



Published in final edited form as:

Psychol Addict Behav. 2008 December ; 22(4): 472–485. doi:10.1037/0893-164X.22.4.472.

Over-The-Counter Nicotine Replacement Therapy: Can its impact on smoking cessation be enhanced?

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Abstract

Nicotine replacement therapies (NRT) are efficacious smoking cessation aids. However, only minimal increases in smoking cessation followed NRT being made available over-the-counter (OTC) which presumably made these treatments more readily available. To better understand why the U.S. did not experience improvements in smoking cessation following the OTC availability of NRT, it is useful to review factors that determine NRT's impact on smoking cessation and how these factors played out with the introduction of OTC NRT. We contend that for NRT to have a greater impact on public health, we need to increase the number of individuals making a quit attempt, the proportion using NRT in a quit attempt, and the effectiveness of each quit attempt. Even small increases in the impact of OTC NRT could yield significant benefits in terms of morbidity and mortality. The remainder of this paper provides examples of interventions designed to target each of the above mentioned factors individually as well as examples of interventions that link increased cessation attempts, increased NRT reach, and increased NRT efficacy in order to synergistically increase the impact of OTC NRT.

Overview

Tobacco smoking is the leading cause of preventable morbidity and mortality in the U.S. and is responsible for more than 430,000 deaths each year (Centers for Disease Control and Prevention [CDC], 2005). Even after years of smoking, adult smokers who quit reduce their risk for premature death and a number of other adverse tobacco-related health consequences (Taylor, Hasselblad, Henley, Thun, & Sloan, 2002; U.S. Department of Health and Human Services [USDHHS] 2004).

Nicotine replacement therapies (NRT) are efficacious smoking cessation aids. NRT is currently used as a stand-alone or adjuvant smoking cessation treatment. NRT reduces the withdrawal symptoms associated with quitting, thereby, increasing the likelihood that a smoker attempting to quit will continue to refrain from smoking (Gourlay, 1994; Silagy, Lancaster, Stead, Mant, & Fowler, 2004; Sutherland, 2002). The increased widespread availability of NRT when NRT was made available over-the-counter (OTC) unfortunately

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has not resulted in a substantial reduction in smoking. This review, similar to the review of Cummings and Hyland (2005), examines potential ways that the impact of OTC NRT on reducing the prevalence of smoking in the US can be enhanced.

Limited impact of OTC NRT

Numerous double-blind placebo-controlled trials demonstrate the effectiveness of all five versions of NRT (gum, patch, inhaler, nasal spray, and lozenges) currently available in the U.S. (see Gourlay, 1994; Silagy et al., 2004; Sutherland, 2002 for reviews). Three of these are available OTC in the US (gum, patch, and lozenge). Gum and patch forms of NRT have been available OTC since 1996, and the lozenge form was approved for OTC use in 2002. The increased availability did not produce meaningful reductions in smoking. The prevalence of cigarette smoking was 24.7% in 1995, the year before nicotine gum and patch went OTC, and was the same (24.7%) in 1997, one year afterward. The smoking rate in 2006, 10 years after the introduction of OTC NRT, was 20.8% (CDC, 2007), a drop of 3.9 percentage points. This compares favorably to the 0.1 percentage point increase from 1985 to 1995, but not to the 12.5 percentage point drop from 1974 to 1985. In order to better understand why the U.S. did not experience substantial improvements in smoking cessation following the introduction of OTC NRT, it is useful to review factors that determine NRT's impact on smoking cessation, how these factors actually played out when NRT was introduced OTC, and why it may have been somewhat unrealistic to expect increases in cessation rates. Finally, we suggest some ways that the impact of OTC NRT on reducing smoking prevalence might be increased.

Determinants of NRT's OTC impact

A useful model of the impact of NRT on smoking cessation is a multiplicative function— $Q \times N \times E$, where Q is the number of individuals making a quit attempt, N is the proportion using NRT in a quit attempt, and E is the effectiveness of the quit attempt. We examine in turn how each of the determinants of this function was affected by the introduction of OTC NRT in the U.S.

What Happened With the Introduction of OTC NRT?

Quit attempts

Data from the National Health Interview Survey (NHIS) administered to a nationally representative sample of the U.S. non-institutionalized population in 1995 revealed that 45.8% of current U.S. daily smokers (i.e., 17.3 million) had stopped smoking for at least one day during the previous 12 months (CDC, 1997). In 1997, the year following the introduction of OTC NRT, an estimated 40.7% of current daily smokers (i.e., 16.0 million) had made an attempt lasting at least one day during the previous 12 months (CDC, 1999a). While the CDC data included only smokers who failed to successfully quit, these data do not support the idea that quit attempts increased after the introduction of OTC NRT if one assumes that the proportion of successful attempts did not change from the pre to post-OTC switch.

State-level survey data also provide information on quit attempts; however, unlike the CDC data, these include both successful and unsuccessful quit attempts. The Massachusetts Tobacco Surveys compared data for adult smokers (defined as current smokers and those who had quit regular smoking within the past year) before the availability of OTC NRT (1993 to 1994) and after the switch (1997 to 1999) (Thorndike, Biener, & Rigotti, 2002). Almost half (48.1%) had made a quit attempt (lasting at least 24 hours) within the previous year in the pre-OTC period and 45.2% of past-year smokers had made a quit attempt after

NRT became available OTC (Thorndike et al., 2002); this difference was not significant ($p = .46$). In contrast, the analysis of Pierce and Gilpin (2002), based on California Tobacco Survey data revealed that there was a 61.4% increase in quit attempts among smokers between 1992 and 1999, with 38.1% reporting a quit attempt lasting a day or more in 1992, 56.0% in 1996, and 61.5% in 1999.

Differences in the findings from these three sources of survey data may be due to methodological differences (e.g., differences in participant selection criteria) as well as differences in concurrent environmental and political factors (e.g., tobacco control efforts within a state) that could not be adequately controlled for due to the absence of a randomized design. Nevertheless, given the CDC and Massachusetts data, it is difficult to argue that overall cessation attempts increased following the introduction of OTC NRT.

Use of NRT after OTC Introduction

Data from various sources suggest that use of NRT for smoking cessation increased subsequent to the introduction of OTC NRT. Sales estimates for nicotine gum and patch suggest that NRT was used in 2 – 3 million quit attempts annually from 1993 to 1995, whereas from 1996 to 1998, when NRT had become available OTC, it was used on 6 – 7 million quit attempts (CDC, 2000; Shiffman et al. 1997). However, purchase of a product does not actually mean that an individual will use the product or even make a quit attempt.

