“Vaping, Smoke & Mirrors”
Janet F. Williams, M.D., FAAP
UTHSC-San Antonio School of Medicine
Department of Pediatrics

Disclosure
Janet F. Williams, MD, FAAP has no relationships with commercial companies to disclose.

Learning Objectives
At the end of this presentation, the participant will be able to:
1. Recount history, epidemiology, pathophysiology and health risks related to the use of e-cigarette & electronic nicotine delivery systems (ENDS).
1. Discuss ENDS marketing to youth, the array of products available, and enacted regulatory actions.
1. Implement ENDS-related health advocacy and distinguish ENDS use from tobacco cessation.

U.S. Tobacco Use & Events 1900 - 2012

Smoking: Exposure & Pathophysiology
- First-, second- & third-hand health risks and significant contributor to cardiovascular morbidity & mortality.
- Increases oxidative stress.
  - Oxidation of low-density lipoprotein cholesterol
  - Inflammatory processes are triggered.
- Contributes to all phases of atherosclerosis; thrombosis.
- Combustion particles produced from traditional smoking release hundreds of chemicals that are inhaled.

Smoking: Exposure & Pathophysiology
Associated with:
- Fetal health issues
- Infant health; SIDS
- Cancer - most
- Lung disease – COPD
- IBD; GERD
- Macular degeneration
- Periodontal disease
- DM, RA, bone health, etc.

USDHHS, 2012
Vaping: What is it really?

- Vaping = inhaling the vapor produced by an electronic nicotine delivery device.
- Perceived benefit of electronic devices is bypassing the ‘conventional’ combustion process; thus, minimizing risk of exposure to nicotine and other dangerous chemicals.

Brief History of Electronic Cigarettes

- 2008 – WHO called for rigorous study to test smoking cessation aid claim.
- 2011 – The court held that e-cigarettes can be sold & (FDA) regulated as ‘tobacco products’ rather than drugs/devices, but not marketed for therapeutic purposes, i.e. smoking cessation.
- By 2014:
  - 200+ different brands
  - $1.7 billion industry
  - Projected 10-year growth to $10 billion
  - Without FDA regulation, nicotine dose ranges 8 – 100 mg/ml/cartridge

Brief Anatomy of an E-cigarette

- Three main parts:
  - Rechargeable lithium battery
  - Vaporization chamber
  - Cartridge
- Cartridge use = pack of 20 tobacco cigarettes
- Buy new
- Refill with e-liquid (e-Juice)

Electronic Nicotine Delivery Systems (ENDS)

- 1st Generation
  - Mimic ‘analog’ cigarettes. Require lithium batteries with prefilled liquid cartridges that are atomized and create vapor once heated.
- 2nd Generation
  - Similar but stronger lithium atomizer. APV or Advanced Personal Vaporizers. Vape pens. Refillable cartridges.
- 3rd Generation
  - Vape mods. Mechanical mods. Strongest lithium capabilities. User can adjust intensity of atomization. ‘Open system’ device.

Youth Use Soars

- 2011 National Youth Tobacco Survey (NYTS) asks, E-cig use?
- NYTS 2011 – 2013:
  - Middle school students ‘ever use’ rose from 1.4% to 3%
  - Current use (past 30 days) rose from 0.6% to 3.9% (a 650% increase)
  - High school students ‘ever use’ rose from 4.7% to 11.9%
  - Current use rose from 1.5% to 13.4% (a 890% increase)
- Other surveys higher rates found: current 18%; ever 29%.
- Highest use: Males, non-Hispanic white, Hispanic
High School Student Use Soars

- From 2013 to 2014:
  - High school students’ use tripled from 4.5% (660,000) to 13.4% (2 million).
- Data from 2011-2014 National Youth Tobacco Surveys

Middle School Student Use Soars

- From 2013 to 2014:
  - Middle school students’ use increased from 1.1% (120,000) to 3.9% (450,000).
- Data from 2011-2014 National Youth Tobacco Surveys

