Infection Control

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Guidelines for the Care, Identification, Treatment and Management of *Clostridium difficile*

Clostridium difficile infection causes serious illness and can cause outbreaks in healthcare settings. Normally it affects the elderly, the debilitated and patients who have had antibiotic treatment. It is important that when a patient presents with diarrhoea the possibility that it may have an infectious cause is considered. Patients presenting with suspected potentially infectious diarrhoea indicative of *Clostridium difficile* must be isolated on symptom onset, if this is not possible, as a minimum enteric precautions must be put in place.

These guidelines provide a standardised and practical approach to the diagnosis, care, management and treatment of *Clostridium difficile* whilst ensuring measures are put in place to minimise cases and ensure appropriate follow up and review occurs enabling compliance with PHE and NICE standards for best practice as well as The Health and Social Care Act 2008 (updated 2015).

S	Suspect that a case may be infective where there is no clear alternative cause for diarrhoea
I	Isolate the patient and consult with the Infection Prevention and Control Team while determining the cause of the diarrhoea
G	Gloves and aprons must be used by staff working within the healthcare setting for all contacts with the patient and their environment
H	Hand washing with soap and water should be carried out before and after each contact with the patient and their environment
T	Test the stool for toxin, by sending a specimen immediately

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GUIDELINES FOR THE CARE, IDENTIFICATION, TREATMENT AND MANAGEMENT OF CLOSTRIDIUM DIFFICILE

Document Type	Infection Prevention and Control Guidelines
Document Purpose	To provide a concise and practical approach to the diagnosis, care, management and treatment of *Clostridium difficile* in the Trust ensuring that cases are managed appropriately and transmission of infection is minimised with consistent provision of clean, safe care. The document sets out to provide set standards for practice.
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Target Audience	All staff working within healthcare settings
Responsible Group	Infection Prevention and Control Committee
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Training and Development

Worcestershire Health and Care NHS Trust recognises the importance of ensuring that its workforce has every opportunity to access relevant training. The Trust is committed to the provision of training and development opportunities that are in support of service needs and meet responsibilities for the provision of mandatory and statutory training.

All staff employed by the Trust are required to attend the mandatory and statutory training that is relevant to their role and to ensure they meet their own continuous professional development.

INFECTION PREVENTION AND CONTROL GUIDANCE FOR THE CARE, IDENTIFICATION, TREATMENT AND MANAGEMENT OF CLOSTRIDIUM DIFFICLE

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INTRODUCTION

Clostridium difficile is one of the major causes of antibiotic-associated diarrhoea and colitis, a healthcare associated intestinal infection that mostly affects elderly patients with other underlying diseases. Infection can also arise within non healthcare settings including home settings.

Clostridium difficile is a bacterium of the family Clostridium. It is an anaerobic bacterium (i.e. it does not grow in the presence of oxygen) and produces spores that can survive for a long time in the environment, its usual habitat is the large intestine, where there is very little oxygen.

It can be found in low numbers in a small proportion (less than 5%) of the healthy adult population and is usually kept in check by the normal, 'good' bacterial population of the intestine. It is common in the intestine of babies and infants, but does not cause disease because its toxins (poisons) do not damage their immature intestinal cells.

SYMPTOMS

Clostridium difficile can cause diarrhoea, ranging from a mild disturbance to a very severe illness with ulceration and bleeding from the colon (colitis) and at worst, perforation of the intestine leading to peritonitis. It can be fatal. Generally, it is only able to do this when the normal, healthy intestinal bacteria have been killed off by antibiotics. When not held back by the normal bacteria, it multiplies in the intestine and produces two toxins (A and B) that damage the cells lining the intestine. The result is a distinctive diarrhoea.

To understand more about ascertaining risk factors for infection, the assessment tool at Appendix 1 can be used. All in patients should be considered at high/very high risk for having or developing *Clostridium difficile.*

Do NOT delay treatment pending stool testing or a positive result if there is suspicion of *Clostridium difficile.*

DEFINITIONS

The definitions below must be used to assist in the identification and management of episodes of *Clostridium difficile* associated diarrhoea.

- ***Clostridium difficile* infection**: one episode of diarrhoea (defined either as stool loose enough to take the shape of a container used to sample it or as Bristol Stool Chart types 5–7, see Appendix 4), that is not attributable to any other cause, including medicines (Appendix 2), and that occurs at the same time as a positive toxin result (with or without a positive *Clostridum difficile* culture) and/or endoscopic evidence of pseudomembranous colitis (PMC).
- **A period of increased incidence (PII) of *Clostridium difficile*:** two or more new cases (occurring >48 hours post admission, not relapses) in a 28-day period on a ward.
- **An outbreak of *Clostridium difficile*:** two or more cases caused by the same strain related in time and place over a defined period that is based on the date of onset of the first case.

