Strategies to Maximize Clients’ Effective Use of FDA-Approved Pharmacotherapy

Christine Garver-Apgar, PhD
Research Director
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Conflicts of Interest Disclosure

The presenter has no conflicts of interest, financial or otherwise, to disclose concerning the contents of the following presentation.
Link to BHWP’s overview video on tobacco cessation pharmacotherapy:

https://www.youtube.com/watch?v=JRZjX-NB7H4
Session Objectives

• Discuss basic concepts of nicotine addiction, cravings, and withdrawal
• Identify ways clinicians can better prepare their clients to make a quit attempt with the help of cessation medications
• Describe strategies that improve medication adherence and address relapse
Nicotine Addiction
Nicotine differs from other drugs of abuse since a greater percentage of those who try it become daily users than those who try other drugs.

Nicotine from a puff of a cigarette reaches the brain within 10 seconds.
Tobacco Cessation Treatment Strategies

<table>
<thead>
<tr>
<th>Treatment Format</th>
<th>Abstinence Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unaided</td>
<td>4-7%</td>
</tr>
<tr>
<td>Self-help</td>
<td>11-14%</td>
</tr>
<tr>
<td>Quitline</td>
<td>11-15%</td>
</tr>
<tr>
<td>Individual counseling</td>
<td>15-19%</td>
</tr>
<tr>
<td>Group counseling</td>
<td>12-16%</td>
</tr>
<tr>
<td>Medication alone</td>
<td>22%</td>
</tr>
<tr>
<td>Medication + counseling</td>
<td>25-30%</td>
</tr>
</tbody>
</table>
Tobacco Dependence Has Two Parts

Tobacco dependence is a 2-part problem

**Physical**
- The addiction to nicotine
  - Treatment
  - Medications for cessation

**Behavior**
- The habit of using tobacco
  - Treatment
  - Behavior change program

Treatment should address both the addiction **and** the habit.

*Courtesy of the University of California, San Francisco*
Tobacco Cessation Medications

The only medications approved by the Food and Drug Administration (FDA) for tobacco cessation are:

- Nicotine gum
- Nicotine lozenge
- Nicotine patch
- Nicotine nasal spray
- Nicotine inhaler
- Bupropion SR tablets
- Varenicline tablets
Pharmacotherapy Efficacy

Abstinence rates compared to placebo at 6 months or greater post-quit

<table>
<thead>
<tr>
<th>Medication</th>
<th>Number of Trials (People)</th>
<th>Estimated Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRT</td>
<td>117 (51,265)</td>
<td>1.6 (1.5-1.7)</td>
</tr>
<tr>
<td>Bupropion</td>
<td>44 (13,728)</td>
<td>1.6 (1.5-1.8)</td>
</tr>
<tr>
<td>Varenicline</td>
<td>14 (6,166)</td>
<td>2.3 (2.0-2.6)</td>
</tr>
</tbody>
</table>
Long-Term (36-month) Quit Rates for Cessation Medications

Percent quit

- Active drug
- Placebo

Nicotine gum
Nicotine patch
Nicotine lozenge
Nicotine nasal spray
Nicotine inhaler
Bupropion
Varenicline
Tobacco Use Cycle

1. Tobacco Product Used
2. Nicotine Absorption
3. Arousal, Mood Modulation, Pleasure
4. Tolerance
5. Withdrawal Symptoms
6. Craving
Nicotine Withdrawal Effects

- Irritability, frustration, anger
- Anxiety
- Difficulty concentrating
- Restlessness, impatience
- Depressed mood
- Insomnia
- Increased appetite

Most symptoms:
- Appear within the first 1–2 days
- Peak within the first week
- Decrease within 2–4 weeks
Nicotine Addiction Cycle

![Graph showing plasma nicotine concentration over the course of a day, highlighting the addiction cycle with peaks and troughs corresponding to pleasure/arousal, neutral zone, and abstinence symptoms.]

- **Pleasure/Arousal**
- **Neutral Zone**
- **Abstinence symptoms**
Maximizing Cessation Medication Effectiveness
The Fagerström Test for Nicotine Dependence

1. How soon after you wake up do you smoke your first cigarette?
   - Within 5 minutes (3 points)
   - 5 to 30 minutes (2 points)
   - 31 to 60 minutes (1 point)
   - After 60 minutes (0 points)

2. Do you find it difficult not to smoke in places where you shouldn't, such as in church or school, in a movie, at the library, on a bus, in court or in a hospital?
   - Yes (1 point) / No (0 points)

3. Which cigarette would you most hate to give up; which cigarette do you treasure the most?
   - The first one in the morning (1 point)
   - Any other one (0 points)

4. How many cigarettes do you smoke each day?
   - 10 or fewer (0 points)
   - 11 to 20 (1 point)
   - 21 to 30 (2 points)
   - 31 or more (3 points)

5. Do you smoke more during the first few hours after waking up than during the rest of the day?
   - Yes (1 point) / No (0 points)

