E-cigarette, or Vaping, Product Associated Lung Injury (EVALI): Summary Report

> Bureau of Epidemiology

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### **Executive Summary**

#### Introduction

Vaping or juuling is the action of inhaling aerosolized substances, such as nicotine or tetrahydrocannabinol (THC, the principal psychoactive component of marijuana) using an electronic cigarette (e-cigarette) or vaping device. The inhaled aerosol may contain volatile organic compounds, heavy metals (e.g. lead, nickel, or chromium), ultrafine particles, carcinogens, and other chemicals. Adverse health effects associated with use of e-cigarettes have been reported in the literature. E-cigarettes typically have the following components: a battery, a heating coil, an atomizer that transforms the e-liquid to an aerosol, an e-liquid cartridge, and a mouthpiece. The device's appearance and components vary by generation. Fourth generations are the most recent and come in many shapes and sizes, including mimicking the appearance of a USB flash drive. These devices have modifiable systems and use refillable or prefilled (pod) cartridges.

Between July and February, an e-cigarette, or vaping, product-associated lung injury (EVALI) outbreak was investigated nationwide, with the peak occurring in September. By the end of the outbreak 2,807 hospitalized EVALI cases or deaths were reported to CDC from all 50 states, the District of Columbia, Puerto Rico, and US Virgin Islands. Nationally, the most frequently vaped products contained THC. Vitamin E acetate, an additive in THC e-cigarette, and vaping, products was found to be strongly associated with EVALI cases. However, there was not enough information to rule out other chemicals of concern.

This document summarizes the results from the Pennsylvania Department of Health (DOH) EVALI outbreak response.

#### Methods

Between August 2019 and February 2020, medical providers and Pennsylvania Poison Control Centers (located in Philadelphia and in Pittsburgh) reported potential EVALI cases to DOH, Allegheny County Health Department, or Philadelphia Department of Public Health. Investigation of potential cases included abstracting medical records to classify patients as confirmed or probable, interviewing patients to obtain exposure information, determining if suspected cases participated in the Pennsylvania Medical Marijuana program, and testing the contents of e-cigarette, or vaping, product samples.

#### Results

One hundred and twenty-eight confirmed (66) or probable (62) EVALI cases were identified in Pennsylvania between August 14, 2019 and February 14, 2020. The earliest symptom onset was May 4, 2019, with hospitalization on May 8th.

Seventy-six percent of cases were male and 59% of cases were white. The median age was 22 years (range = 14–60), and 42% of cases were age 18 to 24 years. The prevalence per 100,000 people of EVALI cases was higher in urban areas (n=108, prevalence=1.15) than rural areas (n=20, prevalence=0.59). In the 3 months prior to symptom onset, 84% (108/128) of EVALI cases vaped any THC-containing product(s), while 56% (71/128) of EVALI cases vaped any nicotine-containing product(s). However, EVALI cases vaped multiple substances; 45% (57/128) of cases vaped both THC- and nicotine-containing product.

A total of 67 (52%) of the 128 EVALI cases completed an interview and provided information on vaping behavior. Of the 67, 26 (39%) reported vaping only THC-containing products, 9 (12%) reported vaping only nicotine-containing products, and 32 (48%) reported vaping both THC- and nicotine-containing products. Among the 58 cases who reported vaping any THC-containing products and completed an interview: 74% vaped daily; 52% bought THC-containing e-cigarette, or vaping, product(s) from an informal source (e.g. dealer or friend); 54% vaped Dank vapes (a class of counterfeit THC-containing products); and 43% used fourth generation devices, typically called mod pods. Among the 41 cases who reported vaping any nicotine-containing e-cigarette, or vaping, product(s) from a store (e.g. convenience store, gas station, supermarket); 61% vaped JUUL products; and 52% used fourth generation devices. Vaping flavored products were reported by EVALI patients who vaped THC (74%) or nicotine (83%).

Among the 128 EVALI cases, 93% had respiratory symptoms, 82% had constitutional symptoms (i.e. fever, chills, myalgia, sweats, joint pain), and 77% had gastro-intestinal symptoms. Fifty-four percent of the 128 EVALI cases had one or more prior physical medical condition, and 50% had a history of anxiety or depression. Forty-six percent of the 128 EVALI cases were severe (i.e. hospital stay of ≥10 days; ICU admission; requirement for endotracheal intubation, continuous positive airway pressure (CPAP), or bilevel positive airway pressure (BiPAP); or death). However, between severe and non-severe cases, there was no observed difference by demographic information, vaping exposure (e.g. THC or nicotine), or prior medical condition. Severe EVALI cases did have a higher proportion of respiratory symptoms than non-severe cases.

Twenty-four THC- or nicotine-containing e-cigarette, or vaping, products associated with 7 EVALI cases were sent for laboratory analysis. Of the 13 THC-containing products: 9 contained a fungicide, 5 contained an insecticide, 4 contained an acaricide, 3 contained a pesticide, 1 contained an herbicide, 1 had medium chain triglycerides, and 12 contained vitamin E acetate. For all 11 of the nicotine only products, none contained unexpected substances.

Only 6 of the 128 EVALI cases participated in the Pennsylvania Medical Marijuana Program. Four of the 6 were interviewed, and all 4 reported obtaining and using vaping products and devices from both the Pennsylvania medical marijuana dispensary and unregulated non-dispensary sources (e.g. vape shop or an informal source).

#### Discussion

Demographic characteristics and exposure data for Pennsylvania EVALI cases were comparable to national numbers. All patients vaped within the 3 months prior to symptom onset, which was expected, as recent vaping was a requirement of the case definition. In Pennsylvania and nationally, no one vaping product or device was used by all EVALI patients. THC-containing products were most commonly vaped by EVALI cases, and vitamin E acetate was found in the THC-containing product samples provided by Pennsylvania EVALI cases. Over half of EVALI cases vaped nicotine-containing products and fourth generation devices were most frequently used. Nicotine-containing e-cigarette, or vaping, products often contain a flavoring. The flavoring compounds have been associated with adverse respiratory outcomes. A clear cause of the Pennsylvania EVALI outbreak was not identified. However, DOH endorses the following CDC EVALI recommendations:

- People should not use THC-containing e-cigarette, or vaping, products obtained from informal sources.
- Vitamin E acetate should not be added to any e-cigarette, or vaping, product.
- Adults using nicotine-containing e-cigarettes, or vaping, products as an alternative to cigarettes should not return to smoking. If they choose to use e-cigarettes as an alternative to cigarettes, they should switch completely and not use both products.
- E-cigarette, or vaping, products should not be used by youths, young adults, or women who are pregnant.
- Adults who do not currently use tobacco products should not start using e-cigarette, or vaping, products.

To quit e-cigarettes or vaping please refer to the following resources:

- For adults: <u>https://www.health.pa.gov/topics/programs/tobacco/Pages/Tobacco.aspx</u>
- For Teens: <u>https://www.health.pa.gov/topics/programs/tobacco/Pages/E-</u> cigarettes.aspx

### Introduction

Vaping or juuling is the action of inhaling aerosolized substances using an electronic cigarette (e-cigarette) [1]. E-cigarettes were introduced to the United States (US) market in 2007 and represent a diverse group of battery powered devices used to heat e-liquid for inhalation [2]. E-liquids are often composed of nicotine, a flavoring(s), and a humectant (e.g. propylene glycol or glycerol) to simulate combustible tobacco smoke [3]. There is evidence that completely switching from combustible tobacco cigarettes to e-cigarettes reduces exposure to toxicants and carcinogens [3]. However, e-cigarettes are not benign; the inhaled aerosol may contain volatile organic compounds, heavy metals (e.g. lead, nickel, or chromium), ultrafine particles, carcinogens, and other chemicals [3]. The devices can also be used to inhale tetrahydrocannabinol (THC, the principal psychoactive component of marijuana), cannabidiol (CBD, a non-psychoactive agent in marijuana or hemp), or other drugs (e.g. synthetic cannabinoids) [4]. Often a diluent (e.g. vitamin E or medium-chain-tryglcerides) is included in the THC e-liquids to increase the quality and appearance, provide desirable aroma or taste, and lower product cost [5]. In addition to e-liquids, some devices may also allow for vaping of dry cannabis plant material or solid THC material (e.g. dab of wax) that is melted during the heating process.

E-cigarette device appearance and components vary by generation; however, they all have the following in common – a battery, a heating coil, an atomizer that transforms the eliquid to an aerosol, an e-liquid cartridge, and a mouthpiece [1,3]. First generation e-cigarettes are designed to mimic the appearance of combustible tobacco cigarettes (or cigars/pipes) and are often called cigalikes or vape sticks. First generation e-cigarettes are disposable and intended for single use. Second generation e-cigarettes have a clear refillable or prefilled eliquid cartridge that is attached to a thin battery. The devices resemble pens, are often called a tank system, and are larger than first generation devices. Third generation devices, such subohm, are square or rectangular, do not resemble combustible tobacco cigarettes and are often called tanks or mods due to the customizable and rebuildable atomizers and batteries. Fourth generation devices, often called mod pods, come in many shapes and sizes, including mimicking the appearance of a USB flash drive. These devices have modifiable systems and use refillable or prefilled (pod) cartridges. Unlike the first three generations of e-cigarettes, mod pods use nicotine salts, which have a lower pH than the free base nicotine used in the other devices. The lower pH in the nicotine salts allows for the inhalation of high levels of nicotine with less throat irritation than free base nicotine.

In the United States, the prevalence of e-cigarette usage varies by age group. According to the National Youth Tobacco Survey, in 2018, 20.8% of high school students reported current (≥1 day in past 30 days) e-cigarette use, with 27.7% of users reported vaping e-cigarettes ≥20 of the past 30 days [6]. For young adults (age 18–24 years) who responded to the National

Health Interview Survey, 7.6% reported using e-cigarettes every day or some days [7]. The prevalence of e-cigarette usage increased from 2017 to 2018 for both high school students and young adults. The prevalence of e-cigarette usage among adults age 25 years or older responding to the National Health Interview Survey did not change significantly from 2014 to 2018 (2018 prevalence: 25-44 = 4.3%, 45-64 = 2.1%,  $\ge 65 = 0.8\%$ ) [7,8]. According to the 2017 Youth Risk Behavioral Survey and the 2017 Behavioral Risk Factor Survey, 11.3% of Pennsylvania high school students reported current ( $\ge 1$  day in past 30 days) e-cigarette use and 4.7% of Pennsylvania adults age 18 years or older reported currently using e-cigarettes some day or every day, respectively [9,10].

