Description of Changes

ABCs:

The changes made to the data elements 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 improve efficiency, and to assist data collectors in capturing data in a standardized fashion to improve accuracy.

The data collection tools for which approval for changes are being sought include:

1. 2024 ABCs Case Report Form *(Attachment #3)*
2. 2024 ABCs Invasive Pneumococcal Disease (IPD) Report Form *(Attachment #4)*

1) **2024 ABCs Case Report Form:**
   There is no impact on burden due to the changes on this form. Change includes:
   a) **Addition of 1 question:** Q6a. Planning Region. ***Justification:*** The U.S. Census Bureau recently approved proposal for CT's planning regions to become county equivalents. The addition of planning region will allow for CT to report the patient residence as planning region rather than county.

2) **2024 ABCs Invasive Pneumococcal Disease (IPD) Report Form:**
   There is no impact on burden due to the changes on this form. Change includes:

   a) Updated overall design of the form to show available all data value sets.
      Justification: Improve data collection and data entry flow

   b) Addition of 4 questions:
      i. Most recent influenza vaccine date
      ii. Most recent COVID-19 vaccine date
      iii. RSV vaccine date (complete for adults ≥65 years only)
      iv. RSV monoclonal antibody date (complete for children <5 years only)

   Justification: Information on these vaccines will help to better assess pneumococcal disease risk and vaccine effectiveness.

   c) Addition of unknown checkboxes for all vaccination date variables.
      Justification: Addition of check boxes will make it easier to indicate when exact vaccination dates are not available to provide.
   d) Removal of Health Care Provider Information questions (Was health care provider information available from the following sources? If yes to any sources, how many providers were contacted?)

      Justification:
      Number and source of Health Care providers no longer needed to assess completeness of the expanded form.

Food Net:

The changes made to the data elements 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 improve efficiency, and to assist data collectors in capturing data in a standardized fashion to improve accuracy.

The data collection tools for which approval for changes are being sought include:

1) **FoodNet Active Surveillance Data Elements List** *(Attachment #5)*

There is no impact on burden due to the changes on these data elements. Changes were made to streamline, collect level of detail needed.

The following data elements have value set changes:

- **a. AgClinicTestType**
    - a. Meridian Curian Campy
- **b. AgSphlTestType**
    - a. Meridian Curian Campy

The following data elements have variable label changes:

- **a. StecHAg**
    - **a.** If *E. coli*, what was the H-antigen number for the isolate?
- **b. StecOAg**
    - **a.** If *E. coli*, what was the O-antigen number for the isolate?
- **c. StecStx**
    - **a.** Was *E. coli* isolate Shiga toxin-producing?

FluSurv-Net:

The changes made to the FluSurv-NET 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.

The data collection tools for which approval for changes are being sought include:

1. FluSurv-Net Influenza Hospitalization Surveillance Network Case Report Form *(Attachment #6)*
2. FluSurv-NET/RSV-NET Laboratory Survey *(Attachment #7)*
3. COVID-19 Vaccination Status on FluSurv-NET Cases (optional form) *(Attachment #8)*

1. FluSurv-NET Influenza Hospitalization Surveillance Case Report Form

For the upcoming 2022-23 influenza season, we made minor changes to the case report form and will continue to harmonize data elements with those collected on the COVID-NET and RSV-NET CRFs. There is no impact on burden due to changes to this form. Changes include:

- For section A, Patient Data, we added “Pharmacy of Record”, “Pharmacy Phone”, “Pharmacy Fax”, and “Pharmacy Address”. However, these items will be optional for FluSurv-NET sites to enter in the 2023-24 season.
- For Section C, Enrollment Information, we deleted the option “Prospective” from the “Case Classification” field.
- For Section C, Enrollment Information, we updated the labels “Homeless/Shelter” to “Homeless/Shelter/Temporary Housing” and “Alcohol/Drug Abuse Treatment” to “Substance abuse treatment center”.
- In Section E, the name of this section was changed from “ICU and Other Interventions” to “Other Interventions and ICU”.
- In Section E, Other Interventions and ICU, “Supplemental Oxygen” was added as a new field with the options of “Yes”, “No”, or “Unknown”.
- In Section E, Other Interventions and ICU, “Vasopressor use” was moved out of this section to the Treatment section (Section K)
- In Section E, Other Interventions and ICU, the order of items was changed, such that now the order appears as: BiPAP or CPAP use, Highflow nasal cannula, Invasive mechanical ventilation, ECMO, Supplemental Oxygen, Renal Replacement Therapy (RRT) or Dialysis, ICU.
- In Section G, Admission and Patient History, in the field “Reason for admission” a new option was added, “Newborn/hospitalized at birth”.
- In Section G, Admission and Patient History, under “Acute signs/symptoms present at admission”, the wording of “Chest pain” was changed to “Chest pain/tightness”.
- In Section G, Admission and Patient History, under “Acute signs/symptoms present at admission, a new option of “Chest congestion” was added under “Respiratory Symptoms”.
- In Section G, Admission and Patient History, the age range for pediatric signs and symptoms was changed from <2 years to <12 years.
- In Section G, Admission and Patient History, under “For cases <12 years” we added the following options/checkboxes: “Irritability/fussiness/excess crying”, “Nasal flaring/grunting/retractions”, “Tachypnea/increased work of breathing”.
- In Section G, Admission and Patient History, “Decreased vocalization/stridor” was changed to “Stridor/decreased vocalization”, and “Dehydration” was changed to “Dehydration/decreased urine output”. “Lethargy” was changed to “Lethargy/decreased activity”.

