

THE EXCHANGE

TOBACCO RECOVERY RESOURCE EXCHANGE

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IMPLEMENTING TOBACCO ASSESSMENT, DIAGNOSIS, AND PHARMACOTHERAPY INTO YOUR CHEMICAL DEPENDENCE PROGRAM



PROFESSIONAL DEVELOPMENT PROGRAM
ROCKEFELLER COLLEGE UNIVERSITY AT ALBANY State University of New York

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We would like to get your feedback about this Technical Assistance document, **Implementing Tobacco Assessment, Diagnosis, and Pharmacotherapy into Your Chemical Dependence Program**. Please take a moment to fill out this Survey and Fax it to us at 518.956.7808.

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IMPLEMENTING TOBACCO ASSESSMENT, DIAGNOSIS, AND PHARMACOTHERAPY INTO YOUR CHEMICAL DEPENDENCE PROGRAM

Introduction

Research^{1,2,3,4} identifies systematic assessment and diagnosis of tobacco dependence and several medications as safe and effective in treating tobacco dependence. We offer this Technical Assistance document to assist professionals implementing tobacco assessment, diagnosis, and pharmacotherapy protocols in their addiction programs, whether they are line staff counselors, mid-level managers, nurses, physicians, or top-level agency leadership.

This document consists of a series of handouts and articles that may be used in developing your program's tobacco assessment, diagnosis, and pharmacotherapy protocols:

Assessment and Diagnosis Resources

- Fagerström Test for Nicotine Dependence (FTND)
- Fagerström Test for Nicotine Dependence-Smokeless Tobacco (FTND-ST)
- Hooked on Nicotine Checklist (HONC)
- DSM-IV-TR Criteria for Nicotine Withdrawal and Nicotine Dependence
- Breath Carbon Monoxide Monitors
- Psychiatry Rx for Change Client Tobacco Assessment
- Psychiatry Rx for Change Withdrawal Symptoms Information Sheet
- Psychiatry Rx for Change Drug Interactions with Smoking

Pharmacotherapy Resources

- Mayo Clinic Nicotine Dependence Center Tobacco Dependence Treatment Medication Summary
- Advice on Using Over-the-Counter Nicotine Replacement Therapy-Patch, Gum, Or Lozenge-To Quit Smoking

¹ Fiore M.C., Jaen, C.R., Baker, T.B., et al. *Treating tobacco use and dependence: 2008 Update. Clinical Practice Guideline*. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.

² Hughes JR, Stead LF, Lancaster T. Antidepressants for smoking cessation. *Cochrane Database of Systematic Reviews* 2007, Issue 1. Art. No.: CD000031. DOI: 10.1002/14651858.CD000031.pub3.

³ Cahill K, Stead LF, Lancaster T. Nicotine receptor partial agonists for smoking cessation. *Cochrane Database of Systematic Reviews* 2008, Issue 3. Art. No.: CD006103. DOI: 10.1002/14651858.CD006103.pub3.

⁴ Stead LF, Perera R, Bullen C, Mant D, Lancaster T. Nicotine replacement therapy for smoking cessation. *Cochrane Database of Systematic Reviews* 2008, Issue 1. Art. No.: CD000146. DOI: 10.1002/14651858.CD000146.pub3.

IMPLEMENTING TOBACCO ASSESSMENT, DIAGNOSIS, AND PHARMACOTHERAPY INTO YOUR CHEMICAL DEPENDENCE PROGRAM



Implementation Planning Tools

You may use the Assessment and Diagnosis Implementation Planning Worksheet to begin to develop a plan to use the above-mentioned tools as a part of your program's tobacco assessment and diagnosis protocols.

The Pharmacotherapy Implementation Planning Worksheet can help you to begin to develop a plan to integrate the use of tobacco treatment medications into your program's treatment protocols.

Follow-up Technical Support through the Tobacco Recovery Resource Exchange

As you work on implementing tobacco assessment, diagnosis, and pharmacotherapy into your program, we strongly encourage you to contact us for guidance and support. Please visit our website, www.tobaccorecovery.org, where you will find out more about our project and our network of Regional Technical Assistance and Training Centers.



TOBACCO RECOVERY RESOURCE EXCHANGE

WWW.TOBACCORECOVERY.ORG

ASSESSMENT AND DIAGNOSIS RESOURCES

Fagerström Test for Nicotine Dependence (FTND)

Fagerström Test for Nicotine Dependence-Smokeless Tobacco (FTND-ST)

Hooked on Nicotine Checklist (HONC)

DSM-IV-TR Criteria for Nicotine Withdrawal and Nicotine Dependence

Breath Carbon Monoxide Monitors

Psychiatry Rx for Change Client Tobacco Assessment

Psychiatry Rx for Change Withdrawal Symptoms Information Sheet

Psychiatry Rx for Change Drug Interactions with Smoking

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FAGERSTRÖM TEST FOR NICOTINE DEPENDENCE (FTND)

1. How soon after you wake up do you have your first cigarette?
 - A. Within 5 minutes (3)
 - B. 6-30 minutes (2)
 - C. 31-60 minutes (1)
 - D. After 60 minutes (0)
2. Do you find it difficult to refrain from smoking in places where it is forbidden?
 - A. Yes (1)
 - B. No (0)
3. Which cigarette would you hate most to give up?
 - A. The first one in the morning (1)
 - B. All others (0)
4. How many cigarettes per day do you smoke?
 - A. 10 or fewer (0)
 - B. 11-20 (1)
 - C. 21-30 (2)
 - D. 31 or more (3)
5. Do you smoke more frequently during the first hours after waking than during the rest of the day?
 - A. Yes (1)
 - B. No (0)
6. Do you smoke even if you are so ill that you are in bed most of the day?
 - A. Yes (1)
 - B. No (0)

TOTAL: _____

Scoring:

7 to 10 points = highly nicotine dependent; 4 to 6 points = moderately nicotine dependent; less than 4 points = less nicotine dependent.

Higher scores indicate that withdrawal symptoms from quitting tobacco are more likely and likely to be stronger.

Source: Heatherton, T.F.; Kozlowski, L.T.; Frecker, R.C.; Fagerström, K.O. (1991). "The Fagerström Test for Nicotine Dependence: A Revision of the Fagerström Tolerance Questionnaire." *British Journal of Addiction*, 86 (9): 1119-27

FAGERSTRÖM TEST FOR NICOTINE DEPENDENCE-SMOKELESS TOBACCO (FTND-ST)

1. How soon after you wake up do you place your first dip?
 - A. Within 5 minutes (3)
 - B. 6-30 minutes (2)
 - C. 31-60 minutes (1)
 - D. After 60 minutes (0)

2. How often do you intentionally swallow tobacco juice?
 - A. Always (2)
 - B. Sometimes (1)
 - C. Never (0)

3. Which chew would you hate most to give up?
 - A. The first one in the morning (1)
 - B. All others (0)

4. How many cans/pouches do you use per week?
 - A. More than 3 (3)
 - B. 2-3 (1)
 - C. 1 (0)

5. Do you chew more frequently during the first hours after waking than during the rest of the day?
 - A. Yes (1)
 - B. No (0)

6. Do you chew if you are so ill that you are in bed most of the day?
 - A. Yes (1)
 - B. No (0)

TOTAL: _____

Source: Ebbert JO, Patten CA, Schroeder DR. The Fagerström Test for Nicotine Dependence-Smokeless Tobacco (FTND-ST). Addictive Behaviors 31(9), 2006, 1716-1721.

THE HOOKED ON NICOTINE CHECKLIST (HONC)

	NO	YES
1. Have you ever tried to quit, but couldn't?		
2. Do you smoke <u>now</u> because it is really hard to quit?		
3. Have you ever felt like you were addicted to tobacco?		
4. Do you ever have strong cravings to smoke?		
5. Have you ever felt like you really needed a cigarette?		
6. Is it hard to keep from smoking in places where you are not supposed to? When you haven't used tobacco for a while ... OR When you tried to stop smoking		
7. Did you find it hard to concentrate because you couldn't smoke?		
8. Did you feel more irritable because you couldn't smoke?		
9. Did you feel a strong need or urge to smoke?		
10. Did you feel nervous, restless or anxious because you couldn't smoke?		
TOTAL SCORE:		

Source: DiFranza, J.R.; Savageau, J.A.; Fletcher, K.; Ockene, J.K.; Rigotti, N.A.; McNeill, A.D.; Coleman, M.; Wood, C. (2002) "Measuring the loss of autonomy over nicotine use in adolescents: The Development and Assessment of Nicotine Dependence in Youths (DANDY) Study." *Archives of Pediatric Adolescent Medicine*. 156:397-403.