Adverse health effects associated with use of e-cigarettes have been reported in the literature [3,11]. However, the third quarter of 2019 was the first time a temporally related e-cigarette, or vaping, product associated lung injury (EVALI) outbreak was reported. The first EVALI cases were reported in July 2019 to the Wisconsin Department of Health Services (July 10) and the Illinois Department of Public Health (July 25) [11]. Nationwide, a sharp increase in cases was observed throughout August with the peak occurring in September [12]. At the end of September 2019, 805 EVALI cases from 46 different states had been reported to CDC [13]. By the end of the outbreak, February 18, 2020, 2,739 EVALI hospitalizations were reported from all 50 states, the District of Columbia, and two territories (Puerto Rico and US Virgin Islands) [14]. Sixty-eight EVALI deaths from 29 states and the District of Columbia were also reported [14]. Vitamin E acetate, an additive in THC e-cigarette, and vaping, products was found to be strongly associated with EVALI cases [5,15,16]. There was, however, not enough information to rule out other chemicals of concern.

The DOH EVALI outbreak response started in August 2019 and ended February 2020. This report summarizes Pennsylvania's EVALI response and provides a descriptive analysis of case specific data collected during the outbreak. Where available, Pennsylvania EVALI case data are compared to national data.

### **Brief Timeline of Response**

- 08/14/2019: Pittsburgh Poison Control Center reported suspected cases of EVALI to the Allegheny County Health Department (ACHD) and the DOH.
- 08/15/2019: DOH started to investigate suspected cases of EVALI.
- 08/16/2019: A Health Alert Network (HAN) was sent out, instructing clinicians and medical professionals to report suspected EVALI cases to the Pennsylvania Poison Control Centers. (https://www.health.pa.gov/topics/prep/PA-HAN/Pages/2019-HAN.aspx)
- 08/26/2019: DOH started officially requesting medical records.
- 08/27/2019: Centers for Disease Control and Prevention (CDC)/Council of State and Territorial Epidemiologists (CSTE) sent out a standardized EVALI working case definition and draft tools (i.e. interview and medical abstraction forms).
- 08/30/2019: The DOH abstraction team started abstracting medical records.
- 09/03/2019: A HAN was sent out with the official CDC Health Advisory. The Advisory instructed clinicians and medical professionals to report suspected EVALI cases to their state or local health department. (https://www.health.pa.gov/topics/prep/PA-HAN/Pages/2019-HAN.aspx)
- 09/05/2019: The DOH interview team started interviewing patients.
- 09/18/2019: CDC updated the standardized EVALI working case definition.
- 09/18/2019: The DOH interview team started using version 2 of patient interview questionnaire.
- 09/23/2019: DOH activated an incident command structure (ICS) to facilitate the EVALI response.
- 09/24/2019–10/4/2019: The DOH abstraction team started using EPI-info to abstract medical records; the abstracted data included variables requested by CDC. The use of the Epi-info form was rolled out in stages to members of the abstraction team.
- 09/26/2019: A HAN was sent out with updated guidance and instructions for clinicians and medical professionals to report suspected EVALI cases to the DOH via the included case reporting form. (https://www.health.pa.gov/topics/prep/PA-HAN/Pages/2019-HAN.aspx)
- 09/27/2019: The first weekly situation report was produced and distributed.

10/01/2019: First complete case data (i.e. all requested variables) was submitted to CDC.

10/01/2019: The DOH interview team started using the version 3 revised questionnaire.

- 10/04/2019: A HAN was sent out with updated guidance and instructions on submitting ecigarette, and vaping, products to Pennsylvania Bureau of Laboratories for testing. (https://www.health.pa.gov/topics/prep/PA-HAN/Pages/2019-HAN.aspx)
- 11/08/2019: The DOH interview team started using the patient questionnaire that corresponded with the CDC EVALI National Case Reporting Form.
- 11/14/2019: The DOH abstraction team started using the abstraction form that corresponded with the CDC EVALI National Case Reporting Form.
- 11/26/2019: First scale back: DOH transitioned to only investigating hospitalizations per CDC request.
- 11/26/2019: DOH started collecting data using REDCap Cloud.
- 01/17/2020: Second scale back: DOH stopped conducting patient interviews.
- 01/29/2020: Third scale back: DOH transitioned to only conducting investigations for severe patients (i.e. admitted to ICU, ECMO, ventilated, or died).
- 02/18/2020: DOH sent their final submission of complete case data to CDC.
- 02/26/2020: DOH stood down the EVALI response.
- 03/05/2020: Last situation report was produced and distributed (Appendix A).

## **EVALI Response Investigation Steps**

- Medical providers or Poison Control Centers reported potential EVALI cases to DOH.
- DOH obtained medical records for reported potential EVALI cases. The complete
  medical record for the health care encounter associated with the lung injury was
  obtained. This included records from the initial medical care facility the patient
  presented at and any medical care facilities the patient was transferred to. In addition
  to the medical records, death certificates and autopsies were requested and
  abstracted for patients who died.
- DOH obtained clinical, demographic, and limited exposure information for each patient by abstracting medical records (and death certificates) using a standard abstraction form. Patients were classified as confirmed or probable according to the CDC case definition. See Appendix B for the CDC case definition.
- The DOH interview team attempted to interview each patient to obtain detailed exposure and demographic information using a structured questionnaire administered over the phone (during the height of the epidemic patients were interviewed prior to having a case classification).
- DOH determined if suspected cases were participants in the Pennsylvania Medical Marijuana Program. For patients who participated in the Pennsylvania Medical Marijuana Program and who were classified as confirmed or probable EVALI cases, when necessary, additional measures (e.g. follow-up telephone interviews or in-person interviews) were attempted to gather information on where e-cigarette, or vaping, products and devices were bought/obtained and which products and devices were used.
- Where available, patient's used vaping product samples and devices were collected and submitted to Pennsylvania Bureau of Laboratories (BOL). Pennsylvania BOL sent the samples and devices to Wadsworth Center, New York State Department of Health public health laboratory, for testing. Product samples and devices were collected from the patient in the medical care facility or by a DOH community health nurse.
- Where appropriate, clinical samples such as bronchoalveolar lavage (BAL), urine, and blood were collected and sent to CDC for testing.

Data was analyzed using SAS 9.4. Exposure and demographic information obtained from the patient interviews took precedence over the same information collected from abstraction of the medical record. Exposure and demographic information from the medical record were used

only when the corresponding data from the patient interviews were missing. All clinical data were obtained from the medical record.

### **Summary of Investigation**

As of February 28, 2020, the Pennsylvania vaping response team investigated 176 reports of vaping associated lung injury. Among the 176 reports under investigation, 35 were ruled out and classified as not a case (including 5 deaths), 128 were assigned a case classification: 66 confirmed and 62 probable. This included 1 confirmed death. Only confirmed or probable hospitalized patients were included in CDC's case count reported on their website. Results stratified by treatment facility are found in Table 1. The majority of reported EVALI patients treated in the emergency department (60%) or an outpatient facility (93%) were classified as not a case. Due to the high proportion of non-cases among non-hospitalized patient reports, DOH stopped investigating non-hospitalized reports at the end on November 2019, in accordance with CDC guidance.

Case classification	Hospitalized	Emergency department only	Outpatient only	Total
Confirmed	66*	0	0	66
Probable	57	4	1	62
Not a case	23†	6	14**	43
Not investigated	4‡	0	1 <sup>++</sup>	5
Total	150	10	16	176

## Table 1. Reports of Suspected EVALI Cases in Pennsylvania Stratified by Facility Type, Jurisdiction, and Classification Status, May 2019–February 2020

\*Includes 1 death

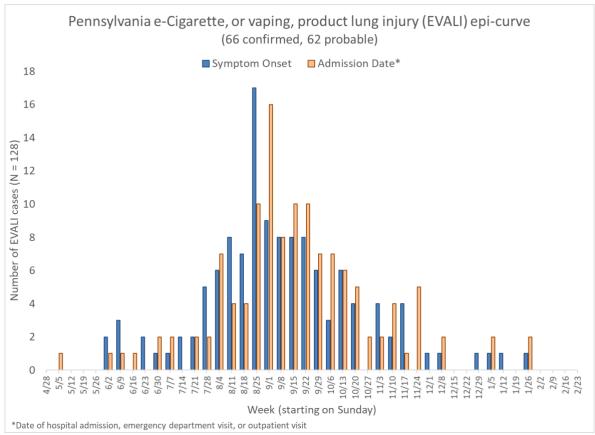
+Five were reports for patients who died.

<sup>‡</sup>These hospitalized patients (2 Allegheny; 2 state) were non-severe reports (not treated in the ICU, given ECMO/ventilation or died) that were not investigated due to the second response scale back. These reports are most likely confirmed or probable cases [17, personal communication with author on February 7, 2020].

\*\*Eight outpatient only reports did not meet the criteria for an investigation because a chest x-ray/CT scan was not medically indicated or the patient's x-ray/CT scan was normal.

††One was an outpatient only report that was not investigated due to the first response scale back of not investigating patients treated only in an outpatient setting.

Figure 1 contains the outbreak epi-curve of the 128 confirmed or probable EVALI cases. The first reported EVALI symptom onset date and treatment date (e.g. emergency department visit or hospitalization) were May 4, 2019 and May 8, 2019, respectively. The peak of the outbreak occurred in late August/early September.



## Figure 1. Epi-curve for Pennsylvania EVALI Outbreak: Cases Reported August 2019 through February 2020

Among the 128 confirmed or probable cases, an interview was completed for 67 patients, 47 patients were lost-to-follow-up (LTFU) after repeated attempts to contact, 8 patients refused to be interviewed, and 6 patients were not contacted due to response scale back when patient interviews were no longer conducted. The mean time between hospitalization (or ED visit) date and interview date was 32 days (standard deviation = 25.8, median=24; range 3–111). A comparison of demographics between interviewed patients and non-interviewed patients can be found in Table 2. The results indicated that interviewed patients were slightly older and had a slightly larger proportion of females; however, the differences were not statistically significant (Gender: Chi-square = 0.3, df = 1, p-value = 0.6; Age group: Cochran-Mantel-Haenszel = 2.8, df = 3, p-value = 0.4). There was a large difference in the 2 groups by proportion of missing information on race and ethnicity. This difference was most likely due to race and ethnicity information being obtained from the

patient interviews as opposed to their medical records. Differences by case status for the 2 groups was not statistically significant (Chi-square = 0.03, df =1, p-value = 0.9).