- In Section G, Admission and Patient History, a new question was added, “Environmental tobacco smoke exposure (for pediatric patients <12 years”, with the options of “Yes”, “No” or “Unknown”.
- In Section I, Bacterial Pathogens, we added the following new specimen sources checkboxes: “Bone/joint aspirate”, “Peritoneal or abdominal fluid/ascites”, and “Wound – Group A Streptococcus (only)”.
- In Section I, Bacterial Pathogens, “Bronchoalveolar lavage (BAL)” was changed to “Bronchoalveolar lavage (BAL), bronchial aspirate/wash” and “Endotracheal aspirate” was changed to “Endotracheal/tracheal aspirate”.
- In Section J, Viral Pathogens, we added the following new viral respiratory pathogens as checkboxes: “Coronavirus 229E”, “Coronavirus HKU1”, “Coronavirus NL63”, “Coronavirus OC43”, and “Coronavirus (not further specified)”.
- In Section J, Viral Pathogens, the checkbox option of “Coronavirus, other” was removed.
- In Section K, Influenza Treatment, we moved “Vasopressor use” from its previous location in Section E.
- Section L was renamed “Chest X-Ray – Based on radiology report only” from “Chest Imaging”.
- In Section L, Chest X-Ray, under “For first abnormal chest x-ray, please check all that apply”, we removed the “Lung infiltrate” and “Interstitial infiltrate” checkboxes and replaced them with one “Infiltrate (lung, interstitial, other)” checkbox.
- In Section M, Discharge Summary, we added the following new discharge diagnoses as checkboxes: “Acute complication of sickle cell”, “Atrial fibrillation (Afib) new-onset or paroxysmal/chronic”, “Cardiac arrest”, and “Supraventricular tachycardia (SVT)”, “Ventricular fibrillation (Vfib)”, “Ventricular tachycardia (V-tach)”. Additionally, the checkbox “Congestive heart failure” was reworded to, “Congestive heart failure exacerbation”.
- In Section O, Pregnancy Information, a new question was added, “Pregnancy complications during current pregnancy (select all that apply)”. The response options/checkboxes included: “None”, “Gestational diabetes”, “Pre-eclampsia”, “Pregnancy-induced hypertension (PIH)”, “Intrauterine growth restriction (IUGR)”, and “Unknown”.
- In Section O, Pregnancy Information, we reformatted the question to indicate pregnancy outcomes at discharge to capture outcome for each fetus. Instructions were added, “If multiple fetuses, indicate outcome at discharge for each fetus in the database separately”.

2. **COVID-19 Vaccination Status on FluSurv-NET Cases:** Additional sources to collect COVID-19 vaccines on FluSurv-NET cases include pharmacy/dispensing records from hospital systems where these records are linked and accessible to program-trained surveillance officers. This is an optional supplemental portion of the FluSurv-Net Influenza Hospitalization Surveillance Network Case Report Form. Because this project will involve automated linkage of FluSurv-NET cases to the state immunization registry, there are no additional burden hours.

3. **FluSurv-NET – Laboratory Survey:** Minimal changes are being made to the lab survey to update laboratory kit names and to clarify existing questions. There is no impact to burden due to changes to this form.

    - At the top of the survey, “Name of person completing the form” was changed to “Name of person responding to questions for laboratory”.
    - At the top of the survey, we added a new field “Title” for the person completing the questions to indicate their role/title.

