Explanation for Program Changes or Adjustments

This is a request for a revision. There are 13 total forms being changed as a part of this revision and no new forms being added. Most of the collection activities remain the same, however, there are a few proposed revisions including minor revised language and rewording to improve clarity and readability of the data collection forms.

In response to the Notice of Decision published in the Federal Register on March 29, 2024 regarding the update of the Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15), the EIP programs (ABCs, FoodNet, FluSurv-NET, and HAIC) under OMB 0920-0978 will comply with the updated standards set for Federal data on Race and Ethnicity by and/or before the March 2029 deadline.

Due to the timing of the Influenza data collection season (October 1), FluSurv-NET has incorporated the updated race and ethnicity (R/E) data standards in their data collection forms as part of this Revision to capture the updated R/E variable at the beginning of their data collection season. The remaining 3 EIP programs (ABCs, FoodNET, and HAIC) will update the R/E variable in a subsequent non-substantive change request to maintain data integrity since their respective data collection period begins on Jan 1. Maintaining data integrity and consistency is paramount to quality data analysis therefore, waiting to incorporate the race and ethnicity changes at the beginning of FY25 for ABCs, FoodNET and HAIC would ensure that the race ethnicity data variable will possess consistent parameters and easier for analysis at the beginning of their data collection cycle as opposed to mid-season.

In this revision, EIP, specifically FluSurv-Net, is requesting an exemption to the requirement to collect more detailed data beyond the minimum categories. The justification for using the minimum race and ethnicity categories are as follows: 1) Detailed data collection would potentially be more burdensome for the state surveillance officers and may not add as much value, given that the additional check boxes will likely have few case counts; 2) There will not likely be sufficient number of cases identified to allow the disaggregated racial/ethnic categories to be analyzed separately; any analysis done will require aggregating the data into the minimum required categories; 3) EIP data collection is primarily conducted through medical record reviews and not through patient interviews. The expanded data collection would be intended for interviews rather than chart reviews, therefore not applicable to EIP data collection; 4) The detailed race/ethnicity

population groups likely comprise a small percentage of the EIP surveillance catchment areas and the collection of these groups could pose additional risk to data privacy and identification of individuals.

Details of each collection instrument for the revision are as follows:

ABCs:

This Revision includes proposed changes to 3 of the 5 approved Active Bacterial Core surveillance (ABCs) forms and no new ABCs data collection tools (form/s) detailed below:

Approved Forms with **no changes** noted:

1) ABC.100.3 ABCs H. influenzae Neonatal Sepsis Expanded Surveillance Form

2) ABC.100.4 ABCs Severe GAS Infection Supplemental Form

Changes to Approved Forms:

1) ABC.100.1 ABCs Case Report Form

2) ABC.100.2 ABCs Invasive Pneumococcal Disease in Children and Adults Case Report Form

3) ABC.100.5 ABCs Neonatal Infection Expanded Tracking Form

ABCs Case Report Form (ABC.100.1)		
Type of Change	**Itemized Changes / Justification**	**Impact to Burden**
Deletion	Removal of “other prior illness” and “specify other prior illness” fields from Q27 Underlying causes or prior illnesses section. **Justification:** Other prior illness has been kept on the form for site use only. Removal of this option from the form will reduce confusion on when to select “No underlying conditions” for sites and improve data edit checks.	No change to burden
ABCs Invasive Pneumococcal Disease in Children and Adults Case Report Form (ABC.100.2)		
Type of Change	**Itemized Change / Justification**	**Impact to Burden**
Addition	Most recent influenza vaccine date **Justification:** Information on these vaccines will help to better assess pneumococcal disease risk and vaccine effectiveness.	No change to burden. Surveillance staff already review patient’s medical chart as well as State immunization information systems (IIS) or vaccine registries, when possible, to check for existing pneumococcal vaccination information

		questions. If influenza vaccination information is available in the same source(s) influenza vaccination date will also be recorded.
Addition	Most recent COVID-19 vaccine date **Justification:** Information on these vaccines will help to better assess pneumococcal disease risk and vaccine effectiveness.	No change to burden Surveillance staff already review patient's medical chart as well as State immunization information systems (IIS) or vaccine registries, when possible, to check for existing pneumococcal vaccination information questions. If COVID-19 vaccination information is available in the same source(s) COVID-19 vaccination date will also be recorded.
Addition	RSV vaccine date (complete for adults ≥65 years only) **Justification:** Information on these vaccines will help to better assess pneumococcal disease risk and vaccine effectiveness.	No change to burden Surveillance staff already review patient's medical chart as well as State immunization information systems (IIS) or vaccine registries, when possible, to check for existing pneumococcal vaccination information questions. If RSV vaccination information is available in the same source(s) RSV vaccination date will also be recorded. This information will only be checked for adults 65 years and older.
Addition	RSV monoclonal antibody date (complete for children <5 years only) **Justification:** Information on these vaccines will help to better assess pneumococcal disease risk and vaccine effectiveness.	No change to burden Surveillance staff already review patient's medical chart as well as State immunization information systems (IIS) or vaccine registries, when possible, to check for existing pneumococcal vaccination information questions. If RSV preventive antibody information is available in the same source(s) RSV preventive antibody date will also be recorded. This information will only be checked for adults children under 5 years old.
ABCs Neonatal Infection Expanded Tracking Form (ABC.100.5)		
Type of Change	**Itemized Change / Justification**	**Impact to Burden**

Deletion	Removal of “other prior illness” and “specify other prior illness” fields from Q14a Maternal underlying or prior illnesses section. **Justification**: Other prior illness has been kept on the form for site use only. Removal of this option from the form will reduce confusion on when to select “No underlying conditions” for sites and improve data edit checks.	No change to burden

FoodNet:

This Revision includes proposed changes to 1 of the 3 approved FoodNet forms and no new FoodNet data collection tools (form/s) detailed below:

Approved Forms with **no changes** noted:

1) FN.200.9 Hemolytic Uremic Syndrome (HUS) Surveillance

2) FN.200.10 FoodNet Clinical Laboratory Practices and Testing Volume

Changes to Approved Forms:

1) FN.200.1 – FN.200.8 FoodNet Active Surveillance Data Elements List

FoodNet Active Surveillance Data Elements List (FN.200.1)		
Type of Change	**Itemized Changes / Justification**	**Impact to Burden**
Value set change for variable AgClinicTestType	The values of “Meridian Curian Shiga Toxin” and “Lab-developed test” were added for the variable AgClinicTestType to assist data collectors in capturing data in a standardized fashion to improve accuracy.	No impact to burden
Value set change for variable AgSPHLTestType	The value of “Meridian Curian Shiga Toxin” was added for the variable AgSPHLTestType assist data collectors in capturing data in a standardized fashion to improve accuracy.	No impact to burden

FluSurv-NET:

This Revision includes proposed changes to 4 of the approved FluSurv-NET forms and no new FluSurv-NET data collection tools (form/s) detailed below:

Changes to Approved Forms:

1) FSN.300.1 Influenza Hospitalization Surveillance Network (FluSurv-NET) Case Report Form

2) FSN.300.2 Influenza Hospitalization Surveillance Project Vaccination Phone Script and Consent Form (English/Spanish)

3) FSN.300.3 Influenza Hospitalization Surveillance Project Provider Vaccination History Fax Form (Children/Adults)

