Emerging Infections Programs (EIP)

OMB Control Number 0920-0978
Expiration Date: 02/28/2019

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 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: 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 HAIC only. As a result of proposed changes, the estimated annualized burden is expected to decrease by 383 hours, from 22,473 to 22,090. The data elements and justifications are described below.

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

1. 2018 Resistant Gram-Negative Bacilli (MuGSI) Case Report Form for Carbapenem-resistant Enterobacteriaceae and *Acinetobacter baumannii* (Att. 1)
2. 2018 Invasive Methicillin-resistant *Staphylococcus aureus* (MRSA) Infection Case Report Form (Att. 2)
3. 2018 *Clostridium difficile* Infection (CDI) Case Report Form (Att. 3). NOTE: the 2018 form combines two approved 2017 forms (the CDI Case Report Form and the CDI Treatment Form) into a single form.
4. Persons in the Community with *Clostridium difficile* infection (CDI): Screening Form (discontinued)
5. Persons in the Community with *Clostridium difficile* infection (CDI): Telephone Interview Form (discontinued)

Detailed Description of Changes

1. **2017 MuGSI Case Report Form for Carbapenem-resistant Enterobacteriaceae (CRE) and *Acinetobacter baumannii* (CRAB)**
   There is no impact on burden due to the changes on this form. Minor changes are being requested for the 2018 MuGSI CRE/CRAB Case Report Form. We are adding a single question, clarifying wording of some questions, and adding a type of infection.

   Changes include:
   a. New Questions (Q16b): *A. baumannii Cultures ONLY*: Did the patient have a sputum culture positive for CRAB in the 30 days prior to the date of culture (Day 1)?
      i. Added this question to capture this additional piece of information.
   b. Q12: Patient Outcome Question: Was the organism cultured from a normally sterile site or urine, ≤ calendar day 7 before death?
      i. Clarified the wording of this question only, changed the < symbol to ≤
   c. Q19: Types of infections: Adding "epidural abscess"
      i. Collecting a new type of infection "epidural abscess"
   d. Q21: Risk Factor Questions: Culture collected ≥ calendar day 3 after hospital admission.
      i. Clarified the wording of this question only, change the > symbol to ≥

2. **2017 Invasive MRSA Infection Case Report Form**
   There is no impact on burden due to the change on this form. One minor change is being requested for the 2018 Invasive MRSA Infection Case Report Form.

   Changes include:
   a. Question 19: Types of MRSA infection associated with culture(s) (check all that apply):
      i. Adding one check box for "epidural abscess". This information was previously captured by checking "meningitis" and "osteomyelitis".

3. **2017 CDI Case Report Form and Treatment Form**
   These approved 2017 forms are combined into a single CDI Case Report Form for 2018. There is no impact on burden due to this format change. Other minor changes are being requested; for example, to clarify wording of some questions.

   Changes include:
   a. Changes to wording for clarification and harmonization that do not affect the meaning of the question or responses
      i. Questions 4a, 4b, 8a, 8c, 9, 10, 11a, 11b, 11c, 11d, 13, 14, 15, 16, 17b, 17c, 18, 19, 20.1, 23 (formerly 24), 23e (formerly 24e), 26
   b. Adding two days to reference period for question about ICU admission (Q17b), rewording question
   c. Adding question about ileus and toxic megacolon described in the medical record somewhere other than on a radiology report (Q20.2e)
   d. Combining questions about diarrhea and upper GI symptoms into a single "symptoms" question (Q20.2d, formerly Q20.2d and 20.2e), reworded question
   e. Adding "pregnancy" to list of underlying conditions (Q21), removed standalone question about pregnancy, post-partum status, and delivery date (formerly Q23)
      i. Post-partum status and delivery date no longer of interest
   f. Removing "edited & correct" from list of CRF status options (Q25)

g. Incorporating standalone treatment form into CRF (now Q24)
h. Checkbox instead of yes/no question for treatment options of probiotics and stool transplant (Q24, formerly on treatment form)
i. Changing date associated with stool transplant from start and stop dates to a single date (Q24, formerly on treatment form)
    i. Stool transplant only ever occurs on a single day; this eliminates a workaround where surveillance officers entered the same date for start and stop date
j. Restructuring treatment data to simplify data collection, eliminated collection of dose and frequency for all medications
    i. Formerly: each change of medication, route, dose, or frequency would be recorded as a separate course of medication
    ii. Currently: each change of medication or route will be recorded as a separate course of medication, without regard to dose or frequency
k. Adding option for duration of course of medication when start and stop days are not available
    i. This eliminates a workaround where surveillance officers assumed that the start date of a medication was the date of incident C.diff+ stool collection when the start date was unavailable.