RISK FACTORS FOR INFECTION

Healthcare staff must be aware of the need for prompt identification of patients who are at risk of *Clostridium difficile*. A risk assessment tool is available for use if required (Appendix 1)

Risk factors include but are not limited to the following:

- Age over 65 years
- Presence of severe underlying disease and/or immuno-suppression (including recent chemotherapy)
- Patient:
    - is on antibiotics now or has been within the last 8 weeks.
    - has had repeated enemas/laxatives/stool softeners or bulking agents

- will have/has recently had gastro-intestinal surgery or non-surgical gastro-intestinal procedure(s)
- has/will have naso-gastric tube insitu
- is on anti-ulcer medication (proton pump inhibitors) or regular antacids
- has been nursed in an intensive care unit in the last 8 weeks
- will be/has been staying in hospital for over one month in the last 8 weeks or had recent healthcare contact
- has had a previous episode of *Clostridium difficile.*

If admitted to an inpatient setting and presenting with two or more risk factors, actively consider:

- Ways in which duration of hospital stay can be shortened and ensure vigilance is in place for signs of symptom onset to ensure prompt identification.
- Minimisation of antibiotics and strict adherence to antimicrobial prescribing guidance.
- Stopping proton pump inhibitors during admission if at all possible.

HOW IS CLOSTRIDIUM DIFFICILE DIAGNOSED?

As speed of diagnosis is important for the efficient use of isolation facilities, healthcare staff should, in line with the SIGHT protocol, ensure that stool specimens are sent for toxin testing as soon as diarrhoea occurs and infection is suspected (DH 2009). This includes recent/current hospital admission, antibiotic use, proton pump inhibitor usage, presence of blood/mucus in stool.

The toxins produced by *Clostridium difficile* can be detected in stool samples by an enzyme immuno-assay (EIA), performed in the local Microbiology Department. If a particularly severe case of colitis is identified, then the laboratory is able to culture faeces in order to isolate the organism. The strain can then be sent to the Local Reference Laboratory for full identification and typing. This may be important in identifying the presence of particularly virulent strains (e.g. the 027 ribotype), or to investigate a possible outbreak.

All liquid samples from those aged over 2 years of age are tested routinely for *Clostridium difficile* however if the disease is clinically suspected, this should also be made clear on the request card.

- All stool samples from those who are over 2 years of age and symptomatic i.e. only liquid/loose stools that take the shape of the container (Bristol Stool Chart types 5–7) will be examined as long as there is not a previous positive result for *Clostridium difficile* in the last 28 days.

Tests undertaken to diagnose *Clostridium difficile* are in accordance with a national mandatory protocol which requires three separate tests to be undertaken:

- The first test (**GDH antigen EIA**) is a screening test. GDH antigen is associated with the presence of the actual *Clostridium difficile* organism. A negative test is therefore regarded as a good negative predictor – i.e. a negative test signifies absence of *Clostridium difficile.*

For specimens testing positive for GDH antigen, two further tests are used:

- The first is an **enzyme immune-assay (EIA) for *Clostridium difficile* toxin**.
  - If both GDH antigen and toxin EIA tests are positive, then this is indicative of toxin producing *Clostridium difficile* and therefore in those who are symptomatic indicative of ***Clostridium difficile* infection** (EIA case which is a reportable case).
  - If the toxin EIA is negative, a further molecular **toxin PCR test** is done:
    - if this test is negative the GDH antigen test is a probable false positive and not indicative of *Clostridium difficile* disease.
    - If it is positive, it signifies probable **colonisation** of a toxigenic strain **of *Clostridium difficile***, even if the toxin is not currently being expressed. Clinical assessment is therefore required to determine further management of the patient, if symptomatic treatment for

Clostridium difficile infection would be recommended and obviously implementation of enteric precautions should be in place for the duration of diarrhoea (type 5-7).

- This testing algorithm although complex increases the reliability of the laboratory diagnosis of patients with *Clostridium difficile* disease and enable prompt diagnosis. The comments made by the laboratory included on specimen results will provide interpretative guidance but further advice regarding individual patients is always available from the Infection Prevention and Control Team.
- In suspected cases of 'silent' CDI, such as ileus, toxic megacolon or pseudomembranous colitis without diarrhoea, other diagnostic procedures, such as colonoscopy, white cell count (WCC), serum creatinine and abdominal CT (computerised tomography) scanning, may be required.
- More than one test may be required if the first test is negative but where there is a strong clinical suspicion of *Clostridium difficile,* treatment must continue even in the absence of the positive result if symptoms are truly indicative of *Clostridium difficile* without other causes for symptom onset being identified. Further samples should be tested on a continued basis until diagnosis established or other cause identified.
- The laboratory will not retest for *Clostridium difficile* toxin positive cases if an individual is still symptomatic within a period of 28 days. In these instances treatment for *Clostridium difficile* should be reviewed.
- Generally liquid stool samples from children under the age of 2 years will not be tested for *Clostridium difficile*. This relates to the possibility for toxigenic strains of *Clostridium difficile* to be present in the absence of symptoms.
- A sudden increase in the number and/or severity of cases detected in a ward/unit or healthcare setting will indicate the need for typing. This will be coordinated by the Infection Prevention and Control Team and will involve samples being sent to the local reference laboratory. If two or more cases within one inpatient area are identified and can be linked then the area may be closed to admissions pending investigation, within wider primary care settings including General Practice a review of risk factors will be undertaken.
- With any cluster of cases, assessment as to whether further typing of stool will be undertaken by the Infection Prevention and Control Team. In inpatient areas, dependent upon the strain identified, it is possible that control maybe achieved by ward closure, intensive cleaning and activity reduction or cessation.
- Endoscopy may also confirm the presence of colitis associated with *Clostridium difficile.*

