

Attachment D: Pediatric 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: _____

REFERENCE Date ____ / ____ / ____

[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 D: Pediatric 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 [parent/ guardian of potential enrollee]?"

___ Yes: person who answered is parent or guardian of 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*

___ 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 your child may be eligible to participate in a public health study. This study is being performed by CDC and your State Health Department. I will need to ask you 4 questions. By answering these 4 questions, I will determine if your child is eligible to participate in the study. Eligible means that you meet criteria to be in the study. If your child is eligible and you agree to participate we will send you a \$20 gift card as a token of appreciation. We are calling you because your child 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 child's 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 Subject 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: _____

REFERENCE Date ____/____/____

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

CASE SUBJECT SCREENING QUESTIONS

Before we continue I will ask you some questions to make sure your child is eligible to participate. These questions are about your child’s 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 child’s 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 ____/____/____]. 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. Today, how is your child's health status?:

- Well.....1
- Ill or sick.....2
- Deceased.....5

If deceased say : “I would like to offer my condolences and apologize for any inconvenience that this call may have caused to you and we do not need to continue with the interview. Thank you for your time.”

- Don't know/Not sure.....7
- Refused.....9

If Don't know / refused say “We are only interviewing parents if the child's health status is known. Thank you for your time”

2. Has your child been diagnosed with *C. difficile* **before** the collection of your child's 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

3. Did your child stay overnight in a hospital, long term care facility, or nursing home in the 12 weeks **before** [Reference 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
- Don't know/Not sure.....7
- Refused.....9

4. Did your child have diarrhea at the time your child's 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

€ CASE € CONTROL

Patient ID: _____

State ID: _____

REFERENCE Date ____ / ____ / ____

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.)

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 any time." [AFTER CONSENT COMPLETE CONTINUE WITH INTERVIEW]

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 dept.]. I am calling about a public health study on an infection called *Clostridium difficile*. For this study we are looking for children who are [insert sex / age group]. Is there a parent or guardian of a child in this group who I can speak with?"
 - ___ Yes: person who answered is parent or guardian of 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
 - ___ 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=]

€ CASE € CONTROL

Patient ID: _____

State ID: _____

REFERENCE Date ____ / ____ / ____

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 your child may be eligible to participate in a public health study. This study is being performed by CDC and your State Health Department. I will need to ask you 6 questions. By answering these 6 questions, I will determine if your child is eligible to participate in the study. Eligible means that you meet criteria to be in the study. If your child is eligible and you 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 the parents of children who **did not** become ill with *C.diff.*. The study is voluntary and involves completing a 30 minute interview over the phone. It will include questions about your child's 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 QUESTIONS]

___ 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; [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."]

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

Control Subject Screening Questions

Before we continue, I will ask you some questions to make sure your child is eligible to participate. These questions are about your child's 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. Today, how is your child's health status?:

Well.....1

Ill or sick.....2

Deceased.....5

If deceased say : "I would like to offer my condolences and apologize for any inconvenience that this call may have caused to you and we do not need to continue with the interview. Thank you for your time."

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

Refused.....9

If Don't know / refused say "We are only interviewing parents if the child's health status is known. Thank you for your time"

€ CASE € CONTROL

Patient ID: _____

State ID: _____

REFERENCE Date ____/____/____

2. Was your child between the ages of [matched case patient age group _____] 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 in that age group. Thank you for your time".)

3. Did your child live in [EIP catchment area counties] on [REFERENCE Date ____/____/____]?

- Yes.....1 (Go to Q.4)
- 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".)

4. Did your child 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.5)
- 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")

5. Has your child ever been diagnosed with *C. difficile* in the past?

- Yes.....1
- No.....2 (Go to Q. 6)
- 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. difficile 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")

6. Did your child have diarrhea within the 12-weeks before [REFERENCE date ____/____/____]? We define diarrhea as 3 or more loose stools in a 24 hour period.

- Yes.....1
- No.....2 (GO TO CONSENT SCRIPT BELOW)
- Don't know/Not sure.....7
- Refused.....9

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

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

€ CASE € CONTROL

Patient ID: _____

State ID: _____

REFERENCE Date ____ / ____ / ____

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]