



# **Protocol for the One month National Surveillance, Typing and Antimicrobial Susceptibility of *Clostridium difficile* infection in Ireland**

## **Summary**

- 1. To obtain enhanced surveillance, typing and antimicrobial sensitivity data on *C. difficile* infection in Ireland over a one month period**
- 2. To examine the feasibility and cost of an Irish *C. difficile* reference laboratory**

**Study coordinators:**

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- Dr. Lorraine Kyne, Consultant in Medicine for the Elderly, Mater Hospital, Dublin and University College Dublin.
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**Study contacts:**

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**2. Laboratory technical queries and address to send specimens:**

**Specimens to:**

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**Department of Microbiology,**  
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## Contents

Method Overview: .....	4
1. Sending Of Stool Samples .....	5
2. How to complete the lab form – SECTION A ONLY.....	6
3. Clinical Data: .....	7
4. How to complete the enhanced form: .....	8
Section 1 - Patient Details:.....	8
Section 2 - Case Type: .....	8
Section 3 - Isolate Details: .....	9
Section 4 - Onset of CDAD Infection:.....	9
Section 5 - Origin of CDAD: .....	9
Section 6 - Severity:.....	10
Section 7 - Antibiotic Exposure:.....	10
Appendix A – Lab form:.....	11
Appendix B – Clinical Data Form .....	12

### Method Overview:

- ❖ The data collection period will run from the 01<sup>st</sup> to the 31<sup>st</sup> of March 2009.
- ❖ Only one sample per patient will be accepted.
- ❖ *All* cases of *Clostridium difficile* infection (CDAD) diagnosed in Irish laboratories (both new and recurrent cases)
- ❖ Positive *Clostridium difficile* Associated Disease (CDAD) stool samples are to be sent to St. Vincents for typing accompanied with original copies of the appropriate form (appendix A).
- ❖ Samples may be batched and stored at +4 degrees for up to 3 days, or –20 degrees for up to a week and then submitted (please refer to section 1 for further details).
- ❖ Corresponding clinical information concerning the CDAD episode are to be recorded and sent to the HPSC.

## 1. SENDING OF STOOL SAMPLES

- Faeces samples from all patients in Ireland who have a diagnosis of CDAD and a positive toxin A/B assay for *C difficile* during the month of March 09 will be submitted via courier to St Vincent's University Hospital Microbiology laboratory between the hours of 9am and 5pm Monday to Friday.
- Only one sample per patient will be accepted.
- Samples sent to St Vincent's University Hospital Microbiology laboratory **MUST HAVE THE APPROPRIATE LAB FORM ATTACHED** (appendix A), with **section A** of the form completed. Please do not complete any of section B.
- Samples may be batched and stored at +4 degrees for up to 3 days, or –20 degrees for up to a week and then submitted. Samples may be transported at room temperature. If you wish to store samples for longer than a week, please contact us directly at the numbers below.
- **Laboratory queries and address to send specimens:**
  - × **Specimens to:**  
Ms Louise Scott,  
Department of Microbiology,  
St Vincent's University Hospital,  
Elm Park,  
Dublin 6.
  - × **Technical Advice:** Ms Louise Scott SVUH  
phone 01 2774450  
e mail [l.scott@st-vincent's.ie](mailto:l.scott@st-vincent's.ie)  
**Or** Dr Katie Solomon UCD  
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## 2. HOW TO COMPLETE THE LAB FORM – SECTION A ONLY

-----  
FOR EACH SAMPLE PLEASE USE AN ORIGINAL FROM AND DO NOT USE  
PHOTOCOPIES  
-----

- Hospital Code: This will be sent to you in advance of the study. This identifier is unique to your hospital and should be documented on all your forms.
- Date specimen: Date specimen taken.
- Patient Surname.
- Patient Forename.
- Date of birth.
- Patient ID: This identifier can be alpha numeric and is decided upon by the participants. Please select an identifier that is meaningful and can be used, if required, to check and validate details
- Sex
- Specimen number: Enter your laboratory ID of the sample sent for typing.
- Specimen date: Please enter date specimen was taken.

