

# New Year, New Drug Therapy Topics

Colleen Catalano, Pharm.D.

It is with honor and great pleasure that I have this opportunity to introduce myself as the new Drug Information Specialist at the University of Washington Medical Center and Harborview Medical Center. I am excited about the opportunity to direct the Drug Information Center and am looking forward to this incredible challenge. Nelda Murri's vision, innovation, faithful service, and leadership over the past many years have established the DIC as a vital resource for UW Medicine. Nelda will be greatly missed. My goal is to continue the established tradition of the DI Center and the *Drug Therapy Topics (DTT)* newsletter and I assure you that the same standards for excellence will be upheld. The newsletter will continue to focus on issues related to the rational, cost-effective prescribing of formulary medications and maintain Dr. Gibaldi's vision to stimulate dialogue among practitioners regarding evolving drug therapies. In addition, we will continue *The D-Zone* as a separate publication written by Doug Black, Pharm. D., Associate Professor, UW School of Pharmacy & Infectious Disease Specialist. We are grateful for his informative and timely contributions to the newsletter. The Drug Information Center would also like to welcome any suggestions for future *DTT* topics and encourage your participation in any of the forthcoming newsletters. The *DTT* will continue to be published on-line at <http://uw.pnrx.org/therapyTopics.asp>. I wish to express my appreciation to Danny Shen, Professor & Chairman, Department of Pharmacy, UW School of Pharmacy and Shabir Somani, Director, UW Medicine Pharmacy Services & Vice Chair and Associate Professor, Department of Pharmacy, UW School of Pharmacy for their ongoing support. I look forward to working with all of you.

## *All is Flux, Nothing Stays Still*

— Heraclitus, Greek philosopher, ca. 535-475 B.C.

## Kicking Butts:

### What the healthcare provider needs to know about smoking cessation

Brooke L. Baltz, Pharm.D.

Tobacco use is a substantial public health problem, with approximately a quarter of the U.S. population dependent on tobacco. Annually, tobacco is responsible for more than 440,000 deaths, making it one of the leading causes of death in the U.S.<sup>1</sup> Furthermore, half of all people who smoke will die prematurely from a tobacco-related illness.<sup>2</sup> Consequences of tobacco use include cardiovascular disease, chronic obstructive pulmonary disease, pregnancy complications, cataracts, osteoporosis, and increased risk of various cancers.<sup>2</sup> However, many of the risks associated with tobacco use are reversible, making it critical to stress the importance of smoking cessation at every opportunity. Studies have shown that regardless of the amount of time a patient has been smoking, they can still benefit from quitting. Within one year, the risk of coronary heart disease is half that of a smoker and in 15 years a former smoker's risk is equal to that of a nonsmoker.<sup>2</sup>

Approximately 70% of smokers report a desire to quit and roughly 43% attempt to quit each year; unfortunately, the majority of these individuals are unsuccessful.<sup>1</sup> Healthcare professionals can play an important role in improving a patient's likelihood of success by encouraging, assessing,

continued

Tobacco use is the single most preventable cause of death in the United States.

Seventy percent of smokers report a desire to quit and roughly 43% attempt to quit each year; unfortunately, the majority of these individuals are unsuccessful.<sup>1</sup>

The two categories of smoking cessation therapies are nicotine replacement therapy (NRT) and non-nicotine pharmacotherapy.

Sixty-seven percent of current and former smokers believe NRT may be just as harmful as cigarettes, which suggests that many smokers may be missing an important opportunity for help.<sup>4</sup>

Using the nicotine patch concomitantly with nicotine gum, inhaler, or nasal spray improves abstinence rates more than using any of the NRTs as monotherapy.

U.S. Public Health Service strategies for effective tobacco cessation counseling are detailed in Table 3.

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and counseling all tobacco users, in addition to explaining pharmacotherapy options available and prescribing when appropriate. This article will provide an overview of the current pharmacotherapies available for smoking cessation including specific treatment considerations for each agent, and address the role of combination pharmacotherapy for smoking cessation.

