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

GenIC No.:	2020001-XXX
EPI AID No. (if applicable):	
Requesting entity (e.g., jurisdiction):	Council of State and Territorial Epidemiologists
Title of Investigation:	E-cigarette associated pulmonary illness
Purpose of Investigation: (Use as much space as necessary)	Introduction 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 has been identified. All case-patients report a history of e-cigarette use. Some case-patients report a history of vaping liquids containing tetrahydrocannabinol (THC) compounds. On August 14 and August 16, the Wisconsin and Illinois Departments of Health, respectively, requested assistance from the Centers for Disease Control and Prevention (CDC) to assist with the investigation of the cases of illness in their states. Since that time, other state and local jurisdictions have requested that CDC facilitate the investigation by aggregating case-patient information at the national level. A multi-state centrally coordinated investigation to severe pulmonary disease associated with e-cigarette use will assist each state/local/territory jurisdiction in making rapid, practical decisions for actions to prevent and control the public health problem. This approach will streamline and strengthen the response, as opposed to multiple state and jurisdictional investigations for the same public health issue. With technical assistance from CDC, states have worked collaboratively to develop a standardized case definition, medical chart abstraction short form, and case interview short form. Data collections for this investigation were first initiated following OMB approval on 8/29/2019 under the Emergency Epidemic Investigations (EEI) Generic ICR (OMB # 0920-1011, exp 1/31/2020). Per the terms of the EEI Generic ICR, data collection was approved for 90 days and therefore the previously approved EEI GenIC expired on 11/27/2019. During that period, the total data collection entailed 1810 standardized case interviews, 2108 medical chart abstractions and 48 specimen manifest forms during the investigation of severe pulmonary disease associated with e-cigarette use (called E-Cigarette or Vaping Associated Lung Injury or EVALI). Data collection was not completed within the original 90 days because new cases were still being reported to CDC from states and territories; therefore, another GenIC approval was requested from OMB that was approved and collection began on 11/26/2019 and was approved for 90 days. Data from state health departments was submitted securely to CDC using the Data Collation and Integration for Public Health Event Response (DCIPHER) platform. On 11/8/2019, CDC reported results from 29 EVALI patient who underwent bronchoalveolar lavage (BAL) and found that all 29 samples contained vitamin E acetate and 23 of 26 samples contained THC ingredients. While at the time it appeared that vitamin E acetate is associated with EVALI, the evidence was not yet sufficient to rule out contribution of other chemicals of concern to EVALI.

This GenIC requested OMB approval to continue to collect data from patients with probable or confirmed cases of EVALI.
Since the start of the outbreak, we were able to streamline the chart abstraction and interview forms included in the initial EEI GenIC approved by OMB in August, 2019 in by identifying the most essential information needed for the investigation to identify cases and associated risk factors for illness. These two forms were replaced by a single National Case Report Form (**National Case Report Form – Standard Version, Appendix 1**).

The National Case Report Form – Standard Version is completed by clinicians or healthcare department staff through medical record abstraction of EVALI cases and includes demographic information, detailed information on past substance use, symptoms, laboratory and radiology findings, hospitalization, interventions, and diagnostic tests performed. The burden for this form is one hour. This form provides the detailed information necessary to inform our understanding of risk factors and clinical course of disease.

In lieu of the National Case Report Form – Standard Version, clinicians or healthcare staff may choose to complete a shorter form (**National Case Report Form – Abbreviated Version**). For respondents who are not able to complete the longer form, this shorter form provides the minimum information necessary to track case counts. This form is also completed by medical record abstraction and includes demographic information and less detailed information about vaping or e-cigarette use and clinical information. The burden for this form is 30 minutes.

When this GenIC was submitted,1500 new cases over the next 90 days were anticipated. This was based on the details provided in case reports received by CDC. CDC estimated that new cases reported from 11/26/2019 and the end of this 90 day collection, would be submitted using the National Case Report Form – Standard Version (Appendix 1) for half of the cases (750) and the National Case Report Form – Abbreviated Version (Appendix 2) for the other half of the cases (750); for an estimated total of 1500 cases. It was anticipated that approximately half of the states would opt to use the shorter form because many states report having less staff time available for data collection as the investigations has progressed.

To supplement information collected through the national case report forms, we received approval for one additional data collection instrument.

Upon request from states, CDC is accepting bronchoalveolar lavage (BAL) samples, blood and urine samples for analysis from confirmed EVALI cases. To submit these samples to CDC, public health laboratory staff of *health departments* complete the **Specimen Manifest Form (Appendix 3)** with information about the sample. This form takes approximately 10 minutes per specimen submitted to complete. At the time of this current approval, CDC had received 48 specimens using this form and anticipated receiving an additional 100 specimens.

	At the conclusion of this GenIC information collection period, a total of 848 National Case Report Form – Standard Version were collected; 0 National Case Report Form – Abbreviated Version were collected and 40 Specimen Manifest forms were collected.
Duration of Data Collection:	90 days
Date Began:	11/26/2019
Date Ended:	2/24/2020
Lead Investigator	
Name:	Peter Briss, MD
CIO/Division/Branch:	NCCDPHP/OD

Complete the following for each instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: National Case Report Form – Standard Version

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 is used to submit information on EVALI cases including demographic information, information on past substance use, symptoms, laboratory and radiologic findings, hospitalization, interventions, and diagnostic tests.
- ☐ 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): Medical record abstraction of cases by state health department staff
- ☐ Biological Specimen Sample
- ☐ Environmental Sample
- ☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	848
Total No. Sampled/Eligible to Respond (B):	NA
Response Rate (A/B):	NA

Data Collection Instrument 2

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): Public health 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):	40
Total No. Sampled/Eligible to Respond (B):	NA
Response Rate (A/B):	NA

(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*
National Case Report Form – Standard Version	Health department staff	848	1	60	848
Specimen Manifest Form	Laboratory staff	40	1	10	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).

EEI Information Collection Request Liaison:
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