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

GenIC No.:	2019004 - XXX
EPI AID No. (if applicable):	
Requesting entity (e.g., jurisdiction):	Wisconsin Division of Public Health
Title of Investigation:	E-cigarette associated pulmonary illness
Purpose of Investigation: (Use as much space as necessary)	211 possible cases of severe pulmonary disease associated with e-cigarette use were reported in 24 states from June 28, 2019 to August 26, 2019, including 1 case-patient death. No etiology had been identified. All case-patients reported a history of e-cigarette use. Some case-patients reported a history of vaping liquids containing tetrahydrocannabinol (THC) compounds. The National Center for Injury Prevention and Control (NCIPC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), National Center for Environmental Health (NCEH), and National Institute for Occupational Safety and Health (NIOSH) worked together to provide technical assistance, coordination, and communication between states investigating those cases. **Data Collection Objectives** The objectives were to assist the state and local health departments with • Establish criteria for identifying cases • Better characterization of potential exposures and evaluate potential non-infectious etiologies • Investigate clinical signs/symptoms, radiographic results, and clinical treatments in cases. This GenIC requested OMB approval was for the medical chart abstraction short form and the case interview short form which were distributed to states who wished to voluntarily use them to collect standardized data. The tool and questionnaire were based on instruments developed by the states to support their own investigations. Additionally, a specimen manifest form was created and used by public health laboratory staff to submit bronchoalveolar lavage (BAL) samples, blood and urine samples to CDC for analysis. If requested by the state, CDC provided staff to assist with data collection within their jurisdiction. As part of public health response within each state, some states collected identifying information for their own purposes, not at the request of CDC. Data included potentially sensitive information (e.g., drug use) since preliminary information indicated some case patients were exposed to product containing THC. CDC used the secure data platform RedCap so that states would be able to securely transmit data to CDC. At the request of states, participating states voluntarily shared de-identified data with CDC via the secure data platform; shared data included key variables that were most critical for understanding the distribution and characteristics of cases nationally and that identified risk factors across states. CDC aggregated key variable data to better understand the distribution and characteristics of cases nationally and identified shared risk factors across states. At the time of the GenIC request, 206 cases were reported, and the GenIC estimated a burden of 500 cases. As cases continued to be identified, the actual number of medical chart abstractions, case interview respondents and specimen manifest respondents were 2,108, 1,810 and 48, respectively.
Duration of Data Collection:	90 days
Date Began:	8/29/2019
Date Ended:	11/27/2019

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Lead Investigator Name:	Joshua Schier
CIO/Division/Branch:	2019 Lung Injury Response

Complete the following for each instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: Case Interview Short 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): This was a descriptive investigation of patients with confirmed e-cigarette associated acute pulmonary disease to systematically collect information about potential exposures to e-cigarettes and specific substances, e-cigarette associated behaviors, and healthcare data related to acute presentations of illness.
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- ☐ Case-Control Study (describe):
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ Other (describe):

Data Collection Mode (check all that apply)

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

- ☒ Face-to-face Interview (describe): This was a descriptive investigation of patients with confirmed e-cigarette associated acute pulmonary disease to systematically collect information about potential exposures to e-cigarettes and specific substances, e-cigarette associated behaviors, and healthcare data related to acute presentations of illness.
- ☒ Telephone Interview (describe): State health department staff conducted telephone-based or in-person interviews of case-patients using a standardized case interview form.
- ☐ 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): 1810

Total No. Sampled/Eligible to Respond (B): 1
Response Rate (A/B): 1810

Data Collection Instrument 2

Name of Data Collection Instrument: Medical Chart Abstraction Short 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):
- ☐ Other (describe):

☐ Environmental Assessment (describe):
☐ Laboratory Testing (describe):
☒ Other (describe): Records Abstraction

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): State health department staff collected medical records and conduct medical chart abstraction.
☐ Biological Specimen Sample
☐ Environmental Sample
☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A): 2108
Total No. Sampled/Eligible to Respond (B): 1
Response Rate (A/B): 2108

Data Collection Instrument 3

Name of Data Collection Instrument: Specimen Manifest 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):
  - ☐ Other (describe):
- ☐ Environmental Assessment (describe):
- ☒ Laboratory Testing (describe): Laboratory staff collected specimens
- ☐ 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: Specimen collection
- ☐ Environmental Sample
- ☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	48
Total No. Sampled/Eligible to Respond (B):	1
Response Rate (A/B):	48

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

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

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

Data Collection Instrument Name	Type of Respondent	No. Respondents (A)	No. Responses per Respondent (B)	Burden per Response in Minutes (C)	Total Burden in Hours (A x B x C)/60*
Case Interview Short Form	patients	1810	1	60	1810
Medical Chart Abstraction Short Form	Public health staff	2108	1	60	2108
Specimen Manifest Form	Laboratory staff	48	1	10	8

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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