

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 assist data collectors in capturing data in a standardized fashion to improve accuracy.

1) 2022 ABCs Case Report Form (Attachment #3)

There is no impact on burden due to the changes on these data elements.

H. influenzae Neonatal Sepsis Expanded Surveillance (HiNSES), 2016-2020 ended at the end of 2020 and Q24c, which is an indicator for HiNSES case, is no longer needed on the ABCs core case report form.

Question 24c. Removing the checkbox:

“Mark if this is a HiNSES fetal death with placenta and/or amniotic fluid isolate, a stillbirth or neonate <22 weeks gestation.

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 assist data collectors in capturing data in a standardized fashion to improve accuracy.

1) FoodNet Active Surveillance Data Elements List (Attachment #4)

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

Value set changes are listed below for the following data elements:

- a. AgClinicTestType**
 - a. Denka Seiken VTEC Screen
- b. AgSphlTestType**
 - a. Denka Seiken VTEC Screen
- c. OtherClinicTestType**
 - a. Beckman Walkaway System
- d. OtherSphlTestType**
 - a. Beckman Walkaway System
- e. PcrClinicTestType**
 - a. BioCode Gastrointestinal Pathogen Panel (GPP)
 - b. Genmark E Plex BCID
 - c. Great Basin Scientific Stool
- f. PcrSphlTestType**
 - a. BioCode Gastrointestinal Pathogen Panel (GPP)
 - b. Genmark E Plex BCID
 - c. Great Basin Scientific Stool
- g. StecOAg**
 - a. '888'=O antigen not tested

Variable label changes are listed below for the following data elements:

- a. Immigrate**
 - a. "Did case-patient immigrate to the U.S.? (within 30 days of onset for *Salmonella* Typhi & *Listeria*, 14 days for *Cyclospora*, and 7 days for all other pathogens)"
- b. TravelInt**
 - a. "Did the case patient travel internationally? (within 30 days of onset for *Salmonella* Typhi & *Listeria*, 14 days for *Cyclospora*, and 7 days for all other pathogens)"

2) FoodNet Hemolytic Uremic Syndrome Data Elements List (Attachment #5)

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

Variable label changes are listed below for the following data elements:

- a. **So157cult (Was a culture for *E. coli* O157 performed or the isolate confirmed to be *E. coli* O157? (at PHL))**
 - a. Yes
 - b. No
 - c. Unknown

The following data elements have been added to the case report form:

- b. **WgsOAnt (O antigen gene identified by WGS)**
 - a. [Free text field]
- c. **WgsHAnt (H antigen gene identified by WGS)**
 - a. [Free text field]

3) Diagnostic Laboratory Practices and Volume Elements List (*Attachment #6*)

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

The following data element has been added:

- a. **Survey_method (For this survey cycle, how were the data for this laboratory collected?)**
 - a. Laboratory verified via phone/in-person visit
 - b. Laboratory verified via email/electronic survey
 - c. Laboratory did not respond, data from previous survey were verified via ELR
 - d. Laboratory did not respond, data not verified

FluSurv-Net:

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) FluSurv-NET Influenza Hospitalization Surveillance Network Case Report Form (Attachment #7)

For the upcoming 2021-22 influenza season, we will continue to harmonize data elements with those collected on the COVID-NET CRF. We will add back several data elements that were previously removed from the 2020-21 season into the new form.