- We added a new question as Question 3, “Does the laboratory currently (or plan to in the next year) send out specimens to be tested with the Karius Test?” The response options included “Yes”, “No”, and “Unknown”. All subsequent questions were renumbered.
- For question 5a (previously question 4a), the “BioSign” checkbox was renamed to “BioSign® Flu A+B or LifeSign LLC Status Flu A & B (Princeton BioMeditech Corp.)”
- For question 6a and 6b (previously questions 5a and 5b), we added the following new checkboxes as molecular assays: "ARIES® Flu A/B & RSV+SARS-CoV-2 Assay", “BioCode® CoV-2 Flu Plus Assay (Applied BioCode Inc)”, “NeuMoDX influenza A/b, RSV, and SARS-Cov-2 Vantage Assay (Qiagen)”, “Panther Fusion SARS-CoV-2/Flu A/B/RSV (Hologic)", “RealStar Influenza Screen & Type RT-PCR", “NxTAG® Respiratory Pathogen Panel + SARS-CoV-2 (Luminex Molecular Diagnostics Inc)”, “Solana Respiratory Viral Panel”. All of the above except for RealStar and Solana included the existing footnote symbol to indicate these kits were “Multiplex for influenza/SARS-CoV-2”.
- For questions 6a and 6b (previously questions 5a and 5b), the following checkboxes were deleted: “eSensor® Respiratory Viral Panel (RVP), (GenMark Diagnostics)”, “Idylla Respiratory IFV-RSV Panel”, “IMDx Flu A/B and RSV for Abbott m2000, (IMDx)”, “Prodesse PROFLU™, (GenProbe/Hologic)”, “Prodesse ProFAST™, (GenProbe/Hologic)”, “Silaris Infuenza A & Btg, (Sekisui Diagnostic)”, “Xpert Xpress Flu Assay, (Cepheid)”, “Xpert Xpress SARS-CoV-2/Flu/RSV, (Cepheid)”, “x-TAG® Respiratory Viral Panel Fast (RVP FAST), (Luminex Molecular Diagnostics Inc)”.
- For questions 6a and 6b (previously questions 5a and 5b), the following wording changes were made to existing kit name checkboxes: “Aptima SARS-CoV-2/Flu/A/B” was changed to “Aptima SARS-CoV-2/Flu/A/B (Hologic).
- For questions 6 and 6b (previously questions 5a and 5b), the footnote for “Simplexa™ Flu A/B & RSV Gen II (Diasorin)” was changed to indicate the test is a “Multiplex for influenza/SARS-CoV-2” test.

4. Provider Vaccination History Form (Pediatric/Adult patients)

No changes have been made to this form. The burden table was updated with the number of responses per respondent after including most recent season's data to calculate the median.

5. Patient/Proxy Influenza Vaccination Phone Script and Consent Form (Pediatric/Adult) in English and Spanish

No changes have been made to this form. The burden table was updated with the number of responses per respondent after including most recent season's data to calculate the median.

HAIC:

The changes made to 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.

The data collection tools for which approval for changes are being sought include:

1. Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF) *(Attachment #9)*
2. Multi-site Gram-Negative Surveillance Initiative (MuGSI) Community-Associated Carbapenemase-Producing Carbapenem-Resistant Enterobacterales (CA CP-CRE) Health interview *(Attachment #10)*
3. Multi-site Gram-Negative Surveillance Initiative (MuGSI) Supplemental Surveillance Officer Survey *(Attachment #11)*
4. Invasive *Staphylococcus aureus* Case Report Form *(Attachment #12)*
5. Invasive *Staphylococcus aureus* Supplemental Surveillance Officer*(Attachment #13)*
6. Invasive *Staphylococcus aureus* Laboratory Survey: Use of Nucleic Acid Amplification Testing (NAAT) *(Attachment #14)*
7. *Clostridioides difficile Infection* (CDI) Case Report and Treatment Form *(Attachment #15)*
8. *Clostridioides difficile Infection* (CDI) Annual Surveillance Officers Survey *(Attachment #16)*
9. Annual Survey of Laboratory Testing Practices for *C. difficile* Infections *(Attachment #17)*
10. Candidemia Case Report Form *(Attachment #18)*
11. Laboratory Testing Practices for Candidemia Questionnaire *(Attachment #19)*

1. Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF)

Justification

The 2023 CRE/CRAB CRF encompassed all the same fields and data elements as the 2023 ESBL/iEC CRF; the prior antimicrobial use questions Q24a and Q24b, outlined in Attachment 2, were the only data elements missing from the 2023 CRE/CRAB MuGSI CRF that were captured on the 2023 ESBL/iEC CRF. Consolidating these forms into one form for 2024 (now known as **Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form**) streamlines training, data entry, and IT resources. The justifications for removal of a question related to patient outcomes is multifactorial: 1) it was tedious to collect, thus increasing the burden of data collection, and 2) the response can be calculated via analytic approaches by CDC, thus reducing the burden of data collection on site partners. The addition of "Sepsis" as an infection type and "Urosepsis" as a sub-choice are to accurately capture these infections, which were previously captured imprecisely as "Bacteremia". Previously, sites would indicate in the comments that "Bacteremia" was selected for Sepsis since there wasn't a "Sepsis" option. The addition of a field to capture the specific organ(s) transplanted allows for us to better describe and quantify infections related to specific organ transplants. Recent literature identified a greater risk for invasive *E. coli* disease in hospitalized patients with a recent diagnostic or interventional medical procedure. Vaccination of patient groups with anticipated urologic diagnostic or invasive procedures has been proposed as a potential intervention. The addition of this new risk factor question allows us to establish baseline surveillance for these procedures associated with *E. coli* disease. Removing the qualifier "…in the 7 days before the DISC" from the question prompt of Q23b allows us to add an additional risk factor beyond that timeframe. This additional risk factor option allows for accurately classifying CRAB cases by their exposure, that would otherwise be misclassified. Finally, we have

