Effect on Smoking Cessation of Switching Nicotine Replacement Therapy to Over-the-Counter Status

Anne N. Thorndike, MD, MPH, Lois Biener, PhD, and Nancy A. Rigotti, MD

Objectives. This study examined whether the change in nicotine replacement therapy sales from prescription to over the counter (OTC) status affected smoking cessation.

Methods. We used the 1993–1999 Massachusetts Tobacco Surveys to compare data from adult current smokers and recent quitters before and after the OTC switch.

Results. No significant change over time occurred in the proportion of smokers who used nicotine replacement therapy at a quit attempt in the past year (20.1% pre-OTC vs 21.4% post-OTC), made a quit attempt in the past year (48.1% vs 45.2%), or quit smoking in the past year (8.1% vs 11.1%). Fewer non-Whites used nicotine replacement therapy after the switch (20.7% pre-OTC vs 3.2% post-OTC, $P = .002$), but the proportion of Whites using nicotine replacement therapy did not change significantly (20.6% vs 24.0%).

Conclusions. We observed no increase in Massachusetts smokers' rates of using nicotine replacement therapy, making a quit attempt, or stopping smoking after nicotine replacement therapy became available for OTC sale. There appear to be other barriers to the use of nicotine replacement therapy besides visiting a physician, especially among minority smokers. (*Am J Public Health.* 2002;92:437–442)

Although many drugs have changed from prescription to nonprescription status in the past decade, there has been little assessment of the effect of this change on outcomes in the population. Nicotine replacement therapy is a safe, effective, and standard treatment of tobacco use.[1–4] Nicotine replacement therapy products were sold only by prescription until 1996. By July 1996, nicotine gum and 2 of the 4 brands of nicotine patches were available without a prescription.[5,6] Most nicotine replacement therapy sales are now over the counter (OTC).

The rationale for changing nicotine replacement therapy from prescription to nonprescription status was to increase smokers' access to the products.[5,6] Visiting a physician to obtain a prescription for nicotine replacement therapy was deemed an unnecessary barrier to acquiring this safe and effective treatment for smoking cessation. Eliminating this barrier was expected to increase the proportion of smokers using nicotine replacement therapy at a quit attempt.[5,7] The effectiveness of a medication is the product of its efficacy and its reach or access.[5,6,8] Therefore, improving smokers' access to nicotine replacement therapy had the potential to increase smoking cessation rates in the US population. Additionally, the OTC availability of nicotine replacement therapy might encourage more smokers to try to quit, which also might produce higher population cessation rates. A decision analysis done before nicotine replacement therapy became available OTC estimated that the switch would result in an additional 450 000 smokers being abstinent at the end of 10 years.[7]

These hypotheses assume that the efficacy of nicotine replacement therapy is maintained when it is used in an OTC situation. However, switching nicotine replacement therapy to OTC status could decrease the success of quit attempts if fewer smokers used the medication with adjuvant behavior therapy, which is recommended by the Food and Drug Administration.[1] Although clinical trials have shown that nicotine replacement therapy is effective with minimal concomitant behavior therapy, the absolute cessation rates in clinical trials are much lower when only minimal behavior therapy is provided.[1,6] The population benefits of increasing smokers' access to the nicotine replacement therapy would be blunted if the product's efficacy declined when it was sold OTC.

The effect of switching nicotine replacement therapy to OTC status on the use of nicotine replacement therapy and on cessation rates at a population level is not known. Sales of nicotine replacement therapy have doubled since its switch to OTC status.[5] Analyses based largely on sales data have projected that the OTC availability of nicotine replacement therapy has increased cessation rates.[5,9] These analyses assume that increased sales of nicotine replacement therapy translate into more smokers using the product for quitting smoking. The validity of this assumption has not yet been confirmed.

We analyzed data from a population-based sample of Massachusetts smokers to assess whether switching nicotine replacement therapy sales from prescription to OTC status increased: (1) the proportion of quit attempts at which nicotine replacement therapy was used, (2) the proportion of smokers who made a quit attempt, (3) the rate of smoking cessation among nicotine replacement therapy users, and (4) the rate of smoking cessation among all smokers. We also examined demographic characteristics of nicotine replacement therapy users before and after the OTC switch to determine whether OTC availability was associated with changes in the use of the drug by certain subgroups of smokers.

