Department of State Health Services
Update on Investigation of Severe Pulmonary Illness among People who have Reported Vaping
As of Feb 17, 2020

Background

Vaping is the use of an electronic device (electronic cigarette, e-cigarette, vaporizer, vape[s], vape pen, dab pen, or other device) to inhale substances (nicotine, marijuana, THC, THC concentrations, CBD, synthetic cannabinoids, flavorings, or other substances). E-cigarettes have been for sale in the United States since 2007.

More than 928,000 Texas adults, 4.7% of the adult population, reported current e-cigarette use in 2017. Younger adults, 18-29 years of age, were more likely to use e-cigarettes compared with adults 45 years of age and older.

In 2018:
- Over 330,000 middle and high school students reported current e-cigarette use. This represents 13% of all Texas students.
- E-cigarette use was three times as prevalent among high school students (18.9%) as middle school students (6%).

Overall, youth use of e-cigarettes has more than quadrupled from 3% in 2012 to 13% in 2018.
More information can be found on the DSHS Vaping website.

Public Health Concern – Case Investigations

The Texas Department of State Health Services (DSHS) is investigating suspected cases of pulmonary disease among individuals who report vaping. On August 14th, DSHS was notified of a potential case of vaping-associated respiratory illness in an adolescent who initially had complaints of shortness of breath, nausea, and vomiting.
As of the date of this report, 312 possible cases have been reported in Texas:
- 132 are classified as confirmed cases.
- 115 are classified as probable cases.
- 4 deaths have been reported.

Data are subject to change as new information is received.

DSHS is using the CDC surveillance case definition (Appendix A), which was updated on September 18, 2019, in anticipation of the upcoming flu season. DSHS will use the updated case definition going forward but will not reclassify previously-reviewed cases, at the direction of CDC.

Similar cases have occurred in multiple other states, many resulting in hospitalization. As of February 4, 2020, CDC reports that 2,758 confirmed and probable cases of hospitalized lung illness associated with the use of e-cigarette products have been reported from 50 states, the District of Columbia, and 2 U.S. territories. Sixty-four deaths have been confirmed in 28 states and the District of Columbia. CDC is discontinuing data collection on February 18, 2020. No infectious disease has been identified among cases and lung illness is likely associated with a chemical exposure. However, it is not known what is causing these illnesses. No specific substance or product has been linked to all cases.

 CDC has identified vitamin E acetate as a chemical of concern among people with e-cigarette, or vaping, product use associated lung injury (EVALI). Recent CDC laboratory testing of bronchoalveolar lavage (BAL) fluid samples (fluid samples collected from the lungs) from 51 patients with EVALI submitted to CDC from 16 states found vitamin E acetate in 94% of the case samples. In comparison, no vitamin E acetate was found in 99 BAL samples submitted from nicotine e-cigarettes users, tobacco smokers, and nonusers enrolled in a tobacco study with Ohio University. Vitamin E acetate might be used as an additive, most notably as a thickening agent in THC-containing e-cigarette, or vaping, products.
Case Characteristics
Of the 247 confirmed or probable cases in Texas:
- 24% are under 18 years of age.
- Cases range in age from 13 through 75 years old, with a median age of 22 years.
- 72% are male.
- 90% cases with available substance information* reported vaping products containing tetrahydrocannabinol (THC), the primary psychoactive ingredient in marijuana.
- 17% cases reported using only THC products.

In Texas and other states, cases have experienced symptoms including cough, shortness of breath, fatigue, nausea, vomiting, and diarrhea. Symptoms have typically worsened over a period of days or weeks before admission to the hospital. Illness severity has varied. Many patients have required supplemental oxygen and some have required high-level intensive care and respiratory support; some have been intubated and/or been placed on extracorporeal membrane oxygenation. Symptoms have not generally improved with antibiotic treatment alone, but some patients have improved with the use of corticosteroids.

What DSHS and Federal Partners Are Doing

DSHS
DSHS is working with local and regional health departments, other states, the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA) to better characterize case demographics, clinical characteristics, and exposures.

DSHS is partnering with local health departments to identify and investigate cases and share important public health information. DSHS is also searching for cases in the Texas Poison Center Network and ESSENCE, the statewide syndromic surveillance system used by Local Health Departments (LHDs), DSHS, and data providers. Cases are reported to DSHS, and a team of physicians and epidemiologists review medical records and interview

*Substances are gathered from interviews and medical records. Cases with missing substance information are removed from substance analyses
patients to learn more about each case with the goal of identifying the cause of the illnesses.