added a checkbox to indicate when a COVID-Net ID would not be required. This will help simplify our edit checks and decrease back and forth with sites during data quality checks.

Description of Changes

For the 2024 Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF), we are proposing minimal changes, including: 1) Consolidating the 2023 Carbapenem-Resistant Enterobacterales (CRE) / Carbapenem-Resistant *Acinetobacter baumannii* (CRAB) MuGSI CRF and the 2023 Extended-Spectrum Beta-Lactamase (ESBL)-Producing Enterobacterales / Invasive *Escherichia coli* (iEC) MuGSI CRF into one form; 2) Revising the "Organism" field to encompass all MuGSI surveillance pathogens; 3) Removing one question related to patient outcomes; 4) Adding two additional types of infections with checkboxes; 5) Adding a field to indicate the organ that was transplanted; 6) Adding a new risk factor question about invasive or diagnostic urologic procedures with sub-choices; 7) Revising the question prompt for CRAB risk factors and including an addition choice; and 8) Updating the language for the time period of interest for capturing COVID-Net IDs, including a checkbox when a COVID-Net ID would not be required. These changes will have minimal impact on the burden of data collection.

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. Any potential increase in time expected to complete the case report form is likely offset by the removal of a question that was burdensome to collect.

Detailed Description of Changes

The following changes (j.– are non-substantive and relate to updated question numbers from consolidating the two 2023 MuGSI forms. Therefore, they are not included in the cross-walk table.

a. Q25a: Did the patient have a positive test(s) for SARS-CoV-2 (molecular assay, antigen, or other viral test, excluding serology) in the 90 days before or day of the DISC?
    i. Updated question number from 24a to 25a
b. Q25b: Specimen collection dates for positive tests in the 90 days before or the day of the DISC:
    ii. Updated question number from 24b to 25b
c. Q26: Was the incident specimen polymicrobial?
    iii. Updated question number from 25 to 26
d. Q27a: Was the incident specimen tested for carbapenemase genes?
    iv. Updated question number from 26a to 27a
e. Q27b: If yes, what testing method was used?
    v. Updated question number from 26b to 27b
f. Q27c: If tested, what was the testing result?
    vi. Updated question number from 26c to 27c
g. Q28a: Was the incident specimen tested for ESBL production or other beta-lactamase genes?
    vii. Updated question number from 27a to 28a
h. Q28b: If tested, what testing method was used?
    viii. Updated question number from 27b to 28b
i. Q29: Susceptibility results

ix. Updated question number from 28 to 29

j. Q30a: Was the case first identified through an audit
   x. Updated question number from 29a to 30a
k. Q30b: CRF status
   xi. Updated question number from 29b to 30b
l. Q30c: SO initials
   xii. Updated question number from 29c to 30c
m. Q30d: Date of abstraction
   xiii. Updated question number from 29d to 30c
n. Q30e: Comments
   xiv. Updated question number from 29e to 30e

2) Multi-site Gram-Negative Surveillance Initiative (MuGSI) Community-Associated Carbapenemase-Producing Carbapenem-Resistant Enterobacterales (CA CP-CRE) Health interview

Justification
This change is necessary to correct an instruction to the interviewer which is incorrect. The instruction states to skip to section "G" which does not exist.

Description of Changes
For the Community-Associated Carbapenemase-Producing Carbapenem-Resistant Enterobacterales (CA CP-CRE) Interview, we are proposing changing the instructions for the interviewer for Q22 to indicate skipping to Section 9 if the interviewee lives alone.

3) Multi-site Gram-Negative Surveillance Initiative (MuGSI) Supplemental Surveillance Officer Survey

Justification for Changes:
In 2024, surveillance for invasive *E. coli* (iEC) will be implemented through MuGSI, so we added iEC to this survey where appropriate. We added a list of response options for several questions that were previously in a free-text format to standardize the completion of the survey across all respondents. We added several questions in order to: learn about healthcare facility and laboratory participation, data sharing from laboratories, recent check-ins with laboratories conducted by MuGSI staff, laboratory testing practices, and data analytic and management practices. Lastly, there were minor word changes made throughout the document for clarity purposes.

