

Public health benefit of over-the-counter nicotine medications

Saul Shiffman, Joe Gitchell, John M Pinney, Steven L Burton, Katherine E Kemper, Eduardo A Lara

Abstract

Objective—To estimate the impact of allowing non-prescription sales of nicotine medications in the United States on increasing the numbers of smokers quitting.

Design—Sales and marketing data were used to compare the use of nicotine medications before and after non-prescription sales, and to estimate the impact of non-prescription sales on quit rates.

Setting—United States.

Main outcome measures—Number of quit attempts using nicotine replacement therapy (NRT) products, number of smokers who quit smoking with over-the-counter (OTC) NRT or with NRT still sold by prescription, and incremental quits attributable to OTC NRT.

Results—Since the US Food and Drug Administration approved nicotine medications for OTC sale in 1996, use of the medications has increased by 152% compared with prior prescription use. With increased use of an efficacious treatment, OTC nicotine medications are estimated to yield from 114 000–304 000 new former smokers annually in the United States.

Conclusions—The broader availability and promotion of effective treatments for tobacco dependence, specifically nicotine gum and patch, increase the number of smokers availing themselves of the medications. This increased use is estimated to contribute substantially to the number of former smokers in the United States.

(*Tobacco Control* 1997;6:306–310)

Keywords: nicotine replacement therapy, smoking cessation

Introduction

Even though the United States has made significant progress in reducing the prevalence of cigarette smoking, one out of every four adults continues to smoke.¹ Prevention of initiation of tobacco use among adolescents is an essential element of a comprehensive tobacco control effort although most of the public health benefit of such interventions will not be realised for decades. Promotion of cessation among current smokers offers the promise of more immediate health benefits.² Nicotine medications such as the nicotine gum and patch are proven effective therapies to assist smoking cessation.³ Nicotine replace-

ment therapy (NRT) typically doubles success rates (compared with placebo).³

In 1984, when nicotine gum was introduced in the United States, and in 1991–1992, when four nicotine patches were introduced, NRT was available by prescription only. Prescription status was deemed appropriate by the US Food and Drug Administration (FDA) because of concerns about the possibilities of abuse and negative consequences of improper use; it was thought that considerable provider assistance was necessary to achieve compliance (especially with nicotine gum, where instruction in chewing technique is helpful). It was also thought that NRT was effective only with considerable behavioural intervention, and labelling required that the medications be used only within a “comprehensive smoking cessation treatment programme”, which was thought to be best delivered under a physician’s care. However, clinical experience with millions of prescriptions revealed that NRT treatments were generally safe.^{4,5} It also became clear that physicians rarely could provide the kind of comprehensive counselling called for in the guidelines, and that, in any case, NRT medications were relatively effective even in the absence of intensive intervention.⁶ Indeed, smoking cessation guidelines issued by an expert panel of the US Agency for Health Care Policy and Research recommended that NRT be part of standard care for every smoker.³

However, the restriction of NRT medications to prescription-only status had become an access barrier to these effective treatments. One survey of smokers showed that 57% were unlikely to see a physician for a medication to help them quit smoking.⁷ To increase access to NRT, in 1996 the FDA approved the switch of three NRTs (Nicorette gum, NicoDerm CQ patch, and Nicotrol patch) from prescription-only (R) to over-the-counter (OTC) availability. In the United States, OTC signifies general sale; products are usually stocked on pharmacy and general merchandising shelves, though some are located near staffed counters because of their comparatively high cost. NRT products are restricted for sale to those aged 18 and older.