THE HOOKED ON NICOTINE CHECKLIST (HONC)

Scoring the Hooked on Nicotine Checklist (HONC)

The HONC is scored by counting the number of YES responses.

Dichotomous Scoring- The HONC as an indicator of diminished autonomy:

- Individuals who score a zero on the HONC by answering NO to all ten questions enjoy full autonomy over their use of tobacco.
- Because each of the ten symptoms measured by the HONC has face validity as an indicator of diminished autonomy, an individual has lost full autonomy if any symptom is endorsed.
- In schools and clinics, individuals who have scores above zero can be told that they are already hooked.

Continuous Scoring- The HONC as a measure of severity of diminished autonomy

- The number of symptoms a person endorses serves as a measure of the extent to which autonomy has been lost.

Source: <http://fmchapps.umassmed.edu/honc/TOC.htm>

DSM-IV-TR CRITERIA: NICOTINE WITHDRAWAL (292.0)

The presence of a characteristic syndrome that develops after abrupt cessation of, or reduction in, the use of nicotine-containing products following a prolonged period (at least several weeks) of daily use.

- A. Daily use of nicotine for at least several weeks
- B. Abrupt cessation of nicotine use, or reduction in the amount of nicotine used, followed within 24 hours by four (or more) of the following signs:
 - 1. dysphoric or depressed mood
 - 2. insomnia
 - 3. irritability, frustration, anger
 - 4. anxiety
 - 5. difficulty concentrating
 - 6. restlessness
 - 7. decreased heart rate
 - 8. increased appetite or weight gain
- C. Symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning
- D. The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder

Source: American Psychiatric Association, (2000). *Diagnostic and Statistical Manual for Mental Disorders - IV, Text Revision*, American Psychiatric Association Press.

DSM-IV-TR CRITERIA: NICOTINE DEPENDENCE (305.1)

A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring at any time in the same 12-month period:

- 1) tolerance, as defined by either of the following:
 - a. A need for markedly increased amounts of the substance to achieve intoxication or desired effect
 - b. Markedly diminished effect with continued use of the same amount of the substance
- 2) withdrawal, as manifested by either of the following:
 - a. The characteristic withdrawal syndrome for the substance
 - b. The same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms
- 3) The substance is often taken in larger amounts or over a longer period than was intended
- 4) There is a persistent desire or unsuccessful efforts to cut down or control substance use
- 5) A great deal of time is spent in activities necessary to obtain the substance (e.g., visiting multiple doctors or driving long distances), use the substance (e.g., chain-smoking), or recover from its effects
- 6) Important social, occupational, or recreational activities are given up or reduced because of substance use
- 7) The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance (e.g., current cocaine use despite recognition of cocaine-induced depression, or continued drinking despite recognition that an ulcer was made worse by alcohol consumption).

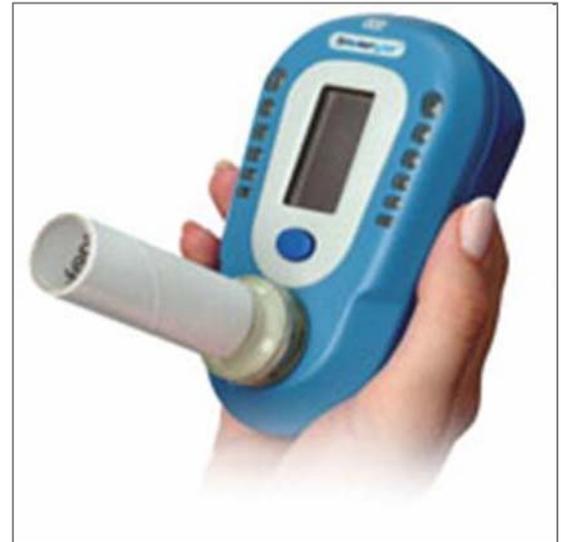
Source: American Psychiatric Association, (2000). *Diagnostic and Statistical Manual for Mental Disorders - IV, Text Revision*, American Psychiatric Association Press.

BREATH CARBON MONOXIDE MONITORS

The CO Monitor as an assessment tool

An important assessment tool that addiction professionals may use with their patients who smoke is a carbon monoxide (CO) monitor. A CO monitor is a device that measures the amount of carbon monoxide in a person's blood. The carbon monoxide (CO) monitor demonstrates an immediate and noninvasive measurement of one of the harmful consequences of smoking.

The test is simple and only requires a person to breathe into the monitor and within seconds it yields a personalized reading. The person utilizing the device exhales a deep breath into a cardboard tube attached to a meter. The reading on the meter provides an estimate of the amount of carbon monoxide in the blood (as opposed to oxygen).



A quick guide to using a CO monitor

- Use a new cardboard tube for each patient. Explain the whole procedure to your patient before you begin.
- Turn the CO monitor on. (A background reading will show—usually 0-3ppm).
- Press 'zero' button (even if the background reading is 0). Monitor shows 'go'.
- Ask your patient to take a deep breath and hold it for 15 seconds.
- Press 'go' as your patient takes a deep breath. Monitor counts down 15 seconds to 0. As soon as 0 is reached, patient seals lips around cardboard tube and blows slowly out through the tube, emptying the lungs of as much air as possible. Monitor counts up to reading. Wait for the reading on the monitor to peak - the highest number reached is your patient's reading in ppm (parts per million). The percentage of the patient's blood which is carrying CO instead of oxygen can be seen if required by pressing % button.
- Explain what the readings mean.
- Turn the CO monitor off between patients.

BREATH CARBON MONOXIDE MONITORS

What the readings mean

The normal level of CO for a nonsmoker depends on background levels in the air, but it is usually between 0 and 6 parts per million. The level of CO for a person who smokes is usually much higher. A person's level of CO varies according to the time of day, the amount of tobacco used, and how the smoke is inhaled. A person who uses a pack of cigarettes per day will commonly have a CO level of about 20 parts per million. A two-pack-a-day user may have a level of about 40 parts per million or greater.

0-6 ppm	Non-smoker
7-10ppm	Light smoker
11-20ppm	Medium smoker
21+ ppm	Heavy smoker

The good news is that after discontinuing smoking, CO levels drop by 50 percent every five to six hours. Usually, carbon monoxide levels return to normal within a few days.

What's your CO score? The CO monitor as a motivational tool

CO monitors are best used as a motivational tool to build patient confidence or *self-efficacy*. CO monitors can fortify patient beliefs that they can succeed at resolving their tobacco dependence.

Checking your CO score should be like participating in a Weight Watchers weigh-in. The long term objective is to simply lower your score to one that indicates improved health. A tremendous amount of positive coaching, information, tools, and motivation are part of the recipe for success at beating tobacco dependence.

Value added

Many patients who use NRT as an adjunctive therapy to become tobacco-free are often under-dosed. This oftentimes occurs if the patient underreports their daily usage levels of cigarettes. Using a CO monitor helps give the clinician an additional tool to assess the patient's level of dependence.

Learn more about CO monitors

To learn more about CO monitors, visit <http://www.breathcotest.com/faq.asp>.

Some of the text in this handout was adapted from information available on the web pages of Manchester Stop Smoking Service located at <http://www.stopsmokingmanchester.co.uk/docs/PROFencouraging.pdf>.