6. Do you still smoke if you are so sick that you are in bed most of the day, or if you have a cold or the flu and have trouble breathing?
   - Yes (1 point) / No (0 points)
# FTND and HSI Scales

<table>
<thead>
<tr>
<th>Dependence Level</th>
<th>Nicotine Replacement Therapy Dosage</th>
<th>Combination Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Patches: 21mg/24hr or 15mg/16hr&lt;br&gt;Inhaler: 6 – 12 cartridges per day&lt;br&gt;Lozenge: 4mg&lt;br&gt;Gum: 4mg</td>
<td>Patches: 21mg/24hr or 15mg/16hr&lt;br&gt;And&lt;br&gt;Lozenge or Gum: 2mg</td>
</tr>
<tr>
<td>FTND: 8+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HSI: 5+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Patches: 21mg/24hr or 15mg/16hr&lt;br&gt;Inhaler: 6 – 12 cartridges per day&lt;br&gt;Lozenge: 4mg&lt;br&gt;Gum: 4mg</td>
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</tr>
<tr>
<td>FTND: 5-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HSI: 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low to Moderate</td>
<td>Patches: 14mg/24hr patch or 10mg/16hr&lt;br&gt;Inhaler: 6 – 12 cartridges per day&lt;br&gt;Lozenge: 2mg&lt;br&gt;Gum: 2mg</td>
<td>Patches: 14mg/24hr or 15mg/16 hr&lt;br&gt;And&lt;br&gt;Lozenge or Gum: 2mg</td>
</tr>
<tr>
<td>FTND: 3-4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HSI: 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>May not need NRT&lt;br&gt;Monitor for withdrawal symptoms&lt;br&gt;Patches: 7mg/24hr patch or 5mg/16hr&lt;br&gt;Lozenge: 2mg&lt;br&gt;Gum: 2mg</td>
<td></td>
</tr>
<tr>
<td>FTND: 1-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HSI: 1-2 (&quot;very low&quot;)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fiore et al. 2008
Link to BHWP’s Clinical Use Guidelines for Pharmacotherapies tool for providers:

NRT Dosage

- Clinicians should communicate to clients that their *initial* recommendation for NRT dosage is based on a validated assessment.
- However, clinicians should be aware that NRT is frequently under-dosed.
- Clients should know that it is extremely difficult to overdose on nicotine.
- If clients experience high levels of cravings when taking NRT as ordered, they can safely increase their dose.

The Fagerström Test for Nicotine Dependence

1. How soon after you wake up do you smoke your first cigarette?
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</tr>
<tr>
<td><strong>Moderate</strong>&lt;br&gt;FTND: 5-7&lt;br&gt;HSI: 4</td>
<td>Patches: 21mg/24hr or 15mg/16hr&lt;br&gt;Inhaler: 6 – 12 cartridges per day&lt;br&gt;Lozenge: 4mg&lt;br&gt;Gum: 4mg</td>
<td>Patches: 21mg/24hr or 15mg/16 hr&lt;br&gt;AND&lt;br&gt;Lozenge or Gum: 2mg</td>
</tr>
<tr>
<td><strong>Low to Moderate</strong>&lt;br&gt;FTND: 3-4&lt;br&gt;HSI: 3</td>
<td>Patches: 14mg/24hr patch or 10mg/16hr&lt;br&gt;Inhaler: 6 – 12 cartridges per day&lt;br&gt;Lozenge: 2mg&lt;br&gt;Gum: 2mg</td>
<td>Patches: 14mg/24hr or 15mg/16 hr&lt;br&gt;AND&lt;br&gt;Lozenge or Gum: 2mg</td>
</tr>
<tr>
<td><strong>Low</strong>&lt;br&gt;FTND: 1-2&lt;br&gt;HSI: 1-2 (“very low”)</td>
<td>May not need NRT&lt;br&gt;Monitor for withdrawal symptoms&lt;br&gt;Patches: 7mg/24hr patch or 5mg/16hr&lt;br&gt;Lozenge: 2mg&lt;br&gt;Gum: 2mg</td>
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- Clients should know that it is extremely difficult to overdose on nicotine.
- If clients experience high levels of cravings when taking NRT as ordered, they can safely increase their dose.
Combination Therapy

Use of two or more forms of tobacco cessation medications can improve cessation rates
Pre-Cessation Nicotine Replacement

Studies show individuals who used NRT before their quit date:

- Did not experience any significant side effects
- Experienced an increase in their quit rates
- Were twice as likely to maintain their abstinence at 6 months
Adherence and Dosing Schedules

Fewest Doses

Patch
Varenicline
Bupropion
Gum/Lozenge

Most Doses
Patch Application: Tips for Clients

• Peel off ½ of the adhesive backing
• Apply adhesive exposed side to skin
• Peel off remaining backing
• Press firmly with palm of hand for 10 seconds
• Make sure patch is firmly adhered to skin
• Do not cut the patch in half
• Carefully dispose of patch after removing
Gum/Lozenge: Directions for Use

