

# The Tobacco Escape Hatch: Using the Patch and other Nicotine Replacement Therapy Agents to Support Quitting

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## Rethink Tobacco Indiana

Grant funded initiative by the Indiana Department of Health's Tobacco Prevention and Cessation to reduce the prevalence of tobacco use among persons with behavioral health conditions by supporting behavioral health treatment facilities through the following activities:

-  Technical Assistance
-  Policy Development
-  Education
-  Specialized Training
-  Resources



[www.RethinkTobaccoIndiana.org](http://www.RethinkTobaccoIndiana.org)



**Tobacco Prevention  
and Cessation**

[www.in.gov/isdh/tpc](http://www.in.gov/isdh/tpc)

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# Presenter



**Karen S. Hudmon, DrPH, MS, RPh, TTS**

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# Learning Objectives

At the completion of this knowledge-based activity, participants will be able to:

- Advise patients about the importance of using medication(s) as an aid for quitting.
- List the five nicotine replacement therapy (NRT) medications and describe standard dosing.
- Summarize recent data describing the efficacy of NRT agents, including combinations of NRT agents, for treating tobacco use and dependence.
- Describe the role of pharmacists in prescribing medications as part of a formal treatment plan for quitting.



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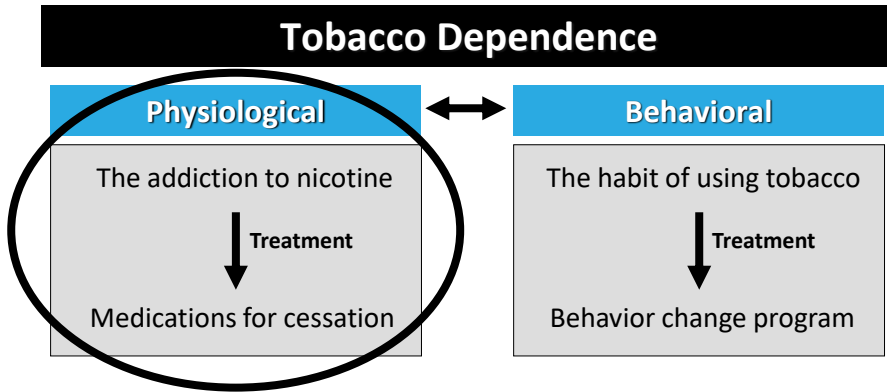
The content for this module derives from the  
Rx for Change: Clinician-Assisted Tobacco Cessation program.



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<https://rxforchange.ucsf.edu>

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# TOBACCO DEPENDENCE: A 2-PART PROBLEM

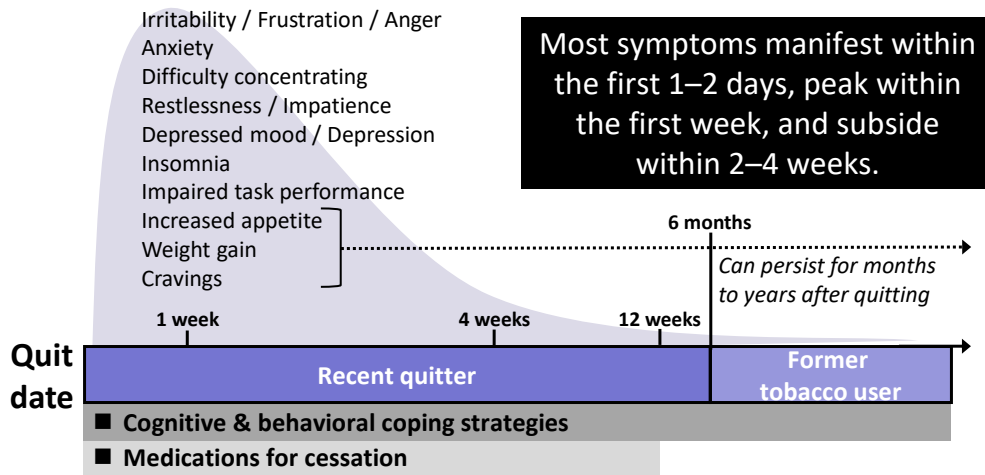


Treatment should address the physiological and the behavioral aspects of dependence.



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# NICOTINE WITHDRAWAL SYMPTOMS: Time Course\* and Management



\*Timeline aspect of the figure is not according to scale.

