Attachment 7: Project Determination

2019 Lung Injury Response - Understanding vaping practices in the United States

Project ID:	0900f3eb81a617e5
Project Contact:	Shaw_Kate M. (atk6)
Organization:	NCIPC/OD/OS
Status:	Pending Clearance
Intended Use:	Project Determination
Estimated Start Date:	12/01/19
Estimated Completion Date:	02/29/20
CDC/ATSDR HRPO/IRB Protocol#:	
OMB Control#:	

Description

Priority

Standard

Determination Start Date

11/15/19

Description

In early July 2019, initial cases of e-cigarette, or vaping, product use associated lung injury (EVALI) were reported to CDC. On August 16, 2019, the Wisconsin and Illinois departments of health submitted a request for CDC Epi-aid assistance to investigate an outbreak of lung injury associated with e-cigarette use, vaping, or dabbing. The investigation rapidly expanded to become a multi-state, centrally organized investigation with a multi-state data collection. As of November 5, 2019, 2,051 lung injury cases associated with the use of e-cigarettes or vaping products have been reported in 49 states, the District of Columbia, and the US Virgin Islands; 39 deaths have been reported among these cases. The specific chemical exposure(s) causing the outbreak is currently unknown. The only commonality among all cases of lung injuries is patientsâ□□ reporting the use of e-cigarette, or vaping, products. Electronic-cigarettes (e-cigarettes) are electronic devices that produce an aerosol by heating a liquid typically containing nicotine, flavorings, and other additives. E-cigarettes can also be used to deliver tetrahydrocannabinol (THC), the principal psychoactive component of cannabis, as well as other derivatives of cannabis, such as cannabidiol (CBD). E-cigarettes are known by many

different names and come in many shapes, sizes and device types. No one compound or ingredient has emerged as the cause of these illnesses to date; and it may be that there is more than one cause of this outbreak. Many different substances and product sources are still under investigation. There is very little data on which to compare EVALI cases to individuals who are vaping the same products at the same frequency but have not developed EVALI (i.e. "□□controls"□□). Comparing cases to people who vape but have not developed EVALI in a timely way is essential for narrowing the list of products, substances, and risk factors requiring further public health investigation and action (e.g., prioritizing samples for laboratory testing and epidemiological surveillance). However, there are insufficient data for guiding the selection of controls for a rigorous case control study, due to a lack of uniformity in demographic characteristics and product brands and types among cases. NCIPC is proposing this information collection to identify the characteristics and behaviors of those who have recently vaped THC-containing products but not developed EVALI compared to vaping-related characteristics of those who have developed EVALI. NCIPC is seeking approval from OMB to conduct a survey via an opt-in internet panel with EVALI controls. A sample of respondents who are already part of the opt-in panel will be invited to participate in this survey to describe their vaping history and experiences. The results of this study will allow us to better target our future laboratory and epidemiological analyses.

Goals/Purpose

The purposes of this study are to (1) Collect data about product types, brands, devices, and frequency of use from a sample of individuals who report vaping Tetrahydrocannabinol (THC)-containing products but who have not developed e-cigarette, or vaping, product use associated lung injury (EVALI) and (2) Determine if the vaping characteristics/behaviors of non-cases (those who vape but have not developed EVALI) are different from the vaping characteristics of EVALI cases.

Objective

The data collected will be used to identify product types, “brands,” devices, and frequency of use (collectively referred to as use characteristics) from a nationally diverse convenience sample of individuals who report vaping THC-containing products but have not developed EVALI. Comparing the frequency of use characteristics between the convenience sample (controls) and EVALI cases will allow us to (1) prioritize follow up on hypotheses about potential causes of the outbreak and (2) refine, target, and prioritize additional information gathering efforts, e.g. epidemiological analyses, laboratory testing, and analysis of pathological specimens.

Activities or Tasks

New Collection of Information, Data, or Biospecimens

Target Population to be Included/Represented

General Population

Tags/Keywords

Electronic Cigarettes: Tetrahydrocannabinol (THC): Lung Injury

CDC's Role

Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided: CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens: CDC employees will participate as co-authors in presentation(s) or publication(s)

Method Categories

Convenience Sample: Individual Interview (Quantitative): Outbreak Investigation: Other

Methods

Data collection will be conducted by YouGov, an opt-in internet panel survey. YouGov specializes in market research and opinion polling through online methods. The company's methodology involves obtaining responses from an invited group of Internet users, and then weighting these responses in line with demographic information. YouGov's US internet panel has over 2 million regionally and socioeconomically diverse respondents.

Collection of Info, Data, or Bio specimens

YouGov will recruit respondents for this data collection using the following inclusion criteria: 1) 18 years or older; 2) no diagnosis of probable or confirmed EVALI in the past year; 3) report vaping or dabbing of THC at least five times in the preceding six months; and 4) reside in one of the selected states. These requirements are intended to identify the specific comparison population of interest. We have intentionally chosen to use the terms vaping/dabbing to isolate THC use over nicotine use via e-cigarettes; this is based on conversations with states involved in the response and those that oversee licit cannabis markets in their state and is intended to use language that is likely to resonate with the target population of interest. The survey instrument was developed: 1) consistent with the current EVALI case interview form; 2) to provide data for use in prioritizing additional epidemiological, laboratory, and pathological investigations in the context of understanding the epidemic of EVALI. The current AOC for the lung injury vaping response will be updated to cover this data collection.

Expected Use of Findings/Results and their impact

The results of this information collection will inform CDC's immediate and future efforts to (1) Narrow the list of products, substances, and risk factors requiring further public health action, epidemiological analyses, and laboratory testing and (2) Reduce CDC's emergency response due to cases of EVALI in the U.S. Data analysis will focus on identifying results of the key research questions.

Will PII be captured?

No

Does CDC have access to the Identifiers

No

Is a certificate or assurance of confidentiality in place or planned?

No

Is a non-disclosure agreement in place?

No

Funding

Funding Type	Funding Title	Funding #	Original Fiscal Year	# of Years of Award

Institutions

Institution	FWA #	FWA Exp. Date	IRB Title	IRB Exp. Date	Funding #
YouGov	FWA00010960	09/11/18			

Staff

Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Staff Role	Email	Phone #	Organization/ Institution
Kate Shaw	12/04/2021				Technical Monitor	atk6@cdc.gov	404-498-0789	NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL

DMP

Proposed Data Collection Start Date	12/01/19
Proposed Data Collection End Date	02/29/20
Proposed Public Access Level	Public
Public Access justification	Data will be made available to the public by request no later than 30 months after the end of data collection (per policy).
How Access Will Be Provided for Data	Data will be made available upon request, possibly with a data use agreement (to be determined). The location of respondents (state) will be removed to protect the identity of respondents. Other variables might be collapsed into categories to further decrease the possibility of identifying respondents (such as age).
Plans for archival and long-term preservation of the data	Data will be stored in an appropriate long-term preservation place as determined by the NCIPC Office of Informatics.

Spatiality (Geographic Location)

Country	State/Province	County/Region
United States	Massachusetts	
United States	New Jersey	
United States	Washington	
United States	New York	
United States	Pennsylvania	

United States	North Carolina	
United States	Tennessee	
United States	Minnesota	
United States	Wisconsin	
United States	Illinois	
United States	Texas	
United States	North Dakota	
United States	Colorado	
United States	Utah	
United States	California	

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research	11/21/19	Angel_Karen C. (idy6) CIO HSC
PRA: **PRA Applies**		11/21/19	Angel_Karen C. (idy6) OMB / PRA