

# **CE Course Handout**

# **E-cigarette-A Friend or A Foe?**

# Saturday, June 20, 2015 2:00pm-4:00pm





# **Objectives**

Upon completion of this course the participants will be able to:

- Discuss nicotine addiction and harm reduction in tobacco control
- Recognize limitations of nicotine replacement therapies
- Recognize different types and parts of e-cigarettes
- Discuss role e-cigarettes in harm reduction and cessation
- Evaluate safety, benefits and disadvantages of eciaarettes
- Describe the current status and future directions of ecigarettes regulations in US

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# Smoking by Age Groups

- 17.3% of adults aged 18-24 years
- 21.6% of adults aged 25–44 years
- 19.5% of adults aged 45–64 years
- 8.9% of adults aged 65 years and older
- 2013—18.1% of American adults smoked o 42.1 million o 20.5% men and 15.8% women
- 70% of adult smokers want to guit

source: http://www.cdc.gov/tobacco/data\_statistics/fact\_sheets/adult\_data/cig\_smoking/i

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# Nicotine Addiction

- Nicotine enters the brain faster than IV drugs and trigger chemical reactions Acetylcholine—increased HR and alertness
- Dopamine and endorphins—pleasure and increased working memory Physical dependence
- Emotional and mental dependence make it hard to stay away from nicotine after you quit
- To guit and stay guit smokers must deal with both the physical and mental dependence



#### Harm Reduction

- A strategy to reduce harm to an individual or society by modifying hazardous behavior that is difficult to prevent
  - Seat belts
  - Promotion of safe sex Needle exchange for drug addicts
- · Harm reduction in tobacco control—cutting down, modified cigarettes, smokeless product, nicotine replacement therapies (NRTs) and electronic cigarettes
- Can contribute to significant reductions in smoking prevalence

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# Harm Reduction in EU

Snus in Sweden and inhaler in UK

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- National Institute for Health & Care Excellence, UK
- Royal College of Physicians report "Harm Reduction in Nicotine Addiction" (2007)
- Some smokeless tobacco products are 90% less harmful than cigarettes
- Promoting ST can reduce smoking by 1-3%
- Switch of 1% could save 60,000 lives in 10 years in UK



#### Harm Reduction in US

- National Cancer Institute— "all tobacco products should be strongly discouraged"
- FDA can evaluate and approve safer tobacco products
- CDC doesn't consider smokeless tobacco safe
- Tobacco companies cannot market smokeless products as less risky



# Limitations of NRTs

- Do not deliver nicotine in the same way
- Lack of behavioral characteristics
- Lack of social acceptability
- Lower level of nicotine
- Expensive

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- Modest impact
- Quit rate 50-70%
  Cigarette-free at 52 weeks 7-10% (without behavioral support)
- Many smokers would like a safer alternative

(similar to smoking ritual)



# **Electronic Cigarettes**

- Mimic smoking
- Relatively inexpensive
- Consumer support (>5 mln e-cigarettes blogs)
- Market position—lifestyle rather than a medical product
- If nicotine delivery can be improved they have a potential to reduce prevalence of smoking

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#### History of Electronic Cigarettes

- 1963—patented by Herbert Gilbert
- 2003—marketed in China
- 2004—introduced in US
- 2008—used by 4 million in US
- 2009—FDA sampled e-cigs
- 2012—\$2 billion industry
- 2014—FDA proposed the regulations
- 2016—will require a license and compliance with quality standards (UK)

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# **E-Cigarettes Structure**

- 1. Battery-operated heating element
- 2. <u>Atomizer</u>—converts the contents of the cartridge into a vapor
- 3. Replaceable <u>cartridge</u> (nicotine and flavorings in propylene glycol)

|                                 | •                                   |          |                                      |      |
|---------------------------------|-------------------------------------|----------|--------------------------------------|------|
|                                 | Battery operated<br>heating element | Atomizer | Replaceable cartridge<br>with liquid |      |
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# Nicotine in ENDD