4. Persons in the Community with *Clostridium difficile* infection (CDI): Screening Form (discontinued)

This form has been discontinued. There is no longer a need for EIP to continue interviewing persons with community-associated CDI. Sufficient interviews have been conducted to describe risk factors for community-associated infection.

5. Persons in the Community with *Clostridium difficile* infection (CDI): Telephone Interview Form (discontinued)

This form has been discontinued. There is no longer a need for EIP to continue interviewing persons with community-associated CDI. Sufficient interviews have been conducted to describe risk factors for community-associated infection.

Justification for changes

The changes made to the HAIC 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. The CDI Screening and Telephone Interview Forms have been discontinued.

Cross walk of 2018 form changes

1. **2018 MuGSI Case Report Form for Carbapenem-resistant Enterobacteriaceae (CRE) and *Acinetobacter baumannii* (CRAB)**

Question on 2017 form	**Question on 2018 form**
	New Question: Q16b. *A. baumannii Cultures Only:* Did the patient have a sputum culture positive for CRAB in the 30 days prior to the date of culture (Day 1)? ☐ Yes ☐ No ☐ Unknown ☐ NA
Q12: Patient Outcome Was the organism cultured from a normally sterile site or urine, < calendar day 7 before death? ☐ Yes ☐ No ☐ Unknown	Q12: Patient Outcome Was the organism cultured from a normally sterile site or urine, ≤ calendar day 7 before death? ☐ Yes ☐ No ☐ Unknown
Q19. Types of infections associated with culture(s) (check all that apply) • None • Unknown • Abscess (not skin) • AV Fistula/Graft infection • Bacteremia • Bursitis • Catheter Site infection • Cellulitis • Chronic ulcer/Wound (non-decubitus) • Decubitus/Pressure Ulcer • Empyema • Endocarditis • Meningitis • Osteomyelitis	Q19. Types of infections associated with culture(s) (check all that apply) • None • Unknown • Abscess (not skin) • AV Fistula/Graft infection • Bacteremia • Bursitis • Catheter Site infection • Cellulitis • Chronic ulcer/Wound (non-decubitus) • Decubitus/Pressure Ulcer • Empyema • Endocarditis • Epidural abscess • Meningitis

Question on 2017 form	**Question on 2018 form**
• Peritonitis • Pneumonia • Phyelonephritis • Septic arthritis • Septic emboli • Septic shock • Skin abscess • Surgical incision infection • Surgical site infection (internal) • Traumatic wound • Urinary tract infection • Other (Specify):_____	• Osteomyelitis • Peritonitis • Pneumonia • Phyelonephritis • Septic arthritis • Septic emboli • Septic shock • Skin abscess • Surgical incision infections • Surgical site infection (internal) • Traumatic wound infection • Urinary tract • Other (Specify):_____
Q21. Risk factors of interest (check all that apply). ☐ Culture collected > calendar day 3 after hospital admission	Q21. Risk factors of interest (check all that apply). ☐ Culture collected ≥ calendar day 3 after hospital admission

2. 2018 Invasive MRSA Infection Case Report Form

Question on 2017 form	**Question on 2018 form**
19. Types of MRSA infection associated with cultures(s) (check all that apply): • None • Unknown • Abscess (not skin) • AV Fistula/Graft infection • Bacteremia • Bursitis • Catheter Site infection • Cellulitis • Chronic ulcer/Wound (non-decubitus) • Decubitus/Pressure Ulcer • Empyema • Endocarditis • Meningitis • Peritonitis • Pneumonia • Osteomyelitis • Septic arthritis • Septic emboli • Septic shock • Skin abscess • Surgical incision • Surgical site (internal) • Traumatic wound • Urinary tract • Other (Specify):_____	19. Types of MRSA infection associated with cultures(s) (check all that apply): • None • Unknown • Abscess (not skin) • AV Fistula/Graft infection • Bacteremia • Bursitis • Catheter Site infection • Cellulitis • Chronic ulcer/Wound (non-decubitus) • Decubitus/Pressure Ulcer • Empyema • Endocarditis • Epidural abscess • Meningitis • Peritonitis • Pneumonia • Osteomyelitis • Septic arthritis • Septic emboli • Septic shock • Skin abscess • Surgical incision • Surgical site (internal) • Traumatic wound • Urinary tract • Other (Specify):_____

