**Burden Memo for the Generic Clearance of Emergency Epidemic Investigation Data Collections (0920-1011)**

| | |
|---|---|
| GenIC No.: | 2016017-XXX |
| EPI AID No. (if applicable): | 2016-033 |
| Requesting entity (e.g., jurisdiction): | New York City Department of Health |
| Title of Investigation: | Undetermined risk factors for Exophiala dermatitidis among oncology patients — New York City, 2016 |
| Purpose of Investigation: (Use as much space as necessary) | The purpose of the investigation was to 1) conduct case-finding; 2) characterize epidemiological and clinical aspects of case-patients, including exposures of interest; 3) conduct an epidemiological study to evaluate potential association between exposures and cases; 4) conduct an assessment of the infection control practices at oncology clinic; 5) perform environmental sampling as indicated by findings of the epidemiologic study; and 6) provide recommendations for preventative measures and remediation. |
| Duration of Data Collection: | 2 weeks |
| Date Began: | June 1, 2016 |
| Date Ended: | June 15, 2016 |
| Lead Investigator | |
| Name: | Amber Vasquez |
| CIO/Division/Branch: | NCEZID/DHQP |

**Complete the following for each instrument used during the investigation.**

**Data Collection Instrument 1**

*Name of Data Collection Instrument:* Medical Chart Abstraction Form

*Type of Respondent*

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☒ Other (describe): Federal employees

*Data Collection Methods (check all that apply)*

☒ Epidemiologic Study (indicate which type(s) below)

- ☐ Descriptive Study (describe):
- ☐ Cross-sectional Study (describe):
- ☒ Cohort Study (describe):
- ☐ Case-Control Study (describe): Data on exposure to medications was collected from medical charts of all 38 patients who received IV medications at Oncology Clinic A
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ Other (describe):

*Data Collection Mode (check all that apply)*

☐ Survey Mode (indicate which mode(s) below):

- ☐ Face-to-face Interview (describe):
- ☐ Telephone Interview (describe):
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
- ☐ Self-administered Internet Questionnaire (describe):

| | |
|---|---|
| ☐ Other (describe): | |
| ☒ Medical Record Abstraction (describe): | Data on exposure to medications was collected from medical charts of all 38 patients who received IV medications at Oncology Clinic A |
| ☐ Biological Specimen Sample | |
| ☐ Environmental Sample | |
| ☐ Other (describe): | |

*Response Rate (if applicable)*

| | |
|---|---|
| Total No. Responded (A): | NA |
| Total No. Sampled/Eligible to Respond (B): | NA |
| Response Rate (A/B): | NA |

**Complete the following burden table. Each data collection instrument should be included as a separate row.**

*Burden Table (insert rows for additional respondent types if needed)*

| Data Collection Instrument Name | Type of Respondent | No. Respondents (A) | No. Responses per Respondent (B) | Burden per Response in Minutes (C) | Total Burden in Hours (A x B x C)/60* |
|---|---|---|---|---|---|
| Medical Chart Abstraction Form | Federal Staff | 2 | 19 | 0 | 0 |
| | | | | | |
| | | | | | |

Return completed form and a blank copy of each final data collection instrument within 5 business days of data collection completion to the EEI Information Collection Request Liaison, Danice Eaton (dhe0@cdc.gov).

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**Burden Memo for the Generic Clearance of Emergency Epidemic Investigation Data Collections (0920-1011)**

| | |
|---|---|
| GenIC No.: | 2016018-XXX |
| EPI AID No. (if applicable): | 2016-036 |
| Requesting entity (e.g., jurisdiction): | Mississippi State Department of Health (MSDH) |
| Title of Investigation: | Undetermined source and risk factors for botulism among prisoners at a correctional facility — Mississippi, 2016 |
| Purpose of Investigation: (Use as much space as necessary) | On June 9, 2016, the MSDH notified the CDC botulism consultation service regarding a suspected outbreak of botulism at a single federal correctional institution. Preliminary information suggests that the affected inmates consumed homemade intoxicant, also known as hooch or pruno.<br><br>The MSDH requested assistance with investigating the scope and identifying the source of the outbreak, determining risk factors for illness, and developing public health recommendations to prevent future outbreaks. |
| Duration of Data Collection: | 90 days |
| Date Began: | 6/13/2016 |
| Date Ended: | 9/11/2016 |
| Lead Investigator | |
| Name: | Kevin Chatham-Stephens |
| CIO/Division/Branch: | CDC/NCEZID/EDEB |

