

Description of Changes

HAIC:

The changes made to the all forms under this non-substantive request will aid in improving surveillance efficiency and data quality to clarify the burden of disease and possible risk factors for disease. This information can be used to inform strategies for preventing disease and negative outcomes. Specifically, changes were made for clarification purposes, to assist data collectors in capturing data in a standardized fashion to improve accuracy.

1) **MuGSI Case Report Form for Carbapenem-resistant Enterobacteriaceae (CRE) and *Acinetobacter baumannii* (CRAB)** (Attachment 3)

Justification for Changes:

The proposed changes will allow the Emerging Infection Program (EIP) sites to report ESBL production and other beta-lactamase results from the local clinical laboratory or state public health laboratory for CRE and CRAB isolates. These data will be helpful for further describing the resistance mechanisms for CRE and CRAB cases.

Estimated Change in Burden:

The requested changes will have no impact on the burden of data collection and are anticipated to have no impact on the time expected to complete the case report form because these data are already included in the reports received from some local laboratories. These data are only available for a subset of CRE and CRAB cases because all laboratories participating in MuGSI CRE and CRAB surveillance do not test for ESBL production or other beta-lactamase genes.

Description of Changes

For the 2021 Carbapenem Resistant Enterobacteriaceae (CRE)/Carbapenem Resistant *A. baumannii* (CRAB) Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF), we are proposing the following changes: 1) we updated the text for Q26a; 2) we updated the labels for the different categories of test methods for Q26b; 3) we added a specify field for the OXA gene for Q26c; 4) we updated the label for the “Other” field to indicate it is referencing other carbapenemase genes for Q26c; 5) we added Q27a-Q27c to collect laboratory testing results for ESBL production and other beta-lactamase genes; 6) we updated the question numbers on the fourth page of the form as appropriate.

Detailed Description of Changes

A. Changes to the original 2021 Carbapenem Resistant Enterobacteriaceae (CRE)/ Carbapenem Resistant *A. baumannii* (CRAB) Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form include:

- a. Question 26a: Was the incident specimen tested for carbapenemase?
 - i. Updated the text for the question to clarify “carbapenemase genes”
- b. Question 26b: If yes, what testing method was used (check all that apply)?
 - i. Updated the label for the molecular test methods and non-molecular test methods
- c. Question 26c: If tested, what was the testing result?

- i. Removed the checkbox for “OXA-48” and the checkboxes for the corresponding results
 - ii. Added “specify” for the “OXA” checkbox
 - iii. Updated the label for the “Other” checkbox to “Other carbapenemase gene (specify)”
- d. Question 27a: Was the incident specimen tested for ESBL production or other beta-lactamase genes?
 - i. This is a new question added to the case report form.
- e. Question 27b: If tested, what testing method was used? (Check all that apply):
 - i. This is a new question added to the case report form.
- f. Question 27c: If tested, what was the result?
 - i. This is a new question added to the case report form.
- g. Question 28: Susceptibility results
 - i. Updated the question number.
- h. Question 29a: Was the case first identified through an audit?
 - i. Updated the question number and text.
- i. Question 29b: CRF status
 - i. Updated the question number
- j. Question 29c: SO initials
 - i. Updated the question number
- k. Question 29d: Date of abstraction
 - i. Updated the question number
- l. Question 29e: Comments
 - i. Updated the question number

2) Multi-site Gram-Negative Surveillance Initiative (MuGSI)- Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (ESBL) (*Attachment 4*)

Justification for Changes:

The proposed changes will allow the Emerging Infection Program (EIP) sites to provide clarification on whether laboratory testing for ESBL production or beta-lactamase genes was performed (Q26b) and report the results for other beta-lactamase genes from molecular testing performed at the local clinical laboratory or state public health laboratory for ESBL isolates (gene variant (specify) for Q26c). These data will be helpful for further describing the resistance mechanisms for ESBL cases.

Estimated Change in Burden:

The requested changes will have no impact on the burden of data collection and are anticipated to have no impact on the time expected to complete the case report form because these data are already included in the reports received from the local laboratories. These data are only available for a subset of ESBL cases because all laboratories participating in MuGSI ESBL surveillance do not test for ESBL production or other beta-lactamase genes.

Description of Changes

For the 2021 Extended-Spectrum Beta-Lactamase (ESBL)-Producing Enterobacteriaceae Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF), we are proposing the following changes: 1) we added Q26b (Was the incident specimen tested for ESBL production or other beta-lactamase genes?) and removed the related responses (None and Unknown) from the former Q26b (What screening/confirmatory method was used for ESBL identification? (Check all that apply)); 2) we updated the text for Q26c and added “Gene variant (specify)” as a response when a molecular test was performed; and 3) we updated the text for Q26d.

Detailed Description of Changes

A. Changes to the original 2021 Extended-Spectrum Beta-Lactamase (ESBL)-Producing Enterobacteriaceae Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form include:

- a. Question 26b: Was the incident specimen tested for ESBL production or other beta-lactamase genes?
 - i. This is a new question added to the case report form.
- b. Question 26c: If tested, what testing method was used? (Check all that apply)
 - i. Updated the text for the question
 - ii. Removed “None” and “Unknown” as a response which is a relevant response for Q26b
 - iii. Added “Gene variant (specify)” as a response when a molecular test was performed
- c. Question 27c: If tested, what was the result?
 - i. Updated the text for the question.