Several U.S. survey studies (e.g., Hyland, Rezaishiraz, Giovino, Bauer, & Cummings, 2005; Pierce & Gilpin, 2002; Reed, Anderson, Vaughn, & Burns, 2005; Thorndike et al., 2002) examined the actual rate of NRT use before and after the switch to OTC status. Data collected in 1993 and 2001 from a large nationally representative sample of smokers participating in the National Cancer Institute's Community Intervention Trial for Smoking Cessation (COMMIT) indicated that annual NRT gum and patch use increased by about 60% from 5.1% to 8.1% ($p < .001$) following the NRT reclassification (Hyland et al., 2005).

Based on their monthly data from the California Tobacco Survey conducted between September 1996 and January 1997, Reed and colleagues (2005) concluded that there were significant increases in the percentage of individuals using the gum ($p < .001$) and the patch ($p < .05$) in a quit attempt lasting at least one day in the months immediately following their OTC introduction (Reed et al., 2005). Pierce & Gilpin (2002) examined the 1992, 1996, and 1999 California Tobacco Survey data and also found that the use of NRT products in the most recent cessation attempt increased significantly from 9.3% in 1992 to 12.7% in 1996 and to 14.0% in 1999, reflecting a 50.5% increase ($p < .001$) between 1992 and 1999.

In contrast, Thorndike et al. (2002) failed to find a difference in the proportion of individuals using NRT during a quit attempt before (1993 to 1994; 20.1%) and after the OTC switch (1997 to 1999; 21.4%). Nevertheless, taken as a whole, the studies suggest that the proportion of NRT-aided quit attempts increased following OTC availability but that the proportion of smokers using NRT on any given quit attempt remained small (8.1% to 21.4%).

Efficacy of NRT

As noted earlier, the impact of OTC NRT will also depend on the efficacy of NRT in the OTC situation. Clinical trials have generally shown that NRT treatment as opposed to placebo treatment double one's odds of quitting (Silagy et al., 2004; USDHHS, 2000) regardless of the type of NRT used (Fiore et al., 2000; Lancaster, Stead, Silagy, & Sowden, 2000) (Lancaster et al., 2000); however, clinical trials of NRT have often evaluated efficacy in conjunction with a behavioral therapy/counseling intervention (Lancaster et al., 2000; Silagy et al., 2004). While behavior therapy/counseling alone has a positive relationship to

cessation, NRT is effective without additional counseling (Hughes, Goldstein, Hurt, & Shiffman, 1999; Silagy et al., 2004). Combining NRT with intensive behavior therapy, generally produces quit rates better than those achieved by either intervention alone (Stitzer, 1999). This suggests an additive effect of combining both therapies rather than an interaction where the effectiveness of NRT would be undermined if behavioral therapy were not used (Stitzer, 1999).

The question arises as to whether NRT would continue to double the odds of quitting when used in more real-world situations, given evidence to suggest that smokers in such situations often fail to take advantage of available behavioral support (e.g., a concomitant self-help guide, one-on-one counseling, or a telephone help line [Orleans et al., 1994]). Multiple clinical trials have tested NRT under OTC conditions. Hughes and colleagues (2003) identified and summarized the findings of two types of studies assessing the efficacy of OTC NRT: those that compare OTC NRT to OTC placebo and those that compare it to prescription NRT. Both types of studies investigate whether NRT works under OTC conditions.

The meta-analysis comparing OTC NRT (all studies used the patch) with placebo included four randomized double-blind studies and showed that when NRT was used as an OTC medication with little or no adjunctive intervention, it worked twice as well as placebo (Hughes, Shiffman, Callas, & Zhang, 2003). In the meta-analysis of OTC versus prescription NRT, two of the four studies were randomized and three involved the patch. The resulting odds ratio and confidence interval indicated that there was no difference between the two conditions (Hughes et al., 2003). When seven of these studies were combined, with one study being excluded due to small sample size and another due to the short duration of follow-up, the long-term (i.e., greater than 6 months) quit rate was 7% (95% CI 4% to 11%).

Taken together these findings suggest that OTC NRT produces comparable quit rates to prescription NRT and that the long term quit rates of OTC NRT are still higher than unaided quit rates (e.g., 3.5 % see Hughes et al., 2003). Moreover, although Hughes et al. described their research as a meta-analysis of the efficacy of OTC NRT, these studies provide some support for the effectiveness of OTC NRT in that they shared characteristics of effectiveness trials (e.g., no ancillary support or intervention, little instruction beyond what was available through labels and in-package materials, no participant exclusionary criteria, and minimal data collection burden [Bauer, et al., 2001]).

Debate remains concerning the effectiveness of OTC NRT outside of clinical trials. For instance, Hyland et al. (2005) found that there were no statistically significant differences in the long-term quit rates of their geographically diverse sample of NRT users before and after the OTC reclassification, despite an increase in NRT use. Similarly, Pierce and Gilpin's (2002) data suggest that despite a significant increase in NRT use after the OTC reclassification, the increased advantage of NRT use in a long-term quit attempt over an unaided quit attempt was no longer evident following the OTC switch. Such findings might suggest a decline in NRT efficacy in the real world OTC situation. Likewise, Thorndike and colleagues (2002) found no difference in successful cessation with NRT before and after the switch. In addition to the previously mentioned problems of drawing conclusions across studies that lack a randomized design, the Pierce and Gilpin (2002) and Thorndike et al. (2002) studies are limited by their cross-sectional design, which makes them prone to memory recall biases. The longer the interval between the cessation attempt and the survey administration, the greater the likelihood that earlier quit attempts may be forgotten, particularly the less salient ones. Unaided quit attempts that fail are more likely to be forgotten than NRT-assisted quit attempts that fail.

Prospective longitudinal studies such as West and Zhou (2007) have the advantage of minimizing recall biases. Although their study was multinational rather than focused on the U.S., NRT was available for OTC purchase in all the countries (e.g., France, Canada, U.K., U.S., and Spain) examined at the time the study was conducted. Smokers who wished to quit within the next 3 months were recruited in two phases (one beginning in 2003 and another in 2004) and were followed up at 3 and 6 months after a quit attempt had been made. When controlling for level of nicotine dependence and phase of participation, the odds of achieving 6-months' continuous abstinence among NRT users who self-initiated a quit attempt without additional behavioral support was 2.2 (95% CI 1.3 to 3.9) times higher than those not using NRT ($p < .005$). The abstinence rates of those not using NRT were similar to those achieved by control participants in clinical trials. Hence, the study provides persuasive evidence of NRT's effectiveness in OTC situations outside the context of clinical trials.

Summary

In general, there is little evidence that overall quit attempts increased following the introduction of OTC NRT. The proportion of NRT-assisted cessation attempts appears to increase following OTC reclassification, but the proportion of quit attempts in which NRT was used remains small. Moreover, results from clinical trials of OTC NRT as well as a recent prospective longitudinal study of OTC NRT in a real world setting strongly suggest that NRT use doubles one's odds of successfully quitting. However, the prevalence of smoking does not appear to have been meaningfully reduced following the OTC availability of NRT.