KEY PREVENTION STRATEGIES

- Isolation of those who have symptoms of possible infection (diarrhoea) and implementation of all enteric precautions (see Section F).
- Hand Hygiene with soap and water to decontaminate hands, followed by thorough drying and application of alcohol based hand gel (hygienic hand rub).
- Adherence to antimicrobial prescribing guidance to minimise risk of illness and also to treat those who are symptomatic.
- Consideration of antimicrobial stewardship to ensure pragmatic and appropriate use of antibiotics within inpatient settings.
- Maintaining a high standard of environmental cleanliness, including the addition of bleach cleaning and adoption of all enteric precautions (see Section C and F).
- Ensuring compliance with all aspects of this guidance.
- Ribotyping of all positive cases within Trust inpatient areas will be undertaken to provide intelligence on possible links between cases.

MANAGEMENT AND TREATMENT OF CLOSTRIDIUM DIFFICILE

Clinicians (doctors and nurses) should apply the following mnemonic protocol (SIGHT) when managing suspected potentially infectious diarrhoea:

S	Suspect that a case may be infective where there is no clear alternative cause for diarrhoea
I	Isolate the patient and consult with the Infection Prevention and Control Team while determining the cause of the diarrhoea
G	Gloves and aprons must be used by staff working within the healthcare setting for all contacts with the patient and their environment
H	Hand washing with soap and water should be carried out before and after each contact with the patient and their environment
T	Test the stool for toxin, by sending a specimen immediately

- Those presenting with diarrhoea should be monitored using a Bristol Stool Chart (see Appendix 4) to ensure that frequency, nature and severity of diarrhoea can be assessed.
- All antibiotics that are clearly not required should be stopped, as should other drugs that might cause diarrhoea (see Appendix 2).
- It is imperative that *Clostridium difficile* is managed as a diagnosis in its own right.
- Consideration must be given by medical staff to the need for review of fluid balance, electrolyte maintenance and nutritional status throughout duration of infection.
- Anti-diarrhoeal agents such as loperamide must not routinely be used to reduce diarrhoea.
- Severity of *Clostridium difficile* can be assessed as follows:
  - **Mild *Clostridium difficile*** is not associated with a raised WCC; it is typically associated with less than 3 stools of types 5–7 on the Bristol Stool Chart per day.
  - **Moderate *Clostridium difficile*** is associated with a raised WCC that is <15 X 109/L; it is typically associated with 3–5 stools per day. Individuals must be monitored on an ongoing basis for frequency and severity of diarrhoea using the Bristol Stool Chart.
  - **Severe *Clostridium difficile*** is associated with a WCC >15 X 109/L, or an acute rising serum creatinine (i.e. >50% increase above baseline), or a temperature of >38.5°C, or evidence of severe colitis (abdominal or radiological signs). The number of stools may be a less reliable indicator of severity.
  - **Life-threatening *Clostridium difficile*** includes hypotension, partial or complete ileus or toxic megacolon, or CT evidence of severe disease.

TREATMENT

Symptomatic patients should be treated with oral metronidazole or vancomycin in accordance with Primary Care Antimicrobial Prescribing Guidance, principles are also detailed overleaf. Oral metronidazole should be started whenever *Clostridium difficile* disease is suspected without waiting for the results of toxin tests and medication must be reviewed. The use of anti-diarrhoeal agents such as loperamide must also be avoided in those with *Clostridium difficile*. In some cases it may be sufficient to stop the implicated antibiotics and ensure the patient is well hydrated. In those with severe cases surgical intervention may be required.

- All antibiotics that are clearly not required should be stopped, as should other drugs that might cause diarrhoea (see Appendix 2).
- Anti-diarrhoeal agents such as loperamide should not be used to reduce diarrhoea.
- Consider requirements for hydration (IVI), nutritional requirements (refer to Dietician/NG feeding), and also Electrolyte correction (K+, Mg++).

- It is essential that a full medical review occurs on suspicion and again on confirmation of infection to ensure clinical history and current medication prescribing is reviewed linked to laxatives and stool softeners; non-steroidal anti-inflammatory drugs (NSAIDs); Proton Pump Inhibitors (PPIs); Cytotoxics and Immunosuppressant drugs.