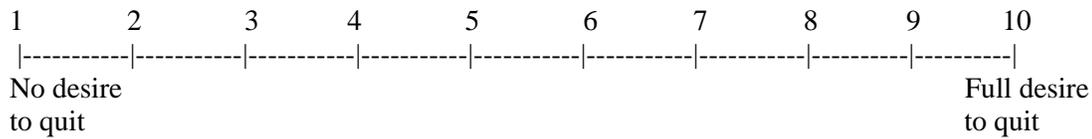
Client Tobacco Assessment

1. What brand of cigarettes do you smoke?
1st _____
2nd _____
3rd _____
2. Do you use tobacco products OTHER THAN cigarettes? (eg. cigars, pipe, snuff, chew, NRT products)
 No
 Yes: _____
3. How many cigarettes did you smoke in the past 7 days? _____ cigarettes
4. How many cigarettes a day do you smoke?
 0 10 or less
 1 11–20
 2 21–30
 3 31 or more
5. How soon after you wake up do you smoke your first cigarette?
 0 After 60 minutes
 1 31–60 minutes
 2 6–30 minutes
 3 Within 5 minutes
6. Which cigarette would you hate most to give up?
 1 First cigarette in the morning
 0 Cigarette during or after meals
 0 Cigarette during or after stressful situations
 0 Cigarette during social situations
 0 None of the above
7. Do you find it difficult to refrain from smoking in places where it is prohibited, such as in church, at the library, or in the movies?
 0 No
 1 Yes
8. Do you smoke more frequently during the first 2 hours of the day than during the rest of the day?
 0 No
 1 Yes
9. Do you smoke when you are so ill that you are in bed most of the day?
 0 No
 1 Yes
10. How old were you when you first tried to smoke a cigarette? _____ years old
11. How old were you when you started smoking cigarettes regularly? _____ years old
12. How old are you now? _____ years old
13. In your lifetime, how many times have you quit smoking for 24 hrs or more? (Do not count hospitalization or incarceration) _____ times
14. In the last year, how many times have you quit smoking for 24 hrs or more? (Do not count hospitalization or incarceration) _____ times
15. In any previous quit attempts, which of the following methods / resources have you used to help you quit? (Check all that apply)
 Quit “cold turkey”
 Gradually cut down
 Stop smoking class/program
 Advice or counseling from a clinician (specify: _____)
 Telephone hotline
 Hypnosis
 Acupuncture
 Nicotine gum
 Nicotine patch
 Nicotine spray
 Nicotine inhaler
 Nicotine lozenge
 Zyban/Wellbutrin for smoking cessation
 Chantix/varenicline
 Other: _____
 Never tried to quit
16. Are you seriously considering quitting smoking within the next 6 months?
 No (**skip to #18) [Precontemplation]
 Yes
17. Are you planning to quit in the next 30 days?
 No [Contemplation]
 Yes [Preparation]
18. The last time you stopped smoking, how long were you abstinent? _____ days / months / years
19. What is the longest time you’ve ever stopped smoking? _____ days / months / years

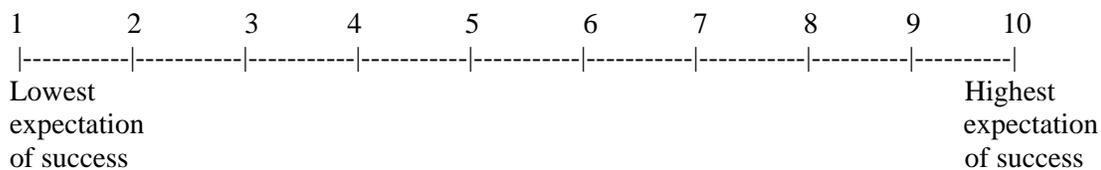
Scoring of FTND: add up points for items #4 thru #9
0-4: low addiction 5: medium addiction 6-10: high addiction

THOUGHTS ABOUT ABSTINENCE

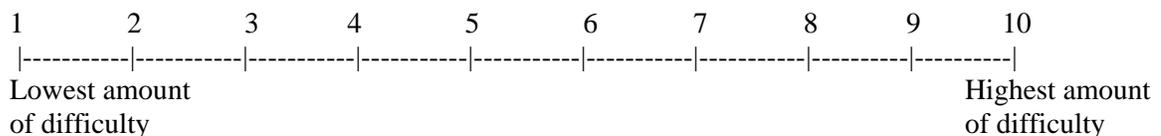
20. First, I'd like to know about how you feel about stopping smoking cigarettes at this time. On a scale of 1 to 10, with 1 representing no desire to quit, give yourself a rating. Circle the number between 1 and 10 that best describes your own desire to stop smoking cigarettes at this time. Remember, the higher the number, the greater your desire.



21. Now, I'd like to know how successful you expect to be quitting smoking cigarettes at this time. Be realistic about this, based on your past experiences and your present strength of motivation. On a scale of 1 to 10, with 1 representing the lowest expectation of success and 10 representing the highest expectation of success, give yourself a rating of your own expectation of success in quitting smoking cigarettes. Remember the higher the number, the greater the expectation of success.



22. Now, I'd like to know how difficult you think it will be for you to keep from smoking cigarettes after having quit. On a scale from 1 to 10, with 1 representing the lowest amount of difficulty and 10 representing the greatest amount of difficulty, give yourself a rating of how difficult you think it will be to quit and remain abstinent. Remember, the higher the number, the more difficult you think it will be for you to quit



23. Lastly, I want to know the GOAL you have chosen for yourself about smoking cigarettes at this time. Please read the goals listed on this page and check the one goal that best represents your own goal at this time, and fill in blanks as indicated.

- ₁ I really don't have a clear goal in mind.
- ₂ I want to use cigarettes in a controlled manner – to be in control of how often I smoke and how much I smoke. I would like to limit that to no more than _____(per limit) per _____(time).
- ₃ I want to be totally abstinent from all cigarette use for a period of time, after which I will make a new decision about whether or not I will smoke cigarettes again. For me, the time period I want to be abstinent for is: _____(time).
- ₄ I don't want smoking cigarettes to be a habit for me anymore, but I would like to be able to occasionally smoke cigarettes when I really have an urge.
- ₅ I want to quit smoking cigarettes once and for all, even though I realize I may slip up and smoke cigarettes once and a while.
- ₆ I want to quit smoking cigarettes once and for all, to be totally abstinent, and never smoke cigarettes ever again for the rest of my life.
- ₇ None of the above applies exactly to me. My own goal is:

Center for Epidemiologic Studies – Depression (CESD) Monitoring Form, NIMH

Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week.

During the past week...	Rarely or none of the time (less than 1 day)	Some or little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
2. I had trouble keeping my mind on what I was doing.	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
3. I felt depressed.	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
4. I felt that everything I did was an effort.	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
5. I felt hopeful about the future.	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0
6. I felt fearful.	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
7. My sleep was restless.	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
8. I was happy.	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0
9. I felt lonely.	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
10. I could not "get going".	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3

Scoring

Score is the sum of the 10 item weights. If more than 2 items are missing, do not score the scale. A score of 10 or greater is considered depressed.

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WITHDRAWAL SYMPTOMS INFORMATION SHEET

Quitting tobacco use brings about a variety of physical and psychological withdrawal symptoms. Most of these symptoms decrease sharply during the first few days after quitting, followed by a continued but slower decline in symptoms during the 2nd and 3rd weeks after quitting. For some people, coping with withdrawal symptoms is like riding a roller coaster—there may be sharp turns, slow climbs, and unexpected plunges. **Most symptoms pass within 2 to 4 weeks after quitting.** Report new symptoms to your health-care provider, especially if severe. Consider the impact of recent medication changes.

SYMPTOM	CAUSE	DURATION	RELIEF
Chest tightness	Tightness is likely due to tension created by the body's need for nicotine or may be caused by sore muscles from coughing.	A few days	<ul style="list-style-type: none"> ▪ Use relaxation techniques ▪ Try deep breathing ▪ Use of NRT may help
Constipation, stomach pain, gas	Intestinal movement decreases for a brief period.	1–2 weeks	<ul style="list-style-type: none"> ▪ Drink plenty of fluids ▪ Add fruits, vegetables, and whole-grain cereals to diet
Cough, dry throat, nasal drip	The body is getting rid of mucus, which has blocked airways and restricted breathing.	A few days	<ul style="list-style-type: none"> ▪ Drink plenty of fluids ▪ Avoid additional stress during first few weeks
Craving for a cigarette	Nicotine is a strongly addictive drug, and withdrawal causes cravings.	Frequent for 2–3 days; can happen for months or years	<ul style="list-style-type: none"> ▪ Wait out the urge, which lasts only a few minutes ▪ Distract yourself ▪ Exercise (take walks) ▪ Use of NRT may help
Depressed mood	It is normal to feel sad for a period of time after you first quit smoking. Many people have a strong urge to smoke when they feel depressed.	1–2 weeks	<ul style="list-style-type: none"> ▪ Increase pleasurable activities ▪ Talk with your clinician about changes in your mood when quitting ▪ Get extra support from friends and family
Difficulty concentrating	The body needs time to adjust to not having constant stimulation from nicotine.	A few weeks	<ul style="list-style-type: none"> ▪ Plan workload accordingly ▪ Avoid additional stress during first few weeks
Dizziness	The body is getting extra oxygen.	1–2 days	<ul style="list-style-type: none"> ▪ Use extra caution ▪ Change positions slowly
Fatigue	Nicotine is a stimulant.	2–4 weeks	<ul style="list-style-type: none"> ▪ Take naps ▪ Do not push yourself ▪ Use of NRT may help
Hunger	Cravings for a cigarette can be confused with hunger pangs; sensation may result from oral cravings or the desire for something in the mouth.	Up to several weeks	<ul style="list-style-type: none"> ▪ Drink water or low-calorie liquids ▪ Be prepared with low-calorie snacks
Insomnia	Nicotine affects brain wave function and influences sleep patterns; coughing and dreams about smoking are common.	1 week	<ul style="list-style-type: none"> ▪ Limit caffeine intake, the effects of which will increase with quitting smoking ▪ Use relaxation techniques
Irritability	The body's craving for nicotine can produce irritability.	2–4 weeks	<ul style="list-style-type: none"> ▪ Take walks ▪ Try hot baths ▪ Use relaxation techniques

