

Description of Changes

HAIC:

The changes made to the 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. **HAIC:** Multi-site Gram-Negative Surveillance Initiative (MuGSI-CRE/CRAB) (Attachment #3)

For the 2022 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 added “address type” to the patient identifier information section; 2) we added a “no evidence for pneumonia” value for Q23c; 3) we clarified the time period for answering Q24a; 4) we updated Q24b to only collect information for the patient’s most recent positive SARS-CoV-2 test; and 5) we added “Complete – Pending data” for Q29b.

The proposed changes will allow the Emerging Infection Program (EIP) sites to report the patient’s address type and further clarify the patient’s chest radiology findings when no evidence of pneumonia was indicated in the medical record. Additionally, it will allow us to solely focus on the patient’s most recent SARS-CoV-2 positive test, which will reduce the burden on the EIP sites since they are no longer required to identify the patient’s first SARS-CoV-2 positive test. Lastly, the EIP sites will be able to set the case report form (CRF) status variable to “Complete – Pending data” when they have completed the required fields on the CRF but are waiting to receive additional information for certain sections of the CRF.

Estimated Change in Burden:

The requested changes will have minimal 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 to complete other sections of the case report form.

Detailed Description of Changes

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

- a. Patient identifier information section
 - i. Added “Address type” as a field
- b. Question 23c: Chest radiology findings
 - i. Added “no evidence of pneumonia” as a value

- c. Question 24a: Did the patient have a positive test(s) for SARS-CoV-2 (molecular assay, serology or other confirmatory test) in the year before or day of the DISC
 - i. Updated the wording of this question to clarify the time period for answering it
- d. Question 24b: If yes, complete the table below for the most recent positive SARS-CoV-2 test on or before the DISC
 - i. Removed the specimen collection date and test type for the patient's first positive test for SARS-CoV-2 on or before the date of incident specimen collection (DISC)
- e. Question 29b: CRF status
 - i. Added "Complete – Pending Data" as a value

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

For the 2022 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 "address type" to the patient identifier information section; 2) we added cefadroxil to the list of antimicrobials used in the 30 days before the DISC; 3) we clarified the time period for answering Q25a; 4) we updated Q25b to only collect information for the patient's most recent positive SARS-CoV-2 test; and 5) we have added "Complete-pending" option to question 28b.

The proposed changes will allow the Emerging Infection Program (EIP) sites to report the patient's address type and to harmonize the list of antibiotics with other HAIC programs. Additionally, it will allow us to solely focus on the patient's most recent SARS-CoV-2 positive test, which will reduce the burden on the EIP sites since they are no longer required to identify the patient's first SARS-CoV-2 positive test.

Estimated Change in Burden:

The requested changes will have minimal 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 to complete other sections of the case report form.

Detailed Description of Changes

- Changes to the Extended-Spectrum Beta-Lactamase (ESBL)-Producing Enterobacteriaceae Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form include:
 - a. Patient identifier information section
 - i. Added "Address type" as a field
 - b. Question 24b: IF yes, check all antimicrobials used in the 30 days before the DISC: (Check all that apply)

- i. Added “Cefadroxil” to the list of antimicrobials
- c. Question 25a: Did the patient have a positive test(s) for SARS-CoV-2 (molecular assay, serology or other confirmatory test) in the year before or day of the DISC
 - i. Updated the wording of this question to clarify the time period for answering it
- d. Question 25b: If yes, complete the table below for the most recent positive SARS-CoV-2 test on or before the DISC
 - i. Removed the specimen collection date and test type for the patient’s first positive test for SARS-CoV-2 on or before the date of incident specimen collection (DISC)
- e. Question 28b. CRF Status
 - i. Added “Complete-Pending” to the values

3. Burden Tables Changes

Unfortunately, the burden table was not updated accurately when submitted in August 2021.

- HAIC Invasive Methicillin-resistant *Staphylococcus aureus* (MRSA) Infection Case Report Form: The MRSA program is anticipating an increase in case counts and adjusted the number of CRFs that would be collected in 2022 accordingly.
- HAIC Invasive Methicillin-sensitive *Staphylococcus aureus* (MSSA) Infection Case Report Form: In 2022, the MSSA program is estimating a decrease in case counts and adjusted the number of CRFs that would be collected in 2022 accordingly.