METHODS

Sample

We analyzed data from the Massachusetts Tobacco Survey conducted from October 1993 through February 1994 to assess smokers' use of nicotine replacement therapy and quit attempts during the period when nicotine replacement therapy was available by prescription only. The Massachusetts Tobacco Survey was a random-digit-dialed telephone survey of a probability sample of Massachusetts housing units with telephones. Initial brief interviews were carried out with 11 463 adult informants who enumerated the mem-

bers of their households. One adult was systematically designated for extended interview. Smokers and minority group members were oversampled. The household response rate was 78%, and 78% of the designated adults completed extended interviews.

Nicotine replacement therapy use after the OTC switch was assessed with data from the Massachusetts Adult Tobacco Survey, an ongoing monthly random-digit-dialed survey that has sampled approximately 225 adults per month since March 1995 with questions similar to those in the Massachusetts Tobacco Survey. The data collection technique and sampling design for the Massachusetts Adult Tobacco Survey were identical to those for the Massachusetts Tobacco Survey, except that smokers and minority group members were not oversampled. The annual household response rates for the Massachusetts Adult Tobacco Survey varied between 68% and 76%, and the response rates for the designated adult respondent varied between 79% and 81%. Detailed information about the methodology of these surveys has been published elsewhere.[10–13]

Measures

The Massachusetts Tobacco Survey and Massachusetts Adult Tobacco Survey contain items that identify smokers, quit attempts, successful quitting, and use of nicotine replacement therapy during a quit attempt that occurred in the past year. A *quit attempt* is defined as a period of abstinence lasting at least 24 hours. A *successful quit attempt* is a quit attempt that was not followed by a return to smoking as of the day that the respondent was interviewed for the survey. A *current smoker* is defined as a person who reports having smoked 100 cigarettes in his or her lifetime and currently smokes "every day" or "some days." A *quitter* is defined as a person who reports having smoked 100 cigarettes in his or her lifetime and currently smokes "not at all." *Past-year quitters* are smokers who quit regular smoking within the past 12 months, and *past-year smokers* are all current smokers and past-year quitters.

Analyses of respondents who made at least 1 quit attempt in the past year included both those who were unsuccessful (i.e., those who were smokers at the time of the survey) and those who were successful (i.e., past-year quitters). Questions on the use of nicotine replacement therapy during the past year's quit attempt were included on the 1993 Massachusetts Tobacco Survey and added to the Massachusetts Adult Tobacco Survey in April 1996. For those who had made a quit attempt in the past year, the survey question about nicotine replacement therapy was: "The last time you tried to quit smoking [or for quitters, 'when you quit smoking'] . . . did you use a medication, like the nicotine patch, nicotine gum, or some other medication to help you quit?" *Nicotine replacement therapy users* were defined as those who reported using either the nicotine patch or nicotine gum during their last quit attempt. Demographic information collected in the surveys included age, sex, race/ethnicity, income level, and education level.

We limited the analysis to respondents either who were smokers at the time of the interview or who had quit within the past year (past-year quitters). This analysis compared data collected by the Massachusetts Tobacco Survey (n=1784 in the pre-OTC period) with data collected by the Massachusetts Adult Tobacco Survey from August 1997 through June 1999 (n=1240 in the post-OTC period). The post-OTC group was limited to smokers and past-year quitters interviewed after July 1997 to ensure that past-year quit attempts occurred during the time that nicotine replacement therapy was available as an OTC medication (i.e., after July 1996). We compared rates of quit attempts, smoking cessation, and nicotine replacement therapy use before and after nicotine replacement therapy became available OTC.