Adapted from materials from the National Cancer Institute.

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DRUG INTERACTIONS WITH SMOKING

Many interactions between tobacco smoke and medications have been identified. Note that it is the tobacco smoke -- not the nicotine -- that causes these drug interactions. Tobacco smoke may interact with medications through pharmacokinetic or pharmacodynamic mechanisms. Pharmacokinetic interactions affect the absorption, distribution, metabolism, or elimination of other drugs, potentially causing an altered pharmacologic response. The majority of pharmacokinetic interactions are the result of induction of hepatic cytochrome P450 enzymes (primarily CYP1A2). Pharmacodynamic interactions alter the expected response or actions of other drugs. The amount of tobacco smoking needed to have an effect has not been established and the assumption is that any smoker is susceptible to the same degree of interaction.

DRUG/CLASS	MECHANISM OF INTERACTION AND EFFECTS
Pharmacokinetic Interactions	
Alprazolam (Xanax)	<ul style="list-style-type: none"> ▪ Plasma concentrations decreased up to 50% among tobacco smokers.
Caffeine	<ul style="list-style-type: none"> ▪ Increased metabolism (induction of CYP1A2); clearance increased by 56%. ▪ Caffeine levels may increase after cessation.
Chlorpromazine (Thorazine)	<ul style="list-style-type: none"> ▪ Decreased area under the curve (AUC) (36%) and serum concentrations (24%). ▪ Smokers may experience less sedation and hypotension and require higher dosages than nonsmokers.
Clozapine (Clozaril)	<ul style="list-style-type: none"> ▪ Increased metabolism (induction of CYP1A2); plasma concentrations decreased 28%.
Flecainide (Tambocor)	<ul style="list-style-type: none"> ▪ Clearance increased by 61%; trough serum concentrations decreased by 25%. ▪ Smokers may require higher dosages.
Fluvoxamine (Luvox)	<ul style="list-style-type: none"> ▪ Increased metabolism (induction of CYP1A2); clearance increased by 25%; decreased plasma concentrations (47%). ▪ Dosage modifications not routinely recommended but smokers may require higher dosages.
Haloperidol (Haldol)	<ul style="list-style-type: none"> ▪ Clearance increased by 44%; serum concentrations decreased by 70%.
Heparin	<ul style="list-style-type: none"> ▪ Mechanism unknown but increased clearance and decreased half-life are observed. ▪ Smokers may require higher dosages.
Insulin	<ul style="list-style-type: none"> ▪ Insulin absorption may be decreased secondary to peripheral vasoconstriction; smoking may cause release of endogenous substances that antagonize the effects of insulin. ▪ Smokers may require higher dosages.
Mexiletine (Mexitil)	<ul style="list-style-type: none"> ▪ Clearance (via oxidation and glucuronidation) increased by 25%; half-life decreased by 36%.
Olanzapine (Zyprexa)	<ul style="list-style-type: none"> ▪ Increased metabolism (induction of CYP1A2); clearance increased by 40–98%. ▪ Dosage modifications not routinely recommended but smokers may require higher dosages.
Propranolol (Inderal)	<ul style="list-style-type: none"> ▪ Clearance (via side chain oxidation and glucuronidation) increased by 77%.
Tacrine (Cognex)	<ul style="list-style-type: none"> ▪ Increased metabolism (induction of CYP1A2); half-life decreased by 50%; serum concentrations threefold lower. ▪ Smokers may require higher dosages.
Theophylline (Theo Dur, etc)	<ul style="list-style-type: none"> ▪ Increased metabolism (induction of CYP1A2); clearance increased by 58–100%; half-life decreased by 63%. ▪ Levels should be monitored if smoking is initiated, discontinued, or changed. ▪ Passive smoking (secondhand smoke) also increases the clearance. ▪ Maintenance doses are considerably higher in smokers.
Tricyclic Antidepressants (TCAs) (imipramine, nortriptyline, etc)	<ul style="list-style-type: none"> ▪ Possible interaction with TCAs in the direction of decreased blood levels, but the clinical importance is not established.

Pharmacodynamic Interactions	
Benzodiazepines (diazepam, chlordiazepoxide)	<ul style="list-style-type: none"> ▪ Decreased sedation and drowsiness. ▪ May be caused by central nervous system stimulation by nicotine.
Beta-blockers	<ul style="list-style-type: none"> ▪ Less effective antihypertensive and heart rate control effects. ▪ May be caused by nicotine-mediated sympathetic activation.
Opioids (propoxyphene, pentazocine)	<ul style="list-style-type: none"> ▪ Decreased analgesic effect; tobacco smoking may increase the metabolism of propoxyphene by 15–20% and pentazocine by 40%. ▪ Higher dosages necessary in smokers. ▪ Mechanism unknown.
Oral contraceptives	<ul style="list-style-type: none"> ▪ Increased risk of cardiovascular adverse effects (e.g., stroke, myocardial infarction, thromboembolism) in women who smoke and use oral contraceptives. ▪ Risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over age 35 years.
Adapted from Zevin S, Benowitz NL. Drug interactions with tobacco smoking. <i>Clin Pharmacokinet</i> 1999;36:425–438.	



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Mayo Clinic Nicotine Dependence Center Tobacco
Dependence Treatment Medication Summary

Advice on Using Over-the-Counter Nicotine
Replacement Therapy-Patch, Gum, or Lozenge-To Quit
Smoking

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Mayo Clinic NDC Tobacco Dependence Treatment Medication Summary