3) **Annual Survey of Laboratory Testing Practices for *C. difficile* Infections** (*Attachment 5*)

Justification and Description of Changes

We are requesting to add five new questions to the Annual Survey of Laboratory Testing Practices for *C. difficile* Infection. Two new questions are intended to capture specific details of an increasingly common algorithm-based *C. difficile* testing, and an additional three questions will capture details of laboratory shortages and changes in testing practices due to the COVID-19 pandemic. We modified the response options for two existing questions to clarify them, and added a commonly specified “other” response option to another question. We also changed the wording of twenty questions to clarify that the survey is only capturing data on lab practices in 2020. Three questions have a new question number but are otherwise unchanged. In total, the requested changes will add 4 minutes to the burden of data collection for each response.

Detailed Descriptions of Changes

- Was this a new laboratory in 2020?
 - o Clarified time period of question
- Did this lab participate in surveillance in 2020?

- o Clarified time period of question
- How often did you receive line lists from this lab in 2020?
 - o Clarified time period of question
 - o Added “Whenever there is a positive case” as a response option to capture a commonly reported “other” response
- How did you receive line lists from this lab in 2020?
 - o Clarified time period of question
- Did you receive specimens from this lab in 2020?
 - o Clarified time period of question
- Types of facilities in your catchment area served by this lab in 2020 (select all that apply):
 - o Clarified time period of question
- 1. Did your laboratory ever send specimens off-site for *Clostridioides difficile* testing in 2020?
 - o Clarified time period of question
- 2. What type and order of testing was routinely used by your laboratory in standard testing for *C. difficile* on December 31, 2020?
 - o Clarified time period of question
- 2a. Which specimens were used during your 2nd line of testing?
 - o Clarified time period of question
- 2b. Which specimens were used during your 3rd line of testing?
 - o Clarified time period of question
- 2c. Did your laboratory perform any onsite testing for *C. difficile* outside of your normal testing algorithm in 2020?
 - o Clarified time period of question
- 3a. Which EIA test kit was used by your laboratory in 2020?
 - o Clarified time period of question
- 3b. Which Nucleic Acid Amplification test was used by your laboratory in 2020?
 - o Clarified time period of question
- 4a. If your laboratory used a multiplexed molecular diagnostic (e.g., Biofire Filmarray GI Panel, Luminex xTAG GPP) to test for several GI pathogens in 2020, did your laboratory suppress the *C. difficile* result so that clinicians could not see it?
 - o Clarified time period of question
 - o Clarified wording of response options
- 4b. If your laboratory used a multiplexed diagnostic in 2020 and the result was suppressed, where does the suppression occur?
 - o Clarified time period of question
 - o Clarified wording of response options
- 5a. If your laboratory used a nucleic acid amplification test (NAAT) (e.g., Cepheid Xpert *C. difficile*) as first line testing followed by a toxin EIA test (whenever NAAT result is positive) in 2020, did your laboratory suppress the positive NAAT result so that clinicians could not see it?
 - o New question
- 5b. If your laboratory used NAAT as first line testing followed by confirmatory toxin EIA testing in 2020, and both the NAAT and toxin EIA results were released to the clinician, did your laboratory provide any comments to help the clinician interpret the test results (e.g., NAAT-positive only result might represent colonization, etc.)?
 - o New question

- 6. What are the LOINC or internal testing codes associated with the tests your lab used in 2020 (e.g. LOINC codes 13957-6, 34713-8, or 54067-4)?
 - Changed question number
 - Clarified time period of question
- 7a. In 2020, did your laboratory experience any shortages in supplies, reagents, and/or test kits for performing *C. difficile* testing (e.g., NAAT or EIA reagents, swabs)?
 - New question
- 7b. If your laboratory experienced a supply shortage for *C. difficile* testing in 2020, how did the shortage affect your laboratory's ability to perform *C. difficile* testing? (Check all that apply)
 - New question
- 7c. In 2020, did your laboratory experience a high demand for COVID-19 testing that limited the availability of staff (e.g., reduced staffing or work time) or the use of equipment to perform *C. difficile* testing?
 - New question
- 8. Did your lab testing algorithm for *C. difficile* change between January 1, 2020 and December 31, 2020?
 - Changed question number
 - Clarified time period of question
- 8a. (If yes) What was the previous type and order of testing performed by your lab in 2020 before it changed its testing algorithm?
 - Changed question number
 - Clarified time period of question
- 8b. Which specimens were used during your 2nd line of testing?
 - Changed question number
- 8c. Which specimens were used during your 3rd line of testing?
 - Changed question number
- 9. Did your lab have a policy to reject stool specimens for *C. difficile* testing in 2020?
 - Changed question number
 - Clarified time period of question
- 9a. Did your rejection policy for stool specimens change between January 1, 2020 and December 31, 2020?
 - Changed question number
 - Clarified time period of question
- 10. How many stool samples did you test for *C. difficile* each month in 2020?
 - Changed question number