AIDS for CESSATION & CASE SCENARIO OVERVIEW

METHODS for QUITTING

- Nonpharmacologic
- Pharmacologic

Combination therapy is preferred.

NONPHARMACOLOGIC METHODS

- Cold turkey: Just do it!
- Unassisted tapering (fading)
  - Reduced frequency of use
  - Lower nicotine cigarettes
  - Special filters or holders
- Assisted tapering
  - QuitKey

NONPHARMACOLOGIC METHODS (cont’d)

- Formal cessation programs
- Self-help programs
- Individual counseling
- Group programs
- Telephone counseling
  - 1-800-QUITNOW
  - 1-800-786-8669
- Web-based counseling
  - www.smokefree.gov
  - www.quitnet.com
- Aversion therapy
- Acupuncture therapy
- Hypnotherapy
- Massage therapy

SCHEDULED GRADUAL REDUCTION of SMOKING

- Gradual reduction of the total number of cigarettes smoked per day
- Computerized unit facilitates reduction:
  - QuitKey
    - Tapering curve developed based on patient’s smoking level
    - 19–24% abstinent at 1 year
    - Includes telephone counseling support

QuitKey SMOKING CESSATION PROGRAM

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**SMOKING CESSATION PROGRAM**

**Stage 1** (7 days)
- Push the SMOKE button every time you smoke, to record smoking habits
- Turn unit on every morning and off every night

**Stage 2** (14–34 days)
- Smoke only when you hear the tone or see the SMOKE SIGNAL; tapers smoking over time
- Press the SMOKE button every time you smoke
- Turn unit on every morning and off every night

**PHARMACOTHERAPY**

“*All patients attempting to quit should be encouraged to use effective pharmacotherapies for smoking cessation except in the presence of special circumstances.*”


**FDA APPROVALS: SMOKING CESSATION**

<table>
<thead>
<tr>
<th>Year</th>
<th>Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>1984</td>
<td>Rx nicotine gum</td>
</tr>
<tr>
<td>1991</td>
<td>OTC nicotine gum &amp; patch; Rx nicotine nasal spray</td>
</tr>
<tr>
<td>1996</td>
<td>OTC nicotine lozenge</td>
</tr>
<tr>
<td>1997</td>
<td>Rx transdermal nicotine patch</td>
</tr>
<tr>
<td>2002</td>
<td>Rx bupropion SR</td>
</tr>
<tr>
<td>2006</td>
<td>Rx varenicline</td>
</tr>
<tr>
<td>2007</td>
<td>OTC nicotine lozenge</td>
</tr>
</tbody>
</table>

**SCHEDULED GRADUAL REDUCTION (cont’d)**

Who is a candidate for scheduled gradual reduction?
- Anyone who wants to quit smoking
- Particularly useful in persons for whom medications might not be a first-line choice, such as pregnant women or teens
- Spit tobacco users (18.4% abstinent after 1 year)

Ordering information
www.quitkey.com or 1-800-543-3744 ($59.95)

**PHARMACOLOGIC METHODS: FIRST-LINE THERAPIES**

Three general classes of FDA-approved drugs for smoking cessation:
- Nicotine replacement therapy (NRT)
  - Nicotine gum, patch, lozenge, nasal spray, inhaler
- Psychotropics
  - Sustained-release bupropion
- Partial nicotinic receptor agonist
  - Varenicline

Currently, no medications have an FDA indication for use in spit tobacco cessation.

**NRT: RATIONALE for USE**

- Reduces physical withdrawal from nicotine
- Allows patient to focus on behavioral and psychological aspects of tobacco cessation

NRT APPROXIMATELY DOUBLES QUIT RATES.
NRT: PRODUCTS

- **Polacrilex gum**
  - Nicorette (OTC)
  - Generic nicotine gum (OTC)

- **Lozenge**
  - Commit (OTC)
  - Generic nicotine lozenge (OTC)

- **Transdermal patch**
  - Nicoderm CQ (OTC)
  - Generic nicotine patches (OTC, Rx)

Nasal spray
- Nicotrol NS (Rx)

Inhaler
- Nicotrol (Rx)

PLASMA NICOTINE CONCENTRATIONS for NICOTINE-CONTAINING PRODUCTS

NRT: PRECAUTIONS

- Patients with underlying cardiovascular disease
  - Recent myocardial infarction (within past 2 weeks)
  - Serious arrhythmias
  - Serious or worsening angina

NRT products may be appropriate for these patients if they are under medical supervision.