- Deliver a spray of nicotine
- Standard dose—8-24 mg/ml per cartridge (up 100!)
- Variable level of nicotine exposure (14.8-87.2 mg/mL)
- High nicotine concentration in cartridges
- Inconsistent product labeling
- Travers, M. (2014) analyzed nicotine content
   32 e-cigs
   1 out of 4 differed by more than 20%
  - Nicotine was found in "nicotine-free" e-cigs
- Vapers can exceed nicotine blood level of traditional smokers

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# **Carcinogens in E-Cigarettes**

- FDA detected diethylene glycol and formaldehyde (2009)
- FDA issued warning letters for various violations (unsubstantiated claims and poor manufacturing practices) of the Federal Food, Drug, and Cosmetic Act (FDCA)
- Study from France (2013)
  - Formaldehyde—carcinogen
    Acrolein— carcinogen, chemical weapon
  - Nickel and chromium



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# Electronic Cigarette Use

- Majority of users—former smokers
- · Higher in younger then in older smokers
- Attractive, affordable and available
- To cut down, to reduce harm or to quit smoking
- Using instead of NRTs



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**E-cigs Survey** 

- 1,347 people from 33 countries
- Average age—43 years, 70% were male and 96% were of white ethnic origin
- Used for smoking cessation for longer duration than NRTS
- Users believe them to be safer •
- 75% didn't smoke for several weeks or months
- 91% reported 'substantially decreased' craving for • tobacco cigarettes
- 70% didn't have as much of an urge to smoke

**Inhalation Effects** 

- Climate conditions
- · Air flow
- Room size
- Number of users in the vicinity
- Type(s) and age of systems being used
- Battery voltage
- Puff length and interval between puffs
- User characteristics
  - AgeGender
  - Experience
     Health status

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#### **ENDD** and Heart

- Farsalinos (2012) Greece
- 42 healthy volunteers (age 25-45 years) 20 regular cigarette smokers 22 ex-smokers using e-cigarettes
- Baseline echocardiogram and hemodynamic measurements
- Exposure 1 cigarette (1mg nicotine, 10mg tar, 10mg CO) E-cig for 7 min (11mg/ml nicotine)
- Repeat echocardiogram and hemodynamic measurements
- No acute adverse effects on cardiac function

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# **ENDD** and Airways

- Gratziou (2012), Greece.
- Instant increase in airway resistance that lasted 10 min
- American Lung Association—secondhand vapor emissions from e-cigs -formaldehyde, benzene and **TSNAs**



#### Physiological Effects of Acute Exposure

- Mouth and throat irritation and dry cough
- No change in heart rate, carbon monoxide level, or plasma nicotine level
- Decrease in respiratory flow resistance similar to cigarette use
- No change in complete blood count (CBC) indices
- No change in lung function
- No change in cardiac function
- No increase in inflammatory markers
- Menthol-negative impact on periodontal ligament fibroblasts

Source: Callahan-Lyon P. Electronic cigarettes: human health effects

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#### ENDD and Desire to Smoke

- Bullen, C. (2013) New Zealand
- 657 participants—adult cigarettes smokers wanting
  - to quit
  - 289—16 mg ENDD
    73—0 mg ENDD
  - 73—0 mg EN
     295—patch

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- Modestly effective, similar to patch, few adverse events
- Further studies—longer-term safety, potential for long-term use and efficacy as a cessation product

#### ENDD and Smoking Reduction

- Polosa et al. (2011)
- 6 month study
- 40 participants unwilling to quit
- Side effects—sore throat, irritation and dry cough
- Results:
  - o 50% reduction in cigarette smoking
  - 22.5% overall quit rate
     EC is proved to be helpful in tobacco cessation



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# Benefits of E-Cigarettes

- Less nicotine absorbed (200°C vs 800°C)
- Fewer toxic chemicals
- Deal with chemical and behavioral aspects
- Smoking reduction, relapse prevention and
- cessationNo serious adverse effects reported



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# Hazards of E-Cigarettes

- Side effects: sore throat, irritation and dry cough
- Sub-standard manufacturing process (diethylene glycol, and other toxins)
- Allow "smoking" in smoke-free areas => increase nicotine exposure
- Delay cessation/dual use



E-Cigarettes & Youth

Novelty of the technology

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- Price and advertisement sensitive
- Fruit and candy flavors (cotton candy, bubble gum, Atomic fireball, orange cream soda)
- Can be refilled with other substances