Mild/Moderate Cases	**Metronidazole 400mg TDS. If responding continue for 14 days** (relapse common if treatment stopped prematurely). If no improvement within 3-5 days (no evidence of reduced frequency, clinical improvement or improved markers), change to **vancomycin orally 125mg QDS**, if responding continue for **14 days**. If a negative result for *Clostridium difficile* is obtained consider stopping BUT if still suspected continue with above treatment regimen and send further samples.
Severe Cases	Should be discussed with the Consultant Microbiologist, will require hospital referral and potential for higher doses of vancomycin (up to 500mg QDS) with other supportive treatment on advice of Consultant Microbiologist.
Relapses (approx 20%)	Possibly due to residual spores, re-infection or further antibiotics, based on time frame from positive and severity of symptoms consider **vancomycin 250mg QDS for 14 days.**
Further Relapses (Reducing Dose)	**Vancomycin 250mg QDS for 14 days and then gradually reduce 125mg QDS for one week, then 125mg TDS for one week then 125mg BD for one week, then 125mg OD for one week then 125mg alternate days for two weeks, then 125mg every third day for two weeks, then cease treatment**. If symptoms present during reducing dose discuss treatment options with the Consultant Microbiologist.
Use of oral vancomycin does not require therapeutic drug monitoring. For further guidance on treatment regimens please refer to the current Antimicrobial Prescribing Guidance.	
In addition to the specific treatment guidance above, for each positive *Clostridium difficile* result clinical advice will be documented on ICE by the Consultant Microbiologist.	
Fidaxomicin is the first in a new class of macrocylic antibiotics that is now licensed by the European Medicines Agency (EMA) for the treatment of *Clostridium difficile* infection (CDI). This medication can only be prescribed by a Consultant Microbiologist and will be done so if failure to respond to above treatment options. It can also be considered if metronidazole is not effective and an individual is colonised with a vancomycin resistant micro-organism.	
Current evidence on the efficacy and safety of faecal microbiota transplant for recurrent *Clostridium difficile* infection is adequate to support this procedure which should only be considered for patients with recurrent infections that have failed to response to antibiotics and other treatment. Referral to specialist care centres should be considered if clinically indicated.	

In addition to treatments detailed above please consider the following:

- **Mild/Moderate Cases**: If no response to treatment but remains clinically well: Consider: abdominal x-ray, flexible sigmoidoscopy, gastro referral and investigations for other causes of diarrhoea. If deteriorating at any point treat as severe and increase vancomycin to up to 500mg QDS, consider urgent abdominal x-ray and consider Colorectal/Gastro referral.
- **Severe Cases:** Will generally be within acute settings or referred into acute settings. The following highlights key clinical interventions which may occur: Commence vancomycin 500mg QDS, consider need for appropriate referral to acute setting for an urgent abdominal x-ray if colonic dilatation noted will require a surgical referral and if no dilatation a gastro

referral should be made. A flexible sigmoidoscopy can be undertaken if diagnosis uncertain. If responding to treatment continue with vancomycin for 14 days and then follow through reducing dose regimen.

PREVENTION OF SPREAD

Always be alert for diarrhoea and consider the possible cause.

- All cases of diarrhoea must be promptly investigated by the clinical team and faeces sent for *Clostridium difficile* toxin testing.
- Stop unnecessary antibiotics, rehydrate patient, and start metronidazole 400 mg TDS immediately if *Clostridium difficile* is suspected.
- Ensure all relevant healthcare staff are aware of current and previous episodes of *Clostridium difficile.*
- Avoid unnecessary antibiotics. Where antibiotics are necessary, avoid high risk agents (cephalosporins, quinolones, clindamycin) particularly in those patients with a previous diagnosis of *Clostridium difficile*.
- Adhere to Primary Care Antimicrobial Prescribing Guidance at all times. Contact the Consultant Microbiologist for advice if required.
- Stop unnecessary ulcer healing drugs if clinically appropriate to do so.
- Remain vigilant for signs of relapse in patients with a history of *Clostridium difficile* or risk factors for illness.
- Although there is limited evidence for probiotics in prevention, further information can be obtained from the Infection Prevention and Control Team.

ENTERIC PRECAUTIONS

Refer to Section F of the Infection Prevention and Control Guidelines folder for further information on Enteric Precautions.

ISOLATION OF POSSIBLE CASES

- Specimens must be sent immediately for *Clostridium difficile* toxin testing (see SIGHT protocol).
- Patients with suspected potentially infectious diarrhoea (at least one episode of diarrhoea) should be moved immediately into a single room with a self contained toilet (or designated commode) and hand wash basin. Accommodation must be uncluttered to aid effective environmental cleaning.
- The Bristol Stool Chart must be used to monitor nature and frequency of diarrhoea.
- All staff entering the room must use Personal Protective Equipment (PPE) (single use disposable plastic apron and gloves) for all direct contact with the patient or their environment, and wash their hands with soap and water before and after patient contact, when removing PPE and on leaving the room. Visitors do not need to wear PPE (aprons and gloves) unless carrying out care activities.
- If isolation in a single room is not possible because the single room capacity is exceeded, consider placement in bay/cohort area. This requires rigorous supervision to maintain cleanliness in toilets/commodes and to ensure precautions in such bays are observed. Advice must be sought from the Infection Prevention and Control Team.
- The patient should remain isolated until there has been no diarrhoea (types 5–7 on the Bristol Stool Chart) for at least 48 hours, and a formed stool has been achieved (types 1–4). If

possible, it is advised that isolation continues until the antibiotic course is completed and following this a 48 hour symptom free period is achieved and a normal stool passed.