NRT: PRECAUTIONS (cont’d)

- Patients with other underlying conditions
  - Active temporomandibular joint disease (gum only)
  - Pregnancy
  - Lactation

NRT products may be appropriate for these patients if they are under medical supervision.

NRT: OTHER CONSIDERATIONS

- NRT is not FDA-approved for use in children or adolescents
- Nonprescription sales (patch, gum, lozenge) are restricted to adults ≥18 years of age
  - NRT use in minors requires a prescription
- Patients should stop using all forms of tobacco upon initiation of the NRT regimen

NICOTINE GUM

- Nicorette (GlaxoSmithKline); generics
  - Resin complex
  - Nicotine
  - Polacrilin
  - Sugar-free chewing gum base
  - Contains buffering agents to enhance buccal absorption of nicotine
  - Available: 2 mg, 4 mg; regular, FreshMint, Fruit Chill, mint, & orange flavor

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### NICOTINE GUM: DOSING

Dosage based on current smoking patterns:

<table>
<thead>
<tr>
<th>If patient smokes</th>
<th>Recommended strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥25 cigarettes/day</td>
<td>4 mg</td>
</tr>
<tr>
<td>&lt;25 cigarettes/day</td>
<td>2 mg</td>
</tr>
</tbody>
</table>

**Recommended Usage Schedule for Nicotine Gum**

<table>
<thead>
<tr>
<th>Weeks 1-6</th>
<th>Weeks 7-9</th>
<th>Weeks 10-12</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 piece q1-2 h</td>
<td>1 piece q2-4 h</td>
<td>1 piece q4-8 h</td>
</tr>
</tbody>
</table>

**DO NOT USE MORE THAN 24 PIECES PER DAY.**

### NICOTINE GUM: DIRECTIONS for USE

- Chew each piece very slowly several times
- Stop chewing at first sign of peppery, minty, or citrus taste or slight tingling in mouth (~15 chews, but varies)
- “Park” gum between cheek and gum (to allow absorption of nicotine across buccal mucosa)
- Resume slow chewing when taste or tingle fades
- When taste or tingle returns, stop and park gum in different place in mouth
- Repeat chew/park steps until most of the nicotine is gone (taste or tingle does not return; generally 30 minutes)

### NICOTINE GUM: CHEWING TECHNIQUE SUMMARY

- Chew slowly
- Chew again when peppery taste or tingle fades
- Stop chewing at first sign of peppery taste or tingling sensation
- Park between cheek & gum

### NICOTINE GUM: ADDITIONAL PATIENT EDUCATION

- To improve chances of quitting, use at least nine pieces of gum daily
- The effectiveness of nicotine gum may be reduced by some foods and beverages:
  - Coffee
  - Juices
  - Wine
  - Soft drinks

Do NOT eat or drink for 15 minutes BEFORE or while using nicotine gum.

### NICOTINE GUM: ADD’L PATIENT EDUCATION (cont’d)

- Chewing gum will *not* provide same rapid satisfaction that smoking provides
- Chewing gum too rapidly can cause excessive release of nicotine, resulting in
  - Lightheadedness
  - Nausea/vomiting
  - Irritation of throat and mouth
  - Hiccups
  - Indigestion
NICOTINE GUM: ADD’L PATIENT EDUCATION (cont’d)

- Side effects of nicotine gum include
  - Mouth soreness
  - Hiccups
  - Dyspepsia
  - Jaw muscle ache
- Nicotine gum may stick to dental work
  - Discontinue use if excessive sticking or damage to dental work occurs

NICOTINE GUM: SUMMARY

ADVANTAGES
- Gum use may satisfy oral cravings.
- Gum use may delay weight gain.
- Patients can titrate therapy to manage withdrawal symptoms.

DISADVANTAGES
- Gum chewing may not be socially acceptable.
- Gum is difficult to use with dentures.
- Patients must use proper chewing technique to minimize adverse effects.