Realistic impact of OTC NRT

While OTC NRT *may* have almost doubled the proportion of quit attempts on which smoking cessation pharmacotherapy was used (see CDC, 2000; Hyland et al., 2005; Pierce & Gilpin, 2002; Reed et al., 2005; Shiffman et al., 1997, but see Thorndike et al., 2002), the impact of this increased NRT use is not easily detectable. This can be better understood by looking again at the determinants of impact. According to our model, the impact of NRT is a multiplicative function— $Q \times N \times E$, where Q is the number of individuals making a quit attempt, N is the proportion using NRT in that attempt, and E is the effectiveness of the quit attempt. Using sample figures to calculate the value of the function can be illustrative. It may be assumed that approximately 40% of smokers (CDC, 2005) make a quit attempt, that NRT is used in 20% of quit attempts (Thorndike et al., 2002), and that 7% are effective as a result of using NRT in real-world situations given that NRT generally doubles the odds of quitting without aids which is estimated as 3.5%. The impact of using NRT can then be expressed as the following function:

$$\begin{aligned} Q \times N \times E &= \text{Impact (where } Q=.40, N=.20, E=.07) \\ .40 \times .20 \times .07 &= .0056 \approx 0.6\% \end{aligned}$$

In other words, the overall quit rate using NRT in the population of smokers would be about 0.6%. Using this same function to estimate the overall quit rate for the remaining 80% of individuals making a quit attempt without NRT or some other effective smoking cessation aid, we obtain the following estimate of smoking cessation rates for those not using NRT:

$$.40 \times .80 \times .035 = .112.$$

Hence, adding .0112 and .0056 we predict that 1.68% of the population will be successful quitters. Now, if we assume that the rate of NRT use was 10% before OTC NRT

availability, these numbers are 0.28% quit using NRT and 1.26% quit without using NRT giving a total of 1.54% quitting. So, we would be trying to detect an increased quit rate of 0.14 percentage points. A statistically difficult task, though an important one from a public health point of view.

Now let's examine the effect of varying parts of this equation, so that we can see how affecting each might change the impact of NRT. First, let's examine how many smokers would quit if everyone making a quit attempt used NRT, but the number making a quit attempt remained the same and the likelihood of successful cessation was unchanged. In this case 2.8% of smokers would successfully quit in a given year. This quit rate would result in the proportion of current smokers going from 20% today to 15% ten years from now (assuming that the number of smokers dying equaled the number of new smokers). If instead each smoker made a quit attempt in a given year and everything else remained constant, then 4.2% of smokers would quit each year. This quit rate would result in the prevalence of smokers going from 20% today to 13% ten years from now. If the effectiveness of NRT was such that everyone quit (and 50% of those without NRT quit), then 24% of smokers would quit in a given year. This quit rate would result in the prevalence of smoking going from 20% today to 1% ten years from now. Clearly, all of these scenarios are extremely unrealistic. While the scenario involving everyone succeeding has a huge impact (and is extremely unrealistic), it is important to note that neither of the other two overly optimistic scenarios (either every smoker trying to quit each year or every quit attempt involving NRT) is likely to reduce the prevalence of smoking below 10% within ten years.

More promising and more realistic are increases in each of the variables in this equation. For instance, if we could achieve 50% increases in the proportion of smokers making a quit attempt (from 40% to 60%) in a given year and a 50% increase in the proportion of those attempts using NRT and get the smoking cessation rates up to those frequently seen in smoking cessation trials (10% without and 20% with NRT), then the annual cessation rate would be 7.8%. This cessation rate would result in the smoking prevalence going from 20% today to 9% ten years from now. Other reasonable scenarios that reduce smoking prevalence to 10% or less in ten years could be devised. All of these, however, would involve increases in all three variables of our equation. Most importantly, these all depend upon increases in the overall effectiveness of any quit attempt. Efforts to decrease the prevalence of smoking and increase the impact of effective pharmacotherapies, such as NRT, need to not only ensure that these therapies are used but to also increase the number of quit attempts made *and the effectiveness of any one quit attempt*. It is only through improvements in all of these areas and improvements in smoking prevention that further substantial reductions in smoking prevalence are likely to be achieved.

While the impact of OTC NRT was small, smoking is the fifth leading cause of death in the U.S. and accounts for between 6 and 8% of U.S. medical costs (Warner, Hodgson, & Carroll, 1999) and even small increases in the impact of an intervention can yield significant benefits in terms of morbidity and mortality. As the above function suggests, for NRT to have a greater impact on public health, we need to increase cessation attempts, the utilization of NRT during a quit attempt, the effectiveness of each quit attempt or better yet develop interventions that target some combination of these. The remainder of this paper addresses potential strategies for maximizing the public health impact of NRT. Some of the proposed strategies have evidence to support them from the literature while others are more speculative.

Ways to Increase the Impact of OTC NRT

Increasing Cessation Efforts

Efforts to increase the number of individuals making a quit attempt can be categorized into those involving Health Care Providers and those involving community-based public health interventions. We suggest increases in both are needed to enhance the impact of OTC NRT on smoking cessation.

Health care provider interventions that increase quit attempts—It is well documented that the provision of cessation advice and support to smokers by health care providers improves cessation rates (Bao, Duan, & Fox 2006; Gorin & Heck, 2004; Silagy et al., 2004). Approximately 70% of smokers visit their primary care provider at least once each year (CDC, 1993) providing a prime opportunity for counseling about cessation and the effectiveness of NRT. Unfortunately, some physicians remain unaware of U.S. Public Health Service clinical practice cessation guidelines (Fiore et al., 2000) that recommend counseling about smoking cessation as well as the use of effective pharmacotherapies (e.g., Cabana, et al., 1999; Longo et al., 2006) while others are missing opportunities to intervene (Denny, Serdula, Holtzman, Nelson, 2003; Ferketich, Khan, & Wewers, 2006; Schnoll, Rukstalis, Wileyto, & Shields, 2006). These missed opportunities occur even among workers at high risk for lung disease because of the potentially synergistic effect of their occupation and tobacco use (Lee et al., 2007). Dentists and pharmacists also appear to miss opportunities to counsel and intervene with patients about smoking cessation (Hu et al., 2006; Hudmon, Prokhorov & Corelli, 2006; Williams, Newsom & Brock, 2000); however, those with formal training in the U.S. public health service practice guidelines are more likely to intervene (Hu et al., 2006; Sinclair et al., 1998).

