Electronic Nicotine Delivery Systems
AKA Electronic Cigarettes or Vape Pens
Fact or Hype?

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Objectives of this presentation

Are ENDS regulated? Tested?
Who is using them and why?
Are they safe?
Are they a cessation device?
What is the public health stance?

More questions than answers!
What are electronic nicotine delivery systems (ENDS) or electronic cigarettes (e-cigarettes)?
Electronic Nicotine Delivery Systems (ENDS)

Many don’t recognize (or use) the term “electronic cigarette”—they are known as “vape pens” or “mods” or ??
Products designed to deliver nicotine to user in aerosol ("vapor") form
ENDS

Made to look like cigarettes, cigars, pipes, hookahs, pens
And many other things
What have you heard about these products?

What are users saying?
What are sellers saying?
What do manufacturers say?
How are they advertised?
From users, sellers, manufacturers

Use of ENDS commonly called “vaping”

Promoted by manufacturers, sellers and users as safe-producing water vapor not smoke

No matter the name – sends nicotine to the brain through the lungs
Who makes ENDS and liquids?

- Reynolds America
- Lollilard
- Altria
- Njoy
- International
- Many others
How are they regulated?
ENDS status with Food & Drug Administration (FDA)

In April 2014, FDA issued proposed regulations identifying ENDS as tobacco products with:

* restrictions on sales to minors
* pre-market review
* mandated ingredient listing

Regulations are pending
Cessation Device?
No electronic nicotine delivery system can be marketed as a smoking cessation device without going through the rigorous approvals of FDA.
FDA has not evaluated any ENDS for safety or effectiveness

Early on, in limited laboratory studies, FDA found issues indicating poor quality control*:

* cartridges labeled 0 nicotine did contain nicotine
* 3 different cartridges with the same label gave off very different amounts of nicotine with each puff

*Subsequent studies by independent researchers have found the same
E-cigarettes have not been fully studied, so consumers currently don’t know:

"the potential risks ... when used as intended"

"how much nicotine or other potentially harmful chemicals are being inhaled"
From FDA’s website—Tobacco Products
It is now illegal to sell ENDS products to anyone under 18

Or

For anyone under 18 to possess, use, buy
Who is using them and why?
Adult (18+) use of ENDS in Missouri 2014

Behavioral Risk Factor Surveillance System:

7% use every day or some days

• 45.7% to quit smoking
• 17% to try a new way of smoking
• 13.7% because friends or family use
• 4% to smoke in places that do not allow smoking

Missouri Tobacco Quitline callers:

• 9% to cut down
• 44% to quit
• 55% when can't use other products
• 7% use every day
• 58% use more than one cartridge a day
Youth use of ENDS in Missouri 2015

High school current use: 22%* of all
★ 68% of current smokers
★ 9.6% of non-smokers

Middle school current use: 7.2%* of all
★ 83% of current smokers
★ 3% of non-smokers

Youth Risk Behavior Survey & Youth Tobacco Survey

* Only 11% & 2.4% currently smoke cigarettes
Marketing & commercial appeal

Why do ENDS appeal to youth?
Marketing & commercial appeal

Promoted heavily online & more widely searched than tobacco products or quitting products.
On-line availability
High tech
ANY MOOD. ANY STYLE. EVERY VAPE.

world’s first

VAPOUR ZEUS
The only flavor of cigarettes is menthol. ENDS and e-juice are available in many flavors.
Marketed where cigarettes can’t be

Take Back Your Freedom
with Stephen Dorff

Using messaging reminiscent of the past

WHY QUIT?
SWITCH TO BLU

Visit blucigs.com

Lady Slim
Electronic Cigarette

Our best seller model especially to women who like a slim e-cigarette. It is super thin and extremely light compared to any a cigarette models.
ENDS deliver nicotine to the brain through the lungs.
Nicotine

- Is addictive
- Is toxic to developing fetuses
- Is a poison
Nicotine is addictive

The DeNoble Files–Your Brain

https://www.youtube.com/watch?v=4tg_rMiOLnA
Nicotine affects the brain

The DeNoble Files–Earmuffs

https://www.youtube.com/watch?v=uFX9F-KD7co
Youth using nicotine

- Are more vulnerable to addiction than adults
- Are more likely to continue use
- May become more heavily addicted
- May have a harder time quitting
Nicotine is a POISON!