1. For Section G, Admission and Patient History, we added new question “Reason for hospital admission” with the following checkboxes: Influenza-related illness, OB/labor and delivery admission, Inpatient surgery procedures, Psychiatric admission needing acute medical care, Trauma, Unknown, and Other, specify.
2. For Section G, Admission and Patient History we added additional checkboxes for signs/symptoms present at admission – Non-respiratory symptoms: Abdominal pain, Anosmia/decreased smell, Chest pain, Conjunctivitis, Diarrhea, Dysgeusia/decreased taste, Fatigue, Headache, Muscle aches/myalgias, Nausea/vomiting, rash; Respiratory symptoms: Hemoptysis/bloody sputum; For cases <2 years: Apnea, Cyanosis, Decreased vocalization/stridor, Dehydration, Hypothermia, Inability to eat/poor feeding, Lethargy.
3. For Section G, Admission and Patient History, we added the question “Alcohol Abuse” with the following checkboxes: Current, Former, and No/Unknown.
4. For Section G, Admission and Patient History, we added the question “Substance Abuse” with the following checkboxes: Current, Former, and No/Unknown.
5. For Section G, Admission and Patient History, we added back in “Substance Abuse Type (current use only)” with the following checkboxes: IVDU, Polysubstance abuse – not otherwise specified, Opioids, Cocaine, Methamphetamines, Marijuana, Unknown, and Other, specify.
6. For Section G, Admission and Patient History, we added new question “Code status on admission” with the following checkboxes: Full code, DNR/DNI/CMO, and Unknown.
7. For Section H, Underlying Medical Conditions, we deleted “Other, specify” free-text fields underneath each major header category.
8. We added back in Section I, Bacterial Pathogens, including question 1 to “Were any bacterial culture tests performed within 7 days of admission? “For patients that died in the hospital, include if bacterial culture tests were performed either 1) within 7 days of admission, 2) within 3 days prior to death, or 3) within 24 hours after death).
9. For Section I, Bacterial Pathogens, we added question 2 “If yes, was there a positive culture for aspergillus, mucormycosis, or a bacterial pathogen?” with the following checkboxes: Yes, No, and Unknown, and allowing up to 5 pathogens being recorded.
10. For Section I, Bacterial Pathogens, we added question 2a “If yes, specify pathogen”.
11. For Section I, Bacterial Pathogens, we added question 2b “Date of culture”.
12. For Section I, Bacterial Pathogens, we added question 2c “Site where pathogen identified” with the following checkboxes: Blood, Sputum, Bronchoalveolar lavage (BAL), Endotracheal aspirate, Pleural fluid, Cerebrospinal fluid (CSF), and Other, specify
13. For Section J, Viral Pathogens, we rephrased Question 1 to “Was patient tested for any of the viral respiratory pathogens within 14 days prior to or within 7 days of admission? (For patients that died in the hospital, include tests performed either 1) within 14 days prior to or within 7 days of admission, 2) within 3 days prior to death, or 3) within 24 hours after death) for clarity.

14. For Section J, Viral Pathogens, we added back in test results for the following viral pathogens: Adenovirus, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, Human metapneumovirus, Rhinovirus/Enterovirus, and Coronavirus, other.
15. We added Section L, Chest Imaging, including question 1 “Was a chest x-ray taken within 3 days of hospitalization?”
16. For Section L, Chest Imaging, we added question 2 “Were any of these chest x-rays abnormal?”
17. For Section L, Chest Imaging, we added question 2a “Date of first abnormal chest x-ray”
18. For Section L, Chest Imaging, we added question 2b “For first abnormal chest x-ray, please check all that apply” with the following checkboxes: Report not available, Air space density, Air space opacity, Bronchopneumonia/pneumonia, Cannot rule out pneumonia, Consolidation, Cavitation, ARDS (acute respiratory distress syndrome), Lung infiltrate, Interstitial infiltrate, Lobar infiltrate, Pleural Effusion, Empyema, and Other.
19. For Section M, Discharge Summary, we changed the checkbox option from “Multisystem inflammatory syndrome in children (MIS-C)” to “Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)”.
20. We added Section O, Pregnancy Information, including question 1 “Total # of pregnancies as of date of admission (Gravida, G)”.
21. For Section O, Pregnancy Information, we added question 2 “Total # of pregnancies that resulted in a live birth as of date of admission (Parity, P)”.
22. For Section O, Pregnancy Information, we added question 3 “Specify total # of fetuses for current pregnancy as of date of admission” with the following checkboxes: 1, 2, 3, >3, and Unknown.
23. For Section O, Pregnancy Information, we added question 4 “Specify gestational age in weeks as of date of admission” and “If gestation age in weeks unknown, specify trimester of pregnancy with the following checkboxes: 1st (0 to 13 6/7 weeks), 2nd (14 0/7 to 27 6/7 weeks), 3rd (28 0/7 to end), and Unknown.
24. For Section O, Pregnancy Information, we added question 5 “Indicate pregnancy status at discharge or death” with the following checkboxes: Still pregnant, No longer pregnant, and Unknown.
25. For Section O, Pregnancy Information, we added question 5a “If patient was pregnant on admission but no longer pregnant at discharge, indicate pregnancy outcome at discharge” with the following checkboxes: Healthy newborn, Ill newborn, Infant died, Miscarriage (intrauterine death <20 weeks GA), Stillbirth (intrauterine death at ≥20 weeks GA), Abortion, and Unknown.
26. For Section O, Pregnancy Information, we added question 5b “Pre-term live birth (<37 weeks GA)” with the following checkboxes: Yes, No, Unknown, and Pre-term delivery, gestational age in weeks.