- If an individual has not been previously isolated on suspicion, because the diagnosis was not suspected, once confirmed, the patient should be isolated as soon as possible after diagnosis and no later than the end of the day of diagnosis. The Infection Prevention and Control Team must be informed and follow up of patient contacts will be considered. A terminal clean of their vacated bed space must occur prior to it being re-occupied.
- Transfer and movement of patients should be minimised but not cause clinical detriment. When attendance at other departments for essential investigations is planned consideration should be given as to how potential cross contamination can be minimised e.g. "last on the list" unless earlier investigation is clinically indicated. The receiving area must be informed of *Clostridium difficile* status to enable minimisation of waiting times/contact with other patients.
- Transfer to other healthcare facilities must include notification of *Clostridium difficile* status, past and present. This includes ensuring transport/ambulance services are aware if it is a current diagnosis.
- Treat linen from those with suspected or confirmed *Clostridium difficile* as infected regardless of the presence of actual soiling, until they have been symptom free for 48 hours and passed a formed stool.
- Within inpatient/residential settings, all healthcare waste that is actually or potentially contaminated with blood/body fluids must be disposed of as yellow bag "hazardous" infected waste in someone who is diagnosed with *Clostridium difficile* and has been symptomatic in the last 48 hours.

HAND HYGIENE

- All health care staff must wash their hands with soap and water before and after contact with patients with suspected or proven *Clostridium difficle* or any other infective diarrhoea and after contact with their immediate environment or body fluids. This is in compliance with the SIGHT protocol and World Health Organisation 5 Moments of Hand Hygiene. Hands should be dried thoroughly.
- All healthcare workers must use single use disposable aprons and gloves for any direct contact with those who are symptomatic or when undertaking activities where there is actual or potential contact with body fluids, including contaminated environment. Gloves and aprons should be removed after use and disposed of as hazardous waste. Healthcare staff must be compliant with bare below the elbows guidance.
- Alcohol based hand gel (hygienic hand rub) **must not** be used as an alternative to soap. It should only be applied **after** washing to rid hands of remaining other micro-organisms.

DECONTAMINATION (see Section C for further guidance on terminal cleaning process)

Inform Housekeeping Staff of the need for bleach cleaning process when case is considered as resolved or following transfer to another area.

- Environmental cleaning of rooms, bed spaces and toilet areas occupied/used by those with confirmed or suspected *Clostridium difficile* must be carried out at least daily using chlorine-containing cleaning agents (at least 1,000 ppm available chlorine). This chlorine based clean must follow a standard detergent clean.
- All commodes must be used with macerator liners and the frame cleaned after each use with a multi surface detergent wipe, where possible a commode should be designated for the patient to use. The Infection Prevention and Control Team may also advise on the use of a chlorine-

containing cleaning agent (at least 1,000 ppm available chlorine) or use of 70% alcohol hard surface disinfectant wipes in specific situations.

- Terminal cleaning of a mattress, bed space, bay or ward area after the discharge, transfer or death of a patient with known or suspected *Clostridium difficile* must be thorough. All areas must be cleaned in accordance with the terminal cleaning guidance in section C which surfaces, fixtures and fittings in addition to any medical devices in the area. This also involves removal of curtains, surfaces where appropriate must receive a detergent and chlorine clean (at least 1,000 ppm available chlorine), followed by replacement of laundered curtains and bed to be re-made with clean linen even if the occupant remain unchanged.

Chlorine-containing cleaning agents must be made up to the correct concentration and stored in accordance with manufacturers' instructions, with particular attention being paid to compliance with Health and Safety regulations (Health and Safety Executive, 2002).

CDI PASSPORT

The CDI passport will be issued to patients on the diagnosis of *Clostridium difficile* infection (Toxin EIA positive cases only) in hospital or by their GP. The holder can then show the card to healthcare staff when they are accessing health services e.g. GP, dentist, pharmacy, hospital etc. to ensure that they are aware of previous history.

Within Worcestershire, cards will be distributed when a toxin EIA positive result is obtained and this will be undertaken as detailed below.

- Within the Trust, the Infection Prevention and Control Team will issue cards to ward area on receipt of a positive sample result for staff to discuss with patient.
- For people who are identified with *Clostridium difficile* from a specimen sent from GP practice, a card will be forwarded to the practice for the GP to either give to or forward to the patient if they believe this is appropriate. Distribution to GP's will occur when a positive result is notified to the Infection Prevention and Control Team by the microbiology laboratory.

Advice to the patient must accompany the distribution of the card and this will be sent out with each card. Recommendations given include:

- The card should be kept in a safe place such as a wallet or purse and carried at all times. If it is issued to a carer for the patient they should keep the card safe.
- There is no explicit guidance on the length of time a card should be retained but locally advice is that this should be for two years.
- The need for the card to be shown to healthcare professionals e.g. pharmacists, dentists etc so that they are aware and can tailor treatment accordingly.

If you are presented with the card by a patient, then you should use your professional discretion about the appropriate action to take. This could include re-considering the need for a medication you wished to prescribe, particularly if antibiotics or proton pump inhibitors; informing other healthcare professionals of relevant medical history or further discussing the case with either the Consultant Microbiologist or Infection Prevention and Control Team.