	Completed interview (N=67)	No interview (N=61) <sup>†</sup>
Gender		
Male	49 (73.1%)	47 (77.1%)
Female	18 (26.9%)	14 (23.0%)
Age(years)		
Mean (SD)	26.1 (9.5)	25.3 (10.0)
Median (Min-Max)	24 (15-60)	21 (14-57)
Age group		
13-17	10 (14.9%)	10 (16.4%)
18-24	25 (37.3%)	29 (47.5%)
25-34	21 (31.3%)	12 (19.7%)
35-44	8 (11.9%)	6 (9.8%)
45-64	3 (4.5%)	4 (6.6%)
65 or older	0 (0.0%)	0 (0%)
Race <sup>‡</sup>		
White	56 (83.6%)	30 (49.2%)
Black	5 (7.5%)	2 (3.3%)
Asian	1 (1.5%)	1 (1.6%)
Other	2 (3.0%)	1 (1.6%)
Missing	3 (4.5%)	27 (44.3%)
Ethnicity <sup>‡</sup>		
Hispanic	11 (16.4%)	2 (3.3%)
Non-Hispanic	50 (74.6%)	26 (42.6%)
Missing	6 (9.0%)	33 (54.1%)
Case status		
Confirmed	35 (52.2%)	31 (50.8%)
Probable	32 (47.8%)	30 (49.2%)

Table 2. Demographic Characteristics Among Interviewed and Non-interviewedConfirmed or Probable EVALI cases in Pennsylvania, May 2019–February 2020\*

\*Cases reported to public health August 2019 through February 2020 †Lost-to-follow-up = 47; Refused = 8; Scale back-stopped interviews = 6 ‡Information on race and ethnicity were often obtained from the interview.

## Medical Marijuana Cases

Among the 176 reports under investigation, 176 were searched against the Medical Marijuana Program's database. Eight patient reports were registered in the program, obtained a physician's certification, completed registration, and purchased from a dispensary in Pennsylvania, in addition to unregulated vape shops, prior to becoming ill.

- Four cases were interviewed and reported obtaining vaping products and/or vaping devices from both Pennsylvania medical marijuana dispensaries and other sources.
  - One classified as probable:
    - Vaped nicotine obtained from gas station
    - Vaped medical marijuana pre-filled vaping cartridges and dab wax purchased from Pennsylvania medical marijuana dispensary
    - Bought battery (what the pre-filled vaping cartridges go into) and dabbing device at an unregulated vape shop in Pennsylvania (not a dispensary)
  - One classified as probable:
    - Vaped medical marijuana from a Pennsylvania medical marijuana dispensary; obtained device also from dispensary
    - Purchased 2 THC vaping cartridges from a friend
  - One classified a confirmed:
    - Vaped medical marijuana cartridges purchased from Pennsylvania medical marijuana dispensary
    - Vaping device bought from an unregulated vape shop in Pennsylvania (not a dispensary)
  - One classified as probable:
    - Obtained vaped nicotine from gas station
    - Purchased vaped medical marijuana cartridges from Pennsylvania medical marijuana dispensary
      - Repeatedly stated symptoms started prior to purchasing medical marijuana
    - Obtained vapes other than THC and CBD cartridge brands from another person
- Two (classified as probable) were not able to be interviewed (1 lost to follow-up and 1 refused), and it is unknown if vaping products or devices were purchased at a non-Pennsylvania licensed medical marijuana dispensary.
- Two were classified as non-cases through medical abstraction; interviews were not conducted.

### **Summary of Demographics**

The majority of confirmed or probable EVALI cases in Pennsylvania were among males, individuals 18-24 years of age, and of white race. The distributions among these categories were similar to nationally observed data (Table 3).

in Pennsylvania (Pa.) and the United States (US) [12], May 2019–February 2020*				
	Pa. (N = 128)	US (N = 2668)		
Gender				
Male	96 (76.2%)	1731 (64.9%)		
Female	32 (25.4%)	875 (32.8%)		
Missing	0 (0%)	62 (2.3%)		
Age (years)				
Median (Min-Max)	22 (14-60)	24 (13-85)		
Age group				
13-17	20 (15.6%)	404 (15.1%)		
18-24	54 (42.2%)	979 (36.7%)		
25-34	33 (25.8%)	631 (23.7%)		
35-44	14 (10.9%)	335 (12.6%)		
45-64	7 (5.5%)	223 (8.4%)		
65 or older	0 (0%)	47 (1.8%)		
Missing	0 (0%)	49 (1.8%)		
Race/ethnicity				
White	75 (58.6%)	1360 (51%)		
Black	6 (4.7%)	64 (2.4%)		
Asian	2 (1.6%)	38 (1.4%)		
Other	2 (1.6%)	109 (4.1%)		
Hispanic	13 (10.2%)	285 (10.7%)		
Missing	30 (23.4%)	812 (30.4%)		
Case status				
Confirmed	66 (51.6%)	1401 (52.5%)		
Probable	62 (48.4%)	1267 (47.5%)		

## Table 3. Demographic Characteristics Among Confirmed or Probable EVALI Cases in Pennsylvania (Pa.) and the United States (US) [12], May 2019–February 2020\*

\*Cases were reported to public health August 2019 through February 2020.

The prevalence per 100,000 people of confirmed or probable EVALI cases was higher in urban areas (n=108, prevalence=1.15) than rural areas (n=20, prevalence =0.59) [18]. Figure 2 contains the prevalence per 100,000 for regions in Pennsylvania, with highest prevalence occurring in the southwest region.

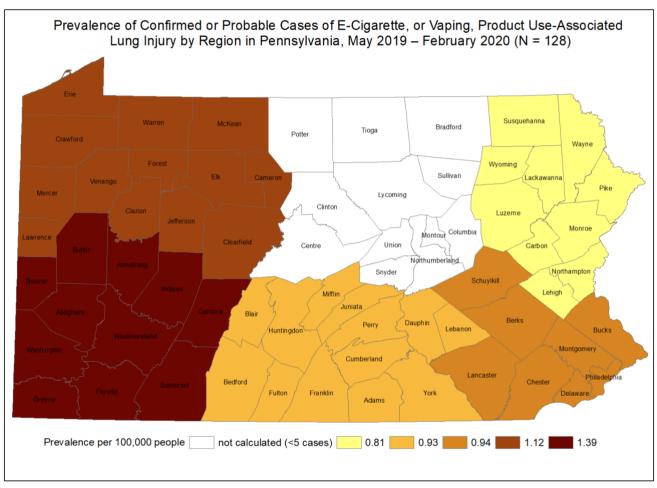


Figure 2. Prevalence Map of Confirmed or Probable EVALI Cases by Region

NOTE: Each number is the prevalence per 100,000 people for that region. Cases were reported to public health August 2019 through February 2020. Denominator data are the 2018 Pennsylvania county specific population estimates [19].

## **Summary of Exposure Results**

Information on the substance vaped was obtained from both the patient interviews and the patients' medical record. Substance use information from the medical record was only used if the corresponding variable from the patient interview was missing or unknown. The majority of the 128 confirmed or probable EVALI patients vaped THC-containing products (Table 4). A

higher proportion of Pennsylvania confirmed or probable EVALI patients vaped both THC and nicotine than the proportion reported for the United States (US) [12]. However, the difference in distributions between Pennsylvania and the US for nonoverlapping THC/nicotine use categories were not statistically significant (chi-square = 4.1, degrees freedom = 4, p-value = 0.4). Limited information on THC toxicology screens suggest patient-reported (interview or medical record) THC usage is accurate. A quarter (32/128) of Pennsylvania EVALI patients were administered a THC toxicology screen; 41% (13/32) obtained type of THC product usage from patient interviews and 59% (19/32) from the medical record. Among the 28 patients with a positive THC toxicology screen, there was agreement with reported THC usage for 27 patients–26 vaped THC-containing products and 1 used marijuana edibles–and THC product used was unknown for 1 patient. Four patients had a negative THC toxicology screen: 2 reported vaping THC-containing products, 1 used combustible marijuana, and, for 1, the medical record did not mention THC product usage.

Many Pennsylvania EVALI patients used multiple products in the 3 months prior to symptom onset. Sixty-three percent (80/128) of PA EVALI patients who vaped THC- or nicotine-containing products also used a combustible product (i.e. combustible tobacco, combustible marijuana). Ten percent (13/128) of PA EVALI patients also vaped CBD oil.

	Pa. (N = 128)	US (N = 2022)
Any THC-containing product	108 (84.4%)	1650 (81.6%)
Any nicotine-containing product	71 (55.5%)	1162 (57.5%)
	Pa. (N = 128)	US (N = 2022)
Both THC- and nicotine-containing product use	57 (44.5%)	834 (41.2%)
Exclusive THC-containing product use	41 (32.0%)	669 (33.1%)
Exclusive nicotine-containing product use	11 (8.6%)	274 (13.6%)
THC- or nicotine-containing product use reported/documented as negative	2 (1.6%)	44 (2.2%)
Missing complete information on THC- or nicotine- product use*	17 (13.3%)	201 (9.9%)

# Table 4. Substances Used in E-cigarette, or Vaping, Products Among Confirmed or Probable EVALI cases in Pennsylvania (Pa.) and the United States (US) [12] May 2019–February 2020

\*Pennsylvania: Ten patients vaped THC-containing products but had unknown use of nicotinecontaining products; 3 patients vaped nicotine-containing products but had unknown use of THCcontaining products; 4 patients vaped but it is unknown if THC- or nicotine-containing products were used. US: MMWR did not publish the specific missing combinations.

