.8 on page 21 and reference should also be made to the National Infection Prevention and Control (NIP&C) Manual: http://www.hps.scot.nhs.uk/haiic/ic/guidedetail.aspx?id=49785.

The Health Protection Scotland (HPS) ‘Checklists for preventing and controlling CDI’ is a useful tool to ensure that recommended practices are implemented: http://www.hps.scot.nhs.uk/haiic/sshaip/publicationsdetail.aspx?id=38848.

Short-guides for managing CDI in healthcare or community settings are provided in Appendix B on page 41 and Appendix C on page 42, respectively, while a full list of documents referred to in the recommendations (e.g. CDI surveillance protocol, CDI Trigger Tool and the National Infection Prevention and Control (NIP&C) Manual) is included in Appendix D on page 43.
2.1. Roles and responsibilities to support the implementation of this guidance

The recommendations set out in this guidance are based on the assumption that care settings have infection prevention and control systems in place in line with existing guidance (see Appendix D on page 43 and links throughout this document).

Organisations should ensure:

- systems and resources are in place to facilitate implementation and monitor compliance to support the reduction of CDI throughout the organisation; and
- effective local surveillance systems are in place to detect increasing incidence (or frequency) and severity of CDI that prompt rapid investigations and implementation of prevention and control interventions.

Infection Prevention and Control Teams should:

- provide expert advice on the application of CDI prevention and control measures in the care setting and on individual patient risk assessments;
- engage with staff to develop systems and processes that lead to sustainable and reliable improvements in relation to application of CDI prevention and control measures; and
- assist in the investigation of any CDI cases that result in severe disease or death.

Health Protection Teams should:

- provide expert advice on the application of CDI prevention and control measures in the care setting and on individual patient risk assessments as required;
- engage with staff to support implementation of infection prevention and control precautions described in this guidance as required; and
- support further investigations when there is an increased number of cases of CDI in care homes in collaboration with relevant staff and General Practitioner.

Managers should ensure that staff:

- are aware and have access to infection prevention and control guidance documents;
- have had instruction and education about the clinical features and routes of transmission, and the epidemiology of CDI; and
- have adequate support and resources available to implement, monitor and take corrective action to ensure compliance with CDI prevention and control policies and procedures.
Staff providing care should ensure that they:

- understand and apply the principles of CDI prevention and control as set out in this guidance;
- maintain competence, skills and knowledge in infection prevention and control through attendance at education and training events;
- communicate the infection prevention and control practices to be undertaken by colleagues, persons, patients, relatives and visitors without breaching confidentiality; and
- report to line managers and document any deficits in knowledge, resources, equipment and facilities or incidents that may result in transmission of infection.

Consultants in Microbiology should ensure:

- that there is participation in the national mandatory CDI surveillance programme;
- that diarrhoeal stool samples are tested and the results interpreted according to the national recommended protocol for testing for CDI;
- that clinical staff are appropriately advised on testing, interpretation of results and treatment of CDI;
- that diarrhoeal stool samples from all CDI cases are stored at -20°C for a period of three months to enable further investigations;
- that infection prevention and control teams are advised and supported in relation to specific CDI issues, e.g. increased number of cases/incidence, outbreaks and changes in practice;
- that Health Protection Teams are advised and supported if there are any implications regarding CDI in the community;
- that Antimicrobial Management Teams (AMTs) are advised and supported in relation to development and maintenance of local antimicrobial policies and stewardship programmes;
- that senior managers are alerted to any issues (deficits in knowledge, resources, equipment and facilities, and incidents) that may result in transmission of infection or changes in the incidence and/or severity of disease; and
- that they assist in the investigation of any CDI cases that result in severe disease or death.
Antimicrobial Management Teams (AMTs) should:
• ensure implementation and compliance monitoring of local antimicrobial prescribing policies that minimise the use of agents associated with CDI; and
• support and advise clinical staff on antimicrobial prescribing and interpret local and national surveillance information on antimicrobial resistance and usage.

General Practitioners should:
• be aware of and follow local antimicrobial guidelines for primary care in the NHS board;
• be aware of major risk factors (see Major risk factors for CDI on page 10) and symptoms of CDI;
• obtain stool specimens from any person with diarrhoea in the community, aged 15 years and over, as early as possible and send the specimen to the local microbiology laboratory requesting testing for C. difficile toxin;
• ensure that the Health Protection Team (or Infection Prevention and Control Team) is alerted within the NHS board if cases occur within a care home;
• seek advice on appropriate infection prevention and control precautions from the Health Protection Team within the NHS board;
• use appropriate infection prevention and control measures as set out in this document when dealing with persons with diarrhoea;
• follow the CDI treatment protocols outlined in section 2.3 on page 24, and seek advice from the local consultant microbiologist if unsure of appropriate steps; and
• assist in the investigation of any community CDI cases that result in severe disease or death.
2.2. Infection prevention and control of CDI

2.2.1. Early diagnosis

Early diagnosis is essential for preventing and controlling CDI.

Symptoms of CDI

The main symptom of CDI is diarrhoea (Box 1 on page 10). However, clinical disease comprises a range of toxin mediated symptoms that can result in more severe cases such as pseudomembranous colitis (PMC), toxic megacolon and peritonitis that can lead to death. Severe CDI is not always associated with diarrhoea (see Guidance on severity assessment of CDI on page 24 and Table 1 on page 32 and Table 2 on page 33).

For mild disease, diarrhoea is usually the only symptom. Other clinical features consistent with more severe forms of CDI include abdominal cramps, fever and leukocytosis (raised white blood cell levels) [9].

Symptoms of CDI, and associated immune reactions, in children differ from those in adults, but the pathology is not well described. Routine testing in children aged under 15 years is not recommended.

Box 1

Definition of diarrhoea

Diarrhoea is defined as the passage of three or more loose or liquid stools per day, or more frequently than is normal for the individual [10].

NB: The frequent passing of formed stools is not diarrhoea.

Major risk factors for CDI

Certain persons are at increased risk of acquiring CDI. The possibility of CDI should be considered when persons with diarrhoea also have:

- Current or recent (within the last three months) use of antimicrobial agents (especially those with a high risk for CDI, e.g. cephalosporins, broad spectrum penicillins, fluoroquinolones and clindamycin);
- Increased age;
- Prolonged hospital stay;
- Serious underlying diseases;
- Surgical procedures (in particular bowel procedures);
- Immunosuppression; and/or
- Use of proton pump inhibitors (drugs which reduce the production of stomach acid).
Testing for *C. difficile* and diagnosis of CDI

Specific recommendations for testing and diagnosis are listed below:

- Implementation of additional infection prevention and control measures should be started as soon as CDI is suspected (do not wait for the laboratory result to confirm diagnosis before initiating treatment and putting control measures in place) (IB).

- Stool specimens must be obtained and sent to the microbiology laboratory as soon as possible after onset of symptoms (i.e. diarrhoea) from persons in care settings and from persons admitted to care settings with diarrhoea (IB).

- CDI testing should only be performed on diarrhoeal stool specimens (a diarrhoeal specimen is a specimen of faeces that conforms to the shape of its container) (IB). Laboratory CDI testing using a two-step algorithm should be available 7 days a week.

- Stool specimens from all CDI cases should be stored by the laboratory at -20°C for a period of three months; in particular, from those with a) severe* CDI, or b) in suspected outbreak situations so that culture and typing can be performed retrospectively, if necessary (IB) (*see section 2.3 on page 24 for definition of severe disease).

- Exclude other causes of diarrhoea before giving the diagnosis of CDI (following the case definition of CDI, Box 2 on page 11). Seek advice from the Infectious Disease Doctor or Consultant Microbiologist (II).

- Norovirus infection is not a reason to exclude CDI as diagnosis, as co-infection with norovirus and *C. difficile* is possible [11, 12, 13]. When a person has tested positive for both *C. difficile* toxin and norovirus a clinical assessment is required to determine the most likely diagnosis (II).

- Stop repeated faecal testing as soon as CDI has been diagnosed. Only when a recurrence of CDI is suspected, repeat the CDI testing and exclude other potential causes of diarrhoea (IB).

- Clearance testing (i.e. test of cure) should not be performed (IA).

### Box 2

**Definition of CDI**

Someone whose stool has been confirmed positive for *C. difficile* infection in a two-step laboratory testing algorithm (using a glutamate dehydrogenase (GDH) or polymerase chain reaction (PCR) screening test followed by a confirmatory test using toxin immunoassay or cell-culture cytotoxicity assay) **at the same time as they have experienced diarrhoea not attributable to any other cause**. or from cases of whose stool *C. difficile* has been cultured at the same time as they have been diagnosed with pseudomembranous colitis (PMC).

No single test or combination of tests should be considered infallible in establishing or excluding the diagnosis of CDI, and the clinical condition of the patient should always be considered when making management and treatment choices.

Symptomatic CDI patients are believed to be the major source of C. difficile transmission and are associated with high rates of environmental contamination.

- Testing of stool specimens from asymptomatic persons is not recommended (IB).
- Routine screening of asymptomatic persons for CDI is not recommended (no evidence supports screening).

Guidance on how to take faecal samples can be accessed from Appendix G on page 48 and from:

(For patients/residents or carers at home); and

(For healthcare staff).


2.2.2. Surveillance

Surveillance is strongly recommended as a tool for monitoring, preventing and controlling CDI. Surveillance is used to identify increases in CDI incidence and/or severity at an early stage. This requires investigation and change in practice to reduce the numbers of cases.

Surveillance requirements

Surveillance of CDI is mandatory in Scotland in persons aged 15 years and over, presenting with diarrhoea in any care setting. Data should be reported to HPS by the diagnostic laboratories.