Hookah (Water Pipe or Narghile)

- Flavored tobacco mixture (shisha) burned using charcoal & flavored smoke inhaled (socially) through a long hose from a water bath.
- Honey, mint, licorice, fruit flavors, etc.
- Water does not filter out toxins: CO, nicotine, tar, heavy metals, aromatic hydrocarbons. Greater smoke exposure 90K ml/session vs. 600 ml/cig. Research shows may absorb more toxins than from cigarette use.
- Cancer, especially lung cancer, and infectious disease risks
- Marketed as safe alternative to smoking. (False claim)
- Newer forms: create vapor for inhalation
  - Use steam stones, but charcoal heat, so same toxins present
  - E-hookah (pen)

Marketing

- Tobacco industry spends over $10 billion/yr on marketing its products in the US alone.
- Media ads: Print, Radio, TV
  - Blu ads: 1000s X 48 networks
  - NJOY ads during Super Bowl
- Internet & social media promotion
- Youth-oriented sponsored &/or sampling events
  - Host of flavors. High youth appeal.
  - Cherry Crush, Chocolate Treat, Gummy Bear, Tropical Punch, Cotton Candy, Peachy Keen, Grape Mint, Melon Slush, etc.
  - Cartoon and popular characters. Celebrities promote in ads & life.
  - Point-of-sale advertising

Marketing Claims

- Smoke virtually anywhere – Have your freedom!
- No tobacco smoke – only vapor!
- Flavors made in the U.S.A.
- Smart alternative to smoking!
- No nicotine. No tar. No guilt!

Are ENDS introducing youth to nicotine addiction?

- Children Health Study = longitudinal follow-up study of students in 12 southern California communities
  - 11th & 12th graders surveyed January - June 2014
  - 24% reported ever-use of e-cigarettes
  - 9.6% reported current use of e-cigarettes
  - 40.5% current e-cig users NEVER used conventional cigs
- Los Angeles longitudinal follow-up: Is e-cig use among 14-yr-olds who never tried combustible tobacco associated with risk of initiating use of 3 combustible tobacco products (cigarettes, cigars, and hookah)?
  - Ever use of e-cigs predicted greater likelihood to report initiation of combustible tobacco use over the next year.
In cartridges, refill solutions, aerosols of ENDS

- Nicotine, plus other substances of known harm/potential harm:
  - Tobacco-specific nitrosamines
  - Aldehydes: formaldehyd, acetaldehyd, acrolein, etc.
  - Metals: cadmium, nickel, lead, chromium, arsenic
  - Volatile organic compounds: toluene, p.m-xylene, propylene glycol, etc.
  - Phenolic compounds
  - Polycyclic aromatic hydrocarbons: anthracene, phenanthrene, pyrene, etc.
  - Tobacco alkaloids: cotinine, myosmine, etc.
- Plus substances of undetermined harm:
  - Flavors
  - Carrier solvents: but are oxidized to same aldehydes as above
  - Drugs: (amino-tadalafil, rimonabant)
  - Particles

What’s in There?

- Juicemaster General = the company’s chief chemist, mixing 4 basic ingredients:
  - Certified organic vegetable glycerin (VG): Main base ingredient. Produces copious vapor. Poor flavor vehicle.
  - Propylene glycol (PG): Carries flavor well. Scant vapor.
  - Flavoring: Suspended in the PG. Food-grade, natural or artificial.
  - Pharmaceutical-grade nicotine: vary from 0 – 36 mg/ml.
    - Low strength: 0 – 6 mg/ml
    - Medium to high strength: 12 mg/ml and higher

Health Impacts

ENDS flavorings meet FDA safety guidelines for ingestion, but there is insufficient evidence for safety regarding inhalation.

- Ex: Diacetyl is butter-flavoring for food items, such as popcorn.
- Reports and evidence appearing that suggest diacetyl inhalation has led to obliterative bronchiolitis and other respiratory effects.

What are Other Concerns?

