Emerging Infections Program (0920-0978)

Revision

Exp. Date XX/XX/XXXX

SUPPORTING STATEMENT PART A: Justification

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- This ICR includes four collections:
  - Active Bacterial Core surveillance (ABCs): active population-based laboratory surveillance for invasive bacterial diseases;
  - Foodborne Diseases Active Surveillance Network (FoodNet): active population-based laboratory

List of Attachments

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2) 60-Days Federal Register Notice
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4) ABCs – 2018 H. Influenzae Neonatal Sepsis Expanded Surveillance Form (HiNSES)
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A. Justification

1. Circumstances Making the Collection of Information Necessary

A three-year OMB clearance revision is requested for "Emerging Infections Program (EIP) OMB No. 0920-0978."

A revision is being submitted to make existing collection instruments clearer and more comprehensive, to add two new collection instruments. These new collection instruments will allow the EIP to better describe community-associated CRE cases, and to identify other known potentially modifiable risk factors or sources for CP-CRE acquisition, such as international travel, previous use of antibiotics, occupation, exposure to animals, household contacts with risk factors for CRE acquisition, and other risk factors.

The new collection instruments include the following:

1. HAIC- Community-Associated Carbapenemase- Producing Carbapenem-Resistant Enterobacteriaceae (CA CP-CRE) Interview Form (with interview introductory script) (Attachment 22) and accompanying instruction manual: HAIC CA CP-CRE Interview Instruction Manual (Attachment 23)
2. HAIC Multi-site Gram-Negative Surveillance Initiative (MuGSI) Supplemental Surveillance Officer Survey (SO) (Attachment 24)

Additionally, the HAIC program has been collecting information through linking identified cases to participating sites state health department's vital records death index to determine if a patient died within 90 days of the case's date of initial culture. The linking between the HAIC surveillance data and the state vital records death index has been ongoing since 2018 and includes retrospective linkage of surveillance data that were collected before 2018. Documentation of the collection of these variables has not been included in previous OMB PRA submissions. This death ascertainment information is not collected through a formal case report form but rather information is sent electronically.

The estimates of the infection incidence generated by this collection provide the foundation for a variety of epidemiologic studies to explore risk factors, spectrum of disease, and prevention strategies.

The Emerging Infections Programs (EIPs) are population-based centers of excellence established through a network of state health departments collaborating with academic institutions; local health departments; public health and clinical laboratories; infection control professionals; and healthcare providers. EIPs assist in local, state, and national efforts to prevent, control, and monitor the public health impact of infectious diseases. Clearance approval for 3 years is sought under this request.

Activities of the EIPs fall into the following general categories: (1) active surveillance; (2) applied public health epidemiologic and laboratory activities; (3) implementation and evaluation of pilot prevention/intervention projects; and (4) flexible response to public health emergencies.

Activities of the EIPs are designed to: (1) address issues that the EIP network is particularly suited to investigate; (2) maintain sufficient flexibility for emergency response and new problems as they arise; (3) develop and evaluate public health interventions to inform public

health policy and treatment guidelines; (4) incorporate training as a key function; and (5) prioritize projects that lead directly to the prevention of disease.

Activities in the EIP Network to which all applicants must participate are:

- Active Bacterial Core surveillance (ABCs): active population-based laboratory surveillance for invasive bacterial diseases.
- Foodborne Diseases Active Surveillance Network (FoodNet): active population-based laboratory surveillance to monitor the incidence of select enteric diseases.
- Influenza: active population-based surveillance for laboratory confirmed influenza-related hospitalizations.

- Healthcare-Associated Infections-Community Interface (HAIC) surveillance: active population-based surveillance for healthcare-associated pathogens and infections.

Table A.1 Listing of all Activities and subprojects included in this ICR package

Activity	**Surveillances/Projects**
ABCs	ABCs Surveillance
	ABCs H. influenzae Neonatal Sepsis Expanded Surveillance (HiNSES)
	ABCs Invasive Pneumococcal Disease in Children and Adults Case Report
	ABCs Neonatal Infection Expanded Tracking
	ABCs Severe GAS Infection Supplemental
FoodNet	FoodNet Active Surveillance
	Hemolytic Uremic Syndrome (HUS) Surveillance
	FoodNet Clinical Laboratory Practices and Testing Volume
Influenza	Influenza Hospitalization Surveillance Network (FluSurv-NET)
	FluSurv-NET Laboratory Survey
HAIC	
	HAIC - CDI Surveillance and Treatment
	HAIC- Annual Survey of Laboratory Testing Practices for C. difficile Infections
	HAIC- CDI Annual Surveillance Officers Survey
	HAIC- Emerging Infections Program C. difficile Surveillance Nursing Home Telephone Survey (LTCF)

	HAIC - MuGSI Carbapenem-resistant Enterobacteriaceae (CRE) and Acinetobacter baumannii (CRAB)
	HAIC - MuGSI Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae and Invasive *E. coli* (ESBL/iEC)
	HAIC- Community-Associated Carbapenemase-Producing Carbapenem-Resistant Enterobacteriaceae (CA CP-CRE) Interview (with interview introductory script) (New)
	HAIC Multi-site Gram-Negative Surveillance Initiative (MuGSI) Supplemental Surveillance Officer Survey (SO) (New)
	HAIC - Invasive Methicillin-resistant Staphylococcus aureus (MRSA) Infection
	HAIC - Invasive Methicillin-sensitive Staphylococcus aureus (MSSA) Infection
	HAIC- Invasive Staphylococcus aureus Laboratory Survey
	HAIC- Invasive Staphylococcus aureus Supplemental Surveillance Officers Survey
	HAIC Candidemia Surveillance
	HAIC- Laboratory Testing Practices for Candidemia Questionnaire

Information in Identifiable Form (IIF) will be collected by each EIP site, and selected identifiers (such as name or medical record number) will be removed prior to its transmission of data to CDC. Please refer to section A.10 for further description of the process for removing selected identifiers from data. Other information that may be collected could include hospitalization history, lab test results and culture information, symptoms, discharge diagnosis, antimicrobial treatments, ICD-9 or ICD-10 codes, healthcare worker status, influenza vaccination status, and underlying medical conditions. Information transmission occurs via a secure CDC website. The case report form does not involve web-based data collection methods, although case report form data are entered into a CDC-developed, approved web-based data management system for some activities and does not refer respondents to websites.

Previous OMB approval terms of clearance stated that CDC will request approval to extend or revise the collection if the agency seeks to continue the information collection activity beyond the period approved. EIP has followed and will continue to follow OMB procedures and will submit change requests and revisions for modifications to collection instruments as needed.

Additional terms of clearance required CDC to continue to add language to its website and reports that clearly caveats the interpretation of longitudinal trends due to changes in the number and characteristics of participating hospitals

***FoodNet.** There is a timeline (https://www.cdc.gov/foodnet/about/timeline.html) that describes changes in FoodNet's surveillance area over time. They also describe changes in their clinical laboratories and how those practices might affect incidence and trends - "More than 700 clinical laboratories in the FoodNet surveillance area test specimens from ill people. These laboratories differ in their routine testing practices for foodborne pathogens and in methods they use. Such differences may contribute to variation in the incidence rate of reported infections between FoodNet sites. To understand current practices and to monitor changes in practices over time, FoodNet conducts periodic surveys of all clinical laboratories within the surveillance area." (https://www.cdc.gov/foodnet/surveys/lab.html#general-surveys).

***HAIC.** Information about the surveillance methods, including the population under surveillance for each year of surveillance can be found at this link: https://www.cdc.gov/hai/eip/index.html . This information is on the individual webpages for each activity, and also is included in the annual reports posted on the webpages for example, see https://www.cdc.gov/hai/eip/pdf/2020-MRSA-Report-508.pdfOn the HAICViz data visualization site (https://www.cdc.gov/hai/eip/haicviz.html), this language is included (using MRSA as an example): "Methods for this surveillance activity have changed over time. MRSA annual reports provide information about changes in methods from year to year. Surveillance areas have changed over time."

The program also includes the following information in HAICViz, on "Understanding HAICViz Data" (https://www.cdc.gov/hai/eip/haicviz.html):

> "Data presented in HAICViz may differ from other HAIC publications since different datasets or methods may be used.
>
> Small numbers for some topics or filters may make year to year changes difficult to interpret.
>
> Since each infection may have unique characteristics, the information available to display differs by individual organism."

***ABC:** Please see: https://www.cdc.gov/abcs/understanding-bfi-data.html . ABCs reports describe the ABCs case definition and the specific methodology used to calculate rates and estimated numbers in the United States for each bacterium by year. The methods, surveillance areas, and laboratory isolate collection areas have changed over time. Additionally, the way missing race data are taken into account changed in 2010. It went from distributing unknown values based on known values of cases by site to use of multiple imputation using a sequential regression imputation method. Given these changes over time, trends should be interpreted with caution.

***On FluSurv-Net:** The website there is no data related to number or characteristics of hospitals. Currently, there is also no explicit information about how surveillance methodology and catchments may have changed over time; CDC commits to rectifying this within the next 60 days. On FluView Interactive, it is mentioned how additional sites were brought on and when (Laboratory-Confirmed Influenza Hospitalizations (cdc.gov)). There are references in footnotes to the implementation of sampling strategies and how catchment areas differ across FluSurv-NET, COVID-NET, and RSV-NET but only specifically since the 2020-2021 seasons (RESP-NET Interactive Dashboard | CDC).

This program is authorized under the Public Health Service Act Sections 301(a)[42 U.S.C. 241(a)], 317(k)(1)[42 U.S.C. 247b(k)(1)], and 317(k)(2)[42 U.S.C. 247b(k)(2)], as amended (Attachment 1).

2. Purpose and Use of Information Collection

ABCs data is critical for documenting disease burden, describing the epidemiology of these bacterial pathogens, detecting emerging infections and epidemics, tracking trends in antimicrobial resistance, contributing to the development and evaluation of new vaccines, developing and assessing public health prevention measures, and improving overall public health practice. ABCs is currently being used to evaluate the effectiveness of meningococcal and pneumococcal vaccines. ABCs data is also used to develop ACIP recommendations for use of bacterial vaccines in children, adolescents, and adults. Surveillance data from ABCs is also used to evaluate non-vaccine interventions for invasive bacterial disease. Continuation of these activities is essential to reduce the burden of invasive disease due to these pathogens.