Data Analysis

The data were weighted to adjust for the probability of selection and to correct for differential nonresponse by stratum. This ensures that the samples for all years are comparable. All analyses were carried out with SUDAAN.[14] We used χ^2 tests for bivariate analyses to test for the difference between distributions. Multiple logistic regression was used to examine the effect of the switch of nicotine replacement therapy from prescription to OTC status on nicotine replacement therapy use (dependent variable) while controlling for demographic characteristics. To determine whether significant changes in the demographics of nicotine replacement therapy users occurred after the OTC switch, we added interaction terms between time (pre-OTC vs post-OTC) and each demographic characteristic to the model.

Further multiple logistic regression analyses examined the simultaneous effects of time and nicotine replacement therapy use on successful quitting (dependent variable) while controlling for demographics. For this analysis, an interaction term between nicotine replacement therapy use and time was added to the regression model to determine whether the change in successful quitting over time (pre- to post-OTC) was significantly different among those who used nicotine replacement therapy compared with those who did not use nicotine replacement therapy during a quit attempt.

To further explore smokers' reasons for using nicotine replacement therapy, we analyzed data from the 512 current smokers interviewed between July 1998 and June 1999. In July 1998, the following question was added to the monthly Massachusetts Adult Tobacco Survey and asked of all current smokers: "Have you ever used the nicotine patch or nicotine gum as a way to delay smoking or cut down on the amount that you smoke?" We estimated the proportion of smokers who reported using nicotine replacement therapy to "delay or cut down" on their smoking but not to quit.

RESULTS

Table 1 shows the demographic characteristics of all respondents who had smoked at some time in the past year (past-year smokers), which included both current smokers and past-year quitters. The only significant demographic difference between the pre-OTC group and the post-OTC group was household income. More respondents in the post-OTC group had an annual household income of greater than $30 000 compared with the pre-OTC group.

Table 2 shows quit attempts and successful quitting before and after nicotine replacement therapy became available for nonprescription sale. Almost half of the past-year smokers

TABLE 1—Characteristics of Past-Year Smokers Before and After Nicotine Replacement Therapy Became Available for Over-the-Counter (OTC) Sale

	Past-Year Smokers Pre-OTC (n = 1784), %	Past-Year Smokers Post-OTC (n = 1240), %	Total (n = 3024), %
Sex			
Male	48.5	46.7	47.7
Female	51.5	53.3	52.3
Age group, y			
18–30	28.3	27.1	27.7
31–45	45.4	40.7	43.1
≥46	26.3	32.2	29.2
Race/ethnicity			
White, non-Hispanic	91.0	89.1	90.1
Non-White	9.0	10.9	9.9
Household income,* $			
≤30 000	42.2	30.5	36.5
>30 000	57.8	69.5	63.5

Note. All percentages are weighted to adjust for sampling design; n's are unweighted.
*$P = .003$ for χ^2 statistic.

TABLE 2—Quit Attempts and Successful Quitting by Past-Year Smokers Before and After Nicotine Replacement Therapy Became Available for Over-the-Counter (OTC) Sale

	Past-Year Smokers Pre-OTC (n = 1784), %	Past-Year Smokers Post-OTC (n = 1240), %	P^a
Attempted to quit in past year	48.1	45.2	.46
Quit smoking during past year	8.1	11.1	.46

Note. All percentages are weighted to adjust for sampling design; n's are unweighted.
[a]P for χ^2 statistic.

made a quit attempt when nicotine replacement therapy was available by prescription only, and this proportion did not change significantly after the switch to OTC status. The proportion of past-year smokers who successfully quit smoking also did not change significantly between the pre-OTC and the post-OTC periods.

When nicotine replacement therapy was available by prescription only, 20.1% of the past-year smokers who had made a quit attempt used the medication. This proportion did not change significantly after the OTC switch (Table 3). Significant changes occurred in the types of smokers who used nicotine replacement therapy before and after it became available for OTC sale. After the OTC switch, persons aged 18 to 30 years were more likely to use the medication at a quit attempt, and smokers older than 45 years were less likely to use it. White smokers were equally likely to use nicotine replacement therapy at a quit attempt pre- and post-OTC, but non-Whites were significantly less likely to use nicotine replacement therapy at a quit attempt after the switch. Post-OTC, the trend was toward a decrease in nicotine replacement therapy use by the lower-income smokers ($30 000 or less) and an increase in use by higher-income smokers (>$30 000), although these differences were not statistically significant.