NICOTINE LOZENGE

Commit (GlaxoSmithKline); generics

- Nicotine polacrilex formulation
  - Delivers ~25% more nicotine than equivalent gum dose
- Sugar-free, mint or cherry flavor (boxed or POP-PAC)
- Contains buffering agents to enhance buccal absorption of nicotine
- Available: 2 mg, 4 mg

NICOTINE LOZENGE: DOSING

Dosage is based on the “time to first cigarette” (TTFC) as an indicator of nicotine addiction

Use Commit Lozenge 2 mg:
- If you smoke your first cigarette more than 30 minutes after waking up

Use Commit Lozenge 4 mg:
- If you smoke your first cigarette of the day within 30 minutes of waking up

NICOTINE LOZENGE: DIRECTIONS for USE

- Use according to recommended dosing schedule
- Place in mouth and allow to dissolve slowly (nicotine release may cause warm, tingling sensation)
- Do not chew or swallow lozenge.
- Occasionally rotate to different areas of the mouth.
- Lozenge will dissolve completely in about 20–30 minutes.

Recommended Usage Schedule for Commit Lozenge

<table>
<thead>
<tr>
<th>Weeks 1-6</th>
<th>Weeks 7-9</th>
<th>Weeks 10-12</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 lozenge</td>
<td>1 lozenge</td>
<td>1 lozenge</td>
</tr>
<tr>
<td>q 1-2 h</td>
<td>q 2-4 h</td>
<td>q 4-8 h</td>
</tr>
</tbody>
</table>

DO NOT USE MORE THAN 20 LOZENGES PER DAY.
NICOTINE LOZENGE: ADDITIONAL PATIENT EDUCATION

- To improve chances of quitting, use at least nine lozenges daily during the first 6 weeks
- The lozenge will not provide the same rapid satisfaction that smoking provides
- The effectiveness of the nicotine lozenge may be reduced by some foods and beverages:
  - Coffee
  - Juices
  - Wine
  - Soft drinks

Do NOT eat or drink for 15 minutes BEFORE or while using the nicotine lozenge.

NICOTINE LOZENGE: ADD’L PATIENT EDUCATION (cont’d)

- Side effects of the nicotine lozenge include
  - Nausea
  - Hiccups
  - Cough
  - Heartburn
  - Headache
  - Flatulence
  - Insomnia

NICOTINE LOZENGE: SUMMARY

ADVANTAGES
- Lozenge use may satisfy oral cravings.
- The lozenge is easy to use and conceal.
- Patients can titrate therapy to manage withdrawal symptoms.

DISADVANTAGES
- Gastrointestinal side effects (nausea, hiccups, and heartburn) may be bothersome.

TRANSDERMAL NICOTINE PATCH

Nicoderm CQ (GlaxoSmithKline); generic

- Nicotine is well absorbed across the skin
- Delivery to systemic circulation avoids hepatic first-pass metabolism
- Plasma nicotine levels are lower and fluctuate less than with smoking

TRANSDERMAL NICOTINE PATCH: PREPARATION COMPARISON

<table>
<thead>
<tr>
<th>Product</th>
<th>Nicoderm CQ</th>
<th>Generic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine delivery</td>
<td>24 hours</td>
<td>24 hours</td>
</tr>
<tr>
<td>Availability</td>
<td>OTC</td>
<td>Rx/OTC</td>
</tr>
<tr>
<td>Strengths</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7-mg patch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14-mg patch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21-mg patch</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TRANSDERMAL NICOTINE PATCH: DOSING

<table>
<thead>
<tr>
<th>Product</th>
<th>Light Smoker</th>
<th>Heavy Smoker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicoderm CQ</td>
<td>&lt;10 cigarettes/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Step 2 (14 mg x 6 weeks)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Step 3 (7 mg x 2 weeks)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;10 cigarettes/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Step 1 (21 mg x 6 weeks)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Step 2 (14 mg x 2 weeks)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Step 3 (7 mg x 2 weeks)</td>
<td></td>
</tr>
<tr>
<td>Generic (formerly Habitrol)</td>
<td>&lt;10 cigarettes/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Step 2 (14 mg x 6 weeks)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Step 3 (7 mg x 2 weeks)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;10 cigarettes/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Step 1 (21 mg x 4 weeks)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Step 2 (14 mg x 2 weeks)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Step 3 (7 mg x 2 weeks)</td>
<td></td>
</tr>
</tbody>
</table>
TRANSDERMAL NICOTINE PATCH: DIRECTIONS for USE

