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

GenIC No.:	2016024-XXX
EPI AID No. (if applicable):	2016-051
Requesting entity (e.g., jurisdiction):	Colombian Ministry of Health and Instituto Nacional de Salud
Title of Investigation:	Undetermined risk factors and modes of transmission for Candida auris infection — Colombia, 2016
Purpose of Investigation: (Use as much space as necessary)	*Candida auris* is an emerging fungus that has caused hospital-associated outbreaks of invasive infections with high mortality. Since May 2016, over 50 cases of *C. auris* infection have been identified in 7 hospitals in 5 cities in Colombia. New cases continue to occur, including seven cases recently reported from a Bogotá hospital in August 2016. Little is known about risk factors for *C. auris* infection or the organism's environmental reservoirs, modes or transmission, and reason for its recent emergence. The Colombian Ministry of Health and Instituto Nacional de Salud (INS) requested CDC assistance with the following objectives: 1. Characterize the burden of *C. auris* infection in Colombia 2. Determine risk factors for infection 3. Identify epidemiologic links between cases 4. Elucidate transmission mechanisms to control ongoing outbreak
Duration of Data Collection:	3 weeks
Date Began:	9/20/216
Date Ended:	10/7/2016
Lead Investigator	
Name:	Paige Armstrong MD MHS
CIO/Division/Branch:	NCEZID/DFWED/MDB

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

Data Collection Instrument 1

Name of Data Collection Instrument: Case Report Form

Type of Respondent

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

X☐ Other (describe): Used for chart abstraction, performed by federal and local MoH and National Institute of Health staff

Data Collection Methods (check all that apply)

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

- X☐ Descriptive Study (describe): Collected data to help describe cases characteristics
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- X☐ Case-Control Study (describe): Data from cases of C. auris candidemia will be analyzed with data from candidemia with other species identify risk factors for this form of cadidemia.
- ☐ 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):

X☐ Medical Record Abstraction (describe): Abstracted data from medical records for cases of C. auris Candidemia and other candidemias at four hospitals

☐ Biological Specimen Sample

☐ Environmental Sample

☐ Other (describe):

Response Rate (if applicable)

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

Data Collection Instrument 2

Name of Data Collection Instrument: Healthcare Provider Interview Questions

Type of Respondent

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

☐ Other (describe):

Data Collection Methods (check all that apply)

X☐ Epidemiologic Study (indicate which type(s) below)
- X☐ Descriptive Study (describe): Helped inform information regarding patient colonization, potential modes of transmission, and overall thoughts from healthcare providers about possible epidemiologic links
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- ☐ Case-Control Study (describe):
- ☐ Other (describe):

X☐ Environmental Assessment (describe): Helped inform information collected from environmental sampling and possible epidemiologic links.

☐ Laboratory Testing (describe):

☐ Other (describe):

Data Collection Mode (check all that apply)

X☐ Survey Mode (indicate which mode(s) below):
- X☐ Face-to-face Interview (describe): 30 minute interviews, face-to-face, voluntary, written consent obtained
- ☐ 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): 10

Response Rate (A/B): 1

Data Collection Instrument 3

Name of Data Collection Instrument: Patient Open-Ended Interview Questions

Type of Respondent

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

X☐ Other (describe): Patients and family members/close contacts of patients

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):

X☐ Environmental Assessment (describe): Better informed level of contact and exposure in patients and family members as swabs were obtain from both to look for C. auris colonization.

☐ Laboratory Testing (describe):

☐ Other (describe):

Data Collection Mode (check all that apply)

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

X☐ Face-to-face Interview (describe): Face-to-face interview, voluntary, written consent obtained

☐ 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):	5
Total No. Sampled/Eligible to Respond (B):	5
Response Rate (A/B):	1

(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 Report Form	Instituto Nacional de Salud Staff	1	50	30	25
Healthcare Provider Interview Questions	Healthcare Staff	10	1	30	5
Patient Open-Ended Interview Questions	General Public	5	1	30	3

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:
Danice Eaton, PhD, MPH
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Epidemiology Workforce Branch
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Burden Memo for the Generic Clearance of Emergency Epidemic Investigation Data Collections (0920-1011)

GenIC No.:	2017001-XXX
EPI AID No. (if applicable):	2017-003
Requesting entity (e.g., jurisdiction):	Michigan Department of Health & Human Services
Title of Investigation:	Undetermined risk factors and modes of transmission for *Shigella sonnei* infection among residents of Genesee and Saginaw Counties – Michigan, 2016
Purpose of Investigation: (Use as much space as necessary)	1. Determine the magnitude of the outbreak and characterize patient morbidity and mortality (if applicable) in the context of individual-level risk factors (e.g., co-morbidities, access to health care, etc.). 2. Combine epidemiologic data from interviews and molecular data (PFGE and WGS) to 1) identify chains of transmission, 2) determine genetic relatedness of *Shigella* isolates from case-patients, and 3) outline the evolution of the outbreak over time and space. 3. Conduct a case-control investigation to identify risk factors for shigellosis in Genesee and Saginaw Counties; among other factors, water type and water use will be examined. 4. Map existing data related to quality of water from municipal systems (e.g., disinfectant residuals, sewage and water main breaks, triggered positives for total coliforms, and other aspects of water quality) and assess spatial and temporal correlations with incident shigellosis. 5. Assess the need for household water testing among cases and controls based on the results of epidemiologic investigation as outlined in objectives 3 and 4.
Duration of Data Collection:	9 days
Date Began:	10/25/2016
Date Ended:	11/2/2016
Lead Investigator	
Name:	R. Paul McClung, EIS Officer
CIO/Division/Branch:	NCEZID/DFWED/WDPB

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):

Data Collection Methods (check all that apply)

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

- ☒ Descriptive Study (describe): Interview of all households containing a reported case of shigellosis during the outbreak period. The first person to become ill in each house was identified; illness information was collected for all household members. Risk factor questions were pertained to household practices or to the first person ill in the house.
- ☐ 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): Telephone interviews were conducted from three call centers: Genesee County, Saginaw County, and MDHHS offices in Lansing, MI. Members of the field team conducted all interviews along with employees and students associated with MDHHS.
- ☐ 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):	90 households
Total No. Sampled/Eligible to Respond (B):	126 households
Response Rate (A/B):	0.71

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, Epi-Aid 2017-003: Shigellosis in Genesee and Saginaw Counties, MI, 2016	Patients	90	1	20	30

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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