Electronic Nicotine Delivery Systems (ENDS):
To Vape or Not to Vape?
With apologies to Shakespeare’s Hamlet!

Maureen O’Brien MS, RN, CNS, PMHCNS-BC, CTTS-M
Clinical Nurse Specialist
Certified Tobacco Treatment Specialist
Tobacco Treatment Program
Department of Psychiatry and Behavioral Science

Objectives

• Describe the health consequences of smoking and 50 years of progress!
• Describe the various types of ENDS products.
• Discuss the promise or peril of ENDS Products
  • How effective are ENDS products in helping people quit?
  • Will ENDS products encourage or discourage youth smoking?
  • How safe are ENDS products to use?
  • Will ENDS products normalize smoking?
NYC adult smoking prevalence has declined by 35% since 2002

The Health Consequences of Smoking: 50 Years of Progress
A Report of the Surgeon General
**Tobacco: Nicotiana tabacum**

- Poisonous plant
- 2 m high, has large leaves & pink flowers.
- Nicotine:
  - Colorless oily liquid chemical
  - Sharp hot taste

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**Chemicals in a Cigarette**

There are more than 4000 chemicals in a cigarette:

- Acetone (nail polish remover)
- Carbon Monoxide (car fumes)
- Acetic acid (vinegar)
- Formaldehyde (preserver)
- Arsenic (poison)
- Ethylamines (insecticide)
- Butane (lighter fluid)
- Nicotine (addictive drug)
- PAH (induces mutation of the P53 gene, major cause of lung cancer)
- Acylamines: damage to DNA of bladder cells
- Benzopyrenes: DNA damage to cervical cells & found in the cervical mucus
- Benzene: chromosomal damage to immune cells leading to acute myeloid leukemia (AML)

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**Smoking – Related Health Risks: A to Z**

- Aortic aneurysm
- Asthma
- Atherosclerosis
- Bladder Cancer
- Bronchitis
- Cervical Cancer
- Chronic airway obstruction
- Colorectal Cancer
- Complications with pregnancy
- Early menopause
- Emphysema
- Esophageal cancer
- Heart attack
- Head & Neck cancers
- Irregular menstrual bleeding
- Ischemic heart disease
- Kidney cancer
- Larynx cancer
- Liver Cancer
- Lower birth weight
- Lower lung function
- Lung cancer
- Mouth cancer
- Myeloid Leukemias
- Pancreatic cancer
- Peripheral vascular disease
- Pneumonia/influenza
- Premature skin wrinkling & aging
- Preterm deliveries
- Pulmonary heart disease
- Reduced fertility
- Reduced oxygen to placenta
- Respiratory TB
- Rheumatic heart disease
- Stomach cancer
- Stroke
- Sudden cardiac death
- Sudden infant death syndrome (SIDS)
- Throat cancer
- Ureter cancer
Smoking Related Health Risks:
U.S. Surgeon General’s Report 2014

- In the United States, smoking causes:
  - 87% of lung cancer deaths
  - 32% of CAD deaths
  - 78% of all cases of COPD
  - One out of three cancer deaths
  - Colorectal and liver cancer
  - Failure rate of treatment for all cancers
  - Diabetes mellitus
  - Rheumatoid arthritis
  - Immune system weakness
  - Increased risk for tuberculosis disease and death
  - Ectopic (tubal) pregnancy and impaired fertility
  - Graft lip and cleft palates
  - Erectile dysfunction
  - Age-related macular degeneration
  - Diminishes overall health status, impairs immune function, and reduces quality of life.
- Secondhand smoke exposure is now known to cause strokes in nonsmokers.