4) FSN.300.4 FluSurv-NET Laboratory Survey

Influenza Hospitalization Surveillance Network (FluSurv-NET) Case Report Form (FSN.300.1)		
Type of change	**Itemized changes/justification**	**Impact to burden**
Revision	**C. Enrollment Information** **8. Race and/or Ethnicity (select all that apply)** • American Indian or Alaska Native • Asian • Black or African American • Hispanic or Latino • Middle Eastern or North African • Multiracial, not otherwise specified • Native Hawaiian or Pacific Islander • White • Unknown **Justification** • Due to change in OMB standards, race and ethnicity questions were combined into a question and allowed for all that applied to be selected. A new category for "Middle Eastern or North African" was added. • Although the OMB standards include a "Not specified" category, this was revised to be "Unknown" to be	Minimal, <1 minute increase

	consistent with past approved case report forms and an “unknown” option is used for almost all other variables and is needed for data cleaning and analysis purposes.
	• OMB standards do not include “Multiracial, not otherwise specified”, but this category will be kept for consistency with previous seasons and situations where medical charts do not specify additional details about multirace. This is not a change and does not impact burden
	• Race/ethnicity will be collected through the minimum categories for the 2024-2025 season, rather than the expanded categories, with the following justification:
	  • Detailed data collection would potentially be more burdensome for the surveillance staff and may not add as much value, given that the additional check boxes will likely have few case counts
	  • There will not likely be sufficient number of cases identified to allow the disaggregated racial/ethnic categories to be analyzed separately; any analysis performed will probably require aggregating the data into the minimum required categories
	  • FluSurv-NET data collection is primarily conducted through medical record reviews and not through patient interviews. The detailed data collection seems to be more intended for interviews rather than chart reviews.
	  • The detailed race/ethnicity population groups likely	

	comprise a small percentage of our surveillance catchment areas and the collection of these groups could pose additional risk to data privacy and identification of individuals	
Revision	**C. Enrollment Information** **14.Where did the patient reside at the time of hospitalization (Indicate type of residence)?** • Private residence • Private residence with services • Homeless/Shelter/Temporary housing • Nursing home/Skilled nursing facility • Substance abuse treatment Center • Hospitalized at birth • Rehabilitation facility • Corrections facility • Hospice • Assisted living/Residential care • LTACH • Group/Retirement home • Psychiatric/Behavioral Health Facility • Other long term care facility • Other, specify: _____ • Unknown **Justification** • Renaming “Psychiatric facility” to “Psychiatric/Behavioral Health Facility” to reflect more inclusive health facility types	No change to burden
Revision	**D. Influenza Testing Results** **1-3. Test** • Rapid Antigen • Standard/Rapid Molecular Assay • Viral Culture • Fluorescent Antibody • Method Unknown **Justification** • Deleted Rapid Molecular Assay and	Minimal, <1 minute decrease

	combined with Standard Molecular Assay to alleviate the burden on sites distinguishing the difference between the two test types. Medical charts may not have additional details on the type of test used for lab confirmation • Deleted Serology because it has not been identified as a mode of lab confirmation for flu hospitalizations in recent seasons	
Addition	**E. Other Interventions and ICU (For Questions 1-5, select the highest level of oxygen support received)** **5. Supplemental Oxygen?** • Yes • No • Unknown **Justification** • Changed the section header to only record the highest level of oxygen support needed only. It would be beneficial to know the highest level of oxygen a patient received during hospitalization as an indicator of disease severity • Added Supplemental Oxygen question to better understand impact of severity of respiratory viral infection upon admission	Minimal, <1 minute increase
Revision	**F. Outcome** **2.If discharged alive, please indicate to where:** • Private residence • Private residence with services • Homeless/Shelter/Temporary housing • Nursing home/Skilled nursing facility • Substance abuse treatment Center • Hospitalized at birth • Rehabilitation facility • Corrections facility • Hospice • Assisted living/Residential care	No change to burden

	• LTACH • Group/Retirement home • Psychiatric/Behavioral Health Facility • Other long term care facility • Other, specify: _____ • Unknown **Justification** • Renaming “Psychiatric facility” to “Psychiatric/Behavioral Health Facility” to reflect more inclusive health facility types	
Revision	**G. Admission and Patient History** **2. Acute signs/symptoms present at admission (began or worsened within 2 weeks prior to admission)(Select all that apply)** **Respiratory symptoms** • Chest congestion • Congested/runny nose • Cough • Hemoptysis/bloody sputum • Shortness of breath/respiratory distress/hypoxia • Sore throat • URI/ILI • Wheezing **Justification** • Added “hypoxia” symptom to the existing symptom of “shortness of breath/respiratory distress” to capture symptoms resulting from low levels of oxygen	No change to burden
Revision	**G. Admission and Patient History** **7. Smoker (tobacco) (for patients > 12 years):** • Current • Former • No/Unknown	Minimal, <1 minute decrease

	Justification • Updated the age limit for smoker (tobacco) question to > 12 years to assess as a risk factor for severe disease among adolescents and adults	
Revision	**G. Admission and Patient History** **9. Alcohol misuse (for patients > 12 years):** • Current • Former • No/Unknown **Justification** • Change question from "Alcohol abuse" to "Alcohol misuse" to use less stigmatizing language • Updated the age limit for alcohol question to > 12 years to assess as a risk factor for severe disease among adolescents and adults	Minimal, <1 minute decrease
Revision	**G. Admission and Patient History** **10. Substance misuse (for patients > 12 years):** • Current • Former • No/Unknown **Justification** • Changed "Substance abuse" question to "Substance misuse" to use less stigmatizing language • Updated the age limit for substance abuse question to > 12 years to assess as a risk factor for severe disease among adolescents and adults	Minimal, <1 minute decrease
Addition	**G. Admission and Patient History** **8. Environmental tobacco smoke exposure**	Minimal, <1 minute increase

	(for pediatric patients ≤12 years) • Yes • No • Unknown **Justification** • Added question to better capture this as a risk factor for respiratory disease among young children and young adolescents	
Revision	**G. Admission and Patient History** **11. Substance Misuse Type or Route (current use only) (select all that apply)** • Cocaine • IVDU • Opioids • Polysubstance abuse – not otherwise specified • Methamphetamines • Marijuana • Other, specify: _____ • Unknown **Justification** • Changed “Substance Abuse Type” to "Substance Misuse Type or Route (current use only)" in the question (no change to selections) to avoid using stigmatizing language	No change to burden
Revision	**H. Underlying Medical Conditions** **1f. Hypertension** Moved “Hypertension” header category to right before “Cardiovascular Disease” section **Justification** • Moved this condition closer to similar conditions for ease of collection for sites	No change to burden
Revision	**H. Underlying Medical Conditions** **1g. Congenital Heart Disease (Specify)**	Minimal, <1 minute increase

	• Atrial septal defect (ASD) • Patent Ductus Arteriosus (PDA) • Pulmonic stenosis • Tetralogy of Fallot • Ventricular septal defect (VSD) **Justification** • Added Patent Ductus Arteriosus (PDA) as a selectable congenital heart disease because it may be more commonly seen than other congenital heart disease options (including ASD and VSD)	
Revision	**H. Underling Medical Conditions** **1c. Diabetes Mellitus (DM)** Moved "Diabetes Mellitus" as new header category for before Chronic Metabolic Disease **Justification** • Moved condition so it is easier for surveillance staff to record condition	No change to burden
Revision	**H. Underlying Medical Conditions** **1q. Other**: • Bedbound • Feeding tube dependent (PEG, see list) • Trach dependent/Vent dependent • Wheelchair dependent • Other, specify: _____ **Justification** • Added new checkbox "Bedbound" under the "Other" header category as one way to assess frailty	Minimal, <1 minute increase
Deletion	Removed entire Bacterial Pathogens section **Justification** • Data collected in previous seasons have demonstrated in part the challenges in determining positive results indicate contaminant or a pathogen-causing disease and the burden in collecting and	2-3 minute decrease in burden

	interpreting these data elements. This section was removed from the case report form.	
Revision	**I. Viral Pathogens** **1b. Coronavirus SARS-CoV-2** Moved location of "Coronavirus SARS-CoV-2" towards the top to be closer to "RSV" **Justification** • Moved location for ease of collection for sites	No change to burden
Revision	**K. Chest X-ray** **1. Was a chest x-ray taken during the first 3 days of admission (for patients ≤17 years)?** • Yes • No • Unknown **Justification** • Revised past and previously OMB-approved question "Was a chest x-ray taken during the first 3 days of admission" to "Was a chest x-ray taken during the first 3 days of admission (for patients ≤17 years)?" to capture community-acquired pneumonia among children and adolescents. The performance of a chest x-ray alone may be an indicator of severe disease for children and adolescents, but not for adults.	Minimal, <1 minute decrease
Deletion	**K. Chest X-ray** **2. Were any of these chest x-rays abnormal?** **2a. Date of first abnormal chest x-ray** **2b. For first abnormal chest x-ray, please check all that apply** **Justification** • Previous analyses used these variables along with discharge diagnoses and/or	1-2 minute decrease in burden