Nicotine can lead to physical dependence, but the addiction to tobacco includes psychological, behavioral, and emotional components as well. Nicotine binds to specific nicotinic receptors in the brain resulting in release of stimulants such as dopamine. This provides a smoker with a positive sensation which reinforces the addictive behavior. While nicotine withdrawal symptoms typically subside in two to four weeks, cravings can continue for years after cessation.<sup>3</sup> Medications are available to address both of these components. The two main categories of smoking cessation therapies include nicotine replacement therapy (NRT) and non-nicotine pharmacotherapy.<sup>2</sup>

Nicotine replacement therapy helps diminish physical withdrawal symptoms and cravings by partially replacing the body's supply of nicotine. Common symptoms of nicotine withdrawal include anxiety, irritability, depressed mood, insomnia, headache, and increased appetite.<sup>3</sup> Nicotine replacement therapy delivers nicotine in a safe form. A recent survey found that 67% of current and former smokers believe NRT may be just as harmful as cigarettes, suggesting many smokers may be missing an important opportunity for help.<sup>4</sup> For those questioning the safety of NRT, it is important to remind the patient that tobacco, not nicotine, is responsible for most of the adverse health effects associated with cigarette smoking.<sup>5</sup>

There are currently five NRT products available: a nicotine patch, nicotine gum, nicotine lozenge, nicotine nasal spray, and a nicotine inhaler. The nicotine patch, gum, and lozenge are available over the counter, while the nicotine nasal spray and inhaler are only available by prescription. All NRT products are similarly safe and effective, produce similar abstinence rates, and are dosed based on the smoking patterns of the patient.

In addition to NRT, other smoking cessation options targeting the psychological component of tobacco addiction include bupropion (Zyban<sup>®</sup> and Wellbutrin<sup>®</sup>) and varenicline (Chantix<sup>®</sup>). Bupropion blocks the reuptake of dopamine, serotonin, and norepinephrine, and thereby decreases withdrawal symptoms (i.e., irritability, anxiety, restlessness) and reduces the craving for cigarettes or the urge to smoke. Bupropion statistically increased abstinence rates by 8-21% at 7 to 12 weeks compared to placebo in several clinical trials.<sup>10</sup> Bupropion is initiated 7 days prior to the planned quit date (to assure full therapeutic effect) and the goal is complete abstinence. If a patient has not quit smoking after 7 weeks of therapy, it is unlikely that continued bupropion therapy will provide the support necessary for the patient to quit, and should be discontinued and other pharmacotherapeutic options investigated.<sup>10</sup>

Varenicline, which was approved by the U.S. Food and Drug Administration (FDA) in 2006, is another smoking cessation option for tobacco addiction. The mechanism of action of varenicline involves partial agonism and antagonism at the neuronal nicotinic acetylcholine receptor  $\alpha 4\beta 2$ .<sup>11</sup> This receptor is believed to act as a primary mediator of the addictive properties of nicotine. As with bupropion, patients initiate varenicline one week before their intended quit date, so that full

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therapeutic effects are present on the quit date. The approved course of varenicline treatment is 12 weeks. Varenicline is well tolerated. The most common adverse effects are nausea, vomiting, headache, abnormal dreams and constipation. Nausea occurs in approximately 30% percent of patients and is generally mild to moderate. Initial titration of the varenicline dose and administration with food reduces the incidence of nausea. Additionally, there have been postmarketing reports of neuropsychiatric symptoms in patients taking varenicline. Varenicline has demonstrated superior efficacy in clinical trials when compared with placebo and bupropion. Varenicline has been compared to bupropion in two double-blind, placebo-controlled studies enrolling a total of 2,045 subjects. Quit rates at 9-12 weeks were 44% in the varenicline arm, 30% in the bupropion arm, and 17% in the placebo group ( $p < 0.0001$ ).<sup>11</sup> Varenicline provides healthcare providers and smokers with an alternative therapy to assist in smoking cessation.

