Counseling Patients about Smoking Cessation in the New Era of Cigarette Alternatives

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Disclosures

Dr. Faulkner has no actual or potential conflicts of interest in relation to this program.

The clinical reviewer, Sarah Dehoney, PharmD, BCPS, has no actual or potential conflicts of interest in relation to this program.

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Type of Activity: Application

Learning Objectives

• **Apply** tools to conduct effective smoking cessation education for patients in the pharmacy setting

• **Discuss** accurate information about the effectiveness of smoking cessation methods based on available data

• **Identify** and dispel myths about e-cigarettes and heat-not-burn products as smoking cessation methods

• **List** recommended uses of smoking cessation strategies including dosage, administration, contraindications, and best practices
Prevalence of Cigarette Smoking

- In 2017, 34.3 million people in the United States (U.S.) were current smokers
  - 15.8% of males
  - 12.2% of females

- Rates of smoking by age group
  - Age 18-24 years: 10.4%
  - Age 25-44 years: 16.1%
  - Age 45-64 years: 16.5%
  - Age 65 years and older: 8.2%

- Adolescence is the most critical time to prevent the initiation of smoking
  - More than 3000 persons under the age of 18 years have their first cigarette each day

Smoking and Disease

- Smoking is the leading cause of preventable death worldwide

- Half of those who smoke today will die of smoking-related disease

- Quitting before age 45 avoids most of the mortality risk
Treatment for Cigarette Smoking Addiction

- Current FDA-approved medications for smoking cessation
  - Nicotine replacement therapy (NRT)
    - Transdermal patch *(available OTC)*
    - Gum *(available OTC)*
    - Lozenge *(available OTC)*
    - Inhaler
    - Nasal spray
  - Bupropion SR (Zyban)
  - Varenicline (Chantix)

Nicotine Replacement

- Stimulates nicotinic receptors in the ventral tegmental area of the brain and the consequent release of dopamine
  - Nicotine is the primary addictive substance in cigarette smoke
- Replacement therapies deliver nicotine more slowly than smoking and result in lower serum levels
  - Can be dose adjusted according to current smoking habits
- May be used in combination (i.e., patch plus an orally administered form) to offset acute cravings
- Adverse event profile
  - Local irritation of mouth/throat
  - Skin irritation
  - Insomnia
  - Nausea
  - Dyspepsia
Nicotine Replacement Dosing

<table>
<thead>
<tr>
<th>Product</th>
<th>Available Doses</th>
<th>Guidelines for Use</th>
</tr>
</thead>
</table>
| Nicotine patches| 7 mg, 14 mg, 21 mg | 1 patch/24 hours  
11+ cigarettes/day: 21 mg x 6 weeks, 14 mg x 2 weeks, 7 mg x 2 weeks  
6-10 cigarettes/day: 14 mg x 6 weeks, 7 mg x 2 weeks |
| Nicotine gum    | 2 mg, 4 mg      | Chew 1 piece every 1-2 hours (chew until the flavor peaks, and then park the gum against the cheek; spit out after 30 min)  
25+ cigarettes/day or 1st cigarette within 30 minutes of waking: start with 4 mg gum; maximum 20 pieces/day, taper over last few weeks |
| Nicotine lozenges| 2 mg, 4 mg      | Use 1 lozenge every 1-2 hours  
20+ cigarettes/day or 1st cigarette within 30 minutes of waking: start with 4 mg lozenge; maximum 24 lozenges/day, taper over last few weeks |
| Nicotine inhaler| 10 mg/cartridge (4 mg delivered) | 6-16 cartridges/day; short continuous puffing for approximately 20 minutes for best result  
*Use for 6 months, taper over last 3 months* |
| Nicotine nasal spray| 100 mg/10-mL bottle | 1 spray into each nostril every hour  
*Do not exceed 5 doses/hour or 40 doses/day* |

Bupropion SR

- **Atypical antidepressant**
- **Mechanism in smoking cessation is not well defined**  
  - Inhibits neurotransmitter reuptake (dopamine and noradrenaline)  
  - Non-competitive nicotine receptor antagonist  
  - Mechanism does not appear to be related to antidepressant activity
- **May be used in combination with NRT**
- **Adverse event profile**  
  - Insomnia  
  - Dry mouth  
  - Nausea
- **Risk of seizures is approximately 1:1500**  
  - Risk based on >13,000 exposures in clinical trials
### Bupropion SR Dosing

