SOP Objective

To provide Healthcare Workers (HCW) with details of the care required to prevent cross-infection in adult patients with known/suspected *Clostridioides difficile* Infection (CDI).

This SOP applies to all staff employed by NHS Greater Glasgow & Clyde and locum staff on fixed term contracts and volunteer staff.

KEY CHANGES FROM THE PREVIOUS VERSION OF THIS SOP

- **Updates to wording Section 3. Daily assessment of Severity by Clinical Team**

Document Control Summary

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Developed by	Infection Prevention and Control Policy Sub-Group
Related Documents	National Infection Prevention and Control Manual: Home NHSGGC CDI Paediatrics SOP NHSGGC Cleaning of Near Patient Equipment SOP NHSGGC Terminal Clean of Ward/Isolation Rooms SOP NHSGGC Twice daily Clean of Isolation Rooms SOP Antimicrobial Prescribing Policies
Distribution/ Availability	NHSGGC Infection Prevention and Control Web Page: www.nhsggc.scot/hospitals-services/services-a-to-z/infection-prevention-and-control
Lead Manager	Director Infection Prevention and Control
Responsible Director	Executive Director of Nursing

CONTENTS

CDI Aide Memoire

Consult SOP and isolate in a single room with:

- ✓ ensuite / own commode
- ✓ door closed
- ✓ IPC yellow sign on door
- ✓ dedicated equipment
- ✓ Bowel Movement Record
- ✓ **Care Checklist** completed daily
- ✓ Daily Severity scoring to be completed by medical staff

Patient Assessed Daily

Patient has been asymptomatic for >48 hours and bowel movements have returned to patients normal.

NO

YES

- ✓ undertake terminal clean of room
- ✓ Stop isolation
- ✓ Continue stool chart until discharge

SOP - Guidelines for patients in isolation:

Hand Hygiene: Liquid Soap and Water

PPE: Disposable gloves and yellow apron

Patient Environment: Twice daily chlorine clean

Patient Equipment: Chlorine clean after use and at least on a twice daily basis

Laundry: Treat as infected

Waste: Dispose of as Clinical / Healthcare waste

Incubation Period: up to 12 weeks

Period of Communicability: until 48 hours asymptomatic and a normal stool passed

Notifiable disease: Yes

Transmission route: direct, indirect contact

1. Responsibilities

Healthcare Workers (HCWs) must:

- Follow this SOP.
  Commence a CDI Care Checklist while patient is symptomatic, update daily and complete the risk assessment for any aspect of transmission based precautions (TBP) for CDI that cannot be implemented

  Clostridioides *Difficile* – IPC Care checklist

- Inform their line manager and a member of the Infection Prevention and Control Team if this SOP cannot be followed.
- Provide written and verbal information on CDI for patients and their relatives as appropriate

  Clostridioides Difficile Fact Sheet

Senior Charge Nurse (SCN) must:

- Ensure that the IPC Care checklist is in place while patient is deemed infectious.
- Ensure that written information is provided / available for patients and relatives.
- Ensure a failure to isolate risk assessment is in place if any aspect of TBPs for CDI cannot be implemented

Managers must:

- Support HCWs and IPCTs in following this SOP.
- Cascade new SOPs to clinical staff after approval by the Board Infection Control Committee (BICC).

Infection Prevention and Control Teams (IPCTs) must:

- Keep this SOP up-to-date.
- Provide education opportunities on this SOP.

- Monitor epidemiology of *Clostridioides difficile* Infection (CDI) within healthcare facility(ies) and advise on infection prevention and control precautions as necessary.
- Advise and support HCWs to undertake a Risk Assessment if unable to follow this SOP.

Occupational Health Service (OHS) must:

- Advise HCW regarding possible infection exposure and return to work issues as necessary

