

Treating Nicotine Dependence: Where Do E-Cigarettes Fit Into Our Puzzle?

Northeast AHEC Lung Cancer & Smoking
Cessation Symposium



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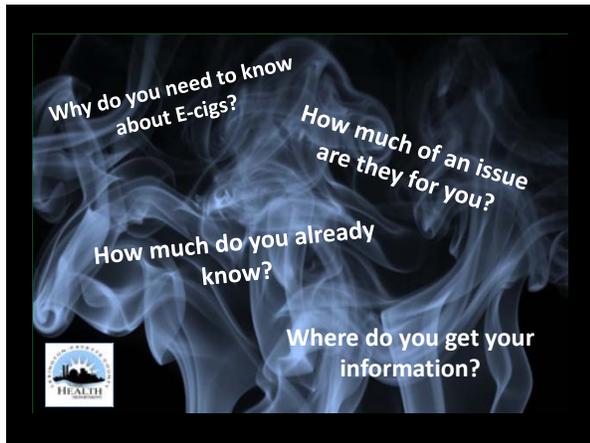
Thanks to Elizabeth Anderson-Hoagland from KY Tobacco
Prevention and Cessation Program for slide content and data

*e-cigarettes and ENDS (electronic nicotine delivery systems are used
interchangeably in this presentation)



WHAT AM I?





Objectives

1. Describe trends from past 5 years in use of e-cigarettes vs. traditional cigarettes
2. Illustrate best practice cessation guidelines for patients who use e-cigarettes
3. Recognize the 3 primary dangers of e-liquids, particularly to children
4. Outline the key components of most recent FDA regulation for e-cigarettes



How e-cigarettes work

Light simulates cigarette glow, indicates when device is ready for use and works as battery indicator

Electronic components include control circuits, pneumatic airflow sensor

Vaporizer atomizes the nicotine smoking liquid in the liquid container

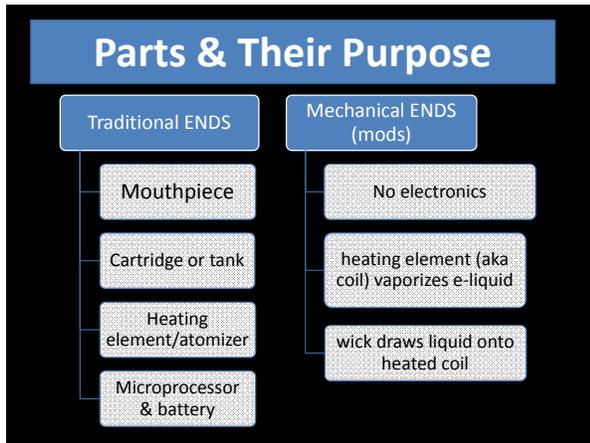
Nicotine liquid container

Nicotine levels compared

Electronic	Equivalent	Traditional
One e-cigarette	100 Puffs per cigarette	6-7 cigarettes
6-24 mg. E-cigarette with 24 mg of nicotine	Nicotine level Nicotine per puff 0.16 mg/puff	0.6-2.4 mg. Cigarette with 1.8 mg of nicotine 0.16 mg/puff

Sources: E-Cig, Winston-Salem Journal

McCLATCHY TRIBUNE



Conventional vs. E-Cigarettes

	E-Cigs
Particulate matter	↑
Tar	↓
Carbon monoxide	↓
Tobacco-specific Nitrosamines	↓
Formaldehyde	↔
Nicotine	↔
Short Term Health Effects	↔
Long Term Health Effects	?

Legend

More than cigarettes	↑
Less than cigarettes	↓
Depends upon product	↔

Americans for Non-Smokers Rights. Electronic Smoking Devices and Secondhand Aerosol. 2015. Available at: <http://no-smoke.org/pdf/ecigarette-secondhand-aerosol.pdf>.