<table>
<thead>
<tr>
<th>Product</th>
<th>Available Doses</th>
<th>Guidelines for Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bupropion SR</td>
<td>150-mg sustained-release tablets</td>
<td>Beginning 7 days before planned quit date, take 150 mg daily for 3 days, then increase to 150 mg twice daily</td>
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<tr>
<td></td>
<td></td>
<td>May use for at least 7 weeks</td>
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<tr>
<td></td>
<td></td>
<td>For patients with moderate/severe hepatic impairment, use 150 mg every other day</td>
</tr>
</tbody>
</table>

### Varenicline

- Considered a nicotine receptor partial agonist/antagonist
  - Lessens symptoms of nicotine withdrawal
  - Inhibits the effects of repeated nicotine exposure

- Not intended to be used with NRT

- Adverse event profile
  - Nausea
  - Insomnia
  - Abnormal dreams
  - Headache
Varenicline Dosing

<table>
<thead>
<tr>
<th>Product</th>
<th>Available Doses</th>
<th>Guidelines for Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varenicline</td>
<td>0.5 mg, 1 mg</td>
<td>Begin varenicline at least 7 days prior to planned quit date; alternatively, patient may quit anytime between days 8 and 35 if higher serum concentrations are preferred.</td>
</tr>
<tr>
<td></td>
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<td>0.5 mg daily for 3 days, then 0.5 mg twice daily through day 7; 1 mg twice daily beginning day 8</td>
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<tr>
<td></td>
<td></td>
<td>Continue for 12 weeks</td>
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<td></td>
<td>May take for an additional 12 weeks to increase long-term abstinence</td>
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<td>For patients with severe renal impairment (CrCl &lt;30 mL/min), begin 0.5 mg daily and titrate to 0.5 mg twice daily</td>
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<td></td>
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<td>For hemodialysis patients, a maximum of 0.5 mg daily may be given</td>
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CrCl, creatinine clearance.

Pharmacologic Agents: Efficacy Comparison

- Success with smoking cessation: review of 267 studies (n=101,804)
  - NRT, bupropion SR, and varenicline all superior to placebo
  - Varenicline superior to NRT
  - Varenicline superior to bupropion
  - No difference between bupropion and NRT
  - No difference between varenicline and combination NRT

- Highest quit rates observed with varenicline and combination NRT

- Treatment should be individualized to the needs and desires of the patient
Multi-Drug Therapy for Smoking Cessation

- Varenicline
- Short-acting NRT
- Bupropion
- Long-acting NRT

Neuropsychiatric Risks Associated with Smoking Cessation Therapies

EAGLES Trial: conducted to determine the incidence of a composite measure of moderate and severe neuropsychiatric adverse events in patients with and without a history of neuropsychiatric illness

Non-psychiatric cohort (n=4028)
- Varenicline group: 1.3%
- Bupropion group: 2.2%
- NRT group: 2.5%
- Placebo group: 2.4%

Psychiatric cohort (n=4116)
- Varenicline group: 6.5%
- Bupropion group: 6.7%
- NRT group: 5.2%
- Placebo group: 4.9%
Cardiovascular Risks Associated with Smoking Cessation Therapies

**EAGLES Trial:** data analysis to determine the time to development of major adverse cardiovascular events (MACE or MACE+) during or after treatment

<table>
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<tr>
<th>Event</th>
<th>Percentage</th>
</tr>
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<tbody>
<tr>
<td>MACE</td>
<td>&lt;0.5%</td>
</tr>
<tr>
<td>MACE+</td>
<td>&lt;0.8%</td>
</tr>
</tbody>
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No observable difference across treatment groups

No difference per group according to Framingham risk scores

The Role of Counseling

- Counseling increases successful quitting even when used without medical intervention

- The combination of medication and counseling is associated with higher quit rates and is preferred if the patient is willing to utilize both
  - Both should be offered regardless of whether the patient is willing to utilize the combination

- “Intensive” counseling is most effective
  - Brief counseling is not as effective, but it is still beneficial for individuals unwilling to participate in longer sessions
Non-FDA Approved Smoking Cessation Therapies

- **Nortriptyline**
  - Mechanism unrelated to antidepressant effects
  - 25 mg by mouth daily beginning 1-2 weeks prior to quit date, titrate to 75-150 mg daily as needed
    - Continue for 12 weeks after quit date
  - Side effects: dry mouth, constipation, nausea, sedation

- **Clonidine**
  - Mechanism unrelated to antihypertensive effects
  - 0.1 mg daily titrated up to 0.75 mg daily (max) or 100-200 mcg patch every 7 days
  - Side effects: sedation, postural hypotension, bradycardia, rebound hypertension