These missed opportunities may be due in part to the fact that many health care providers are reluctant to discuss smoking cessation with their patients (e.g., Vogt, Hall, & Marteau, 2005) and those with negative attitudes are less likely to intervene (e.g., Jossieran, King, Velter, Dressen, & Grizeau, 2000; O'Loughlin et al. 2001). This is unfortunate in view of the fact that most smokers report that they want their physician to address smoking often and those that report receiving assistance in quitting also report higher satisfaction with their care (e.g., Quinn et al., 2005; Stevens et al., 2005).

Given that many health care providers appear to hold negative attitudes towards intervening with smokers, medical and residency training programs should include components designed to change attitudes towards smoking cessation interventions as well as training on how to intervene effectively. In addition, it would seem that there is a role for professional societies and health care plans to provide education to practicing providers about the tobacco cessation guidelines and encourage their adoption and adherence.

Increasing physician skill at intervening in promoting smoking cessation is necessary, but increasing physician utilization of this skill is also necessary. One way to achieve this may be through reimbursing them to intervene. For instance, Millet and colleagues (2007) reported that introduction of a physician pay-for-performance incentive for smoking cessation among English diabetic patients was associated with a significant increase from 2003 to 2005 in the number of patients for whom smoking cessation advice had been documented as well as a corresponding decrease in smoking prevalence from 20.0% to 16.2% (Millet, Gray, Saxena, Netuveli, & Majeed, 2007). If more insurance companies routinely paid physicians for treating nicotine dependence as Blue Cross and Blue Shield of Minnesota does (Manley, 2001) such actions may increase the number of quit attempts made and through this increased number of quit attempts increase the impact of OTC NRT on smoking cessation.

Community public health interventions that increase quit attempts—

Community public health interventions such as anti-smoking media campaigns, quitlines, tobacco taxation, and smoke-free workplaces can all increase quit attempts. Through this increase in quit attempts, these interventions may enhance the impact of OTC NRT.

Anti-smoking media campaigns have been used to increase cessation efforts as well as decrease smoking initiation (Flay, 1987; Hyland, Wakefield, Higbee, Szczypka, & Cummings, 2006; Mudde & De Vries, 1999; Pierce, Macaskill, & Hill, 1990).

Advertisements that tend to arouse high levels of emotion are judged by U.S. audiences as being the most helpful (Biener, Ji, Gilpin, & Albers, 2004; Biener & Taylor, 2002). Such campaigns also appear to promote public support for other tobacco control interventions such as tax increases and clean air laws (CDC, 1999b).

In their review of empirical studies of various state-level and community-level media campaigns in the U.S., Friend and Levy (2002) concluded that well-funded campaigns, in concert with well coordinated tobacco control programs were associated with decreases in smoking prevalence of 6-12%. They note that differences among programs in smoking rates can be partially explained by factors such as the intensity of the campaigns, their duration, the cost of conducting such campaigns, and the concurrent implementation of other tobacco control policies. Further, the campaigns appear to vary in their reach over time, with the greatest impact in the initial period following introduction of the campaign and a tapering off as programs continue.

Telephone quitlines are also an effective means to increase population access to smoking cessation support which may consist of mailed materials, recorded messages, counseling, access to pharmacotherapy, or combinations of these elements (Stead, Perera, & Lancaster, 2006). There is substantial documentation that quitlines, by increasing reach to counseling sessions, also increase quit attempts and cessation rates (Stead, Perera, & Lancaster, 2006). Moreover, multiple call-back (i.e., counselor-initiated) calls are more effective than a single call or written materials alone (Stead, Perera, & Lancaster, 2007). As of 2007, all 50 states in the U.S. offered quitlines (Cummins, Bailey, Campbell, Koon-Kirby & Zhu, 2007).

There is considerable evidence that increasing the price of tobacco through state and federal excise taxes produces a decline in tobacco purchase and use (Hopkins et al, 2001). For example, when Massachusetts and Oregon increased the tax on tobacco as parts of a comprehensive tobacco control initiatives, substantial declines in tobacco use, purchases, or both followed (CDC, 1996, 1999c).

Smoke-free workplaces can reduce cigarette consumption. Moreover, there appears to be an association between the implementation of work place bans and the proportion of employees who become quitters (Brigham, Gross, Stitzer, & Felch, 1994; Longo, Johnson, Kruse, Brownson, & Hewett, 2001). Further, most employees show high acceptance of smoke-free policies (Lin, Stahl, Ikle, & Grannis, 2006).

Summary—Public health interventions that reduce the acceptability of smoking likely increase quit attempts. Health care provider advice to quit also likely increases quit attempts. Increased quit attempts will likely increase the impact of OTC NRT and help reduce overall smoking rates.

Increasing the Proportion of Quit Attempts in which NRT is Used

Increasing the proportion of individuals making a quit attempt who choose to use OTC NRT will increase its impact. Various barriers appear to hinder the more widespread use of OTC NRT during a quit attempt (see also Cummings & Hyland, 2005 for a review). These include

the attitudes and beliefs of consumers, the attitudes and beliefs of health care providers, and the cost of OTC NRT.

Consumer attitudes and beliefs about NRT—Although most smokers in the U.S. and other countries are aware of NRT (e.g., Bansal, Cummings, Hyland, & Giovino, 2004; Etter & Perneger, 2001), a significant number hold inaccurate beliefs that may contribute to their underutilization of such products. For instance, most smokers do not believe NRT is effective (e.g., Bansal et al., 2004; Cummings et al., 2004; McMenamin, Halpin, & Bellows, 2006). Some smokers mistakenly attribute withdrawal symptoms associated with cessation to adverse effects of NRT (Barefoot & Girodo, 1972; Tate, Stanton, Green, Schmitz, Lee, & Marshall, 1994). A number of smokers seem to incorrectly believe that the nicotine in NRT is hazardous to one's health (e.g., Cummings et al., 2006; Cummings et al. 2004) including that it may even cause cancer or a heart attack (Bansal et al., 2004; Etter & Perneger, 2001).

Such perceptions by consumers are clearly not based on a factual understanding of these matters. Neither nicotine gum nor patch use is associated with significant risk for abuse or dependence (e.g., Henningfield, 1995; West et al., 2000). Several studies have documented that persistent use beyond the recommended dosing period is rather uncommon (e.g., Shiffman, Hughes, Di Marino, & Sweeney, 2003; Shiffman, Hughes, Pillitteri, & Burton, 2003). For example, the prevalence of NRT use at one year in smokers receiving smoking cessation treatment outside clinical trials has been reported as 2% for the nicotine patch and 9% for nicotine gum (Hajek, McRobbie., Gillison, 2007). Another study reported that as few as .05% of individuals who used the patch used the patch for two years or more, while 1% use the gum two years or more (Shiffman, Hughes, Pillitteri, et al., 2003). Moreover, although not currently an FDA-approved use of NRT, some have even proposed that NRT be continued with certain smokers (e.g., highly dependent smokers) beyond the typically recommended treatment period of 3 months in order to prevent relapse or to prevent progression to relapse after an initial lapse (Henningfield, Fant, Buchhalter, & Stitzer, 2005; McNeill, Foulds, & Bates, 2001; Shiffman, Gitchell, et al. 2002).