2) **FluSurv-NET/RSV-NET Hospital Laboratory Survey** (*Attachment #8*)

There is no impact on burden due to changes on this form. Changes include:

1. For question 4a, we added new rapid influenza antigen diagnostic test kit names: Acucy Influenza A&B Test and OSOM Ultra Plus Flu A&B Test.
2. We deleted question 4b “If more than one kit is selected above, please select the one kit that is (or will be) used most frequently for rapid influenza diagnostics testing at the laboratory during the current influenza season.
3. For questions 5a and 5b, we added new molecular assay kit names: BioCode Respiratory Pathogen Panel, (Applied BioCode Inc), BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ), CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza A Subtyping Kit), (CDC Influenza Division), CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza B Lineage

Genotyping Kit), (CDC Influenza Division), Cobas SARS-CoV-2 & Influenza A/B (Roche Diagnostics), Cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test, (Roche Diagnostics) , ePlex Respiratory Pathogen Panel 2, (Genmark Diagnostics , FilmArray® Pneumonia Panel plus, (BioFire Diagnostics) , FilmArray Respiratory Panel 2 (Biofire Diagnostics, LLC), FluChip-8G Influenza A+B Assay, (InDevR) , Quest Diagnostics RC COVID-19 +Flu RT-PCR, (Quest Diagnostics) , Sofia 2 Flu + SARS Antigen FIA, (Quidel) , Simplexa Flu A/B & RSV Gen II (Diasorin Molecular), Simplexa™ Flu A/B & RSV Gen II (Diasorin),

4. For questions 5a and 5b, we deleted molecular assay kit names no longer FDA approved: CDC Human Influenza Virus Real-Time RT-PCR Detection and Characterization Panel, CDC Influenza 2009 A(H1N1N)pdm Real-Time RT-PCR Panel.
5. We deleted question 5d “What testing kit does the testing facility use (or will it use) most often to perform influenza A sub-typing during the current influenza season?”.
6. We deleted question 6 “Does the laboratory perform any of the following additional tests to detect influenza (other than RT-PCR or RIDT)?”.
7. For question 7a, we deleted the following checkbox options: Viral culture and Indirect fluorescent antibody (IFA)/direct fluorescent antibody stain (DFA).
8. For question 7b, we deleted the following checkbox options: Viral culture and Indirect fluorescent antibody (IFA)/direct fluorescent antibody stain (DFA).
9. For question 8, we updated the question to “Based on tests that were performed during the 2020-2021 influenza season, approximately what percent of the time are each of these test types used to test for flu overall?”.
10. For question 8, we deleted the following checkbox options: % Viral culture and % Indirect fluorescent antibody (IFA)/direct fluorescent antibody stain (DFA).
11. For question 8, we added the checkbox option “% Other test type”.
12. Questions 10 through 20 about RSV-specific testing practices are collected elsewhere and have been removed from this form to reduce duplication of data collection efforts.

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) Invasive MRSA Infection Case Report Form (Attachment #9)

Minimal changes are being requested for the 2022 Methicillin-resistant *Staphylococcus aureus* (MRSA) Case Report Form. We are proposing the following changes: addition of an existing data element already collected by sites to clarify existing data collection (address type), clarification of the wording for question 34a, addition of a response option to an existing field (SARS-CoV-2 test type), and deletion of variables related to the first positive test for SARS-CoV-2.

The proposed changes will provide the Emerging Infections Program (EIP) sites a standardized way to store a data element they are already capturing and simplify SARS-CoV-2 related data collection. These 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 collected by sites and questions related to the first positive test for SARS-CoV-2 have been removed from the case report form.

