

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

#### **1) 2021 ABCs Neonatal Infection Expanded Tracking Form (Attachment 3)**

There is no impact on burden due to the changes on this form. For Question 3C, currently the case report forms only allow for sites to indicate that gestational age was determined by 1) Dates (Last Menstrual Period), 2) Physical Exam, 3) Ultrasound, or 4) Unknown. With these options when charts indicate that estimated due date (EDD) was determined by Assisted Reproductive Technology (ART) there isn't an appropriate option for sites to select. In 2015, 1.7% of all births were a result of ART, and ART exceeded the national rate in 4 out of 10 EIP states (CA, CT, MD, NY). Additionally, that proportion is much higher in infants born preterm or low birthweight (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5829941/>). In order to accurately capture method for calculating gestational age, the current options available are inadequate. Value set change is listed below for the following data element:

##### **a. Question 3C. Gestational age determined by:**

Added response option '4=Assisted Reproductive Technology' (ART) to select when pregnancy resulted from ART (e.g., in vitro fertilization) and the estimated due date (EDD) was assigned using the ART-derived gestational age

### **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 to streamline, collect level of detail needed, and for consistency with FDD MMG. Value set changes are listed below for the following data elements:

##### **a. AgClinicstesttype, AgSPHLtesttype**

i. Abbott Campylobacter Quik Chek

##### **b. PcrClinic, PcrSphl**

i. Vibrio Value: Negative

##### **a. AgClinicstesttype, AgSPHLtesttype**

ii. Abbott Campylobacter Quik Chek

##### **b. PcrClinic, PcrSphl**

- iii. Vibrio Value: Negative
- c. **OtherClinicTestType, OtherSphlTestType**
  - iv. Microscopy Unspecified
  - v. Modified Acid-Fast
  - vi. Modified Safranin Stain

## 2) FoodNet Diagnostic Laboratory Practices and Volume Data Elements (Attachment 5)

There is no impact on burden due to the changes on these data elements. Recently additional tests have become available for identifying *Listeria*. As a result, protocols for detecting *Listeria* from CSF and blood now vary. The original data element for protocol used to identify *Listeria* was one data element, to accommodate variations in protocols based on specimen there are now two data elements being collected based on the specimen being tested with updated value sets for each:

### a. LisProtocolBld

- i. PCR concurrently used with culture
- ii. PCR performed first, if positive reflex culture performed
- iii. Only PCR panels, no culture is performed
- iv. Only culture, no PCR test is performed

### b. LisProtocolCSF

- i. PCR concurrently used with culture
- ii. PCR performed first, if positive reflex culture performed (routine)
- iii. PCR performed first, if positive reflex culture performed (provider order)
- iv. PCR or culture or some combination thereof based on provider order
- v. Only PCR panels, no culture is performed
- vi. Only culture, no PCR test is performed

## **FluSurv-Net:**

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

### **1) FluSurv-NET Influenza Hospitalization Surveillance Network Case Report Form (Attachment 6)**

In light of the Coronavirus Disease 2019 (COVID-19) pandemic, for the upcoming 2020-21 influenza season, we will harmonize many data elements with those collected on the COVID-NET CRF and maintain the same surveillance approach as in previous years and will continue to provide weekly updates of influenza hospitalization rates through the CDC webpage (FluView). Due to the larger burden of COVID-19 cases expected during the 2020-21 season, we will remove some data fields from the FluSurv-NET CRF to decrease the burden of data collection on sites.

