RESEARCH PAPER

Persistent use of nicotine replacement therapy: an analysis of actual purchase patterns in a population based sample

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Background: In 1996, the US Food and Drug Administration (FDA) approved switching nicotine gum and patch from prescription to over-the-counter (OTC) status. Some expressed concerns that broader availability and lack of physician control might increase persistent use of nicotine replacement therapy (NRT)—that is, use beyond the period specified by the FDA approved label.
Objective: To estimate the incidence of persistent use of OTC nicotine gum and patch for periods of > 3 months, ⩾ 6 months, ⩾ 12 months, and ⩾ 24 months.
Design: Analysis of NRT purchase patterns in data from a population based panel of US households that electronically scanned all household purchases between January 1997 and March 2000.
Subjects: In a national panel of 40 000 US households, 2690 recorded NRT purchases.
Results: Among 805 households that purchased nicotine gum, 2.3% of new purchase incidents led to continuous monthly purchase of gum for ⩾ 6 months. For nicotine patches (2050 households) the percentage was 0.9%. For both gum and patch, the incidence of persistent purchase dropped below 0.4% by 24 months. Allowing one month gaps within a "continuous" purchase run resulted in increased estimates (for gum: 6.7% for ⩾ 6 months and 1.0% for ⩾ 24 months; for patch: 1.7% for ⩾ 6 months and 0.05% for ⩾ 24 months).
Conclusion: Persistent use of nicotine gum and patch is very rare and has not increased with the transition to OTC use, despite removal of physician oversight.

Smoking is the greatest cause of preventable morbidity and mortality in the western world, making smoking cessation an urgent priority. In 1984, nicotine gum became the first medication approved by the Food and Drug Administration (FDA) for smoking cessation. The nicotine patch followed in 1991, and both nicotine gum and patch were switched from prescription only to over-the-counter (OTC) status in the USA in 1996. Currently, nicotine gum and patch are available as a non-prescription product in approximately 70% of the more than 50 countries in which they are registered. The switch from prescription to non-prescription status was intended to increase access to, and use of, nicotine replacement therapy (NRT).[1 2] Indeed, Shiffman *et al*[3] estimated that the switch to OTC NRT in the USA increased use of NRT by 152% and increased the annual incidence of smoking cessation by 10–25%. Although Pierce and Gilpin[4] presented uncontrolled correlational data questioning the efficacy of OTC NRT, a meta-analysis of several randomised controlled trials showed that OTC NRT is efficacious and that the efficacy of NRT is similar under prescription and OTC conditions.[5]

Because intake of nicotine through tobacco use frequently results in dependence,[6] the use of nicotine as a therapeutic agent has periodically raised concern about potential abuse and dependence, although prolonged use of NRT is not thought to be harmful. A clinical study found no untoward effects of five years of nicotine gum use.[7] In addition, the US Public Health Service guidelines[1] and others have suggested that prolonged use of NRT might be necessary for some smokers to maintain abstinence from cigarettes, and prolonged NRT use is clearly healthier and medically preferable to smoking. Nevertheless, some authors have been concerned about persistent use of NRT, despite the fact that experimental evidence indicates that neither nicotine gum nor patch have significant abuse/dependence liability.[8 9]

Historically, the literature has seldom examined dependence on NRT per se, but has instead assessed persistent use—that is, use of gum or patch continuously for periods longer than indicated. Persistent use is one criterion of substance dependence—that is, the substance is taken over a longer period than intended.[10] However, persistent use does not necessarily indicate dependence, because dependence requires other symptoms, such as emergence of withdrawal upon cessation, unsuccessful attempts to stop, surrender of other valued activities in favour of use, and so on.

Persistent use of nicotine gum does occur, but not frequently.[11–13] In a meta-analysis of studies of nicotine gum use,[14] during the time when gum was available only by prescription, 17% of those prescribed nicotine gum continued to use gum at six months (the recommended period), and 8% persisted in using gum for 12 months or more. Thus, the incidence of nicotine gum use persisting for double the recommended period averaged 8% when gum was restricted to prescription use. (To our knowledge, persistent use of the patch has not been examined and has generally been considered less of a concern.)