Prevalence of Smoking and Interest in Quitting In The U.S. Adult Population

Smokers: 34.9%
Current Smokers: 15.1%
70% Interested in quitting
30% Lack the confidence or Not Interested

Source: http://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/

New York State

- Nationally the prevalence of cigarette smoking among adults was 15.1%.
- Currently the prevalence of cigarette smoking among adults ages 18-24 in New York is 14.6% and adults ages 25 and older is 11.7%.
- Putnam County rates are 13.9%
- Adults with poor mental health, less than a high school education or annual incomes of less than $25,000 smoke at much higher rates than the general adult population.

Source: https://www.health.ny.gov/prevention/tobacco_control/
New York State

- About 35,000 high school students smoke. The average age they smoked a whole cigarette for the first time was at 13 years old.
- One-third of whom will die prematurely as a direct result of smoking.
- More than 200,000 children are still exposed to secondhand smoke at home.
- New York State residents’ tax burden from smoking-related healthcare costs is $1,430 per household.
- Annual health care costs in New York State directly caused by smoking is $10.39 billion.

Source: https://www.health.ny.gov/prevention/tobacco_control/

United States PHS Guidelines: Treating Tobacco Use and Dependence

- 1996 - Initial Guideline published
  - Literature from 1975 - 1996
  - Approx. 3,000 articles
- 2000 - Revised Guideline published
  - Literature from 1975 - 1999
  - Approx. 6,000 articles
- 2008 - Updated Guideline published
  - Literature from 1975 - 2007
  - Approx. 8,700 total articles

Tobacco Cessation Pharmacotherapy Guidelines

- Nicotine Transdermal System (Patch) OTC
- Nicotine Gum OTC
- Nicotine Lozenge OTC
- Nicotine Inhalation System Prescription
- Nicotine Nasal Spray Prescription
- Zyban / Wellbutrin Prescription
- Chantix (Varenicline) ** Prescription
ENDS Products Facts
Electronic Nicotine Delivery Systems

- ENDS represent an evolution in a long history of tobacco products in the United States, including conventional cigarettes.
  - Back in 1965, U.S was looking to develop a “safer cigarette” and obtained a patent
  - 2003 China developed and perfected the e-cigarette
  - 2008 the e-cigarette was part of the U.S. market
- ENDS use has increased at an alarming rate
- Sold in more than 50 countries around the world
- In the U.S., an estimated 1 million smokers have switched from traditional cigarettes to electronic cigarettes
- ENDS products are the most commonly used tobacco product among youth in U.S.
  - The e-cigarette is considered a tobacco product under the Family Smoking Prevention and Tobacco Control Act

Four Generations of ENDS Products

- First Generation: E-cigarette... “cigalike”...
  - disposable and rechargeable

Four Generations of ENDS Products

- Second Generation: Vapor... ...
  - Decorative and refillable with E-Juice/Smoke juice

Four Generations of ENDS Products

- Third Generation: Tanks and High voltage devices
Four Generations of ENDS Products

• Fourth Generation: High voltage device—Juul or Juuling
  • A small black electronic cigarette that takes the shape of an elongated flash drive
  • So tasteful that the user is unaware he/she is inhaling a pack of cigarettes with each flavor packed pod they finish.

How ENDS Products work?

• Inhale on a mouthpiece of a device capable of delivering nicotine in aerosolized form
• Mimics the ritual of smoking a cigarette
• Battery-operator vaporizer heats a liquid solution
  • Solution turns into a vapor (looks like smoke from a cigarette)

How a Juul “Jewel” works?

• Heats up a cartridge containing oils to create vapor which quickly dissolves into the air.
• The device is small enough to fit in a closed fist (does not mimic the act of smoking).
• Has a sleek, tech-inspired design that resembles a USB flash drive.
• Comes in many appealing flavors such as mint, mango and crème brulee
Flavor and Nicotine Dose Options

Cartridges can be filled with a liquid form called “e-juice” or “smoke-juice” with multiple flavor and nicotine dose options

Malibu Rum Punch Belgian Cocoa Shamrock Mint

Cotton Candy Gummy Bear Tutti frutti

Source: http://www.halocigs.com/

ENDS: Promise or Peril?