- Chew each piece slowly until the gum releases a peppery taste or a slight tingling occurs
- “Park” the gum between cheek and gum to allow for absorption across the buccal mucosa
- Resume chewing when taste or tingle fades
- When tingle returns, stop chewing and park gum in a different place in mouth
- Repeat process until the tingle is gone (about 30 minutes)
Setting Expectations

• Discuss with clients any preconceived notions they may have about NRT, “mythbusting” if necessary
• Remind clients that NRT addresses only the physical dependence to nicotine and is not addictive
• Clients should *practice* using cessation medications, perhaps even *sampling* multiple medication options
• No evidence that the mode of NRT should match the mode of clients’ tobacco delivery
• Providers should encourage clients to be both flexible with cessation medications and also proactive about approaching their provider with concerns
<table>
<thead>
<tr>
<th>Medications Known or Suspected To Have Their Levels Affected by Smoking and Smoking Cessation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ANTIPSYCHOTICS</strong></td>
</tr>
<tr>
<td>Chlorpromazine (Thorazine)</td>
</tr>
<tr>
<td>Clozapine (Clozaril)</td>
</tr>
<tr>
<td>Fluphenazine (Permitil)</td>
</tr>
<tr>
<td>Haloperidol (Haldol)</td>
</tr>
<tr>
<td>Olanzapine (Zyprexa)</td>
</tr>
<tr>
<td>Thiothixene (Navane)</td>
</tr>
<tr>
<td>Trifluoperazine (Stelazine)</td>
</tr>
<tr>
<td>Ziprasidone (Geodon)</td>
</tr>
<tr>
<td>Mesoridazine (Serentil)</td>
</tr>
<tr>
<td><strong>ANTIDEPRESSANTS</strong></td>
</tr>
<tr>
<td>Amitriptyline (Elavil)</td>
</tr>
<tr>
<td>Clomipramine (Anafranil)</td>
</tr>
<tr>
<td>Desipramine (Norpramin)</td>
</tr>
<tr>
<td>Doxepin (Sinequan)</td>
</tr>
<tr>
<td>Duloxetine (Cymbalta)</td>
</tr>
<tr>
<td>Fluvoxamine (Luvox)</td>
</tr>
<tr>
<td>Imipramine (Tofranil)</td>
</tr>
<tr>
<td>Mirtazapine (Remeron)</td>
</tr>
<tr>
<td>Nortriptyline (Pamelor)</td>
</tr>
<tr>
<td>Trazodone (Desyrel)</td>
</tr>
<tr>
<td><strong>MOOD STABILIZERS</strong></td>
</tr>
<tr>
<td>Carbamazepine (Tegretol)</td>
</tr>
<tr>
<td><strong>ANXIOLYTICS</strong></td>
</tr>
<tr>
<td>Alprazolam (Xanax)</td>
</tr>
<tr>
<td>Diazepam (Valium)</td>
</tr>
<tr>
<td>Lorazepam (Ativan)</td>
</tr>
<tr>
<td>Oxazepam (Serax)</td>
</tr>
<tr>
<td><strong>OTHERS</strong></td>
</tr>
<tr>
<td>Acetaminophen</td>
</tr>
<tr>
<td>Caffeine</td>
</tr>
<tr>
<td>Heparin</td>
</tr>
<tr>
<td>Insulin</td>
</tr>
<tr>
<td>Rasagiline (Azilect)</td>
</tr>
<tr>
<td>Riluzole (Rilutek)</td>
</tr>
<tr>
<td>Ropinirole (Requip)</td>
</tr>
<tr>
<td>Tacrine</td>
</tr>
<tr>
<td>Warfarin</td>
</tr>
</tbody>
</table>

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Relapse Prevention

• Relapse is common but not inevitable
• Relapse prevention begins at the beginning of treatment, not just after a relapse occurs
• Preventing relapse often involves behavioral, cognitive and pharmacological components

The risk of relapse during the first 12 months after stopping tobacco use is over 50%
Relapse Prevention Strategies

• Avoid any tobacco use, particularly in the first two weeks of a quit attempt
• Identify high-risk situations
• Prepare and plan for ways to deal with high-risk situations when they occur
• Enhance self-efficacy through supportive relationships and behaviors that support well-being
Adherence Strategies to Consider

- Counseling
- Telephone or computer-assisted monitoring
- Family Interventions
- Appointment/Refill reminders
- Relapse plan (i.e. do NOT stop medications)
- Peer Support
- Frequent follow-up
Improving Adherence Process

Identify patients at risk for non-adherence
- Comorbid psychiatric conditions
- Comorbid medical conditions with complex treatment regimens
- Higher dependence

Identify non-adherence
- Missed appointments
- Missed refills

Ask patient about non-adherence (nonconfrontational)
- How did they feel on the medication (and off)?
- Did they forget to take it?
- Did they use the medication as instructed?

Change the regimen to meet the patient’s needs.
Promotes evidence-based approaches and best practices to prevent tobacco use and cancer among behavioral health populations

Behavioral Health & Wellness Program

303.724.3713
bh.wellness@ucdenver.edu
www.bhwellness.org