Detailed Description of Changes

A. Changes to the 2021 Methicillin-resistant *Staphylococcus aureus* (MRSA) Case Report Form includes:

- a. Title
 - i. Changed the year from 2021 to 2022
- b. Add data element to top of form
 - i. Address type
- c. Question 34a: SARS-CoV-2
 - i. Update wording of main question
 - ii. Update wording of follow up question
 - iii. Added an additional option for test type
 - iv. Remove questions related to first positive test for SARS-CoV-2
 1. Specimen collection date
 2. Test type

2) Invasive MSSA Infections Case Report Form (Attachment #10)

Minimal changes are being requested for the 2022 Methicillin-sensitive *Staphylococcus aureus* (MSSA) Case Report Form. We are proposing the following changes: addition of an existing data element already collected by sites to clarify existing data collection (address type), clarification of the wording for question 34a, addition of a response option to an existing field (SARS-CoV-2 test type), and deletion of variables related to the first positive test for SARS-CoV-2.

The proposed changes will provide the Emerging Infections Program (EIP) sites a standardized way to store a data element they are already capturing and simplify SARS-CoV-2 related data collection. These 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 collected by sites and questions related to the first positive test for SARS-CoV-2 have been removed from the case report form.

Detailed Description of Changes

A. Changes to the 2021 Methicillin-sensitive *Staphylococcus aureus* (MSSA) Case Report Form includes:

- a. Title
 - i. Changed the year from 2021 to 2022
- b. Add data element to top of form
 - i. Address type
- c. Question 34a: SARS-CoV-2
 - i. Update wording of main question
 - ii. Update wording of follow up question
 - iii. Added an additional option for test type
 - iv. Remove questions related to first positive test for SARS-CoV-2
 1. Specimen collection date
 2. Test type

3) **CDI Case Report Form and Treatment Form** (*Attachment #11*)

For the 2022 Clostridioides difficile Infection (CDI) Surveillance Emerging infection program Case Report Form (CRF), we are proposing several changes. First, we are changing the phrase “date of incident specimen collection” to “DISC” in 15 instances to harmonize with other EIP pathogens’ CRFs. Second, we are reformatting the address section of the CRF to make Address free text and to add Address Type; Address Type is already collected as a part of surveillance activities but the CRF did not previously have room for this data. Third, we are adding two new questions, Question 28 about fever and Question 33d about serum creatinine in order to capture additional data about symptoms and clinical characteristics of C. difficile infection. Because we’re adding these two new questions into the middle of the form, we had to increment the question numbers of 24 other fields. Fourth, we are revamping the question about testing for SARS-CoV-2 infection (now Question 41) to only capture data on the most recent positive test in the year prior to the DISC instead of both the most recent and first positive test any time before the DISC; accordingly, we re-worded the feeder question to clarify the time period and removed two questions about the first positive test for SARS-CoV-2 infection.

As there is a net addition of 0 questions, 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 2022 *Clostridioides difficile* Infection (CDI) Surveillance Emerging infection program Case Report Form (CRF) include:

Address

- Made address free text

Address type

- New field

Question 4. Date of incident C. diff+ stool collection (DISC)

- Added "(DISC)"

Question 15. Was the patient hospitalized on the day of or in the 6 calendar days after the DISC?

- Changed "date of incident C. diff+ stool collection" to "DISC"

Question 16. Where was the patient located on the 3rd calendar day before the DISC?

- Changed "date of incident C. diff+ stool collection" to "DISC"

Question 20. Exposures to healthcare in the 12 weeks before the DISC

- Changed "date of incident C. diff+ stool collection" to "DISC"

Question 20a.1 If yes, date of discharge closest to DISC

- Changed "date of incident C. diff+ stool collection" to "DISC"

Question 26. Was the patient in an ICU on the day of or in the 6 days after the DISC?

- Changed "date of incident C. diff+ stool collection" to "DISC"

Question 27. Symptoms (in the 6 calendar days before, the day of, or 1 calendar day after the DISC)

- Changed "date of incident C. diff+ stool collection" to "DISC"

Question 28. Fever (in the 2 calendar days before or calendar day of the DISC)

- New field

Question 29. Toxic megacolon and ileus (in the 6 calendar days before, the day of, or the 6 calendar days after the DISC)

- Changed question number
- Changed "date of incident C. diff+ stool collection" to "DISC"

Question 30. Was pseudomembranous colitis listed in the surgical pathology, endoscopy, or autopsy report in the 6 calendar days before, the day of, or the 6 calendar days after the DISC?