How effective are ENDS products in helping smokers quit?

ENDS: Promise or Peril?
**Who are the adults vaping?**

- E-cigarettes are used primarily by
  - current smokers (63%)
  - former smokers (24%), most of whom had quit in the past 4 years
- E-cigarette users are more likely to be:
  - Younger
  - Better educated
  - Higher income
  - Both genders
  - Dual users
- The main reasons for e-cigarette use center around perceptions that they are less harmful than cigarettes to users and others

**How effective are ENDS products in helping smokers quit?**

- FDA has not approved electronic cigarettes as an effective and safe smoking cessation treatment
- No compelling evidence that e-cigarette helps smokers quit tobacco smoking
- Studies show that using both e-cigarettes and traditional cigarettes encourage dual smoking not quitting
- Two RCTs have been conducted
  - Bullen et al, 2013: Potential modest effect (7.3% vs. 5.8% with nicotine patches, 4.1% with placebo e-cigs)
  - Caponnetto et al, 2013: Evidence for dual use; tobacco smokers continue to smoke while using e-cigarette, potentially increasing total nicotine intake

**How effective are ENDS products in helping smokers quit?**

- Soneji et al, 2018: “Quantifying population-level health benefits and harms of e-cigarette use in the United States”. The study looked at the risks vs benefits of e-cigarettes
- Findings:
  - ENDS may be beneficial if they reduce smoking rates or prevent or reduce the known adverse health effects of smoking.
  - ENDS may also be harmful, particularly to youth, if they increase the likelihood that nonsmokers or former smokers will use combustible tobacco products or if they discourage smokers from quitting.
  - Controversy over e-cigarettes persist because we do not yet know if e-cigarette use results in more benefit than harm at the population level!
How effective are ENDS products in helping smokers quit?

Recent Trends in E-cig use among Cancer Patients (n=1074, 2012-13)

E-cig users were more likely to report:

- more prior quit attempts (p=.012)
- smoking more cigarettes per day (p=.047)
- greater nicotine dependence (p<.001)

- One year 7d pp smoking abstinence was equivalent for e-cig users (44.4%) and non-users (43.1%)

Borderud et al, 2014, Cancer

ENDS: Promise or Peril?
Will ENDS products encourage or discourage youth smoking?

Tobacco Use* Among Middle School Students in 2016

<table>
<thead>
<tr>
<th>Tobacco Product</th>
<th>Overall</th>
<th>Females</th>
<th>Males</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any tobacco product</td>
<td>7.2%</td>
<td>5.9%</td>
<td>8.3%</td>
</tr>
<tr>
<td>Electronic cigarettes</td>
<td>4.3%</td>
<td>3.4%</td>
<td>5.1%</td>
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<tr>
<td>Cigarettes</td>
<td>2.2%</td>
<td>1.8%</td>
<td>2.5%</td>
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<td>Cigars</td>
<td>2.2%</td>
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<td>2.7%</td>
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<tr>
<td>Smokeless tobacco</td>
<td>2.2%</td>
<td>1.5%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Hookahs</td>
<td>2.0%</td>
<td>1.9%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Pipe tobacco</td>
<td>0.7%</td>
<td>0.6%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Bidis</td>
<td>0.3%</td>
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<td>0.4%</td>
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**Will ENDS products encourage or discourage youth smoking?**

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**ENDS: Promise or Peril?**

**How safe are ENDS products for use?**

The U.S. Surgeon General has concluded that ENDS products can expose users to several potentially harmful chemicals!

- **Nicotine**
  - Nicotine is an addictive substance, and almost all e-cigarettes contain nicotine
  - Experienced users learn how to use e-cigarettes in a way that increases their exposure to nicotine...the more nicotine used, the greater the potential for addiction.
  - An average cigarette yields about 1 mg of absorbed nicotine......1 pod for a Juul is equal to about 1 ppd or 20 mg of absorbed nicotine.
  - Vapor also delivers secondhand (passive) exposure that may cause throat irritation and respiratory distress

How safe are ENDS products for use?