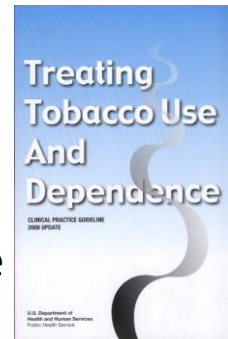
Data from Hughes. (2007). *Nicotine Tob Res* 9:315–327.



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## PHARMACOTHERAPY

“Clinicians should encourage all patients attempting to quit to use effective medications for tobacco dependence treatment, except where contraindicated or for specific populations\* for which there is insufficient evidence of effectiveness.”



\* Includes pregnant women, smokeless tobacco users, light smokers, and adolescents.

**Medications significantly improve success rates.**

Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline*. Rockville, MD: USDHHS, PHS, May 2008.



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## PHARMACOTHERAPY: Use in SPECIAL POPULATIONS

- Pharmacotherapy is **not** recommended for:
  - Pregnant smokers
    - Insufficient evidence of effectiveness
  - Smokeless tobacco users
    - No FDA indication for smokeless tobacco cessation
  - Individuals smoking fewer than 10 cigarettes per day
  - Adolescents
    - Nonprescription sales of nicotine replacement therapy (NRT) products (i.e., patch, gum, lozenge) are restricted to adults  $\geq 18$  years of age
    - NRT use in minors requires a prescription

**Recommended treatment is behavioral counseling.**

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## FDA-APPROVED MEDICATIONS for CESSATION

### Nicotine polacrilex gum\*

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

### Nicotine lozenge\*

- Nicorette (OTC)
- Generic nicotine lozenge (OTC)

### Nicotine transdermal patch\*

- Habitrol (OTC)
- NicoDerm CQ (OTC)
- Generic nicotine patches (OTC)

### Nicotine inhaler \*

- Nicotrol (Rx)

### Nicotine nasal spray \*

- Nicotrol NS (Rx)

### Bupropion SR

- Generic (Rx)

### Varenicline

- Chantix (Rx)

\* Nicotine replacement therapy (NRT) products.



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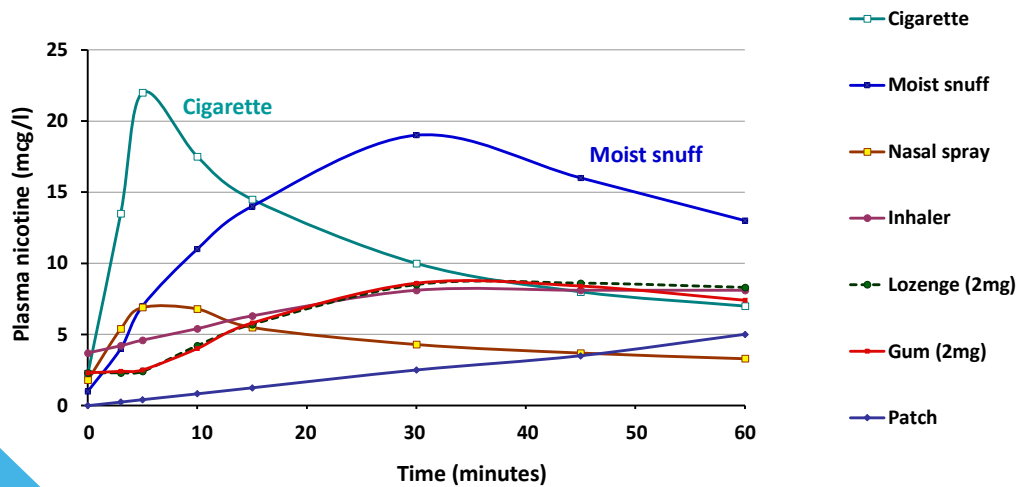
## NICOTINE REPLACEMENT THERAPY (NRT) RATIONALE for USE

- Reduces physical withdrawal from nicotine
- Eliminates the immediate, reinforcing effects of nicotine that is rapidly absorbed via tobacco smoke
- Allows patient to focus on behavioral and psychological aspects of tobacco cessation

**NRT products approximately doubles quit rates.**

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## PLASMA NICOTINE CONCENTRATIONS for NICOTINE-CONTAINING PRODUCTS



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## NRT: PRECAUTIONS

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

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

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## NICOTINE GUM

Nicorette; generics

- Resin complex
  - Nicotine
  - Polacrillin
- Sugar-free chewing gum base
- Contains buffering agents to enhance buccal absorption of nicotine
- Available: 2 mg, 4 mg; original, cinnamon, fruit, and mint (various) flavors