National and local surveillance serve different purposes

The national surveillance identifies overall trends for the 14 Scottish NHS boards and for Scotland overall (including community and hospital cases), and is intended to support the long-term planning and implementation of interventions and monitor their impact.
Local surveillance is intended to monitor the specific number of cases by ward, unit or other care setting, and disease severity in real-time (i.e. daily or weekly at least) to prompt immediate action when an increased number of cases or increased disease severity has been observed.


Specific recommendations for surveillance are:

- All care settings should have local surveillance systems in place (IB).
- Ensure appropriate prompt diagnostic testing of persons with an acute diarrhoeal illness not otherwise explained (IB).
- Determine the ward-, unit- or other care setting-specific baseline incidence of CDI by reviewing cases of recent and previous periods (IB).
- Define a threshold incidence (or frequency) of CDI cases that would trigger implementation of additional infection prevention and control measures (interventions) (IB).
- Be alert to changes in the incidence (or frequency), complications (including recurrences) or severity that may indicate the introduction of new strains (II).

From the specific recommendations given above, local surveillance should comprise the following elements:

1. The incidence (or frequency) of CDI should be monitored in all areas clearly defined by ward, unit or other care setting. The baseline incidence (or frequency) should be available for each area. Care homes should have, or create a system for recording all cases by data and location to aid recognition of an increased number of cases (i.e. incidence) of CDI [15]. If using denominators, these should be defined as all persons at risk of CDI at any given time in each area.

2. The severity of each case of CDI should be categorised and monitored (see Severe CDI and death associated with CDI on page 16).

3. Risk factors (see section 2.2.1 on page 10) should be identified for each case of CDI.

4. Deaths in which CDI is either the primary cause or contributory factor should be recorded and investigated (see Severe CDI and death associated with CDI on page 16).

5. A ‘trigger for action’ (see Box 4 on page 15) should be set for each area. For care homes this should be set at two or more cases occurring within 28 days in the same area [15].

6. Each case of CDI should be assessed with regards to acquisition of disease (i.e. was CDI acquired in the community or other care setting – see CDI epidemiological definitions, Box 3 on page 14 and Figure 1 on page 14). Understanding the source and causes of CDI can help target efforts to reduce infections [15].
Feedback of surveillance data and its interpretations to all relevant persons in the care organisation via the established communication system is essential for preventing and controlling CDI.

Box 3

Epidemiological definitions of CDI (adapted from Kuijper et al., 2006 [14])

Definition of community associated CDI
This is a CDI patient with onset of symptoms while outside a hospital and without discharge from a hospital within the previous 12 weeks – or with onset of symptoms within 48 hours following admission to a hospital without stay in a hospital within the previous 12 weeks.

Definition of healthcare associated CDI
Healthcare associated CDI is defined as when a CDI patient has had onset of symptoms at least 48 hours following admission to a hospital or up to four weeks after discharge from a hospital.

Definition of unknown cases of CDI
This is a CDI patient who was discharged from a hospital 4–12 weeks before the onset of symptoms.

FIGURE 1: Relationships between epidemiological definitions (as in Kuijper et al., 2006 [14])

Admission
↓
48h
↓
Discharge
4 weeks
8 weeks

(*) : - maybe community- or healthcare-associated, depending on case’s history.
- if healthcare-associated, may have been acquired in the same facility or imported from another.
Triggers for action at local level

The local surveillance system should have a trigger (i.e. a threshold) (Box 4 on page 15) that prompts immediate actions and interventions to control CDI. The trigger should contain the incidence and severity of CDI.

Box 4

Definition of ‘triggers for action’:
When cases occur at a rate exceeding the normal number of cases for the unit, ward or other care setting during a specified period of time, or when disease occurs at increased severity, immediate actions and interventions should be introduced.

There is not one trigger that will fit all care settings. For smaller care facilities (including care homes), it may be appropriate to set triggers based on the number of cases within a set time-period (e.g. two or more cases occurring within 28 days in the same area). For larger institutions, statistical process control (SPC) charts may form the basis of a trigger, particularly for wards and specialties with high numbers.


When a trigger has been reached or breached, this may indicate either natural variation in the number of cases or that there may be a developing problem within the care setting. An investigation should be initiated including assessment of cases and their management, infection prevention and control and antimicrobial treatment to establish the cause.

Severe CDI and death associated with CDI

The clinical team responsible for the care of a patient who develops severe CDI, or whose death is associated with CDI, should carry out an investigation into the reasons leading up to the infection (with assistance from GPs when occurring in the community). The investigation should use root cause analysis as outlined in the ‘CDI Severe Case Investigation Tool’ (http://www.hps.scot.nhs.uk/haiic/sshait/publicationsdetail.aspx?id=44042).

Severe CDI, and deaths associated with CDI, should be included as part of all morbidity and mortality reviews and other case reviews on a regular basis as a means of sharing lessons learned to reduce the risk of persons acquiring CDI in the future.

When assessing the severity of individual CDI cases it is recommended that the guidance in section 2.3 is adhered to (see section 2.3 on page 24).


Laboratories should culture C. difficile from all severe cases and submit isolates to the reference laboratory.

Escalation of reporting in incidents

Once an infection incident related to CDI has been identified (i.e. a ‘trigger’ has been reached or exceeded either by increased number of cases or increased severity of cases), it should be assessed by a member of the Infection Prevention and Control Team or the Health Protection Team using the ‘Hospital Infection Incident Assessment Tool (HIIAT)’, which is available at http://www.hps.scot.nhs.uk/haiic/ic/publicationsdetail.aspx?id=43437; and http://www.hps.scot.nhs.uk/haiic/ic/publicationsdetail.aspx?id=43438.

If the risk assessment identifies that the incident is higher than Green (defined as higher than minor impact on patients, services, public health and public anxiety), then the incident should be reported to HPS, by a member of the Infection Prevention and Control Team or the Health Protection Team.

For guidance on outbreaks see section 2.2.10 on page 23.
2.2.3. Education

Education of healthcare staff is one of the most effective measures to limit the spread of C. difficile [1].

The single recommendation on education is:

- Everyone, including care workers and visitors, who enters a confirmed or suspected CDI case’s environment should be educated about the clinical features of transmission and epidemiology of CDI (IA).

All care staff in care settings including hospitals, primary care and community based teams (care homes and care at home), support and auxiliary and also non-medical staff, in particular those involved in cleaning, should receive education on all aspects of CDI.

The education should include information on:

- Basic pathogenic mechanisms of C. difficile;
- Potential reservoirs;
- Route of transmission;
- Symptoms of CDI;
- Risk factors for CDI;
- Standard infection control precautions; and
- Transmission based precautions for CDI.


On-line training materials by NHS Education for Scotland on CDI can be accessed via:

For visitors of CDI cases, this means basic information on what CDI is and what measures should be taken by them to prevent the spread of *C. difficile*.

HPS information leaflets on CDI for hospital patients and visitors; residents and visitors of care homes; and home laundering of patient items can be accessed at:

- [http://www.hps.scot.nhs.uk/haiic/ic/guidelinedetail.aspx?id=38654](http://www.hps.scot.nhs.uk/haiic/ic/guidelinedetail.aspx?id=38654) (Hospital patients and visitors);
- [http://www.hps.scot.nhs.uk/haiic/ic/guidelinedetail.aspx?id=39108](http://www.hps.scot.nhs.uk/haiic/ic/guidelinedetail.aspx?id=39108) (Residents and visitors of care homes); and

### 2.2.4. Patient Placement

The spread of hardy spores of *C. difficile* plays an important role in the transmission of CDI in care settings. Isolation of patients with confirmed or suspected CDI is a key step in preventing the transmission of *C. difficile*.

Specific recommendations for placement of patients with confirmed or suspected CDI are:

- Symptomatic patients should be nursed in single rooms (i.e. isolation) with en-suite facilities, whenever possible (IB).
- If en-suite is not available, a designated toilet or commode (transportable toilet) should be provided for each patient with CDI (IB).
- If isolation in single rooms is not possible, isolation in patient cohorts should be undertaken (IB).
- Cohorted patients should be managed by designated staff, where possible, to minimise the risk of infection to other patients (or staff) (IB).
- Isolation precautions may be discontinued when the patient has been symptom-free for 48 hrs and bowel movements have returned to normal (II).
- Symptomatic CDI patients should not be moved between wards for bed management reasons, to minimise the risk of cross-contamination [15] (IB).
2.2.5. Hand Hygiene

Specific recommendations for hand hygiene as a control measure to reduce the transmission of CDI are listed below.

- Meticulous hand washing using liquid soap and running water and paper towels is recommended for all staff after contact with body substances or body fluids (including faeces), or after contact with the environment of a patient with an enteric illness, i.e. diarrhoea (and/or vomiting) including CDI (IB).

- Washing of hands using liquid soap, running water and paper towels is recommended after removal of gloves and aprons (IB).

- Alcohol-based hand rubs are not effective in removing *C. difficile* spores from hands and should therefore not be the only hand hygiene measure when caring for suspected or confirmed CDI patients (IB).

- Patients and visitors should be strongly encouraged to wash their hands with liquid soap and running water, especially before eating, after using the toilet [16], and when entering and leaving the care setting to minimise the risk of swallowing spores (II).

2.2.6. Personal protective equipment

There is good evidence that environmental contamination plays a role in the transmission of *C. difficile* [17, 18].

Environmental contamination occurs as a result of *C. difficile* spores being expelled into the environment when patients have diarrhoea with large amounts of liquid stools or faecal incontinence. Heavy contamination can be found on floors, toilets, commodes, beds and other frequently touched surfaces.