**Complete the following for <u>each</u> instrument used during the investigation.**

**Data Collection Instrument 1**

*Name of Data Collection Instrument:* Interview questionnaire

*Type of Respondent*

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☒ Patients ☐ Restaurant staff

☒ Other (describe): Inmates from the affected correctional facility who reported exposure to homemade intoxicant

*Data Collection Methods (check all that apply)*

☒ Epidemiologic Study (indicate which type(s) below)

- ☒ Descriptive Study (describe): Case patients and inmates at risk for infection interviewed to identify exposures, risk factors for illness, and relevant symptoms.
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- ☐ Case-Control Study (describe):
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ Other (describe):

*Data Collection Mode (check all that apply)*

☒ Survey Mode (indicate which mode(s) below):

- ☒ Face-to-face Interview (describe): The questionnaire was administered via face-to-face interview
- ☐ Telephone Interview (describe):
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):

- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):
- ☐ Medical Record Abstraction (describe):
- ☐ Biological Specimen Sample
- ☐ Environmental Sample
- ☐ Other (describe):

*Response Rate (if applicable)*

| | |
|---|---|
| Total No. Responded (A): | 33 |
| Total No. Sampled/Eligible to Respond (B): | 34 |
| Response Rate (A/B): | 97.1% |

**Data Collection Instrument 2**

*Name of Data Collection Instrument:* Medical chart abstraction tool

*Type of Respondent*

☐ General public ☒ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☒ Other (describe): Medical charts abstracted by CDC and MSDH staff based on healthcare staff records

*Data Collection Methods (check all that apply)*

☒ Epidemiologic Study (indicate which type(s) below)

- ☒ Descriptive Study (describe): Abstracted medical charts from the prison health services unit and hospitals for exposed inmates that reported signs and symptoms consistent with botulism during the interview. Abstracted data to identify exposures, describe signs and symptoms consistent with botulism, and assess risk factors for severe illness.
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- ☐ Case-Control Study (describe):
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ Other (describe):

*Data Collection Mode (check all that apply)*

☐ Survey Mode (indicate which mode(s) below):

- ☐ Face-to-face Interview (describe):
- ☐ Telephone Interview (describe):
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

☒ Medical Record Abstraction (describe): Copies of medical charts were reviewed using chart abstraction tool. Since patients were often transferred (up to four times) there were multiple charts to abstract for many of the patients.

☐ Biological Specimen Sample
☐ Environmental Sample
☐ Other (describe):

*Response Rate (if applicable)*

Total No. Responded (A): 28
Total No. Sampled/Eligible to Respond (B): 33
Response Rate (A/B): 84% (note: only partial chart abstraction was possible for a some patients)

**Data Collection Instrument 3**

*Name of Data Collection Instrument:* Laboratory test results

*Type of Respondent*

☐ General public ☐ Healthcare staff ☒ Laboratory staff ☐ Patients ☐ Restaurant staff
☐ Other (describe):

*Data Collection Methods (check all that apply)*

☐ Epidemiologic Study (indicate which type(s) below)
- ☐ Descriptive Study (describe):
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- ☐ Case-Control Study (describe):
- ☐ Other (describe):

☐ Environmental Assessment (describe):
☒ Laboratory Testing (describe): CDC routinely performed botulism testing on serum and stool for suspected cases of botulism in many states, including Mississippi and Oklahoma. As part of this investigation, CDC performed testing for the suspected cases in both states when requested by local health authorities.
☐ Other (describe):

*Data Collection Mode (check all that apply)*

☐ Survey Mode (indicate which mode(s) below):
- ☐ Face-to-face Interview (describe):
- ☐ Telephone Interview (describe):
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