Another therapeutic option, which has received fast-track designation from the FDA is a nicotine vaccine called NicVAX<sup>®</sup>. The vaccine stimulates production of antibodies that bind to nicotine in the bloodstream, preventing it from crossing the blood brain barrier and preventing the reinforcing dopamine effect in the central nervous system (CNS) that leads to addiction. The vaccine, therefore, has the potential to reduce relapses, since vaccinated smokers find tobacco less rewarding. Nicotine antibodies persist for 6 to 12 months following vaccination. A recently completed double-blind, placebo-controlled trial in 301 smokers over a 12-month period reported a 16% abstinence rate at 12 months for vaccinated patients versus 6% for placebo ( $p < 0.038$ ). Furthermore, patients in the vaccine group who continued to smoke and also exhibited a high antibody response had a significant reduction in the number of cigarettes smoked over the full 12 months ( $p < 0.022$ ).<sup>1</sup> The vaccine provides a potential advantage over currently available therapies due to its prolonged effect, which helps prevent smokers from ceasing therapy and resuming smoking. If the vaccine proves to be successful, it could be a major advance in smoking cessation and perhaps in preventing tobacco addiction. It is important to note that the vaccine has only been studied in adult smokers and has not been studied for prevention of nicotine addiction in adults or adolescents.<sup>1, 12</sup>

Certain patients may do better with dual therapy, specifically patients with prior failed attempts to quit and those that are highly nicotine dependent. To help identify these patients, different questionnaires are available to assess a patient's level of dependence on nicotine, such as the Fagerstrom Test for Nicotine Dependence (Table 2).<sup>3</sup> Those patients scoring high on this test can be considered for dual therapy. Many patients use the patch to provide stable nicotine levels in combination with a short-acting NRT (nicotine gum, lozenge, inhaler, or nasal spray) for breakthrough cravings. Using the nicotine patch concomitantly with nicotine gum, inhaler, or nasal spray improves abstinence rates more than using any of the NRTs as monotherapy. One study randomly assigned patients to nicotine inhaler plus nicotine patch (intervention group) vs. nicotine inhaler plus placebo patch (control group). At 6 weeks, abstinence rates for the intervention group (60.5%) were significantly higher than the control group (47.5%) ( $p = 0.09$ ).<sup>13</sup>

Bupropion can be used with any of the nicotine replacement therapies mentioned above. In a study examining cessation rates in placebo, nicotine patch only, bupropion only, or both bupropion and nicotine patch, abstinence rates at 12 months were 15.6%, 16.4%, 30.3%, and 35.5%, respectively. Although cessation rates were higher in the combination group compared to bupropion alone, there was no

Varenicline should not be used as first-line therapy and should be restricted for use in patients who have failed on NRTs and/or bupropion or in whom bupropion is contraindicated.

A nicotine vaccine called NicVAX<sup>®</sup>, which has received fast-track designation from the U.S. Food and Drug Administration, is one potential therapeutic option. Nicotine antibodies persist for 6 to 12 months following vaccination.

The mechanism of action of varenicline involves partial agonism and antagonism at the nicotinic receptor subtype  $\alpha 4 \beta 2$  in the brain, which has been linked to the reinforcing effects of nicotine.<sup>11</sup>

Combining interventions such as pharmacotherapy, and behavioral and/or cognitive counseling may improve smoking cessation success rates.

## RESOURCES FOR SMOKING CESSATION

- Harborview Medical Center offers tobacco cessation classes through the HMC Smoke-Free program.
- Classes are led by pharmacists trained in tobacco cessation counseling and are conducted primarily at the HMC Patient and Family Resource Center at no cost to the patient.
- Cessation medications are available via the program and are offered for \$5 per prescription (a 2-week supply).
- All persons are welcome to attend the classes, however, only those patients who have established care with an HMC provider may receive medications.

Other resources available to patients include the Tobacco Quit Line, offered by the Washington State Department of Health, accessible by visiting [www.quitline.com](http://www.quitline.com) or calling 1-800-QUIT-NOW.<sup>16</sup>

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statistical significance.<sup>6</sup> Unlike bupropion, varenicline should not be used with NRT. Varenicline is a partial agonist and antagonist at the nicotine receptor, and thus has a competitive mechanism of action with NRT.

When choosing a pharmacotherapeutic regimen, the smoker's prior quitting history should be reviewed, including reasons for prior failure, barriers to quitting, the effectiveness of previous pharmacologic therapies, and patient preference. Additionally, absolute and relative contraindications to medications should guide therapy selection. If precautions exist, the clinician should discuss the risks/benefits and pros/cons before deciding on a particular therapy.<sup>2</sup> For example, NRTs should be used with caution in certain patient populations, such as pregnant women, those with cardiovascular disease, adolescents, and people who smoke fewer than 10 cigarettes per day. The benefit of NRTs, however, may outweigh the risks of nicotine pharmacotherapy, even in those with cardiovascular disease. Specific contraindications to various medications can be found in Table 1.