3. 2018 CDI Case Report Form

Question on 2017 form	**Question on 2018 form**
4a. LAB/HOSPITAL WHERE TOXIN ASSAY PERFORMED	4a. Laboratory ID where incident specimen identified
4b. PROVIDER ID WHERE PATIENT TREATED	4b. Facility ID where patient treated
8a. DATE OF INCIDENT STOOL COLLECTION POSITIVE FOR C. diff:	8a. Date of incident C. diff+ stool collection
8c. Location of stool collection: (Check one) □ Long Term Acute Care Hospital □ Long Term Care/Skilled Nursing Facility	8c. Location of incident C. diff+ stool stool collection: (Check one) □ LTACH □ LTCF
9. Was patient hospitalized at the time of, or within 7 days after incident C. diff+ stool collection?	9. Was patient hospitalized on the date of or in the 6 calendar days after incident C. diff+ stool collection?
10. Where was the patient a resident 4 days prior to stool collection? (Check one) □ Long Term Acute Care Hospital □ Home □ Long Term Care/Skilled Nursing Facility	10. Where was the patient located on the 3rd calendar day before the date of incident C. diff+ stool collection? (Check one) □ LTACH □ Private Residence □ LTCF
11a. Was stool collected ≥4 days after hospital admission? □ Yes (HCFO) □ No (go to 11b.)	11a. Was incident C. diff+ stool collected at least 3 calendar days after the date of hospital admission? □ Yes (HCFO – go to 11d) □ No
11b. If no, was stool collected at LTCF/SNF/LTACH? □ Yes (HCFO) □ No (go to 11c.)	11b. Was incident C. diff+ stool collected at an outpatient setting for a LTCF resident, or in a LTCF or LTACH? □ Yes (HCFO – go to 11d) □ No
11c. If no, was the patient admitted from LTCF/SNF or another acute care setting? □ Yes (HCFO) □ No (CO – complete CRF)	11c. Was the patient admitted from a LTCF or a LTACH? □ Yes (HCFO – go to 11d) □ No (CO – complete CRF)
11d. If HCFO, was this case selected sampled for full CRF based on sampling frame (1:10)? □ Yes (Complete CRF) □ No (STOP data abstraction here!)	11d. If HCFO, was this case selected sampled for full CRF based on sampling frame (1:10)? □ Yes (Complete CRF) □ No (STOP data abstraction here!)
13. Were other enteric pathogens isolated from stool at the same date incident C. diff+ stool was collected?	13. Were other enteric pathogens isolated from stool collected on the date of incident C. diff+ stool collection?
14. Exclusion criteria for CA-CDI: (Check all that apply) □ Hospitalization (overnight) at any time in the 12 weeks prior to stool collection date □ Overnight stay in LTACH at any time in the 12 weeks prior to stool collection date	14. Exclusion criteria for CA-CDI: (Check all that apply) □ Hospitalization (overnight) in the 12 weeks before the date of incident C. diff+ stool collection □ Overnight stay in LTACH in the 12 weeks

Question on 2017 form	**Question on 2018 form**
□ Residence in LTCF/SNF at any time in the 12 weeks prior to stool collection date	before the date of incident C. diff+ stool collection □ Residence in LTCF in the 12 weeks before the date of incident C. diff+ stool collection
15. Exposures to Healthcare: a. Chronic Hemodialysis prior to incident C. diff + stool: b. Surgical procedure in the 12 weeks prior to incident C. diff + stool: c. ER visits in the 12 weeks prior to incident C. diff + stool: d. Observation/CDU stay in the 12 weeks prior to incident C. diff + stool:	15. Exposures to Healthcare in the 12 weeks before the date of incident C. diff+ stool collection:: a. Chronic Hemodialysis: b. Surgical procedure: c. ER visits: d. Observation/CDU stay:
16. If survived, patient was discharged to: □ Long Term Acute Care Hospital □ Home □ Long Term Care/Skilled Nursing Facility	16. If survived, patient was discharged to: □ LTACH □ Private Residence □ LTCF
17b. ICU Admission (on the day of or within 7 days after incident stool collection)	17b. ICU Admission (in the 2 calendar days before, the day of, or the 6 calendar days after the date of incident C. diff+ stool collection)
17c. Any additional positive stool tests for C. diff ≥2 and ≤8 weeks after the last C. diff+ stool specimen?	17c. Any additional positive stool tests for C. diff ≥2 and ≤8 weeks after the date of incident C. diff+ stool collection?
18. RADIOGRAPHIC FINDINGS (within 7 days before or after incident C. diff+ stool): □ Toxic megacolon □ Ileus □ Neither □ Both □ Not Done □ Information not available	18. RADIOGRAPHIC FINDINGS (in the 6 calendar days before, the day of, or the 6 calendar days after the date of incident C. diff+ stool collection): □ Toxic megacolon □ Ileus □ Both toxic megacolon and ileus □ Neither toxic megacolon nor ileus □ Radiology test not performed □ Information not available
19. Was pseudomembranous colitis listed in the surgical pathology, endoscopy, or autopsy report (within 7 days before or after incident C. diff+ stool)?	19. Was pseudomembranous colitis listed in the surgical pathology, endoscopy, or autopsy report in the 6 calendar days before, the day of, or the 6 calendar days after the date of incident C. diff+ stool collection?
20.1. LABORATORY FINDINGS (within 7 days before or after incident C. diff + stool):	20.1. LABORATORY FINDINGS (in the 6 calendar days before, the day of, or the 6 calendar days after the date of incident C. diff+ stool collection)
20.2. CLINICAL FINDINGS (within 7 days before and up to 1 day after incident C. diff + stool): d. Diarrhea □ Diarrhea by definition (unformed or watery stool,	20.2. CLINICAL FINDINGS: d. Symptoms in the 6 calendar days before, the day of, or 1 calendar day after the date of incident C. diff+ stool collection (Choose all