There is also little evidence that the concurrent use of cigarettes and NRT products are harmful. While the reported prevalence of smoking during NRT use varies widely across studies from 1.3% to 35% (Al-Delaimy, Gilpin, & Pierce, 2005; Hughes, Pillitteri, Callas, Callahan, & Kenny, 2004; Levy, Thorndike, Biener, & Rigotti, 2007; Shiffman, Hughes, Di Marino et al., 2003; Thorndike et al., 2002), the actual quantities of cigarettes and NRT products consumed per day tend to be quite low (e.g., Hughes et al., 2004; Stein, Anderson, & Niaura, 2006), and concurrent use is generally not considered to be particularly dangerous (Joseph et al., 1996; Murray et al., 1996). Moreover, some have advocated NRT use to promote reduced smoking and therefore reduced exposure to tobacco toxins in smokers unable or unwilling to quit (Henningfield et al., 2005; McNeill et al., 2001); however, the use of NRT for this purpose is currently not FDA-approved. Thus, in OTC settings, smokers who are trying to quit may prematurely discontinue NRT use or not even initiate use due to real or perceived side effects associated with the medication.

Some of these misperceptions are likely a result of successful anti-smoking campaigns that accurately portray smoking as dangerous and addicting with nicotine being the agent responsible for this addiction. Moreover, while there is evidence that advertising can positively affect the sale of NRT products (Tauras, Chaloupka, & Emery, 2005), some have expressed concern that current advertising, by promoting NRT products as a solution to the craving for cigarettes when trying to quit, might unintentionally convey the message that smoking is not all that addictive and that it is relatively easy to quit (Bolton, Cohen, & Bloom, 2004). However, available published data on youth do not support such an assertion (e.g., Durkin, Wakefield, & Spittal, 2006; Wakefield & Durrant, 2006). There is also

concern that tobacco companies can dilute or undermine the messages of public-health antismoking media campaigns by virtue of the intensity of their own advertising campaigns which promote the use of tobacco products (Wakefield et al. 2005). One solution would be to have the public health agencies that sponsor antitobacco campaigns join forces with pharmaceutical companies that advertise NRT to create anti-smoking advertisements that while making clear that smoking is dangerous and addicting, also make clear that NRT can be an important aid in quitting smoking.

Many misperceptions and negative attitudes seem to be diminished in those who have previously used NRT (e.g., Bansal et al., 2004; Etter & Perneger, 2001). Further, the longer the duration of use the more favorable the attitude. Positive attitudes towards NRT have also been shown to be related to intention to use NRT during the next quit attempt (Etter & Perneger, 2001). These findings suggest that getting people to try NRT may have lasting benefits regarding their likelihood of using NRT in a future quit attempt.

Another attitude that hinders widespread NRT use is smokers' belief that they should be able to or can quit without the use of aids such as NRT. Most smokers are reluctant to seek formal treatment and around 65 - 80% make a quit attempt without assistance (Fiore et al., 1990; West & Zhou, 2007; Zhu, Melcer, Sun, Rosbrook, & Pierce, 2000). Unfortunately, one-year abstinence rates without assistance are around 2.5% – 5% (Cohen et al. 1989; Hughes, Keely, & Naud, 2004). While generally useful in changing behavior, beliefs about one's personal effectiveness can have a negative impact on NRT use. For instance, Millard, Waranch, and McEntee (1992) observed a negative relationship between beliefs of personal effectiveness and compliance with the recommendation to use gum. Hajek et al. (1999) reported that 43% of participants assigned to the nicotine gum condition in their study, responded that they "do not need it" as a reason for under dosing during the first week of the study.

Health care provider attitudes towards NRT—Although there are fewer studies of health care provider attitudes towards NRT, evidence suggests that providers' attitudes towards NRT, or their attitudes towards certain patient populations may contribute to the underutilization of NRT. For instance, British primary care physicians appeared equally divided as to whether NRT should be made reimbursable. Whereas half believed that making NRT reimbursable would provide an opportunity to introduce a discussion on smoking cessation with their patients, the other half believed it would burden them by adding to their workload (McEwen, West, & Owen, 2001). Further, Mahrer-Imhof, Froelicher, Li, Parker, and Benowitz (2002) noted that it was nurses' attitudes as well as patients' attitudes that may have contributed to lower NRT use than desired in a sample of hospitalized women with cardiovascular disease. The authors speculated that the nurses had doubts about or lack of knowledge about the appropriateness of NRT with their ill but highly addicted sample. Although this study did not specifically concern OTC NRT use, it seems likely that providers' reluctance to discuss NRT use for smoking cessation may contribute to its underutilization whether by prescription or through OTC means. It would seem then that a critical component of efforts to educate health care providers is to promote positive attitudes towards and accurate knowledge about NRT safety, efficacy and use.

Consumer and health care provider's beliefs about the safety and efficacy of NRT may present significant barriers to the greater widespread use of OTC NRT. Presently, too little is known about the beliefs and attitudes of health care providers, and if these parallel those of consumers, then corrective action is an important step towards increasing the widespread utilization of NRT. Consumer attitudes likely reflect two things: a misplaced desire to quit smoking without such aids; and the generalization from successful public health campaigns about the dangers of smoking to those that might be associated with the use of OTC NRT.

Future public health media campaigns should combine resources with pharmaceutical companies and not only emphasize the dangers of smoking, but the utility of NRT and other effective treatments in aiding those trying to quit smoking. Further, if future investigations into consumer attitudes reveals that the hesitancy to use NRT or other available effective smoking cessation aids stems from a belief that one should be able to quit smoking “on one’s own,” then these campaigns also should strive to send the message that, as is the case for other life-threatening illnesses, the use of appropriate effective treatments for smoking cessation is a sign of common sense not weakness.

Cost of OTC NRT—It may be that the cost of each OTC NRT unit purchase as well as the overall cost of OTC NRT is a limiting factor in utilization. In 2007, the average cost of a pack of cigarettes in the U.S. was \$4.63 (Campaign for Tobacco-Free Kids, 2007). Unlike cigarettes that can be purchased in units designed for use in a single day, OTC NRT must be purchased in substantially larger units. While the \$3-\$4/day costs of OTC NRT compares favorably to the daily outlay for smoking, OTC NRT is available only in one to two week packages requiring an outlay of \$19-\$50 or more (e.g., CVS Online Pharmacy Store, 2008). Thus, the smoker trying to quit will need to pay more on any single occasion to get OTC NRT to help him or her to quit than he or she would need to pay to get a pack of cigarettes. As suggested by Cummings and Hyland (2005), it may be that by making OTC NRT available in single day packets and thus reducing the initial financial outlay required more people will try NRT during a quit attempt.