☐ Medical Record Abstraction (describe):
☒ Biological Specimen Sample
☐ Environmental Sample
☐ Other (describe):

*Response Rate (if applicable)*

Total No. Responded (A): 28

| | |
|---|---|
| Total No. Sampled/Eligible to Respond (B): | 33 |
| Response Rate (A/B): | 84% |

**(Additional Data Collection Instrument sections may be added if necessary.)**

**Complete the following burden table. Each data collection instrument should be included as a separate row.**

*Burden Table (insert rows for additional respondent types if needed)*

| Data Collection Instrument Name | Type of Respondent | No. Respondents (A) | No. Responses per Respondent (B) | Burden per Response in Minutes (C) | Total Burden in Hours (A x B x C)/60* |
|---|---|---|---|---|---|
| Interview Questionnaire | Inmates | 33 | 1 | 30 | 17 |
| Medical Chart Abstraction | Federal staff | 0 | 0 | 0 | 0 |
| Medical Chart Abstraction | State staff | 4 | 5 | 30 | 10 |

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**Burden Memo for the Generic Clearance of Emergency Epidemic Investigation Data Collections (0920-1011)**

| | |
|---|---|
| GenIC No.: | 2016019-XXX |
| EPI AID No. (if applicable): | 2016-038 |
| Requesting entity (e.g., jurisdiction): | Wisconsin Division of Public Health |
| Title of Investigation: | Undetermined source of Elizabethkingia anophelis infections among Wisconsin residents — Wisconsin, 2016 |
| Purpose of Investigation: (Use as much space as necessary) | Elizabethkingia anophelis is a rare, gram-negative bacillus identified in 2011 that is intrinsically multidrug-resistant, resulting in high mortality rates ranging from 23 to 52%. Although most E. anophelis infections have occurred in healthcare settings, community-acquired infections have also been reported.<br><br>On January 5, 2016, the Centers for Disease Control and Prevention (CDC) was notified by the Wisconsin Division of Public Health (WDPH) of an outbreak of E. anophelis infections. A joint CDC-WDPH investigation identified 66 cases of primarily community-associated infections, all occurring in southeastern Wisconsin, northeastern Illinois, and western Michigan. Specimen collection dates ranged from November 23, 2015 to May 30, 2016 and the epidemiologic curve seemed to indicate a point source for the infection. Patients have a variety of healthcare-associated and community-associated exposures, as well as co-morbidities. Hypothesis-generating interviews, structured interviews, and environmental sampling did not demonstrate a clear food or water source, personal care product, healthcare product, or healthcare setting as a point source. Although the number of reported cases is decreasing, the number of reported persons with infection in the last quarter was 9 and still well above the baseline of 3-5 reported per year . Identifying a potential point source of infections is critical to prevention of new infections and may inform future community-associated E. anophelis outbreaks. Group ethnographic interviews with small subclusters of patients may identify a common, shared exposure missed by traditional outbreak investigation approaches.<br><br>WDPH requested CDC assistance with: 1) identification of potential exposures though group ethnographic interviews and 2) application of findings from activity 1 to identify prevention and control measures. |
| Duration of Data Collection: | 10 days |
| Date Began: | 7/18/2016 |
| Date Ended: | 7/27/2016 |
| Lead Investigator | |
| Name: | Sharoda Dasgupta |
| CIO/Division/Branch: | NCHHSTP/DHAP/HICSB |

**Complete the following for <u>each</u> instrument used during the investigation.**

**Data Collection Instrument 1**

*Name of Data Collection Instrument:* Ethnographic interview guide

*Type of Respondent*

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☒ Patients ☐ Restaurant staff

☐ Other (describe):

*Data Collection Methods (check all that apply)*

☐ Epidemiologic Study (indicate which type(s) below)

- ☐ Descriptive Study (describe):
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):