1. Added COVID-NET and RSV-NET CaseIDs to identify cases with co-infection.
2. Added CDCTrack variable for tracking sampled records for full chart reviews.
3. For Section C, Enrollment Information, we changed the option “Home with services” to “Private residence with services”.
4. Section E, ICU and Other Interventions, we added BiPAP or CPAP use.
5. Section E, ICU and Other Interventions, we added High flow nasal cannula (e.g. Vapotherm).
6. Section E, ICU and Other Interventions, we added Vasopressor use.
7. Section E, ICU and Other Interventions, we added Renal Replacement Therapy or Dialysis.
8. Section F, Outcome, we added additional checkboxes for patient location when discharged alive – “Against medical advice” and “Discharged to another hospital”.
9. Section G, Admission and Patient History, we deleted the question “Alcohol abuse”.
10. Section G, Admission and Patient History, we deleted the question “Substance abuse”.
11. Section G, Admission and Patient History, we deleted the question “Substance Abuse Type”.
12. Section G, Admission and Patient History, we deleted the question “Current Non-Tobacco Smoking”.
13. We moved options for pre-existing medical conditions from Admission and Patient History section and created a new Section I, Underlying Medical Conditions.
14. For Section I, Underlying Medical Conditions, we added a new Header category labeled “Hypertension”.
15. Section I, Underlying Medical Conditions, we combined the Neurological and Neuromuscular subcategories into one Neurological Disorders category.
16. Section I, Underlying Medical Conditions, we deleted “Total number of pregnancies to date”.

17. Section I, Underlying Medical Conditions, we deleted “Total number of pregnancies to date that result in a live birth”.
18. Section I, Underlying Medical Conditions, we deleted “Total number of fetuses for current pregnancy”.
19. Section I, Underlying Medical Conditions, we deleted “Gestational age in weeks”
20. Section K, Discharge Summary, we deleted “Pregnancy status at discharge”.
21. Section K, Discharge Summary, we deleted “Pregnancy outcome at discharge if no longer pregnant at discharge.
22. Section K, Discharge Summary, we deleted “date of delivery or end of pregnancy if no longer pregnant”
23. We deleted the entire Section J, Bacterial Pathogens, including Were any bacterial culture tests performed with a collection date within three days of admission, positive culture for bacterial pathogen, specify pathogen, site where pathogen identified, date of positive culture, and specify *Staphylococcus aureus* sensitivity.
24. Section K, Viral Pathogens, we changed the timeframe to collect positive viral test date to “within 7 days after admission, and if deceased, 14 days prior to death or 24 hours after death”.
25. Section K Viral Pathogens, we deleted results for Adenovirus, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, Human metapneumovirus, Rhinovirus/Enterovirus, and other Coronavirus.
26. Section K, Viral Pathogens, we added a row for Coronavirus SARS-CoV-2 test result.
27. Section L, Treatment, we deleted “Total Duration (days)”.
28. We deleted the entire Section N, Chest Imaging, including Was chest x-ray taken within 3 days of admission, were any of these chest x-rays abnormal, date of first abnormal chest x-ray, and abnormal checkboxes: report not available, air space density, air space opacity, bronchopneumonia/pneumonia, cannot rule out pneumonia, consolidation, cavitation, ARDS, lung infiltrate, interstitial infiltrate, lobar infiltrate, other, and pleural effusion/empyema.
29. Section O, Discharge Summary, we added new discharge diagnoses: Acute liver failure, Bronchitis, Chronic lung disease of prematurity/BPD, Deep vein thrombosis, Disseminated intravascular coagulation (DIC), Kawasaki disease, Multisystem inflammatory syndrome in children (MIS-C), Other thrombosis/embolism/coagulopathy, Pulmonary embolism, and Toxic shock syndrome (TSS).

2) **FluSurv-NET/RSV-NET Hospital Laboratory Survey** (*Attachment 7*)

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

1. Question 5a & 5b – Added 3 new multiplex assays that detect influenza and SARS-CoV-2 including Biofire Respiratory Panel 2.1 (RP2.1) (BioFire Diagnostics, LLC), CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay (CDC Influenza Division), QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN)
2. Question 5d – Added new multiplex assays that can detect influenza subtype including Biofire Respiratory Panel 2.1 (RP2.1) (BioFire Diagnostics, LLC) and QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN)
3. Question 8 – Changed the season to “2019-2020” season
4. Question 12a & 12b – Added new RSV test kit names including "Cepheid GeneXpert® Infinity-48 System (Cepheid), ePlex® Respiratory Pathogen Panel (GenMark Diagnostics), NxTAG® Respiratory Pathogen Panel (Luminex Molecular Diagnostics Inc.), and Panther Fusion™ Flu A/B RSV (Hologic)
5. Question 12a & 12b – Changed “x-TAG Respiratory Viral Panel Fast (RVP FAST) (Luminex Molecular Diagnostics Inc)” to “xTAG® Respiratory Viral Panel (RVP or RVP FAST or RVP Fast v2) (Luminex Corporation)”
6. Question 18 & 19 – Changed the season to “2019-2020” season