Although the prescription era experience suggested little persistent use, some expressed concerns that broader availability through OTC access and lack of physician control might increase the risk of persistent use of NRT.[15] In OTC products, which are intended for use by consumers without supervision, the FDA relies on product labelling and instructions to structure the user's behaviour,[16] including limiting duration of use. In this study, we evaluate the incidence of persistent use in the

Abbreviations: FDA, Food and Drug Administration; OTC, over-the-counter, NHIS, National Household Interview Survey; NRT, nicotine replacement therapy

OTC setting. In defining persistent use, we referenced the period of use recommended by the FDA approved product instructions, which reduced the recommended period of use from six months to three months when nicotine gum was made available OTC*. Thus, our working definition of persistent use in the OTC context is use for six months or more, for both gum and patch. This represents double the OTC indicated duration, and corresponds to the recommended period of gum use before the OTC switch.

Only one unpublished study has examined persistent use of nicotine gum in the OTC setting. Shiffman *et al*[17] prospectively followed 2656 OTC nicotine gum users enrolled in an optional smoking cessation programme (Nicorette Committed Quitters programme[18]). Six per cent of the sample reported continued gum use at six months; however, the clinical sample that was seeking behavioural treatment may not have been representative of all OTC gum users.

The purpose of the current study was to estimate the incidence of persistent use of OTC nicotine gum and patch using a representative non-clinical sample and an objective measure of NRT use to avoid self report which may be subject to bias. A panel of US households provided information on all their consumer purchases, allowing us to examine purchase patterns for OTC nicotine gum and patch to determine the incidence of persistent use, as inferred from purchases.

METHODS

Participants

ACNielsen, a commercial vendor of research data, maintains a panel of 61 500 households that agree to provide information on all universal product coded (UPC, "bar code") household purchases.[19] Each household records all purchases using an in-home bar code scanner provided by ACNielsen. Scanner data are electronically transmitted to ACNielsen on a weekly basis. In return for consistent participation, ACNielsen sends newsletters, feedback, etc, and households are compensated with points redeemable for free merchandise, with contingencies for weekly data transmissions.

The panel is recruited by mailing to a geographically stratified random panel of US households listed in marketing registries. Responding households are surveyed for demographics and included in the panel as needed to achieve representativeness by matching the profile of US households as represented by the census. Households rotate out of the panel over time and may resign; typically, 80% of households are retained from one year to the next. Household data do not correspond directly to individual use, as smoking households may include more than one smoker. National data indicates that there are 2.3 smokers per smoking household.[20 21] Demographic information on the individual households (for example, household size and income, age, race, education), provided at the time of panel enrollment, was obtained.

We analysed purchase data from January 1997 through March 2000, when the database extraction was initiated. The January 1997 start date was a few months after both gum and patch were switched to OTC sales, allowing some time for OTC products to reach full distribution. (During this time the nicotine inhaler and nasal spray were prescription products and the nicotine lozenge was not available). All OTC NRT brands (Nicorette, NicoDerm CQ, Nicotrol, and various generics), doses of 2 mg and 4 mg gum, 7, 11, 14, 15, 21, and 22 mg patches, flavours (original, mint, and orange gum), colours (opaque and clear patch), and package sizes were tracked, encompassing 78 different bar coded retail packages. For patch, package sizes included seven and 14 count boxes (good for seven and 14 days of recommended daily use, respectively). For gum, package sizes included 48, 60, 108, and 132 count boxes. These would be good for five, seven, 12, and 15 days at the recommended daily dose of nine or more pieces per day. However, daily rate of gum consumption is quite variable, and data suggest that OTC use is below the recommended rate; in one real world OTC study, average use among those using gum in the first six weeks was 5.9 pieces per day (based on data from Shiffman *et al*[18]). At that rate, the various size gum packages could last nine, 11, 19, and 23 days, respectively. Thus, mapping package size onto duration of supply is problematic. Further, we noted that identical scans often appeared two or more times on the same day, suggesting the likelihood that packages were mistakenly scanned repeatedly. Accordingly, we did not attempt to factor the size of each purchase into the analysis.

From the larger panel, 2690 households were identified as having purchased at least one OTC NRT during the period of study. For these households, the mean (SD) tenure in the panel was 39 (14.1) months.