The fundamental rationale for approving OTC sale of NRT was to improve access to and use of NRT products, which had been used by only 20–30% of smokers before 1996.⁷ The underuse of effective treatments is unfortunately characteristic of treatment dynamics in smoking cessation: the most

University of
Pittsburgh, Smoking
Research Group,
Pittsburgh,
Pennsylvania, USA
S Shiffman

Pinney Associates,
Bethesda, Maryland
J Gitchell
J M Pinney

SmithKline Beecham
Consumer Healthcare,
Pittsburgh
S L Burton
K E Kemper
E A Lara

Correspondence to:
Joe Gitchell, Pinney
Associates, Inc., 4800
Montgomery Lane, Suite
1000, Bethesda, Maryland
20814-3433, USA; email:
jgitchell@pinneyassociates.com

efficacious treatments have not been widely disseminated or adopted. (A review by Schwartz showed that the least effective methods of quitting were most accessible through outlets such as the Yellow Pages.⁸) Only a small fraction of quit efforts involve the most intensive and efficacious treatments; for example, behavioural cessation therapy is used in only approximately 3–4% of quit efforts.⁹ This disparity is even greater among medically underserved populations.⁹ Meanwhile, almost all smoking cessation efforts are made without the benefit of formal assistance.⁹ The marked dominance of unaided quitting is unfortunate in that it shows that most smokers use the least effective method of quitting.

Increasing the use of an efficacious smoking cessation method could substantially enhance its public health benefit, as long as it remained efficacious for many users. Because NRT has proven efficacy in a wide variety of contexts, including those with little adjunctive intervention,⁶ it is well-suited for a role as an OTC medication. Specifically, a placebo-controlled study comparing quit rates for NicoDerm CQ ($n = 283$) with those for placebo ($n = 284$) demonstrated that NRT could produce a 171% increase in quit rates in a simulated OTC environment (19% *vs* 7% 28-day continuous abstinence at six weeks).⁵ Studies of each of the NRTs switched to OTC status also demonstrated that use of NRT under OTC conditions yielded efficacy comparable to that observed in real-world prescription practice (without the intensive intervention characteristic of clinical trials). In these OTC studies (consisting of a total of 9016 smokers followed for six months and 5022 smokers followed for one year), one-year continuous abstinence rates were conservatively estimated at 8%.¹⁰ (These figures are likely to underestimate actual success, because they are based on exhaled carbon monoxide-verified complete continuous abstinence—not even a puff allowed—and count all persons lost to follow-up as treatment failures. The latter convention differentially impacts low-contact designs and low-intensity interventions, such as those used in the OTC studies. Thus, this estimate of the quit rate is likely to underestimate systematically real-world success rates.) Given that unaided quitting produces one-year success rates of only 2.5–5%,^{11, 12} increasing use of NRT medications could yield substantial public health benefit.

Before the OTC switch, the hypothetical benefit of increased use attending an R-to-OTC switch of NRT was estimated by Oster and colleagues, who modelled the potential benefit of switching nicotine gum under a variety of assumptions—for example, quit rates and impact on use of behavioural programmes. They estimated that over a 10-year period, an additional 450 000 smokers might be expected to quit because of the OTC availability of nicotine gum.¹³ This finding suggested that OTC held real promise for improving the public health. Oster *et al* based their analysis on hypothetical projections. This updated communica-

tion analyses measures of actual prescription and OTC sales and compares the use of NRT products before and after their OTC marketing.

Methods

Data from the Walsh America database as provided in the Scott-Levin Source Prescription Audit was used to estimate use of prescription NRT products before and during OTC availability of NRT. Walsh America gathers data via an electronic database, updated daily, of prescriptions actually filled in pharmacies. It samples 56% of total American pharmacies (35 300 of 63 000). Scott-Levin gathers monthly data through an exclusive arrangement with the largest national prescription drug plan provider (PCS), which provides coverage/reimbursement for prescriptions filled in almost every pharmacy in the United States. By comparing these two samples (Walsh America, which reports all prescriptions filled at a sample of pharmacies, and PCS, which provides a sample of prescriptions filled at almost all pharmacies), Scott-Levin then generates an estimate of the total number of prescriptions filled. This analysis reveals that on average, the Walsh America pharmacies account for approximately 70% of actual prescription volume and allows projections from the Walsh data to all American prescriptions. We used data for the calendar year 1995 to estimate the number of prescriptions filled before OTC NRT. Data from March through May 1997 were used to estimate the volume of NRT prescriptions after some NRTs were available OTC (two patches remained R after the switch and a prescription nicotine spray was introduced).