2. General Information on *Clostridioides difficile* Infection (CDI)

Communicable Disease/ Alert Organism	*C. difficile* is a Gram positive, anaerobic, spore-forming organism implicated in CDI and pseudomembranous colitis (PMC). The overgrowth of the organism within the large intestine and toxin production causes cellular damage and increased fluid accumulation in the gut. *C. difficile* is part of the normal flora of up to 3% of the adult population and up to 90% of children less than 2 years. Asymptomatic carriage in healthcare patients is relatively common.
Case definition	***Clostridioides difficile* Infection (CDI)** is defined as any patient in whose stool *C. difficile* toxin has been identified at the same time they have experienced diarrhoea not attributable to any other cause; **or** from patients whose stool *C. difficile* has been cultured at the same time as they have been diagnosed with pseudomembranous colitis (PMC). Health Protection Scotland (2017). **Mild CDI:** associated with mild diarrhoea (3 liquid/loose stools or more frequently than normal) **Moderate CDI**: associated with a raised WBC count above normal but <15 x 10^9 /L cells , (typically 3 or more loose/liquid stools per day) **Severe CDI:** when a patient has at least one severity marker including temperature>38.5°C, WBC 15 x 10^9/L cells, 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 x 10^9/L cells or <2 x 10^9/L cells, serum lactate >2.2 mmol/l, end organ failure (mechanical ventilation, renal failure). Recurrence is defined as CDI which re-occurs within 2-8 weeks of previous episode, provided symptoms from previous episode resolved after completion of initial treatment.
Clinical Condition	Clinical onset of CDI often occurs when patients are on antibiotics, or within 4 weeks and up to 12 weeks of finishing a course of antibiotics. Patients may be colonised with *C. difficile* without symptoms. • CDI may present with malaise, abdominal pain, nausea, anorexia, watery diarrhoea, low-grade fever, and a peripheral leukocytosis. Colonoscopy reveals a non-specific diffuse or patchy erythematous colitis without pseudomembranes. • Pseudomembranous colitis (PMC) Sigmoidoscopy reveals raised yellow/ orange plaques from 2-10mm in size scattered over the colorectal mucosa. Patients with PMC have a more serious illness than CDI. Diarrhoea may also contain blood and mucous. ***NB:*** Life-threatening symptoms develop in 1.2-3.2% of patients with CDI. This disease is a very important co-morbidity in frail, elderly patients and can have high in-patient mortality.
Mode of Spread	There is evidence of both direct and indirect spread through the hands of HCWs and patients; and environmental contamination via equipment and instruments, e.g. commodes, bedpans and washbowls. *C. difficile* produces

	spores which can survive for long periods in the environment. Environmental cleaning is paramount.
Incubation period	Up to 12 weeks.
Notifiable disease	Notifiable under Public Health (Scotland) Act 2008 : Yes
Persons most at risk	Certain persons are at increased risk of acquiring CDI. CDI should be considered in persons with diarrhoea who also have : • Current or recent (within last 3 months) use of antimicrobial agents, in particular cephalosporins, broad-spectrum penicillins, fluoroquinolones and clindamycin • Increased age (over 65 years). • Prolonged stay in healthcare settings. • Serious underlying disease • Surgical procedures (in particular bowel procedures). • Immunosuppression (incl. HIV and transplant) • Use of proton pump inhibitors or H2 antagonists, e.g. omeprazole, lansoprazole, which reduce production of stomach acid.

3. Transmission Based Precautions for CDI

Accommodation (patient placement)	The patient should be placed in a single room, with ensuite or own commode. The door to the room must be closed and a yellow IPCT sign placed on the door. If a single room is unavailable the IPCT will help the clinical team to undertake a risk assessment and advise where to nurse the patient. This must be documented on the CDI Care Checklist. Precautions should continue until the patient has been asymptomatic for 48 hours and bowel movements have returned to normal or, on the advice of a member of the IPCT. Transmission based precautions are not recommended for asymptomatic carriers.
Antibiotics	Antibiotic prescribing should be in accordance with the NHSGGC Infection Management Guidelines. Prescribing should be regularly monitored and feedback should be returned to prescribers as appropriate. • NHSGGC Antimicrobial Prescribing Policies • The Management of **Suspected** *Clostridioides difficile* Infection (CDI) in Adults
IPC Care Checklist available	Yes. *Clostridioides difficile* IPC Care Checklist
Healthcare/Clinical Waste	All non-sharps waste should be designated as Healthcare/Clinical Waste (HCW) and placed in an orange clinical waste bag within the room. Please refer to the NHSGCC Waste Management Policy.
Contacts	Specimens should not be sent from patients deemed to be contacts unless they develop loose stools, where there is no other cause for this.
Domestic Services/ Facilities	Domestic staff must follow the NHSGGC Twice Daily Clean of Isolation Rooms SOP. Cleans should be undertaken at least four hours apart
Equipment	

	Patient equipment, e.g. commode, BP cuff, washbowl should be allocated to the patient until no longer considered infectious. Consider single-use or single patient use equipment. Commodes should be decontaminated after each use with chlorine based detergent.
Hand Hygiene	**Alcohol based hand rub is <u>not</u> effective against CDI:** Soap and water must be used for all patients with loose stools. Hand hygiene is the single most important measure to prevent cross infection with CDI. Hands must be decontaminated before and after each direct patient contact, after contact with the environment, after exposure to body fluids and before any aseptic tasks. Patients should be encouraged to carry out thorough hand hygiene.
Health Protection Scotland (HPS) Trigger Tool	The Health Protection Scotland (HPS) Trigger Tool must be completed by the IPCT and Clinical Staff if there are two HAI CDI cases in the same ward in a two week period. IPCNs and ward staff will complete the tool daily until there is no longer a trigger i.e. one or both patients are no longer symptomatic or have been discharged. The following actions will be taken by the IPCT when a trigger is met: - request a terminal clean of the ward at the start of the trigger - advise on enhanced IPC precautions to be in place. - undertake SICPs audit with SCN - hand hygiene audit - ask the antimicrobial pharmacist to review prescribing Findings will be reported to the SCN and ward staff who will liaise with IPC and pharmacy colleagues on any actions required as a result. Following this, should another case of HAI CDI emerge, the IPCT will complete a PAG to determine the requirement for an IMT and ward closure.
Linen	Treat used linen as soiled/infected, i.e. place in a water soluble bag then a clear bag, tied and then into a laundry