Procedure

The analysis was based entirely on archival product scanning data. There was no direct contact with participating households, so data on actual use of NRT or smoking status were not available. Households whose scanner data included an NRT product during the sampling period were considered users of NRT products. For each household, information on all NRT purchases (date, medication type, and medication brand) was collected. Data were blocked by purchase date into calendar months and examined for "runs" of purchases across consecutive months. If a household had more than one "run" of continuous NRT purchase (26.8% of households had multiple runs of NRT gum and 27.6% had multiple runs of NRT patches), one run was selected at random for analysis†. Few households had multiple runs in which more than one of the runs lasted more than three months (that is, 6.8% for gum, 5.5% for patch).

National Household Interview Survey data

To determine the representativeness of the household panel of NRT purchasers, we compared their demographic characteristics to the household characteristics of respondents in the 2000 National Household Interview Survey[22] (NHIS) who said they had used patch or gum, respectively, in the past year. In the NHIS, 497 respondents reported using patch in the past year, and 149 respondents reported using gum. We identified NRT users in the NHIS based on products used on the most recent quit attempt (for current smokers) or product used when quit (for former smokers). We abstracted individual ethnicity and household income, and highest education level.

Outcome definitions

Persistent use was defined by a pattern of continuous monthly purchase—that is, if a household purchased any NRT for two consecutive months, but not the next month, that household was considered to have purchased continuously for two months. Interruption by one month with no purchase was considered to indicate a new episode of use (possibly a new quit attempt). We estimated incidence of persistent purchase for periods of > 3 months (the FDA approved period of use), ≥ 6 months (our major outcome), ≥ 12 months, and ≥ 24 months.

*This change was not based on clinical data, but on a conservative philosophy to limit the duration of use for the OTC medication, since there was not yet experience with wider access to the medication.

†To ensure the stability of our estimates, we examined 1000 different random samplings from these data. Results show gum and patch incidences that are similar to those of the single sample estimates in table 2. Thus, we are assured that the sampling did not introduce bias.

Table 1 Household characteristics of patch and gum purchasers

	Current sample		National Household Interview Survey*	
	Patch (n=2050)	Gum (n=805)	Patch (n=497)	Gum (n=149)
Average months in panel	39.6 (0.30)	39.0 (0.51)	–	–
Average household size	2.6 (0.03)	2.5 (0.05)	2.7 (0.08)	2.8 (0.14)
Median household income	$42500	$47500	$40000	$40000
% White	93.1	94.6	90.1	93.6
% Married	64.9	62.0	56.3	68.0
% Employed†	79.8	79.0	77.7	81.0
% Any college education†	73.8	80.0	62.5	69.5

Table entries are means (with associated standard error) or percentages.
*For smokers who reported using each product in a quit effort in the preceding year.[22]
†Refers to either male or female adult in household.

Sensitivity testing

Purchase of nicotine gum and patch, respectively, was evaluated under various definitions and within various household subsets.

Definition of "continuous" purchase.

To assess the effect of allowing gaps within "runs" of continuous purchase (for example, in case scanning was missed or last month's supply was carried over), we recalculated all of the estimates while allowing a one month gap within periods defined as "continuous" purchase (that is, purchase was considered continuous even if it was interrupted by one or more one month gaps with no purchases.)

Household size

To assess effect of household size, we recalculated estimates using only households said to contain only one person, which may better represent an actual individual's continuous purchase behaviour.

Compliance with scanning

To assess the effect of the household's compliance with scanning of purchases, we recalculated estimates using only households that met compliance criteria specified by ACNielsen as indicating adequate compliance. The compliance criterion specified that single person households had to scan at least $25 worth of goods of any kind in four weeks; for larger households (2+ members) the scanning requirement was $75. Households were considered compliant if they met this criterion in 80% of the four week periods used in the study. Overall, 58.1% of the 2690 households met this compliance criterion.

Data analysis

For each household purchasing gum and/or patch, duration of continuous purchase of gum and of patch was calculated. Some observations were censored (that is, the duration was unknown because the household was purchasing NRT when it entered or exited from the panel or when the observation period ended). Only 3.9% of patch observations and 5.6% of gum observations were censored.

We estimated continuous use rates in two ways. First, we evaluated the incidence of persistent purchase by randomly selecting a single observation per household and estimating the incidence of persistent use. This analysis excluded observations that were censored before the duration interval under analysis—for example, a purchase run that was censored after four months would count as persistent use at the three month point, but would be excluded from estimation of the six month incidence. Second, to better account for censoring, we also constructed survival curves, in which the denominator of households "at risk" was adjusted for censoring. The curves show the probability of continuous purchase at each month, for households under observation, with the time point of 24 months representing the probability of continuous use for 24 months or more. Data analyses were performed using SAS version 8.2 for Windows.