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## NICOTINE LOZENGE

Nicorette Lozenge, Nicorette Mini Lozenge; generics

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



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## NICOTINE GUM & LOZENGE: DOSING

Dose based on the “time to first cigarette” (TTFC)  
as an indicator of nicotine dependence

### Use the 2 mg gum/lozenge:

If first cigarette of the day is smoked  
more than 30 minutes after waking

### Use the 4 mg gum/lozenge:

If first cigarette of the day is  
smoked within 30 minutes of  
waking



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## NICOTINE GUM & LOZENGE: DOSING (cont'd)

### Recommended Usage Schedule

Weeks 1–6	Weeks 7–9	Weeks 10–12
1 piece q 1–2 h	1 piece q 2–4 h	1 piece q 4–8 h

**Do not use more than 24 pieces of GUM  
or 20 LOZENGES per day.**

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## NICOTINE GUM: DIRECTIONS FOR USE



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## NICOTINE LOZENGE: DIRECTIONS for USE

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



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## NICOTINE GUM/LOZENGE: ADDITIONAL PATIENT EDUCATION

- To improve chances of quitting, use at least nine pieces daily during the first 6 weeks
- The gum/lozenge will *not* provide the same rapid satisfaction that smoking provides
- The effectiveness of the nicotine gum/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 gum or lozenge.**



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## NICOTINE GUM/LOZENGE: ADD'L PATIENT EDUCATION (cont'd)

- Adverse effects of nicotine gum and lozenge:
  - Mouth and throat irritation
  - Hiccups
  - Gastrointestinal complaints (dyspepsia, nausea)
- Adverse effects associated with nicotine gum:
  - Jaw muscle ache
  - May stick to dental work



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## NICOTINE GUM/LOZENGE: SUMMARY

### ADVANTAGES

- Might serve as an oral substitute for tobacco
- Might delay weight gain
- Can be titrated to manage withdrawal symptoms
- Can be used in combination with other agents to manage situational urges
- Relatively inexpensive

### DISADVANTAGES

- Need for frequent dosing can compromise adherence
- Gastrointestinal adverse effects (nausea, hiccups, and dyspepsia) may be bothersome
- Specific to nicotine gum:
  - Might be problematic for patients with significant dental work
  - Proper chewing technique is necessary for effectiveness and to minimize adverse effects
  - Chewing might not be acceptable or desirable for some patients



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## TRANSDERMAL NICOTINE PATCH

### Habitrol; NicoDerm CQ; generic

- Continuous (24-hour) nicotine delivery system
- Nicotine is well absorbed across the skin
- Transdermal delivery to systemic circulation avoids hepatic first-pass metabolism
- Plasma nicotine levels are lower and fluctuate less than with smoking



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## TRANSDERMAL NICOTINE PATCH: DOSING

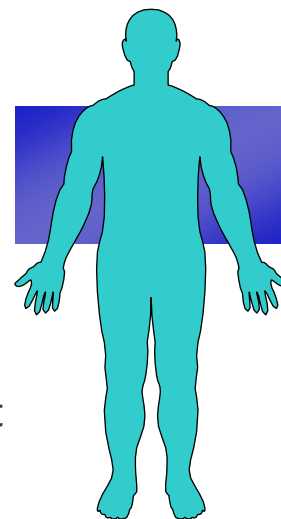
Product	Light Smoker	Heavy Smoker
NicoDerm CQ	≤10 cigarettes/day	>10 cigarettes/day
	Step 2 (14 mg x 6 weeks) Step 3 (7 mg x 2 weeks)	Step 1 (21 mg x 6 weeks) Step 2 (14 mg x 2 weeks) Step 3 (7 mg x 2 weeks)
Habitrol Generic	≤10 cigarettes/day	>10 cigarettes/day
	Step 2 (14 mg x 6 weeks) Step 3 (7 mg x 2 weeks)	Step 1 (21 mg x 4 weeks) Step 2 (14 mg x 2 weeks) Step 3 (7 mg x 2 weeks)



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## TRANSDERMAL NICOTINE PATCH: DIRECTIONS for USE

