

Attachment C: Adult case and control screening forms

Community-associated *Clostridium difficile* Infection (CDI) Risk Factor Study Call Log

PATIENT NAME: _____

STUDY ID: _____

PHONE NUMBER: _____

STATUS OF PHONE NUMBER: _____

PHONE TYPE: Home Office Cell

STATUS CODES: 1=correct, 0=not correct, 9=couldn't determine

ATTEMPT NUMBER	DATE	TIME-OF-DAY CODE	OUTCOME CODE	COMMENTS
1				
2				
3				
4				
5				
6				
7				
8				

TIME-OF-DAY CODES

- 1 = Weekday, 10AM – 11:59AM
- 2 = Weekday, Noon – 4:59PM
- 3 = Weekday, 5PM - 8PM
- 4 = Saturday only, 10AM-11:59AM
- 5 = Weekend, Noon – 4:59PM
- 6 = Weekend, 5PM – 8PM

OUTCOME CODES

- 1 = Enrolled
- 2 = Not home, left message
- 3 = Not home, no message left
- 4 = Refused to participate
- 5 = Unable to answer questions
- 6 = Unable to enroll (after 8 attempts)
- 7 = Need to call back
- 8 = Other, specify in **NOTES**

Public reporting burden of this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-1013).

€ CASE € CONTROL

Patient ID: _____

State ID: _____

[GUIDELINES: A MINIMUM OF 8 ATTEMPTS ON AT LEAST 6 DIFFERENT DATES USING A VALID PHONE NUMBER SHOULD BE MADE BEFORE GIVING UP ON A POTENTIAL CASE OR CONTROL. AT LEAST ONE ATTEMPT SHOULD BE MADE BETWEEN 5-8PM; AND ONE WEEKEND DAY]

Attachment C: Adult case and control screening forms

CASE SUBJECT

INITIAL CALL INTRODUCTION

1. [To the person who answers the phone, IF ADULT, otherwise ask to speak to an adult]: "Hello, my name is _____. I am calling from the [*state health department*]. May I please speak to [*Potential enrollee*]?"
- ___ Yes: person who answered is potential enrollee; [go to case patient call script]
 - ___ Yes: coming to the phone; [go to case patient call script]
 - ___ No: person is unavailable – *record call back time on phone log if given*
 - ___ No: person is deceased: **-STOP- CASE INELGIBLE SAY:**
"I would like to offer my condolences and apologize for any inconvenience that this call may have caused to you. Thank you for your time"
 - ___ No: person is incapacitated; **-STOP- CASE INELGIBLE SAY:**
"Thank you for your time. Have a nice day"
 - ___ Does not speak English; [record language in comment section of phone log.]
 - IF SPANISH SPEAKING: "We will try to call back with someone who speaks Spanish, thank you."
 - IF OTHER LANGUAGE: "Thank you for your time. Have a nice day" [If case speaks a language other than English or Spanish, he/she is not eligible. Record on tracking log as "No English or Spanish." =stop=]

CASE PARTICIPANTS Call Script:

2. "I am calling on behalf of the [*State Health Dept.*] and the Centers for Disease Control and Prevention (CDC) because you may be eligible to participate in a public health study. I will need to ask you 3 questions. By answering these 3 questions, I will determine if you are eligible to participate in the study. Eligible means that you meet criteria to be in the study. If you are eligible and agree to participate we will send you a \$20 gift card as a token of appreciation. This study is being performed by CDC and your State Health Department. We are calling you because you had an infection with a germ called *Clostridium difficile*; sometimes it is also called *C. diff*. The <*state health department*> routinely tracks how often people in your area get sick from *C.difficile* infections and is notified whenever a person develops this infection. Participation is voluntary and involves completing a 30 minute interview over the phone. It will include questions about your illness, healthcare visits, medical history, and recent medications. Please know that your answers will be kept secure and you may choose not to answer any question. May I tell you more about the study?"
- ___ Yes [go to CASE SCREENING]
 - ___ No [go to Q3]

3. "Your participation in this study is very important. We are trying to better understand why people develop *Clostridium difficile* infection. May I schedule a time to talk that would be better for you?"
- ___ Yes [Record day/time on Phone Log].
 - "Thank you very much for your time, I will call you back later."[=STOP=and call the person back at the requested day/time.]
 - ___ No
 - "Sorry to have disturbed you. Good-bye." [=STOP=and record in the interview tracking log as "Refused to participate."]

