Vaping-Associated Pulmonary Illness in New York State

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Public Health Investigation

- First reports of possible vaping-associated pulmonary illnesses were received by the Department in early August 2019
  - Symptoms dated as far back as June 2019
- Communication with CDC revealed a larger national outbreak of illness
  - Over 450 possible cases in 33 states and 1 US territory
- 49 reports have been made in NYS (as of 9/10/19)
Epidemiologic Investigation

- Of the 49 cases reported (as of 9/10/19)
  - Majority patients male (76%)
  - Age
    - Range: 14 - 57 years old
    - Mean: 26 years old
    - Median 20 years old
  - 96% of patients required hospitalization
  - At least 3 patients required intubation
Laboratory Investigation

- Product samples have been sent to Wadsworth Center for testing
- 49 samples from 11 patients have been received by Wadsworth
- Of the 9 patients for whom test results are available, each submitted at least 1 THC vape pen containing vitamin E acetate
Vitamin E Acetate

- Common vitamin supplement not known to be harmful when ingested or applied to the skin
- May be associated with serious health effects when inhaled due to oil-like properties
Department of Health Action

- August 15th – Health Advisory sent to healthcare, substance use and mental health communities, and local health departments

- September 6th – Public Notification
Recent NYS Actions

• Subpoena Issuance
  • Honey Cut Diluting Agent
    • Honey Cut Labs LLC, Santa Monica, CA
  • Uber Thick
    • Floraplex Terpenes, Ypsilanti, MI
  • Pure Diluent
    • Mass Terpenes, Amherst, MA
Recent NYS Actions

• Emergency Regulations
• Requires entities in NYS that sell vaping products to post signage on the dangers of vaping illegal e-cigarette and e-liquid products
E-cigarettes and Vaping

Regulatory Definitions

(a) … “e-cigarette” mean an electronic device that delivers vapor which is inhaled by an individual user, and shall include any refill, cartridge and any other component of such a device.

(b) … “e-liquid” means the solution, substance or material used in an e-cigarette and heated to produce an aerosol or emission to be inhaled by the user, whether the liquid contains nicotine or not.

(c) … “flavored e-liquid” means any e-liquid with a distinguishable taste or aroma, other than the taste or aroma of tobacco or menthol … including but not limited to … any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, herb or spice, or any of a number of “concept flavors” that impart a taste or aroma that is distinguishable from tobacco flavor but may not relate to any particular known flavor.

(1) This includes … products that are not clearly labeled as having no flavor or tobacco flavor only.
National Academy of Science, Engineering and Medicine

**Conclusion 5-1.** There is **conclusive evidence** that in addition to nicotine, **most e-cigarette products contain and emit numerous potentially toxic substances.**

**Conclusion 10-4.** There is **substantial evidence** that some chemicals present in e-cigarette aerosols (e.g., formaldehyde, acrolein) are capable of causing DNA damage and mutagenesis.
Regulatory Process

• Emergency Regulations
  • Amend Section 225 of the Public Health Law, Title 10
  • Add new subpart 9-2 titled: “Required Signage”
Youth Use is an Urgent Public Health Concern

- Nearly 40 percent of 12th grade students and 27 percent of high school students are now using e-cigarettes and this increase is largely driven by flavored e-liquids.
- High school use in 2018 (27.4%) is 160 percent higher than it was in 2014 (10.5%).
- Flavoring is a key youth marketing strategy of the vaping/aerosol industry just as it is in the cigarette, cigar, and smokeless tobacco markets.
- Flavors are a principal marketing strategy that appeals to youth and young adults, and the flavorant chemicals used in e-cigarettes have been approved by the FDA for ingestion but not inhalation.
THE TOBACCO INDUSTRY HAS A KIDS MENU.

FlavorsHookKids.org
Volatile Organic Compounds

Cancer-causing Chemicals

Heavy Metals Such as Nickel, Tin, and Lead

Ultrafine Particles

Flavoring Such as Diacetyl, A Chemical Linked to a Serious Lung Disease

Nicotine
The American Academy of Pediatrics Issues Sweeping Recommendations on Tobacco and E-Cigarettes

Tobacco aside, e-cigarette flavorings may harm blood vessels

What are they?
Electronic cigarettes, also known as e-cigarettes, e-cigs or, most accurately, electronic nicotine delivery systems (ENDS), are devices that deliver an aerosol (incorrectly called ‘vapour’), inhaled by the users and created by heating a solution, usually composed of propylene glycol or glycerin (glycerine) and flavourings, generally with nicotine. While they both contain nicotine, e-cigarettes and traditional cigarettes are entirely different products. Thus, while the vapour from e-cigarettes does not contain some of the harmful substances in traditional cigarettes, it does contain different harmful substances not found in traditional cigarettes, so the health effects of using both can be expected to be greater than either alone. ENDS have been heavily marketed in some countries in recent years. In 2017, about 33% of the European population had tried e-cigs at least once in their life.1

The WHO view on e-cigs
In 2016, the World Health Organization (WHO)2 noted that, while e-cigarettes might be less harmful than conventional cigarettes, e-cigarettes still pose important risks to health, and that ENDS regulation should:
• Deter e-cigarette promotion to non-smokers and young people;
• Minimise potential health risks to e-cigarette users and nonsmokers;
• Preclude unfounded health claims about e-cigarettes;
• Prevent/tax/tobacco involvement of the tobacco industry in the marketing and promoting of e-cigarettes.

The legislative situation in Europe
As of May 2014 all European Union (EU) countries must comply with the EU Tobacco Products Directive that includes regulations for ENDS. The Directive3 states that their packaging should provide information on toxicity and addictiveness, health warnings, and a list of all the substancescontained in the product, including the exact level of nicotine (that should be in a concentration level of no more than 20 mg/ml). The Directive also requires that advertising and promotion rules for tobacco products also apply to electronic cigarettes.
Conclusion 16-1. There is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.

Conclusion 16-2. Among youth and young adult e-cigarette users who ever use combustible tobacco cigarettes, there is moderate evidence that e-cigarette use increases the frequency and intensity of subsequent combustible tobacco cigarette smoking.
NYS Actions

• On Monday, the Governor announced he will propose legislation banning flavorings