DEATH CERTIFICATION

- If a patient with *Clostridium difficile* dies, the death certificate should state whether this was part of the sequence of events leading directly to death or whether it was the underlying cause of death. If either case applies it must be mentioned in Part 1 of the certificate. If *Clostridium*

difficile was not part of the sequence of events leading directly to death but contributed in some way to it, this should be mentioned in Part 2. Deaths where *Clostridium difficile* is noted in Part 1A will be investigated by the Infection Prevention and Control Team to review care and management and enhance future practice.

- If a healthcare professional is in doubt about the circumstances of death when writing the certificate, they should consult with either the Consultant Microbiologist or the coroner for advice.
- Infection prevention and control precautions for handling those who are deceased are the same as those used during life. Faecal soiling around the cadaver should be cleaned first with detergent and then with a chlorine-containing cleaning agent.
- Plastic body bags are not necessary, but may be used as part of routine practice in accordance with standard precautions for all patients dependent upon setting. There is negligible risk to mortuary staff or undertakers provided that standard infection prevention and control precautions are used.

It must be noted that when certifying death there is a legal duty to mention *Clostridium difficile* on a death certificate if it was part of the sequence of events directly leading to death or contributed in some way.

AUDIT MECHANISM

- Infection Prevention and Control Team to follow up all *Clostridium difficile* positive isolates to establish risk factors through a short root cause analysis process.
- All cases within inpatient areas will be followed up on a weekly basis as a minimum by the Infection Prevention and Control Team. Advice will be offered on treatment and enteric precautions. Within General Practice settings a single contact will be made to discuss treatment on receipt of positive result.
- Follow up will routinely occur at 40 days to establish response to treatment.
- Monthly monitoring of *Clostridium difficile* isolates will be undertaken.
- All deaths where *Clostridium difficile* mentioned on Death Certificate as 1a will be managed as a Serious Incident (SI).
- The Clinical Commissioning Groups within Worcestershire will be informed of all Toxin EIA positive cases and participate in a review process to establish any lessons that can be learnt, extrapolate best practice and also make a judgement on whether a case could have been avoided or whether there were any notable lapses in care provision.

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APPENDIX 1

CLOSTRIDIUM DIFFICILE ASSOCIATED DIARRHOEA (CDAD) RISK FACTOR ASSESSMENT
OPTIONAL CHECK LIST/EDUCATIONAL REVIEW TOOL

Clostridium difficile associated diarrhoea (CDAD) occurs when the normal bacteria of the bowel are altered allowing it to flourish and produce toxin. Symptoms ranges from mild to severe diarrhoea to, more unusually, severe inflammation of the bowel. People who have been treated with broad spectrum antibiotics (those that affect a wide range of bacteria), people with serious underlying illnesses and the elderly are at greatest risk.

NAME:…….. DATE OF BIRTH…….. NHS NO……..……..

Scorecard 1 **Critical risk factors associated with CDAD**	**Risk Factor Present**		**Notes**
	Yes	**No**	
Patient is aged over 65 years			
Patient has severe underlying disease (is immuno-suppressed)			
Patient on antibiotics (now or within the last 8 weeks)			

Total the answers 'yes' above and circle the figure in the decision box below

Total 'yes' from Scorecard 1 (please circle)	**Total 'yes' from Scorecard 1 (please circle)**			**Notes**
Total for Scorecard	0-1	2	3	
Level of Risk	Low	Medium	High	**Risk of CDAD**

Scorecard 2 Other Risk Factors	**YES**	**NO**
Individual was/will be on course of antibiotics for more than 5 days		
Individual is having/has had in past 8 weeks multiple antibiotics or multiple courses of antibiotics		
Individual has had repeated enemas		
Individual will have/recently had gastro-intestinal surgery or non-surgical gastro-intestinal procedure(s)		
Individual has/will have naso-gastric tube in situ		
Individual on anti-ulcer medication (proton pump inhibitors)		
Individual on/will be staying on intensive care unit		
Individual will/is likely to stay in hospital for over one month		
Individual has had recent contact with healthcare settings		
TOTAL (1 for each YES response above)		

Determining Level of Risk of having/developing CDAD

Select the level of risk determined from scorecard 1 and then total yes from scorecard 2 above and circle the corresponding figure below.

Scorecard 1 Level of Risk	**Total YES from Scorecard 2 other Risk Factors**				**Notes**
Low	0	1	2	3-9	
Medium	-	0	1	2-9	
High	-	-	0	1-9	
Identified Level of Risk	**Low**	**Medium**	**High**	**Very High**	

Determine whether Individual has Diarrhoea

Scorecard 3 Clinical Signs	Yes	No
Individual has diarrhoea defined by the passage of liquid or watery stools three or more time a day (ref Bristol Stool Chart type 6-7)		

Findings from Assessment of Individuals' Clinical Signs of CDAD

Scorecard 4 Clinical Signs	Yes	No
Diarrhoea has distinctive stool smell/ green appearance		
Patient has fever (pyrexia)		
Individual has loss of appetite		
Individual is nauseous		
Individual is asymptomatic		
Individual has abdominal tenderness		
Individual has a distended abdomen		
Individual is on other treatment which may explain diarrhoea		

Decision: Could the Individual have CDAD?

