E-Cigarettes, Vaping & their Implications

Implications

Scientific Implications
- Historical
  - History of tobacco & Intro to E-cigs
- Public Health
  - Teenage Trends
- Substance Abuse/Addiction
  - Juul; Ingredients/Chemical Make-up & Exposure; Cessation; FDA Response

Social Implications
- Marketing & Language
  - Social Media; Smoking Cessation
- Economical & Political
- Advocacy

Objectives
1. Review the trends in tobacco consumption and the emergence of e-cigarettes
   - Examine trends in teenage use of tobacco since the emergence of e-cigs
   - Look at the emergence of Juul and its role in the tobacco industry with relation to teenage use
2. Discuss the chemical composition of e-cigarettes
   - Review e-cigarette role in smoking cessation, passive exposure
3. Review adverse events related to e-cigarette consumption
   - Examine how certain formulations, or flavors, may be playing a role.
4. Discuss Future Directions, Resources, Advocacy
As of right now...

- 10/1/19
  - 1080 possible cases of lung illness
  - 48 states and 1 US Territory – 80% < 35 years of age
    - 18% under 18 and 27% are 19-20 years of age
  - 18 deaths, 15 states
  - No evidence of infectious disease
  - No specific substance or e-cig product identified
    - Reported use of liquids containing cannabinoid products (THC)

Tobacco Statistics

- As of 2019 – WHO
  - More than 8 million people die annually due to tobacco related diseases
    - More than 7 million – direct tobacco use
    - 1.2 million – 2nd hand smoke

Tobacco Use - Teens

- Current E-cigarette use in teens
  - 27.5%
- 90% adult smokers
  - Started smoking before 18 yrs
    - 2/3 become everyday smokers at or before 18 yrs

https://www.who.int/en/news-room/fact-sheets/detail/tobacco

https://www.tobaccofreekids.org/assets/factsheets/0002.pdf
Emergence of E-cigarette

- Begins with smoking cessation
- Decrease coronary artery disease risk by 50% after one year
- Decrease risk of lung cancer by 50% after 10 years
- Attempting to quit is difficult
- Relapse within 8 days with no assistance
- 3-5% prolonged abstinence of 6-12 months

Emergence of E-cigarette

- Dramatically increased in popularity in 2004
- Addiction driven by multitude of behavioral smoking cues
- Some NRTs do not address
- People using it as a form of smoking cessation
- Lack of evidence
- Initial literature examining efficacy and safety
  - Sparse
  - Limited randomized study designs compared to other NRTs
  - More data required (2)
Juul

- 2 components
  - Bottom – Battery, temperature regulation system
  - Top – E-liquid cartridge also the mouthpiece
- Rechargeable – USB – laptop!!
- Best tasting - 4 flavors
- https://www.juul.com/shop/pods
- Difference
  - No settings
  - Not user modifiable
  - Temp. regulation – prevent overheating and combustion
  - Less likely to burn or explode

JUUL = discrete

- 55% of the e-cigarette market in 2 years (from 5% in 2016)
- FDA decided to crack down on against illegal sales to minors – asking for JUUL documents
- Looks like a flash drive
  - Discrete way to sneak devices into school or in public

https://www.vaporplants.com/what-is-a-vape-pen


NPR

- Talked about vaping in high school
- "...even after an hour and a half or two, I’m chomping at the bit to find my JUUL"
- JUUL Labs – “alternative to adult smokers, not anyone else, not minors”
- Flavors such as cotton candy, Frutti Tutti, cookies and cream, caramel, cherry, crème brûlée
- Safer than cigarettes, and you can use them to quit
- But can also use them to get addicted

Teens and vaping

- 27% high schoolers
- Recently vaped
- 2017: 11%
- < 5% adults use electronic cigarettes
Tobacco Use - KS

9/23/19

- 2017 YRBS
  - 34.8% high school students tried e-cigs
  - 10.6% currently use

Tobacco Use - MO

Gross Under-Estimation
FDA Timeline

- June, 2009
  - Family Smoking Prevention and Tobacco Control Act (TCA)
    - Regulatory authority over tobacco products & smokeless tobacco
    - Grandfathered in products already for sale
    - Created barriers to for new products to break through the market
    - Protect existing brands from competition – fulfill pre-market standards
    - Flavorings banned