- Vapor is not solely water! May contain:
  - propylene glycol/glycerin
  - formaldehyde
  - carbonyls
  - flavor additives
  - tobacco-specific nitrosamines
  - heavy metals
  - diacetyl:
    - a buttery-flavored chemical often added to food products such as popcorn, caramel, and dairy products. However, when inhaled, Diacetyl can cause a serious and irreversible lung disease commonly known as "popcorn lung."


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How safe are ENDS products for use?

- Absorption is related to the size of the particle.
  - Typically the nicotine from a lungful of smoke reaches the brain in 7–10 seconds and is absorbed in the lungs because the smoke particles are very small.
  - Aerosol droplets created by a vaping device are larger than smoke particles and can't get as deeply into the parts of the lung, so deliver nicotine through the mucosal surfaces of the upper aerodigestive tract** (including the lips, mouth, tongue, nose, throat, vocal cords, and part of the esophagus and windpipe).
- Nicotine reach the brain in about 30 seconds

Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4469966/

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How safe are ENDS products for use?

- By the smoker changing their technique, nicotine can be absorbed through the lung parenchyma in direct contact with aerosol (the portion of the lung involved in gas transfer - the alveoli, alveolar ducts and respiratory bronchioles.)**
- Techniques used to deliver more nicotine....
  - exhaling vapor slowly will extract more nicotine than exhaling quickly;
  - exhaling slowly through the nose will extract more nicotine than exhaling straight through the mouth
  - exhaling slowly and using the lips to bulge the cheeks while using the tongue to force the vapor out around the inside of the cheeks will extract more nicotine.

Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4469966/
How safe are ENDS products for use?

Is it safe to inhale ENDS flavorings??

- Some manufacturers claim their flavorings are as safe as food additives
- What's the Truth?
- Flavors in ENDS products: are NOT SAFE WHEN INHALED!!!


How safe are ENDS products for use?

The 2016 U.S. Surgeon General Issues Report on E-Cigarette Use Among Youth states:

- The flavors in e-cigarettes are one of the main reasons youth use them.
- E-cigarette aerosol is not safe
- E-cigarette use is strongly associated with the use of other tobacco products among youth and young adults.
- Most importantly, e-cigarette use among youth is now a significant public health concern and steps must be taken by parents, educators and especially policymakers to discourage use of e-cigarettes

Source: Center for Public Health and Tobacco Health Policy

How safe are ENDS Products for use?

- Nicotine levels in e-cigarette cartridges are a concern! The liquid solution can contain up to 24mg or more of nicotine (a cigarette contains about 1 mg)
- Smoke juice is dangerous to kids & pets if ingested.
- Nicotine poisoning can occur.
  - 1 tsp. (10 mg) nicotine can kill a child
  - 1 Tbsp (30-60 mg) kills an animal or adult

Source: Center for Public Health and Tobacco Health Policy
How safe are ENDS Products for use?

- Increase in calls to poison control centers have increased by over 200%
  - In 2011, 271 cases were reported
  - In 2014, 3,783 calls were reported
- 51% of all cases involved exposure among children younger than 5 years of age.
- 42% of the poison calls involved people age 20 and older.
- Several deaths have been reported related to these poisonings.

Source: Center for Public Health and Tobacco Health Policy

How safe are e-cigarettes for use?

How Prevalent Are Nicotine Poisoning Cases?

<table>
<thead>
<tr>
<th>Year</th>
<th>Calls</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>23 Calls</td>
</tr>
<tr>
<td>2012</td>
<td>480 Calls</td>
</tr>
<tr>
<td>2013</td>
<td>1,543 Calls</td>
</tr>
<tr>
<td>2014</td>
<td>3,763 Calls</td>
</tr>
<tr>
<td>2015</td>
<td>2,200 Calls (through Aug 11)</td>
</tr>
</tbody>
</table>

Source: www.aapcc.org/alerts/e-cigarettes/

How safe are ENDS products for use?