Information on specific brand of product(s)/device(s) used and where they were obtained, frequency of use, and length of time used were collected only from the interview. A total of 67 (52%) of the 128 confirmed or probable EVALI patients completed an interview. The proportion of EVALI confirmed or probable cases who completed an interview and vaped THC-containing products daily was similar for Pennsylvania patients and US patients (Table 5). However, the product source differed given that, in Pennsylvania, half of the EVALI patients bought at least one THC-containing product from a known person or a dealer, whereas, nationally, the largest proportion of EVALI patients (36%) were given the THC-containing product, followed by (30%) buying the THC-containing product from a known person or dealer (Table 5). The brands of THC vaping cartridges used are listed in Table 6. Fifty-four percent of interviewed patients who vaped THC used Dank vapes. In comparison, nationally, 56% of patients reported using Dank vapes, followed by TKO (15%), Smart Cart (13%), and Rove (12%) [20]. Among interviewed Pennsylvania patients, 43% used fourth generation (mod pods) devices to vape THCcontaining products (Table 7). Approximately 74% (43/58) of respondents reported vaping flavored THC-containing products. An additional 12% (7/58) did not report vaping flavored THC-containing products but did report using brands (e.g. TKO, Pure Gold, Moonrock) that typically offer flavored products.

	Pa.*	US <sup>†</sup>
Patient vaped THC products and completed interview	58 (53.7%)	809 (48.3%)
THC frequency of use		
Daily vaped THC	44 (75.9%)	641 (74.1%)
Vaped THC less than daily	5 (8.6%)	224 (25.9%)
Unknown	9 (15.5%)	
Where bought/obtained (THC)? <sup>‡</sup>		
Vape shop	4 (6.9%)	44 (5.4%)
Store (e.g. convenience store, gas station, supermarket)	0 (0.0%)	15 (1.9%)
Popup shop	0 (0.0%)	20 (2.5%)
Person/dealer	30 (51.7%)	240 (29.7%)
Online	2 (3.4%)	43 (5.3%)
Given	7 (12.1%)	294 (36.3%)
Medical marijuana dispensary	4 (6.9%)	27 (3.3%)
Recreational dispensary	0 (0.0%)	63 (7.8%)
Other	0 (0.0%)	177 (21.9%)

#### Table 5. Reported Frequency of Use and Source of THC Used in E-Cigarette, or Vaping, Products Among Confirmed or Probable EVALI Cases in Pennsylvania (Pa.) and the United States (US) [21] May 2019–February 2020

Unknown where obtained**	16	26
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\*Pennsylvania: any THC use = 108; THC frequency denominator = 58; THC bought/obtained denominator = 58

 $\pm$ US: Any THC use: N = 1620; THC frequency denominator = 865; THC bought/obtained denominator = 809

‡Categories are not mutually exclusive.

\*\*For the national numbers, patients in this category did not specifically report buying or obtaining product from the above listed categories; however, they did indicate if they bought from a commercial source, an informal source, or both.

Tat	Table 6. Reported Brands of THC Product Used in E-cigarette, or Vaping, Devices								
Am	Among Confirmed or Probable EVALI cases in Pennsylvania Who Completed an								
Inte	erview (N=58), May 20	19 <b>–</b> Fe	əbruar	y 2020*	-		-		
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Brand	Count <sup>†</sup>	% Total	Count (only one brand)
Dank vapes	31	53.5	16
ТКО	13	22.4	2
Smart Cart	12	20.7	2
Missing	10	17.2	0
Rove	6	10.3	1
Kingpen	3	5.2	0
Chronopoly	3	5.2	1
Dabwood	2	3.5	0
Moonrocks	2	3.5	0
Pure Gold	2	3.5	0
Brass Knuckles	2	3.5	0
Bart Carts	2	3.5	1
Mario Carts	2	3.5	0
Golden gorilla	1	1.7	0
PAX Era	1	1.7	1
Moxie	1	1.7	1
Cresco	1	1.7	0
llera	1	1.7	0
Unknown brand <sup>‡</sup>	1	1.7	0
Missing	10	17.2	0

\*National numbers were not available for comparisons for all brands. Cases were reported to public health August through February 2020.

†Categories are not mutually exclusive; the patient may have reported using more than 1 brand. ‡Patient reported they couldn't recall brand name.

Device type	Count <sup>†</sup>	% Total	Count (one device only)
Disposable e-cigarette or vape (first generation)	3	5.2	3
E-cigarette or vape with refillable cartridge (second generation)	12	20.7	7
E-cigarette or vape with a refillable tank (third generation) <sup>‡</sup>	6	10.3	1
E-cigarette or vape with a prefilled or refillable pod (fourth generation);	25	43.1	19
Missing	21	36.2	

#### Table 7. Reported Devices Used to Vape THC-containing Products Among Confirmed or Probable EVALI cases in Pennsylvania Who Completed an Interview (N=58), May 2019–February 2020\*

\*National numbers were not available for comparison. Cases were reported to public health August through February 2020.

†Categories are not mutually exclusive; the patient may have reported using more than 1 brand.

‡ Includes sub-ohm, mod or modifiable systems

The proportion of EVALI confirmed or probable cases who completed an interview and vaped nicotine-containing products daily was slightly smaller for Pennsylvania patients than US patients (Table 8); however, the difference was not statistically significant (Fisher's exact test p-value = 0.5). In Pennsylvania, 66% of the EVALI patients bought at least 1 nicotine-containing product from a store (e.g. gas station or supermarket), whereas, nationally, the largest proportion of patients (47%) bought nicotine-containing product from a vape shop, followed by (38%) a store (Table 8). This difference may be related to the legalization of THC in other states. Among the 41 interviewed patients who reported using any nicotine-containing e-cigarette products, the most frequently used brand was JUUL (Table 9) and fourth generation devices (mod pods) were most frequently used (Table 10). Approximately 83% (34/41) of patients reported vaping flavored nicotine e-cigarette products.

#### Table 8. Reported Frequency of Use and Source of Nicotine Used in Ecigarette, or Vaping, Products Among Confirmed or Probable EVALI Cases in Pennsylvania (Pa.) and the United States (US) [21] May 2019–February 2020

	Pa.*	US <sup>†</sup>
Patient vaped nicotine products and completed interview	41 (57.7%)	613 (54.3%)
Nicotine frequency of use		
Daily vaped nicotine	32 (78%)	580 (85.2%)
Vaped nicotine less than daily	3 (7.3%)	101 (14.8%)
Unknown	6 (14.6%)	
Where bought/obtained (nicotine)? <sup>‡</sup>		
Vape shop	13 (31.7%)	287 (46.8%)
Store (e.g. convenience store, gas station, supermarket)	27 (65.9%)	235 (38.3%)
Popup shop	0 (0%)	2 (0.3%)
Person/dealer	0 (0%)	15 (2.4%)
Online	3 (7.3%)	54 (8.8%)
Given	8 (19.5%)	91 (14.8%)
Other	1 (2.4%)	57 (9.3%)
Recreational dispensary	0 (0%)	7 (1.1%)
Unknown where obtained**	5	18

\*Pennsylvania: Any nicotine use = 71; nicotine frequency denominator= 41; nicotine bought/obtained denominator= 41

†US: Any nicotine use: N = 1128; nicotine frequency denominator= 681; nicotine bought/obtained denominator= 613

‡Categories are not mutually exclusive.

\*\*For the national numbers, patients in this category did not specifically report buying or obtaining product from the above listed categories; however, they did indicate if they bought from a commercial source, an informal source, or both.

Brand	Count <sup>†</sup>	% Total	Count, one brand only
JUUL	21	51.2	11
Njoy	13	31.7	6
Missing	6	14.6	0
Smok	4	9.8	1
Svorin	3	7.3	1
Vuse	3	7.3	1
Blu	2	4.9	0
Unknown brand <sup>‡</sup>	2	4.9	2
Revlon	1	2.4	0
Flare	1	2.4	0
Fix	1	2.4	0
Quit that Grit	1	2.4	1

Table 9. Reported Brands of THC Product Used in E-cigarette, or Vaping, Devices Among Confirmed or Probable EVALI Cases in Pennsylvania Who Completed an Interview (N=41), May 2019–February 2020\*

\*National numbers were not available for comparison. Cases were reported to public health August through February 2020.

†Categories are not mutually exclusive; the patient may have reported using more than one brand. ‡Patient reported they couldn't recall brand name.

#### Table 10. Reported Devices Used to Vape Nicotine-containing Products Among Confirmed or Probable EVALI Cases in Pennsylvania Who Completed an Interview (N=41), May 2019–February 2020\*

Device type	Count <sup>†</sup>	% Total	Count (one device only)
Disposable e-cigarette or vape (first generation)	2	4.9	1
E-cigarette or vape with refillable cartridge (second generation)	7	17.1	4
E-cigarette or vape with a refillable tank (third generation) <sup>‡</sup>	3	7.3	1
E-cigarette or vape with a prefilled or refillable pod (fourth generation);	22	53.7	17
Missing	13	31.7	

\*National numbers were not available for comparison. Cases were reported to public health August through February 2020.

†Categories are not mutually exclusive; the patient may have reported using more than 1 brand. ‡ Includes sub-ohm, mod or modifiable systems Among the 67 EVALI patients who completed an interview and who reported vaping THCor nicotine-containing products, almost a quarter did not report when they started vaping these specific products (Table 11). Among all users (including those that used both substances), for THC-containing product usage, the plurality of EVALI patients had been vaping THC-containing products for 6 months or less, while, for nicotine-containing product users, the plurality of patients had been vaping nicotine-containing products more than 2 years. Long-term usage of nicotine-containing vaping products and short-term usage of THC-containing products held true for 32 users who reported vaping both THC- and nicotine-containing products; 28% (9/32) reported vaping nicotine-containing products for more than 2 years and 25% (8/32) reported vaping THC-containing products for 6 months or less.

Table 11. Reported Duration of Use Among Pennsylvania EVALI Patients Who Were Interviewed and Reported Vaping THC or Nicotine Products, May 2019–February 2020\*

	THC (n = 58)	Nicotine (n = 41)
6 months	20 (34.5%)	9 (22%)
>6 months to 1 year	10 (17.2%)	4 (9.8%)
>1 year to 2 years	5 (8.6%)	7 (17.1%)
>2 years	8 (13.8%)	10 (24.4%)
Missing	15 (25.9%)	11 (26.8%)

\*Cases were reported to public health August 2019 through February 2020.