- Choose an area of skin on the upper body or upper outer part of the arm
- Make sure skin is clean, dry, hairless, and not irritated
- Apply patch to different area each day
- Do not use same area again for at least 1 week

TRANSDERMAL NICOTINE PATCH: DIRECTIONS for USE (cont’d)

- Remove patch from protective pouch

TRANSDERMAL NICOTINE PATCH: DIRECTIONS for USE (cont’d)

- Peel off half of the backing from patch
- Apply adhesive side of patch to skin
- Peel off remaining protective covering
- Press firmly with palm of hand for 10 seconds
- Make sure patch sticks well to skin, especially around edges

TRANSDERMAL NICOTINE PATCH: DIRECTIONS for USE (cont’d)

- Wash hands: Nicotine on hands can get into eyes or nose and cause stinging or redness
- Do not leave patch on skin for more than 24 hours—doing so may lead to skin irritation
- Adhesive remaining on skin may be removed with rubbing alcohol or acetone
- Dispose of used patch by folding it onto itself, completely covering adhesive area

TRANSDERMAL NICOTINE PATCH: ADDITIONAL PATIENT EDUCATION

- Water will not harm the nicotine patch if it is applied correctly; patients may bathe, swim, shower, or exercise while wearing the patch
- Do not cut patches to adjust dose
  - Nicotine may evaporate from cut edges
  - Patch may be less effective
- Keep new and used patches out of the reach of children and pets
- Remove patch before MRI procedures
TRANSDERMAL NICOTINE PATCH:
ADD'L PATIENT EDUCATION (cont’d)

- Side effects to expect in first hour:
  - Mild itching
  - Burning
  - Tingling
- Additional possible side effects:
  - Vivid dreams or sleep disturbances
  - Headache

- After patch removal, skin may appear red for 24 hours
  - If skin stays red more than 4 days or if it swells or a rash appears, contact health care provider—do not apply new patch
- Local skin reactions (redness, burning, itching)
  - Usually caused by adhesive
  - Up to 50% of patients experience this reaction
  - Fewer than 5% of patients discontinue therapy
  - Avoid use in patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)

TRANSDERMAL NICOTINE PATCH:
SUMMARY

**ADVANTAGES**
- The patch provides consistent nicotine levels.
- The patch is easy to use and conceal.
- Fewer compliance issues are associated with patch use.

**DISADVANTAGES**
- Patients cannot titrate the dose.
- Allergic reactions to the adhesive may occur.
- Patients with dermatologic conditions should not use the patch.

NICOTINE NASAL SPRAY
Nicotrol NS (Pfizer)

- Aqueous solution of nicotine in a 10-ml spray bottle
- Each metered dose actuation delivers 50 µl spray
- 0.5 mg nicotine
- ~100 doses/bottle
- Rapid absorption across nasal mucosa

NICOTINE NASAL SPRAY:
DOSING & ADMINISTRATION

- One dose = 1 mg nicotine
  (2 sprays, one 0.5 mg spray in each nostril)
- Start with 1–2 doses per hour
- Increase prn to maximum dosage of 5 doses per hour or 40 mg (80 sprays; ~½ bottle) daily
- For best results, patients should use at least 8 doses daily for the first 6–8 weeks
- Termination:
  - Gradual tapering over an additional 4–6 weeks

NICOTINE NASAL SPRAY:
DIRECTIONS for USE

- Press in circles on sides of bottle and pull to remove cap
NICOTINE NASAL SPRAY: DIRECTIONS for USE (cont’d)

- Prime the pump (before first use)
  - Obtain facial tissue or paper towel
  - Hold bottle and press on bottom with thumb
  - Pump into tissue until fine spray is observed (6–8 times)
- If pump is not used for 24 hours, prime the pump 1–2 times

Blow nose (if not clear)
- Tilt head back slightly and insert tip of bottle into nostril as far as comfortable
- Breathe through mouth, and spray once in each nostril
- Do not sniff or inhale while spraying

NICOTINE NASAL SPRAY: DIRECTIONS for USE (cont’d)

If nose runs, gently sniff to keep nasal spray in nose
- Wait 2–3 minutes before blowing nose
- Wait 5 minutes before driving or operating heavy machinery (spray may cause tearing, coughing, and sneezing)
- Avoid contact with skin, eyes, and mouth
  - If contact occurs, rinse with water immediately
  - Nicotine is absorbed through skin and mucous membranes