## **HAIC:**

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

### **1) MuGSI Case Report Form for Carbapenem-resistant Enterobacteriaceae (CRE) and *Acinetobacter baumannii* (CRAB) (Attachment 8)**

For the 2021 Carbapenem Resistant Enterobacteriaceae (CRE)/ Carbapenem Resistant *A. baumannii* (CRAB) Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF), we are proposing the following changes: 1) we added a “Streck ARM-D” checkbox as a molecular test for the carbapenemase testing question; 2) we added a checkbox for cefiderocol, ceftazidime, ceftazidime-avibactam, eravacycline, and omadacycline to the susceptibility results question; 3) we added sensititre as a data source for the susceptibility results question; 4) we removed questions 22d, 25, 26, 27a, 28a, 28b, 29a, and 29b that were on the 2020 CRF; 5) we added the CDC 2019-nCoV ID from the National Notifiable Disease Surveillance System (NNDSS); 6) we expanded the CRAB case definition to include cultures from wounds and respiratory sources (i.e., bronchoalveolar lavage, sputum, tracheal aspirate, and other lower respiratory tract); and 7) we added a question about chest radiology findings to be completed for CRAB cases from respiratory sources or CRAB cases from non-respiratory sources with pneumonia.

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**

- A. Changes to the 2021 Carbapenem Resistant Enterobacteriaceae (CRE)/ Carbapenem Resistant *A. baumannii* (CRAB) Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form include:
  - a. Title
    - i. Updated year
  - b. Burden statement
    - i. Updated the estimated average time to complete the form to 28 minutes per response
  - c. Question 11: Incident specimen collection site
    - i. Added the following specimens for CRAB surveillance:
      1. Bronchoalveolar lavage
      2. Sputum
      3. Tracheal aspirate
      4. Wound
      5. Other LRT site
  - d. Question 17a: Types of infection associated with culture(s)

- i. Added a note about completing Q23c for CRAB cases with pneumonia
- e. Question 23c: Did the patient have a sputum culture positive for CRAB in the 30 days before the DISC?
  - i. Updated question number
- f. Question 23b: Risk factors in the 7 days before the DISC
  - i. Updated question number
- g. Question 23c: Chest radiology findings
  - i. Added this question
- h. Question 24a: Did the patient have a positive test(s) for SARS-COV-2 (molecular assay, serology, or other confirmatory test) on or before the DISC?
  - i. Updated question number
- i. Question 24b: If yes, complete table below
  - i. Updated question number
  - ii. Added “antigen” as a test type
- j. Question 24c: COVID-NET Case ID
  - i. Updated question number
- k. Question 24d: NNDSS IDs (please provide at least one of the following when applicable)
  - i. Updated question number
  - ii. Added CDC 2019-nCOV ID
- l. Question 25: Was the incident specimen polymicrobial?
  - i. Updated question number
- m. Question 26a: Was the incident specimen tested for carbapenemase?
  - i. Updated question number
- n. Question 26b: If yes, what testing method was used (check all that apply)
  - i. Updated question number
  - ii. Added Streck ARM-D as molecular test
- o. Question 26c: If tested, what was the testing result
  - i. Updated question number
- p. Question 27: Susceptibility results
  - i. Added sensititre as a data source
  - ii. Added cefiderocol, ceftazidime, ceftazidime-avopivoxil, eravacycline, and omadacycline