Specific recommendations for personal protective equipment as a control measure to reduce the transmission of CDI are listed below.

- All staff should wear disposable gloves for contact with patients who have diarrhoea; this includes contact with body substances and contaminated environment, including the immediate vicinity of the patient (IB).

- Disposable plastic aprons should always be used for managing patients who have diarrhoea (IB).

- Washing hands using liquid soap and running water and paper towels is required after removal of gloves and aprons (IB).
2.2.7. Environmental decontamination

Specific recommendations for environmental decontamination (including cleaning and disinfection) as a control measure to reduce the transmission of CDI are listed below.

- Environments (hospital wards, care homes and other settings where CDI patients are cared for, including the immediate vicinity around a CDI patient) should be cleaned and decontaminated regularly (at least once a day) concentrating on frequently touched surfaces such as tables, chairs, telephones, door handles, flush and tap handles and hand sets, e.g. call bells and bed controls (IB).

- When cleaning and decontaminating it is important to physically remove the spores, i.e. thoroughly wiping, rinsing and drying (II).

- When decontaminating use a disinfectant with 1000 parts per million (ppm) available chlorine (IB).

This may either be a standalone disinfectant (applied after cleaning) or a combined detergent/chlorine releasing solution (see Appendix 7 of the NIP&C Manual). For surfaces that do not tolerate chlorine, please refer to Appendix 11 of the NIP&C Manual, available at: http://www.hps.scot.nhs.uk/haic/ic/guidinedetail.aspx?id=49785.

- When environmental faecal contamination has occurred, staff who encounter this have the responsibility for cleaning and decontamination. Cleaning and decontamination needs to be undertaken as soon as possible (IB).

- Toilets, commodes and items which are likely to be contaminated with faeces should be cleaned meticulously and decontaminated after use (IB).

- After transfer/discharge or once the CDI patient has been symptom free for 48 hours, the patient area/room (including the patient’s bed) should be cleaned and decontaminated thoroughly (i.e. terminal cleaning) (IB).

- Culture of *C. difficile* from environmental samples is not recommended for routine monitoring of environmental contamination (II).

- Any new products/technologies being considered for environmental decontamination should be formally assessed (e.g. cost, benefit, potential hazards, efficacy and user safety) before they are adopted for application in NHSScotland (i.e. reviewed and recommended by National Procurement/ HAI Commodities Group).
2.2.8. Management of care equipment

Spores of *C. difficile* can be transmitted from patient to patient via contact with contaminated care equipment. Care equipment can in some instances be the single source of transmission of *C. difficile* within a unit.

Specific recommendations for management of care equipment as a control measure to reduce the transmission of CDI are listed below.

- Care equipment (such as commodes, blood pressure cuffs and stethoscopes) should be dedicated to a single patient (IB).
- All care equipment should be carefully cleaned and disinfected using a disinfectant with 1000 ppm available chlorine immediately after use (IB).
- Single-use items (including thermometers and other care equipment) should be used when possible (IB).

2.2.9. Antimicrobial stewardship

Use of antimicrobial agents, for therapy or prophylaxis, is the most important predisposing factor for developing CDI.

Background

Exposure to antimicrobial agents leads to disturbance of the normal gut flora, allowing *C. difficile* to proliferate and reach high densities in the colon which may lead to CDI.

Recommendations for the development of institutional antimicrobial stewardship programs have been published by the Infectious Diseases Society of America and the Society of Healthcare Epidemiology of America in 2007 [19].

In principle any antimicrobial agent can predispose for CDI, but some agents have been more frequently implicated in CDI than others [20].

Antimicrobial stewardship should always be promoted as standard in combination with infection prevention and control measures. Good antimicrobial stewardship minimises the antimicrobial exposure of patients in care settings (and elsewhere), and in particular ensures restriction of antimicrobials associated with a high risk of CDI (e.g. cephalosporins, broad spectrum penicillins, fluoroquinolones and clindamycin), thereby reducing the number of patients predisposed to CDI, even if *C. difficile* transmission occurs.

In addition, the more specific recommendations given in the ‘Good Practice Recommendations for Hospital Antimicrobial Stewardship in NHS Scotland’ and ‘Management of Infection Guidance for Primary care for Consultation and Local Adaptation’ should also be followed. These documents can be accessed at:


In particular, note should be taken of the role of AMTs and Primary Care Team in promoting good antimicrobial practice and the responsibility of clinical staff to ensure that antimicrobials are used safely, rationally and effectively in all patients.

Specific recommendations on good **antimicrobial stewardship** to limit the spread of *C. difficile* include:

- Wherever possible stop any non-Clostridial antimicrobial treatment in patients with CDI as soon as possible, considering the risks and benefits of continued treatment (II).
- Ensure local antimicrobial policies are followed and any advice from infection specialists is clearly documented in patients’ notes (II).
- Avoid the use of high-risk agents (e.g. cephalosporins, broad spectrum penicillins, fluoroquinolones and clindamycin) in patients at risk. Use these agents only when medically needed (IB).
- Ensure all antimicrobial prescriptions in care settings are reviewed and that duration of therapy or a stop date is clearly documented where possible (II).
- Audit and feedback are efficient tools in changing prescribing habits [19] (IA).
- Surgical prophylaxis should not be continued beyond 24 hours following an operative procedure, except in specific circumstances [21] (II).


Improved use of antimicrobial agents in care settings can be achieved by defining ‘alert antimicrobial agents’ that require authorisation for use from either a pharmacist or microbiologist [22].

Surveillance of consumption in acute hospitals (as a minimum) of the high-risk agents, by pharmacists in close cooperation with microbiologists, is recommended [23, 24].

Control measures during an outbreak are the same as for individual cases.

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**There is evidence that concurrent implementation of key infection control measures and antimicrobial stewardship can lead to a reduction in CDI incidence [25].**
2.2.10. Specific measures in CDI outbreaks

The key to reducing risk of infection (or controlling an outbreak) is prevention of transmission of C. difficile in conjunction with reducing the number of susceptible persons by antimicrobial stewardship.

Specific recommendations on key measures during outbreaks are:

- Infection prevention and control teams and health protection teams should always be informed where there is an increased number (or severity) of CDI cases (IB).

- All infection prevention and control precautions should be reinforced in case of an outbreak (IB).

- Review standard of environmental cleaning to ensure high quality and frequency of decontamination (II).

- Antimicrobial prescribing (frequency, duration and type of drugs) should be reviewed as soon as possible with emphasis on avoiding the use of high-risk drugs (including 3rd generation cephalosporins, broad-spectrum penicillins, fluoroquinolones and clindamycin) (IB) (see section 2.2.9 on page 21).

- Faecal samples should be stored (at -20°C), so that they can be cultured and typed retrospectively if necessary (IB).

- In order to elucidate the epidemiology of C. difficile, molecular typing of isolates from CDI cases should be discussed with the reference laboratory (Scottish Salmonella, Shigella and Clostridium difficile Reference Laboratory) (IB).

- Implement interim policies for patient admission, placement and staffing as needed to prevent C. difficile transmission (IB).

- Consider closing the ward, unit or other care setting to new admissions (IB).

- Consider terminal cleaning and decontamination to eliminate all potential reservoirs of C. difficile (II).

- When transmission continues review all of the above measures (II).

The Scottish Government guidance on managing public health incidents outlines the roles and responsibilities of Incident Management Teams. This can be accessed at: http://www.scotland.gov.uk/Resource/0039/00392132.pdf.
2.3. Best practice on antimicrobial treatment and management of CDI

Though not formally considered an element of infection prevention and control measures, advice on antimicrobial treatment and management of CDI is given in this guidance.

2.3.1. Treatment and management of CDI

Advice on treatment and management of CDI is based on a combination of evidence based recommendations and expert consensus.

Due to the complexity of CDI and its concurrence with other conditions, most clinical trials on CDI treatment are associated with many confounding factors, and unambiguous conclusions are therefore difficult to make. Furthermore, patient safety issues related to experimental treatment of an already very frail patient population makes randomised prospective clinical trials very difficult to conduct.

This section of the guidance has been updated following recent revision of the ESCMID and PHE documents: ‘Update of the treatment guidance document for Clostridium difficile Infection (CDI)’ [2] and ‘Updated guidance on the management and treatment of CDI’ [3], respectively, as well as ‘Practice guidelines for diagnosis, treatment, and prevention of CDI’ by Surawicz et al. published in the American Journal of Gastroenterology [4]. References within these documents are also considered.

Guidance on severity assessment of CDI

Available evidence suggests that specific treatments determined by disease severity result in superior outcome [2]. When assessing the severity of individual CDI cases (for first and recurrent episodes) it is recommended that the following guidance is adhered to (Box 5 on page 25).
Box 5

**Mild CDI** is not associated with a raised white blood cell (WBC) count; it is typically associated with mild diarrhoea (three loose or liquid stools per day or more frequently than is normal for the person).

**Moderate CDI** is associated with a raised WBC count that is <15 cells x 10⁹/L; it is typically associated with moderate diarrhoea (typically three or more loose or liquid stools per day or more frequently than is normal for the person).

**Severe CDI** is when a patient has at least one severity marker including temperature >38.5°C, or WBC >15 cells x 10⁹/L, or acute rising serum creatinine (>1.5 x baseline), or evidence of severe colitis in CT scan/abdominal X-ray examination, suspicion of PMC, toxic megacolon or ileus.

**Life-threatening CDI** is when a patient has any of the following attributable to CDI: admission to ICU, hypotension with or without need for vasopressors, ileus or significant abdominal distension, mental status changes, WBC ≥35 cells x 10⁹/L or <2 cells x 10⁹/L, serum lactate >2.2 mmol/l, end organ failure (mechanical ventilation, renal failure).