- July, 2009 FDA:
  - Meet definition of drug-delivery devices
  - Discourages using e-cigs
    - Marketed to young people
    - Lack of health warnings
    - Contain carcinogens (diethylene glycol)

- December 2010
  - US Court of Appeals
    - FDA can only regulate e-cigs as a tobacco product, unless therapeutic claims are made
  - April 2011
    - FDA will regulate e-cigs under tobacco products
    - Unless advertised as smoking cessation tool
FDA Timeline

• October 2013
  – EU rejects wholesale ban on e-cigs
    • should contain no more than 30mg/ml of nicotine
    • should carry health warnings
    • should not be sold to anyone under 18 years old
    • subject to the same advertising restrictions as tobacco products

FDA Timeline

• April 2014
  – FDA releases proposed regulation attempting to exert regulatory authority of e-cigarettes as tobacco products
• May 2016 – FDA Issues Regulations

November 2016

• New FDA Director
  – Remake the Nicotine landscape
    • Reduce nicotine in cigarettes to below addictive levels
    • E-cigs are important – safer nicotine products to replace cigarettes
FDA Update

- [https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm)
- “Today, I’m directing the FDA’s Center for Tobacco Products (CTP) to revisit this compliance policy as it applies to deemed ENDS products that are flavored, including all flavors other than tobacco, mint and menthol. The changes I seek would protect kids by having all flavored ENDS products (other than tobacco, mint and menthol flavors or non-flavored products) sold in age-restricted, in-person locations and, if sold online, under heightened practices for age verification.”

Washington post, 2017

- Several senior officials of previous tobacco firms have ties to administration
  - Chad Readler – Acting assistant attorney general for civil division – Represented RJ Reynolds Law Firm previously
    - Contributed $1 Million to inauguration
  - FDA Head Scott Gottlieb
    - Served on board of EC firm Kure until May 2016

- March 15, 2018
- FDA states that they plan to reduce the amount of nicotine levels in cigarettes to help reduce addiction
  - Decrease smoking rates
  - Limit tobacco related deaths
  - Did not specify when or how much
  - NO mention of electronic cigarettes
New Light...
- Postpone with 2018 PMTA submission deadline for four years, until Aug. 8, 2022
- While applications were reviewed, products could remain on the market indefinitely
  • previously only allowed to be sold for one year, even if the FDA had not determined their eligibility

Wired Magazine 2017
- What's inside Vape Juice?
  - Water – vapor
  - Vegetable Glycerin – sugar alcohol
    • Texture enhancer, boosts thickness
    • Also found in moisturizers
  - Propylene Glycol
    • Tasteless, odorless, colorless
    • Flavoring
    • Nicotine

E-Juice
- https://www.vaporfi.com/vape-juice/juice-deals/
- Any flavor you want
  - Combination
- Other ingredients…
Propylene Glycol

- Synthetic liquid that absorbs water
- Base for de-icing solutions
- Anti-freeze
  - Contact with food
  - Absorb extra water; maintain moisture in medications, cosmetics and food
  - “generally recognized as safe”
- In the body:
  - Metabolizes to propionaldehyde
  - FDA: Used in the manufacture of plastics, rubber chemicals; Used as disinfectant, preservatives

Abusing E-cigarettes

- Do not deliver CO or other carcinogens
- Users may “tamper” to deliver larger doses of nicotine
  - “Dripping”
  - Increase exposure to other chemicals
  - Can also mix different liquid solutions
  - Also mix alcohol, THC oils
  - Also increase voltage
  - Increase nicotine yield of vapor
- Others may use it as a way to reduce nicotine consumption
  - Should also use other means of support to help quit - Behavior treatment with counseling (4)
**Vaping and THC**

- Research is limited
- Study in Connecticut
  - 18% high school students who vaped had used e-cigs
    - Hash oil or THC-inhaled
- Less smell than joint, pipe
- Higher concentrations of THC
  - Mild altering and addictive effects.