The number of poison exposure cases linked to ENDS liquids was:

- 1,543 in 2013, a huge increase from 460 in 2012
- *3,783 in 2014*
- *3,067 in 2015*
Why so many poisonings?

Can you find the candy?
Liquid nicotine or “e-juice”

Many devices are refillable with liquid nicotine.

Bottles come as large as 250 mL (about a cup) with nicotine concentrations of 0-72 mg/mL.

At the highest concentration a 250 mL bottle could have **18 grams** of nicotine.
Nicotine

A smoker absorbs ~1 mg of nicotine from a combustible cigarette

A 20 mg/mL ENDS cartridge has the nicotine of about 20 cigarettes

Studies show the average ENDS user consumes 3-5 mL of liquid nicotine a day, some use more than 15 mL a day

Daily inhaling aerosol from 3 mL liquid nicotine is similar in nicotine content to smoking 30 to 40 cigarettes
Liquid nicotine or “e-juice”

The estimated **fatal** dose of nicotine for **adults** is 30-60 mg.

The estimated **fatal** dose of nicotine for **children** is only 10 mg—approximately 4 drops of a maximum strength “e-juice” solution.
Common symptoms of nicotine overdose

- Extreme anxiety
- Cold sweats
- Dizziness
- Headache
- Muscle twitches
- Insomnia
- Tingling sensations
- Confusion
- Palpitations, fast pulse
- Increased blood pressure
- Fatigue and weakness
- Reduced appetite
- Stomach ache and nausea
- Chest pain
- Hearing or vision problems
- Seizures
Reported mild adverse effects of ENDS use

- Headache
- Chest pain/coughing
- Nausea/vomiting
- Dizziness
- Confusion
- Sore throat
- Blurry vision
Reported strong adverse effects of ENDS use

- Pneumonia
- Congestive heart failure
- Disorientation
- Seizure
- Low blood pressure
- Chest pain
- Second degree burns to face
- Loss of vision
What are other potential safety issues?
What’s in the fluid?

Quality of ingredients generally unknown

No requirement to declare all ingredients

Fluids are known to contain:

- nicotine
- flavorings
- humectants
Flavoring

On January 2014 there were at least 7,764 unique flavors

Often the same chemicals “generally recognized as safe” for food & drugs

But not known to be safe:

★ to inhale
★ to deliver nicotine
The primary route to FDA regulatory authority of flavor ingredients

Determines “GRAS” status (generally recognized as safe)

GRAS status applies only to human food, medicine (oral ingestion)
FEMA GRAS Status

No regulatory approval to use GRAS ingredients in ENDS

Claims by manufacturers that the ingredients have GRAS status are “false and misleading”
Some ingredients in flavoring

Diacetyl (used to give foods a buttery or creamy flavor)

*caused a severe & irreversible obstructive lung disease when inhaled by workers exposed to particles of it that were aerosolized (“popcorn lung”)

Acetaldehyde (sugar) for sweetness

*known to make nicotine more addictive
Humectant

Allows aerosol (vapor) production

Most common is propylene glycol

Propylene glycol is FDA approved for use in some products, but inhaling aerosolized nicotine in propylene glycol is not

Some studies show that heating propylene glycol changes its chemical composition, producing small amounts of propylene oxide, a known carcinogen.
Harmless water vapor?

It is claimed ENDS emit “harmless water vapor” so they must be safe

* Is it “just” water vapor?

Research is showing......
What is in the aerosol (vapor)?

Not a water vapor but an aerosol

Aerosol has been found to contain:

* nicotine
* propylene glycol
* fine & ultrafine (UF) particles
* low levels of toxins known to cause cancer (at least 10 have been identified)
* nanoparticles of chromium, nickel, tin
What is in the aerosol?