Additionally, DSHS has:

- Held vaping-specific calls with local jurisdictions to share updates at the national, state and local levels.
- Created a case report form for clinicians and local health departments.
- Released on the DSHS website and disseminated to external stakeholders a health alert on August 16, 2019 (Appendix B) and an update on September 5, 2019 (Appendix C).
- Issued a news release on August 19 advising the public of the issue and reiterating recommendations for health care professionals.
- Responded to more than 70 news media inquiries from state and national outlets.
- Adapted case definition and data collection tools developed by CDC and other states for use in Texas.
- Sent out information to ESSENCE users with key terms to include in medical records.
- Coordinated with FDA, local and regional health departments, and hospitals for vaping product sample collection.
- Developed a document for public consumption with information on the vaping epidemic and resources for parents and posted it to the DSHS Vaping website.
- Provided an update on the health alert to the UT/MD Anderson Cancer Center EndTobacco on September 13, 2019.
- DSHS provided an update on vaping/lung illness ingestion during the DSHS Quarterly Local Health Directors Call on September 23, 2019.
- DSHS provided an update the vaping/lung illness ingestion to the UT/MD Anderson Cancer Center tele-mentoring ECHO session (Project TEACH) on September 24, 2019.
- DSHS provided an update at the DSHS PHR 6/5S Syndromic Surveillance and Regional EPI/BT Workgroup meeting on October 4, 2019.
CDC
CDC is working closely with other state health departments to coordinate and standardize data collection efforts. CDC is assisting states with epidemiological and laboratory investigations and has initiated an incident command structure to coordinate activities. CDC will continue to support states in the refinement of data collection tools and health communication materials, assist in identifying options to facilitate laboratory testing of vaping products and solutions, and facilitate information sharing among state health departments.

In partnership with states, CDC developed a working surveillance case definition and a set of standardized tools to support consistency across state investigations. DSHS has adapted and is using these tools.

CDC is also allowing states to voluntarily share data with them, which CDC will use to provide aggregate case counts and help identify shared risk factors across states.

More information is available on the CDC’s outbreak page.

FDA
FDA is testing samples of vaping products at its Forensic Chemistry Center lab. When vape product samples are available for cases in Texas, DSHS coordinates with the FDA regional office to arrange sample submission. FDA has created a sample collection website with additional information.

Next Steps
- DSHS will continue to partner with local health departments, other states, and federal partners to learn more about the cause of these illnesses.
- DSHS will continue holding weekly vaping-specific calls with local jurisdictions to share updates at the national, state and local levels.
- DSHS will update stakeholders as new resources and state updates are posted to the DSHS website.
- DSHS is developing multimillion dollar campaign to promote cessation of tobacco products and provide education about e-cigarettes and recently passed legislation that increases the minimum age to purchase tobacco products to 21.
Case Status

Table 1. Severe Pulmonary Illness among People who Report Vaping: Case Status

<table>
<thead>
<tr>
<th>Case Status</th>
<th>N (%)  (n=312)</th>
</tr>
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<tbody>
<tr>
<td>Confirmed</td>
<td>132 (42.31%)</td>
</tr>
<tr>
<td>Probable</td>
<td>115 (36.86%)</td>
</tr>
<tr>
<td>Not Case</td>
<td>63 (20.19%)</td>
</tr>
<tr>
<td>Under Investigation</td>
<td>2 (0.64%)</td>
</tr>
</tbody>
</table>

Case Geography (Confirmed and Probable Cases)

Table 2. Severe Pulmonary Illness among People who Report Vaping: Public Health Region

<table>
<thead>
<tr>
<th>Public Health Region</th>
<th>N (%)  (n=247)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Region 1</td>
<td>4 (1.62%)</td>
</tr>
<tr>
<td>Region 2/3</td>
<td>133 (53.85%)</td>
</tr>
<tr>
<td>Region 4/5 N</td>
<td>6 (2.43%)</td>
</tr>
<tr>
<td>Region 6/5 S</td>
<td>43 (17.41%)</td>
</tr>
<tr>
<td>Region 7</td>
<td>31 (12.55%)</td>
</tr>
<tr>
<td>Region 8</td>
<td>14 (5.67%)</td>
</tr>
<tr>
<td>Region 9/10</td>
<td>3 (1.21%)</td>
</tr>
<tr>
<td>Region 11</td>
<td>13 (5.26%)</td>
</tr>
<tr>
<td>Region Unknown</td>
<td>0 (0.00%)</td>
</tr>
</tbody>
</table>

This table contains data on confirmed and probable cases
*County and region may not be available for all cases as we await information from parent, guardian, or health care providers
Figure 1. Severe Pulmonary Illness among People who Report Vaping by Geographic Location in Texas, 17APR2019 through 13FEB2020
Appendix A

2019 Lung Injury Surveillance Case Definition (CDC) – September 18, 2019

### Confirmed

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

3) 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

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).