Description & Examples	Pros & Cons	Comments	Dosing Recommendations
Combination Nicotine Replacement Therapy (NRT)	Pros <ul style="list-style-type: none"> Permits sustained levels of nicotine with rapid adjustment for acute needs More efficacious than monotherapy Cons <ul style="list-style-type: none"> May increase risk of nicotine toxicity Cost 	Comments/limitations Providing two types of delivery system, one passive and one active, appears to be more efficacious. Should be considered for those who have failed single therapy in the past and those considered highly tobacco dependent. Not a FDA approved strategy.	Dosing** Dose the patch as described. Prescribe 2mg gum, 2 mg lozenge, nicotine inhaler or nicotine nasal spray on an as needed basis when acute withdrawal symptoms and urges to use tobacco occur. Adjust dose of patch if frequent use of other NRT: goal is to minimize need for short-acting NRT dosing.
Nicotine Patch (OTC) 24 hour delivery systems 21, 14, 7 mg/24 hr 16 hour delivery systems 15 mg/16 hr (Generic available)	Pros <ul style="list-style-type: none"> Achieve high levels of replacement Easy to use Only needs to be applied once a day Few side effects Cons <ul style="list-style-type: none"> Less flexible dosing Slow onset of delivery Mild skin rashes and irritation 	Comments/limitations Patches vary in strengths and the length of time over which nicotine is delivered. Depending on the brand of patch used, may be left on for anywhere from 16 to 24 hours. Patches may be placed anywhere on the upper body-including arms and back. Rotate the patch site each time a new patch is applied. May purchase without a prescription	Dosing** (24 hour patch) ≥40 cpd = 42 mg/day 21-39 cpd = 28-35 mg/day 10-20 cpd = 14-21 mg/day <10 cpd = 14 mg/day <ul style="list-style-type: none"> If a dose > 42mg/day may be indicated, contact the patient's prescriber. Adjust based on withdrawal symptoms, urges, and comfort. After 4-6 weeks of abstinence, taper every 2-4 weeks in 7-14 mg steps as tolerated.
Nicotine Lozenge (OTC) Delivers nicotine through the lining of the mouth while the lozenge dissolves. 2 mg, 4 mg	Pros <ul style="list-style-type: none"> Easy to use Delivers doses of nicotine approximately 25% higher than nicotine gum Cons <ul style="list-style-type: none"> Should not eat or drink 15 minutes before use or during use Should not be chewed or swallowed Nausea frequent (12-15%) 	Comments/limitations Use at least 8-9 lozenges/day initially. Efficacy and frequency of side-effects related to amount used. May purchase without a prescription	Dosing as Monotherapy Based on time to first cigarette of the day: <30 minutes = 4 mg ≥30 minutes = 2 mg Based on cigarettes/day (cpd) >20 cpd: 4 mg ≤20 cpd: 2 mg Initial dosing is 1-2 lozenges every 1-2 hours (minimum of 9/day). Taper as tolerated
Nicotine Gum (OTC) 2mg, 4mg Flavors: Orange, Mint, Regular The term "gum" is misleading. It is not chewed like regular gum but rather is chewed briefly and then "parked" between cheek and gum. The nicotine is absorbed through the lining of the mouth. (Generic Available)	Pros <ul style="list-style-type: none"> Convenient/Flexible dosing Faster delivery of nicotine than the patches Cons <ul style="list-style-type: none"> May be inappropriate for people with dental problems and those with temporomandibular joint (TMJ) syndrome Should not eat or drink 15 minutes before use or during use Frequent use during the day required to obtain adequate nicotine levels 	Comments/limitations Many people use this medication incorrectly. Review package directions carefully to maximize benefit of product May purchase without a prescription	Dosing as Monotherapy** Based on cigarettes/day (cpd) >20 cpd: 4 mg gum ≤20 cpd: 2 mg gum Based on time to first cigarette of the day: <30 minutes = 4 mg >30 minutes = 2 mg Initial dosing is 1-2 pieces every 1-2 hrs (10-12 pieces/day). Taper as tolerated.

Description & Examples	Pros & Cons	Comments	Dosing Recommendations
<p>Nicotine Nasal Spray</p> <p>Delivers nicotine through the lining of the nose when sprayed directly into each nostril.</p>	<p>Pros :</p> <ul style="list-style-type: none"> • Flexible dosing • Can be used in response to stress or urges to smoke • Fastest delivery of nicotine of currently available products but not as fast as cigarettes <p>Cons</p> <ul style="list-style-type: none"> • Nose and eye irritation is common, but usually disappears within one week. • Frequent use during the day required to obtain adequate nicotine levels 	<p>Comments/limitations</p> <p>Unlike nasal sprays used to relieve allergy symptoms, the nicotine spray is not meant to be sniffed. Rather, it is sprayed against the lining of each nostril once or twice an hour (maximum of five times in one hour).</p> <p>Prescription required for purchase</p>	<p>Dosing as Monotherapy</p> <p>1 spray in each nostril 1-2 times/hr (up to 5 times/hr or 40 times/day)</p> <p>Most average 14-15 doses/day initially</p> <p>Taper as tolerated</p>
<p>Nicotine Inhaler</p> <p>A plastic cylinder containing a cartridge that delivers nicotine when puffed. The inhaler delivers nicotine to the oral mucosa, not the lung, and enters the body much more slowly than the nicotine in cigarettes.</p>	<p>Pros</p> <ul style="list-style-type: none"> • Flexible dosing • Mimics the hand-to-mouth behavior of smoking • Few side effects <p>Cons</p> <ul style="list-style-type: none"> • Frequent use during the day required to obtain adequate nicotine levels • May cause mouth or throat irritation 	<p>Comments/limitations</p> <p>Puffing must be done frequently, far more often than with a cigarette. Each cartridge designed for 80 puffs over 20 minutes of use. Patient does not need to inhale deeply to achieve an effect.</p> <p>Prescription required for purchase</p>	<p>Dosing as Monotherapy</p> <p>Minimum of 6 cartridges/day, up to 16/day</p> <p>Taper as tolerated</p>
<p>Non-nicotine medication</p> <p>Bupropion SR</p> <p>(Generic Available)</p>	<p>Pros</p> <ul style="list-style-type: none"> • Easy to use • Pill form • Few side effects • May be used in combination with NRT (nicotine patches, spray, gum and inhaler)** <p>Cons</p> <ul style="list-style-type: none"> • Contraindicated with certain medical conditions and medications 	<p>Comments/limitations</p> <p>A slight risk of seizure (1:1000) is associated with use of this medication. Seizure risk should be assessed. Risk of seizure is increased if:</p> <ul style="list-style-type: none"> • Personal history of seizures • Significant head trauma/brain injury • Anorexia nervosa or bulimia • Concurrent use of medications that lower the seizure threshold <p>Prescription required for purchase</p>	<p>Dosing: Take doses at least 8 hours apart</p> <p>Start medication one week prior to the Target Quit Date (TQD)</p> <p>150 mg once daily for 3 days, then 150 mg twice daily for 4 days, then</p> <p>On TQD STOP SMOKING</p> <p>Continue at 150 mg BID 12 weeks, or longer if necessary. May stop abruptly; no need to taper.</p>
<p>Non-nicotine medication</p> <p>Varenicline</p>	<p>Pros</p> <ul style="list-style-type: none"> • Easy to use • Pill form • Generally well tolerated • No known drug interactions <p>Cons</p> <ul style="list-style-type: none"> • Nausea is common 	<p>Comments/limitations</p> <ul style="list-style-type: none"> • Nausea is common. Taking the medication with food and titrating the dose as directed will help • It appears that varenicline can be safely used in combination with bupropion and/or NRT. However, efficacy of these combinations has not been shown • Dose must be adjusted if kidney function is impaired <p>Prescription required for purchase</p>	<p>Dosing: TAKE WITH FOOD</p> <p>Start medication one week prior to the Target Quit Date (TQD)</p> <p>0.5 mg once daily X 3 days, then 0.5 mg twice daily X 4 days, then ON TQD STOP SMOKING AND Take 1.0 mg twice daily X 11 weeks</p> <p>If not smoking at the end of twelve weeks, may continue at 1.0 mg twice daily for an additional 12 weeks</p> <p>May stop abruptly. No need to taper.</p>
<p>SMOKELESS TOBACCO (ST) Treatment Recommendations</p>	<p>24 hour nicotine patch:</p> <p>>3 cans or pouches/week = 42 mg/day 2-3 cans or pouches/week = 21 mg/day <2 cans or pouches/week = 14 mg/day</p> <p>Adjust based on withdrawal symptoms, urges, and comfort. After 4-6 weeks of abstinence, taper every 2-4 weeks in 7-14 mg steps as tolerated</p>	<p>Other NRT:</p> <p>Nicotine lozenge: 4mg if > 3 tins/week 2mg if ≤ 3 tins/week</p> <p>Nicotine gum or nicotine lozenge may be combined with nicotine patch as described for cigarette smokers. Nicotine inhaler and nicotine nasal spray are <u>not</u> recommended for use in ST users.</p>	<p>Non-nicotine pharmacotherapy</p> <p>Empiric evidence suggests that bupropion and varenicline may be of benefit in this population of tobacco users, using the dosing guidelines recommended for cigarette smokers.</p>

The table is a summary of recommendations for use of medication in the treatment of tobacco dependence. The most effective dose varies by individual. Costs will vary depending on retailer. (**Some of the dosing recommendations are not contained in current product labeling information). Adapted from Ebbert JO, et al. J Thorac Oncol.2007;2:249-256; Fiore, et.al. U.S. Public Health Service Guideline, June 2000; Schiffman et. Al. Archives of Internal Medicine 2002;162:1267-1276. Varenicline Product Information profile (May,2006)

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Advice on using over-the-counter nicotine replacement therapy-patch, gum, or lozenge-to quit smoking

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Abstract

Although the use of over the counter (OTC) nicotine replacement therapy (NRT) is effective for smoking cessation, many concerns and misunderstandings persist that may reduce the effectiveness of NRT. Clinical practice and public health experts responded to a questionnaire that explored challenges associated with promoting

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proper NRT use and gathered recommendations on overcoming these challenges. Two predominant themes emerged including the identification of policies and practices that hinder NRT use, and smokers' views regarding NRT use. To address these needs, a two-part consensus statement about the use of OTC NRT to quit smoking was developed. The first part of the consensus statement identifies policy issues. The second part of the consensus statement was developed for smokers to reduce misperceptions and concerns about NRT by providing information on safety and the most effective use of NRT. The statement integrates state of the art clinical practice guidelines in a patient-centered format and presents information for policy makers to effectively support quit attempts.