# E-Cigarettes & Youth

Cross sectional analyses of data of 2011 and 2012 National Youth Tobacco Survey

- 2012—6.8% in 6-12th grades report ever using (2011-3.3%)
- 2012—2.1% in 6-12th grades current users (2011-1.1%)
- Among ever users—20% middle school and 7.2% high school users never smoked (overall 9.3%)
- 2013—4.5% of high school students (660,000)
- 2014-13.4% (2 million)



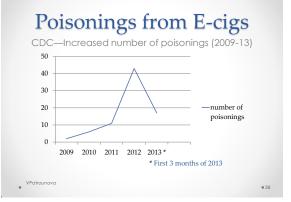
# **Public Health Issues**

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- Second- and third- hand vapor
- Nicotine toxicity due to high % (1 g of nicotine in refill bottle)
- Attempted and completed suicide





Poisonings

- Ingestion, inhalation or absorption through the skin or eyes
- Nausea, vomiting and eye irritation
- Sept 2010—1call per month
- Feb 2014—215 calls per month
- 51% calls—children under age 5
- 42% calls-age 20 and older
- Suicides —IV and ingestions of liquid nicotine



#### Exposure Risks for Non-Users

- Depends on nicotine concentration
- Nicotine from aerosol remains on the surfaces React with nitrous acid (gas appliances)
- Produces TSNAs
- Inhale, ingest or dermal exposure to TSNAs

Note: Exhaled aerosol shows traces of TSNAs— 9 to 450 times less than smoke (=nicotine inhaler)





"Second-hand" Vapor

- Pellegrino, R. (2012) evaluated emissions from ecigarettes and conventional cigarettes
  - 15 times lower than emissions after use of traditional cigarettes
     Less danger for second-hand and third-hand exposure
- Goniewicz, M. (2013) analyzed "second-hand" smoke
  - Exposure to nicotine-10 times less
  - Future research needed on emission of formaldehyde, acetaldehyde and acrolein
  - Found nicotine residue on indoor surfaces after ENDD use
     Can a second-hand exposure reinforce addiction?

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#### Tobacco Products Regulated by FDA

- Cigarettes and cigarette tobacco
- Roll-your-own tobacco
- Smokeless tobacco
- Cigars NO
- Pipe tobacco- NO
- Dissolvable products NO
- Waterpipe tobacco NO
- E-cigarettes NO

Source: http://www.fda.gov/TobaccoProducts/Labeling/ucm388395.htm

#### FDA Proposed Rules on ENDD (2014)

- The age limit to buy products—18
- Health warnings about the potential for addiction to nicotine
- The sale of products in vending machines would be prohibited
- Manufacturers would be required to register all their products and ingredients
- Provide scientific evidence before any claims
- No free samples



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#### FDA Proposed Rules on ENDD

- Public comments till July 2nd, 2015
- 135,000 public comments
- 31 health and medical groups (the American Academy of Pediatrics, the American Academy of Family Physicians and the American Heart Association ) wrote a letter to President Obama
- Gateway to other tobacco products?
- 42 states and 1 territory currently prohibit the sale of e-cigarettes or vaping/alternative tobacco products to minors

Concerns

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#### Future of Tobacco Control

- Goal to eliminate cigarette smoking and tobacco in 50 years
- Provide full access to cessation programs
- Only 50% of population is covered by smoke-free laws
- Warnings on e-cigarettes and other products
- Strict regulations to prevent teens from smoking
- Increase taxation and make tobacco more expensive

#### **Future Research**

- Differences in product engineering, components and toxicity of ENDD
- Content and emission characteristics
- Absorption characteristics
- Potential for addiction
- Long-term effects of use
- 53 scientists believe it can be part of the solution!



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#### at childproof

- Not childproof
- Advertising and promotion of e-cigarettes
- Unregulated

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- Uncertainty about quality standards and performance
- Risk of sustained dual use
- Involvement of tobacco industry



# Conclusion

- Fewer toxicants but no adequate data on long-• term effects
- Respiratory effects
- Increasing number of users
- Second and third hand aerosol exposure need further evaluation
- With proper regulations and manufacturing oversight may facilitate smoking cessation

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