- q. Question 28a: Was case first identified through audit?
  - i. Updated question number
- r. Question 28b: CRF status
  - i. Updated question number
- s. Question 28c: SO initials
  - i. Updated question number
- t. Question 28d: Date of abstraction
  - i. Updated question number
- u. Question 28e: Comments
  - i. Updated question number
- v. Removed the following questions:
  - i. Question 22d. Urine cultures only: Was a blood culture positive in the 3 calendar days before through the 3 calendar days after the DISC for the same MuGSI organism?
  - ii. Question 25. Was the same organism (Q10) cultured from a different sterile site or urine in the 30 days after the DISC?
  - iii. Question 26. Enterobacteriaceae only: Were cultures of sterile site(s) or urine positive for a different organism (Q10) in the 30 days before the DISC?
  - iv. Question 27a. *A. Baumannii* cultures only: Were cultures of other sterile site(s) or urine positive for another *A. baumannii* in the 30 days before the DISC?
  - v. Question 28a. Was the patient positive for the same organism in the year before the DISC?
  - vi. Question 28b. If yes, specify date of culture and state ID for the first positive culture in the year before
  - vii. Question 29a: Enterobacteriaceae only: Was the patient positive for a MuGSI Enterobacteriaceae in the year before the DISC?
  - viii. Question 29b: If yes, specify organism, date of culture, and state ID for the first positive Enterobacteriaceae culture in the year before the DISC?

## **2) Multi-site Gram-Negative Surveillance Initiative (MuGSI)- Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (ESBL) (Attachment 9)**

For the 2021 Extended-Spectrum Beta-Lactamase (ESBL)-Producing Enterobacteriaceae Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF), we are proposing the following changes: 1) we added a checkbox for cefiderocol, eravacycline, and omadacycline to the antimicrobial use in the 30 days before the date of incident specimen collection question; 2) we added a checkbox for cefiderocol, cefoxitin, eravacycline, and omadacycline to the susceptibility results question; 3) we added sensititre as a data source for

the susceptibility results question; 4) we added the CDC 2019-nCoV ID from the National Notifiable Disease Surveillance System (NNDSS); and 5) we added “antigen” as a test type for question 24b.

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

- A. Changes to the 2021 Extended-Spectrum Beta-Lactamase (ESBL)-Producing Enterobacteriaceae Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form include:
  - a. Title
    - i. Updated year
  - b. Burden statement
    - i. Updated the estimated average time to complete the form to 28 minutes per response
  - c. Question 24a: Is antimicrobial use (IV or oral) in the 30 days before the DISC documented
    - i. Updated question number
  - d. Question 24b: If yes, check all antimicrobials used in the 30 days before the DISC
    - i. Updated question number
    - ii. Added checkbox for cefiderocol, eravacycline, and omadacycline
  - e. Question 25a: Did the patient have a positive test(s) for SARS-Cov-2 (molecular assay, serology or other confirmatory test) on or before the DISC
    - i. Updated question number
  - f. Question 25b: If yes for Q25a, complete table below
    - i. Updated question number
    - ii. Add “antigen” as a test type
  - g. Question 25c: COVID-NET Case ID
    - i. Updated question number
  - h. Question 25d: NNDSS IDs
    - i. Updated question number
    - ii. Added CDC 2019-nCoV ID
  - i. Question 26a: Was the incident specimen polymicrobial
    - i. Updated question number
  - j. Question 26b: What screening/confirmatory method was used for ESBL identification
    - i. Updated question number
  - k. Question 26c: If screening/confirmatory method was used, what was the result

- i. Updated question number
- l. Question 27: susceptibility results
  - i. Added checkbox for cefiderocol, ceftazidime, eravacycline, and omadacycline
  - ii. Added sensitivity as a data source

### 3) **Invasive MRSA Infection Case Report Form** (*Attachment 10*)

Minimal changes are being requested for the 2020 Methicillin-resistant *Staphylococcus aureus* (MRSA) Case Report Form. We are proposing the following change: addition of NNDSS CDC 2019 NCOV ID for patients that have a positive SARS-CoV-2 assay.

#### Detailed Description of Changes

- A. Changes to the 2020 Methicillin-resistant *Staphylococcus aureus* (MRSA) Case Report Form includes:
  - a. Title
    - i. Changed the year from 2020 to 2021
  - b. Question 34a: SARS-CoV-2
    - i. Added an NNDSS ID field

### 4) **Invasive MSSA Infections Case Report Form** (*Attachment 11*)

Minimal changes are being requested for the 2020 Methicillin-sensitive *Staphylococcus aureus* (MSSA) Case Report Form. We are proposing the following change: addition of NNDSS CDC 2019 NCOV ID for patients that have a positive SARS-CoV-2 assay.