A number of studies have demonstrated that reduced out-of-pocket cost is associated with increase use of NRT products (Cummings et al. 2006; Curry, Grothaus, McAfee, Pabiniak, 1998; Grigg & Glasgow, 2003; Schauffler et al., 2001) and may lead to increased rates of cessation (Hopkins et al., 2001; Kaper, Wagena, Willemsen, van Schayck, 2005; Schauffler et al., 2001). For example, a randomized control study of California smokers with employer-sponsored coverage found use of NRT products, quit attempts, and quit rates were all significantly higher in the group that received fully covered benefits for OTC NRT products, self-help materials and counseling than the control group that only received a self-help video and pamphlet (Schauffler et al., 2001). The results were particularly interesting in that they showed that health insurers can increase quit rates without requiring that physicians write prescriptions for smoking cessation aids or make referrals.

To be effective, cost decreases for NRT likely to need to be substantial. Miller and colleagues (2002) found that when NRT was made available at half the usual price (i.e., a reduction from \$US 170 to \$US 85) to 232 eligible Australian smokers as part of a state-initiated workplace smoking cessation program, only 39% of participants redeemed at least one of the 10 vouchers they were given to subsidize the cost of the 10-week course of treatment. On the other hand, a large scale distribution program, implemented in New York State by regional tobacco control programs provides evidence that large numbers of smokers can be induced to make a quit attempt through the provision of free NRT and that the greater the supply of free NRT received, the higher the self-reported quit rate (Cummings et al., 2006).

One of the most logical ways to increase the access of NRT to a larger proportion of the population is to increase the number of public and private health plans that provide fully covered benefits for NRT. Only 9.6% of 160 health maintenance organizations (HMOs) surveyed in 2003 provided full coverage for any OTC NRT (McPhillips-Tangum, Rehm, Carreon, Erceg, & Bocchino, 2006). Whereas 38 state Medicaid programs offered some tobacco-dependence treatment for all their recipients in 2005, *only one* state offered coverage for all medication and counseling treatments recommended by the guidelines and *only another six* covered all recommended medications and at least one form of counseling

(CDC, 2006). Because the smoking prevalence among Medicaid patients is 39% higher than that of the general U.S. population (Lethbridge-Cejku, Rose, & Vickerie, 2006), more comprehensive coverage of tobacco dependence treatments is likely to impact a significant proportion of the smoking population.

Even when an insurance plan provides coverage for OTC NRT or other smoking cessation services, physicians and patients are often unaware of this coverage. Solberg et al. (2004) surveyed 100 physicians associated with 9 non-profit health plans, all of which have relatively high performance rates for tobacco cessation support. Although the majority of physicians knew about their health plan's tobacco cessation guidelines, far fewer knew whether the plan covered medications and cessation classes or counseling as well as other tobacco control support such as training in smoking cessation, and reimbursement for treating tobacco use. These results suggest that there is a need to make physicians more aware of what effective tobacco treatments are covered by the insurance plans they accept as well as other aspects of the plan such as the provision of financial incentives for good rates of quit advice. It is likely that this would lead to increased quit attempts among their patients and increased use of NRT in quit attempts.

Reach of OTC NRT may also be limited if health insurance plan enrollees do not know what benefits are covered. For example, at least two studies have documented that Medicaid recipients have poor knowledge about covered benefits for tobacco dependence treatments (McMenamin, Halpin, Ibrahim, & Orleans, 2004; Murphy, Shelley, Repetto, Cummings, & Mahoney, 2003). This is important: in a recent random-digit-dial telephone survey of Medicaid-enrolled smokers, knowledge of Medicaid coverage of effective tobacco treatments was positively associated with use of such interventions (McMenamin, Halpin, & Bellows, 2006).

One way of increasing awareness of coverage of OTC NRT, increasing that coverage, and eliminating any cost barrier to OTC NRT use would be to make universal complete coverage of OTC NRT part of all health plans at either a state or national level. This universal coverage could be advertised in anti-smoking media campaigns and be part of the information provided on state quitlines to callers. A second approach which is already being implemented in almost half of U.S. states (Cummins et al. 2007) is to provide free or subsidized NRT products to quitline callers. However, while quitlines may have increased the reach of effective cessation strategies, their utilization is shockingly low even when free NRT is made available. In the 2004-2005 fiscal year, utilization rate ranged from 01% -4.28% (Cummins et al. 2007), highlighting the fact that cost is but one of multiple barriers to increased use.

Another similar approach to increasing awareness of NRT availability and eliminating cost barriers is to include coupons for free OTC-NRT with all tobacco purchases. These coupons could be funded by an excise tax on tobacco purchases that would have the added benefit of likely increasing quit attempts. These coupons would not only eliminate cost barriers to OTC NRT treatment, but would also serve as constant reminders to smokers about quitting and using NRT in a quit attempt.

Summary—Two important strategies for increasing the proportion of individuals who use OTC NRT during any quit attempt are 1) eliminate consumer and physician misperceptions about the safety, efficacy and utility of NRT treatment, and 2) eliminate cost barriers to OTC NRT use. While more research is needed into consumer and physician attitudes about NRT and how these attitudes affect NRT use, still some suggestions might be made about how to increase NRT adoption. In particular, a strategy that involved media campaigns that emphasize both the dangers of smoking and the utility of OTC NRT and other effective

treatments for smoking combined with either universal complete coverage of OTC NRT through insurers, free NRT available through all state quitlines, or the distribution of coupons for free OTC NRT with all tobacco purchases would seem likely to promote more widespread adoption of NRT use.

Increasing the efficacy of OTC NRT

The efficacy of OTC NRT is clearly a determinant of the overall impact of OTC NRT. The efficacy of OTC NRT can reasonably be asserted to be a function of the overall baseline success rate of quit attempts and the initiation of abstinence, and of the extent to which OTC use of NRT matches the optimal use of NRT. Many studies show that NRT results in around twice as many successful quit attempts as placebo treatment (see earlier section). This is despite a reasonably wide range of placebo treatment success rates. Thus, the assertion that increasing baseline success rates should increase NRT quit rates is reasonable, if unproven. Those who initiate abstinence early in NRT treatment can have about a ten-fold increase in their odds of quitting smoking in the longer term (e.g., Westman, Behm, Simel, & Rose, 1997). Therefore, facilitating early abstinence during NRT treatment and increasing the overall rate of quitting success in a population might be expected to increase the proportion of those who use NRT that successfully quit smoking. Further, many studies have demonstrated that compliant use of NRT is associated with better treatment outcomes (e.g., Jolicoeur et al., 2000; Orleans et al., 1994; Shiffman et al., 2002). Thus, even if the causal direction of this relationship is not clear (e.g., perhaps those more likely to be compliant are those more likely to quit successfully), facilitating high levels of compliance might be reasonably expected to increase the efficacy of OTC NRT and hence OTC NRT's impact.