If the result overleaf is risk level medium, high or very high, PLUS the answer above is 'yes' to diarrhoea, then the individual should be treated as having suspected CDAD.

Regardless of the risk level overleaf, if the answer above is 'yes' to diarrhoea PLUS the individual has clinical signs suggestive of CDAD, then they should be treated as having suspected CDAD.

Regardless of the risk level in Scorecard 1 above or other results, if the answer is 'no' to diarrhoea, then the individual is unlikely to have CDAD.

Record result in decision box below and follow actions as appropriate.

Decision	Please Tick	Notes
Individual has suspected CDAD		
Individual is unlikely to have CDAD		

Action 1: if the patient is asymptomatic and unlikely to have CDAD, no precautions or treatment are necessary - reassure the patient. If there are clinical signs suggestive of pathology, refer for a medical assessment.

Action 2: if the individual has suspected diarrhoea and suspected CDAD, isolate them immediately, collect stool specimen and send to laboratory (request MC&S and C dif), and assess for complications and severity of CDAD. Commence treatment.

Action 3: if the individual is on other drugs that may explain the diarrhoea, these should be stopped where possible and the individual monitored for improvement. Note: a patient suspected of CDAD should still be isolated and treated whilst following this course of action.

Action 4: Antibiotics prescribing for CDAD should be considered for all possible cases with symptoms and risk factors prior to receiving sample results. Refer to PCT Antimicrobial Prescribing Guidance for more information.

Action 5: Document above actions within care plan/case notes.

Date of completion ……..…… **Name ……..……** **Signature……..……**

APPENDIX 2

MEDICINES THAT CAN PRODUCE DIARRHOEA

Diarrhoea is a common adverse drug reaction (ADR) with many medicines. Antimicrobials account for about 25% of drug-induced diarrhoea though most cases are benign (Lee, 2006). While diarrhoea can be associated with most medicines, the ones that are most commonly implicated include:

