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

GenIC No.:	2016008-XXX
EPI AID No. (if applicable):	2016-015
Requesting entity (e.g., jurisdiction):	American Samoa Government, Department of Public Health
Title of Investigation:	Investigation and response to an outbreak of Zika virus disease – American Samoa, 2016
Purpose of Investigation: (Use as much space as necessary)	1. Review and summarize syndromic surveillance data for rash illness and facilitate laboratory testing for evidence of Zika virus infections. 2. Provide technical assistance to describe the epidemiology of suspected and confirmed Zika virus disease cases to direct prevention and control efforts. 3. Provide technical assistance to local authorities to establish surveillance systems to identify Zika virus infections in pregnant women, evaluate for possible congenital infections, and identify Guillain Barré syndrome cases possibly associated with Zika virus infection. 4. Assist with education and increasing awareness of healthcare providers, and the general public regarding Zika virus disease.
Duration of Data Collection:	
Date Began:	February 12, 2016
Date Ended:	March 11, 2016
Lead Investigator	
Name:	Jessica Healy
CIO/Division/Branch:	CSELS, OPHSS, CDC

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

Data Collection Instrument 1

Name of Data Collection Instrument: Patient specimen sampling

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): Specimens from suspected Zika virus cases were obtained and tested for presence of or antibodies against suspected infectious pathogens (e.g., Zika, dengue, chikungunya viruses) at CDC.

☐ 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):	Clinical information abstracted from medical records.
☒ Biological Specimen Sample	Serum samples were collected from suspected Zika virus disease cases to be tested at CDC.
☐ Environmental Sample	
☐ Other (describe):	

Response Rate (if applicable)

Total No. Responded (A):	99
Total No. Sampled/Eligible to Respond (B):	99
Response Rate (A/B):	100%

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*
Patient specimen sampling	Patients	99	1	5	9

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.:	2016009-XXX
EPI AID No. (if applicable):	2016-017
Requesting entity (e.g., jurisdiction):	Brazilian Ministry of Health
Title of Investigation:	Assessment of the association of Zika virus infection and microcephaly – Brazil, 2015–2016
Purpose of Investigation: (Use as much space as necessary)	In October 2015, the Secretary of Health of Pernambuco State was alerted by clinicians to a potential increase in the number of cases of microcephaly; an investigation was launched. On 22 October, the Secretariat confirmed the finding and alerted the national authorities. The following day, the Brazil Ministry of Health sent a notification through International Health Regulations of the occurrence of 26 cases of microcephaly in Pernambuco. On November 11, Brazil declared a national public health emergency and engaged in discussion with international partners. As of January 16, 2016, a total of 3,893 cases of microcephaly had been reported to national authorities from 21 Brazilian States. The majority (86%; 3,402) of cases have been reported in the northeast of the country, including Paraíba State, which had reported 665 cases of microcephaly as of 16 January 2016. To date, Zika virus RNA has been identified in specimens (i.e., brain tissue, placenta, and amniotic fluid) from several infants with microcephaly and from fetal losses in women infected with Zika virus during pregnancy. However, it is not currently known how many of the cases of microcephaly being reported in Brazil are associated with Zika virus infection. On 28 December 2015, U.S. Centers for Disease Control and Prevention (CDC) received official request to assist the Brazil Ministry of Health (MOH) to more thoroughly and rapidly evaluate the potential association of Zika virus infection during pregnancy and subsequent microcephaly in infants. The final results of this investigation will be used to identify prevention and control measures for Zika virus infection and its sequelae. The objectives of the investigation included: 1) describing the potential association of Zika virus infection and microcephaly and other negative outcomes. 2) describing the clinical characteristics and current outcome of children with microcephaly associated with Zika virus infection. 3) providing guidance on public messaging and support with additional aspects of outbreak response.
Duration of Data Collection:	46 days
Date Began:	February 12, 2016
Date Ended:	March 23, 2016
Lead Investigator	
Name:	J. Erin Staples
CIO/Division/Branch:	NCEZID/DVBD/ADB

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

Data Collection Instrument 1

Name of Data Collection Instrument: Survey 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): Mothers of case and control infants completed a questionnaire including questions about familial history of birth defects, pregnancy history (e.g., any complications, gestational age of infant when born) and potential exposures and illnesses during pregnancy. The questionnaire also asked about basic demographic as well as information on the infant as to any medical problems the infant might have and some basic developmental questions. Also, to identify cases of infection, a blood sample was collected from both the mother and infant.
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe): To identify cases of infection, a blood sample was collected from both the mother and infant. The specimen was sent to CDC and tested for Zika and dengue viruses.