Increasing baseline success rates and early abstinence initiation—Baseline success rates and rates of early abstinence initiation can likely be increased by four general strategies: 1) Media campaigns, quitlines, and other types of public health initiatives; 2) Use of cessation counseling services; 3) Encouraging those who have decided to quit to publicly declare this, to publicly set a quit date, and establish a smoke-free household; and 4) the use of rebate or deposit systems to provide incentives for initiating abstinence.

In the earlier section on increasing quit attempts, a number of public health strategies for increasing these were discussed. These strategies for increasing quit attempts will also likely be effective at increasing the effectiveness of each quit attempt. An extension of these efforts would be actions aimed at increasing the likelihood that those quitting smoking make use of cessation counseling services. Similar to the earlier discussion with regards to reducing the cost of NRT, more widespread coverage of cessation counseling costs by insurers is desirable as is more effective dissemination of information about those cessation services that are covered. Moreover, even though quitlines have increased smoker accessibility to effective evidence-based strategies such as counseling and NRT, they still only reach around 1% of smokers in the U.S. Since quitline utilization is positively correlated with level of funding (Cummins et al. 2007) it has been suggested that the public (federal and state governments) and the private sector (private insurance plans and employers) could co-share in funding quitlines (Anderson & Zhu, 2007).

Still, as also discussed earlier, the attitude that one should be able to quit without help may hinder consumer acceptance of cessation counseling services. Further investigation of this issue is warranted. Even without such investigation, designing quit smoking campaigns that make clear that “seeking help for a life-threatening condition is common sense not personal weakness” makes sense. Moreover, providing effective internet-based smoking cessation programs may be an efficient way to reach millions of smokers who prefer to quit on their own (Strecher, 2008). In their recently conducted randomized controlled trial, Brendryen

and Kraft (2008) demonstrated the long-term effectiveness of an internet-based smoking cessation program compared to printed self-help materials (which have been shown to be minimally effective [Lancaster & Stead, 2005]). However, future research is needed to elucidate the active components of such interventions and how to package them for real-world dissemination (Strecher, 2008).

Physicians, other healthcare providers and public health campaigns should also encourage those seeking to quit smoking to make a public declaration of their quit attempt, publicly state their quit date, and make their homes smoke-free even before that quit date. Several studies suggest that people who take behavioral action such as implementing a smoke-free home may be more successful in their cessation attempts (e.g., Gilpin, Messer, & Pierce, 2006; Pizacani et al., 2004).

These measures should increase the social pressures for initiating abstinence and hopefully increase social support during the first few weeks of abstinence. These measures are also ones that many smokers are likely to implement and are likely to aid them in quitting once they have implemented these measures. However, this assertion needs further empirical investigation.

Finally, contingency management systems in which incentives are provided for smoking abstinence have been remarkably effective in promoting the initiation of smoking cessation (e.g., Dallery & Glenn, 2005; Donatelle et al., 2004; Lamb, Morral, Kirby, Iguchi, & Galbicka, 2004; Shoptaw et al., 2002). Use of a deposit return or a rebate of treatment costs upon demonstration of abstinence may prove a means of increasing the effectiveness of NRT. Use of such programs targeting the first day or first few days of a quit attempt in conjunction with NRT could potentially prove synergistic given the strong association of the early initiation of abstinence and long-term success during NRT (e.g., Westman et al., 1997). While such programs are potentially cost-effective, evaluation of how to most effectively implement these programs in conjunction with NRT is needed.

Increasing compliant use of NRT—There is room for improvement in compliance with the guidelines for optimal use of NRT when NRT is used OTC. Presumably changing use patterns so that these are in greater compliance with guidelines for optimal use will increase NRT's effectiveness. However, further investigation into this issue is needed.

Hyland et al. (2005) noted that the median duration of patch use in a cohort of 1,639 smokers decreased from 30 days to 21 days following the 1996 OTC switch.

In one of the few controlled studies addressing compliance in real world settings, OTC NRT was compared to real-world prescription practices. Shiffman et al. (2002) reported that 92.9% of OTC participants, who opted to use the nicotine patch, reported using it during the first two weeks of the study and they used it on almost 78% of days. By six weeks, however, less than half were using the patch as recommended. At the six-week follow-up visit, 98.3% of OTC participants who opted to use nicotine gum reported having done so during the study. However, only a fifth used the recommended daily amount. Similar to the OTC condition, compliance rates for the prescription condition were rather low as well.

Contingency management procedures can also be used to enhance compliance. Mooney, Babb, Jensen, & Hatsukami (2005) demonstrated that paying study participants for chewing nicotine gum according to a prescribed dosage schedule added to a single session of personalized feedback that targeted knowledge and attitudes about nicotine and NRT led to significantly greater gum use compliance than either a single session of standard treatment or of personalized feedback. Although the study did not detect group differences in cessation

rates, the researchers speculated that this was hindered by inadequate statistical power to detect such differences. Future studies could expand on this area of research by examining the value of contingency management alone in increasing NRT use and abstinence rates. If contingency management proves to be useful in increasing medication compliance and abstinence rates in a controlled clinical setting, a larger applied study could be conducted in which smoking cessation outcomes are compared for insurance companies that offer financial rewards in the form of reduced premiums or deductibles for appropriate NRT use to insurance companies that do not offer these incentives.

In summary, compliance with the amount and the duration of use of NRT is often low. As noted earlier, individuals who use NRT as recommended are more likely to be able to quit. Thus, increasing NRT use compliance may enhance its effectiveness.

The above findings suggest that there is a need for more effective consumer education concerning the importance of compliance with directions. Education of consumers can be targeted through several modalities including health care providers as described in other sections of the paper and through pharmaceutical company-sponsored education about their various products. Education programs targeted towards health care providers need to educate providers about the importance of disseminating correct dosing instructions but also how to work with patients on how to maximize medication compliance.

Another resource for improving optimal use of NRT is to use supplemental written materials. There is evidence that smokers using OTC NRT rely on package inserts for their information about how to use the medication (e.g., Bansal et al., 2004; Jolicoeur et al., 2000); however, many smokers may derive limited benefit from these instructions which are written at a level requiring college-equivalent reading skills whereas approximately a third of current smokers in the U.S., have not completed high school or an equivalency diploma (Stevens, McDaniel, Glover, & Wallace, 2007). Stevens and colleagues (2007) recommend that all package inserts be written at the sixth grade reading level and that drawings and graphics be used to supplement step-by-step instructions. Given that current package inserts instruct smokers to refrain from smoking while using NRT, it is possible that some smokers terminate NRT use prematurely because they have begun to lapse back to smoking or failed to quit completely. Moreover, smokers who have discontinued NRT use prematurely may be unwilling to try again. Therefore, efforts by the Food and Drug Administration in combination with pharmaceutical companies at improving the package labeling of NRT products may lead to the enhanced impact of NRT.