The Foodborne Diseases Active Surveillance Network (FoodNet) is the principal foodborne disease component of the Centers for Disease Control and Prevention's (CDC) Emerging Infections Program. FoodNet is a collaborative project among CDC, ten state health departments, the Food Safety and Inspection Service of the United States Department of Agriculture (USDA), and the Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine of the United States Food and Drug Administration (FDA).

The objectives of FoodNet are to determine the burden of foodborne diseases in the United States; monitor trends in the burden of specific foodborne illnesses over time; attribute the burden of foodborne illnesses to specific foods and settings; and disseminate information that can lead to improvements in public health practice and the development of interventions to reduce the burden of foodborne illness. FoodNet was established in 1996 in five sites: Minnesota, Oregon, and selected counties in California, Connecticut, and Georgia. By 2004, the FoodNet surveillance area had expanded to include 10 sites; Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, and Tennessee, and selected counties in California, Colorado, and New York. In 2019, the surveillance area included 50 million persons (15% of the U.S. population).

FoodNet conducts population-based active surveillance for laboratory-based infections of select pathogens and a condition commonly transmitted through food: including *Campylobacter*, *Cyclospora*, *Listeria monocytogenes*, *Salmonella*, Shiga toxin-producing *Escherichia coli* (STEC), *Shigella*, *Vibrio*, *Yersinia* and hemolytic uremic syndrome (HUS) in residents of the FoodNet surveillance area.

In 2019, a pilot for surveillance of Enterotoxigenic E. coli (ETEC) was conducted in select sites. FoodNet collects standardized data elements from Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, and Tennessee and selected counties within California, Colorado, and New York. Previous OMB approval terms of clearance stated the following: any changes to EIP as a result of ETEC pilot will be submitted for review and approval prior to fielding the data collection. FoodNet's ETEC pilot began in 2019. As of 2023, 3 FoodNet site have participated. State FoodNet sites collected laboratory and epidemiologic data for confirmed ETEC cases. Preliminary findings from the states were presented at an internal FoodNet meeting. CDC is currently working to analyze the grouped data to estimate incidence and characterize the epidemiology of ETEC cases, and results will be shared and discussed with our state partners. The pilot has not changed routine FoodNet surveillance activities at this time. Any future changes to FoodNet activities will be submitted for approval. The majority of data elements that are transmitted to the FoodNet program at CDC are collected as part of routine public health follow up at the state. Information is collected through electronic laboratory records, chart review, patient interview, or directly from providers or clinical laboratories. In addition, laboratory practices and testing volume are assessed for clinical laboratories within the surveillance area. FoodNet collects standard data elements for the 7 pathogens (Attachment 8), and for one additional pathogen, Norovirus, as part of clinical laboratory surveillance, and has a case report form for HUS (Attachment 9). All information is housed at the state level in state-specific data systems. An extract of the active laboratory-based surveillance data is made monthly and transmitted to CDC. Data elements for clinical laboratory practices and testing volume are submitted to CDC annually. HUS data is either directly entered or imported into a centralized database and data is reviewed annually. No individually identifiable information is collected at CDC, data are only identifiable at the state level.

The Centers for Disease Control (CDC), National Center for Immunization and Respiratory Diseases (NCIRD) is committed to achieving the "Healthy People 2020" goals of increasing immunization rates and reducing preventable infectious diseases. The Influenza Hospitalization Surveillance Network (FluSurv-NET) aligns with these goals and plays an integral role in protecting America's health. FluSurv-NET is used to obtain population-based surveillance data about laboratory-confirmed influenza-associated hospitalizations in children and adults. These data are used to estimate the national burden of and risk factors for influenza-associated hospitalizations in the United States. The results from this data collection assist the Influenza Division and the CDC in determining which groups are at increased risk for severe outcomes of influenza and in guiding public health interventions and vaccine recommendations. The data are also used to determine the averted burden of influenza through vaccination.

The need for data on influenza impact in children was first highlighted during the 2003-2004 season when anecdotal reports of influenza-associated pediatric deaths and severe complications in otherwise healthy children emerged. When CDC launched an emergency response in December 2003, no systems were in place that could substantiate these anecdotal reports in a timely manner. To address this need, the available surveillance infrastructure of the Emerging Infections Program (EIP) was used to commence FluSurv-NET. In 2005, adult influenza surveillance was added to this platform. In 2006, data from FluSurv-NET were used by the Advisory Committee on Immunization Practices (ACIP) in its decision to expand the ages for which it recommended influenza vaccination from 6-23 month olds to 6- 59 month olds, and to evaluate influenza vaccine effectiveness based on these recommendations. FluSurv-NET data were used by the ACIP in its decision to expand influenza vaccination recommendations for all persons aged 6 months or older. The utility of these data was further underscored during the 2009 H1N1 pandemic. FluSurv-NET data were used to identify groups at highest risk for influenza-associated hospitalizations (e.g., pregnant women during the 2009 H1N1 pandemic), mathematically model the morbidity and mortality burden of the influenza pandemic and provide data for several peer-reviewed journal articles describing seasonal and pandemic influenza among high risk groups in the population. The data collection network is part of the Emerging Infections Program (EIP), an established CDC-state-academic institution collaborative network which includes the states of California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee. Upon verification of an influenza positive laboratory result and confirmation of residence within the pre-defined FluSurv-NET catchment area, each FluSurv-NET site conducts data abstraction of the medical chart and laboratory report to complete the project's standardized case report form. Influenza vaccination status is an important piece of information that is used to evaluate the influenza vaccine program. To obtain as complete an influenza vaccine history as possible sites will use the following sources to collect this information: 1) review the patient's medical chart, 2) consult the state vaccination registry, 3) contact the patient's provider via fax or telephone and/or 4) contact the patient or their proxy. If providers and/or patients or proxies need to be contacted, a Consent Form and Provider Vaccination History Fax Form will be used to obtain influenza vaccination history.

The Healthcare-Associated Infections/Community Interface (HAIC) activity was launched in 2009. The HAIC projects include large-scale projects involving all 10 EIP sites that have their own OMB numbers as well as smaller-scale projects involving fewer than 10 EIP sites. The HAIC activity is a collaboration between CDC and the 10 state health departments and academic partners of the EIP network, in California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee. Healthcare-associated infections (HAIs) are major threats to patient safety and public health in the United States. Elimination of HAIs is a U.S. public health priority. The HAIC activity contributes to the goal of eliminating HAIs through its mission to promote patient safety and healthcare quality by critically evaluating the epidemiology and public health impact of HAIs to understand emerging pathogens and populations-at-risk and to inform prevention interventions. The HAIC activity conducts population-based surveillance for urgent threats to patient safety, including *Clostridioides difficile* infection (CDI), select Gram-negative bacilli, invasive *Candida* infections, and invasive *Staphylococcus aureus* infections.

The HAIC activity also conducts periodic HAI and antimicrobial use prevalence surveys under 0920-0852 (hospital survey, expiration 12/31/2019) and 0920-1165 (nursing home survey, expiration 02/29/2020)—these projects are not population-based surveillance, are methodologically distinct from 0920-0978, and were therefore not incorporated into 0920-0978 and will maintain their own OMB control numbers.

For HAIC activities included in 0920-0978, upon verification of a positive laboratory result, each EIP site conducts data abstraction of the medical chart and laboratory report to complete the standardized case report forms. HAIC data collection forms are used by sites during review of medical records to collect demographic and clinical information on laboratory-confirmed cases of CDI, select Gram-negative bacilli, invasive *S. aureus* infection, and invasive *Candida* infections. Each participating EIP site will destroy identifiers at the earliest opportunity, unless there is a public health or research justification for retaining the identifiers or they are required to by law. For CDI, invasive *S. aureus* infections and invasive *Candida* infections, surveys are every 2-3 years to the laboratories reporting surveillance cases. These surveys are being included in this package. For select Gram-negative bacilli surveillance (i.e., MuGSI), a formal laboratory survey is not conducted. Instead, the sites are instructed to speak with the laboratories serving the EIP catchment area that are reporting cases and determine if any changes have been made to the lab's automated testing instrument (ATI) (including, but not limited to, changes in software or card types or introduction of new technology into the laboratory), what antimicrobial susceptibility breakpoints the laboratory is using for the carbapenem antibiotics and if the laboratory is conducting any confirmatory testing for carbapenemases. Additionally, for MuGSI there are four additional optional variables that are currently under collection, the unique identifier (ID) assigned by the state public health laboratory (i.e., the state public health ID), the National Notifiable Disease Surveillance System (NNDSS) ID that is assigned to a subset of MuGSI cases (i.e., the NNDSS ID), the type of healthcare facility as determined by the Centers for Medicare and Medicaid (CMS) (i.e., the CMS ID), and the type of testing laboratory (e.g., state health department laboratory, clinical laboratory). The collection of the state public health laboratory ID and the NNDSS ID is optional. The collection of the laboratory type and the CMS type is a required component of the MuGSI data management system. All four variables are entered in the MuGSI data management system only and are transmitted to CDC through the secure methods described elsewhere in this package. The type of testing laboratory was added in August of 2018, the state public health ID was added to the system in March of 2019, the CMS type was added in August of 2016, and the NNDSS ID was adding to the system in August of 2021. The purpose of collecting the state public health ID and the NNDSS ID are to link to other data systems at CDC for the purpose of acquiring isolate testing results. The purpose of collecting the laboratory type is to better understand the isolate testing data that is currently being collected through this system as documented on the MuGSI data collection forms. The purpose of collecting the CMS type is to allow for more detailed understanding of the facility types within the system beyond the categories that are currently included on the data collection instrument. Documentation of the collection of these variables have not been included in previous OMB PRA submissions. We are requesting approval to collect these variables currently. These variables do not affect the burden of data collection.

The CDI, MuGSI and invasive *S. aureus* surveillance activities annually survey the EIP program staff to evaluate program quality. Lastly, the CDI program provides a tool for EIP sites to use to

gather information about laboratory utilization among long term care facilities (LTCFs) in the EIP catchment areas.

