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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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## 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

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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.
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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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