Acarbose

Antimicrobials

Biguanides

Bile Salts

Colchicine

Cytotoxics

Dipyridamole

Gold Preparations

Iron Preparations

Laxatives

Leflunomide

Magnesium Preparations, e.g. Antacids

Metoclopramide

Misoprostol

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), e.g. Aspirin, Ibuprofen

Olsalazine

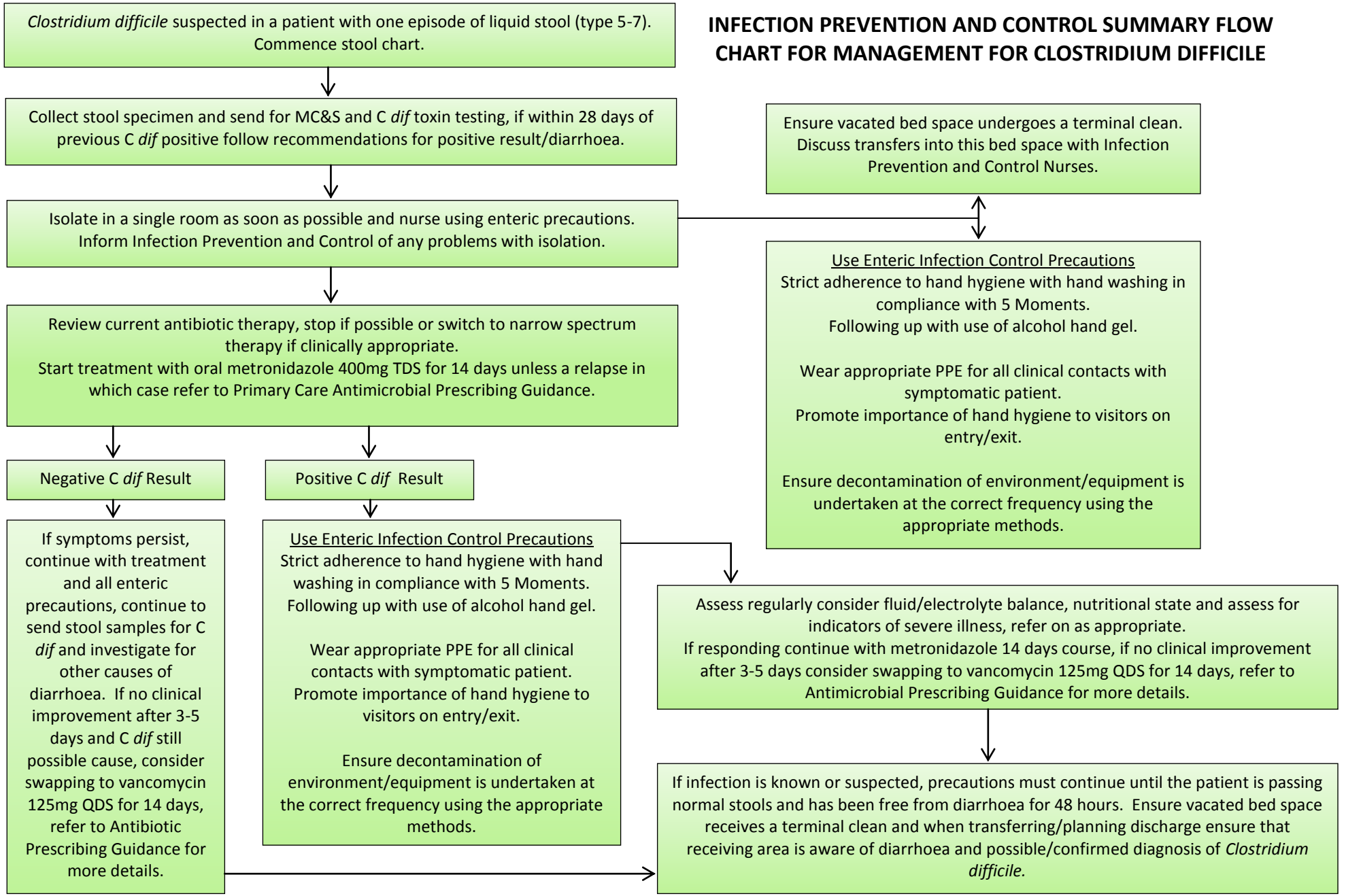
Orlistat

Proton Pump Inhibitors

Ticlopidine.

Alternative diagnoses for the diarrhoea are important; therefore, careful attention should be paid to the temporal relationship between the time that the medicine is first taken and when the diarrhoea first appears. Further information on adverse effects is available from local medicines information centres or by using the 'search by section' facility at http://emc.medicines.org.uk/

INFECTION PREVENTION AND CONTROL SUMMARY FLOW CHART FOR MANAGEMENT FOR CLOSTRIDIUM DIFFICILE



PATIENT STOOL RECORD CHART

Worcestershire NHS

Affix Patient Label or Fill in Details:

First Name……

Surname……

Hospital Number……

Date of Birth……

Consultant……

Trust……

Hospital……

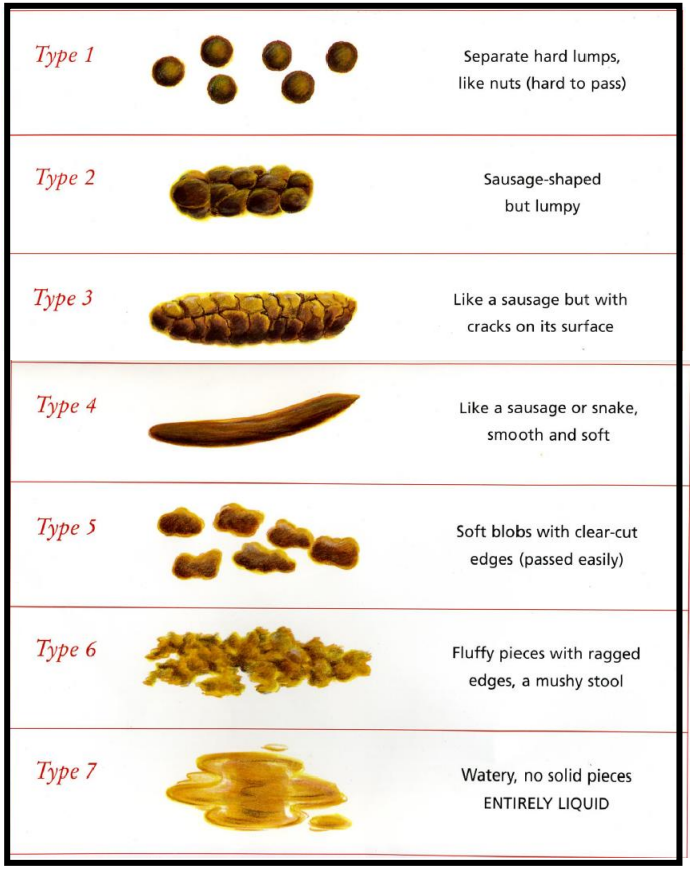
Ward……

Send stool sample following a single episode of diarrhoea (type 5/6/7).

DATE	TIME	CONSISTENCY/DESCRIPTION (Please refer to key and tick all that apply)									COLOUR	SPEC-IMEN SENT	SIGNED
		1	2	3	4	5	6	7	MUCUS	BLOOD			

DEFINITION OF DIARRHOEA Abnormally frequent watery stools (not formed or semi formed)

KEY



IF CLINICAL PICTURE INDICATIVE OF CLOSTRIDIUM DIFFICILE, <u>TREAT IMMEDIATELY</u> (whilst awaiting stool sample result).

IF A PREVIOUS CLOSTRIDIUM DIFFICILE POSITIVE AND SYMPTOMS RECOMMENCE (RELAPSE) REFER TO ANTIMICROBIAL PRESCRIBING GUIDANCE FOR TREATMENT.

DO NOT SEND STOOL SPECIMENS FOR CLEARANCE OF CLOSTRIDIUM DIFFICILE OR FOLLOWING ADMINISTRATION OF LAXATIVES OR ENEMAS.