**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)*
3. **2024 ABCs Case Report Form:**There is no impact on burden due to the changes on this form. Change includes:  
   a) Q6a. Planning Region (Patient Residence) information has been appended to the prior approved County (Patient Residence) variable.

***Justification:*** The state of Connecticut (CT) has been recently approved by the U.S. Census Bureau to report a patient residence by planning regions rather by counties. This crucial information on planning region is critically needed for population-based surveillance. Therefore, this is not a new variable but rather data that is equivalent to an already approved data variable.

1. **2024 ABCs Invasive Pneumococcal Disease (IPD) Report Form:**Only the data value sets of previously approved questions were minimally updated or renamed to better harmonize the data elements; there is no change in scope. There is no impact on burden due to the changes on this form. Change includes:
2. Updated overall design of the form to show available all data value sets.

***Justification:*** Improve data collection and data entry flow

1. 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.

1. 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. Only the data value sets of previously approved questions were minimally updated or renamed to better harmonize the data elements; there is no change in scope.

The data collection tools for which approval for minimal 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 2 data element questions have added “Meridian Curian Campy” to their value set of options:

1. **AgClinicTestType**
   1. Meridian Curian Campy
2. **AgSphlTestType**
   1. Meridian Curian Campy

For the following 3 data element questions the word “isolate” was inserted for better clarification:

1. **StecHAg**
   1. If *E. coli*, what was the H-antigen number for the isolate?
2. **StecOAg**
   1. If *E. coli*, what was the O-antigen number for the isolate?
3. **StecStx**
   1. 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. **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 given they are all within the Respiratory Virus Hospitalization Surveillance Network (RESP-NET) (<https://www.cdc.gov/surveillance/resp-net/dashboard.html>). Only the data value sets of previously approved questions were minimally updated or renamed to better harmonize the data elements; there is no change in scope. There is no impact on burden due to changes to this form. Changes include:

* 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, “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” the 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 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, the following viral respiratory pathogens value set options were updated 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, the following value set options were updated 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, 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”.

1. **FluSurv-NET – Laboratory Survey:** Minimal changes are being made to the lab survey to update laboratory kit names and to clarify existing questions. The updates to the laboratory kit names were made to stay current to the kit nomenclature and to the types of laboratory kits that are made available for testing assays. Only the data value sets of previously approved questions were minimally updated or renamed to better harmonize the data elements. These changes do not indicate the collection of new data and there is no change in scope. There is no impact to burden due to the minimal 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”.
* 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), the following value set options were updated to 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.

1. **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. *(Refer to Burden Table)*

1. **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. *(Refer to Burden Table)*

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

For the 2024 Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF), we are proposing minimal changes including:

1) Consolidating two existing approved forms, 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;

The remainder of the changes include where only data value sets of previously approved questions were minimally updated or renamed to better harmonize the data elements; there is no change in scope.

2) Revising the language and layout of the “Organism” field to more easily discern all MuGSI surveillance pathogens; 3) Removing one question related to patient outcomes; 4) Providing checkboxes for two types of infections that were previously recorded in the comments field; 5) Providing a field to indicate the type of organ that was transplanted, which was previously recorded in the comments field; 6) Updating the language for capturing COVID-Net IDs to include the time period of interest, and providing a checkbox when a COVID-Net ID would not be required; and 7) Providing a checkbox to indicate when antimicrobial susceptibility testing results from the medical record are unavailable to provide clarity when no responses were selected for this question. The changes to the form are non-substantive, and mostly include language modifications and administrative changes. These changes will have minimal impact on the burden of data collection.

Justification for Changes:

The requested changes are non-substantive and largely administrative, such that two previously approved case report forms will be merged into one, single form. The 2023 Carbapenem-Resistant Enterobacterales (CRE)/Carbapenem-Resistant Acinetobacter baumannii (CRAB) MuGSI CRF largely shared the same fields and data elements as the 2023 Extended-Spectrum Beta-Lactamase (ESBL)-Producing Enterobacterales/Invasive Escherichia coli (iEC) MuGSI CRF with one exception; the prior antimicrobial use questions Q24a and Q24b, outlined in Attachment 8, were not on the 2023 CRE/CRAB MuGSI CRF but were on the 2023 ESBL/iEC CRF. Both 2023 forms have been previously OMB-approved, and consolidating these forms into one form streamlines training, data entry, and IT resources.

The justifications for removal of a question related to patient outcomes (Q16, Attachment 8) is multifactorial: 1) it was tedious to collect, thus increasing the burden of data collection, and 2) the response can now be calculated via analytic approaches by CDC, thus eliminating the need for and 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 (Q17a, Attachment 8), which were previously captured as “Bacteremia”. Previously, respondents would indicate in the comments that “Bacteremia” was selected for sepsis since there wasn’t a “Sepsis” option on the prior forms. The addition of these two fields will standardized the collection of these data in a more accurate manner.

Similar to the addition of “Sepsis” and “Urosepsis” options, respondents often indicate in the comments field the solid organ that was transplanted (Q18, Attachment 8). The addition of a field to capture the specific organ(s) transplanted gives respondents a dedicated space to continue entering this information and allows for us to better describe and quantify infections related to specific organ transplants.

Finally, we have included two checkboxes so that respondents can record a non-response. The first checkbox indicates “None or N/A” as a valid response to the question about a COVID-Net ID (Q25c Attachment 8). The second checkbox indicates “No susceptibility data from the medical record are available” as a valid response to Susceptibility Results (Q29, Attachment 8). This improves data quality since we can differentiate these valid non-responses from missing responses.