	ICD-10 discharge codes to define pneumonia. Given the difficulty in interpreting chest radiograph findings and the ability to capture pneumonia with other data collected from the case report form, questions about abnormal chest x-rays and their interpretation were removed	
Addition	**N. Pregnancy Information** **5. Pregnancy complications during current pregnancy? (Select all that apply)** • None • Pre-eclampsia • Intrauterine growth restriction (IUGR) • Gestational diabetes • Pregnancy-induced hypertension (PIH) • Unknown **Justification** • Added question to better characterize pregnancy complications with respiratory infection	Minimal, <1 minute increase
Addition	**R. COVID-19 Vaccine History** Vaccine registry: • Registry reviewed • Registry available but not reviewed (specify) • Registry not available for review Dose Date Dose Product: • Pfizer-BioNTech COVID-19 Vaccine • Moderna COVID-19 Vaccine • Jansen Pharmaceuticals • Novavax COVID-19 Vaccine • AstraZeneca • Unknown • Other, specify	None to minimal; data extracted from state immunization registries and linked for FluSurv-NET cases

	Dose Source: • Registry **Justification**: FluSurv-NET added these new optional fields in participating states where state vaccine registries or immunization information systems are reliable to collect variables related to COVID-19 vaccination status. Similar variables were previously OMB-approved and collected during the 2022-23 season. These fields are currently being extracted from immunization information systems for COVID-19-associated hospitalizations for 2023-24 season in the COVID-NET surveillance platform and used for FluSurv-NET so burden is not impacted. These data elements were added to better understand the association between receipt of COVID-19 and influenza vaccination among influenza hospitalizations. Additionally, collecting COVID-19 vaccination status on FluSurv-NET cases can be explored as an indicator to impute for missing influenza vaccination for analyses. If these elements related to COVID-19 vaccination are beneficial in imputing missing influenza vaccination status and registries remain a reliable source for COVID-19 vaccination, these elements could be collected in lieu of conducting provider and patient/proxy interviews to ascertain influenza vaccination status, which would reduce burden on respondents.	
Phone Script and Consent Form (FSN.300.2)		
Revision	**Race and/or Ethnicity (select all that apply)** • American Indian or Alaska Native • Asian • Black or African American • Hispanic or Latino • Middle Eastern or North African • Multiracial, not otherwise specified • Native Hawaiian or Pacific Islander • White	Minimal, <1 minute increase

	• Unknown
	
	Justification
	• Due to change in OMB standards, race and ethnicity questions were combined into a question and allowed for all that applied to be selected. A new category for “Middle Eastern or North African” was added.
	• Although the OMB standards include a “Not specified” category, this was revised to be “Unknown” to be consistent with past approved case report forms and an “unknown” option is used for almost all other variables and is needed for data cleaning and analysis purposes.
	• OMB standards do not include “Multiracial, not otherwise specified”, but this category will be kept for consistency with previous seasons and situations where medical charts do not specify additional details about multirace. This is not a change and does not impact burden
	• Race/ethnicity will be collected through the minimum categories for the 2024-2025 season, rather than the expanded categories, with the following justification:
	  • Detailed data collection would potentially be more burdensome for the surveillance staff and may not add as much value, given that the additional check boxes will likely have few case counts
	  • There will not likely be sufficient number of cases identified to allow the disaggregated racial/ethnic categories to be analyzed separately; any analysis performed will probably	

	require aggregating the data into the minimum required categories • FluSurv-NET data collection is primarily conducted through medical record reviews and not through patient interviews. The detailed data collection seems to be more intended for interviews rather than chart reviews. • The detailed race/ethnicity population groups likely comprise a small percentage of our surveillance catchment areas and the collection of these groups could pose additional risk to data privacy and identification of individuals	
Revision	Updated Spanish translation consent forms and phone scripts to reflect the new race and/or ethnicity question	No change to burden
Provider Vaccination History Fax Form (FSN.300.3)		
Revision	**Race and/or Ethnicity (select all that apply)** • American Indian or Alaska Native • Asian • Black or African American • Hispanic or Latino • Middle Eastern or North African • Multiracial, not otherwise specified • Native Hawaiian or Pacific Islander • White • Unknown **Justification** • Due to change in OMB standards, race and ethnicity questions were combined into a question and allowed for all that	Minimal, <1 minute increase

	applied to be selected. A new category for “Middle Eastern or North African” was added.
	• Although the OMB standards include a “Not specified” category, this was revised to be “Unknown” to be consistent with past approved case report forms and an “unknown” option is used for almost all other variables and is needed for data cleaning and analysis purposes.
	• OMB standards do not include “Multiracial, not otherwise specified”, but this category will be kept for consistency with previous seasons and situations where medical charts do not specify additional details about multirace. This is not a change and does not impact burden
	• Race/ethnicity will be collected through the minimum categories for the 2024-2025 season, rather than the expanded categories, with the following justification:
	  ◦ Detailed data collection would potentially be more burdensome for the surveillance staff and may not add as much value, given that the additional check boxes will likely have few case counts
	  ◦ There will not likely be sufficient number of cases identified to allow the disaggregated racial/ethnic categories to be analyzed separately; any analysis performed will probably require aggregating the data into the minimum required categories
	  ◦ FluSurv-NET data collection is primarily conducted through medical record reviews and not	

	through patient interviews. The detailed data collection seems to be more intended for interviews rather than chart reviews. • The detailed race/ethnicity population groups likely comprise a small percentage of our surveillance catchment areas and the collection of these groups could pose additional risk to data privacy and identification of individuals	
Revision	Supplemental language was added in form of a notification letter that sites may mail to the patient/proxy prior to the patient interview notifying that the patient/proxy will be contacted by their state health department to obtain influenza vaccination status only. **The supplemental document will not collect any data or information from the patient.** **Justification** • Patient/proxy outreach to obtain influenza vaccination history is burdensome and often result in non-responsiveness, with patients not picking up phone calls from numbers they do not know or hang-up during the patient interview. No responses from patient interview yield unknown vaccination status, which impacts reported influenza vaccination rates. Advanced notice via a mailed letter to patients/proxies of an upcoming phone call may reduce the burden for follow-up.	No changes to burden

FluSurv-NET Laboratory Survey (FSN.300.4)		
Addition	Title **Justification** • Added field for the title of the person completing the survey	Minimal, <1 minute increase
Revision	Select the kit name(s) (manufacturer) for the rapid influenza antigen diagnostic test(s) performed or planned to be used at the laboratory • Acucy Influenza BA&B Test • BD Veritor System for Rapid Detection of Flu A+B (CLIA-waived) • BD Verirot System for Rapid Detection of Flu A+B (Moderately Complex) • BD Veritor System for Rapid Detection of SARS-CoV-2 • Binax NOW Influenza A&B Card 2 • BioSign Flu A+B or LifeSign LLC Status Flu A & B • CareStart Flu A&B Plus • Meridian Bioscience ImmunoCard STAT Flu A&B • OSOM Ultra Plus Flu A&B Test (Sekisui Diagnostics, LLC) • QuickVue Influenza A+B Test • SARS-CoV-2 & Flu A.B Rapid Antigen Test • SEKISUI Diagnostics OSOM Ultra Plus Flu A and B Test Kit • Sofia Analyzer and Influenza A+B FIA (CLIA-waived) • Sofia Analyzer and Influenza A+B FIA • Sofia 2 Flu + SARS Antigen FIA • Sure-Vue Signature Influenza A and B Test Kit • XPECT Influenza A/B **Justification** • Added new kits and removed kits that no longer exist	Minimal, <1 minute increase

Revision	Select kit name(s) (manufacturer) for all molecular assays performed or planned to be used at the laboratory: (Check all that apply) • Alinity M Resp-4 Plex Assay (Abbott) • Aptima SARS-CoV-2/Flu/A/B‡ (Hologic) • ARIES® Flu A/B & RSV+SARS CoV 2 Assay (Diasorin) • BioCode® CoV-2 Flu Plus Assay (Applied BioCode Inc) • BioCode Respiratory Pathogen Panel, (Applied BioCode Inc) • BioFire FilmArray Pneumonia (PN) Panel (Biomerieux) • BioFire FilmArray Pneumonia plus (PNplus) Panel (Biomerieux) • BioFire Respiratory Panel 2.1 (RP2.1) (Biomerieux) • BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) (EUA) (Biomerieux) • CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel • (Influenza B Lineage Genotyping Kit), (CDC Influenza Division) • CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel • (Influenza A Subtyping Kit), (CDC Influenza Division) • CDC Influenza A/H5 (Asian Lineage) Virus Real-Time RT-PCR Primer and Probe Set, (CDC Influenza Division) • CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel • (Influenza A/B Typing Kit), (CDC Influenza Division) • CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay • (CDC Influenza Division) • Cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test, (Roche Diagnostics) • ePlex Respiratory Pathogen Panel 2,	Minimal, <1 minute increase