### **3. CLINICAL DATA:**

- For each specimen included in the study, corresponding clinical information on the patient should also be collected and submitted.
- Variables required are documented on the clinical form (appendix B). Participants should complete this form for each episode per patient and these records should be securely filed for reference.
- When completed the form should be transcribed into an excel database provided.
- This database should be regularly updated with available information and submitted weekly via e-mail to the HPSC for review.
- Excel files should ideally be forwarded on the Friday of each week or at beginning (Monday) of the following week to the following e-mail address:  
[mairead.skally@hse.ie](mailto:mairead.skally@hse.ie)

#### 4. HOW TO COMPLETE THE ENHANCED FORM:

##### ***Section 1 - Patient Details:***

- Hospital Code: This will be sent to you in advance of the study. This identifier is unique to your hospital and should be documented on all your forms. This should correspond with “Hospital Code” as completed on the lab form.
- Patient ID: This identifier can be alpha numeric and is decided upon by the participant. Please select an identifier that is meaningful and can be used, if required to check and validate details. This should correspond with “Patient ID” as completed on the lab form.
- Age: The age of the patient at time of sampling.
- Sex.
- Date of birth.
- Was the patients admitted to hospital?
- Date of admission: If patient was admitted to a hospital, please specify date.

##### ***Section 2 - Case Type:***

- Case type: This variable captures patients who have previously had a CDAD episode prior to the study period and who meet the recurrent case type definition (below). Patients that meet either definition below should be classified as such. Please classify the episode of CDAD according to following definitions:

New Case of CDAD: This is a patient to whom one or more of the following applies;

- × Diarrhoeal\* stools or toxic megacolon, with either a positive laboratory assay for *C. difficile* toxin A (TcdA) and / or toxin B (TcdB) in stools or a toxin-producing *C. difficile* organism detected in stool via culture or other means.
- × Pseudomembranous colitis (PMC) revealed by lower gastrointestinal endoscopy.
- × Colonic histopathology characteristic of *C. difficile* infection (with or without diarrhoea) on a specimen obtained during endoscopy, colectomy or autopsy.



\*Diarrhoea is defined as three or more loose/watery bowel movements (which are unusual or different for the patient) in a 24 hour period.

**Recurrent CDAD Cases:** These are episodes of CDAD which meet the following definition:

- × This is a patient with an episode of CDAD that occurs within 8 weeks following the onset of a previous episode provided that CDAD symptoms from the earlier episode resolved with or without therapy.

### ***Section 3 - Isolate Details:***

- **Specimen ID:** Enter your laboratory ID of the sample sent for typing.
- **Specimen date:** Please enter date specimen was taken.

### ***Section 4 - Onset of CDAD Infection:***

- **Onset of CDAD:** Please specify if onset of CDAD according to the following definition:

- × Healthcare onset » Symptoms start during a stay in a healthcare facility.
- × Community onset » Symptoms start in a community setting, outside healthcare facilities.

- **Location of onset:** Please answer this question only if the onset of CDAD is known to be in a healthcare facility and in which facility this occurred.
- **Date of onset:** Date of onset of symptoms.

### ***Section 5 - Origin of CDAD:***

- **Origin of CDAD:** Please specify the origin of the CDAD episode according to the following definition;

- × Healthcare-associated case
  - » This is a CDAD case with either:
    - Onset of symptoms at least 48 hours following admission to a healthcare facility (healthcare-onset, healthcare-associated).
    - or
    - With onset of symptoms in the community within 4 weeks following discharge from a healthcare facility (community-onset, healthcare-associated).
- × Community-associated case
  - » This is a CDAD case patient with either:
    - Onset of symptoms while outside a healthcare facility, and without discharge from a healthcare facility within the previous 12 weeks (community-onset, community-associated).

Or

(cont'd on next page)

Origin of CDAD Definition cont'd:

- With onset of symptoms within 48 hours following admission to a healthcare facility without residence in a healthcare facility within the previous 12 weeks (healthcare-onset, community-associated).
- × Unknown case
  - » This is a CDAD case patient who was discharged from a healthcare facility 4-12 weeks before the onset of symptoms.

- Origin within a healthcare facility: Please answer this question only if the known to be healthcare associated and in which facility it originated.




***Section 6 - Severity:***

- Severity: Please answer according to the following descriptions
  - × ICU admission – admission to an intensive care unit for treatment of CDAD or its complications (e.g. for shock requiring vasopressor therapy)
  - × Surgery (colectomy) for toxic megacolon, perforation or refractory colitis.