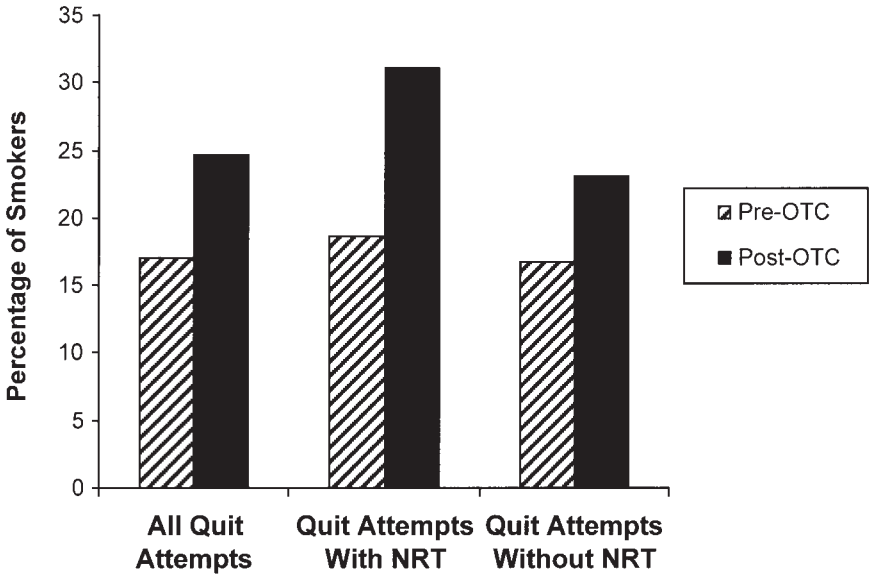
Figure 1 compares the rate of successful quitting among the past-year smokers who made a quit attempt. Overall, the rate of successful quitting increased from 17.1% pre-OTC to 24.7% post-OTC, but this increase was not statistically significant (P=.10). For those who used nicotine replacement therapy at a quit attempt, successful quitting increased from 18.7% to 31.1% (P=.28), and for those who did not use nicotine replacement therapy, successful quitting increased from 16.7% to 23.0% (P=.22). The increase in quit rates between the pre-OTC and the post-OTC periods was higher for nicotine replacement therapy users compared with nonusers (12.4% vs 6.3%), but this difference was not statistically significant (P=.69).

To further explore nicotine replacement therapy use, we analyzed a subgroup of current smokers who were interviewed during the post-OTC period (see the "Methods" section). In this sample, 28.1% of the current smokers had ever used nicotine replacement therapy. Of these, 48.7% used it to "delay smoking or cut down" on smoking but not to make a quit attempt.

DISCUSSION

This was the first study that used data from a population-based survey to analyze nicotine replacement therapy use and smoking cessation before and after the drugs became available for nonprescription sale. Changing the way in which nicotine replacement therapy was sold had the potential for enormous public health effect because nicotine replacement therapy is a first-line therapy for the treatment of tobacco use, the leading preventable cause of death in the United States.[1] Contrary to predictions based on sales data,[5] we found no evidence that switching nicotine gum and patches to OTC status led to statistically significant increases in (1) the use of nicotine replacement therapy at a quit attempt, (2) the likelihood that a smoker made a quit attempt, (3) the success of quit attempts, or (4) the population smoking cessation rates among a representative sample of Massachusetts smokers. Our data did show that the OTC switch was associated with a change in the demographic characteristics of nicotine replacement therapy users.

The rationale for switching nicotine replacement therapy to OTC status was to increase smokers' access to this smoking cessation treatment. We found no evidence for increased use of nicotine replacement therapy at a quit attempt or for an increase in overall quit attempts. These results conflict with



Note. All percentages are weighted to adjust for sampling design. NRT = nicotine replacement therapy; OTC = over the counter.