Flavorings

- Diacetyl – *bronchiolitis obliterans* “popcorn lung”
 - Toffee, chocolate, caramel flavors
- Aldehydes – respiratory irritation, airway constriction
 - Dark chocolate and wild cherry flavors
 - Twice the recommended workplace safety limit for aldehydes vanillin and benzaldehyde
- Cinnamaldehyde – toxic to human lung cells in lab, swollen throats, mouth sores
 - Cinnamon flavors



Tanner PA, Karpinski CD, Brown JL, Luo W, Parkhiser D. Flavor chemicals in electronic cigarette fluids. *Toxicol Appl Pharmacol*. 2014;102:179-187. doi:10.1016/j.taap.2014.02.017.
 Behar RC, Davis B, Wang Y, Bahi V, Liu S, Tolbert P. Identification of toxicants in cinnamon-flavored electronic cigarette refill fluids. *Toxicol in Vitro*. 2014 Mar;28(2):109-108.

Objective #1

Describe trends from past 5 years in use of e-cigarettes vs. traditional cigarettes



Why Big Tobacco Loves Them

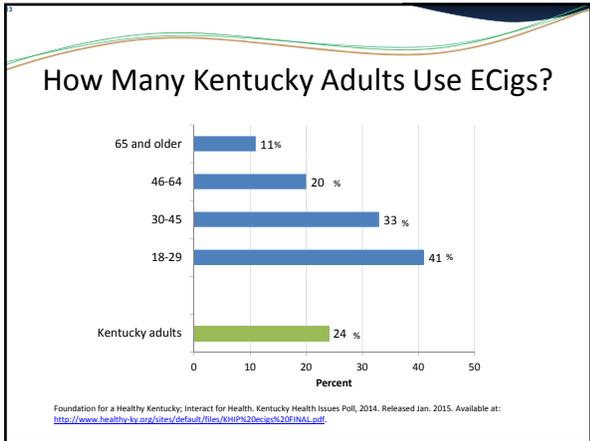
- Cheap to produce & import
- Easy to use with no break
 - ✓ Fast & effective delivery of nicotine
 - ✓ Appealing to young people
 - ✓ Create strong addiction quickly
- Until recently unregulated by FDA

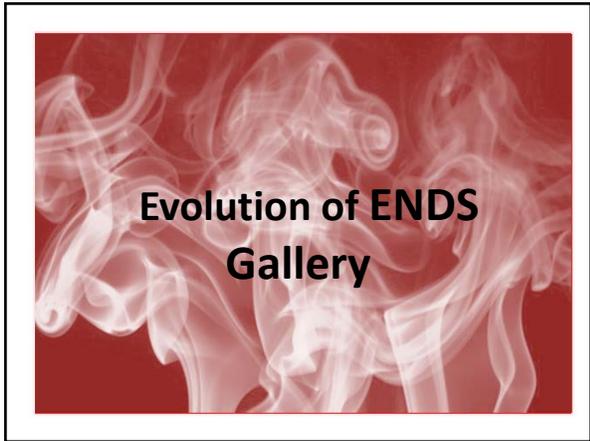


Why do people use e-cigs?

- Perceptions
 - ✓ Healthier than traditional cigarettes
 - ✓ Cessation aide
- Appealing to young people
- Easy to use with no break
- They taste good....over 2,000 flavors of e-liquid



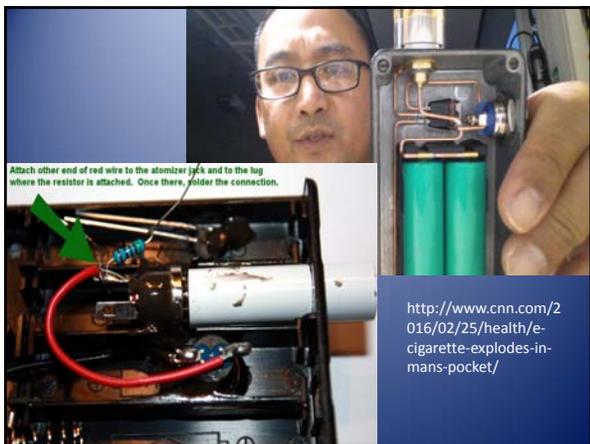




**No Way!
I'm not smoking!**







Next big thing: Temperature controlled devices

- Can vary temp by +/-10 degrees
- Logic = lower, controlled temp is safer
- Avoids overheating carrier liquids
- Prevent "dry puff"





YOUTH USE: Numbers

- Number of teens who use ENDS **tripled** between 2013 & 2014 (CDC, 2014)
- Teen tobacco use has fallen in recent years
- ENDS are predicted to reverse trend
- First studies (new area) suggest teens who use ENDS have a roughly **30% chance of smoking** traditional cigarette within 6 months