Clinical studies indicate improved patient outcome (superiority) of specific treatment strategies depending on severity of disease. However, only little prospective and validated research has been done on clinical predictors of outcome and results from studies assessing risk factors for severe disease are conflicting, which precludes the ability to set a clear list of markers for severity [2, 3]. The markers given in **Box 5 on page 25** are therefore based on consensus agreement of the available evidence and are not exhaustive. Further patient characteristics associated with severity and prognostic markers that can be used to determine increased risk of developing severe or life threatening disease are given in **Table 1 on page 32 and Table 2 on page 33** (adapted from [2]).

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**Severe CDI is not always associated with diarrhoea. Clinicians should therefore consider CDI in patients who show signs of ileus or have sepsis and some of the major risk factors (see Table 1 on page 32 and Table 2 on page 33).**
2.3.2. Treatment of first episode of CDI including mild, moderate and severe disease (Algorithm 1)

Treatment of first episode

Oral metronidazole is recommended for mild and moderate CDI as it is as effective as oral vancomycin and less costly.

Oral vancomycin (125 mg four times daily) is preferred for treatment of severe disease as it is superior to metronidazole in severe cases [2, 3]. Although doses of up to 500mg have been used, there is insufficient evidence to support this [2].

Fidaxomicin demonstrated non-inferiority to vancomycin in the clinical cure of CDI and superiority in reducing recurrence. There is no evidence on the efficacy of fidaxomicin for the treatment of life-threatening disease [2] or severe disease as defined in these guidelines (see Box 5 on page 25).

The Scottish Medicines Consortium does not support the first line use of fidaxomicin in adults with severe CDI as the economic case for the severe patient population has not been demonstrated (http://www.scottishmedicines.org.uk/SMC_Advice/Advice/791_12_fidaxomicin_dificlir/ fidaxomicin_Dificlir).

However, in first recurrences which are considered severe, fidaxomicin may be used on advice of local microbiologists or specialists in infectious diseases (grade of recommendation (II)) (see section 2.3.3 on page 29).

- Treatment should be started as soon as CDI is suspected (do not wait for laboratory result to confirm diagnosis before initiating treatment and putting control measures in place) (IB).
- Treatment of CDI should be initiated based on assessment of symptoms and severity of disease while taking into account individual risk factors of the patient (II) (see Algorithm 1: Treatment of first episode of CDI on page 35).
- When the patient has no severity markers (i.e. mild to moderate disease) treat the first episode with oral metronidazole 400-500 mg three times per day for 10 days (IA).
- When the patient has one or more severity markers (i.e. severe disease) treat the first episode with oral vancomycin 125 mg four times per day for 10 days (IA).
- Fidaxomicin is not recommended for treatment of the first episode of CDI (II).
- For mild to moderate CDI in patients who are intolerant/allergic to metronidazole and for pregnant/breastfeeding woman (due to concerns of placental/breast milk transmission), vancomycin should be used at standard dosing (IA).
- Stop any non-Clostridial antimicrobial treatment in patients with CDI if possible (II).
- Stop any use of anti-motility agents and gastric acid suppressant agents (including proton pump inhibitors) if possible (II).
- It is essential that CDI patients are closely monitored until they are symptom free (II).
• There is insufficient evidence to support administration of probiotics, toxin binding resins and polymers, or monoclonal antibodies for treatment of CDI [2].

• Treatment, and infection prevention and control measures, are the same regardless of the C. difficile ribotype involved (IIB).

Patient assessment

Previous reports on the standard of care for CDI patients has identified the lack of regular review and lack of multidisciplinary assessment of patients prone to electrolyte imbalance, dehydration, malnutrition and pressure sores as factors leading to poor outcome.

• Each patient should be reviewed daily regarding fluid balance, electrolyte replacement, nutrition review, and monitoring for signs of increasing severity (including WBC count, temperature, findings of abdominal examination, bowel movements and overall clinical status of patients) (II).

• For CDI cases in a care home or receiving care at home, daily assessment should involve monitoring for signs of increasing severity (including fever, rigours, and bowel movements) (see Table 1 on page 32) (II).

Treatment response and further patient management

Treatment response is present when either stool frequency decreases or stool consistency improves and parameters of disease severity (clinical, laboratory, radiological) improve and no new signs of severe disease develop. In all other cases, treatment is considered a failure. Treatment response should be observed daily and evaluated after at least three days, assuming the patient is not worsening [2]. Treatment with metronidazole, in particular, may result in a clinical response only after three to five days [2].

The usual duration of therapy is 10 days for patients who are responding to the treatment.

• CDI patients with mild to moderate disease who show improvement during initial metronidazole therapy, as evidenced by decreased number of bowel movements, improvement in WBC, fever and abdominal symptoms should continue to receive this regimen (II).

• For CDI patients with mild to moderate disease whose clinical condition worsens (at any time) or those who fail to improve after five days of metronidazole administration, treatment should be switched to oral vancomycin, 125 mg four times per day for 10 days (II).

• If after 10 days treatment, diarrhoea is still persisting, seek specialist advice and investigate other pathologies that could be responsible for diarrhoea (II).

• Supportive care should be delivered to all patients with severe CDI and includes intravenous fluid resuscitation, electrolyte replacement, and pharmacological venous thromboembolism prophylaxis. In the absence of ileus or significant abdominal distension, oral or enteral feeding should be continued (II).
**Early surgery in patients with life-threatening CDI**

Continued worsening of symptoms, especially an increase in WBC and hypotension, is an indication for surgical, gastroenterology and microbiology/infectious diseases consultations. The more negative prognostic signs a patient has, the earlier surgical consultation and surgical intervention should be considered.

*Surgery is of benefit to patients with life-threatening CDI, and early surgical consultation has been associated with improved survival. Early surgical intervention before the development of shock and organ failure leads to improved survival [3].*

- Surgical consultation should be obtained on all patients with life threatening CDI. Surgery should be considered in patients with any one of the following attributed to CDI: admission to intensive care unit (ICU) for CDI; hypotension with or without required use of vasopressors; ileus or significant abdominal distension; mental status changes, WBC ≥35 cells x 10⁹/L or <2 cells x 10⁹/L; serum lactate >2.2 mmol/l; end organ failure (mechanical ventilation, renal failure, etc.) (IB).

**Treatment when oral administration of antimicrobials is not possible**

In patients whose gastrointestinal tract function is compromised, delivery of orally administered drugs to the colon is not reliable. When oral treatment is not possible, parenteral metronidazole is recommended, preferably combined with intracolonic or nasogastric administration of vancomycin [2].

- For patients with mild to moderate disease in whom oral treatment is not possible, treat with intravenous metronidazole 500 mg three times per day for 10 days [2] (IB).

- For patients with severe disease in whom oral treatment is not possible or ileus is present, treat with intravenous metronidazole 500 mg three times per day for 10 days plus intracolonic vancomycin retention enema 500 mg in 100 ml normal saline four times daily; or treat with intravenous metronidazole 500 mg three times per day for 10 days plus nasogastric administration of vancomycin 500 mg four times per day [2] (II).

- Treatment should be switched to oral administration as soon this route for treatment becomes available again (II).

- Recommended treatments apply to both first and recurrent episodes of CDI.

- See Algorithm 1: Treatment of first episode of CDI on page 35.
2.3.3. Treatment of first recurrence of CDI including mild, moderate and severe disease (Algorithm 2)

Treatment of first recurrence

Recurrent disease (Box 6 on page 29) is caused by either re-infection from a contaminated environment or poor hand hygiene, or relapse from germinating spores in the gut [26]. Poor immune response and persistent disruption of the gut flora appear to be the most important factor in developing multiple episodes of CDI [27, 28].

A vicious cycle can be created when the antimicrobial drug prescribed for CDI disturbs the normal flora of the gut leaving the patient more vulnerable to recurrent infection [20].

A wide variety of prognostic markers for severe or recurrent CDI have been suggested in the literature, which makes it difficult to set a rigid clinical prediction rule. However, results from individual studies, reviews and meta-analyses on prognostic markers for CDI have been evaluated by Debast et al. to reach a consensus on a selection of markers that may be useful in clinical practice to distinguish patients with increased risk for severe or life-threatening CDI and recurrences [2]. For detailed recommendations see Table 1 on page 32 and Table 2 on page 33.

Box 6

Definition of recurrent disease

Recurrence is defined as CDI which re-occurs within eight weeks after onset of a previous episode, provided symptoms from the previous episode resolved after completion of initial treatment [2].

Oral vancomycin is recommended for treatment of first recurrence of CDI, even when the recurrence results in mild disease [2]. Recent studies have shown fewer secondary recurrences with oral fidaxomicin compared to vancomycin after treatment of a first recurrence. However, the evidence for this specific sub-group (patients with recurrent disease) is limited to two phase III studies in a limited number of patients.

Due to the considerably higher cost of fidaxomicin, treatment of first recurrence with this agent should only be initiated following consultation of local microbiologists or specialists in infectious diseases.
There are no data on the efficacy of fidaxomicin for the treatment of severe or life-threatening disease [2].

- Treatment of CDI should be initiated based on assessment of (recurring) symptoms and a positive laboratory test or pending result of laboratory test result plus suspicion of CDI (IB).

- If a patient has a recurrence of CDI after apparently successful treatment of the first episode (i.e. the case has had symptom free days), anti-clostridial antimicrobial treatment should be based on severity assessment (II).