#### Detailed Description of Changes

- A. Changes to the 2020 Methicillin-sensitive *Staphylococcus aureus* (MSSA) Case Report Form includes:
  - a. Title
    - i. Changed the year from 2020 to 2021
  - b. Question 34a: SARS-CoV-2
    - i. Added an NNDSS ID field

### 5) **CDI Case Report Form and Treatment Form** (*Attachment 12*)

For the 2021 *Clostridioides difficile* Infection (CDI) Surveillance Emerging infection program Case Report Form (CRF), we are proposing the following changes: 1) we added the collection of “antigen” test type for our question collecting information about SARS-CoV-2 testing; 2) we added the CDC 2019-nCOV ID from the National Notifiable Disease Surveillance System (NNDSS) so that we can better link these data with our surveillance data at CDC. A single wording change was made for question 9, we removed the word Positive. This is noted because in our previous submission, we documented that this change was made, but the work was mistakenly not removed from the actual CRF.

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.

The changes to the 2021 *Clostridioides difficile* Infection (CDI) Surveillance Emerging infection program Case Report Form (CRF) include:

Question 9. Diagnostic assay for *C. diff*

- Reworded question to remove the word “positive”.
- Change was noted on last year’s application but mistakenly not changed on the CRF
- Response options remain the same

Question 40a. First positive test for SARS-CoV-2 on or before the DISC – Test type

- Added antigen as a response option
- Antigen was previously captured as “other”

Question 40a. Most recent positive test for SARS-CoV-2 on or before the DISC – Test type

- Added antigen as a response option
- Antigen was previously captured as “other”

Question 41b. NNDSS IDs

- Added CDC 2019-nCoV ID as a response option

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

We are not requested any major changes for the Annual Survey of Laboratory Testing Practices for *C. difficile* Infection. The changed documented are to update the date within the survey question (3 questions) and to clarify the wording to better collect testing codes. The requested changes will have no impact on the burden of data collection.

#### Detailed Descriptions of Changes

- Section 1
  - Was this lab audited in 2020?
    - Changed year to 2020 to reflect change in survey year
- Section 2
  - 5. What are the LOINC or internal testing codes associated with the tests your lab currently uses (e.g. LOINC codes 13957-6, 34713-8, or 54067-4)?
    - Clarified that we’re asking for LOINC or internal testing codes
    - Added examples of LOINC codes
  - 6. Has your lab testing algorithm for *C. difficile* changed since January 1, 2020?
    - Changed year to 2020 to reflect change in survey year
  - 7a. Has your rejection policy for stool specimens changed since January 1, 2020?

- Changed year to 2020 to reflect change in survey year

#### 7) **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) the addition of 9 new questions, 2) minor rewording of 6 questions, 3) minor rewording of response options in 7 questions, and 4) renumbering/reordering of 10 questions due to the addition of other questions and/or for ease of use of the form and clarity for the data abstractor.

Five of the 9 new questions that were added relate to COVID-19 and have been included to capture changes in epidemiology in light of the increase in COVID-19 cases within the US. Given that a high proportion of individuals diagnosed with COVID-19 are hospitalized, with many requiring ICU-level care, the risk for hospital-acquired infections, such as candidemia, increases. The Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET) conducts population-based surveillance for laboratory-confirmed COVID-19-associated hospitalizations; however, this system does not collect information on fungal-related infections (such as candidemia) among COVID-19 patients. Therefore, the addition of COVID-19-related questions to the candidemia surveillance case report form provides information about co-infections not collected elsewhere. The collection of epidemiologic data regarding COVID-19 diagnosis and disease risk factors among candidemia patients can provide information on change in incidence, clinical course, and morbidity/mortality. The other 4 new questions relate to prominent risk factors or predictors of candidemia severity/outcomes in current literature, and therefore we plan to incorporate these into CDC's candidemia surveillance system.