FIGURE 1—Successful quitting among past-year smokers who made a quit attempt in the past year.

TABLE 3—Demographic Characteristics of Past-Year Smokers Who Used Nicotine Replacement Therapy (NRT) in a Quit Attempt

	Past-Year Smokers Who Used NRT Pre-OTC (n = 846), %	Past-Year Smokers Who Used NRT Post-OTC (n = 1236), %	P^a	*P* for Change in Use of NRT Over Time[b]
Total (all past-year smokers who made a quit attempt)	20.1	21.4	.76	. . .
Sex				
Male	21.9	21.7	.99	
Female	18.2	21.2	.59	. . .
Age group, y				
18–30	4.8	19.9	.02	
31–45	23.8	27.4	.65	
≥46	27.5	14.9	.10	< .001
Race/ethnicity				
White, non-Hispanic	20.6	24.0	.49	
Non-White	20.7	3.2	.02	.002
Household income, $				
≤30 000	19.5	17.2	.74	
>30 000	18.5	26.1	.24	.43

Note. All percentages are weighted to adjust for sampling design; n's are unweighted and represent the number of past-year smokers who made a quit attempt. OTC = over the counter.
[a]*P* for χ^2 statistic.
[b]*P* for the interaction between time (pre- vs post-OTC) and the demographic factor, adjusting for all other factors in the table.

analyses of nicotine replacement therapy that used sales data.[5,9] On the basis of a large increase in sales of nicotine replacement therapy after 1996, Shiffman et al.[5] estimated that 3.8 million annual new quit efforts were attributable to nicotine replacement therapy being available OTC. Another study compared the pre-OTC and post-OTC rates of "reducing smoking" and quitting smoking in the month before the American Cancer Society's Great American Smokeout in 1995 (pre-OTC) and 1996 (post-OTC).[9] The rate of "reduced smoking" increased significantly between 1995 and 1996 (from 13% to 20%), but the rate of quitting remained unchanged (from 5% to 6%).

Clearly, a discrepancy exists between sales of nicotine replacement therapy and smokers' reports of nicotine replacement therapy use after the OTC switch. We can only speculate about the reasons for this discrepancy. One explanation is that many OTC purchases of nicotine replacement therapy were not used to quit smoking but to reduce smoking or to prevent nicotine withdrawal symptoms for a planned period of tobacco abstinence such as occurs on a long airplane flight. An analysis of a subgroup of smokers interviewed after the OTC switch showed that half of the smokers who had ever used nicotine replacement therapy used it to "delay or cut down" on their smoking but not to quit. We were unable to determine the percentage of nicotine replacement therapy purchased pre-OTC that was not intended for a quit attempt, but we expect that it was smaller. Nicotine replacement therapy purchases also could have been made by a well-intentioned friend or relative of a smoker who was not ready to quit, or the purchase could have been made by a smoker who did not follow through with a quit attempt. Further research is needed to explain this discrepancy.

Our data indicate that the switch of nicotine replacement therapy to OTC sale did not have the anticipated public health effect of significantly increasing cessation rates among Massachusetts smokers. Our results suggest that there are other barriers to using nicotine replacement therapy beyond the requirement of seeing a physician to obtain a prescription. The cost of nicotine replacement therapy is likely to be one barrier. Cost was a barrier to nicotine replacement therapy use when the medication was available by prescription only, but it has been a greater barrier since the OTC switch. Before the switch, third-party

payer reimbursement for nicotine replacement therapy was limited but did exist.[15] After the switch of nicotine replacement therapy to OTC status, fewer health insurance plans covered its cost.[16] The switch of nicotine replacement therapy sales to OTC increased the out-of-pocket costs to a larger proportion of smokers who used it, and this would be expected to reduce nicotine replacement therapy use by low-income smokers. In a 1993 survey of 20 communities nationwide, nicotine patch use was 57% higher among low-income smokers where the state public health insurance program covered it.[17]

When smokers did use nicotine replacement therapy at a quit attempt, they were just as likely to quit smoking after the OTC switch as they were before the switch. In a 1992 survey of nicotine patch users, only half of the respondents received any initial advice or materials about use of the nicotine patch.[18] Although we do not have data about physician advice, it is likely that even fewer smokers using OTC nicotine replacement therapy received advice about the medications. However, our data suggest that the efficacy of nicotine replacement therapy did not decrease after the OTC switch.