- ☐ Case-Control Study (describe):
- ☐ Other (describe):
- ☐ Environmental Assessment (describe):
- ☐ Laboratory Testing (describe):
- ☒ Other (describe): Open-ended, hypothesis-generating ethnographic interviews conducted both in group (in-person) and individual settings (by phone)

*Data Collection Mode (check all that apply)*

- ☒ Survey Mode (indicate which mode(s) below):
  - ☒ Face-to-face Interview (describe): Group ethnographic in-person interviews
  - ☒ Telephone Interview (describe): In-depth individual phone interviews with eligible persons who could not meet for a group ethnographic in-person interview
  - ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
  - ☐ Self-administered Internet Questionnaire (describe):
  - ☐ Other (describe):
- ☐ Medical Record Abstraction (describe):
- ☐ Biological Specimen Sample
- ☐ Environmental Sample
- ☐ Other (describe):

*Response Rate (if applicable)*

| | |
|---|---|
| Total No. Responded (A): | 9 |
| Total No. Sampled/Eligible to Respond (B): | 22 |
| Response Rate (A/B): | 9/22 = 41% |

**Data Collection Instrument 2**

*Name of Data Collection Instrument:* Detailed enterics questionnaire

*Type of Respondent*

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☒ Patients ☐ Restaurant staff

☐ Other (describe):

*Data Collection Methods (check all that apply)*

- ☐ Epidemiologic Study (indicate which type(s) below)
  - ☐ Descriptive Study (describe):
  - ☐ Cross-sectional Study (describe):
  - ☐ Cohort Study (describe):
  - ☐ Case-Control Study (describe):
  - ☐ Other (describe):
- ☐ Environmental Assessment (describe):
- ☐ Laboratory Testing (describe):
- ☒ Other (describe): Structured phone interviews to evaluate exposure to special order fruits or nuts from delivery trucks or local fundraisers

*Data Collection Mode (check all that apply)*

☒ Survey Mode (indicate which mode(s) below):

- ☐ Face-to-face Interview (describe):
- ☒ Telephone Interview (describe): Telephone interviews conducted with a convenience sample of patients to evaluate exposure to special order fruits or nuts from delivery trucks or local fundraisers
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

☐ Medical Record Abstraction (describe):

☐ Biological Specimen Sample

☐ Environmental Sample

☐ Other (describe):

*Response Rate (if applicable)*

Total No. Responded (A): 7

Total No. Sampled/Eligible to Respond (B): 22

Response Rate (A/B): 7/22 = 32%

**Complete the following burden table. Each data collection instrument should be included as a separate row.**

*Burden Table (insert rows for additional respondent types if needed)*

| Data Collection Instrument Name | Type of Respondent | No. Respondents (A) | No. Responses per Respondent (B) | Burden per Response in Minutes (C) | Total Burden in Hours (A x B x C)/60* |
|---|---|---|---|---|---|
| Ethnographic interview guide | Patient | 9 | 1 | 120 | 18 |
| Detailed enterics questionnaire | Patient | 7 | 1 | 60 | 7 |

Return completed form and a blank copy of each final data collection instrument within 5 business days of data collection completion to the EEI Information Collection Request Liaison, Danice Eaton (dhe0@cdc.gov).

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**Burden Memo for the Generic Clearance of Emergency Epidemic Investigation Data Collections (0920-1011)**

| | |
|---|---|
| GenIC No.: | 2016020 |
| EPI AID No. (if applicable): | |
| Requesting entity (e.g., jurisdiction): | Utah Department of Public Health |
| Title of Investigation: | Undetermined Mode of Transmission Zika Virus among Utah Community Members, 2016 |
| Purpose of Investigation: (Use as much space as necessary) | On July 1st, an adult male family contact reported developing a subjective fever and then progressed to develop a rash and conjunctivitis. The family contact had no history of travel or sexual contact with someone who traveled, but had been in contact with the index patient during his period of viremia. Testing of urine obtained 7 days after illness onset for the family contact was positive for Zika viral RNA at the Utah State Public Health Laboratory. Because the family contact did not report travel to a Zika-affected area or sexual contact with anyone who had recently traveled to a Zika-affected area, there is concern about local transmission through a potentially unidentified mode of transmission or by local mosquito-borne transmission.<br><br>The team performed enhanced surveillance of community members residing within 200 meter radius of the properties of interest for evidence of recent Zika virus infection/disease. Community members were surveyed about potential exposures and asked to provide a blood sample for Zika testing. |
| Duration of Data Collection: | |
| Date Began: | |
| Date Ended: | |
| Lead Investigator | |
| Name: | Erin Staples |
| CIO/Division/Branch: | CDC/ DVBD/ADB |