- If the recurrence is mild to moderate CDI, treat with oral vancomycin 125 mg four times per day for 10 days. Oral fidaxomicin 200 mg two times per day for 10 days may be considered only on advice of local microbiologists or specialists in infectious diseases (IB).

- If the recurrence is severe CDI, treat with oral vancomycin 125 mg four times per day for 10 days (IA) or as above when treatment with oral administration of antimicrobials is not possible (page 28) (II). Consider treating severe first recurrence with oral fidaxomicin 200 mg two times per day for 10 days only on advice of local microbiologists or specialists in infectious diseases (II).

2.3.4. Treatment of second and subsequent recurrences of CDI (Algorithm 3)

Treatment of second recurrence

In mild/moderate recurrences of CDI, oral vancomycin and fidaxomicin are equally effective in resolving CDI symptoms, but fidaxomicin has shown to be associated with a lower likelihood of CDI recurrence after a first recurrence [2].

Vancomycin is preferably administered using tapered and/or pulsed regimens. The background for this is that vancomycin is only effective against the vegetative form of *C. difficile* but not the spores. The periodical lower drug concentrations in tapered and pulsed dosing regimens are believed to allow the normal gut flora to recover while suppressing the growth of *C. difficile* vegetative forms [20].

- If the second recurrence is mild to moderate CDI, treat with a tapered and/or pulsed regimen of vancomycin such as 125 mg four times daily for one week, 125 mg three times daily for one week, 125 mg twice daily for one week, 125 mg once daily for one week, 125 mg on alternate days for one week, 125 mg every third day for one week (six weeks in total) [29] (IB).

- Oral fidaxomicin, 200 mg two times per day for 10 days, may be preferred on advice of local microbiologists or specialists in infectious diseases (II).

- At this stage, early consultation for faecal transplant may be considered through conversation with patient/relatives (II).
Treatnent of third and subsequent recurrences

A recent systematic review and a randomised controlled trial on faecal transplantation have been published [30, 31], both of which suggest that this approach is highly effective at resolving recurrent CDI with little adverse effects. Early consultation for faecal transplant during a second recurrence will allow time for preparation if there are further recurrences (see Appendix H on page 50 for a faecal transplant procedure).

If faecal transplantation is not possible, oral treatment with vancomycin using tapered and/or pulsed regimens (or a standard 10 day course of fidaxomicin) are recommended. Efficacy of fidaxomicin for multiple recurrences has not been investigated, although it may be considered based on lower likelihood of CDI recurrence after first recurrence [2].

- Consider treating third and subsequent recurrences with faecal transplantation (nasogastric/rectal infusion of donor faeces) following an initial treatment of vancomycin 500 mg four times per day for four days (IA) (see Algorithm 3: Treatment of second and subsequent recurrence of CDI on page 37 and Appendix H on page 50).

- If faecal transplant is not possible, treat third and subsequent mild/moderate recurrences with a tapered and/or pulsed regimen of vancomycin such as 125 mg four times daily for one week, 125 mg three times daily for one week, 125 mg twice daily for one week, 125 mg once daily for one week, 125 mg on alternate days for one week, 125 mg every third day for one week (six weeks in total) [29] (IB).

- Oral fidaxomicin, 200 mg two times per day for 10 days, may be preferred on advice of local microbiologists or specialists in infectious diseases (II).

- If any recurrence results in severe CDI, then treatment is as above for severe disease (see Algorithm 1: Treatment of first episode of CDI on page 35).

- There is insufficient evidence to support the use of IV immunoglobulin or probiotics for the treatment of recurrent CDI [2].
TABLE 1: Patient characteristics that could reasonably be assumed to correlate positively with severity of colitis in the **absence of another explanation for these findings** (adapted from Debast, S. B., et al., 2013 [2]).

<table>
<thead>
<tr>
<th>Category</th>
<th>Signs/symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical examination</strong></td>
<td>• Fever (core body temperature &gt;38.5ºC).</td>
</tr>
<tr>
<td></td>
<td>• Rigours (uncontrollable shaking and a feeling of cold followed by a rise in body temperature).</td>
</tr>
<tr>
<td></td>
<td>• Haemodynamic instability including signs of distributive shock.</td>
</tr>
<tr>
<td></td>
<td>• Respiratory failure requiring mechanical ventilation.</td>
</tr>
<tr>
<td></td>
<td>• Signs and symptoms of peritonitis.</td>
</tr>
<tr>
<td></td>
<td>• Signs and symptoms of colonic ileus.</td>
</tr>
<tr>
<td></td>
<td>Blood in stools is rare in CDI and the correlation with severity of disease is uncertain.</td>
</tr>
<tr>
<td><strong>Laboratory investigations</strong></td>
<td>• Marked leucocytosis (WBC &gt;15 cells x 10⁹/L).</td>
</tr>
<tr>
<td></td>
<td>• Marked left shift (band neutrophils &gt;20% of leukocytes).</td>
</tr>
<tr>
<td></td>
<td>• Rise in serum creatinine (&gt;50% above the baseline).</td>
</tr>
<tr>
<td></td>
<td>• Elevated serum lactate (≥5 mmol/L).</td>
</tr>
<tr>
<td></td>
<td>• Markedly reduced serum albumin (&lt;30 g/l).</td>
</tr>
<tr>
<td><strong>Colonoscopy or sigmoidoscopy</strong></td>
<td>• Pseudomembranous colitis.</td>
</tr>
<tr>
<td></td>
<td>There is insufficient knowledge on the correlation of endoscopic findings compatible with CDI, such as oedema, erythema, friability and ulceration, and the severity of disease.</td>
</tr>
<tr>
<td><strong>Imaging (including CT)</strong></td>
<td>• Distension of large intestine (&gt;6 cm in transversal width of colon).</td>
</tr>
<tr>
<td></td>
<td>• Colonic wall thickening including low-attenuation mural thickening.</td>
</tr>
<tr>
<td></td>
<td>• Pericolonic fat stranding.</td>
</tr>
<tr>
<td></td>
<td>• Ascites not explained by other causes.</td>
</tr>
<tr>
<td></td>
<td>The correlation of haustral or mucosal thickening, including thumbprinting, pseudopolyps and plaques, with severity of disease is unclear.</td>
</tr>
</tbody>
</table>
TABLE 2: Prognostic markers that can be used to determine (increased risk of developing) severe or life threatening CDI (adapted from Debast, S. B., et al., 2013 [2]). References as numbered in the table are provided in this guidance.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>SoR*</th>
<th>QoE**</th>
<th>Ref(s) not exhaustive</th>
<th>Comment(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (≥65 years)</td>
<td>A</td>
<td>IIr</td>
<td>[32, 33, 34]</td>
<td>Large cohort study on CDI mortality at 30 days, and review of studies of factors associated with CDI outcome [33]. Systematic review of studies describing the derivation or validation of Clinical Prediction Rules for unfavourable outcomes of CDI [34]: in general methodological biases and weak validities.</td>
</tr>
<tr>
<td>Marked leukocytosis (WBC &gt;15 cells x 10^9/L)</td>
<td>A</td>
<td>IIrht</td>
<td>[32, 35, 36 37, 34, 38, 39]</td>
<td>Systematic review [34]: in general methodological biases and weak validities. Cohort study: severity score on malignancy, white blood cell count, blood albumin, and creatinine [35]. Retrospective cohort study on risk factors for severe CDI: death &lt;30 days, ICU, colectomy or intestinal perforation [32].</td>
</tr>
<tr>
<td>Decreased blood albumin (&lt;30 g/L)</td>
<td>A</td>
<td>IIr</td>
<td>[32, 35, 40, 34, 41]</td>
<td>Systematic review [34]: in general methodological biases and weak validities.</td>
</tr>
<tr>
<td>Rise in serum creatinine level (≥133 µmol/L or ≥1.5 times the premorbid level)</td>
<td>A</td>
<td>IIt</td>
<td>[32, 35, 33, 37]</td>
<td>Depending on the timing of measurement around CDI diagnosis [37].</td>
</tr>
<tr>
<td>Comorbidity (severe underlying disease and/or immunodeficiency)</td>
<td>B</td>
<td>IIt</td>
<td>[35, 33, 38, 42]</td>
<td>Comorbidity: wide variety of risk factors described/investigated, including cancer, cognitive impairment, cardiovascular, respiratory and kidney disease [33]. Chronic pulmonary disease, chronic renal disease and diabetes mellitus [42]. History of malignancy [35]. Prior operative therapy, inflammatory bowel disease and intravenous immunoglobulin treatment [38].</td>
</tr>
</tbody>
</table>

* SoR: strength of recommendation to use a (clinical) characteristic as a prognostic marker.

**QoE: quality of evidence (refer to [2]).
TABLE 3: Prognostic markers that can be used to determine (increased risk of) recurrent CDI (adapted from Debast, S. B., et al., 2013 [2]). References as numbered in the table are provided in this guidance.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>SoR</th>
<th>QoE*</th>
<th>Ref(s) not exhaustive</th>
<th>Comment(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (≥65 years)</td>
<td>A</td>
<td>IIrh</td>
<td>[43, 44, 34, 45]</td>
<td>Meta-analysis: [44]. Systematic review: [34]. Prospective validation study of risk factor: [43].</td>
</tr>
<tr>
<td>Continued use of (non-CDI) antimicrobials after diagnosis of CDI and/or after CDI treatment</td>
<td>A</td>
<td>IIrh</td>
<td>[43, 44]</td>
<td>Meta-analysis: [44]. Prospective validation study of risk factor: [43].</td>
</tr>
<tr>
<td>Comorbidity (severe underlying disease) and/or renal failure</td>
<td>A</td>
<td>IIh</td>
<td>[43, 37, 46]</td>
<td>Prospective validation study of risk factor: comorbidity conditions rated by Horn’s index (scoring system for underlying disease severity) [43].</td>
</tr>
<tr>
<td>A history of previous CDI (&gt;1 recurrences)</td>
<td>A</td>
<td>IIl</td>
<td>[47, 40, 48-50]</td>
<td>Data from randomised controlled trials: [47, 49]. Meta-analysis of pivotal randomized controlled trials [40].</td>
</tr>
<tr>
<td>Initial disease severity</td>
<td>B</td>
<td>IIth</td>
<td>[43, 45]</td>
<td>Prospective validation study of risk factor [43]. Long-term population based cohort study [45].</td>
</tr>
</tbody>
</table>

* SoR: strength of recommendation to use a (clinical) characteristic as a prognostic marker.