National Institute on Drug Abuse. Teens using e-cigarettes may be more likely to start smoking tobacco Retrieved from <https://www.drugabuse.gov/news-events/news-releases/2015/08/teens-using-e-cigarettes-may-be-more-likely-to-start-smoking-tobacco> on March 21, 2016

Not Just Youth

VAPE VS JOINT

338°	Average Temperature	2,000+°
about 95%	% of Surviving Cannabinoids	about 12%
seconds	Time Cannabis is Absorbed	about a minute
can be inhaled but is very	Stealth	Not very stealthy
creates many toxic by-products	Health	many toxic by-products from smoke
1-2 minutes to pack, draw & use	Prep Time	3-5 minutes to roll joint

VAPING WISE.COM

Butane Honey Oil (BHO)

	70-80% THC	Wax
~\$100 gram	710	Butter

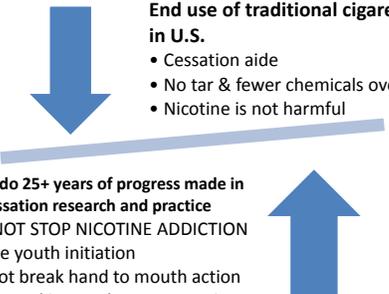


Objective #2

Illustrate best practice cessation guidelines for patients who use e-cigarettes



The Debate...Cessation Aide or Just New Product?



End use of traditional cigarettes in U.S.

- Cessation aide
- No tar & fewer chemicals overall
- Nicotine is not harmful

Will undo 25+ years of progress made in cessation research and practice

- DOES NOT STOP NICOTINE ADDICTION
- Increase youth initiation
- Does not break hand to mouth action
- Portray smoking as glamorous again

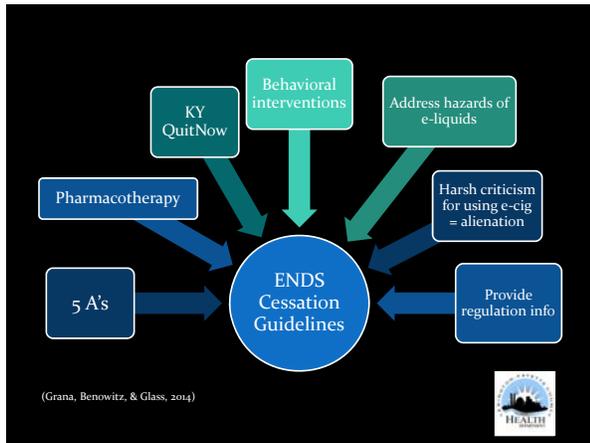


Do e-Cigarettes help people quit smoking?



- Not FDA approved as cessation device
- U.S. Preventive Services Task Force Draft Recommendation released June 1, 2015 found **no evidence that e-cigarettes helped with smoking cessation**
- Have since waived on this statement somewhat (early 2016)





- Driving down numbers of people seeking cessation assistance
- "KY Smokers" do not typically like them
- Most common complaints when used with goal of cessation are mouth and throat irritation

1-800-QUIT-NOW

Other Countries

- UK's Medicines and Healthcare products Regulatory Agency (MHRA) approved a single e-cigarette for clinical use in late 2015
- *e-Voke*, distributed by British American Tobacco, can be "prescribed" as a cessation treatment by National Health Service providers
- In EU ENDS will be classified as tobacco-related products and regulated in 2016



<http://www.nhs.uk>

Rock and a Hard Place...

- Divided PH Community in its efforts to fight Big Tobacco
- Revived financial and marketing power of Big Tobacco
- INCREDIBLY easy for youth to use...don't realize they're ramping up nicotine addiction
- It's difficult to argue with heavy smokers who turn to ENDS & feel better quickly



Up & Down Data

- Some studies show e-cigs as effective as NRT
- Generally e-cig users are more likely to continue smoking regular cigarettes than non-users
- **Dual use is increasing**
- Very recent studies are most conflicting re: improved health outcomes and cessation among e-cig users (*UK study & PHS guidelines*)



Objective #3

Recognize the 3 primary dangers of e-liquids, particularly to children



Nicotine Poisoning



- Kentucky Regional Poison Control Center has reported a **333% increase** in calls about e-liquids
- Nationally poison control centers have seen a **161% increase** in calls about e-liquids
- In 2014 60% ALL calls to KY's poison control hotline were for ingestion of e-liquids by children less than 5 yrs old
- Ingestion of even small amounts can be fatal to a young child



WHAT'S IN THOSE THINGS?