Data from AC Nielsen were used to estimate use of OTC NRT products. AC Nielsen assesses consumer purchase in two ways. First, it tallies a nationally projectable sample of purchases entered at the registers of food, drug, and mass merchandisers by the electronic Universal Product Code (UPC) scanner. Data are collected from a sample of 10 000 outlets (located primarily in the top 50 major markets). Purchases from retail outlets without scanner technology are estimated from a sample of those stores. The sample is then weighted to estimate total unit purchases from all outlets. Comparison of these estimates to factory shipments of goods indicates that the Nielsen estimates understate sales by about 15%. We conservatively assumed that the estimates missed 5% of sales, and adjusted the projected sales accordingly, to estimate total unit sales volume for all OTC NRT products.

To estimate the proportion of unit sales that represented new uses (and presumably, quit attempts), rather than successive purchases within a quit attempt, we relied on Nielsen data from a representative panel of 40 000 households. These households place a UPC scanner in their homes, and scan their purchases after shopping. Data from household panel scanners are collected weekly; households participate in the panel for an average of three years. When an NRT product

appears for the first time in a household's data, this is counted as a new use. (This underestimates new use because it does not account for the possibility that (a) more than one smoker in a household may quit with NRT, and (b) the same smoker may try to quit on two occasions months or even years apart.) The percentage of unit purchases that represent a new use was computed, and applied to the Nielsen retail volume estimates to project the total number of new NRT users.

To estimate OTC use, we used data from March through May 1997, then projected annual use. This period was the longest stretch marked by an absence of major commercial promotions as well as naturally occurring peaks in smoking cessation, and so reflects a stable OTC market. From mid-August 1996 (when the OTC patches became widely available) through the end of May 1997, the weekly volume of new purchases held to $\pm 10\%$ when promotion periods were excluded. Thus, this period should represent a projectable, but very conservative, estimate of OTC use.

Besides ignoring the effect of specific commercial promotions on NRT use, this estimate of steady-state NRT use also excludes the increased NRT use during naturally occurring periods of peak smoking cessation interest, such as the American Cancer Society's Great American Smokeout in November and the New Year. We separately estimated (from these same sources) the increased use of OTC NRT during these periods, because they represent recurring natural surges of smoking cessation interest and NRT use. These estimates were not used in our basic computations of NRT use, but are discussed below.

Results

In 1995, we estimate that 2.5 million quit attempts were made using Rx NRT products. Projecting from March through May 1997 (112 000 new purchases of OTC NRT per week), we estimate 5.8 million quit attempts per year with OTC NRT—more than double the Rx figure for 1995. In addition to these OTC uses, prescription data suggest that prescription NRT was being used at the rate of 500 000 new prescriptions per year, for a total of 6.3 million quit efforts using NRT, 92% of which were OTC products. Thus 3.8 million (6.3 million minus 2.5 million) annual quit efforts are attributable to OTC availability.

A recent FDA analysis of the three switch applications for the currently marketed OTC products found a 12-month quit rate of 8% when results were pooled across studies.¹⁰ Using this conservative estimate of the quit rate, we estimate that 464 000 smokers per year will succeed in quitting with OTC NRT. An additional 40 000 are estimated to have quit using NRT products still sold by prescription, yielding a total of 504 000 NRT-assisted successful quits per year in the OTC era.