**Complete the following for <u>each</u> instrument used during the investigation.**

**Data Collection Instrument 1**

*Name of Data Collection Instrument:* Undetermined Mode of Transmission: Zika Virus among Utah Community Members, 2016

*Type of Respondent*

☒ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☐ Other (describe):

*Data Collection Methods (check all that apply)*

☒ Epidemiologic Study (indicate which type(s) below)

- ☐ Descriptive Study (describe):
- ☐ Cross-sectional Study (describe):
- ☒ Cohort Study (describe): Community Based serosurvey
- ☐ Case-Control Study (describe):
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe): For those who provide blood sample

☐ Other (describe):

*Data Collection Mode (check all that apply)*

☒ Survey Mode (indicate which mode(s) below):

- ☒ Face-to-face Interview (describe): Households within the 200 meter radius were visited by

| | |
|---|---|
| | investigation teams consisting of an interviewer, a phlebotomist, and a person familiar with the location, either an employee of the local health department or other government employee. |
| ☐ Telephone Interview (describe): | |
| ☐ Self-administered Paper-and-Pencil Questionnaire (describe): | |
| ☐ Self-administered Internet Questionnaire (describe): | |
| ☐ Other (describe): | |
| ☐ Medical Record Abstraction (describe): | |
| ☐ Biological Specimen Sample | |
| ☐ Environmental Sample | |
| ☐ Other (describe): | |

*Response Rate (if applicable)*

| | |
|---|---|
| Total No. Responded (A): | |
| Total No. Sampled/Eligible to Respond (B): | |
| Response Rate (A/B): | |

**Complete the following burden table. Each data collection instrument should be included as a separate row.**

*Burden Table (insert rows for additional respondent types if needed)*

| Data Collection Instrument Name | Type of Respondent | No. Respondents (A) | No. Responses per Respondent (B) | Burden per Response in Minutes (C) | Total Burden in Hours (A x B x C)/60* |
|---|---|---|---|---|---|
| Community Investigation Questionnaire | General public | 209 | 1 | 10 | 35 |
| | | | | | |
| | | | | | |

Return completed form and a blank copy of each final data collection instrument within 5 business days of data collection completion to the EEI Information Collection Request Liaison, Danice Eaton (dhe0@cdc.gov).

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**Burden Memo for the Generic Clearance of Emergency Epidemic Investigation Data Collections (0920-1011)**

| | |
|---|---|
| GenIC No.: | 2016021 |
| EPI AID No. (if applicable): | |
| Requesting entity (e.g., jurisdiction): | |
| Title of Investigation: | Healthcare Personnel Risk Assessment Questionnaire and Serosurvey for Zika Virus Exposure—Utah, 2016 |
| Purpose of Investigation: (Use as much space as necessary) | On July 1st, an adult male family contact reported developing a subjective fever and then progressed to develop a rash and conjunctivitis. The family contact had no history of travel or sexual contact with someone who traveled, but had been in contact with the index patient during his period of viremia. Testing of urine obtained 7 days after illness onset for the family contact was positive for Zika viral RNA at the Utah State Public Health Laboratory. Because the family contact did not report travel to a Zika-affected area or sexual contact with anyone who had recently traveled to a Zika-affected area, there is concern about local transmission through a potentially unidentified mode of transmission or by local mosquito-borne transmission.<br><br>The team performed enhanced surveillance of the Health care providers (HCP) involved in the care of the deceased patient. This surveillance included a detailed risk assessment questionnaire and, for those determined to have had significant direct contact with the patient, blood draws to test for the presence of Zika IgM antibody. |
| Duration of Data Collection: | |
| Date Began: | |
| Date Ended: | |
| Lead Investigator | |
| Name: | Bryan Christensen |
| CIO/Division/Branch: | CDC/ DHQP/OD |