The HAIC program also collects information through linking identified cases to the state health department's vital records death index (i.e., death index) to determine if a patient died within 90 days of the case's date of initial culture. Through this linking the following new data elements are obtained: the date of death as reported in the state vital records death index, the date 90 days after the date of initial culture, the site-determined date of death, the patient's outcome at 90 days after the date of initial culture, and any comments from the EIP site staff about the linking process. The linking between the HAIC surveillance data and the state vital records death index has been ongoing since 2018 and includes retrospective linkage of surveillance data that were collected before 2018. These data have been transmitted to CDC since the implementation of this process via excel spreadsheets, using the CDC's Secure Access Management System, for the purpose of better assessing mortality. Documentation of the collection of these variables has not been included in previous OMB PRA submissions. The burden for this linking is listed in the table below. The linking process consists of the following: identification of cases to match to the death index for each HAIC surveillance program, matching of the cases to the death index using established software (e.g., LinkPlus) or a homegrown linking process (e.g., SAS program), review of the matched data for quality purposes, creation of the tracking variables listed above, sharing the data with CDC in its final form. This process takes about 24 hour per pathogen group per surveillance activity (e.g., for MuGSI that includes CRE, CRAB and ESBL the total burden is estimated at 72 hour per year).

Data collected through HAIC population-based surveillance have utility for the government, public health officials, healthcare facilities, and the public. These data have served as the foundation for several important public health reports, including the major national CDC report entitled "Antibiotic Resistance Threats in the United States, 2019" (https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf), an MMWR on invasive MRSA among people who inject drugs (https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a2.htm), CDC Vital Signs reports on CDI (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6109a3.htm) and), *Candida* (http://www.life-worldwide.org/assets/uploads/files/Cleveland%20candidemia%20Atlanta%20Baltimore%20Clin%20Infect%20Dis%202012.pdf) and carbapenem-resistant Enterobacteriaceae (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6209a3.htm). HAIC surveillance is unique in that it collects detailed data on all cases in the population under surveillance, including cases not associated with hospitalizations or other healthcare exposures, and because isolates of the pathogens under surveillance are submitted to CDC for molecular characterization that contributes to enhanced understanding of resistance and transmission.

For the select Gram-negative bacilli program (i.e., MuGSI), based on the medical record review data collected, cases are categorized into epidemiological classes. As mentioned above, isolates are also collected as part of this project. A subset of these isolates undergo testing for carbapenemases. For cases identified to be part of the community-associated (CA) epidemiological class and for cases where the isolate tests have a carbapenemase, that case will

be eligible to have the Community-Associated Carbapenemase-Producing Enterobacteriaceae (CA CP-CRE) health interview conducted. The data collected through this health interview will achieve the following goals: 1) to validate the community-associated case's status and 2) to identify other known potentially modifiable risk factors for CP-CRE acquisition, such as international travel, previous use of antibiotics, occupation, exposure to animals, household contacts with risk factors for CRE acquisition, and other risk factors.

Through the death ascertainment project, the HAIC program also collects information through linking identified cases to participating sites state health department's vital records death index to determine if a patient died within 90 days of the case's date of initial culture. Through this linking the following new data elements are obtained: the date of death as reported in the state vital records death index, the date 90 days after the date of initial culture, the site determined date of death, the patient's outcome at 90 days after the date of initial culture, comments about the linking process. The linking between the HAIC surveillance data the state vital records death index has been ongoing since 2018. These data have been transmitted to CDC since the implementation of this process via excel spreadsheets, using the secure SAMS file transport system, for the purpose of better assessing mortality as a result of a healthcare-associated infection. Documentation of the collection of these variables have not been included in previous OMB PRA submissions. We are requesting approval to collect these variables currently. These variables do not affect the burden of data collection.

3. Use of Improved Information Technology and Burden Reduction

For ABCs case report forms will be entered and maintained at each surveillance area. CDC will provide to each EIP site a REDCap database that mirrors the data collection forms. Surveillance staff at each participating EIP site will enter data from the data collection form into the database. The computerized databases, with personal identifiers removed, will be transmitted to CDC by the fifth of every month. All the forms included in this package will be submitted to CDC electronically. All data transfers to CDC take place via a secure CDC SAMS (secure access management services).

For FoodNet, data are housed in an electronic database at each site and an extract is transmitted to CDC once a month or as needed through CDC's secure access management file transfer. In 2018, FoodNet began piloting a standardized message mapping guide (attached) transitioning data collection to an HL7 format is underway. This will allow for more automated and timely data transmission while reducing staff burden at the sites. FoodNet data elements are incorporated into state case report forms. FoodNet collects standard data elements. FoodNet does not require states to administer a separate standardized questionnaire for routine surveillance data. It is up to the states to decide how best to collect the information required. Sites do complete a standardized case report form for HUS surveillance.

For all laboratory-confirmed influenza cases, a standardized case report form is completed by surveillance officers using data obtained from medical record review. Due to the varied sizes of site catchment areas and differences in health care facilities' electronic reporting capabilities, it is

not feasible to have an electronic reporting form at each site under surveillance. Therefore, data are often obtained from manually reviewing medical and laboratory charts. If influenza vaccine history is not noted in the medical chart or state vaccination registry, telephone and facsimile equipment will be used to contact primary care providers, and if necessary, the patient and/or proxy, to obtain vaccination information.

CDC provides each FluSurv-NET site a Microsoft Access database that mirrors the case report form. Surveillance staff at each participating EIP site enters data from the case report form into the database and submit the complete database, stripped of identifiers, to CDC weekly. Sites that do not use the CDC Access database use local systems which are modeled after the CDC Access database or adapted to meet CDC requirements for data collection and delivery. All data transfers to CDC take place via a secure CDC SAMS or CDC FTP site. At CDC, data from all sites will be concatenated and exported into SAS.

HAIC data for CDI, select Gram-negative bacilli, invasive *Candida* infections, and invasive *S. aureus* infections are collected by EIP site personnel on paper case report forms or electronically (Attachments 16-31). Case tracking information is entered into secure locally housed case tracking systems for CDI and select Gram-negative bacilli; identifiable data (such as name, street address, medical record number) entered into these local systems are not shared with CDC. Case information (without identifiers such as name, medical record number, street address, etc.) from these local systems is then imported or transmitted via a secure web service into CDC-approved, web-based data management systems (including .NET and REDCap systems). Other case report form data for CDI, select Gram-negative bacilli, and invasive *Candida* infections are entered directly by EIP site personnel into these secure web-based systems. The databases used by EIP site personnel for capturing these surveillance data have Certification and Accreditation by the Office of the CDC Chief Information Security Officer (OCISO) for compliance with current information technology security policies and procedures. Data on case patient census tracts are uploaded by EIP site personnel to site-specific, encrypted, secure CDC Secure Access Management Services (SAMS) or CDC File Transfer Protocol (FTP) sites for analysis by CDC project staff. For invasive *S. aureus*, case report forms are entered and maintained in each EIP site. CDC provides each EIP, that participates in *S. aureus* surveillance, with a Microsoft Access database that mirrors the data collection forms. *S. aureus* Surveillance staff at each participating EIP site enter data from the data collection forms into the Access database. The databases, for all HAIC program data collections, with personal identifiers such as name and medical record number removed, are transmitted to CDC by sites on a regular basis. All data from forms included in this package are submitted to CDC electronically. All data transfers to CDC take place via a secure CDC SAMS or CDC FTP site.

The HAIC Annual Survey of Laboratory Testing Practices for *C. difficile* Infection, the HAIC Annual- Invasive *Staphylococcus aureus* Laboratory Survey: Use of Nucleic Acid Amplification Testing (NAAT), and HAIC Candidemia Periodic Laboratory Survey are collected through a REDCap web-based data management system. For each laboratory that responds to these surveys, a staff member at the EIP site enters the response into the system using a unique identifier that CDC cannot link to the identity of the responding laboratory. The data is exported out from REDCap by CDC staff for review and analysis. The CDI and the invasive *S. aureus* surveillance officer's surveys are completed by an EIP staff member and collected in a Microsoft

Word document and emailed to CDC. For the MuGSI surveillance officer's survey, the data will be entered into REDCap by the EIP site staff person completing the survey. The data collected in these surveys is for the purpose of program evaluation and it does not contain identifying facility or laboratory information. EIP sites typically share the data elements obtained from the CDI LTCF survey with CDC through Microsoft Excel spreadsheets. No facility specific information or laboratory information is shared with CDC. A site reports the data elements identified during the LTCF survey in aggregate.

The HAIC MuGSI CA CP-CRE Health Interview will be collected on paper as the phone interview is administered (Attachment 22) and the collected data elements will be entered into a CDC-developed REDCap web-based data management system. Health interviews will be entered using a unique identifier that CDC cannot link to the identity of the responding patient. The data will be exported out of REDCap by CDC staff for review and analysis. No patient level identifying information will be shared with CDC. The databases used by EIP site personnel for capturing data have Certification and Accreditation by the Office of the CDC Chief Information Security Officer (OCISO) for compliance with current information technology security policies and procedures, and therefore this REDCap database will go through the same process.

4. Efforts to Identify Duplication and Use of Similar Information

ABCs is the gold standard for the collection of population- and laboratory-based invasive bacterial disease data in the U.S. No other nationwide surveillance systems which monitor these diseases exist. While similar information may be collected on a sample basis or from a particular area of the country, for most diseases, sampling would not be sufficient for the states' need of conducting prevention or control programs. ABCs collect data from EIP sites in a uniform manner.

ABCs staff routinely attends local, national, and international conferences relevant to the pathogens of interest and communicates frequently with non-federal colleagues at universities and health departments, as well as colleagues within the government in order to prevent duplication of effort.

Much of the information collected by FoodNet (e.g., patient demographics and laboratory data) is already being collected as part of routine public health surveillance at the state level. FoodNet assembles this information to describe it on a national level and to assess changes in incidence over time. We allow sites to use their existing structure and databases to avoid duplicate data entry. All analyses of multi-site data must be proposed and approved by the FoodNet steering committee to avoid duplication of publications.

CDC epidemiologists conduct literature reviews continually to stay informed of the current knowledge-base of influenza. CDC staff also attends local, national, and international conferences relevant to the topic, and communicate frequently with non-federal colleagues at universities and health departments as well as colleagues within the government.

FluSurv-NET provides a unique information collection mechanism. No other system exists in which the breadth of demographic, medical, laboratory and epidemiologic are collected for hospitalized patients with laboratory-confirmed influenza. FluSurv-NET provides a critical set

of data that are used to make influenza vaccination recommendations, mathematically model the overall burden of influenza morbidity and mortality and enhance the understanding of severe influenza.

Due to the uniqueness of this system, the questions contained in the standardized case report form have not been taken directly from another survey. The demographic, clinical and epidemiologic information is characteristic of the data routinely collected through public health surveillance.