	bag. (Brown bag used in Mental Health areas) Please refer to National Guidance on the safe management of linen.
Moving between wards, hospitals and departments (including theatres)	Except in clinical emergencies, transfer of patients who remain in isolation is not advisable. However, acute receiving units have a high patient turnover and transfer of patients is necessary for effective patient flow and to ensure that patients receive the appropriate care within their specialty. Therefore, receiving areas **MUST** be informed of the patient's condition and requirement for a single room **BEFORE** the patient is transferred. Please follow NHSGGC Terminal Clean of Ward/Isolation Rooms SOP
Notice for Door	The yellow IPC isolation sign must be placed on the door to the patient's room. In Mental Health Services (MHS), on advice of IPCT.
Patient Clothing	Whilst patients are symptomatic they should be advised to wear hospital gowns if suitable. If relatives or carers take personal clothing home, staff must place clothing into a domestic water soluble bag then into a patient clothing bag and staff must ensure that a Washing Clothes at Home Leaflet is issued. ***NB:*** It should be recorded in the nursing notes that both the advice and information leaflet have been issued.
Patient Information	Inform the patient and / or if relevant, the patient's relative/ carer of their condition and the necessary precautions if required. Answer any questions and concerns they may have. A CDI Fact sheet for patients and their relatives is available to download from the IPCT web page. ***NB:*** Record in the IPC Care checklist / clinical notes that the fact sheet has been issued. IPCTs are available to speak to patients and / or relatives / carers if required.
Personal Protective Equipment (PPE)	To prevent spread through direct contact PPE (disposable gloves and yellow apron) must be worn for all direct contact

	with the patient or the patient's environment/equipment. If there is a risk of splashing of blood/body fluids, then facial protection i.e. mask/visor should also be considered. Hand hygiene must be performed using liquid soap and water before donning and after doffing PPE. Alcohol based hand rub is not effective against CDI.
Precautions required until	Precautions should continue until the patient has been asymptomatic for 48 hours and bowel movements have returned to normal or, on advice of a member of the IPCT. If symptoms recur, reinstate precautions immediately, send further specimens and inform a member of the IPCT.
Daily and weekly check by IPCT	IPCNs will check daily (Monday -Friday) on the condition of patients with CDI until TBPs are no longer required and thereafter weekly for 4 weeks.

Daily assessment of severity by clinical team	A patient diagnosed with CDI must be reviewed daily by the medical staff regarding fluid balance, electrolyte replacement, nutrition review, and monitoring for signs of increasing severity. Severity assessment (See below) must be scored and documented in the patient notes. Patients must have severity assessment carried out daily by medical staff until patient is asymptomatic for 48 hours and bowel movements have returned to normal. Severity markers include: • Temperature of >38.5°C • Suspicion of PMC, toxic megacolon, ileus • Colonic dilatation in CT scan/ abdominal x-ray >6cm • WBC> 15 x 10^9 /L cells • Creatinine> 1.5 x baseline National guidance on CDI provides a list of severity markers for severe disease based on consensus and therefore is not exhaustive. A template for severity assessment is available from the IPCT. Please see The Management of **Suspected** *Clostridioides difficile* Infection (CDI) in Adults to determine antimicrobial therapy. Clinical cases of CDI In some circumstances the clinical team will treat a patient for CDI because either they have an equivocal result (GDH positive, toxin negative, the patient has C. difficile in their bowel that has the potential to produce C. difficile toxin, however the toxin has not been detected at this time but may cause disease) or without any positive microbiology following assessment of their presentation and symptoms. In these cases severity scores still need to be completed. Referral of severe cases onto Datix is the principle responsibility of IPCTs however if a clinician suspects a severe case of CDI they can also log this onto Datix for review.

	If for clinical reasons the severity assessment is not deemed necessary, e.g. patient requires end of life care; this should be documented in the patient's notes by the clinical team.