**Complete the following for each instrument used during the investigation.**

**Data Collection Instrument 1**

*Name of Data Collection Instrument:* Healthcare Personnel Risk Assessment Questionnaire and Serosurvey for Zika Virus Exposure—Utah, 2016

*Type of Respondent*

☐ General public ☒ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☐ Other (describe):

*Data Collection Methods (check all that apply)*

☒ Epidemiologic Study (indicate which type(s) below)

- ☐ Descriptive Study (describe):
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- ☐ Case-Control Study (describe):
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☒ Other (describe): seroprevalence survey with matched cohort

*Data Collection Mode (check all that apply)*

☒ Survey Mode (indicate which mode(s) below):

| | |
|---|---|
| ☒ Face-to-face Interview (describe): | Investigators administered a detailed questionnaire to determine the level of contact each identified healthcare worker had with the deceased patient. Information collected included type of contact, type of care provided, exposure to blood or body fluids, and use of PPE during care. We also collected relevant information on the employee's history, including recent travel, vaccinations, and pregnancy status. |
| ☐ Telephone Interview (describe): | |
| ☐ Self-administered Paper-and-Pencil Questionnaire (describe): | |
| ☐ Self-administered Internet Questionnaire (describe): | |
| ☐ Other (describe): | |
| ☐ Medical Record Abstraction (describe): | |
| ☐ Biological Specimen Sample | |
| ☐ Environmental Sample | |
| ☐ Other (describe): | |

*Response Rate (if applicable)*

| | |
|---|---|
| Total No. Responded (A): | |
| Total No. Sampled/Eligible to Respond (B): | |
| Response Rate (A/B): | |

**Complete the following burden table. Each data collection instrument should be included as a separate row.**

*Burden Table (insert rows for additional respondent types if needed)*

| Data Collection Instrument Name | Type of Respondent | No. Respondents (A) | No. Responses per Respondent (B) | Burden per Response in Minutes (C) | Total Burden in Hours (A x B x C)/60* |
|---|---|---|---|---|---|
| Health Care Worker Assessment-Cases | Healthcare Worker | 96 | 1 | 10 | 32 |
| Health Care Worker Assessment-Controls | Healthcare Worker | 113 | 1 | 3 | 6 |

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**Burden Memo for the Generic Clearance of Emergency Epidemic Investigation Data Collections (0920-1011)**

| | |
|---|---|
| GenIC No.: | 2016022-XXX |
| EPI AID No. (if applicable): | 2016-046 |
| Requesting entity (e.g., jurisdiction): | Hawaii State Department of Health |
| Title of Investigation: | Undetermined source and risk factors for Hepatitis A virus (HAV) outbreak — Hawaii, 2016. |
| Purpose of Investigation: (Use as much space as necessary) | The objectives of the investigation included: providing epidemiologic support to better elucidate the possible implication of restaurants involved in HAV transmission during the current outbreak, assistance in a case re-analysis to obtain more definitive epidemiologic evidence for suspect food items, facilitate product traceback through data collection and analysis, facilitate clinical review of case data to better understand the potential health impacts suffered by infected persons. |
| Duration of Data Collection: | 5 days |
| Date Began: | August 22, 2016 |
| Date Ended: | August 26, 2016 |
| Lead Investigator | |
| Name: | Monique Foster, MD, MPH |
| CIO/Division/Branch: | NCHHSTP/Division of Viral Hepatitis/Epidemiology and Surveillance Branch |

**Complete the following for each instrument used during the investigation.**

**Data Collection Instrument 1**

*Name of Data Collection Instrument:* Hepatitis A: Supplemental Case Questionnaire

*Type of Respondent*

☒ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☐ Other (describe):

*Data Collection Methods (check all that apply)*

☒ Epidemiologic Study (indicate which type(s) below)