HAIC surveillance for CDI, selected Gram-negative bacilli, invasive *Candida* infections, and invasive *S. aureus* infections provides unique information not available through other systems, including detailed clinical and demographic data on all cases of infection, not limited to healthcare or hospital-associated cases, and isolates of the pathogens under surveillance for testing and molecular characterization. The National Healthcare Safety Network (NHSN, 0920-0666) receives data from U.S. healthcare facilities on CDI, and on selected infections due to *S. aureus*, *Candida*, and select Gram-negative bacilli, and device associated infections that could be caused by *E. coli*. Data received by the NHSN are collected by healthcare facility staff rather than trained epidemiologists and are limited to healthcare-associated cases (i.e., community-associated infections and other infections not requiring hospitalization are generally not included). Unlike HAIC, NHSN does not have an isolate submission component, and patient-level data reported to NHSN are limited (e.g., no information on underlying conditions).

Healthcare facilities participating in NHSN complete an annual survey that provides information to CDC. Data elements that are collected in part of this survey include facility characteristics, microbiology laboratory practices, infection control practices, antibiotic stewardship practices, and facility water management. Questions asked about antifungal susceptibility testing (e.g., *Candida*) and methods used to detect *C. difficile* are similar to the EIP *Candida* and CDI lab survey, however, provide far less detail. There are not specific questions on the NHSN survey that ask about MRSA/MSSA laboratory methods about laboratory testing practices. The HAIC laboratory surveys for *Candida*, CDI and invasive *S. aureus* surveillance are conducted and the questions are are designed to capture changes in trends in the testing methodology for these pathogens over time and to monitor how these changes could impact surveillance. In addition, laboratories that are not targeted by the NHSN survey (e.g., commercial, outpatient, laboratories serving long-term care facilities) participate in the EIP surveys. Lastly, for the EIP laboratories surveys, laboratories are approached based on whether or not they server the EIP catchment area. For NHSN the laboratory is approached if it is in an acute care hospital and that hospital is participating in NHSN

CDC's Antibiotic Laboratory Network (AR Lab Network) provides nationwide laboratory capacity through state and regional laboratories to rapidly detect antibiotic resistance in healthcare, food, and the community and to inform local response to prevent spread and protect people. The AR Lab Network currently collects isolates of *C. difficile*, isolates or patient samples to determine colonization with *Candida* species, and isolates of resistant Gram-negative bacilli (e.g., CRE; please note there is no overlap with the isolate collection of iEC). The AR Lab Network's collection of *C. difficile* isolates do not overlap with or duplicate EIP HAIC activities. *C. difficile* isolate testing is only conducted at a single AR Lab Network regional laboratory: the

Minnesota Department of Health Public Health Laboratory. This laboratory is only testing Minnesota EIP's *C. difficile* isolates, which are not tested by CDC, and the results of the testing are subsequently shared with CDC. Additional *C. difficile* isolates that might be tested by this lab are for special projects, and currently there is no overlap with testing conducted by CDC or other reference laboratory for HAIC CDI surveillance. The collection of CRE and *Candida* isolates through the AR Lab Network could in some instances overlap with CRE isolate collection through the EIP. CDC staff are working to minimize or eliminate potentially duplicative efforts in state or regional laboratories and ensure that EIP HAIC and AR Lab Network isolate activities are complementary. The AR Lab Network does not collect epidemiological data on the isolates that are collected, and therefore the extensive medical record review that is collected through the EIP is unique.

State health departments that participate in the HAIC MuGSI program might currently be conducting a health interview of locally identified CA CP-CRE cases. State health departments are conducting patient interviews as part of their routine state health department response and containment procedures for these highly transmissible pathogens. CDC relied heavily on the existing health interviews developed at state health departments participating in the MuGSI program to develop the final interview forms included in the package. The goal of the current health interview is to replace any locally administered health interviews, to avoid duplication of effort.

The collection of key surveillance characteristics from MuGSI sites (through the MuGSI Supplemental SO Survey) is not duplication of data collection elements. The data elements that will be collected, exist currently at the EIP sites as part of routine surveillance practices, but are not currently communicated to CDC. This data collection tool enables the sites to share these data elements with CDC.

The EIP HAI and antimicrobial use prevalence surveys (0920-0852, 0920-1165) are cross-sectional "snapshots" of all HAIs attributable to acute care hospitals or nursing homes (not limited to specific types of infections reported to NHSN through prospective HAI surveillance or specific laboratory-identified pathogens reported through HAIC population-based surveillance). The surveys are conducted intermittently (e.g., approximately every 4 years in a specific healthcare setting). The survey is conducted throughout the entire facility in all eligible units, rather than being limited to specific unit types within the facility (as in NHSN), with a goal of defining the overall burden of HAIs as well as antimicrobial drug use in that specific healthcare setting.

5. Impact on Small Businesses or Other Small Entities

For all activities, the data collection itself will not impact small businesses because the burden of completing the case report form rests with the surveillance officers appointed by the states, not the hospitals or other healthcare facilities where the cases are identified. However, in some sites, data collection is performed in cooperation with on-site medical personnel (e.g., Infection Control Practitioners or Medical Records Personnel). The impact on these facilities should be minimal since the hospital has entered into an agreement with the State health department.

6. Consequences of Collecting the Information Less Frequently

For ABCs and FoodNet, partnering state health departments submit data collection forms or standardized data elements to CDC on a monthly basis. Prompt notification to CDC allows for timely data analysis, tracking of the effects of prevention measures, and policy development. Collecting data less frequently would result in a delay in analysis and subsequent reports and publications.

Respondents are required to submit FluSurv-NET data to the CDC on a weekly basis during influenza season (October 1-April 30). However, reporting frequency may vary, as some weeks during the seven-month influenza season might not include any influenza cases. It would not be appropriate to collect influenza surveillance data less frequently than weekly because the first step in the control of a given disease is its rapid identification followed by notification to the local health authority that a case of disease exists within a particular jurisdiction. In general, case reports are submitted as soon as possible after the investigation of a case. Prompt notification to CDC allows for identification of epidemics and outbreaks, so that immediate prevention measures can be taken. In order to lessen the burden of weekly reporting, respondents are required to submit as soon as possible data for only seven data elements on the case report form during influenza season. CDC requests the remaining variables to be completed and submitted by September 30.

HAIC EIP personnel will complete data collection on cases as they are identified from laboratory reports on an ongoing basis. Performing data collection on cases as they are identified (versus on a quarterly or annual basis) will allow for rapid classification of cases into epidemiologic categories (e.g. community-associated) and identification of epidemiologic changes, including rates and severity of disease in geographically diverse patient population segments over time. Linking these epidemiological changes to several important determinants of disease, including host susceptibility, practices in prescribing antimicrobials, infection control practices, or the emergence of more virulent strains, requires timely and consistent data collection.

Collection of the laboratory survey data less than annually would prevent our programs from documenting testing method changes that are important to the interpretation of EIP HAIC data. The surveying of HAIC surveillance officers less than once annually would prevent us from ensuring high quality data are being collected and would prevent us from identifying any issues that are ongoing that might need to be addressed. These surveys are important to maintaining high quality data collection for the HAIC program. The LTCF survey is conducted annually across all HAIC pathogens, except candidemia, as part of our surveillance protocols. The CDI program has provided sites with a script to guide them in conducting these calls. It is has been demonstrated that LTCFs can change the laboratories that they contract with frequently, and therefore to assure complete case capture, these providers need to be surveyed annually.

For the HAIC MuGSI CA CP-CRE Health Interview, identified cases will be interviewed as they are identified locally. The data elements on the health interview could help target local prevention efforts to better understand and prevent CP-CRE, and therefore it is important for public health for these interviews to be done as cases are identified.

It is proposed that the MuGSI Supplemental SO survey is collected once annually. Collecting this data less frequently would prevent this program from being adequately evaluated.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

For the reasons described in A.6 above, respondents are required to report information more often than quarterly (monthly). FluSurv-NET requires weekly reporting during the influenza season (October 1- April 30); however, reporting frequency will vary as some weeks during the influenza season might not include influenza cases. Surveillance reports are requested on a periodic basis to permit timely data analysis and prompt initiation of prevention and control measures.

As stated in A.6., delays in reporting could result in serious public health consequences. There are no other special circumstances relating to the guidelines of CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice was published in the Federal Register on 1/31/2022 Volume 87, No. 20, p. 4,891. No comments were received.

B. ABCs and FoodNet are the gold standards for the collection of population- and laboratory-based bacterial disease data in the U.S. CDC conducts a conference call with site surveillance officers to discuss surveillance-related issues monthly. CDC conducts conference calls with ABCs and FoodNet Principal Investigators to discuss bi-monthly and quarterly, respectively. CDC also organizes the annual ABCs and FoodNet Steering Committee meetings with each site's Principal Investigators in attendance and an annual Site coordinator meeting which includes representatives from all sites. These meetings offer the opportunity to discuss ongoing projects and plan for future priorities.

Since FluSurv-NET's inception, consultation with sites has taken place at an annual meeting to address information collection activities. Additionally, monthly conference calls are held with site personnel to ensure that data collection is standardized, efficient and relevant.

CDC staff involved in the HAIC activity conducts quarterly conference calls with EIP site HAIC principal investigators and hold an annual in-person meeting at CDC with the principal investigators and other key participants to discuss progress and scientific direction for the activity. Regular calls are also held with EIP site and CDC project leads and coordinators to discuss progress and challenges for individual projects.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be provided to respondents. EIP sites, at their discretion, may provide resources to catchment area laboratories or healthcare facilities, for example, to enable or enhance isolate collection and submission.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by NCEZID who determined that the Privacy Act does not apply.

As a measure of EIP's data protection plan, the ABCs, FoodNet, FluSurv-NET, and HAIC activity utilize data transfer methods that are password protected to protect the data. CDC and EIP sites have the option to utilize the CDC SAMS platform to transmit data. CDC SAMS is a federal information technology system that gives authorized personnel secure access to non-public CDC applications through a highly secure and password protected and encrypted portal. The SAMS partner portal is a website designed to provide centralized access to public health information and computer applications operated by the CDC. Through this portal EIP sites and CDC can transfer data in a secure portal to keep data protected.