E-cigarettes and Vaping Devices: Electronic Nicotine Delivery Systems (ENDS)

Schematic illustration of a typical e-cigarette.
Current Trends in Vaping

- U.S. national estimates of adolescent vaping and nicotine use
  - Survey of 8th, 10th, and 12th graders (n=13,850)

**INCREASES IN VAPING PREVALENCE AMONG ADOLESCENTS 2017-2018**

Marketing Trends for ENDS

- Use has become associated with being healthier than smoking cigarettes
  - Marketing suggests reductions in negative health consequences and an increase in physical fitness
  - Manufacturers have largely stopped using the term “e-cigarettes”

- Packaging often uses graphics associated with health
  - Photos of fruits and vegetables

- Words used to describe vaping on Twitter
  - “Harmless” (28%)
    - “…ingredients of e-liquids are completely harmless to use and natural”
  - “Health enhancing” (9%)
    - “E-cigs may be better for you than organic produce!”
    - “100% natural #medicine #HealthyLiving #killcancer”
    - “Put vitamins in vape juice so teens get their nutrients”
  - “Smoking cessation” (1%)

Example of exterior sign indicating vaping is healthier than smoking.
### Reasons For Using ENDS
- 95% of U.S. adults believe ENDS are cleaner and healthier than cigarettes
- 93% believe they are more economical than cigarettes
- 76%-88% use them to circumvent smoke-free policies
- 73% use them because they are “trendy”

### ENDS and Nicotine
- Nicotine concentrations in e-juice vary
  - No nicotine
  - Low (6-12 mg/mL)
  - Medium (18 mg/mL)
  - High (24 mg/mL)
- Approximately one-quarter to one-third of the nicotine in e-juice will reach the circulation
  - Less than the concentration achieved through smoking traditional cigarettes
E-juice and Vapors

- Not just harmless water-based vapors
  - Vapors have been found to contain heavy metals
  - At least 20 known carcinogens and teratogenic agents have been identified in e-liquids and vapors
  - Tank systems increase environmental exposure

- Flavorings are marketed as “generally recognized as safe” due to “food grade” designation

- Sweet flavors have frequently been found to contain diacetyl or acetyl propionyl
  - Associated with bronchiolitis obliterans

Trends Associated with Nicotine Content in ENDS

- Puffs per vaping episode vs. nicotine-free e-juice
  - 2.4x with low nicotine concentrations
  - 4.9x with medium nicotine concentrations
  - 3.7x with high nicotine concentrations

- Vaping episodes per day vs. nicotine-free e-juice
  - 2.5x with low nicotine concentrations
  - 2.8x with medium nicotine concentrations
  - 3.9x with high nicotine concentrations

- The odds of initiating cigarette smoking increase approximately 2.4x with each stepwise increase in nicotine content of e-juice

*Environ Health Perspect.*
2014;122(9):A244-9.
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The Role of ENDS in Smoking Cessation

- Vaping devices address several aspects of the addiction to cigarettes
  - Nicotine withdrawal
  - Social aspects
  - Behavioral aspects

- Literature does suggest that vaping may play a role in increasing cessation rates among established smokers
  - Concern that benefits may be offset by use of vaping as a gateway to smoking by non-users

Current Smokers and ENDS Use

- Individuals who smoke cigarettes may become dual users
  - Prolonged exposure to tobacco
  - Decreased tobacco consumption is not a clinically relevant outcome
    - Smoking cessation is always the goal

- No studies have shown that ENDS are superior to FDA-approved smoking cessation aids
  - To date, no ENDS product manufacturer has applied for approval as a smoking cessation aid

- The American Heart Association, American Association for Cancer Research, and American Society of Clinical Oncology do not recommend ENDS as a cessation aid
  - If used, a quit date needs to be set
ENDS Safety Data

- Limited and inconsistent
- Common adverse events reported with vaping
  - Mouth irritation, cough, nausea
- Serious adverse events reported to the FDA (direct causality not always established)
  - Chest pain
  - Congestive heart failure
  - Seizure
  - Tachycardia
  - Severe burns
  - Lung disease
- As little as 5 minutes of use by healthy users results in significant increases in airflow resistance
- Daily use of ENDS has been associated with a doubling of the risk for myocardial infarction