	(Roche Diagnostics) • Lyra Influenza A+B Assay, (Quidel) • NeuMoDX Influenza A/B, RSV, and SARS-CoV-2 Vantage Assay (Qiagen) • Nx-TAG Respiratory Pathogen Panel, (Diasorin) • Nx-TAG Respiratory Pathogen Panel + SARS-CoV-2 (Diasorin) • Panther Fusion® Flu A/B RSV, (Assay Hologic) • Panther Fusion SARS-CoV-2/Flu A/B/RSV assay • QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN) • Quest Diagnostics RC COVID-19 +Flu RT-PCR, (Quest Diagnostics) • RealStar Influenza Screen & Type RT-PCR • Simplexa™ COVID-19 & Flu A/B Direct • Simplexa™ Flu A/B & RSV Direct Gen II (Diasorin) • Solana Influenza A+B Assay, (Quidel) • Solana Respiratory Viral Panel (Quidel) • Verigene® Respiratory Pathogen Nucleic Acid Test (RP Flex), (Luminex) **Justification** • Added new kits and removed kits that no longer exist	

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HAIC:

This Revision includes proposed changes to 5 of 13 approved Healthcare-Associated Infections – Community Interface (HAIC) data collection tools (form/s) detailed below. There are no new collection tools for HAIC.

Approved Forms with **no changes** noted:

1) HAIC.400.2 MuGSI CA CP-CRE Health interview
2) HAIC.400.7 CDI Case Report and Treatment Form
3) HAIC.400.8 Annual Survey of Laboratory Testing Practices for C. difficile Infections
4) HAIC.400.9 CDI Annual Surveillance Officers Survey
5) HAIC.400.10 C. difficile Surveillance Nursing Home Telephone Survey (LTCF)
6) HAIC.400.11 Candidemia Case Report Form
7) HAIC.400.12 Laboratory Testing Practices for Candidemia Questionnaire
8) HAIC.400.13 Death Ascertainment Project

Changes to Approved Forms:

1) HAIC.400.1 Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form
2) HAIC.400.3 MuGSI Supplemental Surveillance Officer Survey
3) HAIC.400.4 Invasive Staphylococcus aureus Infection Case Report Form
4) HAIC.400.5 Invasive Staphylococcus aureus Laboratory Survey
5) HAIC.400.6 Invasive *Staphylococcus aureus* Supplemental Surveillance Officer Survey

Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (HAIC.400.1)		
Type of Change	**Itemized Changes / Justification**	**Impact to Burden**
Correction	For the MuGSI CRF there has been an increase in the number of respondents (from 10 to 11), however, an error was identified in how the number of responses per respondent was previously reported. This has resulted in reduction from 4,770 to 1,581 responded per respondent. While the Avg. burden per response increase from 28 to 29 minutes, there was a decrease in the Current Total burden (in hours) from 21,922 to 8,406.	Decrease
Addition	20. Risk factors: (Check all that apply) Invasive or diagnostic urologic procedure in the year before DISC: • Yes • No • Unknown If yes, check all that apply: • Prostate procedure • Cystoscopy • Other **Justification:** • Added a risk factor response option for "Invasive or diagnostic urologic procedure". Recent literature identified a greater risk for invasive *E. coli* disease in hospitalized patients with a recent diagnostic or interventional medical procedure. Vaccination of patient groups with anticipated urologic diagnostic or invasive procedures have been proposed as an intervention. The addition of this new risk factor questions allows us to establish baseline surveillance for these procedures associated with *E. coli* disease. This information is located in the sections of the medical record that are reviewed for other risk factor responses.	0.5 minute increase.
Addition/ Revision	23b. Risk factors prior to CRAB DISC: • Non-invasive positive pressure ventilation (CPAP or BiPAP) at any time in the 7	0.5-minute increase

	calendar days before the DISC • Nebulizer treatment at any time in the 7 calendar days before the DISC • Mechanical ventilation at any time in the 7 calendar days before the DISC • Visited a wound care clinic at any time in the year before the DISC • None • Removed the qualifier "…in the 7 days before the DISC" from the question prompt of Q23b and added them to the response options. **Justification:** • Addition of a risk factor beyond that timeframe. This additional risk factor option allows for accurately classifying CRAB cases by their exposure, that would otherwise be misclassified. This information is located in the sections of the medical record that are reviewed for other risk factor responses.	
Multi-site Gram-negative Surveillance Initiative (MuGSI) Supplemental Surveillance Officer Survey (HAIC.400.3)		
Type of Change	**Itemized Change / Justification**	**Impact to Burden**
Revision	Site: ___ CA ___ CO ___ CT ___ GA ___ MD ___ MI___ MN ___ NM ___ NY ___ OR ___ TN **Justification:** • Michigan is participating in MuGSI invasive *Escherichia coli* surveillance activity in 2024, "MI" has been included as a response.	No changes to burden
Revision	**Surveillance area characteristics:** 1. What counties are under surveillance for MuGSI activities at your site? a. Carbapenem-resistant Enterobacterales (CRE) surveillance area, please specify:	Increase in burden

	b. Carbapenem-resistant *Acinetobacter baumannii* (CRAB) surveillance area, please specify: c. Extended-spectrum β-lactamases-producing Enterobacterales (ESBL-E) surveillance area, please specify: d. Invasive *Escherichia coli* (iEC) surveillance area, please specify: **Justification:** • Surveillance for invasive Escherichia coli began in 2024, included a response "d. Invasive *Escherichia coli* (iEC) surveillance area, please specify" to this existing question.	
Addition/ Revision	**Surveillance area characteristics:** 2. Is CRE reportable at your state/site? ___ yes ___ no a. If yes: i. Please describe your state reportable definition of CRE:_____ ii. Where in your state is CRE reportable? _____ Statewide _____ Defined area, such as a county(ies). Please specify iii. Is isolate submission to the State Health Department Laboratory required? _____ yes _____ no specify _____ b. If no: i. What mechanism do you have in place that allows for surveillance officers (SOs) to have access to CRE laboratory reports and medical records? _____ Agent of the state _____ State Health Department Regulation _____ Other, please explain: _____ ii. Does your state/site plan to make CRE reportable? ___ yes___ no ___ unknown 1. If yes, when does your state/site plan to make	No changes to burden.

	CRE reportable? • Minor word changes and included an “unknown” response option and one clarifying question “if yes, when does your state/site plan to make CRE reportable?”	
Addition/ Revision	**Surveillance area characteristics:** 3. Is CRAB state reportable at your site? ___ yes___ no a. If yes: i. Please describe your state reportable definition of CRAB:_____ ii. Where in your state is CRAB reportable? _____ Statewide _____ Defined area, such as a county(ies). Please specify iii. Is isolate submission to the State Health Department Laboratory required? _____ yes _____ no specify _____ b. If no: i. What mechanism do you have in place that allows for surveillance officers (SOs) to have access to CRAB laboratory reports and medical records? _____ Agent of the state _____ State Health Department Regulation _____ Other, please explain: _____ ii. Does your state/site plan to make CRAB reportable? ___ yes___ no ___ unknown 1. If yes, when does your state/site plan to make CRAB reportable?_____ • Minor word changes and included an “unknown” response option and one clarifying question “If yes, when does your state/site plan to make CRAB reportable?”.	No changes to burden.
Addition/	**Surveillance area characteristics:**	No change to burden.

