Change Memo for
"Emerging Infections Program"
(OMB Control No. 0920-0978)
Expiration Date: 04/30/2022

Program Contact

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The Centers for Disease Control and Prevention (CDC) requests a nonmaterial/non-substantive change of the currently approved Information Collection Request: "Emerging Infections Program (OMB Control No. 0920-0978)."

Requested changes represent minor modifications to already-approved instruments to include a limited number of data elements pertaining to COVID-19.

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.

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 in 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 Hospitalization Surveillance Network (FluSurv-NET): 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.

This non-substantive change request is for limited additions to the data elements for one of the major activities of the EIP Network, the Healthcare-Associated Infections-Community Interface (HAIC) surveillance. HAIC conducts active population-based surveillance for healthcare-associated pathogens, including antimicrobial-resistant pathogens, and infections. As a result of proposed changes, the estimated annualized burden is expected to increase by 2089 hours, from 21,493 to 23,582. The data elements and justifications are described below.

Proposed additions to the HAIC Forms:

We propose to add one question to the HAIC Case Report Forms, as follows:

- Did the patient have a POSITIVE test(s) for SARS-CoV-2 (molecular assay, serology or other confirmatory test) on or before the DISC? Yes/No/Unknown (DISC=date of incident specimen collection)
    - If yes, complete the following table:

FIRST positive test for SARS-CoV-2 on or	Specimen collection date: _ _ / _ _ / _ _ _ _	Test type: Molecular assay Serology Unknown Other, specify: _____

before the DISC:	or Unknown	
MOST RECENT positive test for SARS-CoV-2 on or before the DISC:	Specimen collection date: _ _ / _ _ / _ _ _ _ or Unknown	Test type: Molecular assay Serology Unknown Other, specify: _____

We also propose collecting COVID-Net and/or NNDSS identification numbers for HAIC surveillance cases to allow linkages between these data systems:

- COVID-NET Case ID
- NNDSS IDs (please provide at least one of the following when applicable):
  - Local Case ID:
  - Local Record ID:
  - State case identifier:
  - Legacy case identifier:

Justification:

The proposed additions address the following CDC COVID-19 response priorities: (1) to maintain and enhance surveillance of COVID-19 and (2) to collect actionable information to increase understanding of COVID-19 disease progression and associated infections. Given that a high proportion of individuals diagnosed with COVID-19 are hospitalized, with many requiring ICU-level care and exposure to mechanical ventilation, the risk for secondary infections, including healthcare-associated infections, may be increased. This includes infections under surveillance in the HAIC, such as those due to gram-negative bacteria (such as carbapenem-resistant *Acinetobacter baumannii* [CRAB], carbapenem-resistant Enterobacteriaceae [CRE] and extend-spectrum beta-lactamase producing Enterobacteriaceae [ESBL]—the Multi-site Gram-negative Surveillance Initiative, or MuGSI) and *Staphylococcus aureus* (SA). Additionally, widespread antibiotic use among patients with COVID-19 could also lead to an increased risk of developing *Clostridioides difficile* infection (CDI). Through the addition of a small number of variables to existing, approved case report forms for long-standing EIP HAIC population-based surveillance for these pathogens, we will be able to describe the proportion of infections occurring in patients with COVID-19 and link to other surveillance programs to access COVID-19-specific data. These data will inform development of surveillance and prevention strategies.

Other data systems:

The Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET) conducts population-based surveillance in the 10 EIP sites for laboratory-confirmed COVID-19-associated hospitalizations. However, this system does not collect detailed information on patients who develop secondary resistant gram-negative bacterial infections, invasive SA infections, or CDI, and does not capture patients who are not hospitalized for COVID-19. By contrast, EIP HAIC surveillance for these pathogens captures all cases occurring in the surveillance catchment areas, whether hospitalized or not, and gathers detailed data on risk factors and outcomes. The COVID-19-related data elements that are being proposed as an addition to the HAIC surveillance case report forms provide information to determine whether SARS-CoV-2 infection preceded the infection due to the HAIC pathogen. To supplement and enhance information on patients with SARS-CoV-2 infection that also meet case definitions for inclusion in HAIC surveillance, we plan to collect the unique patient identification number(s) from COVID-NET to enable data linkage.

The National Notifiable Disease Surveillance System (NNDSS) is also collecting information on patients with SARS-CoV-2. Case data are reported from most jurisdictions and statewide. However, the completeness of these data is unknown. To supplement and enhance information on patients with SARS-CoV-2 infection that also meet case definitions for inclusion in HAIC surveillance, we plan to collect the unique patient identification number(s) from NNDSS to enable data linkage.

We estimate these changes will add three minutes to the previously approved burden for this data collection tool. The previous burden calculated for HAIC forms was 21,493hours. As a result of the changes proposed in this change memo, the burden for the HAIC forms will increase by 2089 hours to 23,582 hours.

Data collection activity	Estimated number of respondents	Estimated number of responses per respondent	Estimated time spent per response (in hours)	Estimated current total burden (in hours)	Estimated total burden after proposed changes (in hours)
MuGSI Case Report Form for Carbapenem-resistant Enterobacteriaceae (CRE) and *Acinetobacter baumannii* (CRAB)	10	500	28/60^	2083	2333
MuGSI Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (ESBL)	10	1104	28/60^	4600	5152
Invasive Methicillin-resistant *Staphylococcus aureus* (MRSA) Infection Case Report Form	10	340	28/60^	1417	1587
Invasive Methicillin-sensitive *Staphylococcus aureus* (MSSA) Infection Case Report Form	10	584	28/60^	2433	2725
CDI Case Report and Treatment Form	10	1650	38/60^	9625	10450
Candidemia Case Report Form	10	200	30/60	1000	1000*
Annual Survey of	10	16	15/60	40	40*

Laboratory Practices for *C. difficile* Infections					
CDI Annual Surveillance Officers Survey	10	1	15/60	3	3*
Emerging Infections Program *C. difficile* Surveillance Nursing Home Telephone Survey (LTCF)	10	45	5/60	38	38*
Invasive *Staphylococcus aureus* Laboratory Survey: Use of Nucleic Acid Amplification Testing (NAAT)	10	11	20/60	37	37*
Invasive *Staphylococcus aureus* Supplemental Surveillance Officers Survey	10	1	10/60	17	17*
Laboratory Testing Practices for Candidemia Questionnaire	10	120	10/60	200	200*
			Total	*21,493 hours*	*23,583 hours*

^ Estimated time spent per response reflects the addition of 3 burden minutes as a result of the proposed changes.
**No change in the estimated burden as the proposed additional questions are not being added to these HAIC forms.*

Attachments with proposed changes highlighted in yellow, including changes to the numbering of existing approved data elements due to the addition of COVID-19-related elements. Note that the final formatting and placement of the proposed COVID-19-related data elements on the case report forms is subject to change:

1. EIP HAIC MuGSI-_CRE/CRAB Case Report Form
2. EIP HAIC MuGSI—ESBL Case Report Form
3. EIP HAIC Invasive MRSA Case Report Form
4. EIP HAIC Invasive MSSA Case Report Form
5. EIP HAIC CDI Case Report and Treatment Form