While the focus of this article is on NRTs and other pharmacotherapeutic options, it is also important to provide concomitant psychosocial treatments (i.e., advice, coaching, counseling, or psychotherapy).<sup>6</sup> Counseling should be offered to all patients contemplating smoking cessation. While cessation pharmacotherapies can be effective on their own, quit rates are higher in patients who also receive psychosocial support, such as cognitive-behavioral strategies. In essence, the pharmacotherapies reduce craving and/or withdrawal symptoms and create a window for patients to address other components of tobacco addiction.

Advice and support from healthcare providers is undoubtedly one of the most valuable interventions that healthcare providers can deliver. While cessation efforts should be provided in all care settings, patient hospitalization provides a particularly valuable opportunity for healthcare providers to educate about the benefits of smoking cessation.

**TABLE 1: PHARMACOTHERAPEUTIC OPTIONS FOR TOBACCO CESSATION**

DRUG	DOSING	PROS <sup>8, 13</sup>	CONS <sup>8, 13</sup>	CASH COST (12 WEEK THERAPY)	CONTRAINDICATIONS/RELATIVE CONTRAINDICATIONS <sup>2, 13</sup>
Nicotine Patch <sup>3, 7, 9</sup> (Nicoderm CQ <sup>®</sup> , Habitrol <sup>®</sup> , Nicotrol <sup>®</sup> )	<ul style="list-style-type: none"> <li>• 10 cigarettes daily → 21 mg/day x 4-6 wks, 14mg/day x 2 wks, 7mg/day x 2 wks</li> <li>• &lt;10 cigarettes daily → 14 mg/day x 6 wks, 7mg/day x 2 wks</li> </ul>	<ul style="list-style-type: none"> <li>• Once daily</li> <li>• OTC</li> </ul>	<ul style="list-style-type: none"> <li>• Slow onset</li> <li>• Not effective for acute cravings</li> </ul>	\$44*	<ul style="list-style-type: none"> <li>• Pregnancy</li> <li>• h/o cardiac disease</li> <li>• Allergy to adhesive tape</li> </ul>
Nicotine Gum <sup>3, 7</sup> (Nicorette <sup>®</sup> )	<ul style="list-style-type: none"> <li>• ≤25 cigarettes daily → 2mg</li> <li>• &gt;25 cigarettes daily → 4mg</li> <li>• wk 1-6: 1 piece Q1-2h</li> <li>• wk 7-9: 1 piece Q2-4h</li> <li>• wk 10-12: 1 piece Q4-8h</li> </ul>	<ul style="list-style-type: none"> <li>• Can control dose</li> <li>• Rapid onset for cravings</li> <li>• Helps with oral fixation</li> <li>• OTC</li> </ul>	<ul style="list-style-type: none"> <li>• Frequent dosing and does not provide consistent blood nicotine levels</li> <li>• GI upset</li> <li>• Poor dentition can limit use</li> </ul>	\$180* (assumes 10 pieces/d)	<ul style="list-style-type: none"> <li>• Pregnancy</li> <li>• h/o cardiac disease</li> <li>• Dentures</li> <li>• Jaw problems</li> </ul>
Nicotine Lozenge <sup>3, 7</sup> (Commit <sup>®</sup> )	<ul style="list-style-type: none"> <li>• 1<sup>st</sup> cigarette within 30 minutes of waking up → 4mg</li> <li>• 1<sup>st</sup> cigarette &gt;30 minutes of waking up → 2mg</li> <li>• See nicotine gum for titration schedule</li> </ul>	<ul style="list-style-type: none"> <li>• Can control dose</li> <li>• Good for break-through cravings</li> <li>• Helps with oral fixation</li> <li>• OTC</li> </ul>	<ul style="list-style-type: none"> <li>• Frequent dosing and does not provide consistent blood nicotine levels</li> <li>• GI upset</li> </ul>	Nonformulary \$450 (assumes 10 lozenges/d)	<ul style="list-style-type: none"> <li>• Pregnancy</li> <li>• h/o cardiac disease</li> </ul>