Revision	4. Is ESBL-E reportable at your state/site? ___ yes ___ no a. If yes: i. Please describe your state reportable definition of ESBL-E:_____ ii. Where in your state is ESBL-E reportable? _____ Statewide _____ Defined area, such as a county(ies). Please specify iii. Is isolate submission to the State Health Department Laboratory required? _____ yes _____ no specify _____ b. If no: i. What mechanism do you have in place that allows for surveillance officers (SOs) to have access to ESBL-E laboratory reports and medical records? _____ Agent of the state _____ State Health Department Regulation _____ Other, please explain: _____ ii. Does your state/site plan to make ESBL-E reportable? ___ yes ___ no ___ unknown 1. If yes, when does your state/site plan to make ESBL-E reportable? • Minor word changes and included an “unknown” response option and one clarifying question “If yes, when does your state/site plan to make ESBL-E reportable”.	
Revision	**Surveillance area characteristics:** 5. Is iEC reportable at your state/site? ___ yes ___ no a. If yes: i. Please describe your state reportable definition of iEC:_____	Increase in burden

	ii. Where in your state is iEC reportable? _____ Statewide _____ Defined area, such as a county(ies). Please specify iii. Is isolate submission to the State Health Department Laboratory required? _____ yes _____ no specify _____ b. If no: i. What mechanism do you have in place that allows for surveillance officers (SOs) to have access to iEC laboratory reports and medical records? _____ Agent of the state _____ State Health Department Regulation _____ Other, please explain: _____ ii. Does your state/site plan to make iEC reportable?___ yes___ no ___ unknown 1.If yes, when does your state/site plan to make iEC reportable? **Justification:** • Surveillance for invasive *Escherichia coli* (iEC) began in 2024, included the corresponding questions that are asked for the other MuGSI surveillance activities. This information is readily available to the EIP site respondent.	
Revision	**Laboratory Participation and Isolate Testing – Part 1** 1. Please describe the clinical laboratories in the MuGSI catchment area: a. CRE i. Proportion of clinical laboratories serving the MuGSI CRE surveillance area with queries installed on their automated testing instrument (ATI) or laboratory information system (LIS): _____ ii. Numerator: Number of clinical laboratories serving the MuGSI CRE surveillance area with queries installed on	Increase in burden

		their ATI or LIS: _____ iii. Denominator: Total number of clinical laboratories that receive and process specimens from residents of the MuGSI CRE surveillance area:_____ iv. Please describe how MuGSI CRE surveillance is conducted at laboratories where ATI/LIS queries are not installed (e.g., HL7 messages from LabCorp): _____ _____ b. CRAB i. Proportion of clinical laboratories serving the MuGSI CRAB surveillance area with queries installed on their ATI or LIS: _____ ii. Numerator: Number of clinical laboratories serving the MuGSI CRAB surveillance area with queries installed on their ATI or LIS: _____ iii. Denominator: Total number of clinical laboratories that receive and process specimens from residents of the MuGSI CRAB surveillance area: _____ iv. Please describe how MuGSI CRAB surveillance is conducted at laboratories where ATI/LIS queries are not installed (e.g., HL7 messages from LabCorp): _____ _____ c. ESBL-E i. Proportion of clinical laboratories serving the MuGSI ESBL-E surveillance area with queries installed on their ATI or LIS: _____ ii. Numerator: Number of clinical laboratories serving the MuGSI ESBL-E surveillance area with queries installed on their ATI or LIS: _____ iii. Denominator: Total number of clinical laboratories that receive and process specimens from residents of the MuGSI ESBL-E surveillance area:_____ iv. Please describe how MuGSI ESBL-E surveillance is conducted at laboratories where ATI/LIS queries are not installed (e.g., HL7 messages from LabCorp): _____	

	_____ d. iEC i. Proportion of clinical laboratories serving the MuGSI iEC surveillance area with queries installed on their ATI or LIS: _____ ii. Numerator: Number of clinical laboratories serving the MuGSI iEC surveillance area with queries installed on their ATI or LIS: _____ iii. Denominator: Total number of clinical laboratories that receive and process specimens from residents of the MuGSI iEC surveillance area:_____ iv. Please describe how MuGSI iEC surveillance is conducted at laboratories where ATI/LIS queries are not installed (e.g., HL7 messages from LabCorp): _____ _____ **Justification:** • Minor word changes for clarification. Included corresponding questions for invasive *Escherichia coli* under "d. iEC" as surveillance began in 2024.	
Addition	**Laboratory Participation and Isolate Testing – Part 1** 2. Did any laboratories drop out of participation in 2023? _____ yes _____ no a. If yes, how many? _____ b. Why did these laboratories drop out of participation? _____ _____ **Justification:** • Added this question to clarify participation of local clinical laboratories surveillance activities in case any are no longer able to participate.	Increase in burden
Addition	**Laboratory Participation and Isolate Testing – Part 1**	Increase in burden

	3. In 2023, did you identify additional laboratories, regardless of location, which identify MuGSI isolates from persons who are residents of the MuGSI surveillance area at your site? _____ yes _____ no a. If yes, how many? _____ b. If yes, how many of these laboratories were added? _____ i. If all new laboratories identified were not added, why not? _____ _____ _____ c. If yes, how did you identify these new laboratories? _____ d. Approximately how many cases are identified at the new laboratories each year among residents of the MuGSI surveillance area? _____ **Justification:** • Added this question to clarify participation of local clinical laboratories in MuGSI surveillance activities in case any new laboratories recently enrolled.	
Revision	**Laboratory Participation and Isolate Testing – Part 1** 4. Did your site send any MuGSI isolates to CDC for characterization in calendar year 2023? _____ yes _____ no a. If yes, please describe how your site determines which MuGSI isolates to send to CDC: i. CRE: _____ ii. CRAB: _____ iii. ESBL: _____ iv. iEC: _____ b. If yes, how many clinical laboratories contributed MuGSI isolates:	Increase in burden

	i. CRE: _____ ii. CRAB: _____ iii. ESBL: _____ iv. IEC: _____ **Justification:** • Minor word changes for clarification. Since surveillance began for invasive *Escherichia coli* began in 2024, included "iEC" response options.	
Revision	**Laboratory Participation and Isolate Testing – Part 1** 5. How many isolates with a specimen collection date in 2023 did you expect to be able to collect from the clinical laboratories? _____ CRE; _____ CRAB; _____ ESBL; _____iEC **Justification:** • Minor word changes for clarification. Since surveillance began for invasive *Escherichia coli* began in 2024, included an "iEC" response option.	Increase in burden
Revision	**Laboratory Participation and Isolate Testing – Part 1** 6. What was the total number of isolates with a specimen collection date in 2023 that were collected from the clinical laboratories _____ CRE; _____ CRAB; _____ ESBL; _____iEC **Justification:** • Minor word changes for clarification. Since surveillance began for invasive *Escherichia coli* began in 2024, included an "iEC" response option.	Increase in burden
Revision	**Laboratory Participation and Isolate Testing – Part 2**	No change in burden.

	2. Type of laboratory: _____clinical laboratory _____public health laboratory _____research laboratory _____reference laboratory **Justification:** • Included response options, rather than a free-text field, for an existing question.	
Revision	**Laboratory Participation and Isolate Testing – Part 2** 3. MuGSI pathogen(s) under surveillance: _____CRE _____CRAB _____ESBL _____iEC **Justification:** • Included response options, rather than a free-text field, for an existing question.	No change in burden.
Addition	**Laboratory Participation and Isolate Testing – Part 2** 4. Method for sharing laboratory reports with your site: _____electronic messaging, such as HL7 _____e-mail _____fax _____EIP staff manually generate reports on-site	Increase in burden

