Emerging Infections Programs (EIP)

OMB Control Number 0920-0978
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Program Contact

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Circumstances of Change Request for OMB 0920-0978

This is a nonmaterial/non-substantive change request for OMB No. 0920-0978, expiration date 02/28/2019, for the Emerging Infections Programs (EIP). 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 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.

This non-substantive change request is for changes to disease-specific data elements for FoodNet and HAIC only. Minor changes are being requested for the 2017 FoodNet and HAIC collection tools to improve surveillance. The changes will have no impact on the burden of data collection.

CDC is requesting changes to the following five forms:

1. HUS Surveillance (Attachment A)
2. FoodNet Variable List (Attachment B)
3. Clostridium difficile Infection (CDI) (Attachment C)
4. Resistant Gram-Negative Bacilli Case Report Form (Attachment D)
5. Methicillin-resistant Staphylococcus aureus (MRSA) HAIC Case Report Form (Attachment E)

The data elements and justifications are described below.

1. HUS surveillance (Attachment A)

- Three new site-transmitted variables were added to the HUS case report form (attached). These are highlighted in yellow and a brief summary/justification is below. (The variables highlighted in green are also new, but are created at CDC not sent by sites).

- New questions added:

1. Was this case epi-linked to a confirmed or probable STEC case? *Justification: Would like to be able to classify STEC-associated HUS cases into CSTE categories (confirmed, probable, suspect) for STEC. Sites are already collecting this information in their state systems, easy for them to report.*
2. Was whole genome sequencing performed on this isolate? *Justification: This will be important for linking in the near future. States can report if known. Not required.*
3. Test type for other pathogens/co-infections (culture or CIDT)? *Justification: Need to have this distinction systematically collected in order to count cases. Information is already being collected in state systems.*

- Some questions in the microbiology section were added to ask about events at clinic, state, and CDC separately (rather than being incorporated into one set of questions). No new information is requested, this just clarifies existing information. *Justification: clarifies flow of testing for detection of STEC. We are better able to understand if guidelines for testing are being used.*

- In addition, the layout of the HUS forms were rearranged to match our new online data collection system, hosted in Redcap. (We previously used an Access database).

2. FoodNet Variable List (Attachment B)

- One new variable was added to be collected for *Salmonella* and *Campylobacter* cases: 'CEA_sampled". This variable denotes whether or not a case was chosen as part of a sampling scheme to be interviewed for exposures. This is only completed by sites who are using sampling scheme, rather than interviewing all cases. *Justification: Gives us a denominator among which to base performance standards.*

- We discontinued collection of 5 variables 'Comorb1' through 'Comorb5' for *Listeria* cases. *Justification: This information is bring collected through another surveillance system (Listeria Iniative) so did not need to continue to be collected through FoodNet.*

- We updated responses for an existing variable 'Outfetal' for *Listeria* cases. Responses are: still pregnant, fetal death, induced abortion, delivery, unknown. *Justification: new responses are consistent with responses in the Listeria Initiative.*

The two variables with proposed changes are highlighted in the attached variable list.

3. *Clostridium difficile* Infection (CDI) (Attachment C)

Minor changes are being requested for the 2017 CDI Case Report Form to improve surveillance for CDI. The changes will have no impact on the burden of data collection.

2017 CDI Case Report Form changes include:

1. Question 17b: ICU Admission:
    - Changed parenthetical to say, "(on the day of or within 7 days after incident stool collection)" to reflect existing instructions for this field.
2. Question 24e: Medications taken 12 weeks prior to incident stool collection date
    - Added numbers (indicating value in data dictionary) to all checkboxes in this question to be consistent with the rest of the case report form.

Question on 2016 form	**Question on 2017 form**
Q17b. ICU Admission (on the day of or after incident stool collection): 1☐ Yes 2☐ No 7☐ Unknown If YES, Date of ICU admission Mo. Day Year ☐☐ ☐☐ ☐☐☐☐	Q17b. ICU Admission (on the day of or within 7 days after incident stool collection): 1☐ Yes 2☐ No 7☐ Unknown If YES, Date of ICU admission Mo. Day Year ☐☐ ☐☐ ☐☐☐☐
Q24e. Was patient treated for <u>previous</u> suspected or confirmed CDI in the <u>prior 12 weeks</u>? ☐ Yes ☐ No ☐ Unknown If YES, which medication was taken (check all that apply, or unknown if applicable): ☐ Metronidazole ☐ Vancomycin ☐ Other (specify):_____ ☐ Unknown	Q24e. Was patient treated for <u>previous</u> suspected or confirmed CDI in the <u>prior 12 weeks</u>? 1☐ Yes 2☐ No 7☐ Unknown If YES, which medication was taken (check all that apply, or unknown if applicable): 1☐ Metronidazole 1☐ Vancomycin 1☐ Other (specify):_____ 1☐ Unknown

4. <u>Resistant Gram-Negative Bacilli Case Report Form (Attachment D)</u>

Minor changes are being requested for the Resistant Gram-Negative Bacilli Case Report Form (also labeled as the 2017 MuGSI Case Report Form (CRF)) to streamline how data is collected for patients with urine cultures. These questions will not impact the burden for chart review.