What to expect (first week):
- Hot peppery feeling in back of throat or nose
- Sneezing
- Coughing
- Watery eyes
- Runny nose

Side effects should lessen over a few days
- Regular use during the first week will help in development of tolerance to the irritant effects of the spray
- If side effects do not decrease after a week, contact health care provider

NICOTINE NASAL SPRAY: ADDITIONAL PATIENT EDUCATION

Advantages
- Patients can easily titrate therapy to rapidly manage withdrawal symptoms.
- Nasal/throat irritation may be bothersome.
- Nasal spray has higher dependence potential.
- Patients with chronic nasal disorders or severe reactive airway disease should not use the spray.

Disadvantages
- Nicotine inhalation system consists of
  - Mouthpiece
  - Cartridge with porous plug containing 10 mg nicotine
- Delivers 4 mg nicotine vapor, absorbed across buccal mucosa
- May satisfy hand-to-mouth ritual of smoking
NICOTINE INHALER: DOSING

- Start with 6 cartridges/day
- Increase pro re nata (prn) to maximum of 16 cartridges/day
- Use for minimum of 3 weeks, maximum of 12 weeks
- Gradual dosage reduction: if needed over additional 6–12 weeks

NICOTINE INHALER: SCHEMATIC DIAGRAM

Air in

Aluminum laminate sealing material

Sharp point that breaks the seal

Porous plug impregnated with nicotine

Mouthpiece

Nicotine cartridge

Air/nicotine mixture out


NICOTINE INHALER: DIRECTIONS for USE

- Align marks on the mouthpiece

NICOTINE INHALER: DIRECTIONS for USE (cont'd)

- Pull and separate mouthpiece into two parts

NICOTINE INHALER: DIRECTIONS for USE (cont’d)

- Press nicotine cartridge firmly into bottom of mouthpiece until seal breaks

NICOTINE INHALER: DIRECTIONS for USE (cont’d)

- Put top on mouthpiece and align marks to close
- Press down firmly to break top seal of cartridge
- Twist top to misalign marks and secure unit

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During inhalation, nicotine is vaporized and absorbed across oropharyngeal mucosa.

- Inhale into back of throat or puff in short breaths.
- Nicotine in cartridges is depleted after about 20 minutes of active puffing.
  - Cartridge does not have to be used all at once.
  - Open cartridge retains potency for 24 hours.
- Mouthpiece is reusable; clean regularly with mild detergent.

Patients may experience mild irritation of the mouth or throat, and an unpleasant taste or cough when first using the inhaler.

- Patients will adapt to these effects in a short time.
- Other (less common) side effects include:
  - Rhinitis
  - Dyspepsia
  - Hiccups
  - Headache

The inhaler may not be as effective in very cold (<59°F) temperatures—delivery of nicotine vapor may be compromised.

- Use the inhaler longer and more often at first to help control cravings (best results are achieved with frequent continuous puffing over 20 minutes).
- Effectiveness of the nicotine inhaler may be reduced by some foods and beverages.

Do NOT eat or drink for 15 minutes BEFORE or while using the nicotine inhaler.

Atypical antidepressant thought to affect levels of various brain neurotransmitters.

- Dopamine
- Norepinephrine

Clinical effects:

- ↓ craving for cigarettes
- ↓ symptoms of nicotine withdrawal
BUPROPION: PHARMACOKINETICS

Absorption
- Bioavailability: 5–20%

Metabolism
- Undergoes extensive hepatic metabolism (CYP2B6)

Elimination
- Urine (87%) and feces (10%)

Half-life
- Bupropion (21 hours); metabolites (20–37 hours)

BUPROPION: CONTRAINDICATIONS

- Patients with a seizure disorder
- Patients taking
  - Wellbutrin, Wellbutrin SR, Wellbutrin XL
  - MAO inhibitors in preceding 14 days
- Patients with a current or prior diagnosis of anorexia or bulimia nervosa
- Patients undergoing abrupt discontinuation of alcohol or sedatives (including benzodiazepines)

BUPROPION: WARNINGS and PRECAUTIONS

Bupropion should be used with extreme caution in the following populations:
- Patients with a history of seizure
- Patients with a history of cranial trauma
- Patients taking medications that lower the seizure threshold (antipsychotics, antidepressants, theophylline, systemic steroids)
- Patients with severe hepatic cirrhosis

BUPROPION SR: DOSING

Patients should begin therapy 1 to 2 weeks PRIOR to their quit date to ensure that therapeutic plasma levels of the drug are achieved.