€ CASE € CONTROL

Patient ID: _____

State ID: _____

*******BEFORE YOU PROCEED, HAVE A CALENDAR IN FRONT OF YOU*******

CASE SUBJECT SCREENING QUESTIONS

Before we continue I will ask you some questions to make sure you are eligible to participate. These questions are about your illness, healthcare contacts, household contacts, other exposures and medical history. It may be difficult to remember some of these things. I would like your best guess for each question. Because I will be asking about specific dates around the time your illness began, it may be helpful for you to have a calendar or datebook in front of you. I can hold while you get these things. The dates we are interested in are between [12 weeks *before* positive specimen collection Date ____/____/____] to [positive specimen collection date ____/____/____]. When Participant returns say “I would like to begin with a few questions to be sure you are eligible to participate in the study”

1. Have you ever been diagnosed with *C. difficile* **before** the collection of your stool specimen on [specimen collection date ____/____/____]?

Yes.....1

(If Yes –STOP Interview and say: “We are only interviewing people who have not had a previous *C. difficle* diagnosis. Thank you for your time”)

No.....2

Don't know/Not sure.....7

Refused.....9

2. Did you stay overnight in a hospital, long term care facility, or nursing home in the 12 weeks **before** [specimen collection date ____/____/____]?

Yes.....1

(If Yes –STOP Interview and say “We are only interviewing people who did not stay in a hospital during that time.” Thank you for your time.

No.....2 (Go to Q.3)

Don't know/Not sure.....7

Refused.....9

(If Don't know/ Refuse- STOP Interview and say: “We are only interviewing people who did not stay in a hospital during that time”. Thank you for your time”)

3. Did you have diarrhea at the time your stool specimen was collected on [specimen collection date ____/____/____]? We define diarrhea as 3 or more loose stools in a 24 hour period.

Yes.....1 **(Go to Consent)**

No.....2

Don't know/Not sure.....7

Refused.....9

(If No, Don't know, Refuse- STOP Interview and say “We are only interviewing people who had diarrhea with their *C. difficile* diagnosis. Thank you for your time.)

CASE CONSENT SCRIPT: GO TO CASE CONSENT AND SAY “Now that I know you are eligible to participate, I would like to share some additional details about the study and obtain your verbal permission for participation. Feel free to stop me and ask questions at

Patient ID: _____

State ID: _____

any time.” [AFTER CONSENT COMPLETE CONTINUE WITH INTERVIEW SECTION 1]

CONTROL SUBJECTS

INITIAL CALL INTRODUCTION

1. [To the person who answers the phone, IF ADULT, otherwise ask to speak to an adult]: “Hello, my name is _____. I am calling from the [*State health department*]. I am calling about a public health study on an infection called *Clostridium difficile*. For this study we are looking for people who are [insert sex / age group: _____]. Is there anyone in your household in this group who I can speak with?”

___ Yes: person who answered is a potential enrollee; [go to control patient call script]

___ Yes: coming to the phone; [go to control patient call script]

___ No: person is unavailable – *record call back time on phone log if given*

___ No: person is deceased: **-STOP- CONTROL INELGIBLE SAY:**

“I would like to offer my condolences and apologize for any inconvenience that this call may have caused to you. Thank you for your time.”

___ No: person is incapacitated; **-STOP- CONTROL INELGIBLE SAY:**

“Thank you for your time”

___ Does not speak English; [record language in comment section of phone log.]

- IF SPANISH SPEAKING: “We will try to call back with someone who speaks Spanish, thank you.”

- IF OTHER LANGUAGE: “Thank you for your time. Have a nice day” [If control speaks a language other than English or Spanish, he/she is not eligible. Record on tracking log as “No English or Spanish.” =stop=]

Control Participants Call Script

2. “I am calling on behalf of the [*State Health Dept.*] and the Centers for Disease Control and Prevention (CDC) because you may be eligible to participate in a public health study. . I will need to ask you 5 questions. By answering these 5 questions, I will determine if you are eligible to participate in the study. Eligible means that you meet criteria to be in the study If you are eligible and agree to participate we will send you a \$20 gift card as a token of appreciation. This study looks at how people living in the community get an illness caused by a germ called *Clostridium difficile* (also called *C. diff*). As part of our study, we need to talk to people **who did not** become ill with *C.diff*. We also need to be sure that the person lived in the same area as someone who did get sick and is around the same age as the ill person. Participation is voluntary and involves completing a 30 minute interview over the phone. It will include questions about your healthcare visits, medical history, and recent medications. Please know that your answers will be kept secure and you may choose not to answer any question. May I tell you more about the study?”