For FluSurv-NET, in addition to using the CDC SAMS platform, sites also have the option to enter data directly into the CDC instance of REDCap (Research Electronic Data Capture) database.
Names or other direct personal identifiers (such as address, medical record number, social

Names or other direct personal identifiers (such as address, medical record number, social security number, etc.) may be collected by the EIP site to assist in managing case information, but they are not shared with CDC. There are no direct personal identifiers in the data submitted to CDC for any of the forms included in this package. Patient information that is collected and shared with CDC include date of birth, age, sex, race, ethnicity, census tract, and clinical dates (e.g., dates of admission and discharge).

Each participating EIP site will destroy identifiers at the earliest opportunity unless there is a public health or research justification for retaining the identifiers or are required to by law. Project paperwork maintained by each participating site will never be submitted to CDC and will remain in a locked, secure location, available only to a minimum number of local project staff, and will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted.

Financial records, supporting documents, statistical records, and all other records pertinent to the grant program must be retained for a minimum of 3 years after the end of a budget period, or until completion and resolution of any audit in process or pending resolution. In all cases, records must be retained until resolution of any audit questions. Property records must be retained in accordance with 45 CFR 92.42. Line lists and CRFs should be retained for a minimum of 3 years in addition to the current surveillance year, or per site regulations. Forms related to special studies should be retained for a minimum of 3 years after the publication of the study, or per site regulations. If storage space becomes an issue, sites are advised to document which paper documents will be destroyed.

FoodNet surveillance is conducted by state health departments as part of routine public health surveillance and, as such, personnel at the state health departments collect personal identifiers

(name, address, phone number) to conduct appropriate public health follow up of cases. Date of birth and a coded FoodNet ID field are transmitted to CDC; however, names, addresses and phone numbers are not. The code linking the FoodNet ID field to other personal identifier is maintained confidentially and securely with the state health department that reported the case; it is not shared with CDC. When surveillance data are requested for analysis by persons at CDC, state or federal partners (e.g., FDA or USDA), or others (e.g., students) an analytic dataset is provided that includes only the minimum number of variables required for the specified analysis; it does not include the FoodNet ID field and certain fields are often aggregated into groups to minimize the ability to link to other data sources to identify a person.

There are no personal identifiers in the database submitted to CDC in the data collected for FluSurv-NET. Thus, the patients whose charts are reviewed will not be able to be identified through data submitted to CDC; only the FluSurv-NET site collecting the case information will be able to link personal identifiers with case information. Additionally, CDC will not have identifying information on patient health care providers. Each hospital where charts are abstracted will be given a numerical ID that can be linked to hospital name only by staff within individual surveillance areas.

Each participating FluSurv-NET site will destroy identifiers at the earliest opportunity unless there is a public health or research justification for retaining the identifiers or they are required to by law. Project paperwork maintained by each participating site will never be submitted to CDC and will remain in a locked, secure location, available only to a minimum number of local project staff, and will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted.

The HAIC activity conducts population-based surveillance for urgent threats to patient safety, including CDI, select Gram-negative bacilli, invasive *Candida* infections, and invasive *S. aureus* infections. As with ABCs surveillance described above, upon verification of a positive laboratory result and confirmation of residence within the pre-defined EIP catchment area, each EIP site conducts data abstraction of the medical chart and laboratory report to complete the standardized case report forms. HAIC data collection forms (previously approved data collection) are used by sites to review medical records and collect demographic and clinical information on laboratory-confirmed cases. The new data collection for iEC will use the existing HAIC MuGSI ESBL data collection form and the existing data collection practices. As with the practice of the other HAIC population-based surveillance activities, the HAIC MuGSI CA CP-CRE Health Interview will be used to interview patients identified through MuGSI to have CA CP-CRE after medical record review and laboratory confirmation. The MuGSI Supplemental SO Survey collects key data elements on surveillance area characteristics (i.e., current state notifiable surveillance definitions), participating laboratory participation and isolate testing methodology, and the types of healthcare facilities a participating laboratory serves. These data are not collected at the patient level.

Information in Identifiable Form (IIF) will be collected by each EIP site. Other information that may be collected could include hospitalization history, lab test results and culture information, symptoms, discharge diagnosis, antimicrobial treatments, ICD-9 and/or ICD-10 codes,

healthcare worker status, influenza vaccination status, and underlying medical conditions. Information transmission occurs via a secure CDC website. The case report form does not involve web-based data collection methods, although case report form data are entered into a CDC-developed, approved web-based data management system for some activities and does not refer respondents to websites.

For HAIC projects, personally identifying information such as names and addresses are not shared with CDC. Date of birth, race, ethnicity, gender, hospitalization dates, specific type of healthcare facility as defined by the Centers for Medicare and Medicaid (CMS), and census tract information are shared with CDC. Only the EIP site collecting the case information will be able to link personal identifiers with case information. Each participating EIP site will destroy identifiers at the earliest opportunity unless there is a public health or research justification for retaining the identifiers or are required to by law. Project paperwork maintained by each participating site will not be submitted to CDC and will remain in a locked, secure location, available only to a minimum number of local project staff, and will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted.

Data collection for HAIC CDI cases (previously approved data collection) includes state and county of residence, age, gender, date of birth, race/ethnicity, date of stool collection positive for *C. difficile*, location of stool collection (i.e. hospital inpatient, long term acute care hospital, long term care/skilled nursing facility, emergency room, or outpatient setting), hospitalization and date of admission, residency prior to stool collection (i.e. hospital inpatient, long term acute care hospital, long term care/skilled nursing facility, emergency room, or outpatient setting), hospital admission due to CDI, presence of other enteric pathogens in stool tested for CDI, exposures to healthcare (i.e. chronic hemodialysis, surgical procedure in the 12 weeks prior to stool collection, or emergency room visit in the 12 weeks prior to stool collection), patient outcome (patient survived and date of discharge or patient died and date of death), colectomy and date of procedure, intensive care unit (ICU) admission and date, CDI recurrence, radiographic findings (including toxic megacolon and ileus), presence of pseudomembranous colitis, clinical findings (including diarrhea and white blood cell counts), Charlson co-morbidity index components, medication used in the 14 days prior to illness onset (including antimicrobial therapy use, immunosuppressive therapy use, and use of proton pump inhibitors or H2 blockers), and CDI treatment information (previously approved data collection). Healthcare facilities are identified by facility identification codes. These facility identification codes are assigned by EIP sites. Local data collectors at participating healthcare facilities and EIP personnel will need to collect information in identifiable form (IIF) for patients within their own facility or catchment area, such as patient name, address, telephone number, date of birth, and medical record number. Except for date of birth, this information will not be transmitted to CDC. CDI cases are also geocoded and census tract numbers are assigned; EIP site personnel strip out geocoded data (e.g., address, latitude, longitude), and the census tract number is shared with CDC. Unique identification codes not containing any patient identifiers are assigned by EIP sites to patients; CDC does not have access to linkages between patient name and patient identification code. EIP sites also collect data from participating laboratories annually and submit the information to CDC: frequency of line lists, if isolates are being collected from the laboratory, what health care

facilities are being served by the laboratory being surveyed, and detailed information about laboratory practices. The Annual CDI Surveillance Officer Survey collects data on laboratory participation, practices and auditing (case identification methodology, current laboratory participation, are specimen collection counts changing, understanding specimen shipping procedures), data edits, information about assurance of case ascertainment, geocoding and facility information. The LTCF survey gathers information about where facilities send samples for testing, and the tool included in this package is a script used to guide calls with the local LTCFs. After this survey is conducted CDC receives the following data elements: unique provider/ facility ID (this is a number that is assigned by the EIP site and does not contain facility identifying information), CMS classification of the facility that was surveyed, documentation if the facility contacted as part of the survey process, and a list of laboratory ids for the laboratories that serve the LTCF (the laboratory ids are set by the site and do not contain identifying information).

Data collected for the HAIC select Gram-negative bacilli surveillance (previously approved data collection, and proposed iEC data collection) are similar to those collected for CDI cases, and include variables such as state, county of residence, age, gender, date of birth, race/ethnicity, weight and height or body mass index, date of collection of specimens positive for select Gram-negative bacilli, types of specimens, location of specimen collection, results of testing performed on the specimen (including pathogens isolated and antimicrobial susceptibility test results), residency prior to specimen collection (including the specific type of healthcare facility as defined by CMS), hospitalization data (including dates), underlying conditions, healthcare exposures and other risk factors for infection, signs and symptoms of infection, and patient outcome. For patients with the ESBLs and for the new iEC data collection, selected organisms, data collection, prior medications are also collected. As with CDI surveillance, healthcare facilities are identified by facility identification codes in the data collection forms. Local data collectors and EIP personnel will need to collect information in identifiable form (including information such as patient name, address, telephone numbers, date of birth, and medical record number), but this information (with the exception of date of birth) is not transmitted to CDC. Cases may also be geocoded and census tract numbers assigned; EIP sites will strip other data (e.g., address, latitude, longitude), and the census tract number will be shared with CDC. Unique identification codes not containing identifiers are assigned by EIP sites to patients; CDC does not have access to any linkages between patient name and patient identification code.as described above for CDI.). For select Gram-negative bacilli surveillance, a formal laboratory survey is not conducted. Instead, the sites are instructed to speak with the laboratories serving the EIP catchment area that are reporting cases and determine if any changes have been made to the lab's automated testing instrument (ATI) (including, but not limited to, changes in software or card types or introduction of new technology into the laboratory), what breakpoints the laboratory is using for the carbapenem antibiotics and if the laboratory is conducting any confirmatory testing for carbapenemases. For the iEC data collection, questions asked of the laboratory staff will focus on if changes to the laboratory information system (LIS) have occurred that could affect case identification (e.g., coding changes or software releases). The MuGSI program will encourage sites to work with their CDI staff when surveying LTCFs to ask about testing methodology around gram-negative organisms.

It is necessary to gather additional information in the HAIC MuGSI CA CP-CRE health interview format to validate the data collected through the medical record review and to meet

one of our program's goal in validation the epidemiological class, and to identify other known potentially modifiable risk factors or sources of CP-CRE acquisition.

