

TOBACCO CESSATION: INCORPORATING MOTIVATIONAL INTERVIEWING AND EXAMINING THE ROLE OF E-CIGS

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Learning Objectives

- Given a patient scenario, identify appropriate pharmacological smoking cessation aids
- Discuss the efficacy and safety of E-cigarettes in the literature
- Apply the spirit of motivational interviewing to patient interactions

FDA Approved Tobacco Cessation Therapies

- Nicotine Replacement Therapy
 - OTC: patch, gum, lozenge
 - Rx only: inhaler, nasal spray
- Varenicline
- Bupropion SR

Nicotine Replacement Products

- Nicotine Patch
 - Dose
 - 21mg/day patch if >10 cigarettes per day
 - 14mg patch if <10 cigarettes per day or <45 kg
 - Counseling
 - Apply on hairless area, rotate sites
 - May remove before bed if vivid dreams occur
 - Do not cut patch

Nicotine Replacement Products

- Nicotine Gum
 - 2mg if smoke < 25 cigarettes/day
 - 4mg if smoke ≥ 25 cigarettes/day
 - 1 piece Q1-2 hours, NTE 24 pieces/day
 - Chew and park method
- Nicotine Lozenge
 - 2mg smoke > 30 minutes of wakening
 - 4mg smoke within 30 minutes of wakening
 - 1 lozenge Q1-2 hours, NTE 20 lozenges/day
 - Rotate lozenge around mouth to decrease irritation

Nicotine Replacement Therapy

- Nicotine Inhaler
 - Inhale deeply into the back of throat or puff in short breaths
 - Initial dosing:
 - 6-16 cartridges per day
 - 1 cartridge = 2 cigarettes



Nicotrol Inhaler (prescribing information), New York, NY: Pfizer Inc, 2008.

Nicotine Replacement Therapy

- Nicotine Nasal Spray
 - ▣ 10mg/mL, 10 mL (200 sprays/unit)
 - ▣ Each spray delivers 0.5mg nicotine
 - ▣ Initial dose is 1-2 sprays IEN per hour
 - ▣ NTE 80 sprays/24 hours
 - ▣ Prime before first use and if not used >24 hours
 - ▣ Nasal irritation: 94% at 2 days, 81% at 3 weeks

Nicotrol Nasal Spray [prescribing information]. New York, NY: Pfizer Inc; 2010.

Bupropion SR

- MOA
 - ▣ Block reuptake of dopamine and norepinephrine
- Dosing
 - ▣ Initiate at least 1 week before quit date
 - ▣ 150mg x 3days, then 150mg BID thereafter
 - ▣ Take in AM and early afternoon to reduce insomnia
- Contraindicated in patients with seizure or eating disorder
- Can delay or lessen weight gain

Varenicline

- MOA:
 - ▣ Partial agonist of nicotinic acetylcholine receptor
- Dosing:
 - ▣ Initiate 7-35 days before quit date
 - ▣ 0.5mgx3 days, 0.5mg BIDx4 days, then 1mg BID thereafter
- Can minimize nausea by taking with food and a full glass of water
- Can cause vivid nightmares
- Concerns in psychiatric conditions and cardiovascular disease

Varenicline- Conflicting Psychiatric ADEs

- FDA Adverse Event Reporting System from 1998 to 2010 identified 3249 of suicidal behavior +/- depression in patients treated for smoking cessation
 - ▣ 90% of events associated with varenicline
- Meta Analysis of 39 RCTs (10,761 patients) found no evidence of increased risk of suicide attempt, suicidal ideation, depression, or death
 - ▣ Varenicline was associated with an increased risk of sleep disorders (OR 1.63) and abnormal dreams (OR 2.38)

FDA Drug Safety Newsletter 2009; 21: Thomas KH et al. *BMJ*. 2011; 343:d1109.

Varenicline- Concerns in CVD

- Trial of 700 patients with stable CVD
 - ▣ Patients treated with varenicline had numerically more non-fatal MI (2 vs 0.9%) and need for coronary revascularization (0.6 vs 1.4%)
- Nationwide cohort study in Denmark
 - ▣ 35,852 patients on varenicline or bupropion
 - ▣ 57 MACE in varenicline vs 60 in bupropion (HR 0.96 CI 0.67-1.39)
 - ▣ Subgroup analysis of patients with PMH CVD did not significantly differ (HR 1.24 CI 0.72-2.12)

Riggall NA. *Circulation*. 2010; 121(2):221-9. Swanson H. *BMJ*. 2012;345:e7176.