Description of Changes
We are requesting several revisions for the 2024 MuGSI surveillance officer survey, which includes the following: adding iEC as a MuGSI pathogen, adding 11 new questions, adding response options for existing questions that were previously free-text fields, and minor word changes. The requested changes will have no impact on the burden of data collection.

Detailed Description of Changes
A. Changes to the 2024 MuGSI Surveillance Officer survey include:
   i. Description
      1. Updated the year

ii. Surveillance area characteristics - Question 1
    1. Added response option for iEC
iii. Surveillance area characteristics – Question 2
    1. Minor word changes and added other response options and one clarifying question
iv. Surveillance area characteristics – Question 3
    1. Minor word changes and added other response options and one clarifying question
v. Surveillance area characteristics – Question 4
    1. Minor word changes and added other response options and one clarifying question
vi. Surveillance area characteristics – Question 5
    1. Added corresponding questions for iEC
vii. Laboratory participation and isolate testing – Part 1 – Question 1
    1. Minor word changes and added corresponding questions for iEC
viii. Laboratory participation and isolate testing – Part 1 – Question 2
    1. Added question
ix. Laboratory participation and isolate testing – Part 1 – Question 3
    1. Added question
x. Laboratory participation and isolate testing – Part 1 – Question 4
    1. Minor word changes and added iEC
xi. Laboratory participation and isolate testing – Part 1 – Question 5
    1. Minor word changes and added iEC
xii. Laboratory participation and isolate testing – Part 1 – Question 6
    1. Minor word changes and added iEC
xiii. Laboratory participation and isolate testing – Part 2
    1. Converted from a table to standalone questions to simplify data reporting
    2. Converted free-text fields to a list of responses for most questions to standardize data reporting
    3. Added 3 new questions: method for sharing laboratory reports, most recent laboratory check-in, and laboratory policy on successive isolates
xiv. Additional information on MuGSI surveillance activities – Question 2
    1. New question
xv. Additional information on MuGSI surveillance activities – Question 3
    1. New question
xvi. Additional information on MuGSI surveillance activities – Question 4
    1. New question
xvii. Additional information on MuGSI surveillance activities – Question 5
    1. New question
xviii. Additional information on MuGSI surveillance activities – Question 6
    1. New question
xix. Additional information on MuGSI surveillance activities – Question 7
    1. Converted from a free-text field to a list of response options
xx. Additional information on MuGSI surveillance activities – Question 8
    1. New question

4) Invasive *Staphylococcus aureus* Case Report Form

Justification for Changes:

Both the MRSA and MSSA CRFs capture the same information. Therefore, combining them into a single form will streamline yearly updates (now known as **Invasive *Staphylococcus aureus* Case Report Form**). Since we are combining the forms into one, we added a field to capture if the form is for an MRSA or MSSA case. Note that this variable already exists in our database, and previously sites would determine this information before completing either an MRSA or MSSA labeled CRF. We added susceptibilities for additional drugs commonly used to treat MRSA infections. Invasive MRSA isolates are often tested for susceptibilities to these drugs but the information is not currently captured in our surveillance. Inclusion of these additional relevant drugs in surveillance is important for understanding and following *S. aureus* resistance patterns over time.

We have also added two questions that ask about indwelling prosthetic devices and if the *S. aureus* infection was associated with the device(s). This will help us better describe and quantify infections related to implantable devices. Finally, we have added a checkbox to indicate when a COVID-Net ID would not be required. This will help simplify our edit checks and decrease back and forth with sites during data quality checks.

Description of Changes

Minimal changes are being requested for the 2024 Invasive *Staphylococcus aureus* Case Report Form. We are proposing the following changes: updating the title of the form so that a single form can be used for both MRSA and MSSA, adding a field to indicate if the case is MRSA or MSSA, collection of susceptibility results for five additional antimicrobial agents, adding two questions about medical devices, adding the time period of interest for capturing COVID-Net ID, and addition of a checkbox to indicate when a COVID-Net ID would not be required. The requested changes will have no impact on the burden of data collection.

Detailed Description of Changes

A. Changes to the 2023 Methicillin-resistant *Staphylococcus aureus* (MRSA) and Methicillin-sensitive *Staphylococcus aureus* (MSSA*)* Case Report Form includes:
    a. Title
        - Changed the year from 2023 to 2024
        - Removed the words “Methicillin-Resistant” and “Methicillin-Sensitive” from respective forms
    b. Question 15a
        - Added question to capture if isolate was MRSA or MSSA
    c. Question 22
        - Added five antimicrobial agents
        - Abbreviated trimethoprim-sulfamethoxazole as TMP-SMX
    d. Question 28a
        - Added question
    e. Question 28b
        - Added question
    f. Question 34a

- Added the time period of interest
- Added a checkbox for None or N/A

5) Invasive *Staphylococcus aureus* Supplemental Surveillance Officer Survey

Justification for Changes:

The addition of a checkbox to each of the questions about NHSN access will allow us to better identify if sites are able to obtain NHSN data that could be used to supplement EIP surveillance data in future analyses. We have added a definition for labs serving the catchment area to questions 1, and 2 of the lab participation and case finding section because the existing wording was not clear to site(s). Likewise, we updated the wording for questions 4 (lab participation and case finding) and 2 (ascertainment of surveillance area and case audits) based on feedback from surveillance site(s). Question 5a (previously a free text field) of the lab participation and case finding section now has checkbox options for the response, which will make data entry and analysis easier. Question 6 (lab participation and case finding) asks if any labs dropped out of participating in the past year; for sites where one or more labs dropped out of participation in the past year, we now capture the number of cases that these labs identified each year. This will allow us to estimate the impact on yearly case counts. We previously asked sites in question 7 (ascertainment of surveillance area and case audits section) if they planned to use data checks to recognize decreasing/increasing case counts or rates of MSSA disease. Now that several years of MSSA data are available, we have removed the question related to planning data checks and have replaced it with a question asking if MSSA data checks for decreasing/increasing case counts or rates of MSSA are used. If so, we ask for a description of the checks and the frequency with which they are used. This allows us to document site-specific data quality checks. Finally, we have removed the three questions in the COVID-19 impact section because the COVID-19 public health emergency declaration expired.

Description of Changes

We are requesting slight revisions to the wording of four questions for the 2023 invasive *Staphylococcus aureus* surveillance officer survey. We also request to add one new checkbox to two separate questions, change an open-ended text response to checkboxes based on past responses, and add 4 new questions. Additionally, we plan to remove four questions. The requested changes will have no impact on the burden of data collection.

Detailed Description of Changes

A. Changes to the 2023 invasive *Staphylococcus aureus* Surveillance Officer survey include:

i. Surveillance Area Characteristics section question 5a

A. Added a new checkbox

ii. Surveillance Area Characteristics section question 5b

A. Added a new checkbox

iii. Lab participation and case finding question 1

A. Updated question wording for clarification

iv. Lab participation and case finding question 2

   A. Updated question wording for clarification

v. Lab participation and case finding question 4

   A. Updated question wording for clarification

vi. Lab participation and case finding section question 5a

   A. Added checkboxes for common responses (was previously a free text field)

vii. Lab participation and case finding section question 6c

   A. Added question to document how many cases surveillance may be missing due to labs dropping out of participation

viii. Ascertainment of surveillance area and case audits question 2

   A. Updated question wording for clarification

ix. Ascertainment of surveillance area and case audits question 7c

   A. Removed question 7c about plans to use checks to recognized increasing/decreasing rates of MSSA

x. Ascertainment of surveillance area and case audits question 8

   A. Added question 8 to capture if sites have checks to recognize increasing/decreasing rates of MSSA

   B. Added question 8a If sites have checks to recognize increasing/decreasing rates of MSSA, describe the check(s) used

   C. Added question 8b If sites have checks to recognize increasing/decreasing rates of MSSA, how often the check(s) are used

xi. COVID-19 impact section

   A. Removed question 1 (did COVID-19 responses activities affect or delay iSA surveillance)

   B. Removed question 1a (if yes how were you able to meet iSA deadlines)

   C. Removed question 1b (if yes, how did COVID-19 response activities delay your iSA work)

6) Invasive *Staphylococcus aureus* Laboratory Survey: Use of Nucleic Acid Amplification Testing (NAAT)

Justification:

The addition of the field documenting when the last lab survey was completed will define the time period since the last survey, which will serve as a frame of reference in question 2, to which we have added clarifying language to clarify what is meant by “during the past year” (either the past 12 months or since

the last survey). Updates to wording and response option order in question 5b will help clarify what we are asking and group similar responses (test types) together; the addition of a methods checkboxes for two responses will help us better understand what methods labs are using to identify S. aureus. The new questions (5h, 5i, and 5j) added to the end of the survey will document future plans to detect S. aureus in the absence of culture, methods that the lab is planning to use, and whether or not an isolate will still be obtained. The answers to these new questions will allow us to monitor if/when labs move away from our established isolate-based case definition and better understand the impact this could have on our isolate-based program.

Description of Changes

We are requesting to add a field capturing the date the lab survey was last completed. This will help provide a frame of reference for question 2, to which we have added clarifying language to define what is meant by "during the past year". In question 5b, we propose changing the order of response options so that the grouping of test types is logical, clarifying the language of one of the response options, and adding a follow up question for two of the options. Not all respondents will be asked these follow-up questions. Additionally, we would like to add three questions; given the skip patterns respondents will only be asked these questions if they plan to change their *S. aureus* testing methods. The requested changes will have minimal or no impact on the burden of data collection.