RESULTS

Subject disposition

Of the 2690 households that purchased NRT products, 2050 (76.2%) purchased patch products and 805 (29.9%) purchased gum products. Only 165 households (6.1%) purchased both gum and patch products during the period of study; these households are included in both gum and patch analyses.

Sample characteristics

Overall, the participants characterised their households as white (93.3%), with a median income of $42 500, 65% headed by married couples, 82% containing at least one employed adult, and 75% having at least one adult who completed college. The sample of households was composed mostly of households with two adult heads (69%), but some were headed by one female (23%) or male (8%) head. There were an average (SD) of 2.6 (1.3) persons in each household, and 29.8% of households had at least one child under 18 years of age. The median age of the head of the household was 45–49 years (age was coded categorically). Household characteristics of the households by patch and gum purchasers are presented in table 1.

Table 1 also shows similar characteristics for NHIS respondents who reported that they had used patch or gum in the preceding year. Comparison suggests that, although the ACNielsen panel is fairly similar to a national sample of NRT users, NRT purchasing households in the ACNielsen panel may have somewhat higher income and more education than the general population of NRT purchasing households. To determine whether any of these differences affected our estimates, we weighted the ACNielsen sample to match the NHIS sample on the demographics presented in table 1. The estimates were essentially unchanged—only one changed by more than 0.2%, and the mean change was 0.065%. We present the unweighted estimates for simplicity of interpretation.

Incidence of persistent purchase

Across purchase incidents, the average duration of continuous patch and gum purchase was 1.4 (1.0) and 1.5 (2.5) months, respectively. Most NRT purchases lasted only one month (76.0% for patch and 84.9% for gum); for both patch and gum, the median duration of a purchase run was one month. The estimated incidence of persistent purchase for periods of > 3 months, $\geqslant 6$ months, $\geqslant 12$ months, and $\geqslant 24$ months are presented in table 2.

Figures 1 and 2 present the conditional probabilities of continuous purchases for one to 24 months (survival curves) of patch and gum, respectively. Separate curves are shown for the

Table 2 Estimated duration of persistent purchase for nicotine patch and gum (% of households)

	Patch (n=2050)	Gum (n=805)
>3 months	2.9	5.2
≥6 months	0.9	2.3
≥12 months	0.1	1.0
≥24 months	0.05	0.4
Persistent purchase (allowing 1 month gap)		
>3 months	5.4	11.3
≥6 months	1.7	6.7
≥12 months	0.4	2.8
≥24 months	0.05	1.0

primary measure of continuous purchase and the more liberal definition of "continuous" purchase allowing a one month gap. Probabilities conditional on past month purchase and adjusted for censoring were slightly higher (< 4.8% increase) than corresponding estimates of incidences.

Sensitivity testing

Definition of "continuous" purchase

We re-assessed continuous purchase while allowing for gaps of up to one month within periods of "continuous" purchase. The average duration of patch and gum purchase, respectively, was 1.6 (1.5) months and 2.2 (3.8) months. Again, most households purchased NRT for only one month (72.3% for patch and 78.5% for gum). Table 2 shows the estimated incidence of various purchase durations.

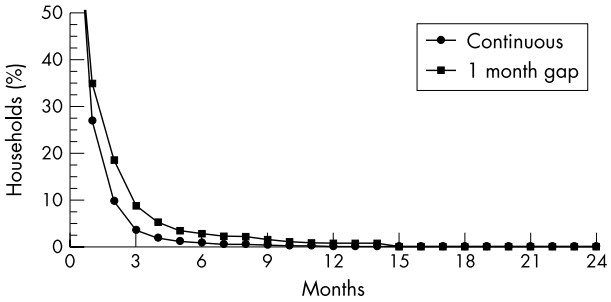

Figure 1 Survival curve showing the probability that households purchasing nicotine patch will still be observed continuously purchasing for up to 24 months. At each point, the graph indicates the percentage of observed households using for *at least* the period indicated on the x axis. Purchase runs are treated as censored if the household leaves the panel in the midst of a run. (Continuous purchase episodes that include one or more gaps of one month without purchase are illustrated by the line labelled "1 month gap".)