RCT of Comparative Efficacy

- Population: 1504 adult smokers motivated to quit
- Intervention: randomized to 1 of 6 treatments
 - ▣ 1. nicotine lozenge
 - ▣ 2. nicotine patch
 - ▣ 3. bupropion SR
 - ▣ 4. nicotine patch +lozenge
 - ▣ 5. bupropion +nicotine lozenge
 - ▣ 6. placebo
- Outcome: Tobacco abstinence at 1 week, 8 weeks, and 6 months

Piper ME et al. *Arch Gen Psychiatry*. 2009;66(11):1253-62

RCT of Comparative Efficacy

- Results: Abstinence at 6 months (OR vs placebo)

	Odds Ratio	P-value
Lozenge	1.76	0.01
Patch	1.83	0.006
Patch +lozenge	2.34	<0.01
Bupropion	1.63	0.025
Bupropion +lozenge	1.74	0.011

- Combination NRT more effective than monotherapy NRT

Piper ME et al. Arch Gen Psychiatry. 2009;66(11):1253-62

Patient Case 1

- 59 year old female
- PMH: diabetes, MI in 2007 s/p stent
- Meds: metoprolol, lisinopril, insulin glargine, aspirin
- Social hx: smoking 1 ppd x30 years
- Presents to the pharmacy expressing interest in tobacco cessation, wondering what options are

Patient Case 1

- Questions for patient:
 - What has she tried in the past?
 - Does she have any dental work?
 - Does she have any psychiatric conditions?
 - Other medications?

Patient Case 1

- Options:
 - NRT
 - Combination of long and short acting
 - Bupropion
 - Varenicline
 - Likely safe as patient has stable CVD
 - Benefits outweigh risks

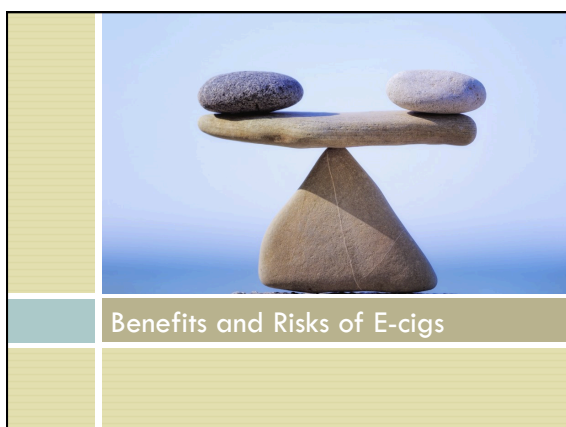
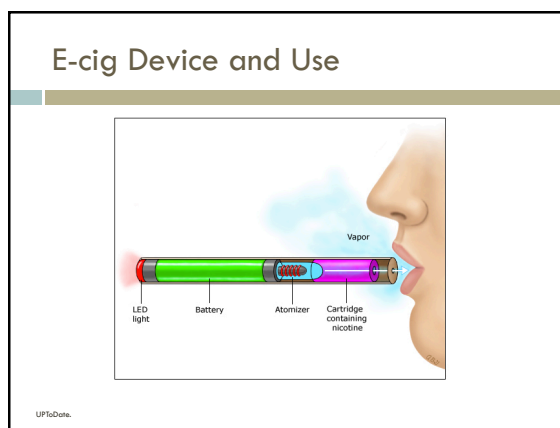
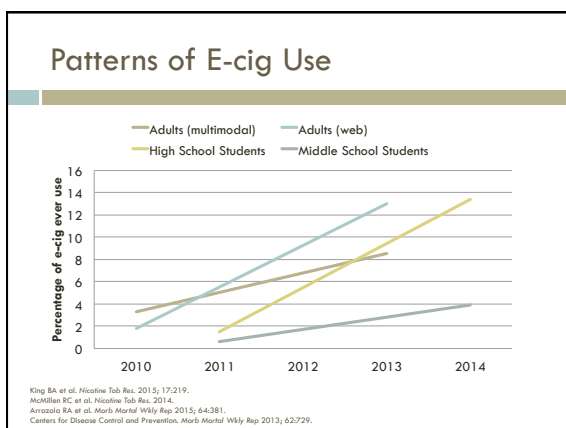
Requirements for Pharmacists Prescribing Tobacco Cessation Therapy

New Mexico Pharmacy Rules and Laws
16.19.26

Requirements

- Complete training course approved by NMBOP
- 0.2 CEU of live ACPE tobacco cessation therapy every 2 years
- Prescriptive authority for FDA approved tobacco cessation drug therapy
 - Both prescription and OTC
- Obtain informed consent from patient
- Pharmacist inform PCP of tobacco cessation therapy

Electronic Cigarettes



- ## Potential Benefit
- ☐ Reduce prevalence of tobacco use as a tobacco cessation aid

Benefit: E-Cig for Smoking Cessation

- Population:
 - 657 adult smokers motivated to quit
- Intervention: 4:4:1 randomization to
 - 16mg nicotine e-cigarette
 - 21mg/day nicotine patch
 - Nicotine free e-cigarette
- Outcome:
 - Biochemically verified abstinence at 6 months

Bullen C et al. *Lancet*. 2013;382(9905):1629-37

Benefit: E-Cig for Smoking Cessation

□ Results:

Abstinence Rates at 6 months
 Nicotine E-cig: 7.3%
 Nicotine Patches: 5.8%
 Nicotine free E-cig: 4.1%

Number at risk	0	50	100	150	200
Nicotine EC	289	108	77	64	5
Patches	295	68	51	43	5
Placebo EC	73	21	16	13	2

Bullen C et al. *Lancet*. 2013;382(9905):1629-37

Potential Harms

- E-cig use in adolescents
- Accidental Ingestion
- Health effects of vapor

Harm: E-cig use in Adolescents

- Study found use of electronic cigarettes significantly increased likelihood of initiation of combustible tobacco smoking (25.2% vs 9.3%)
- Evidence suggests nicotine exposure during adolescence may have lasting consequences on brain development
- Potential to renormalize combustible cigarettes

Lewinsohn AM et al. *JAMA*. 2013 Aug 18;311(7):700-7.
 US Department of HHS, Atlanta (GA). Centers for Disease Control and Prevention (US); 2014.

Harm: Accidental Ingestion

CDC. *Morbidity and Mortality Weekly Report*

Harm: Safety of Vapor Exposure

- There is no data examining long-term effects of e-cigarettes
- Some reports have identified carcinogenic compounds in e-cigarettes
- Pulmonary effects of inhaling propylene glycol or glycerin are unknown


Cheng T. *Toxicol Control*. 2014;23 (Suppl 2):i12-i17.

E-cig Federal Regulations

- April 2014
 - FDA proposed to extend tobacco authority to E-cigs
 - If passed, would require E-cigarettes to:
 - Register with FDA and report product ingredients
 - Requirements to include health warnings
 - Only market products after FDA review

E-cig State Regulations

- April 2015
 - Sale of e-cigarettes and nicotine cartridges to minors prohibited in New Mexico
 - Requires nicotine cartridges to be sold in child resistant packaging



US Preventative Task Force

- September 2015
 - Current evidence is insufficient to recommend e-cigs for tobacco cessation in adults
 - Recommend clinicians direct patients who smoke tobacco to other cessation interventions with established effectiveness and safety.

Summary of E-cigs


- Not regulated by FDA
- Consensus is that e-cigarettes are likely safer than combustible tobacco products
- Long term health risks still not known
- Encourage patients on their interest in smoking cessation
- Recommend FDA approved agent for smoking cessation therapy

Motivational Interviewing

Origin of Motivational Interviewing


William R. Miller

Professor of Psychology and Psychiatry at UNM since 1976



Motivational Interviewing

- Patient-centered directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence
- Collaborative effort



Motivational Interviewing[®] 2nd Edition, Miller & Rollnick, 2002, Guilford Press

Effectiveness in Tobacco Cessation

- Cochrane Review
 - ▣ Population: 28 studies, >16,000 participants
 - ▣ Intervention: MI by PCP, hospital clinician, nurse, or counselor
 - ▣ Results: smoking cessation rate
 - Usual Care: 104 per 1000
 - Motivational Interviewing: 131 per 1000
 - RR 1.26 (95% CI: 1.16 to 1.36)

Lindson-Hawley N. Cochrane Database Syst Rev. 2015;3:CD006936

Motivational Interviewing

- Guiding principles
 - ▣ Express empathy
 - ▣ Develop discrepancy
 - ▣ Roll with resistance
 - ▣ Support self-efficacy

Motivational Interviewing[®] 2nd Edition, Miller & Rollnick, 2002, Guilford Press

Express Empathy

- Reflective listening
 - ▣ Demonstrate that you have heard and understood patient's communication
- Acceptance, not necessarily approval or agreement
- Ambivalence is normal

Motivational Interviewing[®] 2nd Edition, Miller & Rollnick, 2002, Guilford Press

Develop Discrepancy

- Discrepancy between present behaviors and goals motivates change
- Awareness of consequences is important
- Goal is to have the person present reason for change

Motivational Interviewing[®] 2nd Edition, Miller & Rollnick, 2002, Guilford Press

Roll with Resistance

- Use resistive statements as momentum to further explore patient's views
- Affirm and accept patient's fears/concerns
 - ▣ "I can understand your worries about the potential weight gain from stopping smoking. Let's spend some time discussing this"

Motivational Interviewing[®] 2nd Edition, Miller & Rollnick, 2002, Guilford Press

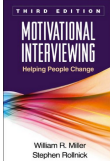
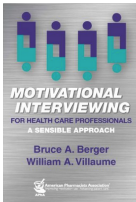
Support Self Efficacy

- Belief that change is possible is an important motivator
- Person is responsible for choosing and carrying out actions to change

Motivational Interviewing 2nd Edition, Miller & Rollnick, 2002, Guilford Press

Motivational Interviewing

- Develops over consistent practice
- For more information:
 - APhA book
 - William Miller book
 - Motivationalinterviewing.com

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