Some with higher concentration of UF particles than cigarette smoke

- UF particles cause respiratory problems, exacerbate asthma, impair lung function
- Fine & UF particles constrict arteries, can trigger heart attack

WHY?
Particulate Matter Sizes

- Fine particles: \(~\) 2.5\(\mu\)m or smaller
- Ultrafine or Nanoparticles: \(~\) >1\(\mu\)m or microns to <100nm or nanometers
- Average Human Hair Diameter: \(~\) 100\(\mu\)m
- Human Red Blood Cell Diameter: 5\(\mu\)m
Secondhand aerosol?

May be less polluting than cigarettes, but still pollutes the air.

Emissions expose non-users to:

* nicotine at levels similar to secondhand smoke—a recent study showed the nicotine was absorbed by those around.

* fine and UF particles and volatile organic compounds (VOCs).
Secondhand aerosol?

Long term health effects on non-smokers are still unknown, but science on potential for negative consequences is mounting.
Existing research does not appear to warrant the conclusion that ENDS are “safe” in absolute terms.

ENDS are not emission-free; emit airborne contaminants that may be inhaled by both the user and those nearby.

ENDS should be considered a source of VOCs and particulates in the indoor environment that have not been thoroughly characterized or evaluated.
ENDS are advertised as:

A better-smelling, cheaper, guilt-free alternative to smoking

A way to circumvent smokefree laws & policies
Why be concerned about advertising to circumvent smokefree?

Using ENDS in public, smokefree areas can undermine smokefree policies & youth prevention efforts by:

"Making enforcement more difficult"

"Giving the appearance that smoking is acceptable"

People are being exposed in the belief that the aerosol is safe.
Cessation product?

ENDS are **not** FDA-approved cessation products.

4 prescription & 3 non-prescription smoking cessation products are FDA-approved:

- **RX:** Varenicline, Bupropion, Nicotine Inhaler, Nicotine Nasal Spray
- **OTC:** nicotine replacement patches, gum, lozenges

These products have been scientifically shown to be effective for smoking cessation and are safe when used as directed.
U.S. Preventive Services Task Force Recommendation on ENDS for Smoking Cessation

• Thus far, the U.S. Preventive Services Task Force (USPSTF) has made the strongest stance about ENDS

• In September 2015, the USPSTF “found the evidence on ENDS use as a smoking cessation tool in adults or adolescents to be insufficient.”

• The USPSTF was only able to identify two randomized, controlled trials that evaluated the effect of e-cigarettes on smoking abstinence in adults. These two studies found mixed results.

U.S. Preventive Services Task Force, 2015
Recent research on ENDS cessation potential

Use of Electronic Cigarettes Among State Tobacco Cessation Quitline Callers, Nicotine & Tobacco Research, May 2013

ENDS users were significantly less likely to have quit smoking 7 months after first calling the Quitline, compared with participants who had never tried ENDS.

Note: Authors affiliated with Alere Wellbeing, Inc. a Quitline Provider
Vaping encourages tobacco smoking?
Does vaping in e-cig ads affect tobacco smoking, urge, intentions, & perceptions in daily, intermittent, & former smokers? Health Communication, March 2015

When see vaping in person or on TV:
★ daily smokers more likely to crave cigarettes
★ former smokers less able to refrain from smoking

As opposed to the same who did not see the behavior
Recent research on quitting behaviors with ENDS


Compared with smokers who never used ENDS, the ENDS (ever) users were:

* significantly less likely to smoke fewer cigarettes
  * and

* significantly less likely to quit for 30 days or more

Ever-users were more likely to report a quit attempt, although not statistically significant

**Conclusion:** Smokers who have used ENDS may be at increased risk for not being able to quit smoking
Other issues of initiation & cessation potential

Surveys showing patterns of dual use (both ENDS & cigarettes) by both adults & youth

Nicotine is addictive & hard to break:

* current smokers may not realize they have not kicked the addiction
* former smokers, believing ENDS are safe, may return to nicotine addiction
Public health approach—cessation

”Can say there is no scientific evidence that ENDS help smokers quit

”Do know they are a nicotine delivery device—and nicotine is addictive

”Recommend only known, tested, safe, products for those trying to quit
Public health approach—safety

With many brands & too few studies yet, conclusions are not definite

We cannot say that they are unsafe—they may be safer than combustible cigarettes, but “safer” is not necessarily “safe”

Cannot say they are safe, but it does appear as if it is not “harmless water vapor”

* in fact, it is not “just” water
* in fact, it is aerosol, not vapor
Public health approach—secondhand smoke (aerosol) exposure

"Because of the unknowns surrounding the aerosol and

"Because ENDS mimic smoking

Public health is taking a cautious approach

"Most prohibit them in smokefree or tobacco-free policies for the
Why include in smokefree policies?

The standard is **Clean Indoor Air**

*not*

**Less Dirty Air**
Recent research on awareness/beliefs

Characteristics Associated With Awareness, Perceptions, and Use of Electronic Nicotine Delivery Systems Among Young US Midwestern Adults, AJPH, March 2013

More than 2/3 of young adults were aware of ENDS

A small proportion had tried/used in past 30 days

Despite the lack of scientific evidence, a large proportion of users & non-users thought they:

* can help people quit smoking
* are less harmful and less addictive than cigarettes
Recent research on users’ opinions

Vaping profiles and preferences: an online survey of electronic cigarette users, Addiction Research, Feb. 2013

Adults surveyed found ENDS:

* satisfying to use
* reduced cravings for tobacco cigarettes
* associated with very few immediate side effects
* tended to be used for a longer duration than NRT
Recent research on safety
Metal & Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette (EC) Cartomizer Fluid and Aerosol, PLOS One, March 2013

Concentrations of 9 of 11 metallic elements in ENDS aerosol were higher than or equal to the
Aerosol from ENDS products can contain high concentration of formaldehyde—a known carcinogen.

Researchers conducted a detailed chemical analysis of the aerosol’s liquid droplets.

Devices dialed up to highest settings had “masked” formaldehyde—could increase the likelihood of formaldehyde deposits in the lung.

Concentration was significantly higher than regular cigarettes—5 to 15 times higher.
Recent research on effect on non-users

Does e-cigarette consumption cause passive vaping? Indoor Air, April 2013

Fine particles, ultrafine particles, and volatile organic compounds were found in the air in increased quantity after the use of an ENDS.

This inhaled aerosol undergoes changes in the human lung.

Passive vaping must be expected from the use of ENDS.
Recent research on secondhand exposure


Non-user may be exposed to aerosol particles smaller than 1,000 nanometers

- similar in size to tobacco smoke and diesel engine smoke

Exact exposure depends on:

- chemical composition of liquid
- operation of the device
- user vaping preferences

Aerosol and gases produced contain nicotine, glycerin/glycols, artificial flavors, and other substances.
Recent research on what is in the aerosol

Reactive free radicals found in ENDS aerosols

These have been shown to be a causal factor in a variety of diseases.

Currently insufficient data to determine the potential harm from exposure to ENDS generated radicals.

Overall levels of radicals significantly lower than in combustible cigarette—degree of damage might be less, but depends on the identity and reactivity of the specific radicals produced.
Recent research on if ENDS use leads to smoking

High school students who had ever used ENDS at baseline were more likely than nonusers to report initiation of combustible tobacco use over the next year.

Past 6-month use of any combustible tobacco product: 30.7% for ENDS ever use vs. 8.1% for ENDS never use

Greater likelihood of use of any combustible tobacco product with odds ratios of 2.65 for cigarette, 4.85 for cigar, 3.25 for hookah
Switching to ENDS from cigarettes is not safe because:

- nicotine is harmful to developing fetus
- nicotine contributes to smoking related preterm delivery
- nicotine alters brain development
- nicotine is thought to contribute to SIDS