Detailed Description of Changes

A. Changes to the 2024 invasive *Staphylococcus aureus* laboratory survey include:
    a. Header questions
        i. Added question
    b. Question 2
        i. Updated question wording
    c. Question 5b
        i. Updated response option wording
        ii. Updated response option order
        iii. Added new sub questions for two options
    d. Question 5g
        i. Added skip pattern
    e. Question 5h
        i. Added question
    f. Question 5i
        i. Added question
    g. Question 5j
        i. Added question

7) *Clostridioides difficile* Infection (CDI) Case Report and Treatment Form

Justification:

For each diagnostic assay in Q9, we are adding an option for "unknown". This will give surveillance officers a complete list of possible values of each assay for data completeness. We are also adding a specify field under the solid organ transplant field to specify which organ was transplanted. This data is used in analyses and is currently captured in the comments field; adding this field will standardize data entry. We are changing the word "medication" to "treatment" in a question about treatment in the past year to clarify

that we want to capture non-pharmaceutical treatment such as fecal microbiota transplant as well as medication. We have also made two changes to the COVID-Net ID question. The first was to add the time period to the question to clarify for surveillance officers which data they should be looking for. We are also adding a checkbox to capture "none or N/A" for situations where no ID could be located. This information was previously captured in the ID field but this change will standardize data entry.

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.

Detailed Description of Changes

The changes to the *Clostridioides difficile* Infection (CDI) Surveillance Emerging infection program Case Report Form (CRF) include:

- Question 9. Diagnostic assay
  - Added option for "unknown" to each diagnostic assay sub-question
- Question 21. Underlying conditions; Transplant, solid organ
  - Added a field to specify organ transplanted
- Question 34.f.1. If YES, which treatment was taken?
  - Changed the word "medication" to "treatment"
- Question 37. COVID-Net Case IDs
  - Clarified the time period of the question
  - Added a checkbox for "none or N/A"

8) *Clostridioides difficile* Infection (CDI) Annual Surveillance Officers Survey

Justification:

We are requesting to change the wording of several questions to clarify that the survey is only capturing data on laboratory practices in 2023. There are no other changes to the survey. The requested changes will not change the burden of data collection for each response.

Detailed Description of Changes

Changes to the CDI Surveillance Officers Survey Include:

Question 2. In 2023, did any laboratories drop out of participation?

- Changed year to 2023 to reflect change in survey year

Question 3. In 2023, did you identify any additional laboratories inside or outside of your catchment area which identify *C.diff* assays from persons who are residents of your catchment area?

- Changed year to 2023 to reflect change in survey year

Question 10. Did your site complete a physician/outpatient provider survey in 2023?

- Changed year to 2023 to reflect change in survey year

Question 13. For each facility that treated a case in 2023, please provide the following

- Changed year to 2023 to reflect change in survey year

9) Annual Survey of Laboratory Testing Practices for *C. difficile* Infections

Justification:

We are requesting to change the wording of several questions to clarify that the survey is only capturing data on laboratory practices in 2023. There are no other changes to the survey. The requested changes will not change the burden of data collection for each response.

Detailed Description of Changes

Changes to the CDI Laboratory Survey Include:

- Was this a new laboratory in 2023?
  - Changed year to 2023 to reflect change in survey year
- How often did you receive line lists from this lab in 2023?
  - Changed year to 2023 to reflect change in survey year
- How did you receive line lists from this lab in 2023?
  - Changed year to 2023 to reflect change in survey year
- Did you receive specimens from this lab in 2023?
  - Changed year to 2023 to reflect change in survey year
- Was this lab audited in 2023?
  - Changed year to 2023 to reflect change in survey year
- Types of facilities in your catchment area served by this lab in 2023
  - Changed year to 2023 to reflect change in survey year
- Did your laboratory ever send specimens off-site for Clostridioides difficile testing in 2023?
  - Changed year to 2023 to reflect change in survey year
- 2a. Which testing method(s) for Clostridioides difficile (C. difficile) did your laboratory perform in 2023?
  - Changed year to 2023 to reflect change in survey year
- Did your laboratory use this testing method for Clostridioides difficile (C. difficile) in 2023?
  - Changed year to 2023 to reflect change in survey year
- Did you use this testing method in this way for all of 2023?
  - Changed year to 2023 to reflect change in survey year
- 3a. Which EIA test kit was used by your laboratory in 2023?
  - Changed year to 2023 to reflect change in survey year
- 3b. Which Nucleic Acid Amplification test was used by your laboratory in 2023?
  - Changed year to 2023 to reflect change in survey year
- 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 2023, did your laboratory suppress the C. difficile result so that clinicians could not see it?
  - Changed year to 2023 to reflect change in survey year
- 4b. If your laboratory used a multiplexed diagnostic in 2023 and the result was suppressed, where does the suppression occur?
  - Changed year to 2023 to reflect change in survey year
- 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 2023, did your laboratory suppress the positive NAAT result so that clinicians could not see it?
  - Changed year to 2023 to reflect change in survey year
- 5b. If your laboratory used NAAT as first line testing followed by confirmatory toxin EIA testing in 2023, 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.)?
    - Changed year to 2023 to reflect change in survey year
- 6. What are the LOINC or internal testing codes associated with the tests your lab used in 2023 (e.g. LOINC codes 13957-6, 34713-8, or 54067-4)?
    - Changed year to 2023 to reflect change in survey year
- 7. Did your lab have a policy to reject stool specimens for C. difficile testing in 2023?
    - Changed year to 2023 to reflect change in survey year
- 7a. Did your rejection policy for stool specimens change between January 1, 2023 and December 31, 2023?
    - Changed year to 2023 to reflect change in survey year
- 8. How many stool samples did you test for C. difficile each month in 2023?
    - Changed year to 2023 to reflect change in survey year

