

We are requesting a non-substantive change to the study entitled “Risk Factors for Community-Associated *Clostridium difficile* Infection through the Emerging Infections Program” OMB control number 0920-1013. The proposed changes do not impact methodology of the study or burden. The proposed changes are intended to: improve clarity of a confusing question or script, to clarify the time period in question given we ask participants about various time points in relation to their exposures / disease, to improve the flow of the interview, or to remove questions that were deemed unnecessary / offensive after performing interviews.

Form	Current Question/Item	Requested Change
<u>Pediatric Case and Control Screening Form</u>	Case & Control subject initial call introduction Script Text (question 2)	Have rearranged text for succinctness and clarity in both case and control scripts. Interviewees needed clarification on who would receive a token of appreciation.
Pediatric Case and Control Screening Form	Case & Control subject screening questions script (prior to question 1)	We have added script to indicate that these are the questions that will be asked to determine eligibility for the study.
Pediatric Case and Control Screening Form	Case and Control Screening question 1	We have re-worded the question to be more sensitive as it is asking about deceased children. We will allow the parent to answer how the child is instead of reading the choices which include ‘dead’
Pediatric Case and Control Screening Form	Case Screening question 5	We have moved this question to the interview for data entry purposes. Only those who are eligible will need to answer this question. It is now in section 2, Q6 of the interview.
<u>Pediatric Case and Control Interview Form</u>	Section 1, Q 3	We have clarified that only controls will have this date information available at this point. Cases are asked this later in the interview.
Pediatric Case and Control Interview Form	Section 2, Q 6-9	Have added clarification about the time frame we are inquiring about

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Pediatric Case and Control Interview Form	Section 3, Q 10A, 11A	We have changed the description of Ambulatory / outpatient procedure center because people did not understand 'ambulatory'.
Pediatric Case and Control Interview Form	Section 4, Q 12A	We have clarified the timeframe of interest. We have also fixed a typo in the age ranges so that they match that in the adult interview and appropriately separate pediatric and adult age ranges (18 years and older)
Pediatric Case and Control Interview Form	Section 4, Q 13, 14	We have clarified the timeframe.
Pediatric Case and Control Interview Form	Section 4, Q 14A	The previous provided table was confusing and difficult to fill out if multiple people were in daycare. We have simplified the question.
Pediatric Case and Control Interview Form	Section 4, Q 17A	We removed this question as children 1-5 years would be unlikely to help with toileting.
Pediatric Case and Control Interview Form	Section 4, Q 18	We have defined volunteering as many people were unclear about what types of activities may be included.
Pediatric Case and Control Interview Form	Section 5, Q 20	We have clarified the timeframe as people were trying to remember what they ate in the past
Pediatric Case and Control Interview Form	Section 5, Q 22, 22A	We have clarified the timeframe
Pediatric Case and Control Interview Form	Section 6, Q 24	We have included IV as a description
Pediatric Case and Control Interview Form	Section 6, Q 26	We included eye ointment as well as eye drops as both can be antibiotics
Pediatric Case and Control Interview Form	Section 6, Q 28	We have removed the qualifying language about putting people at risk for C. diff as we have not done

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		this for other medications asked about, we do not know this to be true, and it caused concern in people who were on these medications
<u>Adult Case and Control Screening Forms</u>	Case & Control subject initial call introduction Script Text (question 2)	Have rearranged text for succinctness and clarity in both case and control scripts. Interviewees needed clarification on who would receive a token of appreciation.
Adult Case and Control Screening Forms	Case & Control subject screening questions script (prior to question 1)	We have added script to indicate that these are the questions that will be asked to determine eligibility for the study.
Adult Case and Control Screening Forms	Case Subject Screening question 3A	We have moved this question to the interview for data entry purposes. Only those who are eligible will need to answer this question. It is now in section 2, Q6 of the interview.
Adult Case and Control Screening Forms	Control Subject Screening question 4	We have clarified the timeframe as it was a mistake as written and different from the pediatric form. There was a potential to enroll a control as a case if using the 12 week cut off.
<u>Adult Case and Control Interview</u>	Section 1, Q 3	We have clarified that only controls will have this date information available at this point. Cases are asked this later in the interview.
Adult Case and Control Interview	Section 2, Q 6-9	Have added clarification about the time frame we are inquiring about
Adult Case and Control Interview	Section 3, Q 10A, 11A	We have changed the description of Ambulatory / outpatient procedure center because people did not

Form	Current Question/Item	Requested Change
		understand 'ambulatory'.
Adult Case and Control Interview	Section 4, Q 12A, 13, 14	We have clarified the timeframe of interest.
Adult Case and Control Interview	Section 4, Q 14A	The previous provided table was confusing and difficult to fill out if multiple people were in daycare. We have simplified the question.
Adult Case and Control Interview	Section 4, Q 18, 19	We have defined volunteering as many people were unclear about what types of activities may be included.
Adult Case and Control Interview	Section 4, Q 20 (deleted)	We deleted Q20 which was referring to the interviewee being in adult daycare. Several subjects were offended by this question and given we are not interviewing proxies, it is unlikely that an enrolled subject would require daycare.
Adult Case and Control Interview	Section 5, Q 21	We have clarified the timeframe as people were trying to remember what they ate in the past
Adult Case and Control Interview	Section 5, Q 23, 23A	We have clarified the timeframe
Adult Case and Control Interview	Section 6, Q 24	We have included IV as a description
Adult Case and Control Interview	Section 6, Q 25	We included eye ointment as well as eye drops as both can be antibiotics
Adult Case and Control Interview	Section 6, Q 27	We have removed the qualifying language about putting people at risk for C. diff as we have not done this for other medications asked about, we do not know this to be true, and it caused concern in people who were on these medications