### **Summary of Medical Results**

Information on symptom onset was available for 125 of the 128 Pennsylvania EVALI cases. The mean number of days between symptom onset and medical treatment (e.g. hospitalization or emergency department visit) was 9.5 days (standard deviation = 14.9) with a median of 5 days (minimum = 0, maximum = 101). Almost all 128 EVALI patients had respiratory symptoms (n=119, 93%) defined as shortness of breath, chest pain, a cough, difficulty breathing, wheezing, or hemoptysis. Constitutional symptoms (i.e. fever, chills, myalgia, sweats, joint pain) were the next most common (n=105, 82%), followed by gastro-intestinal symptoms defined as nausea, vomiting, diarrhea, or abdominal pain (n=98, 77%). A total of 116 EVALI patients (91%) had more than 1 of the above listed symptoms.

Among the 128 confirmed or probable EVALI cases, 69 (54%) had 1 or more prior medical condition(s), not including mental health, recorded in their medical record. Table 12 provides a

summary of these conditions. Of the 49 EVALI patients with a prior mental health condition, 41 suffered from anxiety and depression. Using information from the patient interviews, an additional 23 patients reported suffering from or taking medication for anxiety or depression. Combining the 2 data sources, 50% (n=64) of the 128 EVALI cases had a history of anxiety or depression.

## Table 12. Prior Medical Conditions as Recorded in the Medical Records for Confirmedor Probable Pennsylvania EVALI Cases, May 2019–February 2020\*

Medical history	Count	% Total
Mental health (e.g. depression, anxiety, bipolar, ADHD, PTSD, schizophrenia) <sup>†</sup>	49	38.3
Respiratory disease (e.g. asthma, COPD, cystic fibrosis, pneumonitis)	28	21.9
Other (e.g. fibromyalgia, HIV, migraines, arthritis, celiac disease) <sup>‡</sup>	20	15.6
Heart disease (e.g. heart attack, hypertension, coronary artery disease)	16	12.5
GI disease (e.g. Crohn's disease, IBS, GERD)	11	8.6
Cancer	3	2.3
Diabetes	2	1.6

\*Cases were reported to public health August through February 2020.

+For 25 patients, mental health was the only prior medical condition.

‡The Other category is exclusive and does not include patients with a history of respiratory disease, heart disease, diabetes, cancer, GI disease, or a mental health condition.

Among the 128 confirmed or probable EVAIL cases, there were more severe cases in Pennsylvania (46%) as compared with the US (32%) [Chi-square = 11.0, df = 1, p-value = 0.001] (Table 13). Severe EVALI cases were defined, using the CDC definition, as hospital stay of  $\geq$ 10 days; ICU admission; requirement for endotracheal intubation, continuous positive airway pressure (CPAP), or bilevel positive airway pressure (BiPAP); or death [21]. Among the 128 Pennsylvania EVALI cases, 20.3% (n=26) were very severe–requiring extracorporeal membrane oxygenation (ECMO), mechanical ventilation, or resulting in death.

Severity	Pa. (N = 128)	US (N = 2533)
Not severe	69 (53.9%)	1723 (68.0%)
Severe*	59 (46.1%)	810 (32.0%)
Died <sup>†</sup>	1 (1.7%)	57 (7%)
ICU admission <sup>†</sup>	55 (94.9%)	‡
ECMO <sup>†</sup>	7 (11.9%)	‡
Mechanical vent <sup>†</sup>	25 (42.4%)	‡
CPAP/BiPAP <sup>†</sup>	27 (45.8%)	‡
Hospitalization ≥10 days	28 (47.5%)	‡

Table 13. Severity of Confirmed or Probable EVALI Cases in Pennsylvania (Pa.) and
the United States (US) [21] May 2019–January 2020

\*CDC's definition of a severe EVALI case = hospital stay of ≥10 days; ICU admission; requirement for endotracheal intubation, continuous positive airway pressure (CPAP), or bilevel positive airway pressure (BiPAP); or death. Pennsylvania cases were reported to public health August 2019 through February 2020. US cases were reported to public health July 2019 through January 2020.

†Denominator equals number of severe EVALI cases.

‡National data was not available.

Comparing the demographic characteristics of severe and non-severe EVALI cases (Table 14), there was no statistically significant difference. However, a larger proportion of females had severe EVALI (32%) than non-severe EVALI (19%). While a slightly larger proportion of severe EVALI cases vaped only THC (37%) and a slightly smaller proportion vaped both THC and nicotine (49%) than non-severe EVALI cases (exclusive THC=28%, THC and nicotine=55%), the difference was not statistically significant (Table 15). Additionally, for EVALI patients who used any THC, or who used any nicotine, there was also no statistically significant difference between severe patients and non-severe patients (Table 16). Table 17 contains information on THC or nicotine product use stratified by duration of use and severity of outcome. The proportions are similar; however, the large amount of missing data may be missing not at random. Therefore, statistical tests were not complete.

	Severe (n=59) Non-severe (n=69)		Statistical test
Gender			
Male	40 (67.8%)	56 (81.2%)	Chi-square = 3.0, df =
Female	19 (32.2%)	13 (18.8%)	1, p-value = 0.08
Age(years)			
Mean (SD)	26.8 (10.9)	24.8 (8.5)	
Median (Min-Max)	23 (14-60)	22 (15-53)	
Age group			
13-17	10 (16.9%)	10 (14.5%)	
18-24	23 (39.0%)	31 (44.9%)	
25-34	13 (22.0%)	20 (29%)	Cochran-Mantel-
35-44	9 (15.3%)	5 (7.2%)	Haenszel = $3.2$ , df = 4, p-value = 0.5
45-64	4 (6.8%)	3 (4.3%)	•
65 or older	0 (0%)	0 (0%)	
Race			
White	40 (67.8%)	46 (66.7%)	
Black	3 (5.1%)	4 (5.8%)	Cochran-Mantel-
Asian	0 (0%)	2 (2.9%)	Haenszel = $2.2$ , df = 4,
Other	2 (3.4%)	1 (1.4%)	p-value = 0.7
Missing	14 (23.7%)	16 (23.2%)	
Ethnicity			
Hispanic	4 (6.8%)	9 (13.0%)	Cochran-Mantel-
Non-Hispanic	37 (37.0%)	39 (39.0%)	Haenszel =1.4, df = 2,
Missing	18 (18.0%)	21 (21.0%)	p-value = 0.5

## Table 14. Demographic Characteristics Among Severe and Non-severe Confirmed orProbable Pennsylvania EVALI cases, May 2019–February 2020\*

\*Cases were reported to public health August 2019 through February 2020.

## Table 15. Substances Used in E-cigarette, or Vaping, Products Among Severe and Non-severe Pennsylvania EVALI Cases, May 2019–February 2020\*

	Severe (n=53)	Non-severe (n=56)	Statistical test
Both THC- and nicotine- containing product use	26 (49.1%)	31 (55.4%)	
Exclusive THC- containing product use	22 (37.3%)	19 (27.5%)	Chi-square = 0.7, df = 2, p-value = 0.7
Exclusive nicotine- containing product use	5 (19.2%)	6 (19.4%)	

\*Not included are: 2 patients with THC- or nicotine-containing product use documented as no in the medical record; 10 patients who vaped THC products but unknown use of nicotine products; 3 patients vaped nicotine products but unknown use of THC products; 4 patients vaped but unknown if THC or nicotine products. Among those EVALI cases not included, 13 were non-severe and 6 were severe. Cases were reported to public health August 2019 through February 2020.

## Table 16. THC or Nicotine Product Used in E-cigarette, or Vaping, Products AmongSevere and Non-severe Pennsylvania EVALI cases, May 2019–February 2020\*

	Severe (n=56)	Non-severe (n=65)	Statistical test
Any THC-containing product	49 (87.5%)	59 (90.8%)	Chi-square = 0.3, df =
No THC-containing product	7 (12.5%)	6 (9.2%)	1, p-value = 0.6
	Severe (n=56)	Non-severe (n=58)	Statistical test
Any nicotine-containing product	32 (57.1%)	39 (67.2%)	Chi-square = 1.2, df =
No nicotine-containing product	24 (42.9%)	19 (32.8%)	1, p-value = 0.3

\*Not included are: 7 patients with unknown THC product use (3 severe, 4 non-severe); 14 patients with unknown nicotine product use (3 severe, 11 non-severe). Cases were reported to public health August 2019 through February 2020.

	THC (	n = 58)	Nicotine (n = 41)		
	Severe	Severe Non-severe		Non-severe	
6 months	10 (34.5%)	10 (34.5%)	1 (5.6%)	8 (34.8%)	
>6 months to 1 year	3 (10.3%)	7 (24.1%)	1 (5.6%)	3 (13%)	
>1 year	6 (20.7%)	7 (24.1%)	10 (55.6%)	7 (30.4%)	
Missing	10 (34.5%)	5 (17.2%)	6 (33.3%)	5 (21.7%)	

Table 17. Reported Duration of Use Among Pennsylvania EVALI Patients WhoWere Interviewed and Reported Vaping THC or Nicotine Products Stratified byDuration of Use, May 2019–February 2020\*

\*Due to the large amount of missing duration of use information and the potential for the missingness to be not at random because use start date was not collected on the current EVALI National Case Reporting Form (i.e. REDCap form), statistical significance was not calculated (THC missing duration: 40% of 10 severe and 0% of 5 non-severe did not collect start date; nicotine missing duration: 33% of 6 severe and 40% of 5 non-severe did not collect start date). Cases were reported to public health August 2019 through February 2020.

The proportion of severe EVALI patients with respiratory symptoms (98.3%; [58 of 59]) was statistically higher than the proportion of non-severe EVALI patients with respiratory symptoms (88.4% [n=61 of 69]) [Fisher's Exact test = 0.03, p-value = 0.04]. This was expected as part of the severe EVALI definition included treatment for severe respiratory symptoms. No difference was observed for GI symptoms (severe: 71.2% [42 of 59]; non-severe: 81.2% [56 of 69]; Chi-square =1.8, df = 1, p-value = 0.2) or constitutional symptoms (severe: 76.3% [45 of 59]; non-severe: 87.0% [60 of 69]; Chi-square =2.5, df = 1, p-value = 0.1).