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.

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

1. 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?
   * 1. Updated question number from 24a to 25a
2. Q25b: Specimen collection dates for positive tests in the 90 days before or the day of the DISC:
   * 1. Updated question number from 24b to 25b
3. Q26: Was the incident specimen polymicrobial?
   * 1. Updated question number from 25 to 26
4. Q27a: Was the incident specimen tested for carbapenemase genes?
   * 1. Updated question number from 26a to 27a
5. Q27b: If yes, what testing method was used?
   * 1. Updated question number from 26b to 27b
6. Q27c: If tested, what was the testing result?
   * 1. Updated question number from 26c to 27c
7. Q28a: Was the incident specimen tested for ESBL production or other beta-lactamase genes?
   * 1. Updated question number from 27a to 28a
8. Q28b: If tested, what testing method was used?
   * 1. Updated question number from 27b to 28b
9. Q29: Susceptibility results
   * 1. Updated question number from 28 to 29
10. Q30a: Was the case first identified through an audit
    * 1. Updated question number from 29a to 30a
11. Q30b: CRF status
    * 1. Updated question number from 29b to 30b
12. Q30c: SO initials
    * 1. Updated question number from 29c to 30c
13. Q30d: Date of abstraction
    * 1. Updated question number from 29d to 30c
14. Q30e: Comments
    * 1. Updated question number from 29e to 30e
15. **Multi-site Gram-Negative Surveillance Initiative (MuGSI) Community-Associated Carbapenemase-Producing Carbapenem-Resistant Enterobacterales (CA CP-CRE) Health interview**

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.

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.

1. **Invasive *Staphylococcus aureus* Case Report Form**

Description of Changes

Minimal changes are being requested for the 2024 Methicillin-resistant *Staphylococcus aureus* (MRSA) and Methicillin-sensitive *Staphylococcus aureus* (MSSA) Case Report Form, these changes are related to combining of two forms into a single case report form.

We are proposing the following changes: updating the title of the form to reflect the use of a single form for both MRSA and MSSA, adding a field to indicate if the case is MRSA or MSSA, revising the language for an existing question to add the period of interest for capturing COVIDNet ID, and the addition of a checkbox to indicate when a COVIDNet ID would not be required. The requested changes will have no impact on the burden of data collection.

Justification

Both the previous MRSA and MSSA CRFs captured essentially the same information. Combining them into a single form is an administrative change that will streamline yearly updates. Since we are combining the forms into one, we added a field for MRSA or MSSA, which indicates which of the old forms would have been used in the past. Note that this variable already exists in our database, and sites already had to determine this information before completing either an MRSA or MSSA labeled CRF. Finally, we have added a checkbox to indicate when a COVIDNet ID would not be required. This will help simplify our data quality checks, which currently require sites to communicate with us the same information when there is a blank value of COVID-NET CASE ID (triggering a potential data error). Therefore, it actually will reduce burden on our surveillance sites.

Detailed Description of Changes

1. Changes to the 2023 Methicillin-resistant *Staphylococcus aureus* (MRSA) and Methicillin-sensitive *Staphylococcus aureus* Case Report Form include:
   1. Title
      * Changed the year from 2023 to 2024
      * Removed the words “Methicillin-Resistant” and “Methicillin-Sensitive” from respective forms
   2. Question 15a
      * Added question to capture if isolate was MRSA or MSSA
   3. Question 34a
      * Added the period of interest
      * Added a checkbox for None or N/A
2. ***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.

Only the data value sets of previously approved questions were minimally updated or renamed to better harmonize the data elements; there is no change in scope. 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”

1. ***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.

Only the data value sets of previously approved questions were minimally updated or renamed to better harmonize the data elements; there is no change in scope.

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

1. **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.

Only the data value sets of previously approved questions were minimally updated or renamed to better harmonize the data elements; there is no change in scope.

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

1. **Candidemia Case Report Form**

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.

Only the data value sets of previously approved questions were minimally updated or renamed to better harmonize the data elements; there is no change in scope.

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:

1. Title
   * + Year changed from 2023 to 2024
2. Footnotes
   * + Changed version year to 2024
     + Changed last updated date from “7/29/2022” to “7/29/2023”
3. Question 23: *Candida* species
   * + Added “*Candida auris* (CAU)” as a response option
4. Question 24: Antifungal susceptibility testing
   * + Added checkbox for “CAU” under “Species” column
5. Question 25: CIDT
   * + Updated the wording for this question
6. Questions 26a: Subsequent positive *Candida* blood cultures
   * + Added checkbox for “CAU” under “Species identified” field
7. Question 40: Underlying conditions
   * + Added a text field to capture the solid organ(s) that were transplanted
8. Question 52
   * + Updated the wording for this question
     + Removed the single checkbox and added “Yes/No/Unknown” response options
9. Question 55b: EIP COVID-Net Case ID
   * + Removed previous checkbox response options and added a single response option for “None or N/A”
10. 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).

Only the data value sets of previously approved questions were minimally updated or renamed to better harmonize the data elements; there is no change in scope.

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:

1. Title:
   * + Year changed from 2023 to 2024
2. Footnotes
   * + Changed version year to 2024
3. Question 13: CIDTs
   * + Minor change to question wording (‘culture independent diagnostic tests (CIDTs)’ to ‘PCR molecular tests’)
4. Question 16: Other CIDTs
   * + Minor change to question wording (‘CIDTs’ to ‘PCR molecular tests’)
5. Question 17: CIDT future plans
   * + Minor change to question wording (‘culture independent diagnostics’ to ‘PCR molecular tests’)