### 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.
Appendix B

HEALTH ALERT:
Severe Lung Disease Among Persons Who Report Vaping
August 16, 2019

Background
The Texas Department of State Health Services (DSHS) is investigating suspected cases of pulmonary disease among individuals who report vaping. Similar cases have occurred in multiple other states, some resulting in hospitalization. All suspect cases reported vaping with products including nicotine and/or tetrahydrocannabinol (THC). Evaluation for infectious diseases was negative in all patients.

DSHS is working with other states and the Centers for Disease Control and Prevention to better characterize case demographics, clinical characteristics, and exposures.

Clinical Presentation
Individuals experienced respiratory symptoms including cough, shortness of breath, and fatigue. Some also experienced nausea, vomiting, and diarrhea. Symptoms worsened over a period of days or weeks before admission to the hospital. Illness severity has varied, and in some cases, severe lung disease has been reported.

On imaging, chest radiographs have demonstrated bilateral opacification, and CT imaging has demonstrated diffuse ground glass opacification.

Recommendations for Clinicians
Health care providers should:

- Ask patients presenting with respiratory symptoms about vaping history. If possible, inquire about the types of products used and methods of use.
- If vaping fluid commonly used by the patient is available, ask that it be set aside (not used) in case it is needed for testing.
- Be aware that some suspect cases have required high-level intensive care and respiratory support.

Suspected cases should be reported to the Texas Department of State Health Services at 512-776-7268.

Suspected cases include those with inhalation drug use* within 90 days prior to symptom onset AND clinical signs and symptoms** of respiratory dysfunction.
* Includes vaping or smoking of any plant or chemical, including nicotine, marijuana, THC concentrate, CBD, synthetic cannabinoids, or other.

** Includes shortness of breath, pleuritic chest pain (i.e., pain with inspiration), cough with or without hemoptysis, hypoxia (pulse oximetry <=95%), with or without fever.

**Recommendations for the Public**
People who experience difficulty breathing, cough, or other symptoms in the days or months after vaping should seek immediate medical attention.

**For More Information**
For questions:  
DSHS Environmental Surveillance and Toxicology Branch  
512-776-7268  
epitox@dshs.texas.gov  
Get the facts about electronic cigarettes:  
www.dshs.texas.gov/tobacco/E-Cigarettes/  
Information for health care providers on adolescents and E-cigarette use:  
www.txhealthsteps.com/static/courses/escape-the-vape/sections/section-1-1.html
Appendix C

UPDATED HEALTH ALERT:
Severe Pulmonary Illness Among Persons Who Report Vaping
September 5, 2019

Background
The Texas Department of State Health Services (DSHS) continues to investigate severe pulmonary illness among people who have reported vaping*. Some cases in Texas have reported vaping products containing nicotine and/or tetrahydrocannabinol (THC). Similar cases have occurred in multiple other states, some resulting in hospitalization.

DSHS is working with local health departments, other states, and the Centers for Disease Control and Prevention to better characterize case demographics, clinical characteristics, and exposures.

* Inhalation drug use with 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 Presentation
Individuals experienced respiratory symptoms including cough, shortness of breath, and fatigue. Some also experienced nausea, vomiting, and diarrhea. Symptoms worsened over a period of days or weeks before admission to the hospital. Illness severity has varied, and in some cases, severe lung disease has been reported. Many patients have required supplemental oxygen. Some have required assisted ventilation and oxygenation, and some were intubated.

Evaluation for infectious diseases was negative in all cases and no alternative diagnosis (e.g., rheumatologic or neoplastic process) has been identified as the underlying cause of illness.

Radiologic findings have varied. On imaging, chest radiographs have demonstrated bilateral opacification, and CT imaging has demonstrated diffuse ground-glass opacification. Radiographic abnormalities have not been present in all patients upon initial presentation.
Disease Reporting
Cases with similar clinical presentation and history of vaping should be reported to DSHS by calling 512-422-0925 (24 hours a day, 7 days a week).