Comparing the proportion of EVALI patients with a medical history of at least 1 prior medical condition (81.4% [48 of 59]) to non-severe EVALI patients with a medical history of at least one prior medical condition (66.7% [46 of 69]), a statistically significant difference was not observed (Chi-square = 3.5, df = 1, p-value = 0.06). The non-statistically significant difference remained when the prior medical condition did not include mental health conditions (severe: 40.7% [24 of 59]; non-severe 30.4% [21 or 69]; Chi-square = 1.5, df = 1, p-value = 0.2).

### **Summary of Lab Results**

The Bureau of Labs received results from 36 products associated with 15 confirmed or probable EVALI cases. The information for the found substances are summarized in Table 18 and detailed information on each substance combination is provided in the bullets below.

- Twelve products had nicotine only.
- One product had THC and nicotine (indicative of mixing nicotine and THC vaping pens together) as well as the following:
  - Vitamin E acetate at 4.51%
  - Positive for pesticides and a fungicide (i.e. Myclobutanil)
- For the 23 products which had THC, additional compounds found are as follows:
  - Twenty products had vitamin E acetate (min = 3.9%; max = 73.6%; mean = 49.0%, standard deviation = 15.2) and
    - 16 positive for pesticides
      - 3 fungicide (i.e. myclobutanil)
      - 1 acaricide (i.e. bifenazate)
      - 3 fungicides (i.e. myclobutanil, trifloxystrobin) and insecticides (i.e. Imidacloprid, diazinon)
      - 7 fungicides (e.g. myclobutanil, trifloxystrobin, paclobutrazol), insecticides (e.g. malathion, methoxyfenozide, bifenthrin), and acaricides (i.e. etoxazole, bifenazate)
      - 2 pesticide synergist (i.e. piperonyl butoxide)
    - 4 negative for pesticides
  - Two products had medium chain triglycerides and
    - 1 with triethyl citrate and positive for pesticides: a fungicide (i.e. Myclobutanil, trifloxystrobin), insecticide (i.e. Methoxyfenozide), and acaricide (i.e. Bifenazate)
    - 1 positive for pesticides: a fungicide (i.e. Myclobutanil), herbicide (i.e. Metolachlor Metabolite), an acaricide (i.e. Bifenazate) and insecticides (e.g. Imidacloprid or bifenthrin)
  - One product had pesticides only: fungicides (i.e. Myclobutanil, Thiabendazole), insecticides (i.e. Bifenthrin, Imidacloprid urea), and an acaricide (i.e. Bifenazate)

In summary, to date, of the 36 products tested, 20 contained a pesticide (17 contained a fungicide, 13 contained an insecticide, 11 contained an acaricide, 1 contained an herbicide); 21 contained vitamin E acetate; 2 had medium chain triglycerides, 1 had triethyl citrate, and 12 contained nicotine with no unexpected substances.

	Nicotine	THC	Vitamin E acetate	Medium chain triglycerides	Triethyl citrate	Pesticide	Total for each substance combination
	Present						12
	Present	Present	Present			Present	1
		Present	Present			Present	16
		Present	Present				4
		Present		Present	Present	Present	1
		Present		Present		Present	1
		Present			- ,	Present	1
Total for each individual substance	13	24	21	2	1	20	

## Table 18. Summary of Lab Results for 36 Vaping Products Associated with 15 Confirmed or Probable EVALI Cases

\*See bulleted list for specific type of pesticide.

### **Discussion**

Between August 2019 and February 2020, Pennsylvania investigated 128 confirmed or probable EVALI cases. Nationally, 2,807 hospitalized EVALI cases or deaths were reported to CDC from all 50 states, the District of Columbia, Puerto Rico, and US Virgin Islands [14]. Demographic characteristics and exposure data for Pennsylvania EVALI cases were comparable to national numbers. Three-quarters of Pennsylvania EVALI patients were male, 58% were white, and 42% were 18 to 24 years of age. All patients vaped within the 3 months prior to symptom onset, which was expected, as vaping was a requirement of the case definition. In Pennsylvania and nationally, no single vaping product or device was used by all EVALI patients. However, 97% of Pennsylvania EVALI patients were known to have vaped a THC-containing product, a nicotine-containing product, or both. For 3%, the type of product vaped was unknown. Half of Pennsylvania EVALI patients did not have a reported prior physical medical condition that may have put them at higher risk of EVALI. However, a large proportion of Pennsylvania EVALI patients had a history of depression or anxiety, which may be associated with unreported physical medical conditions or with self-medication with THC- or nicotine-containing products.

Both nationally and in Pennsylvania, THC-containing products were most commonly vaped by EVALI cases [21]. According to patient interviews, the majority of THC-containing products were obtained from informal sources [21]. Dank Vapes, a class of counterfeit THCcontaining products, were the most frequently reported vaped product brand both in Pennsylvania and nationally [11,16,19]. However, most patients vaped more than 1 brand of THC-containing product. Among Pennsylvania-tested vaping cartridges provided by EVALI patients, 21 of the 24 samples containing THC also contained vitamin E acetate in varying concentrations. Other studies have identified vitamin E acetate in THC-containing vaping cartridges. The Food and Drug Administration identified vitamin E acetate in 80% of THCcontaining product samples linked to confirmed or probable EVALI patients [15]. Vitamin E acetate has also been found in THC-containing vaping products tested at multiple state laboratories [16,22]. CDC identified vitamin E acetate in 94% of BAL samples from 51 confirmed or probable EVALI cases [5]. Minnesota law enforcement identified vitamin E acetate in illicit THC-containing vaping cartridges seized during the outbreak, September 2019. In comparison, THC-containing vaping liquid seized in 2018 did not contain vitamin E acetate [16]. These studies and national data with Pennsylvania exposure data suggests that unregulated (e.g. obtained from an informal source) THC-containing vaping products and vitamin E acetate within these products may be associated with Pennsylvania EVALI cases. However, sample sizes of tested product were small and not all EVALI patients vaped THCcontaining products, indicating other chemicals of concern may play a role. Additionally, while three-quarters of interviewed Pennsylvania patients reported vaping THC-containing products

daily, a dose-response relationship could not be determined because information on the amount of product vaped was missing for almost all respondents.

A little over half of interviewed patients, both nationally and in Pennsylvania, reported vaping nicotine-containing product either solely or in combination with THC-containing products. Among interviewed cases, the majority of respondents obtained e-cigarette nicotine-containing products from a legal source such as a store (e.g. gas station, supermarket) or a vape shop. Among Pennsylvania EVALI cases, JUUL was the most frequently reported nicotine-containing e-cigarette product used. JUUL Laboratories also controls the largest market share (29%) in the US and is the most commonly used nicotine-containing e-cigarette product [23]. None of the Pennsylvania-tested nicotine-containing e-cigarette product samples contained any unexpected substances (e.g. vitamin E acetate, pesticides). However, many of the nicotine-containing (and THC-containing) e-cigarette products in the US market also contain various flavors [24]. These flavoring compounds, such as diacetyl or 2,3-pentanedione, have been associated with adverse respiratory outcomes [3,25]. Since the majority of interviewed Pennsylvania patients who vaped nicotine-containing products reported using flavored nicotine, this may be 1 possible EVALI exposure pathway.

It is unclear if products from Pennsylvania's Medical Marijuana Program were associated with the EVALI outbreak. However, less than 5% of Pennsylvania EVALI cases (n=6) were also participants in Pennsylvania's Medical Marijuana Program. Only 4 of the 6 patients were able to be interviewed, and all 4 reported obtaining and using vaping products and devices from both the Pennsylvania medical marijuana dispensary and non-dispensary sources (e.g. vape shop or an informal source). Further, products from Pennsylvania's Medical Marijuana Program are closely regulated through a tracking system and also through the testing of products at approved laboratories, making contamination less likely.

#### Limitations

The outbreak investigation mainly captured EVALI cases severe enough to require treatment in a hospital or emergency department. Milder cases not captured in this investigation may have a different exposure pattern. Recall bias may have affected patients' response. While most patients were interviewed within a month of hospitalizations, for 10 patients the interview occurred 2 months or more after hospitalization. Patients may also have been reluctant to provide information on illicit drug use or patients may have a different lexicon for vaping products and devices (e.g. the word pods or cartridges used interchangeably). The patients' medical record often contained incomplete or discordant exposure information; as such, there may be misclassification in the THC- or nicotine-containing product categories. The outbreak investigation tools went through several revisions; some information was collected on the first version of the tool and not the revised version, questions were phrased differently potentially eliciting different responses. Products samples were not able to be obtained from all patients.

### **Recommendations**

As part of the summary of the EVALI response, DOH endorses the CDC EVALI recommendations [14]:

- People should not use THC-containing e-cigarette, or vaping, products, particularly from informal sources like friends, family, or in-person or online dealers.
- Vitamin E acetate should not be added to any e-cigarette, or vaping, products. Additionally, people should not add any other substances not intended by the manufacturer to products, including products purchased through retail establishments.
- Adults using nicotine-containing e-cigarette, or vaping, products as an alternative to cigarettes should not go back to smoking; they should weigh all available information and consider using approved smoking cessation methods

   (<u>https://www.health.pa.gov/topics/programs/tobacco/Pages/Tobacco.aspx</u>). If they choose to use e-cigarettes as an alternative to cigarettes, they should completely switch from cigarettes to e-cigarettes and not partake in an extended period of dual use of both products that delays quitting smoking completely. They should contact their health care professional if they need help quitting tobacco products, including e-cigarettes, and if they have concerns about EVALI.
- E-cigarette, or vaping, products (nicotine- or THC-containing) should never be used by youths, young adults, or pregnant people (<u>https://www.health.pa.gov/topics/programs/tobacco/Pages/E-cigarettes.aspx</u>).
- Adults who do not currently use tobacco products should not start using e-cigarette, or vaping, products.
- THC use has been associated with a wide range of health effects, particularly with prolonged frequent use. The best way to avoid potentially harmful effects is to not use THC-containing e-cigarette, or vaping, products.
- Persons engaging in ongoing cannabis use that leads to significant impairment or distress should seek evidence-based treatment by a health care professional.