- Changed question number
- Changed "date of incident C. diff+ stool collection" to "DISC"

Question 31. Colectomy (related to CDI)

- Changed question number

Question 32. Were other enteric pathogens isolated from stool collected on the DISC?

- Changed question number
- Changed "date of incident C. diff+ stool collection" to "DISC"
- Added "Astrovirus", "Enteroaggregative *E. coli* (EAEC)", "Enteropathogenic *E. coli* (EPEC)", "Enterotoxigenic *E. coli* (ETEC)", "Sapovirus", and "*Yersinia enterocolitica*" as response options

Question 33. LABORATORY FINDINGS (in the 6 calendar days before, the day of, or the 6 calendar days after the DISC)

- Changed question number
- Changed "date of incident C. diff+ stool collection" to "DISC"

Question 33a. Albumin \leq 2.5 g/dl

- Changed question number

Question 33b. White blood cell count \leq 1,000/ μ l

- Changed question number

Question 33c. White blood cell count \geq 15,000/ μ l

- Changed question number

Question 33d. Serum creatinine $>$ 1.5 mg/dl

- New field

Question 34. MEDICATIONS TAKEN in the 12 weeks before the DISC

- Changed question number
- Changed "date of incident C. diff+ stool collection" to "DISC"

Question 34a. Proton pump inhibitor (e.g. Omeprazole, Lansoprazole, Pantoprazole, Rabeprazole)

- Changed question number

Question 34b. H2 Blockers (e.g. Famotidine, Ranitidine, Cimetidine)

- Changed question number

Question 34c. Immunosuppressive therapy

- Changed question number

Question 34d. Antimicrobial therapy

- Changed question number
- Changed "date of incident C. diff+ stool collection" to "DISC"
- Added "Yes, name unknown", "Cefadroxil", "Cefiderocol", "Eravacycline", "Omadacycline", and "Vancomycin (PO for prophylaxis)" as response options

Question 34e. Was patient treated for suspected or confirmed CDI in the 12 weeks before the DISC?

- Changed question number
- Changed "date of incident C. diff+ stool collection" to "DISC"

Question 35. Treatment for incident CDI

- Changed question number

Question 36. Previous unique CDI episode (>8 weeks before the DISC)

- Changed question number
- Changed "date of incident C. diff+ stool collection" to "DISC"

Question 37. Any recurrent C. diff episodes following this incident C. diff episode?

- Changed question number

Question 38. CRF Status

- Changed question number

Question 39. Initials of S.O.

- Changed question number

Question 40. Date of abstraction

- Changed question number

Question 41. 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?

- Changed question number
- Changed "on or before the DISC" to "in the year before or day of the DISC"

Question 41a. If YES, complete below for MOST RECENT positive test for SARS-CoV-2 in the year before or date of the DISC:

- Changed question number
- Changed wording to limit the scope of the question

Question 41a.1. Specimen collection date

- Added question number
- Reworded question

Question 41a.2: Test type

- Added question number
- Reworded question

Question 42a. COVID-NET Case ID

- Changed question number

Question 42b. NNDSS IDs

- Changed question number

4) HAIC CDI Surveillance Officers Survey (Attachment #12)

We are requesting to change the wording of four questions to clarify that the survey is only capturing data on surveillance practices in 2021. There are no other changes to the survey. The requested changes will not change the burden of data collection for each response.

Description of Changes:

Changes to the CDI Surveillance Officers Survey Include:

Question 2. In 2021, did any laboratories drop out of participation?

- Changed year to 2021 to reflect change in survey year

Question 3. In 2021, 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 2021 to reflect change in survey year

Question 10. Did your site complete a physician/outpatient provider survey in 2021?

- Changed year to 2021 to reflect change in survey year

Question 13. For each facility that treated a case in 2021, please provide the following

- Changed year to 2021 to reflect change in survey year

5) **Annual Survey of Laboratory Testing Practices for *C. difficile* Infections** (Attachment #13)

We are requesting to change the wording of twenty four questions to clarify that the survey is only capturing data on lab practices in 2021. There are no other changes to the survey. The requested changes will not change the burden of data collection for each response.