Initial treatment
- 150 mg po q AM x 3 days

Then...
- 150 mg po bid
- Duration, 7–12 weeks

BUPROPION: USE in PREGNANCY

- Category C drug
- Use only if clearly indicated
- Attempt nondrug treatment first

BUPROPION: ADVERSE EFFECTS

Common side effects include the following:
- Insomnia (avoid bedtime dosing)
- Dry mouth

Less common but reported effects:
- Tremor
- Skin rash
BUPROPION: ADDITIONAL PATIENT EDUCATION

- Dose tapering not necessary when discontinuing treatment
- If no significant progress toward abstinence by seventh week, therapy is unlikely to be effective
  - Discontinue treatment
  - Reevaluate and restart at later date

BUPROPION SR: SUMMARY

ADVANTAGES
- Bupropion is an oral formulation with twice-a-day dosing.
- Bupropion might be beneficial for patients with depression.

DI SADVANTAGES
- The seizure risk is increased.
- Several contraindications and precautions preclude use.

VARENICLINE

Chantix (Pfizer)

- Nonnicotine cessation aid
- Partial nicotinic receptor agonist
- Oral formulation

VARENICLINE: MECHANISM of ACTION

- Binds with high affinity and selectivity at $\alpha_4\beta_2$ neuronal nicotinic acetylcholine receptors
  - Stimulates low-level agonist activity
  - Competitively inhibits binding of nicotine
- Clinical effects
  - ↓ symptoms of nicotine withdrawal
  - Blocks dopaminergic stimulation responsible for reinforcement & reward associated with smoking

VARENICLINE: PHARMACOKINETICS

Absorption
- Virtually complete after oral administration; not affected by food

Metabolism
- Undergoes minimal metabolism

Elimination
- Primarily renal through glomerular filtration and active tubular secretion; 92% excreted unchanged in urine

Half-life
- 24 hours

VARENICLINE: USE in PREGNANCY and LACTATION

- Category C drug
- Use only if potential benefit justifies potential risk
- Attempt nondrug treatment first
- Unknown if drug excreted in human breast milk
**Varenicline: Dosing**

Patients should begin therapy 1 week PRIOR to their quit date. The dose is gradually increased to minimize treatment-related nausea and insomnia.

<table>
<thead>
<tr>
<th>Treatment Day</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1 to day 3</td>
<td>0.5 mg qd</td>
</tr>
<tr>
<td>Day 4 to day 7</td>
<td>0.5 mg bid</td>
</tr>
<tr>
<td>Day 8 to end of treatment*</td>
<td>1 mg bid</td>
</tr>
</tbody>
</table>

* Up to 12 weeks

---

**Varenicline: Adverse Effects**

Common side effects (≥5% and twice the rate observed in placebo-treated patients) include:

- Nausea
- Sleep disturbances (insomnia, abnormal dreams)
- Constipation
- Flatulence
- Vomiting

---

**Varenicline: Additional Patient Education**

- Doses should be taken after eating, with a full glass of water
- Nausea and insomnia are side effects that are usually temporary.
  - If symptoms persist, notify your health care provider
- Dose tapering not necessary when discontinuing treatment

---

**Varenicline: Summary**

**ADVANTAGES**

- Varenicline is an oral formulation with twice-a-day dosing.
- Varenicline offers a new mechanism of action for persons who previously failed using other medications.

**DIADVANTAGES**

- May induce nausea in up to one third of patients.
- Post-marketing surveillance data not yet available.