☐ Other (describe):

Data Collection Mode (check all that apply)

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

- ☒ Face-to-face Interview (describe): Mothers were interviewed face-to-face by Brazilian MOH staff about exposures and habits during pregnancy and infant health.
- ☐ Telephone Interview (describe):
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

☐ Medical Record Abstraction (describe):

☒ Biological Specimen Sample: Blood specimens will be tested at CDC for Zika virus and dengue virus (a closely related virus that elicit antibodies that can cross-react on Zika virus assays) IgM antibodies using an enzyme-linked immunosorbent assay (ELISA) per methods described elsewhere. For samples testing positive for Zika or dengue virus IgM antibodies, plaque reduction neutralization test using a 90% cut-off (PRNT90) will be performed using Vero cells for Zika and dengue viruses. For infants who test negative for IgM antibodies against Zika virus, their serum sample will be tested by RT-PCR for Zika viral RNA. Specimen collection, storage, and transport have been performed according to local procedures and protocols.

☐ Environmental Sample

☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	613
Total No. Sampled/Eligible to Respond (B):	637
Response Rate (A/B):	96%

Data Collection Instrument 2

Name of Data Collection Instrument: Chart Extraction Form

Type of Respondent

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

☒ Other (describe): Public health personnel from the CDC and Brazil MOH investigation team

Data Collection Methods (check all that apply)

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

- ☒ Descriptive Study (describe): For case infants (with microcephaly), medical charts were reviewed to determine test results for congenital infectious disease and to obtain imaging and clinical laboratory findings.
- ☐ 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): Public health personnel from the CDC and Brazil MOH investigation team performed medical chart reviews for cases only to determine test results for congenital infectious diseases as well as obtain imaging and clinical laboratory findings.

☐ Biological Specimen Sample

☐ Environmental Sample

☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	165
Total No. Sampled/Eligible to Respond (B):	189
Response Rate (A/B):	87.3%

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*
Survey Questionnaire	General public (cases and controls)	613	1	30	307
Chart Abstraction	Other (1-2 US federal staff and 1 non-federal staff)	3	55	30	83

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.:	2016010-XXX
EPI AID No. (if applicable):	2016-014
Requesting entity (e.g., jurisdiction):	Wisconsin
Title of Investigation:	Undetermined source of Elizabethkingia meningoseptica bloodstream infection among Wisconsin residents — Wisconsin, 2016
Purpose of Investigation: (Use as much space as necessary)	1) Identify common source of infection though patient interviews and abstracted clinical data. 2) If one or more exposures emerge as suspected source of infection, evaluate association though epidemiological analysis and environmental investigation. Based on findings from objectives 1 and 2, develop interventions to prevent further infections.
Duration of Data Collection:	
Date Began:	2/15/2016
Date Ended:	5/12/2016
Lead Investigator	
Name:	Lina I Elbadawi
CIO/Division/Branch:	OPHSS CSELS DSEPD

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

Data Collection Instrument 1

Name of Data Collection Instrument: Case Investigation Form

Type of Respondent

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

☒ Other (describe): Proxies (closest relative) for patients who could not be interviewed (deceased, dementia, hospitalized at time of interview)

Data Collection Methods (check all that apply)

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

- ☒ Descriptive Study (describe): Collection of demographic, and exposure data
- ☐ 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): Face to face or telephone interview of patients or proxies
- ☒ 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):	61
Total No. Sampled/Eligible to Respond (B):	61
Response Rate (A/B):	100%