Summary—Increasing the efficacy of OTC NRT will increase its impact. Public health measures aimed at increasing the overall likelihood of smoker's success on any one quit attempt will indirectly increase the efficacy of OTC NRT. Getting smokers to publicly declare their intentions to quit and quit date, and getting smokers to make their households smoke-free will enhance the social pressure to quit and hopefully increase initial success at quitting. Similarly, deposit return or rebates based on the verified initiation of abstinence will likely facilitate the early initiation of abstinence, which has been associated with greatly increased odds of long term success with NRT. Further, investigation is, however, needed on how to effectively implement each of these proposed interventions.

Importance of Combining Strategies

As noted in the earlier section on our multiplicative model, the greatest impact on smoking cessation is likely to be seen from increasing quit attempts, NRT use and NRT effectiveness. We feel that efforts that use interventions targeting multiple components of the model are likely to have the greatest impact. Examples of this already exist (Miller et al. 2005). For example, a large scale free NRT distribution program was attempted in New York City in a

context of increases in city and state cigarette taxes, implementation of smoke-free workplace regulations, and public anti-smoking campaigns focusing on the dangers of second-hand smoke, and the increased emphasis of citywide education of physicians in tobacco cessation strategies. The first 35,000 eligible smokers from New York City who called the New York State Smokers' Quitline received a six-week supply of nicotine patches. The self-reported quit rate at six months for Quitline callers who received NRT was significantly higher than for those who did not receive free NRT (Miller et al., 2005). Hollis and colleagues (2007) reported a similar combination of interventions, e.g., use of a state-operated tobacco quitline, multisession telephone support and free NRT, as well as mass media campaigns, and encouragement of physicians and health plans to encourage smokers to call the quitline yielded higher cessation rates than interventions with less intense levels of telephone or NRT support.

A final example is one that would have tobacco manufacturers revise their tobacco packaging. Just as cigarette packages in the U.S. now carry labels warning of the health risks of smoking, cigarette packages could also contain package inserts that offer advice on how to quit and coupons that could be redeemed for free NRT. While empirical validation is warranted, these examples underscore our premise that multi-component interventions that combine community, workplace, or state-wide strategies to increase cessation attempts with specific interventions such as increasing awareness of and efficacy of NRT while removing barriers to use may be useful in bringing about clinically significant reductions in the prevalence of tobacco use.

Intervention Costs

All interventions have some associated costs, and the benefits of these interventions are widely distributed in a manner that does not always allow those paying for the costs to reap the benefits of the intervention. Further, questions arise as to the benefits of multi-component interventions relative to their increased costs, how benefits and costs are defined, and who should bear the cost. The benefits of smoking cessation interventions include medical-costs-saved, life-years-saved, increased worker productivity and reduced life insurance costs. Moreover, these benefits can accrue to smokers, environmentally-exposed nonsmokers, insurers, and employers. Research exists on the cost-effectiveness of some of the intervention components. For instance, there is evidence that provider cessation counseling is cost effective (e.g., Cummings, Rubin & Oster, 1989), that pharmacotherapy is cost-effective (e.g., Fiscella & Franks, 1996), and that health care interventions such as counseling in combination with NRT are cost-effective both in terms of medical costs and years of life saved (e.g., Curry et al., 1998; Wasley, McNagny, Phillips, & Ahluwalia, 1997). However, in general, the costs and benefits of the combined interventions are unknown and it should not be assumed *a priori* that more intensive or multi-faceted interventions are ultimately the most effective or cost-effective despite some support for this assumption (e.g., Croghan et al, 1997; Cromwell, Bartosch, Fiore, Hasselblad, & Baker, 1997; Friend & Levy, 2001; Levy & Friend, 2002). This issue should be part of the evaluation of the effectiveness of any of these interventions.

It would seem reasonable that both private and public health insurance plans, smokers, governments, pharmaceutical companies, and tobacco companies all play a role in covering the costs associated with increasing the impact of NRT given the apparent benefits to all of these (with the exception of tobacco companies). Certainly, for any intervention that is cost-effective at reducing medical costs within a couple of years, states might consider requiring insurers to provide coverage for this intervention. States might also consider working with providers of smoking cessation pharmacotherapies in the development of joint anti-smoking/smoking-cessation pharmacotherapy advertising campaigns. Finally, a portion of state

tobacco taxes should be consistently set aside for both smoking prevention and smoking cessation efforts which should include efforts that promote the use of effective smoking cessation aids such as OTC NRT.

Summary and Concluding Remarks

Tobacco smoking is the leading cause of preventable morbidity and mortality in the U.S. (CDC, 2005) Reducing the population prevalence of smoking through an increase in smoking cessation is the most immediate way to bring about a reduction in morbidity and mortality. Unfortunately, despite the development of a number of effective smoking cessation interventions, the prevalence of smoking has remained fairly stable over the past 15 years.

The present paper focused on a specific segment of the smoking cessation puzzle, namely, understanding why the introduction of an effective pharmacotherapy tool such as NRT did not bring about the large declines in smoking after it became available OTC and what can be done about it. We contended that the impact of NRT is a multiplicative function that depends on the number of individuals making a quit attempt, the proportion using NRT in a quit attempt and the effectiveness of the quit attempt. We examined how each of these determinants was affected by introduction of OTC NRT and argued its impact on smoking cessation may have been understandably small. Nevertheless, even small increases in the impact of a cessation intervention can bring about significant benefits in morbidity and mortality. We concluded that efforts to substantially increase the public health impact of NRT need to focus on bringing about increases in each variable in the multiplicative function. However, we also emphasized that the biggest impact of OTC NRT is likely to ensue from developing and implementing interventions that target some combination of all three. Examples of interventions designed to bring about increases in cessation attempts, the proportion of individuals using NRT in a cessation attempt, the efficacy of cessation attempts, and combinations of all three are also provided.

It should be noted that while we have offered a selection of research-based and more speculative strategies for increasing the impact of OTC NRT on smoking cessation rates, we believe that this multi-pronged conceptual approach is useful with other existing (e.g., varenicline) or yet-to-be developed evidence-based pharmacotherapy interventions. Of course, the untested intervention approaches will need research backing before being implemented on a large scale. In addition, we acknowledge that while these interventions may be costly, both public and private sectors of society need to share the cost. In conclusion, we assert that the U.S. needs national policy that is backed by the kind of strength and political will that the tobacco industry has used to promote their products.

Acknowledgments

This work was supported by a grant from the National Institute of Health (RO1 DA13304).

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