E-LIQUID NICOTINE STRENGTH GUIDE

Regular Cigarette	E-liquid Nicotine
Unfiltered, very strong	Super High - 36mg
Full Flavored, Strong	Extra High - 24mg
Regular (most)	High - 16mg
Light	Med - 11mg
Ultra-light	Low - 8mg
Freedom from Nicotine!	No Nicotine - 0mg





- Children drawn to bright colors, scents, & flavorings
- 2,200+ flavors
- Prolonged skin exposure can be fatal to an adult
- Refills come in gallons with varying concentrations





Child Proof Packaging

- Until recently manufacture of liquid not regulated by FDA or other entity
- Inconsistent levels of nicotine
- No child proof packaging
- No ingredient lists
- Unknown effects



Legacy: Electronic Cigarette Fact Sheet, May 2014. Available at: [http://www.fda.gov/oc/ohrt/electronic-cigarette-fact-sheet-05-2014.pdf](#). Accessed Feb. 18, 2015.

Objective #4

Outline the key components of most recent FDA regulation for e-cigarettes



 *Quick history of regulation*

- April 2014: FDA promised regulation
- Child Nicotine Poisoning Prevention Act of 2015 that requires childproof signed 2015



May 6, 2016... "Deeming Regulation"
Gave FDA authority to regulate ENDS

- Effective August 8, 2016
- Includes "components"....e-liquids, vials, cartridges, tanks, drip tips
- Establishes *federal* minimum age of sale of 18 years old
- Vape shops that mix e-liquids considered manufacturers; subject to the requirements and restrictions for manufacturers
- Prohibits "**unapproved modified risk claims**" (provides formal process for making these claims)
- Requires submission to FDA of **ingredients and health documents for all tobacco products**

<http://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm>

What's NOT in the "Deeming Regulation"

- No ban on Internet sales
- No change to statutory grandfather date of February 15, 2007
- DOES NOT address childproof packaging

Warning Labels

- Requires new addictiveness labels for all tobacco products
- Must be permanently placed on main panel of product and/or carton
- Also required in advertising

"WARNING: This product contains nicotine. Nicotine is an addictive chemical"

<http://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm>

Substantial Equivalence

- **NEW** ENDS may not be legally marketed in the United States unless FDA has issued exemption
- If new product raises *different* health questions it is not substantially equivalent
- If **NEW** product meets following criteria it *may continue* to be marketed unless FDA issues order that new product is **NOT** substantially equivalent to an appropriate predicate product
 - It was commercially marketed after February 15, 2007 but before March 22, 2011
 - A *Substantial Equivalence Report* was submitted by March 22, 2011

<http://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm>

WHAT??

Substantial Equivalence...“has been found by FDA to either have same characteristics as a **PREDICATE TOBACCO PRODUCT** or has different characteristics than the predicate tobacco product but information submitted demonstrates that the new product does not raise different questions of public health”

Predicate Tobacco Product...“was commercially marketed in the United States (other than in a test market) as of Feb. 15, 2007, or a product previously found to be substantially equivalent by FDA and in compliance with the requirements of the Food Drug & Cosmetic Act (FD&C Act)”

<http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/SubstantialEquivalence/default.htm>

Research Challenges

- Use data available in large numbers have short-medium duration (1-2 yrs)
- HARD to study and compare use to traditional cigarettes & NRT
 - ✓ varying levels of nicotine in models and e-liquids
 - ✓ user variance, dual use
 - ✓ cannot dose exactly to compare to placebos for RCT
- Use and addiction rates are growing MUCH faster than research about long-term health effects and cessation

The “safer” question about e-cigs

Best Practice

- No conclusive answer....DO NOT recommend them
- Nicotine is the most addictive drug currently available...most ENDS deliver some level of nicotine
- Get VERY serious about importance of keeping tobacco, e-cigs, & e-liquids away from children
- 5 A's...2A's & R no longer considered sufficient

REFER TO CESSATION RESOURCES, every patient, every time (please!!!)