***Section 7 - Antibiotic Exposure:***





- Antibiotic exposure in eight weeks prior to onset:
  - × If the antibiotic exposure is known and the patient was exposed to antibiotics in the eight weeks prior to onset, please detail as accurately as possible those antibiotics.
  - × If the patient had no exposure in previous eight weeks then select no.
  - × If there is no information available on patient's antibiotic history please select "unknown"

## APPENDIX A – LAB FORM:

	<b>National <i>Clostridium difficile</i> Surveillance Project March 2009</b> <b>LABORATORY FORM</b>	 <small>Fidhreachan na Seirbhíse Sláinte Health Service Executive</small>	 4511042				
<b>Section A - To Be Completed in Primary Laboratory and Sent with Specimen</b>							
Hospital code <span style="border: 1px solid black; padding: 2px 5px;">H</span> <span style="border: 1px solid black; padding: 2px 5px;"></span> <span style="border: 1px solid black; padding: 2px 5px;"></span>							
<b>Patient Details:</b>							
Patient surname <span style="border: 1px solid black; display: inline-block; width: 100px; height: 1.2em; vertical-align: middle;"></span>							
Patient forename <span style="border: 1px solid black; display: inline-block; width: 100px; height: 1.2em; vertical-align: middle;"></span>		Date of Birth <span style="border: 1px solid black; padding: 0 5px;"> </span> / <span style="border: 1px solid black; padding: 0 5px;"> </span> / <span style="border: 1px solid black; padding: 0 5px;"> </span> <span style="border: 1px solid black; padding: 0 5px;"> </span>					
Patient ID <span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span>		Sex <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown					
<b>Specimen Details:</b>							
Specimen number <span style="border: 1px solid black; display: inline-block; width: 100px; height: 1.2em; vertical-align: middle;"></span>		Specimen date <span style="border: 1px solid black; padding: 0 5px;"> </span> / <span style="border: 1px solid black; padding: 0 5px;"> </span> / <span style="border: 1px solid black; padding: 0 5px;">2</span> <span style="border: 1px solid black; padding: 0 5px;">0</span> <span style="border: 1px solid black; padding: 0 5px;">0</span> <span style="border: 1px solid black; padding: 0 5px;">9</span>					
<b>Section B - For Completion by Reference Laboratory Only</b>							
Reference lab number <span style="border: 1px solid black; display: inline-block; width: 100px; height: 1.2em; vertical-align: middle;"></span>							
<b>Results:</b>							
Culture result C. difficile isolated? <input type="checkbox"/> Yes <input type="checkbox"/> No		Ribotype result <span style="border: 1px solid black; display: inline-block; width: 60px; height: 1.2em; vertical-align: middle;"></span>					
		Toxinotype <span style="border: 1px solid black; display: inline-block; width: 60px; height: 1.2em; vertical-align: middle;"></span>					
<b>Antibiotic Results:</b>							
	MIC	S	R		MIC	S	R
Vancomycin	<span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span>	<input type="checkbox"/>	<input type="checkbox"/>	Meropenem	<span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span>	<input type="checkbox"/>	<input type="checkbox"/>
Metronidazole	<span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span>	<input type="checkbox"/>	<input type="checkbox"/>	Cefotaxime	<span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span>	<input type="checkbox"/>	<input type="checkbox"/>
Moxifloxacin	<span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span>	<input type="checkbox"/>	<input type="checkbox"/>	Cefuroxime	<span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span>	<input type="checkbox"/>	<input type="checkbox"/>
Clindamycin	<span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span>	<input type="checkbox"/>	<input type="checkbox"/>	Rifampicin	<span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span>	<input type="checkbox"/>	<input type="checkbox"/>
Erythromycin	<span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span>	<input type="checkbox"/>	<input type="checkbox"/>	Ciprofloxacin	<span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span>	<input type="checkbox"/>	<input type="checkbox"/>
Piperacillin / Tazobactam	<span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span>	<input type="checkbox"/>	<input type="checkbox"/>	Levofloxacin	<span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span>	<input type="checkbox"/>	<input type="checkbox"/>
Amoxycillin - clavulanate	<span style="border: 1px solid black; display: inline-block; width: 80px; height: 1.2em; vertical-align: middle;"></span>	<input type="checkbox"/>	<input type="checkbox"/>				