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# **Appendix A: Final Situation Report**

SITUATION REPORT - #18	INCIDENT Statewide Severe Lung Injuries / Vaping (KC-HIMS 62372)	OPERATIONAL PERIOD START: 02/12/2020 0900 END: 02/24/2020 0900	REPORTING UNIT PADOH	FORM – 04/09 ICS 209 - Short
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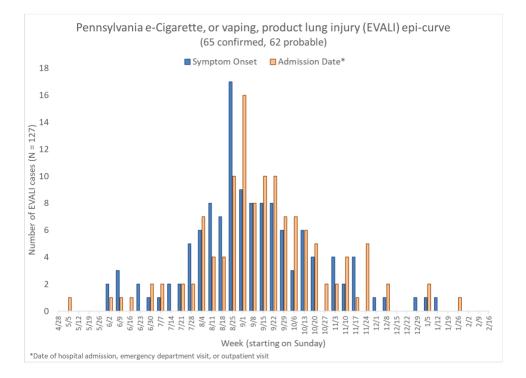
The following reports on activities for the period shown: 2/12/2020 - 3/02/2020

## CURRENT SITUATION

- NATIONAL UPDATE: Source CDC
- As of 02/18/2020, the CDC reports 2,807 confirmed or probable hospitalized cases of ecigarette, or vaping, product use-associated lung injury (EVALI) in 50 states and 2 U.S. territories. There were 68 reported deaths in 29 states and the District of Columbia.
  - National ED data and active case reporting from state health departments around the country show a sharp rise in symptoms or cases of EVALI in August 2019, a peak in September 2019, and a gradual, but persistent decline since then.
  - Reasons for the decline are likely multifactorial and may be related to the following:
    - Increased public awareness of the risk associated with THC-containing ecigarette, or vaping, product use as a result of the rapid public health response.
    - Removal of vitamin E acetate from some products.
    - Law enforcement actions related to some illicit products.
  - As of December 3, 2019, CDC will only report hospitalized EVALI cases and EVALI deaths regardless of hospitalization status.
  - CDC is decentralizing their response and will no longer request/collect EVALI cases from states after February 18<sup>th</sup>.

## • PA UPDATE: Source PADOH

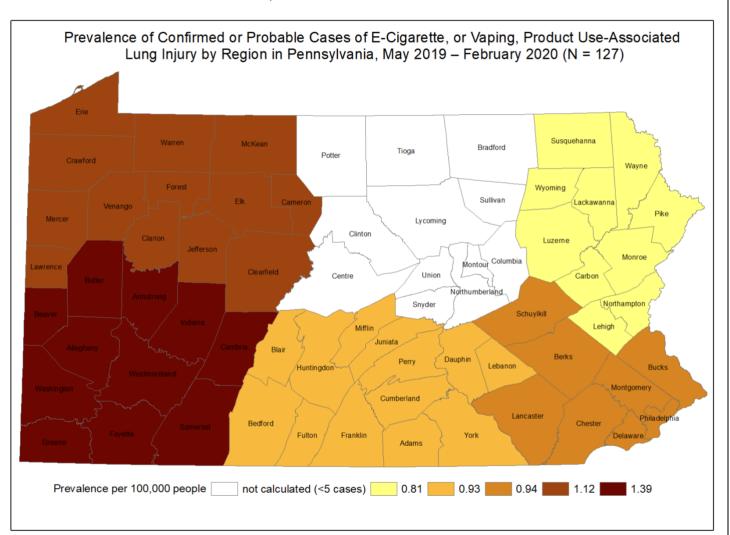
- As of 3/02, PADOH has had reports of 176 suspected cases of e-cigarette, or vaping, product use-associated lung injury (EVALI), including 6 deaths.
  - 128 were classified as confirmed (n=66 [of which 66 were hospitalized or died) or probable (n=62 [of which 57 were hospitalized) cases.



Note: this graph does not include 1 confirmed case as this was abstracted after completion of the graph.

• Age range = 14 – 60 years; average = 26 years; 96 males, 32 females

Prevalence of the 128 confirmed/probable cases per 100,000 people by urban counties (n = 108, prevalence = 1.14) and rural counties (n = 20, prevalence = 0.59).



Note: this map does not include 1 confirmed case as this was abstracted after completion of the map

- 45 reports were determined not to be a case and 5 were not investigated due to scaling back of the response (e.g., non-severe case or treated in an outpatient setting only).
- 6 deaths = 1 confirmed and 5 were determined to not be a case
- The medical marijuana program investigated 8 cases (1 confirmed, 5 probable, and 2 not a case) who participated in the medical marijuana program and were dispensed vaping products. Of the 6 confirmed or probable cases:
  - 4 were interviewed and their vaping products and devices were obtained from both PA medical marijuana dispensaries and other sources
  - 2 were not interviewed (1 lost to follow up; 1 refused) and it is unknown if products/devices were obtained from non-PA medical marijuana dispensary
- On 10/04/2019 a Pennsylvania Health Alert Network (PAHAN) was issued regarding Severe Lung Injury associated with using E-Cigarette Products. The link can be found <u>here</u>.
- On 10/21/2019 the Philadelphia Department of Public Health issued a Health Alert Network (PDPH\_HAN) regarding E-Cigarette/Vaping Associated Lung Injury. The link can be found <u>here</u>.
- A press release was issued on 10/04/2019 warning against vaping illegally obtained products. The link can be found <u>here</u>.

Jurisdiction*	Investigating	MedRec Requested	MedRec Received	Abstractor Assigned	Interview Assigned	Completed Interview			Probable	Not a case	Need Info	Abstraction In Progress
Allegheny	27	27	27	27	27	16	11	17	4	6	0	0
Allentown	3	3	3	3	3	1	2	1	0	2	0	0
Bucks	5	5	5	5	5	2	3	0	4	1	0	0
Chester	5	5	5	5	5	2	3	0	2	3	0	0
Erie	4	4	4	4	4	1	3	2	2	0	0	0
Montgomery	12	12	12	12	12	5	7	5	6	1	0	0
Philadelphia	15	15	15	15	15	5	10	5	6	4	0	0
Wilkes-Barre	1	1	1	1	1	1	0	1	0	0	0	0
State	104	104	104	104	104	43	61	35	38	31	0	0
Total	176	176	176	176	176	76	100	66 <sup>+</sup>	62	48++	0	0

\*County and Municipal Health Departments (CMHDs) report updated numbers for medical records requested/received, interview status, and abstraction status (e.g., case classification) COB each Friday. As a result, CMHD numbers in the above table may be lagged by a week. Please reference the last page of the Situation Report to see which CMHDs are conducting which aspects of the investigation.

<sup>†</sup>Confirmed (including 1 death)

<sup>+†</sup>Including the investigation of 5 deaths, 4 reports not investigated due to the patient being non-severe (not treated in the ICU, ECMO, or ventilated) and 1 report not investigated due to the patient treated in an outpatient setting only.

lurisdiction	Hospitalized	ED only	Outpatient
Allegheny	26	1	0
Allentown	3	0	0
Bucks	5	0	0
Chester	4	1	0
Erie	4	0	0
Montgomery	11	0	1
Philadelphia	10	4	1
Vilkes-Barre	1	0	0
tate	87	4	14
otal	150	10	16
Confirmed/probable	123	4	1
Not a case	27*	6	15
Inder investigation	0	0	0

<sup>+</sup>4 individuals did not meet preliminary criteria for a full investigation

#### **CRITICAL ISSUES**

- Waiting to receive results from Wadsworth for 19 samples obtained from 10 patients
- Reviewing PA's data in the CDC DCIPHER system to make sure there were no translation errors when the data collected using the version 1 and version 2 of the National Case Reporting form and reported to CDC were incorporated into DCIPHER.

#### CASUALTY REPORT (Civilian/Federal);

Six deaths investigated. One was a confirmed vaping associated severe lung injury death and 0 five were determined to not be a case.

#### ACCOMPLISHMENT

- As of 3/2 PADOH has investigated 176 reports of EVALI cases, with 100% percent being assigned a classification.
- Reported 126 (fully abstracted and classified) cases to CDC. Two were not reported because 0 abstraction was completed after the final reporting deadline, at which point CDC closed the national investigation.
- o Of the 128 confirmed and probable EVALI cases 67 (53%) completed an interview, 56 (44%) were lost-to-follow-up or refused an interview and 5 (4%) were not interview due to the scale

back of the response. While doing parallel interview/abstraction investigations, interviews were attempted for 15 non-cases (9 interviews were completed and 6 were lost-to-follow up).

- The CDC sent PADOH a batch of records that were missing data. BoE entered the missing data and returned the records to CDC.
- A letter from PADOH and FDA has been sent to 129 investigated patients. The PADOH cover letter introduces the FDA letter which requests vaping patients participate in FDA's vaping associated lung injury investigation. The PADOH letter indicates that while PADOH has not shared patient information with the FDA to date, if subpoenaed we may have to.
- BoL submitted BAL samples from a WV resident hospitalized in PA to the CDC for testing.
   PADOH will share the results with WV DOH when we receive them.
- Last week, two vaping devices were shipped to Wadsworth or CDC.
- As of 12/17, the BOL has shipped 41 vaping product samples (from 15 different patients) to the Wadsworth Lab, and 20 clinical (autopsy) samples to CDC.
- BOL has received results for 24 products: 1 had THC and Nicotine (had vitamin E acetate and pesticides), 10 had Nicotine only (no pesticides), 12 had THC (of these 12, 10 had vitamin E acetate, 1 had medium chain triglycerides, 1 had both vitamin E acetate and medium chain triglycerides).
- Update of the Master Line List has been automated and incorporates once a day essential information from each of the investigation groups (i.e., healthcare data collection, medical group/abstractions, interview).
- PADOH continues to follow-up with high priority cases (cases involving deaths, clusters of cases, and medical marijuana cases).
- The letter indicating PA DOH and CMHD staff are collecting and shipping vaping product samples as part of their job duties has been written and approved by legal.
- On, 1/23, CMHD representatives were part of a call with the Division of Tobacco Prevention (DTP) and their Regional Primary Contractors to discuss collaborations in vaping prevention messaging and outreach.
- The data analysis team met on 1/9/2020 to discuss initial plans for analysis of the PA EVALI data.
- Operations participated in a call with the CMHD on 11/21 to discuss state and national vaping awareness resources that are available to the counties. The counties are looking for information, data, and resources to be used to create prevention outreach materials.
- Andy and Dr. Watkins met with HAP leadership on 10/4 via telephone conference to educate them on our stance on this issue, and to urge them to ask hospitals to send us vaping product samples as soon as possible, and to ask hospitals to send medical records to the state and local jurisdictions as soon as possible.
- The process for packaging and sending vaping product samples was sent out via a PA-HAN and via an email to CMHD vaping leads.
- A coordination meeting to incorporate BHPRR into the EVALI response was held 10/31 and 11/4
- A PADOH/CMHD Coordination call was held 9/25/2019 and 10/18/2019
- Response Team has participated in several multi-state calls.