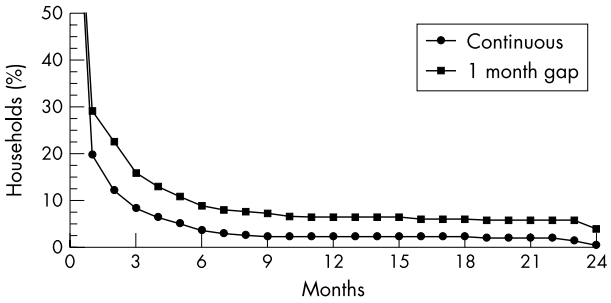

Figure 2 Survival curve showing the probability that households purchasing nicotine gum will still be observed continuously purchasing for up to 24 months. At each point, the graph indicates the percentage of observed households using for *at least* the period indicated on the x axis. Purchase runs are treated as censored if the household leaves the panel in the midst of a run. (Continuous purchase episodes that include one or more gaps of one month without purchase are illustrated by the line labelled "1 month gap".)

Household size

Continuous purchase patterns were similar for one person and multiple person households. The average duration of purchase was 1.4 (1.0) and 1.4 (1.1) months for the patch and 1.8 (3.1) and 1.5 (2.2) months for gum, for one and multiple person households, respectively. Similarly, most one and multiple person households purchased NRT for only one month (one person households: 75.0% for patch and 85.6% for gum; multiple person households: 76.3% for patch and 84.6% for gum).

Compliance with scanning

Among households deemed compliant, results were similar to the overall sample. The average duration of NRT purchase for patch was 1.4 (1.2) months and for gum was 1.4 (1.9) months, and most purchased NRT for only one month (76.1% for patch and 86.5% for gum). Among households that did not meet compliance standards, average duration of NRT purchase was 1.4 (0.8) months for patch and 1.7 (3.1) months for gum, with most households purchasing NRT for one month (75.9% for patch and 82.3% for gum).

DISCUSSION

To address speculation about rates of persistent use of OTC NRT beyond the recommended period of use, we analysed patterns of nicotine gum and patch purchase in a population cohort. Most purchases of either gum or patch were short lived, with the vast majority lasting only for a single month. Nevertheless, we did observe some incidence of persistent use beyond the recommended period of three months for nicotine gum and patch. Using a liberal definition of continuous purchase, 6.7% of gum purchases resulted in purchase episodes lasting at least six months; for nicotine patch, this occurred on 1.7% of purchase episodes. For both NRT forms, purchase continued to decline over time: only 2.8% of gum and 0.4% of patch purchase episodes lasted one year or more. Thus, the data suggest that use beyond the FDA recommended period is rare.

Even in the OTC setting, where there is no required physician oversight and gate keeping, and only the product label to provide guidance, smokers rarely seem to use the gum or patch beyond the indicated period. When nicotine gum was only available by prescription, and indicated for six months of use, it was estimated that 17% used it for six months or more, and 8% for 12 months or more.[14] In this study, the incidence of gum use was lower at both intervals, suggesting that the incidence has at least not risen since nicotine gum was switched from prescription to OTC. Although this may seem counter-intuitive, in prior studies of analgesics and benzodiazepines, when patients were allowed to self dose, they used less medication and for a shorter time than what a physician would have prescribed.[23] Thus, perhaps smokers fear dependence on NRT and, in the absence of physician encouragement to continue use, do not persist in use as readily. In addition, the decrease in the FDA recommended duration of use from six months to three months may have discouraged persistent use. Another possible reason for the lower rates of persistent use is that the easier access with OTC NRT may recruit less dependent users than those who used prescription NRT; however, existing data suggest this is not the case.[24] Also, most OTC NRT use is paid for out of pocket and perhaps most prescription use was paid by insurance; however, in reality very little prescription use was paid by insurance.[25] Finally, the lower incidence may be an artifact of different study methods.

That a small proportion of users persist in NRT use suggests that a few smokers may need longer treatment with nicotine replacement in order to manage prolonged withdrawal[26]

and/or to avoid relapse to smoking, which is still a substantial risk even after three months of abstinence.[27] Indeed, the Public Health Service guideline[1] (page 80) and other smoking cessation experts have recommended that some smokers use NRT for longer than the recommended period in order to maximise success. While this study provided no information on the motivation for persistent use, other data sources suggest that most use is motivated not by dependence but by the wish to prevent relapse to smoking.[17 28]

We did not assess dependence on NRT products. Persistent use may not indicate dependence on the gum or patch. Indeed, one study[28] found that actual nicotine dependence is rare among persistent users—that is, this study estimated that < 15% of those who used nicotine gum for more than three months met *Diagnostic and statistical manual of mental disorders/ International classification of diseases* (DSM/ICD) criteria for dependence.