For the questions we have proposed minor changes to the question wording or response options, these changes were made to both increase clarity based on feedback from data abstractors, as well as, include information on risk factors that have been shown to influence candidemia outcomes in current literature.

The requested changes to the data collection form are estimated to increase the time required for data collection by 10 minutes per case report form. Despite the changes to the data collection tool, the overall burden estimate has increased by only 133 hours total across all sites. The number of records from each site was overestimated in last year's burden table (previous estimate of 200). The new estimated number of responses is based on 2019 surveillance data and is approximately 170 case report forms per site. We have updated the number of records in the burden table, resulting in an overall minor increase in burden hours from the previous year.

Changes to the Candidemia case report form for 2021 include:

- a. Title:
  - ix. Year changed from 2020 to 2021
- b. Footnotes:
  - x. Changed version year to 2021
  - xi. Changed last updated date from '7/9/2019' to '7/21/2020'
- c. Question 25: Antifungal susceptibility testing
  - xii. Removed "NS" interpretation option

- d. Question 26: Additional non-Candida organisms
  - xiii. Changed question number to 29
- e. Question 26a: Additional non-Candida organisms
  - xiv. Changed question number to 29a
  - xv. Removed “NS” interpretation option for AFST data table
- f. Question 27: Infection with *Clostridioides difficile*
  - xvi. Changed question number to 30
  - xvii. Changed the wording of the timeframe for clarification from ‘90 days before or 30 days after the DISC’ to ‘on the day of or in the 89 days before or 29 days after the DISC’
- g. Question 27a: Infection with *Clostridioides difficile*
  - xviii. Changed question number to 30a
- h. Question 28: Any subsequent positive Candida blood cultures
  - xix. Changed question number to 26
- i. Question 28a: If yes, provide dates
  - xx. Changed question number to 26a
- j. Question 29: Documented negative Candida blood culture
  - xxi. Changed question number to 27
  - xxii. Added in parenthesis “(in which no blood cultures after this negative culture were positive in the 29 days after the DISC)” for question clarification
- k. Question 29a: If yes, date of negative culture
  - xxiii. Changed question number to 27a
- l. New question: MDROs
  - xxiv. Added question 28 (‘On the day of or in the 6 days before the DISC, was the patient known to be colonized with or being managed as if they were colonized with a multi-drug resistant organism (MDRO) (e.g., on contact precautions)? MDROs include CRE, CRPA, CRAB, MRSA, and VRE.’)
- m. New question: MDROs
  - xxv. Added question 28a (‘If yes, specify organisms’)
- n. Question 30: Types of infection/colonization
  - xxvi. Changes question number to 31
  - xxvii. Re-organized, added to, and edited response options according to the following:
    - 1. Removed ‘abscess’ category option (and removed sub-options under ‘abscess’)

2. Removed 'Peritonitis' category option
  3. Removed 'Respiratory specimen with Candida' category option
  4. Removed 'Septic emboli' category option (and removed sub-option under 'septic emboli')
  5. Removed 'Brain' category option
  6. Added "abdominal" category option and added the following sub-options: 'Hepatobiliary or pancreatic,' 'GI tract,' 'Abscess (specify),' 'Peritonitis/peritoneal fluid,' and 'Splenic' under the abdominal category
  7. Added 'Esophagitis' category option
  8. Added 'Oral/thrush' category option
  9. Added the word 'wounds' to the 'skin lesions' category option
  10. Added 'Pulmonary' category option, and added the following sub-options: 'abscess' and 'respiratory specimen with *Candida*' under the pulmonary category
  11. Added 'septic emboli' category under the 'Endocarditis' category (as a sub-category), and added a specification for 'septic emboli'
- o. Question 31: hospitalized
    - xxviii. Changed question number to 32
  - p. Question 31a: date of admission
    - xxix. Changed question number to 32a
  - q. Question 31b: Was the patient transferred
    - xxx. Changed question number to 32b
  - r. Question 32: prior location to DISC
    - xxxi. Changed question number to 32c
    - xxxii. Reworded the question and timeframe for the question for clarification (added 'or, if not hospitalized, where was the patient located on the 3rd calendar day before the DISC')
    - xxxiii. Added in an additional answer choice ('hospital inpatient')
  - s. Question 40: underlying conditions
    - xxxiv. Added 2 additional response options ('hepatitis B, chronic', 'hepatitis B, acute')
  - t. Question 47: surgeries
    - xxxv. Changed timeframe of question from '89 days before the DISC' to '90 days before, not including the DISC'
    - xxxvi. Added a specification for type of abdominal surgery