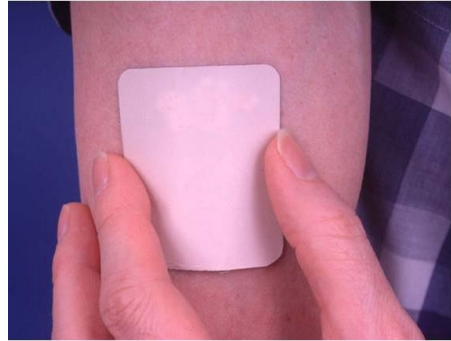
- Choose an area of skin on the upper body or upper outer part of the arm
- Make sure skin is clean, dry, hairless, and not irritated
- Apply patch to different area each day
- Do not use same area again for at least 1 week



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## TRANSDERMAL NICOTINE PATCH: DIRECTIONS for USE (cont'd)

- Remove protective liner and 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
- Water will not harm the nicotine patch if it is applied correctly; patients may bathe, swim, shower, or exercise



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## TRANSDERMAL NICOTINE PATCH: ADD'L PATIENT EDUCATION (cont'd)

Common adverse effects include:

- Irritation at the patch application site (generally within the first hour)
  - Mild itching, burning, tingling
  - Avoid use in patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)
- Sleep disturbances
  - Abnormal or vivid dreams
  - Insomnia



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## TRANSDERMAL NICOTINE PATCH: SUMMARY

### ADVANTAGES

- Once-daily dosing associated with fewer adherence problems
- Of all NRT products, its use is least obvious to others
- Can be used in combination with other agents; delivers consistent nicotine levels over 24 hrs
- Relatively inexpensive

### DISADVANTAGES

- When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms
- Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)



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## NICOTINE INHALER

### Nicotrol Inhaler

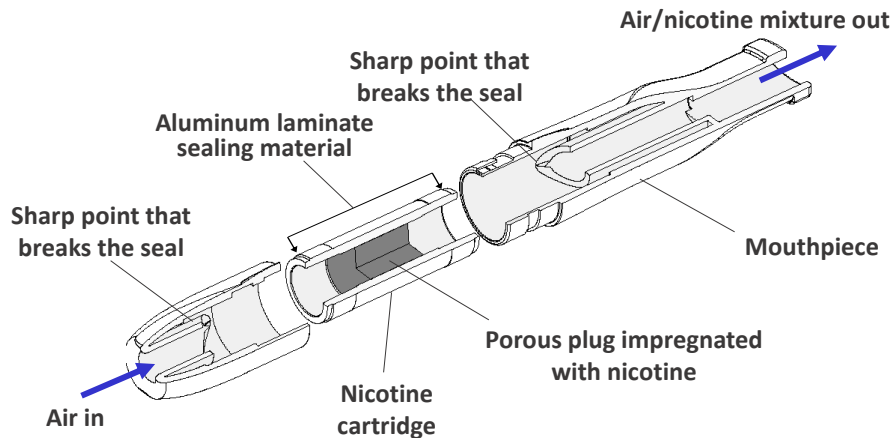
- Nicotine inhalation system consists of:
  - Mouthpiece
  - Cartridge with porous plug containing 10 mg nicotine and 1 mg menthol
- Delivers 4 mg nicotine vapor, absorbed across buccal mucosa



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## NICOTINE INHALER: SCHEMATIC DIAGRAM



Reprinted with permission from Schneider et al. (2001). *Clinical Pharmacokinetics* 40:661–684. Adis International, Inc.



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## NICOTINE INHALER: DOSING

- Initial treatment (up to 12 weeks)
  - Start with at least 6 cartridges/day during the first 3–6 weeks of treatment
  - Increase as needed, to maximum of 16 cartridges/day
  - In general, use 1 cartridge every 1–2 hours
- Gradually reduce daily dosage over the following 6–12 weeks
- Recommended maximum duration of therapy is 6 months



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## NICOTINE INHALER: DIRECTIONS for USE

- 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 min of puffing
  - Cartridge does *not* have to be used all at once—try different schedules (e.g., 5 minutes at a time) to find what works best
  - Open cartridge retains potency for 24 hours



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## NICOTINE INHALER: ADD'L PATIENT EDUCATION

- Use inhaler at room temperature (>60°F)
  - Cold environments: nicotine vapor delivery may be compromised
- Use the inhaler longer and more often at first to help control cravings (best results achieved with frequent continuous puffing over 20 min)
- Effectiveness might be reduced by some foods and beverages

