

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

GenIC No.:	202001-0920-007
EPI AID No. (if applicable):	
Requesting entity (e.g., jurisdiction):	Council of State and Territorial Epidemiologists
Title of Investigation:	2019-nCoV Investigation, United States, 2020
Purpose of Investigation: (Use as much space as necessary)	<p>In December of 2019, an outbreak of a novel coronavirus (SARS-Cov-2), capable of causing severe illness, was identified in in central China. This virus rapidly spread to countries throughout the world including the US. In January of 2020, the first known case of COVID-19 was identified in the US and cases were expected to increase. At that time, human-to-human transmission of the virus had been confirmed. However, how easily or sustainably the virus was spreading between people was not known. In response to this emergency, the Council of State and Territorial Epidemiologists (CSTE) requested CDC assistance with a multi-state response to COVID-19. The forms approved under this EEI GenIC were used to respond to this request.</p> <p>Objectives of Investigation</p> <p>The objectives of the investigation were to identify cases and contacts of cases who were at risk for illness, understand the risk factors for disease and transmission, describe the clinical characteristics of disease, and identifying ways to control transmission. The data gathered from this investigation were used to inform the U.S. public health response to COVID-19 and aid efforts to prevent and control the spread of the virus.</p> <p>This memo describes the burden associated with the use of the three forms approved under the EEI GenIC. Because of the evolving nature of the pandemic, forms used were sometimes modified from the original in individual investigations. Final versions of the forms are attached.</p> <ol style="list-style-type: none"> 1. 2019-nCoV Case Report Form. This form was used to provide information on COVID 19 cases, including demographic information, clinical presentation and course, medical history, 2019-nCoV laboratory testing, and exposure history. 2. 2019-nCoV Patient Under Investigation (PUI) Form. This form was used to provide information on individuals who were under investigation as a potential 2019-nCoV case. It was combined with the case report form on February 24th, to reduce burden to states. 3. Combined CRF PUI form 4. 2019-nCoV Household/Close Contact Investigation Form. This form provided information on close contacts of 2019-nCoV cases who were at risk for infection. 5. 2019 nCoV Household Questionnaire. This form provided information on households of 2019-nCoV cases who were at risk for infection. 6. 2019 nCoV Household member symptom diary. This form provided information on symptoms of household members of cases at risk for infection. 7. 2019 nCoV Household animal questionnaire. This form provided information on pets of 2019-nCoV cases who were at risk for infection. 8. 2019 nCoV Household close out form. This form provided information on household of 2019-nCoV cases who were at risk for infection.
Duration of Data Collection:	90 days
Date Began:	1/25/2020
Date Ended:	4/23/2020
Lead Investigator	
Name:	Dan Jernigan
CIO/Division/Branch:	Incident Manager, CDC - National Center for Immunization and Respiratory Diseases

Complete the following for each instrument used during the investigation.

Data Collection Instrument 1

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Name of Data Collection Instrument:

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):

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

Data Collection Instrument 2

Name of Data Collection Instrument:

Type of Respondent

General public Healthcare staff Laboratory staff Patients Restaurant staff

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Other (describe): Information was gathered and reported by public health department officials but obtained from patients or their medical records

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): Information is gathered and reported by public health department officials but obtained from patients or their medical records. This form was used early in the time period of the epidemic to collect information on suspected cases. The case report form was solely used after February 24, 2020

Data Collection Mode (check all that apply)

- Survey Mode (indicate which mode(s) below):
 - Face-to-face Interview (describe): Patient interviews either face-to-face or by telephone were the most common method of data collection.
 - Telephone Interview (describe): Patient interviews either face-to-face or by telephone were the most common method of data collection.
 - Self-administered Paper-and-Pencil Questionnaire (describe):
 - Self-administered Internet Questionnaire (describe):
 - Other (describe):
- Medical Record Abstraction (describe): Although a less common method, information was sometimes obtained from clinical records.
- Biological Specimen Sample
- Environmental Sample
- Other (describe):

Response Rate (if applicable) N/A

Total No. Responded (A): 19,923
Total No. Sampled/Eligible to Respond (B): n/a
Response Rate (A/B): n/a

Data Collection Instrument 3

Name of Data Collection Instrument: Combined CRF PUI form

Type of Respondent

- General public Healthcare staff Laboratory staff Patients Restaurant staff
- Other (describe): Information is gathered and reported by public health department officials but obtained from patients or their medical records

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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): Also used in field studies to investigate risk factors and symptoms of cases.
- Environmental Assessment (describe):
- Laboratory Testing (describe):
- Other (describe): Reporting form used to report cases to CDC

Data Collection Mode (check all that apply)