Texas Health and Safety Code Ch. 161 (Sec. 161.0211) requires DSHS to conduct epidemiologic or toxicologic investigations of human illnesses or conditions and of environmental exposures that are harmful or believed to be harmful to the public health.

Recommendations for Clinicians
Health care professionals should:

- Where appropriate, ask patients about history of inhalation drug use with electronic devices. If possible, inquire about the types of products used and methods of use.
- Be aware that the illness can worsen over time and some suspect cases have required high-level intensive care and respiratory support.
- During patient assessment, ensure that “vape”, “vaping”, or “e-cigarette” is noted in the chief complaint history when applicable.
- If vaping products used by the patient are available, ask that they be set aside (not used) in case it is needed for testing.
- At the direction of the U.S. Food and Drug Administration (FDA), DSHS will coordinate product specimen submission related to this investigation. If you have collected samples, please contact DSHS at 512-422-0925 for sample submission instructions.

Additional recommendations for clinicians from the Centers for Disease Control and Prevention are available here: https://emergency.cdc.gov/han/han00421.asp.

Recommendations for the Public
While this investigation is ongoing, if you are concerned about these specific health risks, consider refraining from using e-cigarette products. People who experience difficulty breathing, cough, or other symptoms in the days or months after vaping should seek immediate medical attention.

Additional recommendations for the public from the Centers for Disease Control and Prevention are available here: https://emergency.cdc.gov/han/han00421.asp.

For More Information
For questions:
DSHS Environmental Surveillance and Toxicology Branch
512-776-7268 or 512-422-0925
epitox@dshs.texas.gov
Get the facts about electronic cigarettes:
www.dshs.texas.gov/tobacco/E-Cigarettes/
Information for health care providers on adolescents and E-cigarette use:
www.txhealthsteps.com/static/courses/escape-the-vape/sections/section-1-1.html
Appendix D

Laboratory Clinical Specimen Collection and Storage Guidance for Lung Injury Associated with E-Cigarettes, or Vaping

The purpose of this document is to provide sample collection and storage guidance for clinicians in the care of patients who meet the probable or confirmed case definitions for lung injury associated with e-cigarettes, or vaping. CDC recommends that clinicians consult their local or state health department for the department’s recommendations on collection and storage of clinical samples. This document supplements CDC’s guidance by providing specific information for reporting in Texas.

Prior to submitting samples, complete this form (https://www.dshs.state.tx.us/tobacco/pdf/TX-Vaping-Case-Report-Form.pdf) and call 512-422-0925 to discuss sample submission, then follow directions to submit the form to the DSHS Environmental Surveillance and Toxicology Branch. DSHS will confirm that the samples are eligible to be submitted the state public health laboratory and will provide State Case ID numbers and further instructions.

SPECIMEN TYPES

CDC has indicated clinical specimens (e.g., plasma/serum, urine, bronchoalveolar lavage (BAL)) could be used for investigative testing. At this time, CDC is prioritizing BAL fluid for testing. Plasma/serum and urine samples will only be accepted in conjunction with BAL samples from the same patient. See below for detailed guidance for collection, handling, and shipping of these samples. PLEASE NOTE: If specimens are tested by CDC, CDC will report results to the Texas Department of State Health Services (DSHS) and results will then be forwarded to the submitter.

SPECIMEN COLLECTION AND HANDLING

Specimen Collection Time Point

- Clinical specimens (urine and plasma) are to be collected ONLY at the time when BAL fluid is to be collected or upon Patient Admission to Hospital

Specimen Labeling and Handling
• All specimens must be labeled with at least two patient specific identifiers, but must include: the State Case ID number and the patient’s medical record number.
• The identifiers must appear on all primary containers and the associated submission form.
• A manifest with the CDC Case ID, State Case ID, Patient Medical Record number, specimen type, and collection date must be included with the shipment.
• Specimens must be labeled as to type (e.g. serum, urine, etc.).

Bronchoalveolar lavage fluid (BAL fluid) samples

• Due to the invasive nature of BAL sampling, the decision and timing for a patient to undergo BAL should be left to the judgement of the treating clinicians.
• Optimal timing: These specimens may be obtained at any time during the clinical course but may be most informative if obtained prior to initiation of antimicrobial or steroid therapy. If antibiotics or steroids have been initiated, course and duration should be noted on the back of the G-2A form.
• Specimen collection: Collect specimens in sterile containers. BAL fluid should undergo culture and routine centrifugation followed by cellular analyses and cytopathology, including lipid and other staining, as clinically indicated at the local institution.