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



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## NICOTINE INHALER: SUMMARY

### ADVANTAGES

- Might serve as an oral substitute for tobacco
- Can be titrated to manage withdrawal symptoms
- Mimics the hand-to-mouth ritual of smoking
- Can be used in combination with other agents to manage situational urges

### DISADVANTAGES

- Need for frequent dosing can compromise adherence
- Cartridges might be less effective in cold environments ( $\leq 60^{\circ}\text{F}$ )
- Cost of treatment



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## NICOTINE NASAL SPRAY

### Nicotrol NS

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



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## 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 as needed to maximum dosage of 5 doses per hour or 40 mg (80 sprays; ~½ bottle) daily
- At least 8 doses daily for the first 6–8 weeks
- Termination:
  - Gradual tapering over an additional 4–6 weeks
  - Recommended maximum duration of therapy is 3 months



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## NICOTINE NASAL SPRAY: ADDITIONAL PATIENT EDUCATION

- What to expect (first week):
  - Hot peppery feeling in back of throat or nose
  - Sneezing, coughing, watery eyes
  - Runny nose
- Adverse 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 adverse effects persist after a week, contact health care provider and consider alternative treatment



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## NICOTINE NASAL SPRAY: SUMMARY

### ADVANTAGES

- Can be titrated to rapidly manage withdrawal symptoms
- Can be used in combination with other agents to manage situational urges

### DISADVANTAGES

- Need for frequent dosing can compromise adherence
- Nasal administration might not be acceptable/desirable for some patients; nasal irritation often problematic
- Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease
- Cost of treatment



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## COMBINATION PHARMACOTHERAPY

### Combination NRT [first-line, recommended treatment approach]

- Long-acting formulation (patch)
  - Produces relatively constant levels of nicotine

#### PLUS

- Short-acting formulation (gum, inhaler, lozenge, nasal spray)
  - Allows for acute dose titration as needed for nicotine withdrawal symptoms

### Other combinations [evidence less compelling]

- Bupropion + NRT
- Varenicline + NRT
- Varenicline + bupropion SR



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# TREATMENT OPTIONS

## Multiple Treatment Comparison Meta-Analysis

Comparison	Odds ratio (95% CI)
Nicotine gum vs Placebo	1.7 (1.5–1.9)
Nicotine patch vs Placebo	1.9 (1.7–2.1)
Other NRT* vs Placebo	2.0 (1.8–2.4)
Combination NRT vs Placebo	2.7 (2.1–3.7)
Bupropion SR vs Placebo	1.9 (1.6–2.1)
Varenicline vs Placebo	2.9 (2.4–3.5)

\*Includes nicotine nasal spray, lozenge, and inhaler

Cahill et al. (2013). *Cochrane Database Syst Rev* 5:CD009329.

**Strong evidence that combination NRT and varenicline are more effective than bupropion SR or NRT monotherapy**

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## COMBINATION NRT: TREATMENT REGIMENS

- **Nicotine patch**

Dose: 21 mg/day x 4–6 weeks → 14 mg/day x 2 weeks → 7 mg/day x 2 weeks

**PLUS**

- **Nicotine gum or lozenge** (2 mg/4 mg; based on TTFC)

Dose: Use 1 piece q 1–2 hours as needed

**OR**

- **Nicotine inhaler** (10 mg cartridge; delivers 4 mg nicotine vapor)

Dose: Use 1 cartridge q 1–2 hours as needed

**OR**

- **Nicotine nasal spray** (0.5 mg/spray)

Dose: Use 1 spray in each nostril q 1–2 hours as needed



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# “Drugs don’t work...

...in patients who don’t take them.”