Nicotine Inhaler <sup>8, 9</sup> (Nicotrol <sup>®</sup> )	<ul style="list-style-type: none"> <li>• 6 to 16 cartridges daily for up to 12 wks, then gradual 6-12 wk reduction if needed</li> </ul>	<ul style="list-style-type: none"> <li>• Mimics smoking</li> <li>• Can control dose</li> <li>• Good for break-through cravings</li> </ul>	<ul style="list-style-type: none"> <li>• Multiple dosing</li> <li>• Expensive</li> <li>• Requires Rx</li> <li>• Need to inhale intensely</li> </ul>	Nonformulary \$1,150 (assumes 10 cartridges/d)	<ul style="list-style-type: none"> <li>• Pregnancy</li> <li>• h/o cardiac disease</li> <li>• h/o asthma, allergies, reactive airway disease</li> </ul>
Nicotine Nasal Spray <sup>3, 7, 9</sup> (Nicotrol NS <sup>®</sup> )	<ul style="list-style-type: none"> <li>• 1 spray in each nostril 1-2 times/hr at least 8 times daily, with max duration=3 months</li> </ul>	<ul style="list-style-type: none"> <li>• Higher nicotine levels</li> <li>• Good for break-through cravings</li> </ul>	<ul style="list-style-type: none"> <li>• Multiple dosing</li> <li>• Expensive</li> <li>• Many AEs (75% experience nasal/throat irritation or sneezing)</li> <li>• Requires Rx</li> </ul>	Nonformulary \$520 (assumes 15 doses/d)	<ul style="list-style-type: none"> <li>• Pregnancy</li> <li>• h/o cardiac disease</li> <li>• h/o asthma, allergies, reactive airway disease</li> </ul>
Varenicline <sup>2, 11</sup> (Chantix <sup>®</sup> )	<ul style="list-style-type: none"> <li>• 0.5mg qday x 3 days; 0.5mg BID x 4 days; 1mg BID for completion of treatment (12 wks)</li> <li>• severe renal impairment (maximal dose is 0.5mg BID)</li> </ul>	<ul style="list-style-type: none"> <li>• Initiate prior to quit date</li> </ul>	<ul style="list-style-type: none"> <li>• Requires Rx</li> <li>• Expensive</li> <li>• Little effect on weight gain</li> <li>• Nausea</li> </ul>	\$465*	<ul style="list-style-type: none"> <li>• Pregnancy category C</li> </ul>
Bupropion <sup>2, 9, 10</sup> (Zyban <sup>®</sup> )	<ul style="list-style-type: none"> <li>• 150 mg/day x 3 days then increase to 150 mg twice daily x 8-12 wks</li> </ul>	<ul style="list-style-type: none"> <li>• Initiate prior to quit date</li> <li>• Decreases cravings</li> </ul>	<ul style="list-style-type: none"> <li>• Seizure risk</li> <li>• Requires prescription</li> </ul>	\$33*	<ul style="list-style-type: none"> <li>• Current/past seizure disorders</li> <li>• Use of drugs that reduce the seizure threshold (antidepressants, anti-psychotics, anticonvulsants)</li> <li>• Pregnancy Category C</li> <li>• Bulimia or anorexia</li> <li>• Use of MAO-I in previous 14 days</li> </ul>

\* HMC and UWMC Outpatient Pharmacy Costs. These prices do not reflect the discounted medication costs for patients enrolled in Harborview Medical Center smoking cessation program.

**VARENICLINE:**

The FDA has informed healthcare professionals of reports of several serious symptoms, including suicidal thoughts, aggressive, erratic behavior, and drowsiness in patients who have taken varenicline (Chantix®). The FDA is currently reviewing these cases, along with other recent reports. A preliminary assessment reveals that many of the cases reflect new-onset suicidal ideation, depressed mood, and changes in emotion and behavior within days to weeks of initiating varenicline treatment. The role of varenicline in these cases is not clear. Patients should be monitored for mood and behavior changes when taking varenicline. Patients taking this product should report behavior or mood changes to their physician and use caution when driving or operating machinery.