Guidance for retaining BAL fluid samples left over from routine clinical evaluation:

BAL Fluid for Further Cytopathologic Evaluation
• Remaining uncentrifuged BAL fluid and supernatant from centrifuged BAL fluid should be labeled as such and be retained.
• Up to 10 unstained cytology slides prepared from the cell pellet should be briefly fixed in formalin and retained for future evaluation.
• Excess cell pellet after cytopathologic evaluation can be divided in half, with half being fixed in formalin and stored at room temperature for further cytopathologic evaluation. The other half should be set aside for Chemical or Lipid Analysis (see below)

BAL Fluid Submission for Chemical or Lipid Analysis
• Place remaining uncentrifuged fluid and centrifuged supernatant from centrifuged fluid into sterile vials with external caps and internal O-ring seals. If there is no internal O-ring seal, then seal tightly with the available cap and secure with Parafilm®.
• Label each specimen container with the patient’s medical record number, state case ID number, the specimen type, subsection of lung lavaged, and the date the specimen was collected.
• FREEZE the BAL Fluid Sample for Chemical or Lipid Analysis at freezer temperatures of -20 °C or lower and store frozen.
• SEE BELOW FOR SHIPPING INSTRUCTIONS.

Plasma Samples

• For each patient, collect up to 8 mL of blood in two (2) 4-mL PURPLE-top (K2 - EDTA) plastic tubes. (Note: DO NOT use gel separators.)
• Mix contents of tubes by inverting them 8 -10 times.
• Label tubes in order of collection. Example: #1, #2.
• Centrifuge blood tubes for 15 minutes at 1000 to 1300 g-force to separate the plasma from whole blood cells within 6 hours of collection. Check with the centrifuge rotor manual (or RCF to RPM table) for the proper RPM (e.g. 2400 RPM) to use with your specific rotor.
• Aliquot plasma into cryotubes with corresponding collection sequence number (e.g. #1, #2)
• Label each specimen container with the patient’s medical record number, state case ID number, the specimen type, and the date the specimen was collected.
• FREEZE these specimens at freezer temperatures of -20 °C or lower and store frozen.
• SEE BELOW FOR SHIPPING INSTRUCTIONS.

Urine Samples

• For each patient, collect approximately 40 mL to 60 mL of urine in a screw-cap urine cup without preservative.
• Transfer 8 mL to 10 mL of urine to a urine collection tube(s) with no preservative. (Example: BD 364991 Vacutainer® Urinalysis Transfer Straw Kit: 8.0 mL, 16 x 100 mm Plus Plastic Conical Tube, without preservative, or similar)
• Indicate on the tube how the sample was collected if the method was other than “clean catch” (example: catheterization).
• Label each specimen container with the patient’s medical record number, state case ID number, the specimen type, and the date the specimen was collected.
FREEZE these specimens at freezer temperatures of -20 °C or lower and store frozen.
SEE BELOW FOR SHIPPING INSTRUCTIONS.

SPECIMEN SHIPPING

Specimens should be shipped in a biohazard bag and stored on enough dry ice to keep specimens frozen. Please only ship the same specimen types together in a box (e.g., BAL fluids only in one box, plasma tubes only in one box, etc.)
Do not ship on Fridays or before government holidays. Ship specimens Monday-Thursday by overnight delivery.
Complete a DSHS G-2A Serology Specimen Submission Form (September 2017 revision):
  o A separate G-2A is required for each specimen (plasma, urine, etc.) submitted
  o A submitter ID is required to submit specimens. To request a submitter ID, please complete the Submitter Identification (ID) Number Request Form available at www.dhs.texas.gov/lab/MRS_forms.shtm#Microbiological and follow the instructions for submitting the form. Please include an email address in section 3 of the Submitter ID Request Form for a faster response.
    o Tips for completing G2-A form:
      ✓ Section 2 – Patient Information: Place patient’s State Case ID number in the “Last Name” field, leave “First Name” field blank, and place patient’s medical record # in the “Medical Record #” field; complete date of collection field
      ✓ Section 3 – Specimen Source or Type: check the “Other” box and write in specimen type
      ✓ Section 9 – CDC Reference Tests: check the “Other” box and write in Vaping
Ship to the physical address: TX DSHS Lab Services, ATTN: Walter Douglass 512-776-7569, 1100 W. 49th Street, Austin TX, 78756
Record the shipping tracking number and notify your local health department that a specimen is being shipped.