It is hard to estimate how many of these smokers might have attempted to quit had OTC NRT not been so readily available and so effectively promoted. We estimated the number of *incremental* quits attributable to

Table 1 Annual incremental 12-month data for quitters successful because of availability of over-the-counter (OTC) nicotine replacement therapy (NRT) medications

	NRT users who would have attempted quitting without OTC NRT marketing		
	100%	50%	0%
Unaided quit rate = 2.5%	209 000	257 000	304 000
Unaided quit rate = 5.0%	114 000	209 000	304 000

Numbers represent the number of successful quits per year, over and above those that would have been achieved if NRT had only been available by prescription.

OTC NRT under a variety of assumptions: first, that all NRT users would have tried to quit anyway; second, that none would have tried to quit without OTC NRT; and third, that half would have tried to quit anyway. We also used two estimates of the success rate of unaided quitting. Cohen *et al* suggest that 5% of smokers who try to quit on their own remain abstinent for one year.¹² However, Hughes reported that only 3% were abstinent for as long as six months, leading to a one-year estimated quit rate of 2.5%.¹¹ Accordingly, we modelled unaided quit rates of 2.5% and 5%. Finally, we computed the incremental number of quits: that is, the number of one-year quits over and above the number estimated for Rx -only NRT in 1995.

Table 1 shows the number of estimated incremental quits; that is, successful quits that would not have occurred without OTC availability of NRT products. If none of the smokers who used OTC NRT would otherwise have attempted quitting, the number of incremental quits totals 304 000. Conversely, if all NRT users would have tried quitting anyway, and if the unaided quit rate is as high as 5%, then 114 000 incremental quits are attributable to OTC NRT.

The number of incremental 12-month quitters resulting from a year of OTC availability of NRT is conservatively estimated to lie between 114 000 and 304 000. Given the estimate that 1.2 million smokers quit annually in the entire smoking population,¹⁴ this represents a significant contribution to smoking cessation.

Discussion

The magnitude of the apparent benefit of the OTC availability of nicotine medications is striking. Although the conservatively estimated continuous abstinence rates remain low, the comparable rates for NRT users are substantially greater than for unaided quitting, consistent with the finding that NRT generally doubles quit rates.³ Because the population impact of treatment depends on use as well as absolute efficacy, broad availability and use of NRT medications appear to have had substantial population impact.

We estimate that OTC NRT medications may have increased smoking cessation in the entire American population of smokers by 10% to 25%. This is all the more noteworthy because the figures are likely to underestimate the impact. First, we excluded periods of special commercial promotions from our

estimates (to estimate sustainable volume conservatively). Second, we excluded naturally occurring periods of peak smoking cessation interest, such as the Great American Smokeout and the New Year, which were also associated with promotional efforts. The Great American Smokeout and associated promotions have been demonstrated to increase cessation activity.¹⁵ In fact, these two week-long periods of enhanced use are estimated (by extensions of the methods used here) to boost the impact of OTC NRT by about 7%, accounting for approximately 266 400 new NRT quit attempts and an additional 8000–21 300 incremental quits. In sum, when the increased cessation activity for these two periods is considered, the total number of annual successful quitters resulting from OTC NRT is estimated at 122 000–325 000.

It is also noteworthy that rates of OTC use have been strikingly stable. As noted, weekly sales have not varied by more than 10%, except during increases related to more intensive promotions. This experience is in sharp contrast to the initial marketing of R nicotine patches, when demand surged and then quickly bottomed out. Patches were first promoted widely in March 1992, at which time sales skyrocketed 240% over the first two months of 1992 (based on Walsh America data). Only four months later, sales had fallen back to baseline, and a month later fell *below* the baseline, never to recover. Although it is impossible to predict future NRT use, OTC sales show no signs of abating, nor of the boom-and-bust cycle that marked the introduction of prescription patches. Based on experience to date, the increased use due to OTC availability appears sustainable.