---

**Pharmacologic Methods: Second-Line Therapies**

- Clonidine (Catapres transdermal or oral)
- Nortriptyline (Pamelo oral)

---

**Herbal Drugs for Smoking Cessation**

- Lobeline
  - Derived from leaves of Indian tobacco plant (Lobelia inflata)
  - Partial nicotinic agonist
  - No scientifically rigorous trials with long-term follow-up
  - No evidence to support use for smoking cessation

LONG-TERM (≥6 month) QUIT RATES for AVAILABLE CESSATION MEDICATIONS

<table>
<thead>
<tr>
<th>Medication</th>
<th>Active Drug</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine gum</td>
<td>19.6</td>
<td>11.5</td>
</tr>
<tr>
<td>Nicotine patch</td>
<td>14.6</td>
<td>8.6</td>
</tr>
<tr>
<td>Nicotine lozenge</td>
<td>16.4</td>
<td>8.6</td>
</tr>
<tr>
<td>Nicotine nasal spray</td>
<td>23.9</td>
<td>11.5</td>
</tr>
<tr>
<td>Nicotine inhaler</td>
<td>5.1</td>
<td>1.1</td>
</tr>
<tr>
<td>Bupropion</td>
<td>10.2</td>
<td>5.3</td>
</tr>
<tr>
<td>Varenicline</td>
<td>9.3</td>
<td></td>
</tr>
</tbody>
</table>


COMBINATION PHARMACOTHERAPY

- Combination NRT
  - Long-acting formulation (patch)
    - Produces relatively constant levels of nicotine
    - PLUS
  - Short-acting formulation (gum, lozenge, inhaler, nasal spray)
    - Allows for acute dose titration as needed for withdrawal symptoms

- Bupropion SR + NRT
  - The safety and efficacy of combination of varenicline with NRT or bupropion has not been established.

COMPLIANCE IS KEY to QUITTING

- Promote compliance with prescribed regimens.
- Use according to dosing schedule, NOT as needed.
- Consider telling the patient:
  - "When you use a cessation product it is important to read all the directions thoroughly before using the product. The products work best in alleviating withdrawal symptoms when used correctly, and according to the recommended dosing schedule."

COMPARATIVE DAILY COSTS of PHARMACOTHERAPY

<table>
<thead>
<tr>
<th>Medication</th>
<th>Cost per day, in U.S. dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhale</td>
<td>$6.07</td>
</tr>
<tr>
<td>Gum</td>
<td>$5.81</td>
</tr>
<tr>
<td>Bupropion SR</td>
<td>$5.73</td>
</tr>
<tr>
<td>Lozenge</td>
<td>$5.26</td>
</tr>
<tr>
<td>Cigarettes (1 pack/day)</td>
<td>$4.26</td>
</tr>
<tr>
<td>Varenicline</td>
<td>$4.22</td>
</tr>
<tr>
<td>Patch</td>
<td>$3.91</td>
</tr>
<tr>
<td>Nasal spray</td>
<td>$3.67</td>
</tr>
</tbody>
</table>

WORKSHOP: CASE SCENARIOS

- Case scenarios
- Range of 1–15 minutes for each interaction
- Two roles
  - Clinician
  - Patient
LEARNING FORMAT (cont'd)

- Break into groups of two
- Alternate roles as the clinician and the patient
- Class discussion following each case

The CLINICIAN

- Brief description of the patient and the setting
- Tailor your messages based on each patient’s needs and readiness
  - Step 1: **ASK** about tobacco use
  - Step 2: **ADVISE** patient to quit
    - Clear, strong, personalized, sensitive
  - Step 3: **ASSESS** readiness to make a quit attempt

- Step 4: **ASSIST** with the quit attempt
  - Assess tobacco use history
  - Assess key issues for the upcoming or current quit attempt
  - Help patient to choose methods for quitting and facilitate the quitting process
- Step 5: **ARRANGE** follow-up care
  - Schedule a time to either meet or call patient

The PATIENT

- Brief description of the patient and the setting
- General guidelines for responses to clinician’s queries

The CLINICIAN (cont’d)

- **A few helpful hints...**
  - Use ACTIVE listening and open-ended questions
  - Show EMPATHY
  - EXPLORE patients’ history, beliefs, motivations, and perceived barriers prior to making recommendations; consider cost issues
  - RESIST temptation to move patients too quickly
  - Refer to **TOBACCO CESSATION COUNSELING GUIDESHEET**

SUMMARY: CASE SCENARIOS

- Use this class time to apply your new knowledge and practice your new counseling skills.
- Many of the counseling skills learned in the *Rx for Change* program can be applied to behaviors other than tobacco use
- Don’t wait too long to apply your new skills in the “real world”