- xxxvii. Added checkbox for type of abdominal surgery ('open abdomen', 'laparoscopic', or 'unknown')
- u. Question 48: pancreatitis
  - xxxviii. Changed timeframe of question from '89 days before the DISC' to '90 days before, not including the DISC'
- v. Question 49a: urinary tract procedures
  - xxxix. Changed timeframe of question from '89 days before the DISC' to '90 days before, not including the DISC'
- w. Question 53: indwelling devices
  - xl. Added minor edits to question wording for clarification (added 'or other devices')
  - xli. Added "invasive mechanical ventilation" as a response option
- x. New Question: systemic steroids
  - xlii. Added question 55 ('Did the patient receive any systemic steroids in the 30 days before, not including the DISC?')
- y. Question 55: TPN
  - xliii. Changed question number to 56
- z. Question 56: Antifungals before
  - xliv. Changed question number to 57
- aa. Question 57: Antifungals after
  - xlv. Changed question number to 58
- bb. Question 58: antifungal medications not given
  - xlvi. Changed question number to 59
  - xlvii. Added clarification to one of the response options ("or contaminated")
- cc. Question 59: antifungal medications specified
  - xlviii. Changed question number to 60
- dd. New question: contamination
  - xlix. Added question 61 ('Does the chart indicate that the incident specimen was considered a contaminant or was considered to not be indicative of true of infection?')
- ee. New question: ID physician
  - l. Added question 62 ('Was the patient under the care of an infectious disease physician on the day of the DISC or within the 6 days after the DISC?')
- ff. New questions: COVID-19 Questions
  - li. Added 5 new questions related to COVID-19 ('COVID-19 Questions 1-5');

1. 'Did the patient have a positive SARS-CoV-2 test result (molecular assay, serology, or other confirmatory test) from a specimen collected in the 30 days before the DISC or on the DISC?'
  - a. '1a. If yes, date of specimen collection for initial positive SARS-CoV-2 test:'
2. 'Did the patient receive invasive mechanical ventilation in the 30 days before the DISC, not including the DISC?'
3. 'Did the patient receive dialysis or renal replacement therapy (RRT) in the 30 days before the DISC, not including the DISC?'
4. 'If patient received any systemic steroids in the 30 days before the DISC, not including the DISC (question 55), are any of the following scenarios true? (check all that apply)'
5. 'Did the patient receive any of the following immunomodulatory drugs in the 30 days before the DISC, not including the DISC? (check all that apply)'
  - a. '5a. If yes (and patient had a positive SARS-CoV-2 test), were any of the immunomodulatory drugs given as part of treatment/management for COVID-19?'

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

Minimal changes are being requested for the 2020 Candidemia Lab Survey. We are proposing the following changes: 1) the addition of 2 new questions, 2) minor rewording of 8 questions, and 3) renumbering of 13 questions due to the addition of new questions.

The 2 new questions ensure appropriate skip logic within the survey for 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 increase clarity based on feedback from respondents.

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 11 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 records in the burden table, resulting in an overall decrease in burden hours from the previous year.

Changes to the Candidemia laboratory survey for 2021 include:

- a. Title:
  - iii. Year changed from 2020 to 2021
- b. New question: yeast identification
  - liii. Added question 7 ('Does this laboratory offer yeast identification either onsite or sent to another laboratory?')