Data Collection Instrument 2

Name of Data Collection Instrument: Appendix 2: Medical Abstraction Form

Type of Respondent

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

☒ Other (describe): CDC and WI Division of Public Health staff

Data Collection Methods (check all that apply)

- ☐ Epidemiologic Study (indicate which type(s) below)
  - ☒ Descriptive Study (describe): Clinical exposures
  - ☐ 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): Abstraction of records
- ☐ 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):	

Data Collection Instrument 3

Name of Data Collection Instrument: Appendix 3: Case Series

Type of Respondent

☐ General public ☒ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff
☒ Other (describe): CDC and WI Division of Public Health staff

Data Collection Methods (check all that apply)

☐ Epidemiologic Study (indicate which type(s) below)
- ☒ Descriptive Study (describe): Case-series
- ☐ 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): Collect variables describing patient history and clinical course
☐ 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):

(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 Investigation Form	Patients and proxies	61	1	75	77

Medical Abstraction Form	State health department staff	4	5	75	25
Medical Abstraction Form	Federal staff	8	6	0	0
Case Series Form	State health department staff	9	5	60	45
Case Series Form	Federal staff	3	3	0	0

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

GenIC No.:	2016011-XXX
EPI AID No. (if applicable):	2016 - 020
Requesting entity (e.g., jurisdiction):	Puerto Rico Department of Health
Title of Investigation:	Rapid assessment of blood collection and use in Puerto Rico to prevent transfusion-transmitted Zika virus infection - Puerto Rico, 2016
Purpose of Investigation: (Use as much space as necessary)	1) Quantify blood collections and use within affected area, including all blood collection organizations and healthcare facilities, and estimating of proportion of recipients at highest risk of poor outcome (e.g., pregnant women, neonates); 2) Quantify the proportion of platelet and plasma collections within affected area that are subjected to pathogen reduction technology; 3) Assist partners in identifying safe sources of blood products for transfusion within affected area to prevent transfusion transmitted Zika; 4) Assist with response planning for investigation of suspected transfusion-transmitted Zika virus; 5) Assist partners with identifying resources needed to ensure sustainability of local blood services during the Zika virus epidemic.
Duration of Data Collection:	15 days
Date Began:	February 10, 2016
Date Ended:	February 24, 2016
Lead Investigator	
Name:	Amber Vasquez
CIO/Division/Branch:	NCEZID/DHQP/Prevention and Response Branch

Complete the following for each instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: PR Zika blood collection and use survey

Type of Respondent

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

☒ Other (describe): Medical Directors and Supervisors of Blood Collection Organizations and Hospitals

Data Collection Methods (check all that apply)

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

- ☒ Descriptive Study (describe): Blood collection assessment: Information obtained from blood collection organizations and hospitals for characterization of local blood collection methods and blood product utilization. Data used to estimate the volume of blood products needed for transfusions to recipients and the volume which could be subjected to pathogen reduction technology. Information used to inform the maintenance of a safe and available blood supply and prevent transmission of Zika virus infection through transfusions.
- ☐ 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):	Information obtained through face-to-face interviews with the directors and supervisors of blood collection agencies and hospitals
☒ Telephone Interview (describe):	Information obtained through telephone interviews to the directors and supervisors of blood collection agencies and hospitals
☐ Self-administered Paper-and-Pencil Questionnaire (describe):	
☐ Self-administered Internet Questionnaire (describe):	
☒ Other (describe):	Self-administered electronic questionnaire – encrypted and password protected – distributed to blood collection agencies and hospitals
☐ Medical Record Abstraction (describe):	
☐ Biological Specimen Sample	
☐ Environmental Sample	
☐ Other (describe):	

Response Rate (if applicable)

Total No. Responded (A):	63
Total No. Sampled/Eligible to Respond (B):	68
Response Rate (A/B):	92.6%

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*
Blood Collection and Use Survey	Blood Collection Organizations; Hospitals	63	1	60	63