- ☒ Descriptive Study (describe): Cases who did not initially report exposure to the implicated restaurant or food item were re-contacted to better elucidate their true exposures to a source of the outbreak.
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- ☐ Case-Control Study (describe):
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ Other (describe):

*Data Collection Mode (check all that apply)*

☒ Survey Mode (indicate which mode(s) below):

- ☐ Face-to-face Interview (describe):
- ☒ Telephone Interview (describe): Cases who did not initially report exposure to the implicated restaurant or food item were contacted via telephone and then the accompanying questionnaire was completed by trained interviewers.
- ☐ Self-administered Paper-and-Pencil

Questionnaire (describe):

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☐ Medical Record Abstraction (describe):

☐ Biological Specimen Sample

☐ Environmental Sample

☐ Other (describe):

*Response Rate (if applicable)*

| | |
|---|---|
| Total No. Responded (A): | 47 |
| Total No. Sampled/Eligible to Respond (B): | 103 |
| Response Rate (A/B): | 46% |

**Complete the following burden table. Each data collection instrument should be included as a separate row.**

*Burden Table (insert rows for additional respondent types if needed)*

| Data Collection Instrument Name | Type of Respondent | No. Respondents (A) | No. Responses per Respondent (B) | Burden per Response in Minutes (C) | Total Burden in Hours (A x B x C)/60* |
|---|---|---|---|---|---|
| Hepatitis A: Supplemental Case Questionnaire | General Public | 47 | 1 | 5 | 4 |

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**Burden Memo for the Generic Clearance of Emergency Epidemic Investigation Data Collections (0920-1011)**

| | |
|---|---|
| GenIC No.: | 2016023-XXX |
| EPI AID No. (if applicable): | 2016-049 |
| Requesting entity (e.g., jurisdiction): | South Carolina Department of Health and Environmental Control |
| Title of Investigation: | Undetermined source for *Salmonella* Infantis infections among detention center inmates — South Carolina, 2016 |
| Purpose of Investigation: (Use as much space as necessary) | On July 27, 2016, the South Carolina Department of Health and Environmental Control notified CDC of a cluster of illnesses with isolates matching a rare, emerging strain of Salmonella Infantis, defined by the PFGE pattern JFXX01.0787. Salmonella Infantis is known to cause long-term, asymptomatic infections. It also causes more severe infections than other common Salmonella serotypes.<br><br>The South Carolina cluster includes four isolates that matched a multistate outbreak strain that CDC is currently investigating. The four isolates were from inmates in a county detention center that reported 131 cases of gastrointestinal illness. Illness onset began on July 12, with the majority of cases reported within 24 hours. The source of the infection among this cluster is currently unknown.<br><br>This Salmonella Infantis strain is of particular public health interest because previous isolates matching this PFGE pattern have been found to contain a large, mobile plasmid containing a CTX-M-65 type extended-spectrum beta-lactamase, as well as resistance to 9-10 other drugs. Together, this strain has been resistant to ampicillin, ceftriaxone, chloramphenicol, sulfisoxazole, tetracycline, nalidixic acid, and trimethoprim/sulfamethoxazole and had intermediate susceptibility to ciprofloxacin and gentamicin and is associated with more severe illness.<br><br>Phylogenetic analysis revealed that clinical isolates from this cluster group closely with the previous isolates characterized, as well as a CTX-M-65-positive isolate from retail chicken. This evidence indicate that infections may be associated with consumption of chicken meat. Due to frequent association of this strain with a clinically important multidrug resistance, the epidemic potential of the MDR plasmid, and the potential association with chicken, an urgent public health response is warranted.<br><br>The purpose of the investigation was to<br>1) Describe the extent of the cluster of gastroenteritis among detention center inmates.<br>2) Assess exposures and risk factors for acquisition of Salmonella Infantis infection.<br>3) Describe the clinical course of illness of affected patients including severity of infection, treatment and outcomes.<br>4) Determine if persons previously reporting illness are currently shedding Salmonella Infantis PFGE pattern, JFXX01.0787.<br>5) Based on findings of the investigation, recommend measures to reduce inmate risk and for ongoing surveillance. |
| Duration of Data Collection: | |
| Date Began: | 8/16/16 |
| Date Ended: | 8/26/16 |
| Lead Investigator | |
| Name: | Sarah Luna |
| CIO/Division/Branch: | NCEZID/DFWED/EDEB |