**Passive exposure**

- Summarize and review all studies examining potential adverse effects of passive exposure to EC
- Compare to background and cigarette smoke exposures
- Articles from 1996 to 2015
  - Effects from passive exposure in animals and humans, vapor analysis directly or in ambient air
- 16/312 studies relevant
  - EC vapor compared to background levels: formamide/methylene, formamide/propylene glycol
  - EC vapor compared to cigarette smoke: lower levels of every compound except nickel, silver
- Small sample sizes, impact of animal studies
- Further research needed (6)

**Effect of nicotine on developing human**

- Adolescents
  - ~250,000 used EC
    - Nearly half intending to use cigarettes
  - Higher cognitive function development continues into 20s
  - Period of neural remodeling, synaptic pruning
  - Cholinergic matures
    - Cognitive maturation, executive function
  - Smoking associated with effects on working memory, attention
  - More likely to become dependent on nicotine and traditional smoking (6)
NEJM

- 886 participants – randomly assigned
  - NRT of their choice, or combo – up to 3 months provided
  - E-cig starter pack
- Weekly behavioral support for at least 4 weeks
- Primary Outcome:
  - Sustained abstinence for one year
  - E-cig group: 18% 1 year abstinence rate; NRT group: 9.9%
  - E-cig group - Mouth or throat irritation, but did use their assigned product more

Takeaway

- E-cigarettes were more effective for [traditional] smoking cessation than nicotine-replacement therapy,
- when both products were accompanied by behavioral support.
- Also became addicted to E-cigs
  - “The rate of continuing e-cigarette use was high”

Introduction to smoking?

- Increasingly popular among youth
- In never-smokers
  - Associated with cigarette smoking
  - Studies from California, Hawaii, Mid-Atlantic
  - US, Canada, UK samples
- Meta-analysis – greater than 3-fold increase risk of cigarette smoking
  - E-cig users compared to never-smokers
Higher nicotine use

- Evaluate if e-cigs with higher nicotine concentrations is associated with increased increases in combustible smoking
- Prospective cohort study – 10 high schools in LA
  - Surveys given to students in 10th and 11th grades
    - Reported e-cigs in the last 30 days and nicotine level
      - None: low (1-5mg/mL); med (6-17mg/mL); high (<18)
  - 6 month follow up
    - Frequency in the last 30 days – 0, 1-2, >3
    - Daily intensity

JAMA, 2017

- 181 students – 96 boys; 85 girls
- Each increase in nicotine concentration vaped
  - Associated with a 2.26 (95%, CI 1.28-3.98) increase in the odds of frequent vs no smoking
  - 1.65 (95% CI, 1.09-2.51) increase in the odds of frequent vs. no vaping
- Higher nicotine concentration – Greater number of cigarettes smoked/day
- More vaping episodes/day compared to no nicotine
- Similar for increased puffs/vaping
- Using e-cigs with higher nicotine concentrations by youths may increase frequency and intensity of smoking and vaping

What about “Experimenters”

- Using E-cigs and progressing to smoking
  - Smoked cigarettes but not yet > 100
  - 12-17 years of age via survey with 1 year follow up from the Population Assessment of Tobacco and Health Survey
- When using E-cigarettes vs not:
  - 2x more likely to:
    - Established smoker – > 100 cigarettes
    - Current smoker – smoked in the last 30 days
    - Both established and current smoker
- Among experimenters:
  - E-cigarettes use positively and independently associated with progression to current est. smoking, suggesting that e-cigarettes do not divert from, and may encourage cigarette smoking

Juul Chemistry

**E-cigs & Vape Pens**
- Freebase Nicotine
- Basic pH
- Throat Irritation
- Limited tolerability
- Good stability

**Juul**
- Nicotine salt
  - With Benzoic Acid
- Acidic/Neutral pH
- Smoother hit to throat
- Increased tolerability
- Improved stability

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**Why??**

- "...new analysis of Juul’s marketing campaign suggests it targeted youth from its inception."
- Stanford Research into the Impact of Tobacco Advertising
  - Looked at thousands of social media posts
  - "patently youth-oriented"
  - "borrowed directly from the tobacco industry playbook"
- New public health crisis
  - April 2018 – FDA demanding submit documents
  - Marketing, research, sales to youth. Restrict sales of flavored vape devices online & in stores
Marketing