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.:	2016012-XXX
EPI AID No. (if applicable):	2016-023
Requesting entity (e.g., jurisdiction):	Illinois Department of Public Health
Title of Investigation:	Undetermined source, mode of transmission, and risk factors for an outbreak of group A *Streptococcus* among residents of a long term care facility — Chicago, Illinois, 2016
Purpose of Investigation: (Use as much space as necessary)	1. To evaluate the causes and extent of the ongoing group A Streptococcus outbreak, including risk factors for carriage and disease among residents. 2. To assess current infection control practices and provide recommendations for enhanced control to halt further spread of group A Streptococcus in the facility. Infection control practices at the facility will be assessed by Federal staff directly observing practices in the facility; OMB approval not requested for this component. 3. To identify other measures for disease control which may include performing additional screening for group A streptococcal carriage and implementation of antibiotic treatment to protect facility residents and staff.
Duration of Data Collection:	2 weeks
Date Began:	3/21/16
Date Ended:	4/1/16
Lead Investigator	
Name:	Chris Van Beneden
CIO/Division/Branch:	CDC/NCIRD/DBD/RDB

Complete the following for each instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: Appendix 1. Invasive GAS in LTCF 2016 Employee Survey

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): Employees and wound care team staff completed a questionnaire to assess risk factors for infection with group A *Streptococcus*, their infection control practices, and possibility of household contacts who are infected with group A *Streptococcus*.
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- ☐ Case-Control Study (describe):
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe): Isolates of group A *Streptococcus* from the facility staff were forwarded to CDC Streptococcus Laboratory for molecular typing following local procedures. Clinical specimens were collected and processed by the facility itself as part of routine clinical care and infection control practices.

☐ 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): Staff of the facility who came in contact with the patients or were identified as potential sources of group A *Streptococcus* transmission at the facility were asked to complete a questionnaire.
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

☐ Medical Record Abstraction (describe):

☐ Biological Specimen Sample: Group A streptococcal isolates from staff of the facility were forwarded by the Illinois Department of Public Health to the *Streptococcus* Laboratory at CDC for molecular typing following local procedures for collection and transport (results to be listed on Appendix 2).

☐ Environmental Sample

☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	182
Total No. Sampled/Eligible to Respond (B):	242
Response Rate (A/B):	75%

Data Collection Instrument 2

Name of Data Collection Instrument: Appendix 2. Resident Record Extraction Form

Type of Respondent

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

☒ Other (describe): Federal, state, and facility staff will assist with medical record abstraction

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): Performed a case-control study to determine various risk factors for group A streptococcal disease among the residents of the facility
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe): Isolates of group A *Streptococcus* from the facility residents were forwarded to CDC Streptococcus Laboratory for molecular typing following local procedures. Clinical specimens were collected and processed by the facility itself as part of routine clinical care and infection control practices.

☐ 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): Medical records of residents were abstracted by the investigative team to characterize the epidemiology of the outbreak and determining the risk factors and possible sources transmission.
- ☒ Biological Specimen Sample: Group A streptococcal isolates from residents of the facility were forwarded by the Illinois Department of Public Health to the *Streptococcus* Laboratory at CDC for molecular typing following local procedures for collection and transport.
- ☐ Environmental Sample
- ☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	48
Total No. Sampled/Eligible to Respond (B):	48
Response Rate (A/B):	100%

Data Collection Instrument 3

Name of Data Collection Instrument: Appendix 3. Wound Care Survey

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): Wound care team staff completed a questionnaire to assess risk factors for infection with group A *Streptococcus*, their infection control practices.
- ☐ 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): Each wound care team members completed a questionnaire.