**QoE: quality of evidence (refer to [2]).
Algorithm 1: Treatment of first episode of CDI

**Severity markers:**
- Temperature >38.5°C.
- Suspicion of PMC, toxic megacolon, ileus.
- Evidence of severe colitis in CT scan/Xray.
- WBC >15 cells x 10⁹/L.
- Acute rising serum creatinine >1.5 x baseline.

**Patient has no severity markers:**
- Treat with oral metronidazole 400-500 mg three times a day for 10 days (IA).
- Rehydrate patient.

**Daily assessment of patient with mild to moderate disease:**
- Observe bowel movement, symptoms (e.g. WBC, fever and hypotension), nutrition and fluid balance and for signs of increasing severity (II).
- If condition does not improve after five days of treatment with metronidazole or worsens at any time, patient should be switched to treatment with vancomycin (125 mg four times a day for 10 days) (II).
- If oral route is not available: metronidazole i.v. 500 mg three times a day 10 days (IB).
- If after 10 days treatment, diarrhoea still persists, seek specialist advice (II).

**Patient has one severity marker:**
- Treat with oral vancomycin 125 mg four times a day for 10 days (IA).
- Rehydrate patient.
- Surgical consultation should be obtained on all patients with life threatening disease, i.e. if any one of the following: admission to ICU for CDI; hypotension with or without required use of vasopressors; ileus or significant abdominal distension; mental status changes, WBC ≥35 cells x 10⁹/L or <2 cells x 10⁹/L; serum lactate >2.2 mmol/l; end organ failure (mechanical ventilation, renal failure, etc (IB).
- If oral route is not available or ileus is detected, treat with 500 mg metronidazole i.v. three times a day for 10 days plus vancomycin 500 mg four times a day (intracolonic or nasogastric) until ileus is resolved (II).

**Daily assessment of patient with severe disease:**
- Observe bowel movement, symptoms (e.g. WBC and hypotension), nutrition and fluid balance and for signs of increasing severity (II).
- Supportive care: intravenous fluid resuscitation, electrolyte replacement, and pharmacological venous thromboembolism prophylaxis. In the absence of ileus or significant abdominal distension, oral or enteral feeding should be continued (II).
- Gastroenterology and microbiology consultations. CT scanning/abdominal X-ray; consider PMC, toxic megacolon, ileus or perforation.
Algorithm 2: Treatment of first recurrence of CDI

Treatment of CDI should be initiated based on assessment of symptoms and severity of disease while taking into account individual risk factors of the patient (II).

Severity markers:
- Temperature >38.5°C.
- Suspicion of PMC, toxic megacolon, ileus.
- Colonic dilatation in CT scan/abdominal X-ray >6 cm.
- WBC >15 cells x 10⁹/L.
- Acute rising serum creatinine >1.5 x baseline.

Patient has no severity markers:
- Treat with oral vancomycin 125 mg four times a day for 10 days (IA), or oral fidaxomicin 200 mg twice daily for 10 days (on advice of local microbiologists or specialists in infectious diseases (II)).
- Rehydrate patient.

Daily assessment of patient with mild to moderate disease:
- Observe bowel movement, symptoms (e.g. WBC, fever and hypotension), nutrition and fluid balance.
- If condition does not improve after five days, seek specialist advice (II).

Patient has one severity marker:
- Treat with oral vancomycin 125 mg four times a day for 10 days (IA). Consider treating severe first recurrence with oral fidaxomicin 200 mg two times per day for 10 days only on advice of local microbiologists or specialists in infectious diseases (II).
- Rehydrate patient.
- Surgical consultation should be obtained on all patients with life threatening disease i.e. if any one of the following: admission to ICU for CDI; hypotension with or without required use of vasopressors; ileus or significant abdominal distension; mental status changes, WBC ≥35 cells x 10⁹/L or <2 cells x 10⁹/L; serum lactate >2.2 mmol/l; end organ failure (mechanical ventilation, renal failure, etc (IB).
- If oral route is not available or ileus is detected, treat with 500 mg metronidazole i.v. three times a day for 10 days plus vancomycin 500 mg four times a day (intracolonic or nasogastric) until ileus is resolved (II).

Daily assessment of patient with severe disease:
- Observe bowel movement, symptoms (e.g. WBC and hypotension), nutrition and fluid balance and for signs of increasing severity (II).
- Supportive care: intravenous fluid resuscitation, electrolyte replacement, and pharmacological venous thromboembolism prophylaxis. In the absence of ileus or significant abdominal distension, oral or enteral feeding should be continued (II).
Algorithm 3: Treatment of second and subsequent recurrence of CDI

Patient has no severity markers:
- Treat with a tapered and/or pulsed regimen of vancomycin such as 125 mg four times daily for one week, 125 mg three times daily for one week, 125 mg twice daily for one week, 125 mg once daily for one week, 125 mg on alternate days for one week, 125 mg every third day for one week (II).
- Oral fidaxomicin 200 mg twice daily for 10 days may be preferred (on advice of local microbiologists or specialists in infectious diseases (II)).
- If second recurrence, begin consultation with patient/relative on suitability for faecal transplantation (II).
- Multiple recurrent CDI (third and subsequent episodes) may then be treated with faecal transplantation (nasogastric infusion of faeces), including vancomycin 500 mg four times a day for four days (IA).
- Oral vancomycin 125 mg four times a day for 10 days (IA).
- Rehydrate patient.
- Surgical consultation should be obtained on all patients with life threatening disease i.e. if any one of the following: admission to ICU for CDI; hypotension with or without required use of vasopressors; ileus or significant abdominal distension; mental status changes, WBC ≥35 cells x 10⁹/L or <2 cells x 10⁹/L; serum lactate >2.2 mmol/l; end organ failure (mechanical ventilation, renal failure, etc (IB).
- If oral route is not available or ileus is detected, treat with 500 mg metronidazole i.v. three times a day for 10 days plus vancomycin 500 mg four times a day (intracoliconic or nasogastric) until ileus is resolved (II).

Daily assessment of patient with mild to moderate disease:
- Observe bowel movement, symptoms (e.g. WBC and hypotension), nutrition and fluid balance.
- If condition does not improve, seek specialist advice (II).

Severity markers:
- Temperature >38.5°C.
- Suspicion of PMC, toxic megacolon, ileus.
- Colonic dilatation in CT scan/abdominal X-ray >6 cm.
- WBC >15 cells x 10⁹/L.
- Acute rising serum creatinine >1.5 x baseline.

Patient has one severity marker:
- Treat with oral vancomycin 125 mg four times a day for 10 days (IA).
- Rehydrate patient.
- Surgical consultation should be obtained on all patients with life threatening disease i.e. if any one of the following: admission to ICU for CDI; hypotension with or without required use of vasopressors; ileus or significant abdominal distension; mental status changes, WBC ≥35 cells x 10⁹/L or <2 cells x 10⁹/L; serum lactate >2.2 mmol/l; end organ failure (mechanical ventilation, renal failure, etc (IB).
- If oral route is not available or ileus is detected, treat with 500 mg metronidazole i.v. three times a day for 10 days plus vancomycin 500 mg four times a day (intracoliconic or nasogastric) until ileus is resolved (II).

Daily assessment of patient with severe disease:
- Observe bowel movement, symptoms (e.g. WBC and hypotension), nutrition and fluid balance and for signs of increasing severity (II). If patient no longer shows any more severity markers treat as in left-hand box of this algorithm).
- Supportive care: intravenous fluid resuscitation, electrolyte replacement, and pharmacological venous thromboembolism prophylaxis. In the absence of ileus or significant abdominal distension, oral or enteral feeding should be continued (II).
- Gastroenterology and microbiology consultations. CT scanning/abdominal X-ray; consider PMC, toxic megacolon, ileus or perforation.
2.4. Advice for members of staff with diarrhoea and/or confirmed CDI

Advice for care staff with diarrhoea and/or confirmed CDI:
As care staff could potentially infect vulnerable patients (and co-workers and visitors), staff who have diarrhoea should not work, and if CDI is confirmed and treated, should not return to work until treatment is completed and symptoms (i.e. diarrhoea) have been absent for at least 48 hours.

If a member of staff is diagnosed with CDI, this should be reported to Occupational Health (or equivalent arrangement for ill health).

If the infection was acquired at work the incident should be reported by the employing care facility/care home to the Health and Safety Executive under RIDDOR.


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i These recommendations are not evidence-based but should be implemented to protect the health of staff members, patients and visitors.
Appendix A: Grading of evidence and categories for implementation in clinical practice

Grading of evidence
The level of evidence for the key recommendations listed in section 2.2 on page 10 of this guidance was graded in the systematic literature review by the ESGCD [1].

For the section on ‘Best practice on antimicrobial treatment of CDI’ (section 2.3 on page 24) the level of evidence was graded by HPS according to the approach described in the review by ESGCD 2008 [1] (and in this appendix).