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Keywords: Nicotine replacement therapy; Harm reduction; Smoking; Tobacco; Policy

1. Introduction

A group of experts in public health and clinical aspects of the use of Nicotine Replacement Therapy (NRT) herein offers a two-part consensus statement about the use of over-the-counter (OTC) NRT to quit smoking. These products have been widely used and hundreds of randomized clinical trials have consistently found NRT works as a smoking cessation aid (e.g., [Fiore, Bailey et al., 2000](#)). Some non-randomized studies have suggested NRT may not be effective as typically used by consumers when purchased OTC (e.g., [Pierce & Gilpin, 2002](#); [Thorndike, Biener, & Rigotti, 2002](#)), whereas others have found it is effective when used in this manner ([Cummings, Fix et al., 2006](#); [Cummings, Hyland et al., 2006](#); [Fiore, Thompson et al., 2000](#); [Hughes, Shiffman, Callas, & Zhang, 2003](#); [Miller et al., 2005](#); [Solomon, Scharoun, Flynn, Secker-Walker, & Sepinwall, 2000](#)). Despite this, surveys indicate many smokers do not believe NRT works ([Bansal, Cummings, Hyland, & Giovino, 2004](#); [Etter & Perneger, 2001](#)). Studies also have found that, even though most experts agree nicotine via NRT is not a carcinogen, is not atherogenic and unlikely to cause dependence, the public and health professionals have significant concerns about NRT as a cause of cancer, heart attacks and addiction ([Benowitz & Gourlay, 1997](#); [Fiore, Bailey et al., 2000](#); [Foulds, Burke, Steinberg, Williams, & Ziedonis, 2004](#); [Henningfield, Fant, Buchhalter, & Stitzer, 2005](#); [Lillington, Leonard, & Sachs, 2000](#); [McEwen, West, & Owen, 2001](#); [Royal College of Physicians of London, 2000](#)). These concerns and misunderstandings about NRT likely influence the effectiveness of NRT.

The lead authors developed an extensive questionnaire examining clinical and public health issues related to the use of NRT, including an in-depth survey of the concerns and potential benefits of long-term use of NRT. A panel of experts with broad expertise in clinical practice and public health responded. Several of the contributing experts ([Counts, Cummings, DiFranza, Foulds, Hughes, Hurt, Niaura, Sachs, and Selby](#)) have a great deal of experience delivering cessation services to smokers with and without NRT (and with other products); others are experts in public health issues related to NRT use and smoking ([Bowen, Cohen, Cummings, Ferrence, Fox, Giovino, Kozlowski, and Warner](#)). The individual responses to the survey reflected the breadth of the panel's expertise and experiences, providing a rich and complex set of ideas addressing the clinical, practical, and policy issues involved with long-term NRT use. Many of the themes brought to light were interrelated, however, as the lead authors evaluated the results of the survey, they found that two distinct sets of information emerged: one highlighted the range of information needed by smokers to make the best use of NRT products that are available as smoking cessation tools; the other brought to light information needed by policy makers to enable actions that support the efforts of smokers making quit attempts.

2. Method

To address these issues, the authors prepared a first draft of a two-part consensus statement; the first section provided a brief consensus statement on issues for policy makers concerning NRT; the second section provided a more detailed set of information focused on the informational needs of smokers considering or using NRT. These statements were sent to the experts and revised according to their feedback. The statements were again sent to the experts and revised again according to their feedback. The statements presented here are supported by each expert but because of differing levels of involvement in this effort, some preferred to be listed as co-authors and some preferred to be acknowledged as participants.

3. Policy issues

3.1. Comparing NRT to cigarettes

Although NRT was initially approved by the Food and Drug Administration as prescription medication, most NRT products in the US are now available as OTC products, presenting a regulatory anomaly. Tobacco products that contain nicotine are readily available without detailed instructions in use (of course advertising, promotion and simple observation is all that is needed for a novice to become a smoker) and without detailed warnings. In contrast, much safer NRT products come with detailed warnings, cautions and instructions that may seem threatening to some, especially compared to the brief warnings on tobacco product labels. Some greater equity between the availability of tobacco products and NRTs has been achieved as NRTs have become available without a prescription. However, a regulatory imbalance persists between tobacco products and NRTs. The regulation of NRTs ensures that they meet safety and quality standards, yet the warning language that accompanies them may give a false sense of risk to smokers and impede their ability to make sound comparative risk judgments about using these products to quit smoking. In thinking about any risks of using NRT, we encourage a comparison to the many known risks of smoking cigarettes and stress that there is not much for the smoker to worry about. NRT poses no new risks to smokers who have usually been using nicotine in much higher doses from cigarettes for many years. NRT has been judged safe to use (Benowitz, 1998; Joseph, Norman et al., 1996; McRobbie & Hajek 2001). We expect that from time to time evidence will emerge that points to some possible disease risk from nicotine (e.g., Dasgupta et al., 2006), but the decades of experience with NRT in smokers indicates that NRT represents a safe alternative to cigarettes. We do not recommend that non-smokers use NRT.

3.2. The cost of NRT: Barrier and burden

The lack of availability of NRT in small quantities and the relatively high cost of NRT may be barriers to effective NRT use. Because the smallest quantity of patches available is a seven day supply, users need to spend approximately \$32 (premium) or \$21 (generic; CVS Online Pharmacy, 2006) in order to get access to any NRT. In contrast, a pack-a-day smoker can easily purchase a daily supply for approximately \$4 for premium brand (Marlboro) and \$2.70 for deep discount brands (Citigroup Global Markets Inc., 2006). Most NRTs are now available as OTC products, and unfortunately this results in some health insurance plans denying coverage. The high cost of NRTs could present a barrier to their use for many smokers and impose an undue burden on lower and middle income individuals, in particular. Because

smoking is more prevalent among those of lower socioeconomic status and cessation is less likely in this group (Barbeau, Leavy-Sperounis, & Balbach, 2004; Centers for Disease Control and Prevention, 2004), the cost of NRT is one factor that could be modified to help reduce the burden of health disparities and increase social equity.

Policies should be implemented to help provide lower income smokers with low-cost sources of NRT (West, DiMarino, Gitchell, & McNeill, 2005). Just as higher cigarette taxes can prevent tobacco use and motivate cessation of tobacco (e.g., World Bank, 1999), the availability and price of NRT is an important factor in whether tobacco users will consider using it to help them quit (Tauras & Chaloupka, 2003). It should not be expected that smokers should be willing to pay a high price for stop smoking medications simply because they are willing to spend a substantial amount on cigarettes. The money a smoker is willing to pay for cigarettes is influenced by addiction and reinforced by the pleasure received from smoking. Conversely, NRT is associated with the discomfort of stopping smoking, presenting an additional barrier to its use. While it may not be feasible to eliminate discomfort as a barrier to quitting and NRT use, cost is a modifiable barrier. Several studies have shown that the provision of free NRT can induce large number of smokers to make a quit attempt and can assist them in stopping smoking (Bauer, Carlin-Menter, Celestino, Hyland, & Cummings, 2006; Cummings, Fix et al., 2006; Cummings, Hyland et al., 2006; Curry, Grothaus, McAfee, & Pabiniak, 1998; Fiore, Thompson et al., 2000; Jaén, Cummings, Shah, & Aungst, 1997; Solomon et al., 2000; Miller et al., 2005; West et al., 2005).