Read the complete MedWatch Safety Alert and FDA communication about the ongoing safety review of varenicline at: [http://www.fda.gov/cder/drug/early\\_comm/varenicline.htm](http://www.fda.gov/cder/drug/early_comm/varenicline.htm)

**TABLE 2: FAGERSTROM TEST FOR NICOTINE DEPENDENCE<sup>3</sup>**

ITEM	PATIENT RESPONSE OPTIONS	CODING
1. How soon after you wake up do you smoke your first cigarette?	Within 5 minutes 6-30 minutes 31-60 minutes After 60 minutes	3 2 1 0
2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., In church, at the library, in a cinema)?	Yes No	1 0
3. Which cigarette would you hate most to give up?	The first one in the morning Any other	1 0
4. How many cigarettes per day do you smoke?	10 or less 11-20 21-30 31 or more	0 1 2 3
5. Do you smoke more frequently during the first hours after waking than during the rest of the day?	Yes No	1 0
6. Do you smoke if you are so ill that you are in bed most of the day?	Yes No	1 0

\* Patient scale scores are computed as a sum of the items; possible range is 0 to 10. Significant dependence is associated with a score higher than 5.

**TABLE 3: U.S. PUBLIC HEALTH SERVICE STRATEGIES FOR EFFECTIVE TOBACCO CESSATION COUNSELING<sup>2</sup>**

	MOTIVATED The 5 A's	UNMOTIVATED The 5 R's
INTERVENTION	<ol style="list-style-type: none"> <li><b>Ask</b> all patients whether they smoke and if they are interested in quitting.</li> <li><b>Advise</b> patients about the health risks associated with tobacco and the benefits of quitting.</li> <li><b>Assess</b> a patient's readiness to quit.</li> <li><b>Assist</b> in the quit process by educating patients about strategies (i.e. pharmacotherapy and behavioral changes to improve success).</li> <li><b>Arrange</b> for follow-up by phone or in person.</li> </ol>	<ol style="list-style-type: none"> <li>Educate patients about the <b>relevance</b> of continued tobacco use to their specific health concerns or reasons to quit.</li> <li>Discuss the <b>risks</b> associated with continued smoking.</li> <li>Emphasize the <b>rewards</b> and benefits of quitting (e.g., improved health and cost savings).</li> <li>Address <b>roadblocks</b> or barriers that are specific concerns for the patients (e.g., weight gain).</li> <li><b>Repetition reinforces</b> the importance of asking and educating patients about quitting at every visit.</li> </ol>

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**P&T COMMITTEE BRIEF SUMMARY** November 20, 2007

FORMULARY ADDITIONS	DOSAGE FORM(S), STRENGTH(S)	THERAPEUTIC CLASSIFICATION	USE	USUAL ADULT STARTING DOSE
Hydroxocobalamin (Vitamin B <sub>12</sub> )	1000mcg/mL vials	Natural vitamin B12 derivative	Treatment of cyanide poisoning	5 grams IV infusion over 15 minutes. Second dose of 5 grams may be administered by IV infusion for a total dose of 10 grams.
Aliskiren (Tekturna®)	150mg tablet 300mg tablet	Antihypertensive	Add-on therapy to an ACEI/ARB in resistant hypertension or hyperkalemia	150mg by mouth once daily
Maraviroc (Selzentry®)	150mg tablet 300mg tablet	Antiretroviral	Restricted to patients with CCR5 positive HIV as demonstrated by a trophile test.	150mg to 600mg by mouth twice daily.
Polymyxin B 5,000 units + Neomycin 3.5 mg + Bacitracin Zinc 400 units (per gram)	15gm, 30gm, and 454 gm	Topical triple antibiotic	Post operative wound care as adjunctive treatment for burns and prevention of skin graft loss. Restricted to burn service only.	Apply to affected area once to three times daily.

**Other Actions**

MEDICATION	ACTION
Vancomycin Oral Suspension (compounded in pharmacy)	Allow substitution by pharmacy of compounded vancomycin oral suspension for vancomycin capsules in hospitalized patient.
Ursodiol (Urso®)	DELETE URSO 250 from formulary and REPLACE with ursodiol 300mg with automatic substitution by pharmacy.
Aprotinin (Trasylol®)	DELETE aprotinin from formulary, and conduct the class review as recommended.