The quality of each study (i.e. level of evidence) was determined according to standards of the Oxford Centre for Evidence Based Medicine.

<table>
<thead>
<tr>
<th>Levels of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a Systematic review (with homogeneity) of randomised controlled trials.</td>
</tr>
<tr>
<td>1b Individual randomised controlled trial (with narrow confidence interval).</td>
</tr>
<tr>
<td>1c Studies with the outcome ‘all or none’.</td>
</tr>
<tr>
<td>2a Systematic review (with homogeneity) of cohort studies.</td>
</tr>
<tr>
<td>2b Individual cohort study (including low-quality randomised controlled trials; e.g.&lt;80% follow-up).</td>
</tr>
<tr>
<td>2c Outcomes research, ecological studies.</td>
</tr>
<tr>
<td>3a Systematic review (with homogeneity) of case-control studies.</td>
</tr>
<tr>
<td>3b Individual case-control study.</td>
</tr>
<tr>
<td>4 Case series (and poor quality cohort and case-control studies).</td>
</tr>
<tr>
<td>5 Expert opinion without explicit appraisal, or based on physiology, bench research or ‘first principles’.</td>
</tr>
</tbody>
</table>

Grades of recommendation:

A is given when consistent with level 1 studies.

B is given when consistent with level 2 or 3 or extrapolations from level 1.

C is given when consistent with level 4 or extrapolations from level 2 or 3.

D (or II) is given when consistent with level 5 or where there are troubling inconsistent or inconclusive studies of any level.

Further explanations of this grading system can be accessed at: http://www.cebm.net/index.aspx?o=1025.
Categories for implementation in clinical practice

Categories for implementation in clinical practice were (in the review by ESGCD [1]) generated based on the HICPAC guidelines.

<table>
<thead>
<tr>
<th></th>
<th>HICPAC Categories for implementation in clinical practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>IA</td>
<td>Strongly recommended for implementation and strongly supported by well-designed experimental, clinical or epidemiological studies.</td>
</tr>
<tr>
<td>IB</td>
<td>Strongly recommended for implementation and strongly supported by some experimental, clinical or epidemiological studies and a strong theoretical rationale.</td>
</tr>
<tr>
<td>IC</td>
<td>Required for implementation, as mandated by state regulation or standard (may vary among different states/countries).</td>
</tr>
<tr>
<td>II</td>
<td>Suggested for implementation and supported by suggestive clinical or epidemiological studies or a theoretical rationale.</td>
</tr>
<tr>
<td>Unresolved issue</td>
<td>Practices for which insufficient evidence exists or no consensus regarding efficacy exists (no recommendation).</td>
</tr>
</tbody>
</table>
Appendix B: Short guide to managing CDI in healthcare settings

Symptomatic patient – diarrhoea: Implement contact precautions pending diagnosis.

• Submit sample to laboratory for toxin testing.

Toxin positive

Clinical team:
• Assess patient symptoms.
• Review and stop antimicrobial treatment where possible.
• Treat as per guidance (Algorithms 1-3).
• Implement infection control measures.
• Monitor clinical condition.

Infection Control Team:
• Ensure infection control measures and local surveillance systems are in place.
• Determine if CDI trigger is breached.

Investigations of cases/triggers etc:
• Where an investigation indicates a true rise in cases, complete the HIIAT.
• Alert AMT to review antimicrobial prescribing.
• Review infection control procedures.
• Consider establishing a problem assessment group.

Local surveillance:
• Produce regular (weekly/monthly/as appropriate) surveillance reports for ward, units, etc.
• Agree triggers for individual units.
• Produce regular reports for Clinical Governance Committee, Risk Management, AMTs, Infection Control Committees, NHS boards, etc.

Severe CDI or death associated with CDI:
• For severe cases, consider referral to surgeon/ID physician.
• Complete Severe CDI Case Investigation Tool.

Morbidity/mortality reviews:
• Review all severe cases and deaths due to CDI whilst under care of the clinical team as part of regular morbidity/mortality meetings or clinical case reviews.
• Report back any lessons learned to the Infection Control Team for inclusion in surveillance and/or infection control reports.

Oversight of local and national surveillance data:
• The Chief Executive/Senior Manager must ensure appropriate reporting systems, checks and action plans are in place and implemented.
• Infection Control Committee/Clinical Governance Committee/Risk Management/AMTs should have oversight of trends in surveillance data dependent on local arrangements.
• Agreed action plans should be in place to control the level of CDI.

• Carry out laboratory tests as per protocol, and store samples for three months at -20°C.
• Submit isolates to reference laboratory as per protocol.

• Submit sample to laboratory for toxin testing.
Appendix C: Short guide to managing CDI in the community

Symptomatic patient – diarrhoea: **Implement contact precautions pending diagnosis.**

- GP submits sample to laboratory for toxin testing.
- Laboratory tests on stool with feedback of toxin positive to GP.
- GP contacts care home/Health Protection Team to inform them of CDI case.

Toxin positive

**Care Home manager:**
- Log cases (as part of local surveillance).
- Contact Health Protection Team/ICT for advice on management and if a CDI patient dies or CDI is on the death certificate.
- Review infection prevention and control measures.

**GP:**
- Assess patient to determine if hospitalisation is required.
- Assist investigations of all community severe cases and deaths due to CDI.
- Follow CDI treatment protocols.

**Health Protection Team/Infection Control Team:**
- Give advice on management and infection prevention and control; set triggers and investigate cases when triggers are breached or exceeded.
- Review all community severe cases and deaths due to CDI.
- Report to relevant people/organisations.
- Report back any lessons learned.

See also, the Regulation of Care (Scotland) Act 2001 which can be accessed from: [http://www.opsi.gov.uk/legislation/scotland/acts2001/asp_20010008_en_1](http://www.opsi.gov.uk/legislation/scotland/acts2001/asp_20010008_en_1).
Appendix D: Links to associated documents

Standards

Testing for C. difficile

CDI surveillance


How to collect stool specimens


Reporting


Infection prevention and control

Patient leaflets:

(Hospital patients and visitors);

(Residents and visitors of care homes); and

(Home laundering of patient items).

Infection prevention and control supporting documents:


Antimicrobial management


Education


Outbreaks


Treatment

Scottish Medicines Consortium advice on use of fidaxomicin in adults with CDI: http://www.scottishmedicines.org.uk/SMC_Advice/Advice/791_12_fidaxomicin_dificlir/fidaxomicin_Dificlir.
Appendix E: Glossary

**Anaerobic**  
Living or active in the absence of free oxygen.

**Antimicrobial**  
A substance that kills or inhibits the growth of microorganisms such as bacteria, viruses, fungi, or protozoans. This includes antibiotics, antivirals, antifungals and antiparasitics.

**Antimicrobial (antibiotic) prescribing policy**  
A set of guidance for the careful and sensible use of antibiotics and other antimicrobial drugs.

**Cohort**  
A group of individuals with some characteristics in common (in this case, infection with CDI).

**Endemic**  
The constant presence of an agent or health condition (such as CDI) in a particular geographical location or population.

**Endoscope**  
A medical instrument for examining the interior of a hollow body organ or for minor surgery.

**Epidemiology**  
The study of the determinants and distribution of health related events in a population and the application of that study in the prevention and control of health problems.

**Hypochlorite**  
A chemical compound containing chlorine; used for disinfection.

**Immunocompromised**  
Any condition in which the body is unable to develop a normal immune response.

**Incidence**  
A measure of the frequency with which new cases of illness, injury or other health condition occurs among a population during a specified period.

**Normal gut flora (microflora)**  
The microorganisms that normally live inside the digestive tract of animals.

**Peritonitis**  
Inflammation of the membrane (peritoneum) that lines the abdominal cavity.
**Polymerase chain reaction**
A molecular technique for amplifying and creating multiple copies of nucleic acids (such as DNA and RNA) from a sample.

**Primary care**
A term for health services provided at the local community level, including GPs, pharmacists, dentists and midwives. Primary care is usually the first point of contact with the healthcare system by a patient.

**Proton pump inhibitor**
A group of drugs whose main action is to reduce the production of stomach acid.

**Pseudomembranous colitis (PMC)**
Inflammation of the large intestine (colon) characterised by the presence of pseudomembranes, which are raised yellow plaques on the intestinal surface.

**Ribotype**
A term used to describe different strains of an organism based on molecular methods which examine differences in the nucleic acid of the ribosome (the protein making machinery of the cell).

**Risk factor**
An aspect of personal behaviour or lifestyle, an environmental exposure, or a hereditary characteristic that is associated with an increase in the occurrence of a particular disease, injury, or other health condition.

**Root cause analysis**
A process for identifying the basic or causal factor(s) that underlie a problem.

**Spores**
A highly resistant, resting phase displayed by some types of bacteria.

**Sporicidal**
The ability to kill bacterial spores.

**Toxic megacolon**
Acute, severe inflammation of the colonic wall accompanied by extreme dilatation of the colon.
Appendix F: Guidance development group

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Epidemiologist

Prof. John E Coia
Consultant Clinical Microbiologist

Dr. Martin Connor
Consultant Microbiologist

Dr. Anne Marie Karcher
Consultant Microbiologist and Lead Infection Prevention & Control Doctor

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Health Protection Nurse Specialist

Lisa Ritchie
Nurse Consultant Infection Control

Margaret Tannahill
Consultant Nurse Infection Control

Dr. Christopher McGuigan
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Assistant Director of Nursing Infection Control

Robert Wilson
Infection Control Manager

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Project Lead for Scottish Antimicrobial Prescribing Group
Appendix G: Guidance on how to take faecal samples


How to collect a faecal specimen at home

Information for Patients or Carers

The doctor or nurse will explain why a stool (faecal) specimen is required, how this should be obtained and when your results will be available. You will be supplied with the correctly labelled specimen container and laboratory form. The information in this sheet may help if you have to provide a stool (faecal) specimen at home.