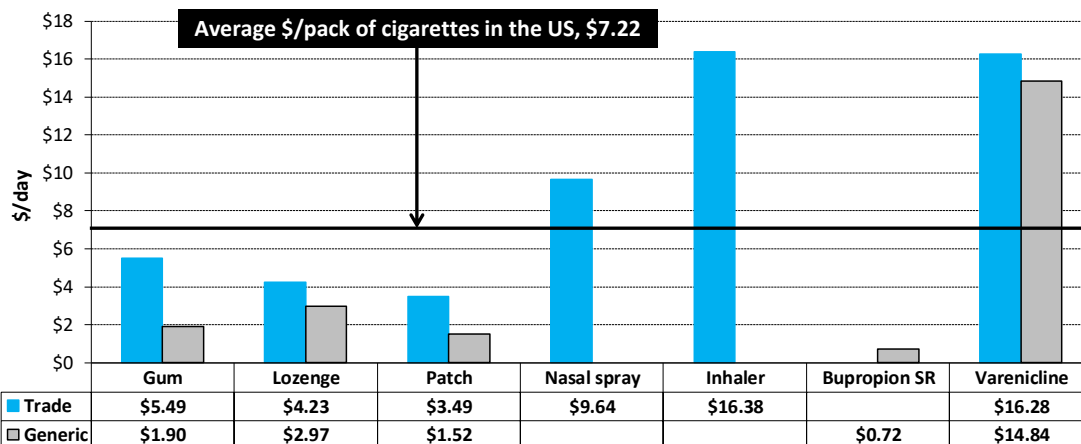
*C. Everett Koop, M.D., former U.S. Surgeon General*



**Medication adherence should be addressed at each encounter.**

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## COMPARATIVE DAILY COSTS of PHARMACOTHERAPY



\*Wholesale acquisition cost from Red Book Online. Thomson Reuters, October 2021.



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# The Role of Pharmacists in Tobacco Cessation

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## Why Pharmacies?

- Accessible, extended hours/weekends/holidays<sup>1</sup>
  - Dispensing medications to treat tobacco-related diseases / immunizations
  - Enhanced access to uninsured/underinsured, rural areas
  - Decisions to quit are often spontaneous
- Medications are safe and effective / patients need more timely access to the most effective cessation modalities
- Comparable efficacy as other interventions
- Ability to reach all segments of the population, including patients who are uninsured or under-insured



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State*	OTC nicotine medications	Prescription nicotine medications	Varenicline and bupropion SR
Arizona	✓	✓	
Arkansas	✓	✓	
California	✓	✓	
Colorado	✓	✓	✓
Idaho	✓	✓	✓
<b>Indiana</b>	✓	✓	✓
Iowa	✓	✓	
Maine	✓		
Minnesota	✓	✓	
Missouri	✓	✓	
New Mexico	✓	✓	✓
<i>North Dakota</i>	✓	✓	✓
Oregon	✓	✓	✓
<i>West Virginia</i>	✓	✓	✓
<i>Vermont</i>	✓	✓	✓

**States where pharmacists have prescriptive authority for tobacco cessation medications**

\* States listed in *italics* are pending.

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## Indiana Protocol: Medications Covered

- Nicotine gum
- Nicotine lozenge
- Nicotine transdermal patch
- Nicotine oral inhaler
- Nicotine nasal spray
- Bupropion SR oral tablets
- Varenicline oral tablets
- Combination of these products (based on data)

**All medications with an FDA indication for smoking cessation are included.**

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## How does it work?

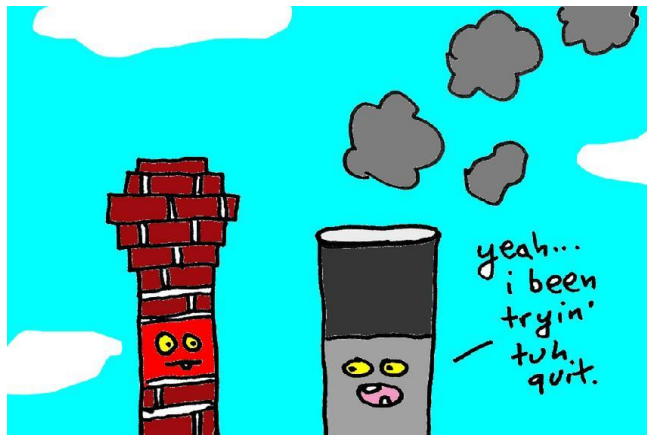
- Schedule a time to meet with the pharmacist
  - Intake form / health screening
  - Select appropriate medication(s) for quitting
  - Prescription is written and filled, and medication counseling is provided
  - Behavioral counseling is either provided by the pharmacist AND/OR through a referral to the Indiana Tobacco Quitline or other evidence-based program
- Required follow-up appointment with the pharmacist within 14 days after quit-date
- Final contact with the pharmacist at the end of the medication regimen

[www.QuitSmokingPharmacies.com](http://www.QuitSmokingPharmacies.com)



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## Questions and comments?



www.olliebrock.com



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