**Complete the following for <u>each</u> instrument used during the investigation.**

**Data Collection Instrument 1**

*Name of Data Collection Instrument:* Case Interview Form

*Type of Respondent*

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

X☐ Other (describe): Detention center detainees

*Data Collection Methods (check all that apply)*

☐ Epidemiologic Study (indicate which type(s) below)

- ☐ Descriptive Study (describe):
- ☐ Cross-sectional Study (describe):
- X☐ Cohort Study (describe): Demographic and clinical characteristics, food exposures, medication exposures and medical history of inmates at the detention center during the outbreak was collected
- X☐ Case-Control Study (describe): Food exposures associated with illness was collected
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ Other (describe):

*Data Collection Mode (check all that apply)*

☐ Survey Mode (indicate which mode(s) below):

- X☐ Face-to-face Interview (describe): Individual interviews with persons who reported illness during the outbreak.
- ☐ Telephone Interview (describe):
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

☐ Medical Record Abstraction (describe):

☐ Biological Specimen Sample

☐ Environmental Sample

☐ Other (describe):

*Response Rate (if applicable)*

| | |
|---|---|
| Total No. Responded (A): | 66 |
| Total No. Sampled/Eligible to Respond (B): | 81 |
| Response Rate (A/B): | 0.81 |

**Data Collection Instrument 2**

*Name of Data Collection Instrument:* Control Screening and Interview Form

*Type of Respondent*

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

X☐ Other (describe): Detention center detainees

*Data Collection Methods (check all that apply)*

☐ Epidemiologic Study (indicate which type(s) below)

- ☐ Descriptive Study (describe):
- ☐ Cross-sectional Study (describe):
- X☐ Cohort Study (describe): Demographic and clinical characteristics, food exposures, medication exposures and medical history of inmates at the detention center during the outbreak was collected
- X☐ Case-Control Study (describe): Food exposures associated with illness was collected
- ☐ Other (describe):
- ☐ Environmental Assessment (describe):
- ☐ Laboratory Testing (describe):
- ☐ Other (describe):

*Data Collection Mode (check all that apply)*

- ☐ Survey Mode (indicate which mode(s) below):
  - X☐ Face-to-face Interview (describe): Individual interviews with persons who did not report illness during the cluster.
  - ☐ Telephone Interview (describe):
  - ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
  - ☐ Self-administered Internet Questionnaire (describe):
  - ☐ Other (describe):
- ☐ Medical Record Abstraction (describe):
- ☐ Biological Specimen Sample
- ☐ Environmental Sample
- ☐ Other (describe):

*Response Rate (if applicable)*

| | |
|---|---|
| Total No. Responded (A): | 159 |
| Total No. Sampled/Eligible to Respond (B): | 267 |
| Response Rate (A/B): | 0.60 |

**(Additional Data Collection Instrument sections may be added if necessary.)**

**Complete the following burden table. Each data collection instrument should be included as a separate row.**

*Burden Table (insert rows for additional respondent types if needed)*

| Data Collection Instrument Name | Type of Respondent | No. Respondents (A) | No. Responses per Respondent (B) | Burden per Response in Minutes (C) | Total Burden in Hours (A x B x C)/60* |
|---|---|---|---|---|---|
| Case Interview Form | Person | 66 | 1 | 45 | 50 |
| Control Screening and Interview Form | Person | 159 | 1 | 30 | 80 |
| | | | | | |

Return completed form and a blank copy of each final data collection instrument within 5 business days of data collection completion to the EEI Information Collection Request Liaison, Danice Eaton (dhe0@cdc.gov).

**EEI Information Collection Request Liaison**:
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