The ability to sustain smokers' interest in quitting with NRT may be attributable, in part, to the intensive advertising and promotional campaigns that have characterised the OTC market in NRT. Besides television advertising that is estimated to have reached almost every smoker in the United States, these marketing efforts have included promotion of programmes sponsored by voluntary associations and other activities to promote cessation. Although many promotional activities promote particular products, this marketing and outreach effort also brings smoking cessation messages before the public in unparalleled intensity. This makes it particularly plausible that many of the quit efforts involving OTC NRTs are incremental efforts that would not otherwise have occurred. Although these projections need to be confirmed by direct population studies of prevalence and cessation, the middle-ground estimates of approximately 225 000 incremental quits—an increase of almost 20%—are probably quite realistic.

Although these estimates are heartening, it is likely that even greater population impact could be achieved by further improving access. Currently, the cost of NRT products is one of several potential barriers to access. Only about a fifth of NRT users have household incomes below \$20 000; a third describe their financial circumstances as less than "comfortable"

(SBCH data on file). Although the *daily* cost of NRT treatment in the United States is comparable to the cost of smoking a pack and a half per day, some smokers may not have or may be unwilling to spend the concentrated up-front cost of an NRT purchase—seven days' worth of therapy at a minimum. Thus, low-income groups—where smoking is increasingly concentrated and where quit rates are low—have the least improved access to effective smoking cessation treatment. Accordingly, access could be improved by partial or complete coverage of NRT products.¹⁶ A 1995 survey of managed-care organisations showed uneven and often restricted coverage of NRT products when they were available only by prescription.¹⁷ Although a comparable survey has not assessed coverage of OTC products, it seems clear that coverage has diminished (health plans [companies providing or paying for health services] rarely cover OTC products and of the plans surveyed in the above study, when asked to predict if their plan would cover OTC NRT, only 10–14% (depending on patch or gum) believed they would.) In this instance, coverage of OTC NRT could potentially have significant public health benefit by increasing cessation.

The demonstration that effective treatment can be made widely available is especially salient given the renewed emphasis on smoking cessation (see resolutions adopted at the 10th World Conference on Tobacco or Health—page 277 of this issue of *Tobacco Control*)—and the possibility that new resources may be available to support it. The proposed tobacco industry settlement currently under review in the United States contains provisions for funding of smoking cessation treatment. Nicotine replacement is not the sole approach to treatment of tobacco dependence, but our data suggest the possibility that it can make effective treatment widely available.

The benefits of OTC NRT need to be weighed against the realisation of any potential risks associated with broader marketing and availability of NRT. These risks were thought to include use/abuse by teenagers or non-smoking adults, and any harm resulting from use of NRT products (including concern about use beyond the recommended period). At FDA request, companies marketing these products have conducted extensive surveillance activities, including surveys of smokers and non-smokers, interviews with school-based, drug-abuse prevention coordinators, media tracking, and follow-up of cohorts of NRT users. The methods and results are too extensive to be described here, but preliminary analyses of some of these data (to be reported in a later publication) demonstrate no significant indication of misuse of the current OTC NRT medications or of unexpected adverse experiences. Expanded availability was also thought to increase the likelihood that NRT medications would be used by smokers for purposes other than quitting—for example, to reduce smoking, perhaps in situations where smoking is forbidden. Surveillance has not turned up any indication of such use. In any

case, it has been suggested that such use, if it occurred, would not pose a public health risk, but instead would yield a public health benefit compared with continued tobacco use.¹⁸ Thus, there is little realised risk to offset the substantial benefit of increased cessation activity.

These data suggest that OTC availability of NRT medications has resulted in a public health benefit. Of course, further research questions remain. It would be useful to describe how use of NRT medications is distributed across groups of smokers, and to help identify effective methods to expand access to the groups most in need of treatment. Research on the impact of reimbursement and coverage policies would also be useful. Finally, research may help identify methods of maximising the benefit of NRT under minimal-intervention OTC conditions, while minimising any risks associated with it.

Conclusions

The switch to over-the-counter availability for nicotine medications appears to have begun to fulfil its promise of increased access. This paper demonstrates how increased availability of treatment can result in increased use, suggesting the potential for substantial public health benefit. There are likely hundreds of thousands of NRT-assisted continuous quitters in the United States who would not have become former smokers without OTC NRT. The American population could see a benefit in decreased morbidity and mortality in the coming years as a result.

