Emerging Infections Programs (EIP)
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Justification for Change Request for OMB 0920-0978

This is a nonmaterial/non-substantive change request for OMB No. 0920-0978, expiration date 05/31/2021, for the Emerging Infections Programs (EIP). All requested changes represent minor modifications to already-approved instruments including revised formatting, rewording, new answer options, and the addition/subtraction of a limited number of questions. Larger changes are being packaged together into a revision ICR that will be submitted later 2019.

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 changes to the disease-specific data elements for ABC, FoodNet, FluSurv-NET, and HAIC. The changes made to the all forms under this non-substantive request will aid in improving surveillance efficiency and data quality to clarify the burden of disease and possible risk factors for disease. This information can be used to inform strategies for preventing disease and negative outcomes. Specifically, changes were made for clarification purposes, to assist data collectors in capturing data in a standardized fashion to improve accuracy. As a result of proposed changes, the estimated annualized burden is expected to decrease by 790 hours, from 39,673 to 38,883. The data elements and justifications are described below.

The forms for which approval for changes are being sought include:

ABC:

- 2021 ABCs Neonatal Infection Expanded Tracking Form (Attachment 3)

Food Net:

- FoodNet Active Surveillance Data Elements List (Attachment 4)
- Diagnostic Laboratory Practices and Volume Data Elements List (Attachment 5)

FluSurv-NET:

- Influenza Hospitalization Surveillance Network Case Report Form (Attachment 6)
- FluSurv-NET/RSV Hospital Laboratory Survey (Attachment 7)

HAIC:

- Resistant Gram-Negative Bacilli (MuGSI) Case Report Form for Carbapenem-resistant Enterobacteriaceae and *Acinetobacter baumannii* (Attachment 8)
- 2020 Multi-site Gram-Negative Surveillance Initiative (MuGSI)- Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (ESBL) (Attachment 9)
- 2020 Invasive Methicillin-resistant *Staphylococcus aureus* (MRSA) Infection Case Report Form (Attachment 10)
- 2020 Invasive Methicillin-sensitive *Staphylococcus aureus* (MSSA) Infection Case Report Form (Attachment 11)
- CDI Case Report and Treatment Form (Attachment 12)
- Annual Survey of Laboratory Testing Practices for *C. difficile* Infections (Attachment 13)
- Candidemia Case Report (Attachment 14)
- Laboratory Testing Practices for Candidemia Questionnaire (Attachment 15)
- Invasive *Staphylococcus aureus* Laboratory Survey: Use of Nucleic Acid Amplification Testing (NAAT) (Attachment 16)

Estimated Annualized Burden Hours

As a result of proposed changes to forms highlighted in yellow, the estimated annualized burden is expected to decrease by 790 hours from 39,673 to 38,883.

The following table is updated for the entire 0920-0978 burden table. The forms included in this change request are highlighted:

Type of Respondent	Form Name	No. of respondents	No. of responses per respondent (Current)	No. of responses per respondent (Corrected)	Avg. burden per response (in hours)	Current Proposed Changes	After Proposed Changes
State Health Department	ABCs Case Report Form	10	809		20/60	2697	2697
	ABCs Invasive Pneumococcal Disease in Children Case Report Form	10	22		10/60	37	37
	ABCs *H. influenzae* Neonatal Sepsis Expanded Surveillance Form	10	6		10/60	10	10
	ABCs Severe GAS Infection Supplemental Form	10	136		20/60	453	453
	ABCs Neonatal Infection Expanded Tracking Form	10	37		20/60	123	123
	FoodNet Campylobacter[1]	10	850	**970**	21/60	3297	**3395**
	FoodNet Cyclospora[1]	10	3	**42**	10/60	272	**70**
	FoodNet Listeria monocytogenes[1]	10	13	**16**	20/60	50	**53**
	FoodNet Salmonella[1]	10	827	**855**	21/60	2761	**2993**
	FoodNet Shiga toxin producing E. coli[1]	10	190	**290**	20/60	683	**967**
	FoodNet Shigella[1]	10	290	**234**	10/60	355	**390**
	FoodNet Vibrio[1]	10	25	**46**	10/60	56	**77**
	FoodNet Yersinia[1]	10	30	**55**	10/60	80	**92**
	FoodNet Hemolytic Uremic Syndrome	10	10		1	100	**100**
	FoodNet Clinical Laboratory Practices and Testing Volume	10	70	n/a	20/60	233	**233**
	FluSurv-Net Influenza Hospitalization Surveillance Network Case Report Form	10	977	n/a	17/60	4167	**2768**
	FluSurv-Net Influenza Hospitalization	10	333		5/60	278	**278**