At the present time, it might be made more widely known that OTC NRT is legally available online both from national and international websites at lower cost than many local sources, although this would be of limited value to those without internet access or credit cards. Health insurers (i.e., Medicaid) and employers should ensure adequate coverage with no or minimal deductibles (Halpin, Bellows, & McMenamin, 2006). Several studies have found that lowering the out of pocket cost of stop smoking medications by increasing insurance coverage or reducing co-pays increases utilization and promotes greater rates of cessation (Curry et al., 1998; West et al., 2005). Making NRT available in smaller, unit size boxes may reduce the cost and could make it more financially viable for smokers to experiment with NRT products to find the one best suited, or tailored, to their individual needs and preferences (McClure & Swan, 2006; Schneider et al., 2006).

3.3. Public health surveillance

We encourage that national surveys on tobacco use or other health behaviors include questions on patterns of use of NRT. Surveillance can provide much needed population level data on amount, rate, and duration of NRT use, as well as usage patterns in relationship to smoking cessation and relapse. Surveillance can also help in identifying emerging public health problems as they relate to patterns of NRT use. Also, there are concerns that the use of NRT as a temporary aid to abstaining in a smoke-free environment may help smokers to continue smoking in the long term (Stratton, Shetty, Wallace, & Bondurant, 2001), but we know of no data supporting this as a public health problem. It should be noted that several countries (e.g., Austria, Brazil, Canada, Denmark, France, Norway, Portugal, and Venezuela) have already accepted “temporary abstinence” (i.e., temporarily abstaining from cigarettes in situations where smoking is prohibited) as an approved indication for NRT (Pfizer Canada Inc., 2004; Shiffman, Fant, Buchalter, Gitchell, & Henningfield, 2005). Although current data suggest non-cessation use of OTC NRT is rare (Cummings & Hyland, 2005; Hughes et al., 2003); efforts to make access to NRT easy should be accompanied by continued monitoring of this possibility. Survey

Table 1
Outline of statement to consumers

-
1. NRT is one good *tool* to help you quit smoking. But NRT can't do all the work for you—you have to help—and it is not the only tool to help you stop smoking.
 2. Don't worry about the safety of using NRT to stop smoking: NRT is a safe alternative to cigarettes for smokers.
 3. Do be cautious about using NRT while pregnant.
 4. NRT is less addictive than cigarettes and it is not creating a new addiction.
 5. Stop using NRT only when you feel very sure you can stay off cigarettes.
 6. If the amounts of NRT you are taking do not help you stop smoking, talk with your health care provider about using (1) more NRT, (2) more than one type of NRT at the same time, (3) other smoking cessation medicines at the same time, or (4) telephone or in person advice on quitting tips.
 7. If NRT helps you stop smoking, but you go back to smoking when you stop using NRT, you should seriously think about using NRT again the next time you try to stop smoking.
 8. Make sure you are using the *gum or lozenge* in the best way:
 - Park the gum between your teeth for 2–3 min between chews — fast chewing doesn't allow the nicotine to be absorbed from the lining of the mouth and can cause nausea.
 - Don't drink anything (including coffee, orange juice, beer, wine, or sodas) for at least 15 min before and *nothing while using* nicotine gum or lozenge, so your mouth can absorb the nicotine.
 - Make sure you get the right amount of nicotine — people who smoke more than 10 cigarettes per day should use a 4 mg piece of gum or lozenge.
 9. Make sure you are using the *patch* in the best way:
 - *If you can't stop having a few cigarettes while using the patch, it is best to keep the patch on.* Don't let a few slips with cigarettes stop you from using the patch to quit smoking.
 - You may need to add nicotine gum or lozenges to help get over the hump or you may need to use more than one patch at a time. Talk to your healthcare provider about this.
 10. If the price of NRT is a concern, try to find “store brand” (generic) NRT products which are often cheaper than the brand name products.
 11. Do whatever it takes to get the job done—it is not a weakness to use medicine to stop smoking.
-

questions could be asked about this concern, to see if such temporary use was associated with increased or decreased quit attempts.

4. Statement for consumers

The statement is written for smokers who use or who are thinking of using over-the-counter (OTC) Nicotine Replacement Therapy (NRT) but is also relevant for individuals using other forms of tobacco (e.g., pipes, cigars, smokeless tobacco) (Table 1). Note that in several countries, all NRT is OTC. We hope that policy makers and health care professionals will read and make use of the information in the statement, because it addresses widespread misunderstanding of NRT. We encourage health communication specialists to use this statement to help develop communications on NRT use. We support the dissemination of this statement for non-commercial purposes on multiple websites or photocopying this statement for distribution, provided credit is given to the source and a link is provided to the journal home page at <http://www.sciencedirect.com/science/journal/0306460>.

“NRT” is Nicotine Replacement Therapy for helping tobacco users quit. NRT products include the nicotine patch, gum and lozenge, and these products are sold “over-the-counter” (OTC) without a healthcare provider's prescription. The nicotine in these products replaces, to some degree, the nicotine from cigarettes in a safe form to help smokers stop smoking. Reading NRT package labels and inserts

gives important information about what it is and how it works. The makers of NRT are under strict rules on what can and cannot be written on the NRT label about how to use NRT.

If you are thinking about using NRT, you probably have some questions and an expert may not be on hand to answer them. To help smokers get all the answers they need, a group of smoking research experts and clinical experts wrote this statement containing some of the most helpful and important facts you need to know about using NRT. This statement has not been approved by the FDA (Food and Drug Administration) or by any other regulatory agency; but it does represent the judgment of research and clinical experts. If you are able to consult with your health care provider on these issues, we advise that you do so, knowing that there are some NRT products and other tobacco cessation products available only by prescription.

1. NRT is one good tool to help you quit smoking. But NRT can't do all the work for you—you have to help—and it is not the only tool to help you stop smoking.

You could be disappointed if you think using NRT or anything else will make quitting smoking *easy*. But using NRT could make quitting *easier* by reducing your cravings or the bad feelings you have when you stop smoking. Like other tools, NRT can help you—if you are also willing to put some work into it. Not everyone will find NRT helpful. Keep in mind that there are other tools available for stopping smoking. You can try other NRT's by prescription such as the oral inhaler and the nasal spray or non-nicotine medications in tablet form such as bupropion or Varenicline (Chantix). You also can talk to your health care provider, call your state telephone quit-line, or call 1-800-QUITNOW for tips on quitting.

2. Don't worry about the safety of using NRT to stop smoking: NRT is a safe alternative to cigarettes for smokers.

Studies show that NRT is a safe alternative to cigarettes for smokers, and DOES NOT cause cancer or heart attacks, even for smokers who already have had heart attacks or heart disease. Also, nicotine is not the really dangerous chemical in cigarettes. Cigarette smoke contains many harmful chemicals, and it is these, not nicotine, that are responsible for the heart attacks, cancer, and lung disease. The risks of cigarette smoking are much greater than the risks of NRT. Cigarette smoking causes suffering (such as breathlessness, difficult breathing or pain from cancer or heart disease) and, in the end, can cause early death in half of long-term smokers.

NRT has been found to be very safe for nearly every user, yet some smokers and even some health care workers have mistaken health concerns about NRT. Some people think that the nicotine patch is dangerous for heart patients, but this is not true.

Nicotine and thus NRT does not cause cancer, but some recent studies suggest that it might be better for those who are undergoing treatment for cancer to stop smoking without using NRT. Those diagnosed with cancer should talk with their doctor about whether they should prefer using an FDA approved non-nicotine stop smoking medication (e.g., bupropion [Zyban] or varenicline [Chantix] over NRT.

If you have just had some serious new heart or heart-related problem (for example, heart attack or stroke) within the past 4 weeks, NRT is likely safe to use at that time, but, under these circumstances, you should talk with your health care provider about taking this or any medication. Cigarettes should clearly be avoided just after a heart problem, and NRT, especially the short-acting gum or lozenge, has been used to help individuals with recent heart problems who are having trouble staying off cigarettes. Know that cigarette smoking is very dangerous compared to NRT and you should be avoiding smoking. For those

who have not just had a new heart problem and have longer-term heart problems, NRT has been found to be safe to use.

NRT packages come with many warnings and directions that can lead a person to believe that NRT is far more risky than it actually is. It is a mistake to think that any NRT product is as dangerous as cigarettes. NRT does not kill, it saves lives!

