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

GenIC No.:	2016002-XXX
EPI AID No. (if applicable):	Epi-Aid 2016-004
Requesting entity (e.g., jurisdiction):	Ministry of Agriculture Haiti
Title of Investigation:	Undetermined risk factors associated with increase in bites from rabid dogs, resulting in at least one human death, Gonaives, Haiti, 2015.
Purpose of Investigation: (Use as much space as necessary)	Early September 2015, a four year old girl died from a rabies like illness in Gonaives, Haiti. According to a preliminary investigation conducted late September, the child was bitten on the stomach by an aggressive dog, owned by the household (dog died about a week after the bite incident). Prior to her death, she exhibited clinical symptoms of rabies: agitation, paralysis on the right side, and hydrophobia. She was not taken to the hospital and the case was not officially reported through Haiti's National Surveillance System (NSS). Furthermore, a preliminary investigation by the Ministry of Agriculture identified at least six dogs in this rural community with rabies-like illness and a Ministry of Health investigation identified an additional 5 bite victims that had not sought treatment nor reported the rabies exposure to a healthcare professional. This was extremely concerning, given the case fatality of rabies is almost 100% if bite victims do not seek care for post-exposure prophylaxis (PEP) treatment as soon as possible. Furthermore, the breakdown of reporting to the NSS may adversely impact PEP and canine rabies vaccination procurement, leading to a potential shortage when another outbreak occurs. To develop effective prevention and control measures, an investigation was conducted to identify additional cases and risk factors for rabies infection and care-seeking behavior for those who were bitten. The goal of this investigation were to: 1) Identify additional bite victims and refer for immediate treatment at a medical center 2) Assess knowledge of rabies and barriers to care if bitten 3) Estimate the rabies vaccination rates among pet owners 4) Assess public health officials knowledge of treatment for rabies, availability of PEP at their treatment center, and if and how they are reporting these cases to the National Surveillance System
Duration of Data Collection:	84 Days
Date Began:	11/2/2015
Date Ended:	1/25/2016
Lead Investigator	
Name:	Ryan Wallace
CIO/Division/Branch:	NCEZID/DHCPP/PRB

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

Data Collection Instrument 1

Name of Data Collection Instrument: Community 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): Our goals were to describe the epidemiology of the outbreak, and assess treatment seeking behaviors and response capabilities in order to to make recommendations for controlling the outbreak and preventing cases of Haiti.

☐ 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): We interviewed bite victims and community members about: their vaccination behavior for their household pets (dogs and cats), had contact with rabid animals, their knowledge about rabies, and their health care seeking behavior after a bite.

☐ 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): 108

Total No. Sampled/Eligible to Respond (B): Not available.

Response Rate (A/B): Denominator not available, therefore we cannot calculate response rate.

Data Collection Instrument 2

Name of Data Collection Instrument: Medical Provider Interview 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): Our goals were to assess reporting capabilities and rabies knowledge in order to to make recommendations for controlling the outbreak and preventing cases of Haiti.

☐ 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): We interviewed medical providers about their knowledge about rabies and reporting of rabies into the National Sentinel Surveillance System.
  - ☐ 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):	9
Total No. Sampled/Eligible to Respond (B):	Not available.
Response Rate (A/B):	Denominator not available, therefore we cannot calculate response rate.

Data Collection Instrument 3

Name of Data Collection Instrument: Rabies Official Interview Survey

Type of Respondent

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

☒ Other (describe): Rabies Officials

Data Collection Methods (check all that apply)

- ☒ Epidemiologic Study (indicate which type(s) below)
  - ☒ Descriptive Study (describe): Our goals were to assess reporting capabilities and rabies knowledge in order to to make recommendations for controlling the outbreak and preventing cases of Haiti.
  - ☐ 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): We interviewed rabies officials about their knowledge about rabies and reporting of rabies into the National Sentinel Surveillance System.
  - ☐ 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):	10
Total No. Sampled/Eligible to Respond (B):	Not available.
Response Rate (A/B):	Denominator not available, therefore we cannot calculate response rate.

Data Collection Instrument 4

Name of Data Collection Instrument: Public Health Official Interview 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): Our goals were to assess reporting capabilities and rabies knowledge in order to to make recommendations for controlling the outbreak and preventing cases of Haiti.
  - ☐ 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): We interviewed public health officials about their knowledge about

	rabies and reporting of rabies into the National Sentinel Surveillance System.
☐ 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):	7
Total No. Sampled/Eligible to Respond (B):	Not available.
Response Rate (A/B):	Denominator not available, therefore we cannot calculate response rate.

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 Survey	General Public	108	1	10	18
Medical Providers Interview Survey	General Public	9	1	60	9
Rabies Official Interview Survey	General Public	10	1	60	10
Public Health Official Interview Survey	State Employee	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.:	2016005-XXX
EPI AID No. (if applicable):	2016-007
Requesting entity (e.g., jurisdiction):	Puerto Rico Department of Health
Title of Investigation:	Undetermined risk of exposure for human-to-human spread of rabies following mongoose-associated human rabies case among contacts of case patient, Puerto Rico, 2015
Purpose of Investigation: (Use as much space as necessary)	The purpose of the investigation was to perform standardized risk assessments of community members and healthcare workers who may have been exposed to the patient during his infectious period to determine need for post-exposure prophylaxis.
Duration of Data Collection:	1 week
Date Began:	12/8/2015
Date Ended:	12/15/2015
Lead Investigator	
Name:	Ashley Styczynski (lead EISO)
CIO/Division/Branch:	NCEZID/DHCPP/PRB

Complete the following for each instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: Community Assessment