Page 1 of 1

## APPENDIX B – CLINICAL DATA FORM

  6531		<b>National Clostridium difficile Surveillance Project March 2009 Clinical Details</b>	 <small>Freilínacannacht na Seirbhíse Stáite Health Service Executive</small>
<b>1. Patient Details:</b>			
Hospital Code: <div style="border: 1px solid black; padding: 2px;">H</div>	Patient ID: <div style="border: 1px solid black; padding: 2px;">  </div>	Age: <div style="border: 1px solid black; padding: 2px;">  </div>	Sex: M <input type="checkbox"/> F <input type="checkbox"/> Unk <input type="checkbox"/>
Date of birth: <div style="border: 1px solid black; padding: 2px;">  /  /  </div>	Was the patient admitted to hospital? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown →		If admitted please give date of admission: <div style="border: 1px solid black; padding: 2px;">  /  /  20  </div>
<b>2. Case Type:</b>			
<input type="checkbox"/> New <input type="checkbox"/> Recurrent <b>Please refer to page two for new and recurrent case definitions.</b>			
<b>3. Isolate Details:</b>			
Specimen ID: <div style="border: 1px solid black; padding: 2px;">  </div>		Specimen date: <div style="border: 1px solid black; padding: 2px;">  /  /  2009  </div>	
<b>4. Onset of C difficile Infection (CDAD):</b>			
<u>Healthcare onset:</u> Symptoms start during a stay in a healthcare facility. <input type="checkbox"/>		<u>Community onset:</u> Symptoms start in a community setting, outside healthcare facilities. <input type="checkbox"/>	
Date of onset: <div style="border: 1px solid black; padding: 2px;">  /  /  2009  </div>			
If patients onset of CDAD was within a health care facility, please specify in which facility this occurred: <input type="checkbox"/> This hospital <input type="checkbox"/> Other hospital <input type="checkbox"/> Nursing home <input type="checkbox"/> Other			
<b>5. Origin of C difficile Infection (CDAD):</b>			
<b>Health-care associated case:</b> This is a CDAD case with either *Onset of symptoms at least 48 hours following admission to a healthcare facility (healthcare - onset, healthcare-associated) <input type="checkbox"/> or *Onset of symptoms in the community within 4 weeks following discharge from a healthcare facility (community onset, healthcare-associated)			
<b>Community-associated case:</b> This is a CDAD case with either *Onset of symptoms while outside a healthcare facility, and without discharge from a healthcare facility within the previous 12 weeks (community-onset, community-associated) <input type="checkbox"/> or *Onset of symptoms within 48 hours following admission to a healthcare facility without residence in a healthcare facility within the previous 12 weeks (healthcare-onset, community-associated)			
<b>Unknown case:</b> This is a CDAD case who was discharged from a healthcare facility 4-12 weeks before the onset of symptoms <input type="checkbox"/> If patients origin of CDAD was within a health care facility, please specify in which facility this occurred: <input type="checkbox"/> This hospital <input type="checkbox"/> Other hospital <input type="checkbox"/> Nursing home <input type="checkbox"/> Other			
<b>6. Severity: (if applicable)</b>			
ICU Admission for CDAD treatment or its complications		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
Surgery (colectomy) for toxic megacolon, perforation or refractory colitis.		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
<b>7. Antibiotic Exposure:</b>			
Exposure to antibiotics in eight weeks prior to onset? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
<input type="checkbox"/> Penicillin		<input type="checkbox"/> Carbapenem (e.g. Meropenem)	
<input type="checkbox"/> Quinolone		<input type="checkbox"/> Macrolide (e.g. Clarithromycin, Erythromycin)	
<input type="checkbox"/> Cephalosporin		<input type="checkbox"/> Other 1 <div style="border: 1px solid black; padding: 2px;">  </div>	
<input type="checkbox"/> Clindamycin		<input type="checkbox"/> Other 2 <div style="border: 1px solid black; padding: 2px;">  </div>	



**Definitions of Clostridium difficile Infection - CDAD Type**

***Clostridium difficile* Infection - associated disease (CDAD) case:**

This is a patient to whom one or more of the following criteria applies:

- Diarrhoeal\* stools or toxic megacolon, with either a positive laboratory assay for *C. difficile* toxin A (TcdA) and/or toxin B (TcdB) in stools or a toxin-producing *C. difficile* organism detected in stool via culture or other means.
- Pseudomembranous colitis (PMC) revealed by lower gastrointestinal endoscopy.
- Colonic histopathology characteristic of *C. difficile* infection (with or without diarrhoea) on a specimen obtained during endoscopy, colectomy or autopsy.

***C. difficile* Infection - recurrent CDAD case:**

This is a patient with an episode of CDAD that occurs within 8 weeks following the onset of a previous episode provided that CDAD symptoms from the earlier episode resolved with or without therapy

**\*Diarrhoea is defined as three or more loose/watery bowel movements (which are unusual or different for the patient) in a 24 hour period**