- Survey Mode (indicate which mode(s) below):
 - Face-to-face Interview (describe): When used for field investigations, face-to-face interviews were one way of obtaining information.
 - Telephone Interview (describe): When used for field investigations, telephone interviews were one way of obtaining information.
 - Self-administered Paper-and-Pencil Questionnaire (describe):
 - Self-administered Internet Questionnaire (describe):
 - Other (describe):
- Medical Record Abstraction (describe): When used for field investigations, medical record abstraction was one way of obtaining information.
- Biological Specimen Sample
- Environmental Sample
- Other (describe): Instrument is used for reporting cases to CDC. Data are reported by public health officials but can be gathered through patient interviews and/or medical record abstraction

Response Rate (if applicable)

Total No. Responded (A): 268,269
 Total No. Sampled/Eligible to Respond (B): n/a
 Response Rate (A/B): n/a

Data Collection Instrument 4

Name of Data Collection Instrument: 2019 nCoV Household Close Contact Investigation

Type of Respondent

- General public Healthcare staff Laboratory staff x Patients Restaurant staff
- Other (describe):

Data Collection Methods (check all that apply)

- Epidemiologic Study (indicate which type(s) below)
- Descriptive Study (describe): This form was used in investigations that followed close contacts of 2019-nCoV cases who were at risk for infection.

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

Response Rate (if applicable) N/A

Total No. Responded (A):

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

Response Rate (A/B):

Data Collection Instrument 5

Name of Data Collection Instrument:

Type of Respondent

- General public Healthcare staff Laboratory staff x 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):

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Data Collection Mode (check all that apply)

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

Face-to-face Interview (describe):

Information from close contacts was collected through face-to face or telephone interviews.

Telephone Interview (describe):

Information from close contacts was collected through face-to-face or telephone interviews.

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) N/A

Total No. Responded (A):

106

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

n/a

Response Rate (A/B):

n/a

Data Collection Instrument 6

Name of Data Collection Instrument: 2019 nCoV Household member symptom diary

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):

This form was used in investigations that followed close contacts of 2019-nCoV cases who were at risk for infection.

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 from cases close contacts was collected through face-to face or telephone interviews.

Telephone Interview (describe):

Information from cases and close contacts was collected through face-to-face or telephone interviews.

Self-administered Paper-and-Pencil Questionnaire (describe):

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

Response Rate (if applicable) N/A

Total No. Responded (A):

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

Response Rate (A/B):

Data Collection Instrument 7

Name of Data Collection Instrument:

Type of Respondent

- General public Healthcare staff Laboratory staff x 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):

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):

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Response Rate (if applicable) N/A

Total No. Responded (A):	106
Total No. Sampled/Eligible to Respond (B):	n/a
Response Rate (A/B):	n/a

Data Collection Instrument 7

Name of Data Collection Instrument: 2019 nCoV Household Close Contact Investigation

Type of Respondent

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

Data Collection Methods (check all that apply)

Epidemiologic Study (indicate which type(s) below)
 Descriptive Study (describe): This form was used in investigations that followed close contacts of 2019-nCoV cases who were at risk for infection.
 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 from close contacts was collected through face-to face or telephone interviews.
 Telephone Interview (describe): Information from close contacts was collected through face-to-face or telephone interviews.
 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) N/A

Total No. Responded (A):	106
Total No. Sampled/Eligible to Respond (B):	n/a
Response Rate (A/B):	n/a

Data Collection Instrument 8

Name of Data Collection Instrument: 2019 nCoV Household close out form

Type of Respondent

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- General public
 Healthcare staff
 Laboratory staff
 x Patients
 Restaurant staff
 Other (describe):

Data Collection Methods (check all that apply)

- Epidemiologic Study (indicate which type(s) below)
 Descriptive Study (describe): This form was used in investigations that followed close contacts of 2019-nCoV cases who were at risk for infection.
 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 from close contacts was collected through face-to face or telephone interviews.
 Telephone Interview (describe): Information from close contacts was collected through face-to-face or telephone interviews.
 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) N/A

Total No. Responded (A): 106
 Total No. Sampled/Eligible to Respond (B): n/a
 Response Rate (A/B): n/a

(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*

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1. 2019-nCoV Case Report Form	Information reported by public health official gathered from patient	228,409	1	30	114,205
2. 2019 nCoV Patient Under Investigation Form	Case/patient	39,859	1	30	19,923
3. Combined CRF and PUI form	Information reported by public health official gathered from patient	536,537	1	30	268,269
4. 2019 nCoV Household/Close Contact Investigation Form	Case or contact of the case	318	1	30	159
5. 2019 nCoV Household Questionnaire	Case or contact of the case	106	1	30	53
6. 2019 nCoV Household member symptom diary	Case or contact of the case	318	1	30	159
7. 2019 nCoV Household animal questionnaire	Case or contact of the case	106	1	30	53
8. 2019 nCoV Household close out form	Case or contact of the case	106	1	30	53

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
 EIS Program Staff Epidemiologist
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