- Child Nicotine Poisoning Prevention Act
  - Enacted in January 2016
  - This law requires any container of liquid nicotine that is sold, manufactured, distributed, or imported into the United States to be placed in packaging that is difficult to open by children under 5 years of age.

Source: Center for Public Health and Tobacco Health Policy
ENDS: Promise or Peril?
Will ENDS products renormalize smoking?
Will ENDS products renormalize smoking?

Activities of the E-cigarette Companies

- The e-cigarette market has grown and changed rapidly, with notable increases in total sales of e-cigarette products, types of products, consolidation of companies, marketing expenses, and sales channels.
- As prices of e-cigarette products have declined, sales have sharply increased.
- E-cigarette marketing approaches have been used in the past for marketing conventional tobacco products to youth and young adults.
- E-cigarettes are marketed by promoting flavors and using a wide variety of media channels that have broad reach among youth:
  - Television
  - Point-of-sale
  - Magazines,
  - Promotional activities
  - Radio, and the Internet.

Source: Center for Public Health and Tobacco Health Policy

Will e-cigarettes renormalize smoking?

Flavor and Nicotine Dose Options

Cartridges can be filled with a liquid form called "e-juice" or "smoke-juice" with multiple flavor and nicotine dose options:

- Malibu Rum Punch
- Belgian Cocoa
- Shamrock Mint
- Cotton Candy
- Gummy Bear
- Tutti Frutti
Cigarette ads and smoking scenes in movies and television DOUBLE the chances of teens starting to smoke!

Marketing strategies to entice children smoke
ENDS: Promise or Peril?
The Facts on the FDA’s New Tobacco Rule

The FDA regulates all tobacco products: hookah, e-cigarettes, dissolvables (ORBS), smokeless tobacco, cigarettes, all cigars, roll-your-own tobacco, pipe tobacco, and future tobacco products that meet the statutory definition of a tobacco product.

- It requires health warnings on roll-your-own tobacco, cigarette tobacco, and certain newly regulated tobacco products
- Bans the distribution of free samples
- Manufacturers of newly regulated tobacco products that were not on the market as of February 15, 2007, will have to show that products meet the applicable public health standard set by the law.
- Restricts youth access to newly regulated tobacco products by:
  - not allowing products to be sold to those younger than 18 and requiring age verification via photo ID
  - not allowing tobacco products to be sold in vending machines (unless in an adult-only facility).

Source: https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm

AACR/ASCO ENDS Policy Statement

- Supports regulation of all ENDS by the FDA
- ENDS manufacturers should be required to register with the FDA
- Report all ingredients and nicotine concentration
- Encourages FDA to require health warnings and safety labels on all products
- Encourages FDA to restrict youth-oriented marketing of ENDS
  - Restrict gifts/giveaways, hats/T-shirts, youth-oriented advertising
  - Prohibit ENDS liquid from containing candy and youth-friendly flavors
  - Encourages prohibiting use of ENDS anywhere combustible cigarette use is banned (second and third hand smoke exposure)
  - Require child proof e-liquid refill bottles
- Encourages developing standards for regulation of ENDS internationally

Summary

• Tobacco use in any form is not safe
• ENDS products are considered tobacco products
• E-cigarette use is rising rapidly among adults and youth
• E-cig users are more likely to be nicotine dependent, consume more cigarettes per day, and have made fewer prior quit attempts
• No evidence that e-cig use increases the likelihood of achieving smoking abstinence
• Without FDA regulation, products are being used without evidence of safety or effectiveness in helping smokers quit
• Safe, effective cessation medication alternatives exist
• Counseling + evidence-based cessation medications greatly increase quit success

Stay Tuned, more science is coming!

QUESTIONS