- c. New question: yeast identification location
  - liv. Added question 8 ('Where is yeast identification done?')
- d. New instructions: between questions 8 and 9
  - lv. New instructions state: 'Answer the following questions for the lab selected in question 8.'
- e. Question 7: How yeast is identified
  - lvi. Changed number of question to 9
  - lvii. Minor change to wording (changed the word 'your' to 'this')
- f. Question 8: Chromager
  - lviii. Changed number of question to 10
  - lix. Minor change to wording (changed the word 'your' to 'this')
- g. Question 9: Types of isolates for species-level identification
  - lx. Changed number of question to 11
- h. Question 10: T2Candida Panel
  - lxi. Changed number of question to 12
  - lxii. Changed skip logic question numbers in response options from 'go to 10a/go to 11' to 'go to 12a/go to 13'
  - lxiii. Minor change to wording (changed the word 'your' to 'this')
- i. Question 11: BioFire
  - lxiv. Changed number of question to 13
  - lxv. Changed skip logic question numbers in response options from 'go to 11a/go to 12' to 'go to 13a/go to 14'
  - lxvi. Minor change to wording (changed the word 'your' to 'this')
  - lxvii. Deleted Question 11b: Biofire reflexive use
- j. Question 12: Future CIDTs
  - lxviii. Changed number of question to 14
  - lxix. Minor changes to wording of question (changed the word 'your' to 'this,' changed numbers '10/11' to '12/13' in question)
  - lxx. Removed phrase 'Yes to Q17 or Q18' in 'not applicable' response option
- k. Question 13: AFST
  - lxxi. Changed number of question to 15

- lxxii. Minor changes to wording (changed the word ‘your’ to ‘this,’ added ‘either onsite or sent to another laboratory’ for clarification)
- lxxiii. Removed instructions ‘Continue to Page 2’ in ‘yes’ response option
- l. Question 14: AFST location
  - lxxiv. Changed number of question to 16
  - lxxv. Changed question wording from ‘check all that apply’ to ‘check the most applicable’
  - lxxvi. Added an additional answer choice (‘Sent to other local/regional, non-affiliated reference or public health laboratory’)
- m. New instructions: between questions 16 and 17
  - lxxvii. New instructions state: ‘Answer the following questions for the lab selected in question 16.’
- n. Question 15: AFST drugs
  - lxxviii. Changed number of question to 17
- o. Question 16: AFST methods
  - lxxix. Changed number of question to 18
- p. Question 17: AFST results reporting
  - lxxx. Changed number of question to 19
- q. Question 18: FAST type of isolate
  - lxxxii. Changed number of question to 20
- r. Question 19: AFST performed
  - lxxxiii. Changed number of question to 21
  - lxxxiii. Minor change to question wording (deleted ‘automatically/reflexively’ for each species specific sub-question)
  - lxxxiv. Minor changes to skip logic pattern:
    - 1. Changed ‘go to 19ai/19bi/19ci/19di’ to ‘go to 21ai/21bi/21ci/21di’ in the ‘performed automatically/reflexively’ option choices
    - 2. Added ‘go to 21ai/21bi/21ci/21di’ in the ‘performed with a clinician’s order’ option choices

9) **Invasive *Staphylococcus aureus* (iSA) Laboratory Survey: Use of Nucleic Acid Amplification Testing (NAAT)** (Attachment 16)

We are requesting slight re-wording of five existing questions for the 2021 invasive *Staphylococcus aureus* laboratory survey to increase question clarity. We are also requesting the addition of three questions and a comment field; two of the added questions will not be answered by every respondent given the skip patterns. The requested changes will have no impact on the burden of data collection.

Detailed Description of Changes

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

- a. Question 1
  - i. Updated question wording and skip pattern
- b. Question 1a
  - i. Updated question wording
- c. Question 2
  - i. Added question
- d. Question 2a
  - i. Added question
- e. Question 3
  - i. Updated question wording, question number, and skip pattern
- f. Question 3a
  - i. Updated question wording, question number, and skip pattern
- g. Question 3b
  - i. Updated question number
- h. Question 3c
  - i. Updated question number and skip pattern
- i. Question 3d
  - i. Updated question number
- j. Question 3e
  - i. Updated question wording and question number
- k. Question 3f
  - i. Added question
- l. Question 4
  - i. Updated question number
- m. Comments
  - i. Added comments field