Our data indicate a significant shift in the likelihood of nicotine replacement therapy use among young adults who tried to quit smoking. Visiting a physician to obtain a prescription may have been a particular barrier for young adult smokers. Our data also show that fewer non-White smokers used nicotine replacement therapy at a quit attempt after the OTC switch, and these racial/ethnic differences remained even after income level was controlled for. These findings raise concern about access to OTC nicotine replacement therapy across the population.

The pre-OTC rate of nicotine replacement therapy use in Massachusetts (20.1%) was somewhat higher than data from other population-based surveys.[17,19] A 1993 survey reported that 22.4% of the smokers and recent quitters had used nicotine replacement therapy at a quit attempt in the previous 2 years (i.e., approximately 11.2% per year),[17] and the 1993 California Tobacco Survey reported that 12.7% of the past-year smokers had used a prescribed medication for smoking cessation.[19] However, this discrepancy does not explain why nicotine replacement therapy use in Massachusetts did not increase even further after the OTC switch.

Our results should be considered in the context of other environmental factors influencing the behavior of Massachusetts smokers between 1993 and 1999. The Massachusetts Department of Public Health initiated its Tobacco Control Program in 1994, after the 1993 Massachusetts Tobacco Survey used in our analysis. This program included smoking cessation services, a mass media counteradvertising campaign, and promotion of state and local policies to deter tobacco use.[20] We expected that the Massachusetts Tobacco Control Program would have stimulated increased use of nicotine replacement therapy, especially after the OTC switch. Although we did see an increase in the success of all quit attempts after 1993, we did not see any change in the proportion of smokers who used nicotine replacement therapy.

A second factor that should be considered is the influence of marketing new products at specific times, such as the introduction of the nicotine patch in 1992 and the introduction of the OTC nicotine gum and patch in 1996. Nicotine patch sales surged in 1992 and then declined to less than half of that rate from 1993 to 1996, when sales of nicotine replacement therapy doubled again until 1998.[21] Our pre-OTC data on nicotine replacement therapy use may be partially elevated by the 1992 surge in patch use, but most of the pre-OTC responses reflected use of nicotine replacement therapy in 1993, when patch sales had decreased.

Another environmental factor that occurred during the post-OTC period was the introduction of bupropion to the US market in 1997. This medication may have reduced nicotine replacement therapy use by some smokers in the post-OTC survey, but the effect is not likely to be large because the new drug was available by prescription only.

In conclusion, this was the first study to examine the effect of switching nicotine replacement therapy from prescription to OTC status on treatment outcomes. We found no evidence that the rate of smoking cessation or the rate of nicotine replacement therapy use at a quit attempt increased significantly in Massachusetts after the switch. Although the barrier of visiting a physician for a prescription was removed, access to nicotine replacement therapy does not appear to have improved. Cost is a major barrier to use of the medication, and policymakers, insurers, physicians, and the pharmaceutical industry should address this issue in the future to attempt to increase access to these treatments. Future research should explore other factors that deter or prevent smokers from using nicotine replacement therapy and determine whether a substantial amount of nicotine replacement therapy products are purchased for reasons other than quitting smoking. ■

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Contributors

A.N. Thorndike designed the study, collaborated in the analysis, and wrote the paper. L. Biener designed the Massachusetts tobacco surveys and collaborated in designing the analyses for the paper and in the writing of the paper. N.A. Rigotti participated in the design, supervised the analysis, and contributed to the writing of the paper.

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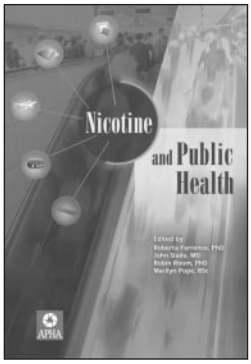

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