The authors gratefully acknowledge the support of SmithKline Beecham Consumer Healthcare (SBCH) in preparation of this manuscript. The authors not affiliated with SBCH have received research grant support from SBCH and have been consultants to SBCH as well as to other sponsors of nicotine replacement therapy products.

1 US Centers for Disease Control and Prevention. Cigarette smoking among adults—United States, 1994. *MMWR* 1996;45:588–90.

- 2 US Department of Health and Human Services. *The health benefits of smoking cessation. A report of the Surgeon General, 1990*. Rockville, Maryland: Public Health Service, Centers for Disease Control, Office on Smoking and Health, 1990. (DHHS Publication No (CDC) 90-8416.)
- 3 Fiore MC, Bailey WC, Cohen SJ, et al. *Smoking cessation. Clinical Practice Guideline No 18*. Rockville, Maryland: US Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, April 1996. (AHCPR Publication No 96-0692.)
- 4 US Food and Drug Administration. Transcript of the Joint Meeting of the Nonprescription Drugs Advisory Committee and the Drug Abuse Advisory Committee of the Food and Drug Administration, Rockville, Maryland: Food and Drug Administration, 28 September 1995.
- 5 US Food and Drug Administration. Transcript of the Nonprescription Drugs Advisory Committee of the Food and Drug Administration. Rockville, Maryland: Food and Drug Administration, 19 April 1996.
- 6 Silagy C, Mant D, Fowler G, Lodge M. Meta-analysis on efficacy of nicotine replacement therapies in smoking cessation. *Lancet* 1994;343:139–42.
- 7 Gallup Organization. *Smokers' attitudes towards quitting*. Princeton, New Jersey: Gallup Organization, 1993.
- 8 Schwartz JL. *Review and evaluation of smoking cessation methods: the United States and Canada, 1978–1985*. Bethesda, Maryland: US Department of Health and Human Services, Public Health Service, National Cancer Institute, 1987. (NIH Publication No 87-2940.)
- 9 Fiore MC, Novotny TE, Pierce JP, et al. Methods used to quit smoking in the United States: do cessation programs help? *JAMA* 1990;263:2760–5.
- 10 Winchell CJ, Wright C, Burke L, et al. Long-term abstinence in users of OTC nicotine replacement. *Clin Pharmacol Ther* 1997;61:191.
- 11 Hughes JR, Gulliver SB, Fenwick JW, et al. Smoking cessation among self-quitters. *Health Psychol* 1992;11:331–4.
- 12 Cohen S, Lichtenstein E, Prochaska JO, et al. Debunking myths about self-quitting: evidence from 10 prospective studies of persons who attempt to quit smoking by themselves. *Am Psychol* 1989;44:1355–65.
- 13 Oster G, Delea TE, Huse DM, Regan MM, Colditz GA. The benefits and risks of over-the-counter availability of nicotine polacrilex ("nicotine gum"). *Med Care* 1996;34:389–402.
- 14 Giovino GA, Shelton DM, Schooley MW. Trends in cigarette smoking cessation in the United States. *Tobacco Control* 1993;2(suppl):S3–10.
- 15 US Centers for Disease Control and Prevention. Impact of promotion of the Great American Smokeout and availability of over-the-counter nicotine medications, 1996. *MMWR* 1997;46:867–71.
- 16 Schaffer HH. Defining benefits and payment for smoking cessation treatments. *Tobacco Control* 1997;6(suppl 1):S81–5.
- 17 Pinney Associates. *Smoking cessation and managed care—1995*. Bethesda, Maryland: Pinney Associates, 1995.
- 18 Warner KE, Slade J, Sweanor DT. The emerging market for long-term nicotine maintenance. *JAMA* 1997;278:1087–92.