	Surveillance Project Vaccination Phone Script Consent Form (English)						
	FluSurv-Net Influenza Hospitalization Surveillance Project Vaccination Phone Script Consent Form (Spanish)	10	333		5/60	278	278
	FluSurv-Net Influenza Hospitalization Surveillance Project Provider Vaccination History Fax Form (Children/Adults)	10	333		5/60	278	278
	FluSurv-NET Laboratory Survey	10	23	n/a	10/60	38	38
	HAIC - MuGSI Case Report Form for Carbapenem-resistant Enterobacteriaceae (CRE) and *Acinetobacter baumannii* (CRAB)	10	500	n/a	28/60	2333	2333
	HAIC - MuGSI Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (ESBL)	10	1104	n/a	28/60	5152	5152
	HAIC - Invasive Methicillin-resistant *Staphylococcus aureus* (MRSA) Infection Case Report Form	10	340	n/a	28/60	1587	1587
	HAIC - Invasive Methicillin-sensitive *Staphylococcus aureus* (MSSA) Infection Case Report Form	10	584	n/a	28/60	2725	2725
	HAIC - CDI Case Report and Treatment Form	10	1650	n/a	38/60	10450	10450
	HAIC Candidemia Case Report[2]	10	200	170	40/60	1000	1134
	HAIC- Annual Survey of Laboratory Testing Practices for *C. difficile* Infections.	10	16	n/a	15/60	40	40
	HAIC- CDI Annual Surveillance Officers Survey	10	1		15/60	3	3
	HAIC- Emerging Infections Program *C. difficile Surveillance Nursing Home Telephone Survey (LTCF)*	10	45		5/60	38	38
	HAIC- Invasive *Staphylococcus aureus* Laboratory Survey: Use of Nucleic Acid Amplification Testing (NAAT)	10	11	n/a	20/60	37	37

	HAIC- Invasive *Staphylococcus aureus* Supplemental Surveillance Officers Survey	10	1		10/60	17	17
	HAIC- Laboratory Testing Practices for Candidemia Questionnaire[3]	10	120	20	11/60	45	**37**
TOTAL						**39,673**	**38,883**

[1]FoodNet pathogens (highlighted in table below in red) response numbers have been updated. The number of responses submitted with the non-substantive change for 2020 were inconsistent with what was submitted in 2019's revision, but the total burden was consistent with the 2019 revision. However, the number of responses per respondent continues to change each year as the number of enteric pathogens has been increasing. The number of responses per respondent now reflects the average number of reports for the last 3 years (2017-2019) sent to FoodNet as yearly variation, sometimes with large swings, can occur due to outbreaks or other unpredicted changes such as use of more sensitive diagnostic tests. In order to provide the best estimate each year, the number of responses per respondent for FoodNet pathogens under surveillance will be updated yearly using a 3 year rolling average. As a result of updating the No. of responses per respondent the annualized burden is expected to increase by 483 hours (7,554 to 8,037).

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

[3] HAIC- Laboratory Testing Practices for Candidemia Questionnaire: The requested changes to the survey tool are estimated to increase the time required for data collection by 1 minute per response. The new estimate is 11 minutes per response. Despite the changes to the data collection tool, the overall burden estimate has decreased as the number of respondents per site was overestimated in prior years. The number of records from each site was overestimated in last year's burden table (previous estimate of 120). The new estimated number of responses is based on the 2019 surveillance data (number of labs in each surveillance site) and is approximately 20 respondents per site. We have updated the number of records in the burden table, resulting in an overall decrease in burden hours from the previous year.