- ☐ 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):	7
Response Rate (A/B):	100%

(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*
Appendix 1. Invasive GAS in LTCF 2016 Employee Survey	Healthcare staff	182	1	15	45.5
Appendix 2. Resident Record Extraction Form	State and local	4	12	45	36
Appendix 3. Wound Care Survey	Healthcare staff	7	1	15	2

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.:	0920-1011
EPI AID No. (if applicable):	2016013-XXX
Requesting entity (e.g., jurisdiction):	Uganda Ministry of Health
Title of Investigation:	Undetermined sources and risk factors for a Rift Valley Fever Outbreak—Uganda
Purpose of Investigation: (Use as much space as necessary)	To assist the Ugandan Ministry of Health and the Ugandan Viral Research Institute (UVRI) conduct a serosurvey on humans and livestock in Kabale District, Uganda.
Duration of Data Collection:	3 weeks
Date Began:	04/1/2016
Date Ended:	04/22/2016
Lead Investigator	
Name:	Trevor Shoemaker
CIO/Division/Branch:	NCEZID/DHCPP/VSPB

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

Data Collection Instrument 1

Name of Data Collection Instrument: Human 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): Villagers and their livestock were assessed with a serosurvey and risk factor and knowledge/attitudes/practice survey
- ☐ 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): Interview done at designated sites in the village
- ☐ Telephone Interview (describe):
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

☐ Medical Record Abstraction (describe):

☒ Biological Specimen Sample: Blood sample taken at time of interview

☐ Environmental Sample

☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	657
Total No. Sampled/Eligible to Respond (B):	657
Response Rate (A/B):	100%

Data Collection Instrument 2

Name of Data Collection Instrument: Livestock 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): Livestock questionnaire administered recording information about all animals from which a blood specimen was collected
- ☐ 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): Animal owner or herdsman gave responses to questionnaire
- ☐ Telephone Interview (describe):
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

☐ Medical Record Abstraction (describe):

☒ Biological Specimen Sample: Blood specimen collected from all animals

☐ Environmental Sample

☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	1,052
Total No. Sampled/Eligible to Respond (B):	1,052
Response Rate (A/B):	100%

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*
Risk Factor Questionnaire	General Public	657	1	20	219
Livestock Questionnaire	General Public	1,052	1	1	1052

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.:	2016014-XXX
EPI AID No. (if applicable):	2016-026
Requesting entity (e.g., jurisdiction):	Connecticut Department of Public Health
Title of Investigation:	Undetermined risk factors for E.coli O157 among visitors to a goat farm—Connecticut, 2016
Purpose of Investigation: (Use as much space as necessary)	1.) Identify risk factors for E.coli O157 infection at this event by conducting a cohort investigation among event attendees 2.) Identifying potential environmental sources of infection through on-site assessments and unstructured interviews 3.) Develop public health recommendations for the goat dairy to prevent future outbreaks at this venue and address gaps in community understanding of risk factors for transmission of E. coli O157
Duration of Data Collection:	10 days
Date Began:	March 28, 2016
Date Ended:	April 8, 2016
Lead Investigator	EIS Officer
Name:	Kelly Gambino Shirley
CIO/Division/Branch:	NCEZID/DFWED/ORPB

Complete the following for each instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: Telephone Interview Form

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): A case control study was conducted among visitors to the goat dairy from March 1, 2016 to March 25, 2016.
- ☐ 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): A telephone interview was conducted using a standardized questionnaire to query visitors to the goat dairy about activities and exposures.
- ☐ 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):	73
Total No. Sampled/Eligible to Respond (B):	106
Response Rate (A/B):	69%

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*
Telephone Interview Form	Visitors to goat farm	73	1	30	37

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

GenIC No.:	2016015-XXX
EPI AID No. (if applicable):	#2016-029
Requesting entity (e.g., jurisdiction):	
Title of Investigation:	Undetermined agent, source, mode of transmission, and risk factors for Guillain-Barre Syndrome in the setting of Zika virus transmission – Colombia, 2016
Purpose of Investigation: (Use as much space as necessary)	To perform a case-control study to determine a possible association of Guillain-Barre Syndrome and previous Zika virus infection
Duration of Data Collection:	
Date Began:	4/12/16
Date Ended:	4/26/16
Lead Investigator	
Name:	Jim Sejvar
CIO/Division/Branch:	NCEZID/DHCPP/OID

Complete the following for each instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: Case Control Form (English & Spanish versions)