Clinical review assessment (CRA) and Reporting of Severe Cases of CDI	A Clinical Review is required if the patient: • has severe or life threatening CDI • was admitted to ITU for treatment of CDI or its complications • had endoscopic diagnosis of pseudomembranous colitis with or without toxin confirmation • had surgery for the complications of CDI (toxic megacolon, perforation or refractory colitis) • died within 30 days following a diagnosis of CDI where it is recorded as either the primary or a major contributory factor on the death certificate • had persisting CDI where the patient has remained symptomatic and toxin positive despite two courses of appropriate therapy
Deaths due to CDI (Underlying or Contributing)	Patients who have died will have their cause of death reviewed as soon as possible via the ward death certificate records. If death certificate records are not available, the lead IPCN will contact the General Manager (GM) for the service, and advise them that the records are not available. The Lead Infection Prevention and Control Doctor (LIPCD), Infection Prevention and Control Manager (IPCM), Associate Nurse Director, Infection Prevention and Control (ANDIPC), Clinical Services Manager (CSM) and Lead Nurse for the area must be informed of all patients who died in hospital who are or who have been positive for CDI during their current admission, and the cause of death if available. Medical staff completing a death certificate in which CDI is noted (part 1 or 2) should discuss this with the consultant in charge of the patient's clinical care and refer case to the Procurator Fiscals Office. If CDI is placed on part 1, medical staff should inform the CSM and GM for the area. Medical staff should familiarise themselves with NHSGGC Guidance on the Completion of Medical Certificates of Cause of Death.
Specimens required	Faecal specimens from any patient who has loose stools must

	be sent if no other cause of diarrhoea is known (Norovirus is not a reason to exclude CDI as a diagnosis as co-infection is possible). If negative and loose stools persist, another two samples should be sent at 24-hour intervals. Relevant clinical information must be supplied with the specimen. Stool specimens should be obtained as soon as possible after onset of diarrhoea. Toxin testing should only be requested on stool specimens that conform to the shape of the container. See ***Appendix 1***. • Send faecal specimens from patients who develop loose stools for culture and sensitivity– mark the form for *C. diff* toxin testing if CDI is suspected. • There is no requirement to send clearance specimens from patients who become asymptomatic. • Only when a relapse of CDI is suspected should you repeat the toxin testing and exclude other potential causes of diarrhoea, and 48 hours after completion of treatment. • Specimens should not be sent whilst patient is on treatment.
Stool Charts	It is the responsibility of staff looking after the patient within the area to record signs and symptoms of infection as appropriate, e.g. Bowel Movement Record, Appendix 1. The date, time, size and nature of the stool should be recorded while symptomatic and continued until discharge in order to reduce the risk of cross infection.
Surveillance	Surveillance of CDI is mandatory in Scotland and is reported to HPS by the Diagnostic Laboratory. Local surveillance in NHSGGC is returned to wards with a prevalence of CDI monthly using Statistical Process Control Charts (SPCs). The trigger for action is when the numbers in a ward reach the upper control limit in the SPC. SPCs are not a substitute for local referral by clinical staff and IPCTs but should be used to monitor trends and promote quality improvement.

Terminal Cleaning of Room	Follow NHSGGC Terminal Clean of Ward/Isolation Rooms SOP If isolation is discontinued and the patient remains in hospital, undertake a terminal clean of the patient's room, including bed, bed locker, chair and table. Consider moving the patient to a new bed-space for ease of access. ***NB:*** relapse and re-infection from the environment can be as high as 20% in patients with CDI.
Visitors	Visitors are not required to wear aprons and gloves unless performing personal care. Visitors should be advised to decontaminate their hands with liquid soap and water on leaving the room/ patient. Visitors should be advised not to sit on the patient's bed at any time during visiting.

4. Evidence Base

http://www.nipcm.hps.scot.nhs.uk/

https://www.hps.scot.nhs.uk/a-to-z-of-topics/clostridioides-difficile-infection/

Accurate Recording of Deaths from Healthcare Associated Infection and Action. Scottish Government Health Directorates. CMO (2011) 13.

Vale of Leven Hospital Inquiry Report (2014)

Appendix 1 – Bowel Movement Record (adapted from the Bristol Stool Scale)

BOWEL MOVEMENT RECORD

Name: Month: _____ Year: _____

Date	Time	Size S-small M-medium L-large S M L	Type 1 Separate hard lumps like nuts (hard to pass)	Type 2 Sausage shaped but lumpy	Type 3 Like a sausage but with cracks on surface	Type 4 Like a sausage or snake, smooth and soft	Type 5 Soft blobs with clear-cut edges (passed easily)	Type 6 Fluffy pieces with ragged edges, a mushy stool	Type 7 Watery, no solid pieces (entirely liquid)	Staff Initials
	am pm									
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Adapted from the Bristol Stool Scale developed by KW Heaton and SJ Lewis at the University of Bristol, 1997