Data collected for the HAIC invasive S. aureus surveillance (previously approved data collection) are similar to those collected for CDI cases, and include variables such as state, county of residence, age, gender, date of birth, race/ethnicity, weight and height or body mass index, date of collection of specimens positive for S. aureus, types of positive specimens, location of initial specimen collection, results of antimicrobial susceptibility testing performed on the specimen, residency prior to specimen collection, hospitalization and ICU admission data (including date of hospital and ICU admissions), underlying conditions, type of infection associated with the culture, healthcare exposures and other risk factors for infection, and patient outcome. As with CDI surveillance, healthcare facilities are identified in the data collection forms by facility identification codes. Local data collectors and EIP personnel will need to collect information in identifiable form (including information such as patient name, address, telephone numbers, date of birth, and medical record number), but this information (except for date of birth) is not transmitted to CDC. Cases may also be geocoded and census tract numbers assigned; EIP sites will strip other data (e.g., address, latitude, longitude), and the census tract number will be shared with CDC. Unique identification codes not containing identifiers are assigned by EIP sites to patients; CDC does not have access to any linkages between patient name and patient identification code. The invasive *S. aureus* program collects data from participating laboratories annually, the EIP site staff collect information the type of laboratory being surveyed, current testing methods for *S. aureus,* the use of culturing techniques and if culture independent diagnostic tests (CIDTs) are being utilized at the laboratory. The Annual invasive *S. aureus* Surveillance Officer Survey collects data on surveillance area characteristics (including is the pathogen reportable locally, are isolates collected and submitted to CDC for testing, what parts of the invasive *S. aureus* program the site is participating in, does the site have access to their states' NHSN *S. aureus* data, and if so how are those data being used locally), laboratory participation and case finding (including the number and types of laboratories that are serving the catchment area, culture sources from which *S. aureus* is being identified form, case finding methods, how laboratory data is being share with the EIP site staff, have laboratories stopped participating in surveillance), data edits (including information if a site edits there data beyond the required CDC data edits), ascertainment of surveillance area and case audits (including how an audit case is defined and how these types of cases are contributing to case counts, what auditing methods are being used, how case ascertainment is being conducted), geocoding, and feedback on CDC staffs performance.

Data collected for the HAIC Candidemia program (previously approved data collection) are similar to those collected for CDI cases, and include variables such as state, county of residence, age, gender, date of birth, race/ethnicity, date of incident specimen collection location of specimen collection, results of testing performed on the specimen (including *Candida* species and antimicrobial susceptibility test results), residency prior to specimen collection, hospitalization data (including dates), underlying conditions, healthcare exposures and other risk factors for infection, signs and symptoms of infection, and patient outcome. As with CDI surveillance, healthcare facilities are identified in the data collection forms by facility identification codes. Local data collectors and EIP personnel will need to collect information in identifiable form (including information such as patient name, address, telephone numbers, date of birth, and medical record number), but this information (with the exception of date of birth) is

not transmitted to CDC. Cases may also be geocoded and census tract numbers assigned; EIP sites will strip other data (e.g., address, latitude, longitude), and the census tract number will be shared with CDC. Unique identification codes not containing identifiers are assigned by EIP sites to patients; CDC does not have access to any linkages between patient name and patient identification code. The Candidemia Periodic Laboratory Survey collects the following information: type of laboratory being surveyed, the types of facilities that the laboratory serves, is mycology testing capabilities, capacity and testing methodology.

Privacy Impact Assessment Information

1. Respondents are informed about the voluntary nature of their response.

2. For FluSurv-NET, consent forms are obtained from patients undergoing telephone interview for influenza vaccination history. Copies of the consent form will be retained at the participating site and will not be submitted to CDC. CDC only receives vaccine status information and does not receive any personally identifiable information.
   For the medical review component of HAIC, consent is not applicable as EIP personnel perform review of existing medical record data in participating facilities or via remote access and submit these data to CDC in a secure manner, as described previously, without having any interaction with individual patients. Information received by CDC are stored in secure databases (certification and accreditation at appropriate level according to current information security procedures and standards) or will be uploaded by EIP site personnel to site-specific encrypted, secure CDC FTP sites or other secure sites meeting current information security requirements. Case-specific information received by CDC will be provided only to those individuals at CDC with a need to know.

3. Project case report forms maintained by each participating site will not be submitted to CDC, and will remain in a locked, secure location, available only to a minimum number of local project staff, and will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the surveillance project, or for other research for which the use or disclosure of protected health information would be permitted. Each participating EIP site will destroy identifiers at the earliest opportunity, unless there is a public health justification for retaining the identifiers or are required to by law.

4. For the HAIC MuGSI CA CP-CRE Health Interview, cases will be contacted via phone with the use of telephone interview introductory script and consent (agreement) to participate will be obtained from patients undergoing the telephone health interview. Copies of the interview introductory script will be retained at the participating site and will not be submitted to CDC. CDC will receive the information collected during the health interview, but this information is not identifiable. Information received by CDC for this health interview will be stored in a secure manner (certification and accreditation at appropriate level according to current information security procedures and standards). Case-specific information received by CDC will be provided only to those individuals at CDC with a need to know.

5. This submission has been reviewed by NCEZID who determined that the Privacy Act does not apply.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

The data collection forms included in this package constitute public health surveillance and are not considered human subjects research. Therefore, the protocols associated with the forms included in this package are not subject to IRB review.

Justification for Sensitive Questions

For ABCs, epidemiological characteristics such as age, race, sex, geographic location, etc., are collected only when these factors may produce health problems. Clinical and laboratory data are collected and analyzed with the purpose of contributing valuable knowledge to the field of public health.

For FoodNet, clinical and laboratory data are collected and analyzed with the purpose of contributing valuable knowledge to the field of public health. Data collected for FoodNet surveillance are not considered sensitive. However, persons can refuse to provide any information that they consider to be sensitive.

In FluSurv-NET, age and variables related to documentation of laboratory-confirmed influenza-associated hospitalization are of central importance to this study. Additional clinical and, underlying health conditions, influenza vaccination status, diagnosis with secondary bacterial co-infections, and ICU admission are necessary for determining rates of influenza-associated complications and factors associated with these complications. Questions about pregnancy, past medical history or chronic conditions are asked to clarify any risk factors for influenza or assess confounding factors of illness. Questions about race and ethnicity are asked in order to clarify risk factors for influenza and evaluate race and ethnicity in the context of influenza infection. All race and ethnicity questions meet OMB's minimum standards for collecting race and ethnicity information.

For HAIC surveillance, demographic and clinical data (including information on the presence of HIV/AIDS and other chronic conditions, smoking, drug and alcohol use, and incarceration) are collected from medical records and analyzed to describe risk factors for infection with important healthcare-associated and antimicrobial-resistant pathogens.

For the HAIC MuGSI CA CP-CRE Health Interview demographic, clinical data will be collected and analyzed to better understand the epidemiology of community-associated CP-CRE and to hypothesize about possible prevention measures.

12. Estimates of Annualized Burden Hours and Costs

For this revision, the total estimated burden is 53,784 hours. The previous approval (non-substantive change request approved 12/15/2021) was for an estimated annual burden of 38,810 hours.

A. ABCs: The total burden estimate for the ABCs collection activity is 3,495 hours and is shown in Table A.12-A1. The use of pneumococcal 15-valent and 20-valent conjugate vaccines have recently been approved for adults ages 65 and older creating a need to expand the IPD case report form to capture vaccination information for this older age group. The estimated number of annual responses has been adjusted accordingly from 22 to 127 and the net change in burden is a 175 hour increase.

B. FoodNet: The total burden estimate for the FoodNet collection activity is 8,370 hours and is shown in Table A.12-A1 No changes in burden since the previous non-substantive submission approved in 12/15/2021.

C. FluSurv-NET: The total burden estimate for the Influenza FluSurv-NET collection activity 4,043 hours and is shown in Table A.12-A1. No changes in burden since the previous non-substantive submission approved in 12/15/2021. The number of responses varies by influenza season and the current burden estimates are based on previous experience and feedback from stakeholders using these instruments.

D. HAIC: The total burden estimate for HAIC collection activity is 46,048 hours and is shown in Table A.12-A1. HAIC will be expanding surveillance for MuGSI to include iEC by using the existing *Multi-site Gram-Negative Surveillance Initiative – Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae* form with a total of 17,500 burden hours; Two new HAIC collection instruments are being added with a total of 53 burden hours; Additionally, the Death Ascertainment Project is adding 1920 hours.

Table A.12-A1. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of respondents	No. of responses per respondent	Avg. burden per response (in hours)	Total burden (in hours)
State Health Department	ABCs Case Report Form	10	809	20/60	2697
	ABCs Invasive Pneumococcal Disease in Children and Adults Case Report Form	10	127	10/60	212
	ABCs *H. influenzae* Neonatal Sepsis Expanded Surveillance Form	10	6	10/60	10
	ABCs Severe GAS Infection Supplemental Form	10	136	20/60	453
	ABCs Neonatal Infection Expanded Tracking Form	10	37	20/60	123
	FoodNet Campylobacter	10	970	21/60	3395
	FoodNet Cyclospora	10	42	10/60	70
	FoodNet Listeria monocytogenes	10	16	20/60	53
	FoodNet Salmonella	10	855	21/60	2993
	FoodNet Shiga toxin producing E. coli	10	290	20/60	967
	FoodNet Shigella	10	234	10/60	390
	FoodNet Vibrio	10	46	10/60	77
	FoodNet Yersinia	10	55	10/60	92
	FoodNet Hemolytic Uremic Syndrome	10	10	1	100
	FoodNet Clinical Laboratory Practices and Testing Volume	10	70	20/60	233
	FluSurv-Net Influenza Hospitalization Surveillance Network Case Report Form	10	764	25/60	3183

	FluSurv-Net Influenza Hospitalization Surveillance Project Vaccination Phone Script Consent Form (English)	10	333	5/60	278
	FluSurv-Net Influenza Hospitalization Surveillance Project Vaccination Phone Script Consent Form (Spanish)	10	333	5/60	278
	FluSurv-Net Influenza Hospitalization Surveillance Project Provider Vaccination History Fax Form (Children/Adults)	10	333	5/60	278
	FluSurv-NET Laboratory Survey	10	16	10/60	26
	HAIC - MuGSI Case Report Form for Carbapenem-resistant Enterobacteriaceae (CRE) and *Acinetobacter baumannii* (CRAB)	10	500	28/60	2333
	HAIC - MuGSI Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (ESBL/iEC)	10	4200	25/60	17,500
	HAIC - Invasive Methicillin-resistant *Staphylococcus aureus* (MRSA) Infection Case Report Form	10	340	28/60	1587
	HAIC - Invasive Methicillin-sensitive *Staphylococcus aureus* (MSSA) Infection Case Report Form	10	584	28/60	2725
	HAIC - CDI Case Report and Treatment Form	10	1650	38/60	10450
	HAIC Candidemia Case Report	10	170	40/60	1134
	HAIC- Annual Survey of Laboratory Testing Practices for *C. difficile* Infections	10	16	19/60	51
	HAIC- CDI Annual Surveillance Officers Survey	10	1	15/60	3
	HAIC- Emerging Infections Program *C. difficile Surveillance Nursing Home*	10	45	5/60	38

	Telephone Survey (LTCF)				

	HAIC- Invasive *Staphylococcus aureus* Laboratory Survey	10	11	20/60	37
	HAIC- Invasive *Staphylococcus aureus* Supplemental Surveillance Officers Survey	10	1	10/60	2
	HAIC- Laboratory Testing Practices for Candidemia Questionnaire	10	20	13/60	43
	HAIC MuGSI CA CP-CRE Health interview (new)	10	10	30/60	50
	HAIC MuGSI Supplemental Surveillance Officer Survey (new)	10	1	15/60	3
	HAIC Death Ascertainment Project	10	8	1440/60	1,920
TOTAL					**53,784**

B. The following table shows estimated burden costs associated with each instrument. The mean hourly wage for epidemiologists was used (https://www.bls.gov/oes/current/oes191041.htm).