## RESOURCES ASSIGNED

- Incident Command S. Watkins (BoE), A. Pickett (BPHP)
- PIO B. Lauffer (Communications)
- Planning Section Chief J. Godin (BPHP)
- Situation Unit Leader S. Singer (BPHP)
- Operations Section Chief TBD
- Investigative Branch Director L. Harduar-Morano (BoE)

- Prevention/Outreach Branch Director B. Caboot (HPRR)
- CMHD Liaison R. Camuso (BPHP)
- Medical Group Director K. Nalluswami (BoE)
- Data Team Lead A. Longenberger (BoE)
- Data Collection Group Lead K. DiRitto (BPHP)
- Interview Group Lead J. Shirk (BoE)
- Laboratory Group Lead J. Okraska (BoL)
- PLANNED ACTIVITIES (next 24 72 hours)
  - As of 2/26/20, PA DOH will no longer be conducting investigations of potential, newly identified EVALI cases.
  - Incorporate vaping product sample results received from Wadsworth and clinical samples received from CDC into the PA data set and into CDC DCIPHER.
  - o Document exchange between CMHDs through PA-HAN Documents System.
- ADDITIONAL INFORMATION
  - On 12/20/209, CDC published an MMWR with updated guidance for clinicians regarding prevention of rehospitalization and deaths.
  - PADOH does not share case or product information with law enforcement. Samples sent to Wadsworth Lab are deidentified.
  - CDC has published a website for the national investigation: <u>https://www.cdc.gov/tobacco/basic\_information/e-cigarettes/severe-lung-disease.html</u>
  - $\circ$   $\;$  This will be the final situation report for this EVALI activation.

## COUNTY CONTACTS AND RESPONSIBILITY FOR DATA COLLECTION/ABSTRACTION

CMHD	County Contact	Conduct Interviews	Request Records	Abstract Records	Pick up Samples
Allegheny	Molly Nace	CMHD	CMHD	CMHD	CMHD
Allentown	Tom Broadhead	PADOH	PADOH	PADOH	CMHD
Bethlehem	Kristen Wenrich	CMHD	PADOH	PADOH	
Bucks	Mackenzie Raub	PADOH	PADOH	PADOH	CMHD
Chester	Lauren Ernst	PADOH	PADOH	PADOH	CMHD*
Erie	Jeff Quirk	CMHD	PADOH	PADOH	CMHD
Montgomery	Feba Cheriyan	CMHD	CMHD	PADOH	PADOH
Philadelphia	Emily Klein	CMHD	CMHD	CMHD	CMHD
Wilkes Barre	Delphine Torbik	CMHD	CMHD	CMHD	CMHD
York	Eva Walker	PADOH	PADOH	PADOH	CMHD

\*Chester County requested a letter from PADOH authorizing them to transport the samples for investigation.

Submitted by: S. Singer, Planning Section	DISTRIBUTION: Vaping Response Team (BPHP, BCHS, BOE, BOL, CMHD)
	PADOH Leadership Team (SOH, EDS, DS- HPCP)

# **Appendix B: CDC Case Definitions**

## 2019 LUNG INJURY SURVEILLANCE PRIMARY CASE DEFINITIONS SEPTEMBER 18, 2019

#### Confirmed Case:

Using an e-cigarette ("vaping") or dabbing\* in 90 days prior to symptom onset

#### AND

Pulmonary infiltrate, such as opacities, on plain film chest radiograph or ground-glass opacities on chest CT

#### AND

Absence of pulmonary infection on initial work-up. Minimum criteria are:

1. A negative respiratory viral panel

#### AND

2. A negative influenza PCR or rapid test, if local epidemiology supports influenza testing

#### AND

All other clinically-indicated respiratory infectious disease testing (e.g., urine Antigen for *Streptococcus pneumoniae* and *Legionella*, sputum culture if productive cough, bronchoalveolar lavage (BAL) culture if done, blood culture, HIV-related opportunistic respiratory infections if appropriate) are negative

#### AND

No evidence in medical record of alternative plausible diagnoses (e.g., cardiac, rheumatologic, or neoplastic process).

#### Probable Case:

Using an e-cigarette ("vaping") or dabbing\* in 90 days prior to symptom onset

#### AND

Pulmonary infiltrate, such as opacities, on plain film chest radiograph or ground-glass opacities on chest CT

#### AND

Infection identified via culture or PCR, but clinical team\*\* believes this infection is not the sole cause of the underlying lung injury **OR minimum criteria** to rule out pulmonary infection not met (testing not performed) and clinical team\*\* believes infection is not the sole cause of the underlying lung injury

#### AND

No evidence in medical record of alternative plausible diagnoses (e.g., cardiac, rheumatologic, or neoplastic process).



U.S. Department of Health and Human Services Centers for Disease Control and Prevention

C5311294-F 10/16/2019

#### Footnotes

\*Using an electronic device (e.g., electronic nicotine delivery system (ENDS), electronic cigarette, e-cigarette, vaporizer, vape(s), vape pen, dab pen, or other device) or dabbing to inhale substances (e.g., nicotine, marijuana, THC, THC concentrates, CBD, synthetic cannabinoids, flavorings, or other substances).

\*\*Clinical team caring for the patient.

Notes: these case definitions are meant for surveillance and not clinical diagnosis. These case definitions are subject to change and will be updated as additional information becomes available if needed.

For more information visit CDC's Lung Injury response website: www.cdc.gov/lunginjury.

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## 2019 LUNG INJURY SURVEILLANCE CASE DEFINITION FOR OUT-OF-HOSPITAL DEATHS (CDC) — OCTOBER 4, 2019

- This case definition is ONLY meant to be used to determine case status for individuals who die outside of the hospital or prior to hospital admission (e.g., at home, in route to the hospital, or in the emergency department), for whom chest imaging and clinical evaluation outlined in the Lung Injury Surveillance Primary Case Definition have not been performed. This case definition is NOT intended to be used to classify case status for surviving individuals or for individuals who die in the hospital, for whom chest imaging and clinical evaluation were performed.
- This case definition integrates pathologic findings from the microscopic review of lung tissue specimens. As medicolegal jurisdiction allows, autopsies should be considered for deaths among persons with a history of e-cigarette, or vaping, product use associated lung injury (EVALI), who had antecedent respiratory or gastrointestinal symptoms, or are suspected of having possible EVALI.
- Fixed tissue specimens from autopsy can be sent to the CDC Infectious Diseases Pathology Branch for histopathologic review and other testing. Guidelines for specimen submission are available on the <u>Health Departments Page</u> of CDC's Lung Injury response website: <u>www.cdc.gov/</u> <u>lunginjury</u>.
- This case definition is being used for public health surveillance purposes only and should not be
  used for clinical diagnostics or forensics. Persons meeting this case definition will not be counted
  separately; they will be included in the total count of confirmed and probable cases in conjunction
  with confirmed and probable cases that meet the <u>Lung Injury Surveillance Primary Case Definition</u>.

#### Confirmed Case:

History of e-cigarette product use, or vaping,\* in the 90 days prior to death

## AND

Pathologic evidence of acute lung injury (e.g., diffuse alveolar damage, acute fibrinous pneumonitis or bronchiolitis, or organizing pneumonia often with vacuolated or foamy macrophages and/or pneumocytes)

## AND

Absence of pulmonary infection<sup>\*\*</sup> (e.g. influenza, *S. pneumoniae, Legionella*, and other infectious diseases, including HIV-related infections as appropriate, as evidenced by microscopy, immunohistology, microbiology<sup>\*\*\*</sup>, or molecular testing)

## AND

No evidence of alternative plausible diagnoses for the lung injury in medical record or at autopsy



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#### Probable Case:

History of e-cigarette product use, or vaping,\* in the 90 days prior to death

#### AND

Pathologic evidence of acute lung injury (i.e., diffuse alveolar damage, acute fibrinous pneumonitis or bronchiolitis, or organizing pneumonia often with vacuolated or foamy macrophages and/or pneumocytes)

#### AND

A positive result on testing for pulmonary infection\*\* (e.g., influenza, *S. pneumoniae, Legionella*, and other infectious diseases, including HIV-related infections as appropriate, as evidenced by microscopy, immunohistology, microbiology\*\*\*, or molecular testing), however medical examiner or other forensic pathologist believes infection is not the sole cause of the underlying lung injury

#### AND

No evidence of alternative plausible diagnoses for the lung injury in medical record or at autopsy

#### Footnotes

\* Using an electronic device (e.g., electronic nicotine delivery system (ENDS), electronic cigarette, e-cigarette, vaporizer, vape(s), vape pen, dab pen, or other device) to inhale substances (e.g., nicotine, marijuana, THC, THC concentrates, CBD, synthetic cannabinoids, flavorings, or other substances). This definition also includes "dabbing," which involves superheating substances that contain high concentrations of THC and other plant compounds (e.g., cannabidiol) with the intent of inhaling the aerosol.

\*\* Does not include positive results from postmortern microbiologic testing thought to represent normal viral or bacterial colonization of nasopharynx, or postmortern bacterial overgrowth of lung tissues or blood.

\*\*\* Recommended microbiology: Nasopharyngeal and/or lung swab testing for influenza, lung swab testing for respiratory viruses, postmortem cultures of lung tissue and blood. Interpretation of postmortem cultures may be complicated because of bacterial overgrowth resulting from tissue breakdown. Medical examiners and other forensic pathologists should contact their local or state health department for assistance if such testing is not readily available at their agency. Fixed autopsy tissue specimens can also be sent to the Infectious Diseases Pathology Branch at CDC for histopathologic evaluation, and infectious disease testing, including immunohistochemistry and molecular testing, as indicated (https://www.cdc.gov/tobacco/basic\_information/e-cigarettes/severe-lung-disease/healthcare-providers/pdfs/ specimen-submission-req.pdf).

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