10) HAIC Candidemia Case Report Form *(Attachment #14)*

Justification:
For three questions that ask about species, we are adding a response option for *Candida auris* (CAU), a species of concern as it's often multi-drug resistant and a common cause of outbreaks in healthcare settings. Adding an option for this species will allow us to quickly identify any new *C. auris* cases reported within candidemia surveillance catchment areas.

We are adding a text field to capture the organ(s) involved in solid organ transplants if that underlying condition is met. This will allow us to incorporate liver and kidney transplants into the calculation of the Charlson Comorbidity Index, a method for estimating risk of death from comorbid diseases.

Previously, we had a single checkbox to capture if a central line was in place for more than 2 calendar days. To ensure staff have reviewed this question and didn't accidentally skip over it, we are removing that single checkbox and changing this question to a "Yes/No/Unknown" response format.

The COVID-Net Case ID question previously had checkboxes for scenarios where the ID is unavailable. To condense this section and harmonize with other HAIC program CRFs, we are replacing those checkboxes with a single option to capture when there isn't a COVID-Net Case ID or it's not applicable.

For questions with minor wording changes, these changes were made to increase clarity based on feedback from laboratory colleagues and/or data abstractors.

Detailed Description of Changes

Minimal changes are being requested for the 2024 Candidemia Case Report Form (CRF). We are proposing the following changes: 1) addition of response options for six questions and 2) minor question rewording for two questions to increase clarity on the CRF. The requested changes will have no impact on the burden of data collection.

Changes to the Candidemia Case Report Form for 2024 include:

a. Title
   - Year changed from 2023 to 2024

b. Footnotes
   - Changed version year to 2024
   - Changed last updated date from “7/29/2022” to “7/29/2023”

c. Question 23: *Candida* species
   - Added “*Candida auris* (CAU)” as a response option

d. Question 24: Antifungal susceptibility testing
   - Added checkbox for “CAU” under “Species” column

e. Question 25: CIDT
   - Updated the wording for this question

f. Questions 26a: Subsequent positive *Candida* blood cultures
   - Added checkbox for “CAU” under “Species identified” field

g. Question 40: Underlying conditions
   - Added a text field to capture the solid organ(s) that were transplanted

h. Question 52
   - Updated the wording for this question
   - Removed the single checkbox and added “Yes/No/Unknown” response options

i. Question 55b: EIP COVID-Net Case ID
   - Removed previous checkbox response options and added a single response option for “None or N/A”

j. Antifungal susceptibility testing – additional *Candida* isolates
   - Added checkbox for “CAU” under “Species identified” field

11) Laboratory Testing Practices for Candidemia Questionnaire

Justification

Minimal changes are being requested for the 2024 Candidemia Lab Survey. We are proposing the following changes: 1) update the year in the title and footnotes and 2) minor rewording of three questions.

The wording in three questions was updated to clarify question intent. We are interested in capturing data on PCR molecular tests used by facilities in the catchment area and not solely culture-independent diagnostic tests (CIDTs).

The requested changes will have no impact on the burden of data collection.

Detailed Description of Changes

Changes to the Candidemia Laboratory Survey for 2024 include:

a. Title:
   - Year changed from 2023 to 2024

b. Footnotes
   - Changed version year to 2024

c. Question 13: CIDTs
   - Minor change to question wording (‘culture independent diagnostic tests (CIDTs)’ to ‘PCR molecular tests’)
d. Question 16: Other CIDTs
   - Minor change to question wording (‘CIDTs’ to ‘PCR molecular tests’)
e. Question 17: CIDT future plans
   - Minor change to question wording (‘culture independent diagnostics’ to ‘PCR molecular tests’)