Marketing Now

https://www.juul.com/community

Advertising at Schools

- NYT – 7/25/2019
  - Paid numerous schools
    - $10,000 – $134,000
    - “deployed a sophisticated program to enter schools and convey its messaging directly to teenage children,”…

$1.3 million: average bonus Juul employees …

- December, 2018 – 35% Juul was purchased by Altria
  - Parent company of Philip Morris
  - Valued at $38 billion
  - More valuable than Airbnb, SpaceX
- $2 billion in bonuses - $1.3 million/person
- During a time when trying to “improve lives of billions of adult smokers”

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Immune response to the Lungs

- From 2011 to 2015
  - E-cigarette use increased by 900% in high school students
- Sputum samples from
  - 15 E-cigarette users, 14 cigarette users and 15 non-smokers
- Sputum samples analyzed
  - E-cigs
    - Neutrophil granulocyte, Neutrophil extracellular trap
  - Cigs & E-cigs increases in:
    - MMP9, thioredoxin, aldehyde detoxification, oxidative stress - Mucus production – MUC5AC – bronchitis, asthma, wheeze, bronchiectasis

Conclusion

• “Comparing harm of e-cigarettes with cigarettes is like comparing apples to oranges…”

• “Our data shows that e-cigarettes have a signature of harm in the lung that is both similar and unique, which challenges the concept that switching from cigarettes to e-cigarettes is a healthier alternative.”

But it’s safer...

• “You’re inhaling water vapor…”

• Previous reports of eosinophilic pneumonia, lipid pneumonia

• Previously healthy (except for mild asthma) 18 yo female presented to the ED with cough, SOB, pleuritic chest pain

• Began e-cigarettes 2-3 weeks prior – last used a few days before onset of symptoms

• Labs: Elevated WBC with left shift and CRP 17.4

• CXR – b/l opacities; Chest CT: dependent atelectasis, septal thickening, moderate fluid in the lungs

• PICU on broad spectrum antibiotics – worsened

• Breathing tube placed needing a lot of oxygen

• B/L chest tubes for worsening fluid in the lungs

• Scope for fluid negative for infections, significant WBC and inflammatory markers

• Started on 40mg IV steroids twice daily

• Based on symptoms, imaging, inciting agent, lab results and response to steroids – diagnosed with hypersensitivity pneumonitis
Eosinophilic pneumonia

- 18 yo female
- Presented with cough, shortness of breath, chest pain
- Started vaping 2 months prior
- Low oxygen saturations on exam
- Blood count showed elevated white blood cells, 0.5% eosinophils
- CXR – possible pneumonia – started on antibiotics
- Had worsening saturations, respiratory distress
- Chest CT – patchy airspace disease and nodules

AEP

- Worsening respiratory failure – transferred to ICU
- Bronchoscopy performed
  - 26% eosinophils
  - No microbes noted
- Diagnosis of acute eosinophilic pneumonia
- High dose systemic steroids administered
  - Marked improvement in 2 days
Case report

- Life-threatening Vesicular Bronchial Injury Requiring Veno-Venous Extracorporeal Membrane Oxygenation rescue in an Electronic Nicotine Delivery System User
- Came into ED with chest pain and dyspnea
- Admitted for work up
- Increased respiratory support despite normal CXR
- CT showed nodular infiltrates in the lower lobes, mediastinal adenopathy
- Admitted to e-cigarette use – equal to 2 packs/day cigarettes
- Mechanically ventilated with breathing tube
**Thomas et al case report**

- Bronchoscopy:
  - “extensive airway trauma and thermal injury”
  - Eventually underwent VV ECMO – lung bypass
  - Eventually improved over time

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**Case report**

- Previous research:
  - Capable of heating liquid solutions to temperature 350°C
  - Undergo conversion/breakdown
    - Formaldehyde, acetaldehyde, acetone, acrolein, propanal, butanal, glycoal, methylglyoxal
    - Acrolein, formaldehyde, acetaldehyde – pulmonary irritants
    - Probable carcinogen, necrosis of living tissues
    - Propanal – pulmonary edema
    - Butanal – toxic pneumonitis
    - More volatile and reactive when heated