___ Yes; [go to CONTROL SCREENING]

___ No; [go to Q 3].

3. “Your participation in this study is very important. We are trying to better understand why people develop *Clostridium difficile* infection. May I schedule a time to talk that would be better for you?”

___ Yes [“=STOP=and call the person back at the requested day/time. Record day/time on Phone Log].

- “Thank you very much for your time.”[=STOP= and call back at requested day and time.]

___ No

- “Sorry to have disturbed you. Good-bye.” [=STOP= and record on interview tracking log as “Refused to participate.”]

€ CASE € CONTROL

Patient ID: _____

State ID: _____

€ CASE € CONTROL

Patient ID: _____

State ID: _____

*******BEFORE YOU PROCEED, HAVE A CALENDAR IN FRONT OF YOU*******

Control Subject Screening Questions

Before I continue, I need to ask you a few questions to be sure you are eligible to participate. These questions are about your healthcare contacts, household contacts, other exposures and medical history. It may be difficult to remember some of these things. I would like your best guess for each question. Because I will be asking about specific dates, it may be helpful for you to have a calendar or datebook in front of you. The dates we are interested in are between [12 weeks *before Matched CASE participant's* Reference Date ____/____/____] to [matched case *participant's* Reference Date ____/____/____]. I can hold while you get these things. Do you need a minute to go get any of these items?

When Participant returns say "I would like to begin with a few questions to be sure you are eligible to participate in the study"

1. Were you between the ages of [matched case patient age group _____] on [REFERENCE Date ____/____/____]?

- Yes.....1 (Go to Q.2)
- No.....2
- Don't know/Not sure.....7
- Refused.....9

(If No, Don't know / Refuse STOP Interview and say: "We are only interviewing patients in that age group. Thank you for your time".)

2. Did you live in [EIP catchment area counties] on [REFERENCE Date ____/____/____]?

- Yes.....1 (Go to Q.3)
- No.....2
- Don't know/Not sure.....7
- Refused.....9

(If No, Don't know / Refuse STOP Interview and say: "We are only interviewing patients who lived in that area. Thank you for your time".)

3. Did you stay overnight in a hospital, long term care facility, or nursing home in the 12 weeks *before* [REFERENCE Date ____/____/____]?

- Yes.....1
- No.....2 (Go to Q.4)
- Don't know/Not sure.....7
- Refused.....9

(If Yes -STOP Interview and say: "We are only interviewing people who did not stay in a hospital during that time." Thank you for your time.)

(If Don't know / Refuse STOP Interview and say "We are only interviewing people who did not stay in a hospital during that time. Thank you for your time")

4. Had you ever been diagnosed with *C. difficile* in the past?

- Yes.....1
- No.....2 (Go to Q.5)
- Don't know/Not sure.....7
- Refused.....9

(If Yes -STOP Interview and say: "We are only interviewing people who have not had a previous C. difficle diagnosis. Thank you for your time.)

(If Don't know / Refuse STOP Interview and say "We are only interviewing people who did not have C. difficile in the past. Thank you for your time")

€ CASE € CONTROL

Patient ID: _____

State ID: _____

5. Did you have diarrhea between [12 weeks before REFERENCE date ____/____/____] and [REFERENCE date ____/____/____]? We define diarrhea as 3 or more loose stools in a 24 hour period.

Yes.....1

(IF YES- STOP Interview and say “We are only interviewing people who did not have diarrhea. Thank you for your time.)

No.....2 ***(GO TO CONTROL CONSENT SCRIPT BELOW)***

Don't know/Not sure.....7

Refused.....9

(If Don't know / Refuse STOP Interview and say “We are only interviewing people who did not have diarrhea. Thank you for your time”)

CONTROL CONSENT SCRIPT: GO TO CONTROL CONSENT AND SAY “Now that I know you are eligible to participate, I would like to share some additional details about the study and obtain your verbal permission for participation. Feel free to stop me and ask questions at any time.” [AFTER CONSENT COMPLETE CONTINUE WITH INTERVIEW SECTION 1]