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): Evaluation of risk factors and exposures among GBS patients and neighborhood controls
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe): Serologic assays to be performed on blood specimens to determine antecedent Zika and/or dengue virus infections

☐ Other (describe):

Data Collection Mode (check all that apply)

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

- ☒ Face-to-face Interview (describe): Face-to-Face interviews using the specified questionnaire
- ☐ Telephone Interview (describe):
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

☐ Medical Record Abstraction (describe):

☒ Biological Specimen Sample: Blood sample collected by phlebotomist for serologic testing

☐ Environmental Sample
☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A): 129
Total No. Sampled/Eligible to Respond (B): 141
Response Rate (A/B): 91.5%

Data Collection Instrument 2

Name of Data Collection Instrument: Chart abstraction form (English & Spanish versions)

Type of Respondent

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

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): Review of medical records of cases to determine inclusion criteria
- ☐ 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 collected from medical records of patients suspected to have GBS to determine whether they met the case definition
☐ Biological Specimen Sample
☐ Environmental Sample
☐ Other (describe):

Response Rate (if applicable)

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

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 control form	General public	129	1	15	33
Chart abstraction form	Public health personnel	8	11	20	30

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

GenIC No.:	2016016-XXXX
EPI AID No. (if applicable):	2016-031
Requesting entity (e.g., jurisdiction):	Arizona Department of Health Services
Title of Investigation:	Undetermined transmission and risk factors for multidrug-resistant *Mycobacterium tuberculosis* among Tribal members — Arizona, 2016
Purpose of Investigation: (Use as much space as necessary)	1) Determine the chain or chains of transmission 2) Identify and prioritize contacts 3) Estimate the scope of transmission 4) Develop a plan for contacts with presumed multidrug-resistant TB infection and ensure that treatment and evaluation recommendations are made in close consultation with clinical TB experts in the management of drug-resistant TB 5) Facilitate communications among involved agencies to assist with the coordination of contact investigations
Duration of Data Collection:	2 weeks
Date Began:	5/9/2016
Date Ended:	5/20/2016
Lead Investigator	
Name:	Krista Powell
CIO/Division/Branch:	CDC, Division of TB Elimination

Complete the following for each instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: Case Abstraction Form

Type of Respondent

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

☒ Other (describe): Medical and Public Health Charts

Data Collection Methods (check all that apply)

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

- ☒ Descriptive Study (describe): Investigators collected data to describe the demographic features of patients, determine the frequency of clinical and social risk factors for TB disease, and identify contacts.
- ☐ 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): Federal staff on the investigation team abstracted patient medical/public health records.
- ☐ 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):

Data Collection Instrument 2

Name of Data Collection Instrument: Case Interview Form

Type of Respondent

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

☒ Other (describe): Patient proxy

Data Collection Methods (check all that apply)

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

- ☒ Descriptive Study (describe): Investigators conducted semi-structured, face-to-face interviews of patients or their proxies meeting the outbreak TB case definition to estimate infectious periods, identify contacts exposed during the infectious period, and determine potential transmission sites.
- ☐ 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): Investigators met in person with case and proxy to conduct semi-structured 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):	2
Total No. Sampled/Eligible to Respond (B):	2
Response Rate (A/B):	100%

Data Collection Instrument 3

Name of Data Collection Instrument: Tuberculosis Contact Screening Form

Type of Respondent

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff
☒ Other (describe): Contacts to case(s)

Data Collection Methods (check all that apply)

☒ Epidemiologic Study (indicate which type(s) below)
- ☒ Descriptive Study (describe): Investigators conducted semi-structured, face-to-face interview of contacts to cases to estimate infectious periods, identify additional contacts exposed during the infectious period, and determine potential transmission sites.
- ☐ 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): Investigators met in person with contacts to conduct semi-structured 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):	1
Total No. Sampled/Eligible to Respond (B):	43
Response Rate (A/B):	2.3%

(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 Abstraction Form	Chart	2	2	0	0
Case Interview Form	Case/Proxy	2	1	60	1
Tuberculosis Contact Screening Form	Contact	1	1	15	1

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