Type of Respondent	Form Name	Total burden hours	Hourly wage rate	Total respondent costs
State Health Department	FluSurv-Net	278	$40.20	$11,175.60
	HAIC- Invasive *Staphylococcus aureus* Laboratory Survey	37	$40.20	$1,487.40
	ABCs Case Report Form	2697	$40.20	$108,419.40
	ABCs Invasive Pneumococcal Disease in Children and Adults Case Report Form	212	$40.20	$8,522.40
	ABCs *H. influenzae* Supplemental Survey	278	$40.20	$11,175.60
	ABCs Neonatal Sepsis Expanded Surveillance Form	2	$40.20	$80.40
	ABCs Severe GAS Infection Supplemental Questionnaire	10	$40.20	$402.00
	FluSurv-Net Laboratory Testing Practices and Testing Volume	278	$40.20	$11,175.60
	Influenza Hospitalization Surveillance Project	453	$40.20	$18,210.60
	HAIC CA CP-CRE Health Interview	50	$40.20	$2,010.00
	HAIC MuGSI Supplemental Surveillance Officer Survey	3	$40.20	$120.60
	HAIC Death Ascertainment Project	1920	$40.20	$77,184.00
TOTAL		54007	$40.20	$2,161,996.20
	HAIC - MuGSI Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (ESBL/EC)	17,500	$40.20	$703,500.00
	HAIC – Invasive Methicillin-resistant *Staphylococcus aureus* (MRSA) Infection Case Report Form	1587	$40.20	$63,797.40
	HAIC – Invasive Methicillin-sensitive *Staphylococcus aureus* (MSSA) Infection Case Report Form	2725	$40.20	$109,545.00
	FoodNet Shiga toxin-producing E. coli	390	$40.20	$15,678.00
	FoodNet Shigella	77	$40.20	$3,095.40
	FoodNet Vibrio	92	$40.20	$3,698.40
	FoodNet Yersinia	100	$40.20	$4,020.00
	FoodNet Hemolytic Uremic Syndrome	233	$40.20	$9,366.60
	FoodNet Clinical Laboratory Practices and Testing Volume	3183	$40.20	$127,956.60
	FluSurv-Net Influenza Hospitalization Surveillance Network Case Report Form	2725	$40.20	$109,545.00
	HAIC - CDI Case Report and Treatment Form	10450	$40.20	$420,090.00
	HAIC Candidemia Case Report	1134	$40.20	$45,586.80
	HAIC- Annual Survey of Laboratory Testing Practices for *C. difficile* Infections.	51	$40.20	$2,050.20
	HAIC- CDI Annual Surveillance Officers Survey	3	$40.20	$120.60
	HAIC- Emerging Infections Program *C. difficile* *Surveillance Nursing Home Telephone Survey (LTCF)*	38	$40.20	$1,527.60

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are not costs to respondents other than their time.

14. Annualized Cost to the Federal Government

Estimated cost based on 2021 figures

Active Bacterial Core surveillance (ABCs) - Active population-based laboratory surveillance for invasive bacterial diseases

Table 14-1: Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Principal Investigator (0.8 FTE); CDC Surveillance Coordinator (0.8 FTE); Program Analyst (1.0 FTE), Data Manager (1.0 FTE)	360,500
	Subtotal, Direct Costs to the Government	360,500
Cooperative Agreement Expenses	California Site Cost and Fees	618,891
	Colorado Site Cost and Fees	555,401
	Connecticut Site Cost and Fees	658,516
	Georgia Site Cost and Fees	1,001,682
	Maryland Site Cost and Fees	909,459
	Minnesota Site Cost and Fees	1,082,372
	New Mexico Site Cost and Fees	625,390
	New York Site Cost and Fees	517,356
	Oregon Site Cost and Fees	621,587
	Tennessee Site Cost and Fees	1,003,498
	Subtotal, Contracted Services	7,594,151
	TOTAL COST TO THE GOVERNMENT	7,954,651

Foodborne Diseases Active Surveillance Network (FoodNet)

Table 14-2: Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)

Direct Costs to the Federal Government	CDC Principal Investigator (1.0 FTE); CDC Doctoral staff (2.0 FTE); CDC surveillance officers (2.0 FTE); Epidemiology Fellows (4.0 ORISE Fellows)	850,000
	Subtotal, Direct Costs to the Government	850,000
Cooperative Agreement Expenses	California Site Cost and Fees	616,000
	Colorado Site Cost and Fees	568,000
	Connecticut Site Cost and Fees	493,000
	Georgia Site Cost and Fees	772,000
	Maryland Site Cost and Fees	293,000
	Minnesota Site Cost and Fees	853,000
	New Mexico Site Cost and Fees	287,000
	New York Site Cost and Fees	587,000
	Oregon Site Cost and Fees	562,000
	Tennessee Site Cost and Fees	640,000
	Subtotal, Contracted Services	5,671,000
	TOTAL COST TO THE GOVERNMENT	6,521,000

Influenza - All Age Influenza Hospitalization Surveillance Network

Table 14-3: Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Project Officer (1.0 FTE); CDC Principal Investigator (0.8 FTE); Data Manager (1.5 FTE)	526,291
	Subtotal, Direct Costs to the Government	526,291
Cooperative Agreement Expenses	California Site Cost and Fees	725,848
	Colorado Site Cost and Fees	296,117
	Connecticut Site Cost and Fees	436,605
	Georgia Site Cost and Fees	519,341
	Maryland Site Cost and Fees	307,522
	Minnesota Site Cost and Fees	491,373
	New Mexico Site Cost and Fees	490,340

	New York Site Cost and Fees	626,887
	Oregon Site Cost and Fees	517,111
	Tennessee Site Cost and Fees	598,892
	Subtotal, Contracted Services	5,010,036
	TOTAL COST TO THE GOVERNMENT	5,536,327

Healthcare Associated Infections-Community Interface (HAIC)

Table 14-4: Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC HAIC Directors (2.0 FTE), Principal Investigators (3.0 FTE); CDC Surveillance Coordinators (3.25FTE); HAIC Coordinator (0.25 FTE), Business Analysts (0.75 FTE), Laboratory Scientists (6.0FTE); AMD Science Contributions (1.0 FTE), Data Manager (1.0 FTE); Statistical Consultation (0.2), Contractor Support (3.0)	2,622,917
	Subtotal, Direct Costs to the Government	2,622,917
Cooperative Agreement Expenses	California Site Cost and Fees	904,000
	Colorado Site Cost and Fees	978,000
	Connecticut Site Cost and Fees	1,554,000
	Georgia Site Cost and Fees	2,037,000
	Maryland Site Cost and Fees	1,226,000
	Minnesota Site Cost and Fees	1,537,000
	New Mexico Site Cost and Fees	689,000
	New York Site Cost and Fees	1,651,000
	Oregon Site Cost and Fees	1,045,000
	Tennessee Site Cost and Fees	1,777,000
	Subtotal, Contracted Services	13,398,000
	TOTAL COST TO THE GOVERNMENT	16,020917

Annualized Total Cost to the Federal Government	36,032,895

15. <u>Explanation for Program Changes or Adjustments</u>

This is a request for a revision. The majority 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.

CDC is also requesting the use of 2 new forms: HAIC- Community-Associated Carbapenemase-Producing Carbapenem-Resistant Enterobacteriaceae (CA CP-CRE) Interview Form (with interview introductory script and accompanying Interview Instructions Manual) and HAIC Multi-site Gram-Negative Surveillance Initiative (MuGSI) Supplemental Surveillance Officer Survey (SO). These forms will allow the EIP HAIC to better detect, identify, track changes in active population-based surveillance for healthcare-associated pathogens and infections.

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

- *ABCs Case Report Form* – A non-substantive change request was OMB approved on 12/15/2021. In addition, in this revision two data elements were suspended and minor updates to response options were made to three data elements. There is no change to the burden for this revision.
- *ABCs Invasive Pneumococcal Disease (IPD) in Children and Adults Case Report Form* – The use of pneumococcal 15-valent and 20-valent conjugate vaccines have recently been approved for adults ages 65 and older creating a need to expand the IPD case report form to capture vaccination information for this older age group. The estimated number of annual responses has been adjusted accordingly from 22 to 127. In this revision, no additional questions were added to the form. The net change in burden is a 175 hour increase.
- *ABCs H. influenzae Neonatal Sepsis Expanded Surveillance Form (HiNSES)*— A non-substantive change request was OMB approved on 9/13/2018. There is no change to the burden for this revision.
- *ABCs Neonatal Infection Expanded Tracking Form* – A non-substantive change request was OMB approved on 9/13/2018. In this revision five data elements were suspended, and one new data element was added to more comprehensively capture discharge capture information on discharge diagnosis that may include an ABCs pathogen. There is no change to the burden for this revision.
- *ABCs Severe GAS Infection Supplemental Form* – For this revision, no change to content or burden.
- *FoodNet Active Surveillance Data Elements* –In this revision, two data elements have value set changes. Changes were made to streamline, collect level of detail needed, and for consistency with the FDD MMG. There is no change to burden.
- *FoodNet Hemolytic Uremic Syndrome Case Report Form* –In this revision no changes were made and there is no change to burden.
- *FoodNet Clinical Laboratory Practices and Testing Volume Data Elements* — In this revision no changes were made and there is no change to burden.
- *FluSurv-NET – Case Report Form* – A non-substantive change request was OMB approved on 12/15/2021. There is no change to the burden for this revision.
- *FluSurv- NET – Vaccination Phone Script Consent Form (English/Spanish)* – For this revision, no change to content or burden.