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**Danger in the vapor? ECMO for adolescents with status asthmaticus after vaping**

Lauer et al. *AnnalsATS* 14:3, March 2017

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Organizing pneumonia related to electronic cigarette use: A case report and review of literature

Mohammadsadeghi, Farzad, Hashemi, Masoom, Mandana, Ameli, Leela, Varzandi, Niloufar

Tao. HE et al. *AnnalsATS* 14:3, March 2017
Fires...

- [https://fox61.com/2019/02/13/vape-pen-explodes-on-delta-flight/](https://fox61.com/2019/02/13/vape-pen-explodes-on-delta-flight/)

Electronic Cigarettes and Vaping Devices

**Aldehydes & Respiratory Defenses**

- **Acetaldehyde, Acrolein, Crotonaldehyde**
  - Respiratory inflammation
  - Impair innate and adaptive immune cell responses
  - Reduce mucociliary transport – Salathe et al
    - "slow ciliary beat frequency, dehydrate airway fluid, make mucus more sticky”
  - Dysregulate antioxidant responses
  - Increase infection susceptibility
  - Lead to emphysema and COPD

**References**

Flavor Implications

- Increased area of research interest
- Cinnamon
  - Suppress Nicotine Metabolism – CYP2A6
  - Inhibits immune cell functions
    - Macrophages, Neutrophils, Natural Killer Cells

Other Implications

- Nicotine poisoning
  - Ingestion
- Seizures
  - FDA investigating
- Packaging
  - Made to look like cough syrup

Future directions/research

- Evidence to help regulators write reasonable regulations
- Smoking cessation and initiation
- Safety and toxicity
- Use by non-smokers
- Dual use with cigarettes
- Use in public spaces
- Flavor and nicotine content
- Messaging regarding continuum of risk
- “Chasing a moving target” (12)
Summary Table Slide – Wyandotte County

<table>
<thead>
<tr>
<th>Population Group</th>
<th>Percentage Living within One Mile of Tobacco Retailer</th>
<th>Percentage Living within One Mile of Grocery Store</th>
<th>Which retailer type do people live closest to?</th>
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<tbody>
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<td>Total</td>
<td>76.7%</td>
<td>63.9%</td>
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<td>White</td>
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<td>86.6%</td>
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<td>71.4%</td>
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Summary Table Slide – Johnson County

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<th>Population Group</th>
<th>Percentage Living within One Mile of Tobacco Retailer</th>
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Cigarette Prices and Cigarette Sales, United States, 1970-2017

Data Sources: Cigarette, F.D. and Tobacco, using Triad methodology.
Children's Mercy Kansas City

**Taxing...**

**2019 TOBACCO TAXES**

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<th>State</th>
<th>Small Tax</th>
<th>Cigarette &amp; Rolling Tobacco Tax</th>
<th>E-Cigarettes Tax</th>
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https://www.tobaccofreekids.org/assets/factsheets/0146.pdf

https://truthinitiative.org/research-resources/smoking-region/tobacco-use-kansas-2019

https://truthinitiative.org/research-resources/smoking-region/tobacco-use-missouri-2019
Banning E-cigs

9/25/18

- Michigan
- New York
- Massachusetts
- Rhode Island
"Comparing harm of e-cigarettes with cigarettes is like comparing apples to oranges..."

"Our data shows that e-cigarettes have a signature of harm in the lung that is both similar and unique, which challenges the concept that switching from cigarettes to e-cigarettes is a healthier alternative."

Resources

- American Thoracic Society
  - https://www.thoracic.org/advocacy/tobacco-kids.php
- CDC
  - https://www.cdc.gov/tobacco/basic_information/e-cigarettes/index.htm
- AAP
Resources

• ALA
• History with FDA

References

References


References

16. Goldenson, Nicholas et al. Associations of Electronic Cigarette Nicotine Concentration With Subsequent Cigarette Smoking and Vaping Levels in Adolescents