- Risks to the ‘vaper’ vs. ‘passive’ (second- or third-hand) exposure
- Propylene glycol, glycerol, nicotine, carbonyls and aerosol particulates
- Some hydrocarbon ingredients do not have established harm threshold.
- Heavy metals
- Indoor air quality
- Design flaws and leaks from cartridge reservoirs found.
- Long-term effects remain unknown.
- Other substances (of abuse) can be vaporized: cannabis, etc.
Health Impacts

- Adverse Effects:
  - The FDA does not endorse the safety of electronic devices for smoking cessation.
  - Reported adverse health effects from use & exposure to e-cigarettes.
  - Pneumonia
  - Seizures
  - Disorientation
  - Congestive heart failure
  - Hypotension
  - Other health problems

Health Impacts

- E-cigarettes vs. cigarettes
  - Call rate reflects exposure.
  - Both mostly aged 0-5 years: 51% vs 95%; e-cigs also 20 years and older (42%)
  - E-cig: Ingestion (69%), inhalations (17%), eye (8.5%), skin 5.9%. Cig ingestion (98%).
  - E-cig reported adverse effects 58% vs 36% cig calls, mostly nausea, vomiting, eye irritation.

Health Impacts

- American Association of Poison Control Centers:
  - In 2015 through July 31, AAPCC has received 1,983 reports of some type of ENDS and liquid nicotine exposure, i.e. ingested, inhaled, absorbed by skin or eye, etc. (Not all exposures are poisonings or overdoses.)

Health Impacts

- Nicotine Toxicity
  - Acute Nicotine Toxicity
    - LD 50 estimate = 0.8 -13 mg/kg
    - Early symptoms:
      - Vomiting, tachycardia, grunting respirations, truncal ataxia
      - Late Symptoms (0.5- 4 hrs)
        - Lethargy
        - Respiratory Failure
  - Liquid Nicotine Poisoning
    - Colorful, flavored liquid with inconsistent labeling and regulation.
    - Bottles not childproof, various sizes: 10 – 30 ml.
    - Ingestion of 5 ml (1 tsp) of 1.8% (18 mg/ml) solution could be lethal to 90-kg person.
    - Symptoms: vomiting, tachycardia, grunting respirations, truncal ataxia
    - Supportive care. Atropine or scopolamine to reverse cholinergic effects.

Advocacy

- AAP 2014 President James M. Perrin, MD, called for national leadership to address the urgent need for control of electronic delivery systems and their counterparts in order to protect children.
Advocacy

- In 2014, the FDA proposed a new ruling that would allow regulation oversight and...
  - require manufacturers to register and disclose their products’ ingredients with the FDA.
  - prevent tobacco companies from making health claims about e-cigarettes and other products without FDA review.
  - establish 18 as the nationwide minimum age to purchase e-cigarettes and all other types of tobacco products legally.
  - ban free samples and vending machine sales of e-cigarettes and all other tobacco products in areas accessible by children under age 18, such as shopping malls.
  - require warning labels for e-cigarettes and cigars.

Regulation of ENDS Sale to Minors

U.S. states prohibiting sales to minors, as reported Nov. 2014.

Prohibition of indoor smoking &/or ENDS Use

U.S. states prohibiting indoor smoking and/or ENDS use, as reported Nov. 2014.

Regulation in TEXAS

- Texas SB 97: Went into effect 10/01/2015.
  - Includes prohibition of sales to minor; consequences for minor found to possess, purchase or consume e-cigarette.
  - All e-liquids sold in Texas must have a child-resistant cap unless sold as pre-filled cartridges. Also applies to e-liquids from out-of-state sales shipped into Texas.
  - Retail locations must post a notice that includes warnings and dangers for minors as well as related fines and misdemeanors (Class C) for purchasing an e-cigarette.