	_____other, please specify_____ _____unknown **Justification:** • Added this question to clarify how laboratories share information on MuGSI cases with EIP staff. This information is readily available to the EIP site for each laboratory.	
Revision	**Laboratory Participation and Isolate Testing – Part 2** 5. Method for case identification: _____automated testing instrument _____laboratory information system _____medical record _____other, please specify_____ _____unknown **Justification:** • Included response options, rather than a free-text field, for an existing question.	No change in burden
Revision	**Laboratory Participation and Isolate Testing – Part 2** 7. Carbapenem confirmatory testing method a. *Please report the carbapenem confirmatory testing method(s) performed for each MuGSI organism separately*. kirby bauer:_____CRE _____CRAB _____ESBL _____iEC	No change in burden

	other, please specify: _____CRE _____CRAB _____ESBL _____iEC laboratory not testing _____CRE _____CRAB _____ESBL _____iEC unknown _____CRE _____CRAB _____ESBL _____iEC **Justification:** • Included response options, rather than a free-text field, for the existing question.	
Revision	**Laboratory Participation and Isolate Testing – Part 2** 8. Carbapenemase testing method a. *Please report the carbapenemase testing method(s) performed for each MuGSI organism separately.* **Non-molecular test methods** carbaNP: _____CRE _____CRAB _____ESBL _____iEC carbapenemase inactivation method: _____CRE _____CRAB _____ESBL _____iEC CPO detect: _____CRE _____CRAB _____ESBL _____iEC disk diffusion/ROSCO disk e-test: _____CRE _____CRAB _____ESBL _____iEC modified carbapenemase inactivation method: _____CRE _____CRAB _____ESBL _____iEC	No change in burden

	modified hodge test: _____CRE _____CRAB _____ESBL _____iEC RAPIDEC: _____CRE _____CRAB _____ESBL _____iEC Other, please specify: _____CRE _____CRAB _____ESBL _____iEC laboratory not testing: _____CRE _____CRAB _____ESBL _____iEC unknown: _____CRE _____CRAB _____ESBL _____iEC **Molecular test methods** automated molecular assay: _____CRE _____CRAB _____ESBL _____iEC carba-R: _____CRE _____CRAB _____ESBL _____iEC check points: _____CRE _____CRAB _____ESBL _____iEC MALDI-TOF MS: _____CRE _____CRAB _____ESBL _____iEC next generation nucleic acid sequencing: _____CRE _____CRAB _____ESBL _____iEC polymerase chain reaction: _____CRE _____CRAB _____ESBL _____iEC streck ARM-D: _____CRE _____CRAB _____ESBL _____iEC	

	other, please specify:_____ _____CRE _____CRAB _____ESBL _____iEC laboratory not testing: _____CRE _____CRAB _____ESBL _____iEC unknown: _____CRE _____CRAB _____ESBL _____iEC **Justification:** • Included response options, rather than a free-text field, for the existing question.	
Revision	**Laboratory Participation and Isolate Testing – Part 2** 9. ESBL production testing method a. *Please report the ESBL production testing method(s) performed for each MuGSI organism separately*. broth microdilution – ESBL well:_____CRE _____CRAB _____ESBL _____iEC broth microdilution – ATI flag: _____CRE _____CRAB _____ESBL _____iEC broth microdilution – manual: _____CRE _____CRAB _____ESBL _____iEC disk diffusion: _____CRE _____CRAB _____ESBL _____iEC e-test: _____CRE _____CRAB _____ESBL _____iEC molecular test, please specify_____CRE _____CRAB _____ESBL _____iEC other non-molecular test, please specify:_____CRE _____CRAB _____ESBL _____iEC laboratory not testing: _____CRE _____CRAB _____ESBL _____iEC unknown: _____CRE _____CRAB _____ESBL _____iEC **Justification:**	No change in burden

	• Included response options, rather than a free-text field, for the existing question.	
Revision	**Laboratory Participation and Isolate Testing – Part 2** 10. Organism identification method† a. *Please report the organism identification method(s) performed for each MuGSI organism separately.* MALDI-TOF: _____CRE _____CRAB _____ESBL _____iEC polymerase chain reaction: _____CRE _____CRAB _____ESBL _____iEC whole genome sequencing: _____CRE _____CRAB _____ESBL _____iEC DNA sequencing, please specify:_____CRE _____CRAB _____ESBL _____iEC rRNA gene sequencing, please specify:_____CRE _____CRAB _____ESBL _____iEC biochemical tests, please specify:_____CRE _____CRAB _____ESBL _____iEC immunological techniques, please specify:_____CRE _____CRAB _____ESBL _____iEC other, please specify:_____CRE _____CRAB _____ESBL _____iEC laboratory not testing:_____CRE _____CRAB _____ESBL _____iEC unknown: _____CRE _____CRAB _____ESBL _____iEC Please specify the database or library for the instrument(s) selected above:_____ **Justification:** • Included response options, rather than a free-text field, for the existing question.	No change in burden
Revision	**Laboratory Participation and Isolate Testing – Part 2** 11. Culture-independent diagnostic test:	No change in burden

	_____yes, please specify the type of test_____ If yes, is a positive test result always followed up by a culture? _____ yes _____ no _____ unknown _____no _____unknown • Included response options, rather than a free-text field, for the existing question.	
Revision	**Laboratory Participation and Isolate Testing – Part 2** 12. Isolate submission to state public health laboratory _____yes _____no _____unknown **Justification:** • Included response options, rather than a free-text field, for the existing question.	No change in burden
Addition	**Laboratory Participation and Isolate Testing – Part 2** 13. Most recent year a check-in was completed for the laboratory: _____ **Justification:** • Added this question which is readily available because EIP staff complete this check-in with each laboratory on an annual basis.	Increase in burden
Addition	**Laboratory Participation and Isolate Testing – Part 2** Please describe the participating laboratory's policy on maximum duration of referral	Increase in burden

	for antimicrobial susceptibility testing for successive isolates of the same MuGSI organism. Successive isolates are defined as two microorganisms with similar identification that was cultured from the same patient at two different time points. Please indicate if the policy differs depending on whether successive isolates were cultured from the same specimen source or different specimen source. _____ **Justification:** • Added this question for clarification about isolate testing practices at each laboratory, which has implications on MuGSI case reporting. This information is readily available for EIP staff.	
Addition	**Additional information on MuGSI surveillance activities** 2. In 2023, did your site update its inventory of facilities within the MuGSI surveillance area? _____ yes _____ no a. If no, why not? _____ _____ b. If yes, how many facilities serve the MuGSI surveillance area? _____ c. If yes, how many facilities have you identified the clinical laboratory that serves it?_____ **Justification:** • Added this question for clarification about the facilities participating in MuGSI surveillance activities at the EIP sites. This information should be readily available because EIP staff complete this inventory on an annual basis.	Increase in burden
Addition	**Additional information on MuGSI surveillance activities** 3. Does your site run a data edit program in addition to the CDC edit program that is sent out monthly? This could include the data edits available on the	Increase in burden

	MuGSI Case Management System dashboard. _____ yes _____ no a. If yes, how often: _____ Monthly _____ Quarterly _____ Other time frame, specify: _____ _____ Never b. If yes, what type of edits are you running? Do you think they would be helpful to add to edits generated by CDC? _____ **Justification:** • Added this question for clarification about data cleaning at the EIP sites. This information should be readily available for EIP staff since it relates to their routine roles and responsibilities.	
Addition	**Additional information on MuGSI surveillance activities** 4. Did your site geocode MuGSI cases in 2023? _____ yes _____ no a. If yes, what is the most recent year of surveillance data that was geocoded? _____ b. If no, why not? **Justification:** • Added this question for clarification about MuGSI cases being geocoded, which is required on an annual basis, so this information is readily available for EIP staff.	Increase in burden
Addition	**Additional information on MuGSI surveillance activities** 5. Did your site match MuGSI cases to the state vital statistics death registry in 2023? _____ yes _____ no	Increase in burden

	a. If yes, what is the most recent year of surveillance data that was matched?_____ b. If no, why not? _____ **Justification:** • Added this question for clarification about MuGSI cases being matched to the state vital statistics death registry, which is required on an annual basis, so this information is readily available for EIP staff.	
Addition	**Additional information on MuGSI surveillance activities** 6. Did your site complete CRF re-abstractions in 2023? _____ yes _____ no a. If yes, what was the most recent year of surveillance data with CRFs re-abstracted? _____ b. If no, why not? _____ **Justification:** • Added this question for clarification about MuGSI chart re-abstractions, which is required on an annual basis, so this information is readily available for EIP staff.	Increase in burden
Revision	**Additional information on MuGSI surveillance activities** 7. What is the IRB determination for MuGSI at your site? ____Research ____Non-Research ____Other ____Unknown **Justification:** • Justification: Included a response option for this existing question, instead of the previous free-text response.	No change in burden
Addition	**Additional information on MuGSI surveillance activities** 8. General comments_____ **Justification:** • Added a free-text field for any general comments related to the information	No change in burden.

	collected on the survey.	