3. *Do be cautious about using NRT while pregnant.*

Some studies suggest that pregnant women should try to stop smoking WITHOUT the use of NRT, if they can. It is very important for the health of the unborn baby to stop smoking cigarettes. If you can quit smoking without NRT, that is great. If you believe that you need NRT to stop smoking during pregnancy, talk to your health care provider; it may still be useful to get you off cigarettes. After the birth of the child, it is still very important for a mother not to smoke, and for NO ONE to smoke around the child.

4. *NRT is less addictive than cigarettes and it is not creating a new addiction.*

Some smokers worry about *becoming* addicted to NRT or *becoming* ‘hooked on’ the gum, lozenge, or patch. While it is true that the nicotine in NRT products is addictive, smokers are already addicted to nicotine—they get a lot more of it from each cigarette they smoke than from any NRT product.

Smokers usually do not get as much nicotine from NRTs as from cigarettes, nor do they find NRT as enjoyable to use as cigarettes. This is because breathing in smoke through the lungs gives the brain a rush of nicotine while NRT gives nicotine more slowly through the skin or lining of the mouth. In fact, most smokers don’t use enough NRT to get all the help they could to stop smoking. While some smokers could find it hard to stop using NRTs because of the nicotine in these products, there are two important things to remember: first, even using a NRT for a very long time is much less harmful to health than smoking for the same amount of time; second, stopping an NRT is not likely to be as hard as stopping smoking.

5. *So, how long should you use NRT?*

NRT product labels say that the product should be used for 8 or 12 weeks, depending on the product. For some smokers, this is enough time to stop smoking for good. Some smokers do not need to use NRT that long to stop smoking. Other smokers may need to use NRT for several months or even years to stay off cigarettes. If NRT is helping you not smoke, we suggest you do not even think about cutting down on it unless (a) you believe you have a side-effect from NRT or (b) you have 14 days in a row with no cravings or withdrawal or near slips back to smoking. Using NRT longer than 8 to 12 weeks is not dangerous. Going back to cigarettes is very dangerous and could kill you! In fact, it is a common problem with NRT, that people don’t even use it for the whole recommended 8–12 week period. We suggest you stop using NRT only when you feel very sure you can stay off cigarettes. If it ever comes down to a choice of using NRT or returning to smoking, stay on the NRT. A good rule of thumb is that if you are able to easily resist smoking without any cravings in situations that would have made you smoke in the past, you are ready to stop the NRT.

6. *If the amounts of NRT you are taking do not help you stop smoking, talk with your health care provider about using (1) more NRT, (2) more than one type of NRT at the same time, (3) other smoking cessation medicines at the same time, or (4) telephone or in person advice on quitting tips.*

Even though the NRT packages say you should not use more than one NRT, most experts agree that, for some smokers, using more than one type of NRT product at the same time can be helpful in stopping smoking and is safe. The patch, for example, gets nicotine to your brain very slowly but does so for many hours.

Nicotine gum and lozenge get nicotine to your brain faster than the patch (but not as fast as cigarettes) but they deliver nicotine for short periods of time. Nicotine gum or lozenge can be useful to increase nicotine levels at those times when it is very hard to keep from smoking while using the patch alone. Instead of smoking a cigarette when you are wearing the patch, try a piece of the nicotine gum or the lozenge to get over the urge first. These urges to smoke do not last very long. In using more than one NRT product at the same time, pay attention to how you are feeling—your own reactions can be a guide to whether you are getting too little nicotine or overdoing it. Prescription smoking cessation medicines can be used with NRT; but you need to talk with a health care provider about a prescription and whether using that medicine with NRT is a good idea for you.

7. If NRT helps you stop smoking, but you go back to smoking when you stop using NRT, you should seriously think about using NRT again the next time you try to stop smoking.

Many medicines need to be used over and over again to deal with health problems that do not go away completely. For problems like asthma, diabetes, and high blood pressure, medicine often needs to be taken for a long time—not just a few weeks. Just as an asthma medication that helped an asthma attack before is likely to help again, NRT is likely help a smoker stop again if it was helpful before.

Some smokers keep going back to cigarettes after quitting for a time. If that happens to you, you should try to stop smoking again as soon as you can and use ways or tools that helped you quit before. If NRT helped you stay off cigarettes, even for a few days, definitely think about using it again. New NRTs that work better and are more appealing may be available since the last time you quit. If NRT use was not that helpful to you, look for other ways to quit smoking but make sure you were using enough NRT and used it in the best way the first time before you give up on it.

8. Make sure you are using the gum or lozenge in the best way:

- Park the gum between your teeth for 2–3 min between chews — fast chewing does not allow the nicotine to be absorbed from the lining of the mouth and can cause nausea.
- Do not drink anything (including coffee, orange juice, beer, wine, or sodas) for at least 15 min before and *nothing while using* nicotine gum or lozenge, so your mouth can absorb the nicotine.
- Make sure you get the right amount of nicotine — people who smoke more than 10 cigarettes per day should use a 4 mg piece of gum or lozenge.

9. Make sure you are using the patch in the best way:

- *If you can't stop having a few cigarettes while using the patch, it is best to keep the patch on.* Do not let a few slips with cigarettes stop you from using the patch to quit smoking.
- You may need to add nicotine gum or lozenges to help get over the hump or you may need to use more than one patch at a time. Talk to your healthcare provider about this.

10. The cost of NRT.

If the price of NRT is a concern, try to find “store brand” (generic) NRT products which are often cheaper than the brand name products. There is no reason to think that brand name NRT works better than store brands. And keep in mind how much cigarettes cost. Putting your cigarette money toward NRT can in the long run save you a lifetime of cigarette money. And if you can find the money for cigarettes, you probably

can find the money for NRT. Think about buying NRT over the Internet. It is legal to do so and can be cheaper. Some health benefit plans, including some Medicaid providers, pay for NRT, and some state Health Departments and telephone quitlines provide NRT at no cost if you engage in the telephone counseling.

11. Do whatever it takes to get the job done—it is not a weakness to use medicine to stop smoking.

Some people think that if you really want to quit smoking, you *should* be able to just do it without any help. While it is true that not everyone “needs” medicine to stop smoking, it is also true that not everyone needs medicine to treat asthma, diabetes, or high blood pressure. NRT is only one tool that can help in the hard job of stopping smoking. Those who quit smoking with or without NRT are both making the same smart move for their health—they are becoming ex-smokers.

Levels of addiction vary, and what life throws at you varies from person to person. Maybe one person had an easier time quitting because they were not living or working with other smokers. Maybe one person had a harder time because they had other problems (stress) to deal with. You are not competing with other smokers, you are competing against your cigarettes. If you find NRT helpful and you need to use it for a long time to stay off cigarettes, do not be disappointed or worried—be proud of yourself because you have stopped smoking.

The most important thing about quitting is to *stop* using cigarettes—it does not mean you are a “better person” with a “stronger will” if you try to quit smoking without using medicine or other help.

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IMPLEMENTATION PLANNING TOOLS

Assessment and Diagnosis Implementation Planning
Worksheet

Pharmacotherapy Implementation Planning Worksheet

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ASSESSMENT AND DIAGNOSIS IMPLEMENTATION PLANNING WORKSHEET

Task Description	Resources Required	Staff Assigned	Deadline
Acquire assessment and diagnostic tools	<input type="checkbox"/> CO Monitor(s) <input type="checkbox"/> FTND <input type="checkbox"/> FTND-ST <input type="checkbox"/> HONC <input type="checkbox"/> DSM-IV Diagnostic Criteria <input type="checkbox"/> Other (Specify):		
Define program's assessment protocol			
Train clinical staff on how to use assessment and diagnostic tools			
Review patient assessment and diagnostic information in clinical supervision, case reviews, and chart audits			

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PHARMACOTHERAPY IMPLEMENTATION PLANNING WORKSHEET

Task Description	Resources Required	Staff Assigned	Deadline
Acquire guidelines on the use of tobacco treatment pharmacotherapy and disseminate guidelines to all clinical staff			
Define program capacity to connect patients to tobacco treatment pharmacotherapy	<input type="checkbox"/> Healthcare providers <input type="checkbox"/> Pharmacy <input type="checkbox"/> Medication dispensing protocols <input type="checkbox"/> Medication monitoring protocols		
Define program's tobacco treatment pharmacotherapy protocol			
Train clinical staff on how to implement tobacco treatment pharmacotherapy protocol			
Review patient use of tobacco treatment pharmacotherapy in clinical supervision, case reviews, and chart audits			