Detailed Descriptions of Changes

- Was this a new laboratory in 2021?
 - o Changed time period of question
- Did this lab participate in surveillance in 2021?
 - o Changed time period of question
- How often did you receive line lists from this lab in 2021?
 - o Changed time period of question
- How did you receive line lists from this lab in 2021?
 - o Changed time period of question
- Did you receive specimens from this lab in 2021?
 - o Changed time period of question
- Types of facilities in your catchment area served by this lab in 2021 (select all that apply):
 - o Changed time period of question
- 1. Did your laboratory ever send specimens off-site for *Clostridioides difficile* testing in 2021?
 - o Changed 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, 2021?
 - o Changed time period of question
- 2c. Did your laboratory perform any onsite testing for *C. difficile* outside of your normal testing algorithm in 2021?
 - o Changed time period of question
- 3a. Which EIA test kit was used by your laboratory in 2021?
 - o Changed time period of question
- 3b. Which Nucleic Acid Amplification test was used by your laboratory in 2021?

- o Changed 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 2021, did your laboratory suppress the *C. difficile* result so that clinicians could not see it?
 - o Changed time period of question
- 4b. If your laboratory used a multiplexed diagnostic in 2021 and the result was suppressed, where does the suppression occur?
 - o Changed time period of question
- 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 2021, did your laboratory suppress the positive NAAT result so that clinicians could not see it?
 - o Changed time period of question
- 5b. If your laboratory used NAAT as first line testing followed by confirmatory toxin EIA testing in 2021, 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 Changed time period of question
- 6. What are the LOINC or internal testing codes associated with the tests your lab used in 2021 (e.g. LOINC codes 13957-6, 34713-8, or 54067-4)?
 - o Changed time period of question
- 7a. In 2021, 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)?
 - o Changed time period of question
- 7b. If your laboratory experienced a supply shortage for *C. difficile* testing in 2021, how did the shortage affect your laboratory's ability to perform *C. difficile* testing? (Check all that apply)
 - o Changed time period of question
- 7c. In 2021, 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?
 - o Changed time period of question
- 8. Did your lab testing algorithm for *C. difficile* change between January 1, 2021 and December 31, 2021?
 - o Changed time period of question
- 8a. (If yes) What was the previous type and order of testing performed by your lab in 2021 before it changed its testing algorithm?
 - o Changed time period of question
- 9. Did your lab have a policy to reject stool specimens for *C. difficile* testing in 2021?
 - o Changed time period of question
- 9a. Did your rejection policy for stool specimens change between January 1, 2021 and December 31, 2021?
 - o Changed time period of question
- 10. How many stool samples did you test for *C. difficile* each month in 2021?
 - o Changed question number

6) **HAIC Candidemia Case Report** (Attachment #14)

Minimal changes are being requested for the 2020 Candidemia Case Report Form (CRF). We are proposing the following changes: 1) addition of 1 question about address type 2) renumbering/reordering of 5 questions that were previously added related to COVID and now being moved and better incorporated into the CRF for ease of use of the form and clarity for the data abstractor 3) subsequent renumbering of other questions as a result of reordering the 5 questions mentioned above of.

Along with other HAIC programs, one question was added to collect information about the type of address listed. The 5 questions added during COVID-19 and are still relevant and were moved to better and more appropriately incorporate them into the CRF. Some specifically address COVID-related risk factors and may be of interest given that the trajectory of the pandemic is difficult to predict. However, many reflect broader epidemiologic interests and healthcare-related risk factors for candidemia beyond COVID and are relevant to incorporate into the CRF more permanently.

The requested changes to the data collection form are not estimated to increase the time required for data collection or the overall burden estimate.

We have updated the number of records in the burden table, resulting in no change in burden hours from the previous year.

Detailed Description of Changes

Changes to the Candidemia case report form for 2021 include:

- a. Title:
 - i. Year changed from 2021 to 2022
- b. Footnotes:
 - i. Changed version year to 2022
 - ii. Changed last updated date from '7/21/2020' to '7/17/2021'
- c. New Question: Address type
- d. COVID-19 Question 1: SARS-CoV-2 test results
 - i. Changed to question number 56
- e. COVID-19 Question 2: Mechanical ventilation
 - i. Changed question number to 35
- f. COVID-19 Question 3: Dialysis or renal replacement therapy
 - i. Changed question number to 36
- g. COVID-19 Question 4: Reason for systemic steroid use
 - i. Changed question number to 58a and text from 'If patient received any systemic steroids in the 30 days before the DISC (question 55), not including the DISC, are any of the following scenarios true' to 'If yes, what was the reason steroids were administered'
- h. COVID-19 Question 5: Immunomodulatory drugs
 - i. Changed question number to 60
- i. Question 35-53
 - i. Changed question number by 2
- j. Question 54-56
 - i. Changed question number by 3
- k. Question 57-59
 - i. Changed question number by 4