2017 MuGSI Case Report Form changes include:

1. Question 14a: Was the urine collected through an indwelling urethral catheter?
   - Changed question to just ask about this single catheter type, in 2016 version we were asking for several catheter types, including clean catch, in and out catheter, condom catheter, other type and unknown.
2. Question 14c: Signs and Symptoms associated with urine cultures. Please indicate if any of the following symptoms were reported during the 5 day time period including the 2 calendar day before and the 2 calendar days after the date of initial culture
   - Reduced the number of signs and symptoms that are being collected.
3. Question 14d: Was a blood culture positive in the 3 calendar days before though the 3 calendar days after the initial urine culture for the same MuGSI organisms?
   - New question, this question will not require medical record review, the surveillance officer collects this information as part of the routine surveillance.

Question on 2016 form	**Question on 2017 form**
Q14a: How was urine collected?	Q14a: Was the urine collected through an indwelling urethral catheter?

☐Clean Catch ☐In and Out Catheter ☐Indwelling Catheter ☐Other:_____ ☐Unknown	☐Yes ☐No ☐Unknown
Q14c: Signs and Symptoms associated with urine culture. Please indicate if any of the following symptoms were reported during the 5 day time period including the 2 calendar days before and the 2 calendar days after the day of initial culture: ☐Altered mental status ☐Acute pain, swelling or tenderness of the testes, epididymis or prostate ☐Chills ☐Cloudy ☐Costovertebral angle pain or tenderness ☐Dysuria ☐Fever ☐Frequency ☐Hematuria ☐Incontinence ☐Leukocytosis ☐Malodorous ☐Purulent discharge ☐Pyuria	Q14c: Signs and Symptoms associated with urine culture. Please indicate if any of the following symptoms were reported during the 5 day time period including the 2 calendar days before and the 2 calendar days after the day of initial culture: ☐None ☐Costovertebral angle pain or tenderness ☐Dysuria ☐Fever ☐Unknown ☐Frequency ☐Suprapubic tenderness ☐Urgency Symptoms for patients ≤ 1 year of age only: ☐Apnea ☐Bradycardia ☐Lethargy ☐Vomiting

☐Retention ☐Suprapubic tenderness ☐Unspecified abdominal pain/tenderness ☐Urgency ☐Unknown ☐Other (specify):_____ ☐None	
	NEW QUESTION Q14d. Was a blood culture positive in the 3 calendar days before though the 3 calendar days after the initial urine culture for the same MuGSI organism? ☐Yes ☐No ☐Unknown

5. Methicillin-resistant *Staphylococcus aureus (MRSA)* (Attachment E)

Minor changes are being requested for the 2017 MRSA Case Report Form to improve surveillance for MRSA. The changes will have no impact on the burden of data collection.

Change	Justification
Added 17b: "date of first SA blood culture after which SA not isolated for 14 days"	needed to better track length of duration of illness
Question 20, added fields for birth weight and estimated gestational age	needed to better describe infants with disease
Added question 22, susceptibility results for five antimicrobial drugs	needed to validate status of cases, perform surveillance for emerging resistance of public health concern, and better describe epidemiology of strains

Burden

The annualized burden hours and cost to reporting jurisdictions to submit these data to CDC does not change from the original estimates in the "Estimates of Annualized Burden Hours and Costs" section in A.12 of OMB No. 0920-0978.

The forms with requested changes are highlighted in the table below. Note: the three forms highlighted in green are included in the FoodNet Variables List (Attachment B).

A.12A. Estimates of 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
	Invasive Methicillin-resistant *Staphylococcus aureus* ABCs Case Report Form	10	609	20/60	2030
	ABCs Invasive Pneumococcal Disease in Children Case Report Form	10	22	10/60	37
	ABCs Non-Bacteremic Pneumococcal Disease Case Report Form	10	125	10/60	208
	Neonatal Infection Expanded Tracking Form	10	37	20/60	123
	ABCs Legionellosis Case Report Form	10	100	20/60	333
	Campylobacter	10	637	20/60	2123
	Cryptosporidium	10	130	10/60	217
	Cyclospora	10	3	10/60	5
	Listeria monocytogenes	10	13	20/60	43
	Salmonella	10	827	20/60	2757
	Shiga toxin producing E. coli	10	90	20/60	300
	Shigella	10	178	10/60	297
	Vibrio	10	20	10/60	33
	Yersinia	10	16	10/60	27
	Hemolytic Uremic Syndrome	10	10	1	100
	Influenza Hospitalization Surveillance Project	10	400	15/60	1000

	Case Report Form				
	Influenza Hospitalization Surveillance Project Vaccination Telephone Survey	10	100	5/60	83
	Influenza Hospitalization Surveillance Project Vaccination Telephone Survey Consent Form	10	100	5/60	83
	2015 ABCs H. influenza Neonatal Sepsis Expanded Surveillance Form	10	6	10/60	10
EIP site	CDI Case Report Form	10	1650	20/60	5500
	CDI Treatment Form	10	1650	10/60	2750
	Resistant Gram-Negative Bacilli Case Report Form	10	500	20/60	1667
Person(s) in the community infected with *C. difficile* (CDI Cases)	Screening Form	600	1	5/60	50
	Telephone interview	500	1	40/60	333
Total					22,806