Examples of specimen containers.

How to collect a stool specimen at home:

**Step 1.** Place a clean wide mouth container (for example empty plastic food container/one-litre ice cream carton, or a potty) in the toilet bowl or place a clean newspaper or plastic wrap over the toilet seat opening (If the stool is very watery this may not be possible).

**Step 2.** Pass the stool into the potty, plastic container or onto newspaper or plastic wrap.

**Step 3.** Place small scoopfuls of the stool into the specimen container using the spoon built into the lid of the specimen container (or the wooden stick, if supplied). Try to make sure that any parts of the stool which appear bloody, slimy or watery are put into the specimen container. If possible try not to mix urine with the stool sample – do not worry if this not possible.

**Step 4.** Do not overfill the specimen container (the fill line indicates the required amount). Try not to spill the stool on the outside of the specimen container. If this happens clean the outside of the specimen container with soap and warm water, then wash your hands thoroughly with soap and warm running water and dry.

**Step 5.** Put on the specimen container lid and screw on tightly. Wash your hands thoroughly with soap and warm running water and dry.

**Step 6.** Dispose of the remaining stool in the potty, plastic container or newspaper into the toilet.

**Step 7.** If you have used a reusable container such as a potty, clean with your usual toilet cleaner. Ensure the potty is clean and dry before reuse. If you have used plastic wrap, newspaper or a disposable container, wrap these in newspaper then put into a disposable bag and place in your outside bin.

**Step 8.** Place the specimen container in the plastic bag attached to the specimen request form (or the envelope provided if for posting) and make sure the bag/envelope is properly sealed.

**Step 9.** Wash your hands thoroughly with soap and warm running water and dry.

**Step 10.** Deliver to the doctor’s surgery or post it as soon as possible (preferably the same day).

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When and how to obtain a faecal specimen from a patient

Information for Healthcare Staff

A faecal specimen (single) should be obtained as soon as possible following onset of symptoms of diarrhoea.

Definition of diarrhoea:
Diarrhoea is defined as the passage of 3 or more loose or liquid stools per day, or more frequently than is normal for the individual (usually at least 3 times in a 24 hour period). Diarrhoea is usually a symptom of gastrointestinal infection, which can be caused by a variety of bacterial, viral and parasitic organisms. The frequent passing of formed stools is not diarrhoea.

Preparation for faecal specimen collection:
Gather all relevant equipment:
- Clean, disposable/reusable bedpan or similar container.
- Leak proof sterile specimen container preferably with attached spoon or a clean disposable spatula.
- Leak proof sealable bag (with separate compartment for the specimen).
- Laboratory request form (if possible complete patient details before obtaining the specimen).

Examples of specimen containers

NB Use Standard Infection Control Precautions and Contact Precautions throughout this procedure. For further information please refer to the Guidance for obtaining faecal specimens from patients with diarrhoea (Background Information).

Procedure:
1. Explain the need for the procedure to the patient including the reason for the test (e.g. symptoms of diarrhoea), when and how the results will be given.
2. Ask the patient to pass faeces into the bedpan or container avoiding if possible passing urine at the same time.
3. Put on gloves and aprons to receive the bedpan.
4. Transfer faeces into a leak proof sterile specimen container using the spoon built into the container or a clean spatula to the fill line of the specimen container (or as a minimum covering the cone shape of the container). If the specimen contains blood, pus or mucus try to get these into the container.
5. Put on the container lid and secure. Avoid contaminating the outside of the container.
6. Discard bedpan and contents as usual. Discard other healthcare waste as defined in local policy.
7. Remove gloves and apron and wash and dry hands.
8. Place the specimen container directly into the leak proof sealable bag (The outside of this bag must not be visibly contaminated).
9. Wash and dry hands.
10. Ensure the transport of specimen within 2 hours of collection (If necessary specimens can be refrigerated for up to 24 hours at 4°C in a designated non-food fridge).

Additional Information:
- A negative test result does not necessarily exclude infection especially if clinical symptoms are highly suggestive. These cases should be discussed with the Consultant Medical Microbiologist or Infection Control Doctor.
- Normally only 1 faecal specimen is required per patient. There are exceptions to this and your Infection Control/Health Protection Team will advise.
- Larger amounts of faeces may be required for food borne pathogens.
- If a faecal specimen cannot be obtained from a neonate then a rectal swab is usually sufficient.
- Document in the medical and nursing notes when the faecal specimen was taken and the reason(s) this was required.
- Stool charts should be used to monitor bowel pattern when patients have diarrhoea.
- Consultation with the Infection Control Doctor or Microbiologist may be required where additional stool sampling is necessary to perform specific types of diagnostic tests.
- The laboratory request form should contain relevant clinical information. Which may include:
  - Name.
  - CHI no or Date of Birth (if CHI not known).
  - Ward details/GP Practice.
  - Name and contact details of Clinician requesting the test.
  - Test required such as culture and sensitivity/virology.
  - Date/time faecal specimen was obtained.
  - Date of onset of symptoms.
  - Nature of symptoms.
  - Duration of symptoms.
  - Any current or recent antibiotic history (up to 3 months previously).
  - Relevant medical history and or diagnosis.
  - Travel history.
  - If the faecal specimen has been contaminated with urine or obtained from an incontinence product.
Appendix H: Faecal Transplant Procedure

Introduction
There are a number of reported methods for carrying out faecal transplant; for example, administration via the upper GI tract (nasogastric/nasojejunal tube) or lower GI tract (retention enema/colonoscopically). The decision on route of administration will depend on local expertise and patient preference.

Regardless of route of administration, the screening of donors and transplant administration remain similar. The method described in this procedure has been shown to be efficacious¹, however clinicians may use other published methods.

Donor identification and screening
Identifying a family member(s)/relative(s) as a potential donor is often more aesthetically acceptable to the patient. The key aspects to determine donor suitability for screening are that the potential donor has had:

- No diarrhoeal illness in the preceding six months: and
- No antibiotics in the preceding six months.

If the potential donor fulfils the above criteria then they should be screened for communicable illness, i.e. blood and stool testing including, serology for hepatitis A, B and C, HIV and syphilis.

The potential donor is also required to provide three stool samples, which have been tested for enteric pathogens including: culture for standard bacterial pathogens; *Clostridium difficile* culture (or antigen) and toxin analysis; and microscopy for ova, cysts and parasites. These stool samples should be collected on separate days.

If there is no evidence of communicable disease then the donor is suitable as a faecal transplant donor.

Faecal transplant preparation
The preparation of the faecal transplant is carried out in a clean room with working surfaces protected by absorbent covering. The individual preparing the transplant should wear personal protective equipment consisting of a water repellent apron, disposable gloves and a full face visor.

After preparation (see below) all environmental surfaces and equipment must be decontaminated or disposed of as per Appendices 7 and 11 of the National Infection Prevention and Control Manual.

The transplant faeces must be prepared on the day of the transplant, i.e. the donor must provide a fresh sample of faeces:

- 30 g of faeces is homogenised with 150 ml of 0.9% saline. This is achieved by using a single use container designed for mixing liquid and powder (e.g. a protein shake container).
• This mixture is then filtered using five unfolded gauze swabs. This filtering must be repeated in order to obtain a liquid solution.

• 50 ml of the liquid solution should be transported and administered to the patient via a nasogastric tube.

As the anaerobic bacteria will die quickly, the transplant must be administered within six hours of obtaining the donor stool.

**Faecal transplant recipient treatment and transplant administration**

Prior to faecal transplant the recipient will require treatment doses of oral vancomycin, 125 mg four times daily, to keep the recipient diarrhoea free and reduce *C. difficile* burden within their bowel.

The recipient should be admitted the day prior to the transplant. The vancomycin must be stopped at time of admission and the recipient commenced on a 20 mg of dose of oral omeprazole to reduce stomach acidity.

The morning of the transplant a further 20 mg dose of omeprazole must be administered.

A nasogastric tube must be passed and the recipient will require a chest X-ray to confirm the position of the nasogastric tube in the stomach.

50 ml of the prepared faecal transplant is administered down the nasogastric tube. This is followed with a 20 ml flush of water. The nasogastric tube is then removed and the patient encouraged to eat normally.

The transplant recipient can be discharged from hospital following four hours of observation post transplant unless clinical condition necessitates.

**Reference**

1. Aas J, Gessert GE and Bakken JS. Clinical Infectious Diseases 2003; 36: 580-5
Appendix I: HPN Guideline feedback form

HPN Guideline Feedback Form

Section A – About the Document (Guideline)

Guideline Title:

Author:

Publisher:

Date of Publication:

Section B – About the Evaluation

Reviewer’s Name:

Reviewer’s Occupation:

Reviewer’s Organisation:

Reviewer’s Contact Email Address: (Optional)

Date of Evaluation:

Section C – Comments

1. Does the Guideline meet your needs/inquiry at the time of evaluation? (Please explain why this is the case.)

2. Is there anything lacking in the Guideline? (Please explain.)

3. Do you have any other comments?

An electronic version of this form can be downloaded here: http://www.hps.scot.nhs.uk/about/guidancedevelopment.aspx

Once completed please return this form to: NSS.HPN@nhs.net
References


15. Health Protection Agency and the Department of Health, *Clostridium difficile Infection: How to Deal with the Problem*. January 2009