- l. Question 61-62
 - i. Changed question number by 3

7) **Laboratory Testing Practices for Candidemia Questionnaire** (*Attachment #15*)

Minimal changes are being requested for the 2022 Candidemia Lab Survey. We are proposing the following changes: 1) the addition of 5 new questions, 2) minor rewording of 2 questions, and 3) renumbering of 10 questions due to the addition of new questions.

There were 2 new questions added about proficiency testing for yeast identification and susceptibility testing. There were also 3 new questions added about culture-independent diagnostic tests to ensure appropriate skip logic within the survey, increase ease of analysis, and provide additional information necessary to assess laboratory capacity not previously included. For the questions we have proposed minor changes to the question wording or response options, these changes were made to accommodate changes in questions numbers and skip logic.

The requested changes to the survey tool are estimated to increase the time required for data collection by 1 minute per response. The new estimate is 12 minutes per response. Despite the changes to the data collection tool, the overall burden estimate has decreased as the number of respondents per site was overestimated in prior years. The number of records from each site was overestimated in last year's burden table (previous estimate of 120). The new estimated number of responses is based on the 2019 surveillance data (number of labs in each surveillance site) and is approximately 20 respondents per site. We have updated the number of hours in the burden table.

Detailed Description of Changes

Changes to the Candidemia laboratory survey for 2021 include:

- a. Title:
 - i. Year changed from 2021 to 2022
- b. New question: proficiency testing for yeast identification
 - i. Added question 12 ('How does this laboratory meet proficiency testing requirements for yeast identification?')
- c. New question: culture independent diagnostic tests (CIDTs)
 - i. Added question 13 ('Does this laboratory employ culture-independent diagnostic tests (CIDT) to identify Candida from blood specimens?')
- d. New question: reflexive culturing practices with BioFire
 - i. Added question 15b ('If Yes, does this lab reflexively culture blood if you get a positive result on BioFire?')
- e. New question: other CIDTs
 - i. Added question 16 ('How does this laboratory meet proficiency testing requirements for antifungal susceptibility testing, if performed?')
- f. New question: proficiency testing for susceptibility testing
 - i. Added question 21 ('How does this laboratory meet proficiency testing requirements for yeast identification?')

- g. Question 13: BioFire
 - i. Changed number of question to 15
 - ii. Minor change to wording of responses (changed instructions from ‘go to 13a’ to ‘go to 15a’ and ‘got to 14’ to ‘go to 16’)
- h. Question 14: plans for CIDTs
 - i. Changed number of question to 17
 - ii. Minor change to wording (changed the word ‘If No for both Question 12 and 13’ to ‘If No for both Question 13’ and added ‘specify’ when responding ‘Yes’)
- i. Question 12: T2Candida
 - i. Changed number of question to 14
- j. Question 15-18
 - i. Changed number of question by 3
- k. Question 19-21
 - i. Changed number of question by 4

8) Invasive *Staphylococcus aureus* (ISA) Laboratory Survey: Use of Nucleic Acid Amplification Testing (NAAT) (Attachment #16)

We are requesting slight revisions to the wording of one question for the 2021 invasive *Staphylococcus aureus* surveillance officer survey. We are also requesting the addition of ten questions; although there are ten additional questions, skip patterns will result in respondents answering 4 or 5 additional questions. The requested changes will have minimal impact on the burden of data collection.

Detailed Description of Changes

A. Changes to the 2021 invasive *Staphylococcus aureus* Surveillance Officer survey include:

- i. Data edits section question 2
 - 1. Added “lead-in” question
 - 2. Added follow up question for a negative response
- ii. Geocoding section question 1
 - 1. Changed wording of question 1
 - 2. Added follow up question for positive response
 - 3. Added follow up question for negative response
- iii. New question(s): Vital Records Linkages
- iv. New question(s): COVID-19 impact