E-cigarettes & Smoking Cessation

- Cochrane Database Systematic Review 2014
  - Claims for use to reduce smoking risks, aid smoking cessation
  - Identified 13 studies: 2 RCT, 11 cohort studies
  - Only two studies showed ‘EC helped smokers stop long-term’ compared with placebo EC. (Small number, results GRADE ‘low,’ wide confidence intervals, so need more research.)
  - One trial showed no difference compared with nicotine patches.
  - Possibly, for those unable to quit, may help reduce cigarette consumption.
**Tobacco Use Cessation**

Counseling the patient (or parent) trying to use electronic devices for tobacco/cigarette cessation:

- Offer support and acknowledge their quit attempt(s)
- Counsel about very limited evidence of effectiveness or safety of electronic device use for this purpose.
- Redirect to FDA-approved cessation therapies:
  - OTC Nicotine gum, patch, lozenge
  - Rx Pharmacotherapy: bupropion, varenicline
  - Combine with counseling, support group
- Assess readiness to quit during each patient visit.

---

**Tobacco Use Cessation**

Counseling the patient (or parent) interested in cessation:

- 2 A's + R: Ask, Assist, Refer
- Motivational enhancement/Intervention
- Don’t Be Silent About Smoking social marketing campaign: www.talkforyourpatients.org
- 5 R's when not ready: Relevance, Risks, Rewards, Roadblocks, Repetition
- Medicaid coverage reimburses 6 sessions/12 mo. for all

---

**Cessation Resources & Patient Education**

- Quitline: 1-877-YES-QUIT or 1-800 QUIT NOW
  - Toll-free #, trained counselor; free series, Eng/Span/other
  - www.naquitline.org All 50 states, PR, Guam, D.C.; Canada, Mexico
- National Cancer Institute - Free expert help:
  - Quitline 1-800-44U-QUIT
  - quitSTART apps – free, made for teens (adults OK, too)
  - SmokefreeTXT – mobile text messaging; free; 24/7; for ages 13 – 99)
  - Facebook group; IM; SmokefreeMOM, etc.
  - Quit Plan

---

**Cessation Resources & Patient Education**

- Centers for Disease Control and Prevention: www.cdc.gov
  - Connected to http://Smokefree.gov
  - Research, fact sheets, reports
  - Best Practices; State & community resources
  - Social media smoking-related tips and topics
  - NIDA for TEENS: Drug Facts

---

**Cessation Resources & Patient Education**

- American Academy of Pediatrics: www.aap.org
  - AAP Resource links: www.HealthyChildren.org , etc.
  - Section on Tobacco Control – Training/CME
  - Counseling techniques & cessation training for clinicians
  - Julius B. Richmond Center of Excellence – Resources to protect families from tobacco and secondhand smoke risks
  - Comprehensive listing of cessation plans, resources, online tools

---

**Cessation Resources & Patient Education**

- American Cancer Society: Quit For Life program (phone/Web)
- American Lung Association: Freedom from Smoking adult program; Tips for Parents to talk with kids; List of smoke-free colleges
- Provider Toolkit - http://tobaccodependence.chestnet.org American
  - College of Chest Physicians: Tobacco Dependence Treatment Toolkit
- Pharmaceutical companies
  - Interactive cessation programs/tools for patients & providers
Conclusions

- ENDS are heavily marketed to youth.
- **DO NOT** believe ENDS only produce harmless “water vapor.”
  - The full extent of vaping’s direct health & environmental effects as well as passive exposure to vaping are currently unknown.
  - Use is rapidly rising in the U.S., particularly by youth. Vaping does not preclude tobacco use and may predispose to smoking.
  - Research evidence supports the Surgeon General in warning minors, pregnant women and women of child-bearing age against using nicotine-containing products, including ENDS.

**The ENDS**

Conclusions

- The FDA **DOES NOT** approve ENDS as a tobacco quit-aid.
- SB97 becomes Texas law October 1, 2015, prohibiting the sale of ENDS to minors, and imposing consequences to vendors and to minors found in possession.
- As part of routine medical home care and safety advice, all patients and families should be screened for tobacco & nicotine use, smoke exposure, and ENDS vapor & liquid nicotine exposure risks.