Invasive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface Case Report Form (HAIC.400.4)		
Type of Change	**Itemized Changes / Justification**	**Impact to Burden**
Addition/Revision	22. SUSCEPTIBILITY RESULTS (S=Sensitive (1), I=Intermediate (2), R=Resistant (3), NS=Non-susceptible (4), SDD=Susceptible dose-dependent (5), U=Unknown/Not Reported (9) Cefazolin □S □I □R □U Cefoxitin □S □R □U **Ceftaroline □S □SDD □R □U** Clindamycin □S □I □R □U **Daptomycin □S □I □R □U** **Doxycycline □S □I □R □U** **Linezolid □S □R □U** Nafcillin □S □I □R □U Oxacillin □S □R □U **Tetracycline □S □I □R □U** TMP-SMX □S □I □R □U Vancomycin □S □I □R □U **Justification:** • Added antimicrobial agents “Daptomycin”, “Doxycycline”, “Ceftaroline”, “Linezolid”, and “Tetracycline” as these drugs are commonly used to treat *S. aureus* infections; isolates are often tested for susceptibilities to these drugs but the information is not currently captured in our surveillance. Inclusion of these additional relevant drugs in surveillance is important for understanding and following invasive *S. aureus* resistance patterns over time. • Updated wording of one antimicrobial agent from “Trimethoprim-sulfamethoxazole” to “TMP-SMX”, a commonly used abbreviation	0.5-minute increase
Addition	28a. Does the patient have (check all that apply) Implanted cardiac device (e.g., prosthetic heart value, pacemaker, AICD, LVAD) □Yes, specify:___ □No □Unknown If yes, is it associated with the MRSA/MSSA infection? □Yes □No □Unknown Implanted orthopedic device (e.g., prosthetic joint or orthopedic □Yes, specify:___ □No □Unknown If yes, is it associated with the MRSA/MSSA infection? □Yes □No □Unknown	0.5-minute increase

	hardware? Non-dialysis vascular graft □Yes □No □Yes □No □Unknown □Unknown **Justification:** • *S. aureus* is an important cause of implanted device-associated infections; these questions will allow us to better describe and quantify infections related to implanted devices	
Addition	28b. Does the patient have another type of implanted prosthetic device that was associated with the infection? □ Yes, specify:_____ □ No □ Unknown **Justification:** • Many invasive *S. aureus* infections are associated with implanted devices; these questions will allow us to better describe and quantify infections related to implanted devices	Increase
Revision	29. □ Transplant, solid organ:_____ **Justification:** • A specify box has been added to the CRF to capture the solid organ that was transplanted (for instances where the patient had a solid organ transplant). • This information was previously captured in the "general comments" section of the form	No change to burden
Invasive *Staphylococcus aureus* Laboratory Survey (HAIC.400.5)		
Type of Change	**Itemized Change / Justification**	**Impact to Burden**
Revision	CDC's Healthcare-Associated Infections Community Interface (HAIC) *Staphylococcus aureus* **2024** Laboratory Survey: Use of Nucleic Acid Amplification Testing (NAAT).	No change in burden

	• Updated the title of the survey by replacing “2023” with “2024” **Justification:** • This will inform respondents to the year of interest	
Addition	**Date Survey Last Completed: _____** • Adding a field “Date Survey Last Completed” **Justification:** • This will define the time-period since the last survey, which will serve as a frame of reference for question 2	Increase
Revision/Addition	5b. Which tests do you use to detect *S. aureus* directly from a sterile site source without culture (sterile site sources only, i.e., blood, CSF, pleural fluid, bone, etc.)? Please check all that apply. □ T2Bacteria® Panel…Date started _____ **□ Other FDA-approved test, specify___ Date started __** **Method: □ PCR □ Next generation sequencing (NGS)** **□ Other, specify _____** □ Karius Test™… Date started_____ □ Other, Lab developed test (detects MRSA or SA)… Date started _ **Method: □ PCR □ Next generation sequencing (NGS)** **□ Other, specify _____** **Justification:** • Changed the wording for one option from “Other commercial test, specify” to “Other FDA-approved test, specify” to help clarify what we are asking • Added follow-up questions for labs using Other FDA approved tests and/or other lab developed tests to capture the testing method being used. This will contribute to a better	Increase

	understanding of how labs are identifying *S. aureus*	
Revision	5g. Where do you plan to have these tests performed? ◘ On-site ◘ Send out, please specify lab _____ - **END SURVEY** • Added a skip pattern ("END SURVEY")	No change in burden
Addition	5h. Which tests do you plan to use to detect *S. aureus* directly from a sterile site source without culture? (sterile site sources only, i.e., blood, CSF, pleural fluid, bone, etc.)? Please check all the apply. ◘ T2Bacteria® Panel…Date started _____ ◘ Other FDA-approved test, specify___ Date started __ ◘ Karius Test™… Date started_____ ◘ Other, Lab developed test (detects MRSA or SA)… Date started _ 5i. Will all positive tests directly from sterile sources (without positive culture) appear in the *S. aureus* surveillance laboratory line lists? ◘ Yes ◘ No ◘ Unknown 5j. Will you still obtain an isolate for *S. aureus* or MRSA if these tests are used? ◘ Yes-END SURVEY ◘ No-END SURVEY ◘ Unknown – END SURVEY **Justification:** • Added to understand how commonly culture-independent tests are used for detecting invasive *S. aureus* and whether these isolates are being reported to surveillance, either through appearance of the culture-independent test in the surveillance laboratory line lists or through existing isolate-based reporting. This information can inform estimates of potential underreporting of cases to isolate based surveillance.	0.5-minute increase
Invasive *Staphylococcus aureus* Supplemental Surveillance Officer Survey (HAIC.400.6)		

Type of Change	Itemized Change / Justification	Impact to Burden
Revision	**2023** HAIC Invasive *Staphylococcus aureus* Supplemental Surveillance Officer Survey • Updated the title of the survey by replacing "2022" with "2023" **Justification:** • This will inform respondents to the year of interest	No change to burden
Revision	Please answer the following questions for the year **2023**. The purpose of the survey is to verify and document current surveillance procedures, including cases ascertainment and auditing methods. Please enter your responses into the corresponding REDCap database. If you have any questions, please contact Kelly Jackson (gqv8@cdc.gov). • Updated the introductory text of the survey by replacing "2022" with "2023" **Justification:** • This will inform respondents to the year of interest	No change to burden
Revision	Surveillance area characteristics 3. Did your site send MRSA/MSSA isolates to CDC for characterization in **2023**? ___yes ____no • Updated the question text by replacing "2022" with "2023" **Justification:** • This will inform respondents to the year of interest	No change to burden
Revision	Surveillance area characteristics 5a. If yes: i. Please mark which NHSN data your site can access	No change to burden

	_____ Hospital MRSA LabID event _____ Hospital central line-associated bloodstream infection (CLABSI) data _____ **Hospital Antimicrobial Use and Resistance (AUR) Option** _____ Dialysis event • Added a checkbox for "Hospital Antimicrobial Use and Resistance (AUR) Option" **Justification:** • This will allow us to better identify if sites are able to obtain this NHSN data that could be used to supplement EIP surveillance data in future analyses.	
Revision	Surveillance area characteristics 5b. If no: i. Please mark which NHSN data can be accessed _____ Hospital MRSA LabID event _____ Hospital CLABSI data _____ **Hospital AUR Option** _____ Dialysis event • Added a checkbox for "Hospital AUR Option" **Justification:** • This will allow us to better identify if sites are able to obtain this NHSN data that could be used to supplement EIP surveillance data in future analyses.	No change in burden
Revision	Lab Participation and Case Finding *Please answer the following questions for hospitals and labs under surveillance for **2023.*** • Updated the introductory text to the "Lab Participation and Case Finding" section by replacing "2022" with "2023"	No change in burden

<table>
<tr><td></td><td>Justification:

• This will inform respondents to the year of interest</td><td></td></tr>
<tr><td>Revision</td><td>Lab participation and case finding

1. Please list the total number of each type of lab serving (i.e., routinely processes “sterile site” specimens from residents of the surveillance area) your MRSA surveillance catchment area (both inside and outside of the catchment area) and the total number of each type of lab participating (i.e., submit test results when available) in surveillance (both inside and outside the catchment area):

• Added “i.e., routinely process “sterile site” specimens from residents of the surveillance area” prior to “your MRSA surveillance catchment area” and following “lab serving”

Justification:

• This wording was added to improve clarity of the question</td><td>No change in burden</td></tr>
<tr><td>Revision</td><td>Lab participation and case finding

2. If different catchment that MRSA, please list the total number of each type of lab serving (i.e., routinely processes “sterile site” specimens from residents of the surveillance area) your MSSA surveillance catchment area (both inside and outside of the catchment area) and the total number of each type of lab participating (i.e., submit test results when available) in surveillance (both inside and outside the catchment area):