ENDS Regulations

- Food Drug and Cosmetic Act and Tobacco Control Act
  - Granted the FDA the authority to regulate false or misleading statements in tobacco marketing
  - Included only cigarettes, cigarette tobacco, roll-your-own cigarettes, and smokeless tobacco
- Deeming Rule (2016)
  - Expanded FDA regulatory authority to include ENDS, pipe tobacco, cigars, hookah, and e-liquids
  - Also includes “components and parts” of the above
    - Atomizers, batteries (with or without variable voltage), cartomizers (atomizer plus replaceable fluid-filled cartridge), digital display/lights to adjust settings, tank systems, flavors, vials that contain e-liquids, programmable software
Identifying Tobacco Users

- More than 80% of smokers have at least 1 medical visit each year
  - Less than half report receiving advice to quit

- In 2015, approximately two-thirds of active smokers reported wanting to quit
  - Over half reported making an attempt to quit in the previous 12 months
  - Young adults are more likely to try to quit than older adults

- Goal should be to screen everyone and advise all smokers to quit

The Fully Informed Smoker

- Four levels of being “informed”

  - Level 1: Having an idea that smoking can be bad for your health
  - Level 2: Being aware that particular diseases are caused by smoking
  - Level 3: Accurately appreciating the meaning, severity, and probabilities of developing tobacco-related diseases
  - Level 4: Accepting and understanding that all risks inherent in the first 3 levels are the smoker’s personal risks
The 5 A’s

- **Ask** about tobacco use
- **Advise** to quit
- **Assess** willingness to make a quit attempt
- **Assist** in the quit attempt
- **Arrange** follow-up

Addressing Unwillingness to Quit: The 5 R’s

- **Relevance:** Why is quitting important to the individual?
- **Risks:** What might happen if smoking continues?
- **Rewards:** What can the individual look forward to if they quit?
- **Roadblocks:** What does the patient think the barriers to quitting are? Are they real? Are there misconceptions that can be remedied?
- **Repetition:** If at first you don’t succeed…
Preparing to Quit and Dealing with Relapses

• Some patients may prefer to taper cigarette use prior to setting their quit date
  • No difference in quit rates compared to those who quit abruptly

• Make sure the patient understands that a relapse during the quit attempt is not a failure
  • Two-thirds of patients who relapse after a quit attempt are willing to try again within 30 days
  • There is insufficient evidence to support any behavioral intervention to help short-term quitters avoid relapse

Preventing Relapses

• For those who seem most concerned about relapse, or who have already done so after a quit attempt, extended pharmacological therapy may be warranted
  • An additional 12 weeks (or more) of varenicline has been shown to prevent relapse in some users
  • Data are mixed for NRT
  • Data do not show that extended use of bupropion SR aids in maintaining abstinence

• Relapsing after discontinuing medication therapy does not preclude the use of the same therapy again
Debunking Common Smoking Myths

• If I stop smoking, I’m going to gain a lot of weight
  • Average gain is 5-10 pounds
  • Not an inevitability

• Filters get rid of the toxins in cigarettes
  • Tar is decreased
  • Increased ventilation = slower burn = more puffs per cigarette

• The danger of second-hand smoke is minimal
  • Risks of cardiovascular disease and lung cancer are increased

• Light/menthol cigarettes are not as bad for you
  • Can be more damaging due to deeper inhalations and longer exposure

• I only smoke when I (fill in the blank), so my exposure is limited
  • Even occasional smoking increases health risks

Pharmacists and Smoking Cessation

• Pharmacists are the most likely healthcare professionals to have regular interactions with patients who wish to quit

• Several states allow autonomous prescribing of smoking cessation medications
  • Statewide protocols or independent prescribing

• Collaborative practice in many other states
Pharmacists and Smoking Cessation

• There are many reasons why pharmacists do not engage in cessation efforts
  • Perceived need for training
  • Perception that behavioral counseling is beyond their role
  • Unwillingness to strain relationships with customers
  • Lack of time or space
  • Lack of ongoing customer relationships
  • Lack of support from management

• Ask, Advise, and Assess are most easily accomplished and take no substantial training
  • Referrals for Assist and Arrange can be accomplished to complete the cessation attempt

Resources for Patients and Clinicians

• “Pharmacists: Help Your Patients Quit Smoking”
  • CDC guide for pharmacists
  • Resources for both pharmacists and patients

• National Cancer Institute Quitline: 1-877-44U-QUIT
  • Trained counselors available M-F, 8 AM-8 PM

• State Quitlines: 1-800-QUIT-NOW
  • Support available 24/7
  • Trained cessation coaches who offer a choice of services, including telephone counseling, self-help materials, and referrals to community programs

CDC, Centers for Disease Control and Prevention.
Thank you!