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): To conduct contact tracing and standardized risk assessments for persons with possible exposures to the case patient to ascertain which individuals require post-exposure prophylaxis
- ☐ 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): We interviewed patient community contacts to determine that nature and extent of their exposure to the patient
- ☒ Telephone Interview (describe): We interviewed patient community contacts to determine that nature and extent of their exposure to the patient
- ☐ 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):	38
Total No. Sampled/Eligible to Respond (B):	39
Response Rate (A/B):	97%

Data Collection Instrument 2

Name of Data Collection Instrument: Healthcare Worker Assessment

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): To conduct contact tracing and standardized risk assessments for healthcare workers with possible exposures to the case patient to ascertain which individuals require post-exposure prophylaxis

☐ 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): We interviewed healthcare worker contacts to determine nature and extent of contact with case patient

☒ Telephone Interview (describe): We interviewed healthcare worker contacts to determine nature and extent of contact with case patient

☐ 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):	39
Total No. Sampled/Eligible to Respond (B):	39
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*
Community Risk Assessment (English/Spanish)	General public/ patients	38	1	15	9.5
Healthcare Worker Assessment	Healthcare workers	39	1	15	9.75

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

GenIC No.:	2016006-XXX
EPI AID No. (if applicable):	2016-008
Requesting entity (e.g., jurisdiction):	North Carolina
Title of Investigation:	Undetermined risk factors for ocular syphilis — North Carolina, 2015
Purpose of Investigation: (Use as much space as necessary)	The North Carolina Division of Public Health (NC DPH) reported an increase in cases of syphilis with ocular manifestations, out of proportion to the rise in syphilis cases for the state. At the time the Epi-Aid was called, 38 cases of ocular syphilis were reported in 2015, compared to 12 cases in 2014. Ocular syphilis can be a serious manifestation of syphilis, and can occur during any stage of syphilis. Ocular syphilis may lead to decreased visual acuity including permanent blindness. In North Carolina, at least two cases of blindness attributed to ocular syphilis occurred recently. To address this unexplained rise in cases, an investigation was urgently needed. NC DPH requested CDC assistance with this investigation to describe the cases and clinical course of ocular syphilis, identify factors influencing risk for ocular syphilis and blindness and identify prevention and control measures.
Duration of Data Collection:	90 days
Date Began:	December 13, 2015
Date Ended:	February 12, 2015
Lead Investigator	
Name:	Sara Oliver, MD, MSPH
CIO/Division/Branch:	NCHHSTP/DSTDP/ESB

Complete the following for each instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: Data abstraction 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): Potential risk factors and the clinical course of those diagnosed with ocular syphilis were described using data collected from state surveillance data and medical record abstraction.
- ☐ 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):

☐ Self-administered Paper-and-Pencil Questionnaire (describe):	
☐ Self-administered Internet Questionnaire (describe):	
☐ Other (describe):	
☒ Medical Record Abstraction (describe):	Charts from patients identified as a potential ocular syphilis case were reviewed. All information was collected on the data abstraction form.
☐ Biological Specimen Sample	
☐ Environmental Sample	
☐ Other (describe):	

Response Rate (if applicable)

Total No. Responded (A):	83
Total No. Sampled/Eligible to Respond (B):	83
Response Rate (A/B):	1 (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*
Appendix 1. Data Abstraction Form	Federal Staff	5	16	0	0 *All Respondents were Federal Employees

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.:	2016007-XXX
EPI AID No. (if applicable):	2016-009
Requesting entity (e.g., jurisdiction):	Brazil Ministry of Health
Title of Investigation:	Undetermined agent, source, mode of transmission, and risk factors for an outbreak of Guillain-Barré Syndrome, Bahia – Brazil, 2016
Purpose of Investigation: (Use as much space as necessary)	The purpose of the investigation was to perform a case-control study of GBS cases to determine the cause of GBS and correlation with risk factors, exposures, or medical history.
Duration of Data Collection:	3 weeks
Date Began:	1/18/2016
Date Ended:	2/5/2016
Lead Investigator	
Name:	Jim Sejvar/Ashley Styczynski (lead EISO)
CIO/Division/Branch:	NCEZID/DHCPP/PPHO

Complete the following for each instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: Case Control 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): Cases and controls underwent in-person interviews to ascertain information about activities, antecedent signs and symptoms of illness, and exposures in the two months prior to onset of neurologic illness for cases and the same time period for their age-matched controls.
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe): Serum, whole blood, and urine samples were collected at the time of interview and are undergoing testing for suspected infectious pathogens.

☐ Other (describe):

Data Collection Mode (check all that apply)

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

- ☒ Face-to-face Interview (describe): A symptom and exposure questionnaire was administered to cases and controls through face-to-face interviews (Appendices 1a and 1b).
- ☐ Telephone Interview (describe):
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):

- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):
- ☐ Medical Record Abstraction (describe):
- ☒ Biological Specimen Sample: Serum, whole blood, and urine samples were collected at the time of interview and are undergoing testing for suspected infectious pathogens.
- ☐ Environmental Sample
- ☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	126
Total No. Sampled/Eligible to Respond (B):	126
Response Rate (A/B):	100%

Data Collection Instrument 2

Name of Data Collection Instrument: Chart Abstraction Form

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): Charts of suspected cases of GBS were reviewed to confirm the diagnosis and record onset and types of symptoms present during the neurologic illness and any preceding viral-like illness
- ☐ 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 to gather objective information about cases and controls after obtaining consent (Appendices 2a and 2b).

☐ Biological Specimen Sample

☐ Environmental Sample

☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	74
Total No. Sampled/Eligible to Respond (B):	74
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*
Case Control Questionnaire (English and Portuguese)	General public/ patients	126	1	15	32
Chart Abstraction Form (English and Portuguese)	Public health personnel	2	37	30	37

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