Innovative Approaches to Nicotine Dependence in People with Serious Mental Illness

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Global Forum on Nicotine
Smoking Rates among People w/Mental Illness
2-4 times the General Population!

Smith et al, 2014 (NESARC, n=43,093)
Dickerson et al, 2013 (n=991)
An “Epidemic” of Early Mortality: Cardiovascular Disease is the Primary Cause

<table>
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<th>Year</th>
<th>AZ</th>
<th>MO</th>
<th>OK</th>
<th>RI</th>
<th>TX</th>
<th>UT</th>
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<td>1997</td>
<td>26.3</td>
<td>25.1</td>
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<td></td>
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<td>31.8</td>
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</table>

Compared with the general population, people with major mental illness lose 25-30 years of life expectancy.

Colton CW, Manderscheid RW. Prev Chronic Dis [serial online]. Available at: URL:http://www.cdc.gov/pcd/issues/2006/apr/05_0180.htm
Differential Mortality Gap Increased Significantly Over Three Decades

Why Are Smoking Rates So Much Higher Among People with Serious Mental Illness?

• **Biological vulnerability**: Nicotinic receptor and other brain abnormalities in schizophrenia.

• **Misinformation**: Providers and family members think people need cigarettes to manage symptoms and that quitting will cause relapse; lack of appreciation of the range of health risks of smoking.

• **Social norms**: Smoking occupies a prominent place in the culture (Morris, 2009; Davis 2010)
Addressing Tobacco Dependence in SMI: Kitchen Sink Approach

- Pharmacotherapy
- Behavioral Support
- Technology
- Incentives
- Harm Reduction for Chronic Smokers who Struggle to Quit
Pharmacotherapy and Behavioral Support

• Combination therapy is best: with medication and/or NRT AND 8-12 weeks of CBT, 50-60% successfully quit

• However, relapse rates are very high after once treatment ends
Technology

• Let’s Talk About Smoking*
• NCI Apps
• Smokefree.gov
• Web-based CBT

Incentives: Cash To Quit

• Cochrane Review (2015) of 21 studies (n=8400): incentives were superior over 6 months, but effects rarely sustained at 3 month follow-up.
• Few trials of incentives for tobacco cessation in SMI.
• Medicaid-funded trial (Breathe Well, Live Well) comparing 3 approaches: Prescriber Visit, Prescriber Visit + Quitline, Prescriber Visit + Telephone CBT AND Incentives for Abstinence (up to $450 over 4 weeks).
BWLW: Percent Confirmed Abstinent
(n=661)
accounting for gender and dependence severity

p=.02; OR=1.7
Harm Reduction

• **Definition:** Public health policies designed to reduce the negative social and/or physical consequences associated with various human behaviors.

• **Applied to smoking:** NRT – Minimize the harmful effects of toxins in cigarette smoke to reduce CVD and cancer risk, but maintains nicotine addiction.

• **Problem with NRT:** Does not deliver nicotine effectively (smokers don’t get the “hit” they want, and the hand-to-mouth ritual is lacking for patch, gum, lozenge, nasal spray).
Provided ecigs for 4 weeks
Assessments of CO, cigs/week, ecig use every week
Demographics (n=19):
  Mean age=42 (range=20-66)
  Diagnoses of schizophrenia or severe mood disorder
  Used tobacco 23.6 ± 15 years
  Past year quit attempts 4±8 times
Cigarette and Breath CO Among Smokers with SMI Using E-cigs for One Month

# Cigarettes

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<th>Baseline</th>
<th>4-Weeks</th>
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<td># Cigarettes</td>
<td>191.8</td>
<td>66.69</td>
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$t=3.6, p=.005$

Breath CO

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<th>End of Study</th>
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<td>Breath CO</td>
<td>27.37</td>
<td>15.21</td>
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$t=3.246, p=.004$
Enrolled 240 participants with schizophrenia or BPD who smoke and who have tried to quit but cannot and are not currently trying.

Study sites: Kentucky and Massachusetts

Random assignment to free e-cigarettes (NJOY) and assessments for 8 wks, or assessment only for 8 wks, with follow up at 13 and 26 wks.
Satisfaction: Enjoyment from E-Cigarettes

(1=very unsatisfied, 2=unsatisfied, 3=neutral, 4=satisfied, 5=very satisfied)
Satisfaction: Enjoyment of E-Cigarettes Compared to Cigarettes

(1=very unsatisfied, 2=unsatisfied, 3=neutral, 4=satisfied, 5=very satisfied)
Tobacco Use (smokes/day) for Participants Completing 8 Weeks (p<.001)

Baseline     8 Wks
Baseline     8 Wks

Ecig          51%

Comparison

Baseline     19.8
Baseline     17.58

8 Wks         4.5%
CO Level for Participants Completing 8 Weeks (p=0.019)

Baseline   8 Wks

Ecig

Baseline  8 Wks

Comparison
Tobacco Use (0-5 smokes/day) Among Participants Completing 8 Weeks

- **Baseline**: Starting point
- **2 weeks**: Significant increase
- **4 weeks**: Steady state
- **6 weeks**: Decline
- **8 weeks**: Further decrease

**Legend**:
- **Ecig**
- **Control**
CO Level 0-5 Among Participants Completing 8 Weeks

Baseline  2 weeks  4 weeks  6 weeks  8 weeks

- Ecig
- Control
How Can We Evaluate the Effect of ENDS?

• ENDS are widely available but not FDA approved so no ability to study ENDS as therapeutic with federal funds.

• NIDA developed SREC for use in clinical trials.
  – (can be used in studies evaluating the use of ENDS to reduce exposure to more harmful tobacco products, but not studies investigating the treatment of nicotine addiction with cessation as an aim).

• Very difficult to quantify ENDS use

• No 2 ENDS are the same
FDA Regulatory Activity

- **August 2016:** FDA rule requiring ENDS Premarket Review by 8/8/22
  1) reports of studies of health risk; 2) list of ingredients; 3) manufacturing methods; 4) packaging and labeling; 5) samples of product. (Cost estimated at $125,000-$500,000.)

- **March 15, 2018:** FDA issued proposed plan to reduce nicotine in cigarettes to minimal or non-addictive level

- **March 13, 2019:** FDA issued statement of intent to more strictly regulate flavoring in ENDS and accelerate time for submitting Premarket Review to 8/8/21.

- **FDA Commissioner (2019):** “...we’re advancing new policies to encourage the development of products that can deliver nicotine to currently addicted adult smokers without all of the harmful effects of combustion.”
On the Horizon…..

• More research on health impacts of ENDS, including VISTA outcomes (NNAL)
• Impact of reducing nicotine in cigarettes on ENDS use
• Breathe Well, Live Well 2.0
  Statewide Initiative Targeting People w/SMI Age 18-35
  - Let’s Talk About Smoking
  - Access to NRT
  - Incentives for Abstinence (up to $390)
  - BWLW Supportive Counseling
  - Care2Quit (engaging supportive people)
  - NCI Smoking Cessation App (and rewards for using)
Interview with Consumers

- https://www.youtube.com/watch?v=poGsQtpIMQc&feature=youtu.be