- *FluSurv-NET – Vaccination Phone Script (English/Spanish)* – For this revision, no change to content or burden.
- *FluSurv-NET Provider Vaccination History Fax Form (Children/Adults)* – For this revision, no change to content or burden.
- *FluSurv-NET Laboratory Survey* – For this revision, no change to content or burden.
- *HAIC - C. difficile infection (CDI) Surveillance Case Report Form* – For this revision, no change to content or burden.
- *HAIC- Annual Survey of Laboratory Testing Practices for C. difficile Infection* – For this revision, no change to content or burden.
- *HAIC- CDI Annual Surveillance Officers Survey* – For this revision, no change to content or burden.
- *HAIC- Emerging Infections Program C. difficile Surveillance Nursing Home Telephone Survey* – For this revision, no change to content or burden.
- *HAIC- Multi-site Gram-Negative Surveillance Initiative – (MuGSI-CRE/CRAB)* – The proposed changes will allow the Emerging Infection Program (EIP) sites to report the time when the incident specimen was collected, which is a critical data element for determining the case status. Additionally, we are allowing for non-molecular testing results and susceptibility results to be reported from newer test methods (CPO Detect for non-molecular carbapenemase testing and Accelerate Pheno System for susceptibility results) to be reported for MuGSI cases. Lastly, we modified the format of the table for the susceptibility results to allow for these data to be reported from multiple data sources. For this revision, no change to burden.

  HAIC- Multi-site Gram-Negative Surveillance Initiative – Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (ESBL/iEC) – For this revision the existing Multi-site Gram-negative Surveillance Initiative - Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (ESBL) form is being expanded to collect data on invasive Escherichia coli (MuGSI – ESBL/iEC). The objectives of expanding the MuGSI data collection to include invasive Escherichia coli (iEC) infections are as follows: 1) to build a comprehensive surveillance system that can increase the current understanding of the epidemiology of iEC; 2) to monitor trends of iEC in the EIP catchment area and to monitor changes in disease occurrence as vaccines are developed and implemented; 3) to discover leverage points in the patient care process that could be used for implementing or improving infection prevention and control measures to reduce severe disease (e.g., sepsis) through the collection of patient risk factor data; 4) to characterize specific serotypes that are causing iEC in the EIP catchment area and to monitor changes ins serotypes over time.

- *HAIC- Methicillin-resistant Staphylococcus aureus (MRSA) Case Report Form* – For this revision, no change to content and a slight change to the burden.
- *HAIC- Methicillin-sensitive Staphylococcus aureus (MSSA) Case Report Form* – For this revision, no change to content and a slight change to the burden.
- *HAIC- Staphylococcus aureus Laboratory Survey: Use of Nucleic Acid Amplification Testing (NAAT)* – For this revision, no change to content or burden.
- *HAIC- Candidemia Case Report Form* – For this revision, no change to content or burden.

- *HAIC- Candidemia Periodic Laboratory Survey* – For this revision, no change to content or burden.
- *HAIC- Community-Associated Carbapenemase- Producing Carbapenem-Resistant Enterobacteriaceae (CA CP-CRE) Interview* (with interview introductory script and accompanying instruction manual) -- This a new data collection instrument that will allow the EIP to better describe community-associated CRE cases, and to identify other known potentially modifiable risk factors or sources for CP-CRE acquisition, such as international travel, previous use of antibiotics, occupation, exposure to animals, household contacts with risk factors for CRE acquisition, and other risk factors. The estimates of the infection incidence generated by this collection provide the foundation for a variety of epidemiologic studies to explore risk factors, spectrum of disease, and prevention strategies. This data collection serves as a supplementary source of data to an existing MuGSI surveillance data.
- *HAIC Multi-site Gram-Negative Surveillance Initiative (MuGSI) Supplemental Surveillance Officer Survey (SO)* -- This survey will allow CDC to collect information on various characteristics of the MuGSI surveillance being carried out at each of the participating MuGSI sites on an annual basis. This information will be valuable for staff to better understand the processes and underlying network that makes up the MuGSI program. These data will also be used to evaluate the MuGSI program.
- *HAIC* Death Ascertainment Project (data transmitted electronically) -- The HAIC program also collects information through linking identified cases to the state health department's vital records death index (i.e., death index) to determine if a patient died within 90 days of the case's date of initial culture. Through this linking the following new data elements are obtained: the date of death as reported in the state vital records death index, the date 90 days after the date of initial culture, the site-determined date of death, the patient's outcome at 90 days after the date of initial culture, and any comments from the EIP site staff about the linking process. The linking between the HAIC surveillance data and the state vital records death index has been ongoing since 2018 and includes retrospective linkage of surveillance data that were collected before 2018. These data have been transmitted to CDC since the implementation of this process via excel spreadsheets, using the CDC's Secure Access Management System, for the purpose of better assessing mortality. Documentation of the collection of these variables has not been included in previous OMB PRA submissions. The burden for this linking is listed in the table below. The linking process consists of the following: identification of cases to match to the death index for each HAIC surveillance program, matching of the cases to the death index using established software (e.g., LinkPlus) or a homegrown linking process (e.g., SAS program), review of the matched data for quality purposes, creation of the tracking variables listed above, sharing the data with CDC in its final form. This process takes about 24 hour per pathogen group per surveillance activity (e.g., for MuGSI that includes CRE, CRAB and ESBL the total burden is estimated at 72 hour per year).

16. Plans for Tabulation and Publication and Project Time Schedule

For ABCs, CDC will provide each surveillance area with several forms of feedback including data integrity checks and summary tables. Specifically, data from multiple sites will be

concatenated approximately 3 weeks after receipt at CDC. Feedback from sites to local hospitals, laboratories, and other constituents is at the discretion of each site.

CDC generates pathogen-specific ABCs surveillance reports annually (https://www.cdc.gov/abcs/reports-findings/surv-reports.html). CDC also summarizes data for presentation in written manuscripts for peer-reviewed journals, and at national and local scientific meetings. These analyses are on-going throughout the calendar year.

For FoodNet, surveillance data are reviewed monthly at CDC, and published yearly in an MMWR and are publicly available online through a web-based interface (https://wwwn.cdc.gov/foodnetfast/).

For FluSurv-NET, prospective surveillance will be conducted for hospital admissions occurring each influenza season between October 1 and April 30.

Activity	Time Schedule
Begin prospective case finding and chart review	October 1
Weekly: sites send data to CDC	October 1- April 30
End prospective case finding	April 30
Sites submit finalized prospective data to CDC	September 30
Data Analysis	Continuous throughout and following data collection
Presentation of findings	Continuous throughout and following data collection
Manuscript Preparation	Continuous throughout and following data collection

For HAIC, CDC provides each EIP site with several forms of feedback including data integrity checks. HAIC staff members at CDC and in the sites are engaged in an ongoing fashion in data analysis, and it is routine each year (throughout the year) for several abstracts and papers to be presented at national meetings and published in peer-reviewed journals. Feedback from sites to local hospitals, laboratories, and other constituents is at the discretion of each site. CDC also produces an annual report for CDI (https://www.cdc.gov/hai/eip/clostridium-difficile.html) and MRSA (https://www.cdc.gov/hai/eip/saureus.html). HAIC's Annual Laboratory Surveys for invasive *S. aureus* and CDI are conducted annually. Laboratory outreach is planned annually for Gram-negative surveillance. The HAIC Candidemia Periodic Laboratory Survey is conducted approximately every two to three years. The invasive *S. aureus*, *MuGSI* and the CDI Annual Surveillance Officers survey is conducted annually. The CDI LTCF survey is also conducted annually. The data collected from these survey tools are used to inform surveillance, to ensure standard data collection practice and data quality. These data are not collected for the sole purpose of publishing, although data elements that are collected could be used to inform data analysis or appear in a publication.

The HAIC MuGSI CA CP-CRE Health Interview will be conducted on an ongoing basis as cases are identified through routine surveillance practices. These data will not only be helpful in reaching our project objectives, but these data will help local and state public health agencies better characterize these infections in the community and will be a valuable source of data for local prevention efforts. Therefore, these data are not collected for the sole purpose of publishing; however, these types of interviews are not occurring at all state health departments and therefore sharing these data through publication will be important.

EIP will be developing an approach to (or guidance for) making EIP datasets publicly available, in accordance with recently issued requirements. The policy at CDC (SDAP – Scientific Data Access Project) is still new and precisely what is required and by when appears to be still under discussion. A plan will be forthcoming.

ABCs now publishes the full complement of ABCs publicly available data at Data.cdc.gov: https://data.cdc.gov/browse?q=abcs%20bactfacts&sortBy=relevance. These are aggregate datasets with ABCs bacterium-specific case counts and rates by key demographic and laboratory characteristics which underpin the data visualizations on the ABCs BactFacts website: https://www.cdc.gov/abcs/bact-facts-interactive-dashboard.html. Public use datasets are downloadable in a variety of formats (CSV; CSV for Excel; RDF; RSS, TSV for Excel; XML) for offline use with any standard statistical software package.

FoodNet publishes surveillance data online through a web-based interface (https://wwwn.cdc.gov/FoodNetFast/).

FluSurv-NET has made hospitalization rates publicly available through FluView Interactive (https://gis.cdc.gov/GRASP/Fluview/FluHospRates.html). Cumulative and weekly rates have been published, as well as rates by season, age group, sex, and race/ethnicity. Additionally, demographic and clinical data on hospitalizations are publicly available (https://gis.cdc.gov/grasp/fluview/FluHospChars.html).

HAIC has made surveillance data available through HAIC Viz (https://www.cdc.gov/hai/eip/haicviz.html). This data is updated on an annual basis. Additionally, the underlying data populating the HAIC Viz platform is available on data.cdc.gov.

17. Reasons Display of OMB Expiration Date is Inappropriate

Data collections for ABCs and HAIC forms remain constant from one expiration date to the next. In order to make the most efficient use of the forms that have already been distributed to state health department personnel we request that the OMB expiration date not be printed on these forms. Therefore, the display of the OMB expiration date is not appropriate. For FoodNet and FluSurv-NET the expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the Paperwork Reduction Act Submission certification.