Question on 2017 form	**Question on 2018 form**
≥ 3/day for ≥ 1 day) ☐ Diarrhea documented, but unable to determine if it is by definition ☐ No Diarrhea documented ☐ "Asymptomatic" documented in medical record ☐ Information not available e. Upper GI Symptoms ☐ Nausea ☐ Vomiting ☐ Neither ☐ Both ☐ Information not available	that apply) ☐ Diarrhea by definition (unformed or watery stool, ≥ 3/day for ≥ 1 day) ☐ Diarrhea documented, but unable to determine if it is by definition ☐ Nausea ☐ Vomiting ☐ "Asymptomatic" documented in medical record ☐ No diarrhea, nausea, or vomiting documented ☐ Information not available
[question did not exist]	e. Other findings in the 6 calendar days before, the day of, or the 6 calendar days after the date of incident C. diff+ stool collection ☐ Toxic megacolon ☐ Ileus ☐ Both toxic megacolon and ileus ☐ Neither toxic megacolon nor ileus ☐ Information not available
21. UNDERLYING CONDITIONS: (Check all that apply) If none or no chart available, check appropriate box ☐ None ☐ Unknown ☐ AIDS ☐ Chronic Cognitive Deficit ... ☐ Hematologic Malignancy ☐ Metastatic Solid Tumor	21. UNDERLYING CONDITIONS: (Check all that apply) ☐ None ☐ Unknown ☐ AIDS ☐ Chronic Cognitive Deficit … ☐ Hematologic Malignancy ☐ Metastatic Solid Tumor ☐ Pregnancy
23. At time of incident C. diff+ stool, patient was: ☐ Pregnant ☐ Post-partum ☐ Neither ☐ Unknown Delivery Date: _____	[removed question]
24. MEDICATIONS TAKEN 12 WEEKS PRIOR TO INCIDENT STOOL COLLECTION DATE (including current hospital stay if collection date > admission date) (If none or no chart available, check appropriate box)	23. Medications taken in the 12 weeks before the date of incident C. diff+ stool collection
24e. Was patient treated for previous suspected or confirmed CDI in the prior 12 weeks?	23e. Was patient treated for previous suspected or confirmed CDI in the 12 weeks before the date of incident C. diff+ stool collection?

Question on 2017 form	**Question on 2018 form**
25. CRF Status: □ Complete □ Incomplete □ Edited & Correct □ Chart unavailable after 3 requests	25. CRF Status: □ Complete □ Incomplete □ Chart unavailable after 3 requests
26. Previous unique CDI episode (>8 weeks prior to this episode):	26. Previous unique CDI episode (>8 weeks before the date of incident C. diff+ stool collection):
[Treatment form] Probiotics □ Yes □ No If yes, specify: _____	24. □ Probiotics (specify): _____
[Treatment form] Stool transplant □ Yes □ No Start Date: _____ Stop Date: _____	24. □ Stool transplant Date: _____
[Treatment form] [For each of up to 4 courses of Vancomycin] Route: □ PO □ Rectal □ Unknown Start date: _____ Stop date: _____ Dosage: □ 125mg □ 250mg □ 500mg □ Other: _____ □ Unknown Frequency: □ Once a day □ BID □ TID □ QID □ Other: _____ □ Unknown Taper: □ Yes □ No	24. [For each of up to 6 courses of treatment] □ Vancomycin (PO) □ Vancomycin (Rectal) □ Vancomycin (Unknown route) □ Vancomycin taper (any route) □ Metronidazole (PO) □ Metronidazole (IV) □ Metronidazole (Unknown route) □ Fidaxomicin □ Rifaximin □ Nitazoxanide □ Other (specify): _____ Start date: _____ Stop date: _____ or Duration (days): _____