• Added “i.e., routinely process “sterile site” specimens from residents of the surveillance area” prior to “your MSSA surveillance catchment area” and following “lab serving”

Justification:

• This wording was added to improve clarity of the question</td><td>No change in burden</td></tr>
<tr><td>Revision</td><td>Lab participation and case finding

4. Indicate the percentage contribution of each case finding method to your site’s total SA case counts (100%) in 2023.

<table><tr><td>Case Finding</td><td>% MSSA Case</td><td>% MRSA Case</td><td>Method</td></tr></table></td><td>No change in burden</td></tr>
</table>

	Method used?	Count Contribution	Count Contribution	
	□ Y □ N			NETSS/NEDSS or other passive state reporting system
	□ Y □ N			**Routinely received** line lists from *hospital* labs
	□ Y □ N			Routinely received line lists from *Commercial/outpatient* labs
	□ Y □ N			Routinely received line lists from *dialysis referral* labs
	□ Y □ N			Regular lab visits; *frequency:* _____
	□ Y □ N			ICPs submitting case report form
	□ Y □ N			Isolates being received at state lab
	□ Y □ N			NHSN
	□ Y □ N			Other, please specify: _____
	a. Do you expect this distribution and/or percentage values to change in **2024**? _____ yes _____ no i. If yes, please explain why: _____ • Updated the text of question 4 to replace "2022" with "2023" • This will inform respondents to the year of interest • Updated the text of the second method listed from "Retrospective review of received line lists from *hospital* labs" to "Routinely received line lists from *hospital* labs" • This wording was updated to improve clarity of the question • Updated the text of question 4a to replace "2023" with "2024" • This will inform respondents to the year of interest			
Revision	Lab participation and case finding 5. For labs reporting invasive SA, how many of the participating labs are providing case reports through direct electronic messaging, such as HL7 messaging?			No change in burden

	_____ a. If less <100%, how else are you receiving reports (**check all that apply**)? **□ Secure email** **□ Fax** **□ Manual surveillance on-site** **□ Mailed hard copies** **□ State electronic reporting system** **□ Other, specify: _____** • Updated question 5a to add "check all that apply" • Updated the response type from a free text response to checkboxes **Justification:** • Replacing free text field with checkboxes will make data entry and analysis easier	
Revision/Addition	Lab participation and case finding 6. Did any labs drop out of participation in **2023**? _____ yes _____ no a. If yes, how many? _____ b. Why did these labs drop out of participation?_____ **c. Approximately how many cases did this/these lab(s) identify each year among residents of your catchment area?** • Updated the text of question 6 to replace "2022" with "2023" • This will inform respondents to the year of interest • Added question 6c, "Approximately how many cases did this/these lab(s) identify each year among residents of your catchment area"	0.5-minute increase

<table>
<tr><td></td><td>This will allow us to estimate the impact of non-participating labs on yearly case counts</td><td></td></tr>
<tr><td>Revision</td><td>Lab participation and case finding

7. In 2023, did you identify any additional labs, regardless of location, which identify invasive SA isolates from persons who are residents of your catchment area?

_____ yes _____ no
Updated the text of question 7 to replace “2022” with “2023”
Justification:
This will inform respondents to the year of interest</td><td>No change in burden</td></tr>
<tr><td>Revision</td><td>Data Edits

2. Did your site complete CRF re-abstractions during 2023? ___ yes ____ no
Updated the text of question 2 to replace “2022” with “2023”
Justification:
This will inform respondents to the year of interest</td><td>No change in burden</td></tr>
<tr><td>Revision</td><td>Ascertainment of surveillance area and case audits

1. How did your site define an audit case in 2023?
Updated the text of question 1 to replace “2022” with “2023”
Justification:
This will inform respondents to the year of interest</td><td>No change in burden</td></tr>
<tr><td>Revision</td><td>Ascertainment of surveillance area and case audits

2. Indicate the percentage contribution of each finding method to your site’s <u>audit counts</u> (100%) in <u>2023</u><table><tr><td>Audit Method used?</td><td>% MSSA Audit Count Contribution</td><td>% MRSA Audit Count Contribution</td><td>Method</td></tr><tr><td>□ Y □ N</td><td></td><td></td><td>NETSS/NEDSS or other passive state reporting</td></tr></table></td><td>No change in burden</td></tr>
</table>

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<tr><td></td><td>
<table>
<tr><td></td><td></td><td></td><td>system</td></tr>
<tr><td>□ Y □ N</td><td></td><td></td><td>Routinely received line lists from <u>hospital</u> labs</td></tr>
<tr><td>□ Y □ N</td><td></td><td></td><td>Routinely received line lists from <u>Commercial/outpatient</u> labs</td></tr>
<tr><td>□ Y □ N</td><td></td><td></td><td>Routinely received line lists from <u>dialysis referral</u> labs</td></tr>
<tr><td>□ Y □ N</td><td></td><td></td><td>Regular lab visits; frequency: _____</td></tr>
<tr><td>□ Y □ N</td><td></td><td></td><td>ICPs submitting case report form</td></tr>
<tr><td>□ Y □ N</td><td></td><td></td><td>Isolates being received at state lab</td></tr>
<tr><td>□ Y □ N</td><td></td><td></td><td>NHSN</td></tr>
<tr><td>□ Y □ N</td><td></td><td></td><td>Other, please specify: _____</td></tr>
</table>

Updated the text of question 2 to replace “2022” with “2023”
This will inform respondents to the year of interest
Updated the text of the second method listed from “Retrospective review of received line lists from <u>hospital</u> labs” to “Routinely received line lists from <u>hospital</u> labs”
This wording was updated to improve clarity of the question

</td><td></td></tr>
<tr><td>Revision</td><td>Ascertainment of surveillance area and case audits

3d. How many laboratories did you audit in 2023?
Updated the text of question 3d to replace “2022” with “2023”
Justification:
This will inform respondents to the year of interest</td><td>No change in burden</td></tr>
<tr><td>Revision</td><td>Ascertainment of surveillance area and case audits

4. In 2023, did your site update its inventory of facilities within the EIP catchment area? ___yes ___no
Updated the text of question 3d to replace “2022” with “2023”
This will inform respondents to the year of interest</td><td>No change in burden</td></tr>
<tr><td>Deletion</td><td>Ascertainment of surveillance area and case audits

7. Does your site have checks in place to recognize decreasing/increasing</td><td>Decrease</td></tr>
</table>

	case counts or rates of MRSA disease? _____ yes _____ no a. If yes, please describe the check(s) that you use b. If yes, how often are the check(s) used? **a.If yes, do you plan to use these for MSSA once more surveillance data are available? ___yes ___ no** • Deleting question 7b sub-question a ("if yes, do you plan to use these for MSSA once more surveillance data are available") because we now have several years of surveillance data available and are adding a question about site checks to recognize decreasing/increasing case counts or rates of MSSA disease.	
Addition	Ascertainment of surveillance area and case audits 8. Does your site have checks in place to recognize decreasing/increasing case counts or rates of MSSA disease? _____ yes _____ no a. If yes, please describe the check(s) that you use b. If yes, how often are the check(s) used? **Justification:** • This new question asks if MSSA data checks for decreasing/increasing case counts or rates of MSSA are used. If so, we ask for a description of the checks and the frequency with which they are used. • This allows us to document site-specific data quality checks.	0.5-minute increase
Revision	Geocoding 1. Did your site geocode SA cases in **2023**? ___yes ___no	No change in burden

	• Updated the text of question 3d to replace “2022” with “2023” **Justification:** • This will inform respondents to the year of interest	
Revision	Vital records linkages 1. Did your link SA cases to vital records (mortality matching) in **2023**? ___yes ___no • Updated the text of question 3d to replace “2022” with “2023” **Justification:** • This will inform respondents to the year of interest	No change in burden
Deletion	COVID-19 impact section 1. Did COVID-19 response activities affect or delay 2022 iSA surveillance work (e.g., unable to meet iSA deadlines during 2022)? ___ yes __ no a. If no, how were you able to meet iSA deadlines? b. If yes, how did COVID-19 response activities delay your iSA work? **Justification:** • We have removed all questions in the COVID-19 impact section because the COVID-19 public health emergency declaration expired.	0.5-minute decrease