Question on 2017 form	**Question on 2018 form**
[Treatment form][For each of up to 4 courses of Metronidazole] Route: □ PO □ IV □ Unknown Start date: _____ Stop date: _____ Dosage: □ 125mg □ 250mg □ 500mg □ Other: _____ □ Unknown Frequency: □ Once a day □ BID □ TID □ QID □ Other: _____ □ Unknown Taper: □ Yes □ No	
[For each of up to 4 courses of Fidaxomicin] Start date: _____ Stop date: _____ Dosage: □ 200mg □ Other: _____ □ Unknown Frequency: □ Once a day □ BID □ TID □ QID □ Other: _____ □ Unknown	

Question on 2017 form	**Question on 2018 form**
[Treatment form][For each of up to 4 courses of Nitazoxanide] Start date: _____ Stop date: _____ Dosage: ☐ 500mg ☐ Other: _____ ☐ Unknown Frequency: ☐ Once a day ☐ BID ☐ TID ☐ QID ☐ Other: _____ ☐ Unknown	
[Treatment form][For each of up to 4 courses of Rifaximin] Start date: _____ Stop date: _____ Dosage: ☐ 400mg ☐ Other: _____ ☐ Unknown Frequency: ☐ Once a day ☐ BID ☐ TID ☐ QID ☐ Other: _____ ☐ Unknown	

Question on 2017 form	**Question on 2018 form**
[Treatment form][For each of up to 6 courses of other medication] Specify: _____ Start date: _____ Stop date: _____ Route: □ PO □ Rectal □ IV □ IM □ Unknown Dosage: □ Specify: _____ □ Unknown Frequency: □ Specify: _____ □ Unknown	

Table A.1 Estimated Annualized Burden Hours

As a result of proposed changes to forms highlighted in yellow, the estimated annualized burden is expected to decrease by 383 hours, from 22,473 to 22,090. The changes to the amended forms have no impact on burden estimates. The discontinuation of the CDI Screening and Telephone Interview Forms will result in a 383 hour reduction in annual burden.

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	Avg. burden per response (in hours)	Total burden (in hours) - APPROVED	Total Burden (in hours) - REQUESTED
State Health Department	ABCs Case Report Form	10	809	20/60	2697	2697
	Invasive MRSA Infection Case Report Form	10	609	20/60	2030	2030
	ABCs Invasive Pneumococcal Disease in Children Case Report Form	10	22	10/60	37	37
	ABCs Non-Bacteremic Pneumococcal Disease Case Report Form	10	125	10/60	208	208
	Neonatal Infection Expanded Tracking Form	10	37	20/60	123	123
	Campylobacter	10	637	20/60	2123	2123
	Cryptosporidium	10	130	10/60	217	217
	Cyclospora	10	3	10/60	5	5
	Listeria monocytogenes	10	13	20/60	43	43
	Salmonella	10	827	20/60	2757	2757
	Shiga toxin producing E. coli	10	90	20/60	300	300
	Shigella	10	178	10/60	297	297
	Vibrio	10	20	10/60	33	33
	Yersinia	10	16	10/60	27	27
	Hemolytic Uremic Syndrome	10	10	1	100	100
	Influenza Hospitalization Surveillance Project Case Report Form	10	400	15/60	1000	1000

	Influenza Hospitalization Surveillance Project Vaccination Telephone Survey	10	100	5/60	83	83
	Influenza Hospitalization Surveillance Project Vaccination Telephone Survey Consent Form	10	100	5/60	83	83
	2015 ABCs H. influenza Neonatal Sepsis Expanded Surveillance Form	10	6	10/60	10	10
EIP site	CDI Case Report Form (combines the 2017 Case Report Form and Treatment Form into single form with same overall burden)	10	1650	~~20/60~~ 30/60 (incorporation of Treatment Form)	5500	5500 + 2750 = 8250 (incorporation of Treatment Form)
	~~CDI Treatment Form~~ (no longer a separate form; part of the CDI Case Report Form for 2018)	~~10~~	~~1650~~	~~10/60~~	2750	0
	Resistant Gram-Negative Bacilli (MuGSI) CRE/CRAB Case Report Form	10	500	20/60	1667	1667
Person(s) in the community infected with *C. difficile* (CDI Cases)	Screening Form **(discontinued)**	~~600~~	~~1~~	~~5/60~~	~~50~~	0
	Telephone interview **(discontinued)**	~~500~~	~~1~~	~~40/60~~	~~333~~	0
Total					22,473	22,090