Initially, the low incidence of persistent use may seem puzzling; if nicotine is provided to nicotine dependent individuals, one might expect persistent use to be common. Making NRT available without prescription might also have been expected to increase persistent use, because NRT would be available without monitoring or gate keeping by a physician. However, we saw no evidence of increased persistent use. However, the dependence potential of nicotine (and other drugs) also depends on their method of delivery and rate of administration.[29] Compared to cigarette smoking, which delivers boli of nicotine to the brain within 10 seconds and achieves peak plasma concentrations after 5–10 minutes,[30] nicotine delivery via NRT is quite slow with peak plasma concentrations occurring after 20–30 minutes for gum[31] and 6–12 hours for various nicotine patches.[32 33] In any case, formal studies of abuse liability[34–36] have consistently shown that nicotine gum and patch have very low abuse liability. These forms of nicotine administration are simply not very reinforcing and, indeed, do not regularly maintain use even for as long as recommended by the instructions.

We observed a higher incidence of persistent use for nicotine gum versus nicotine patch. This may be driven by the gum's greater frequency of use and its ad libitum dosing, as both have been linked to dependence potential.[37] On the other hand, ad libitum dosing lends itself to use for other reasons as well (for example, to prevent relapse during situations that arise after the recommended period of use).

It is important to recognise that even the very low rates of *incidence* (that is, the rate of new cases of persistent use, among smokers who initiate gum use) will lead to higher rates of *prevalence* (that is, at any one time, the cross sectional proportion of users engaged in persistent use). Since most NRT use is very short lived and most users quickly exit the using population, whereas persistent users stay in and accumulate during a period of observation, persistent users are drastically overrepresented in any cross sectional sample of NRT users. The difference in incidence and prevalence is a function of the duration of the condition. In our data, allowing for one month gaps in use, the incidence of persistent gum use was 6.7%. That is, among those who start using nicotine gum, 6.7% are likely to still be using it after six months. Among those who engaged in persistent use in this sample, the duration of such use averages 8.6 months (that is, once users cross the six month threshold, they use for another 8.6 months, on average). Using the formula specified in Kleinbaum *et al*[38] (prevalence = [incidence × duration]/[1 + (incidence × duration)]) and assuming steady state conditions, we estimate that 36.6% of current gum users (in cross section) are engaged in persistent use‡. Thus, the risk of a new gum user proceeding to persistent use is low, but the probability of any current gum user being a persistent user is moderate. Casual observers often fail to make this distinction between prevalence and incidence and incorrectly assume that the observed prevalence indicates a high incidence or risk of persistent use. This confusion may explain some of the media attention that persistent use has received.[39–41] In any case, persistent use of nicotine replacement products is not associated with any known medical risks and is associated with smoking abstinence.[7]

Our study did not assess whether some persistent use of NRT may have been for smoking reduction or to avoid smoking restrictions. However, other studies suggest such use is uncommon.[28] Although logic and some data suggest persistent use of NRT accompanied by smoking reduction would produce a health benefit and increase the probability of later cessation,[42] further research is needed to verify this.

The data in our study also confirm prior suggestions[1 43] that *under* utilisation of NRT is a significant clinical problem. The vast majority of purchase episodes lasted only one month, even though both gum and patch are indicated for 2–3 months of use. In all likelihood, the large majority of cessation of NRT was due to relapse to smoking (NRT labelling warns against using the products when smoking). However, even when smokers are abstinent, NRT use is too often terminated prematurely, likely reducing clinical success.[1 44] Many smokers believe the risk of addiction to NRT is similar to that for cigarettes,[45] and this may be one reason smokers terminate use too early. Our data suggest addiction to NRT is very rare; thus educating smokers about this should encourage them to complete the recommended course of NRT.

This study suffered from several limitations which moderate our conclusions. First and foremost, the data analysed related only to NRT *purchases*. Actual NRT use was inferred from these purchases, but the linkage is imperfect (for example, some NRT products may be purchased but not used). The purchase data themselves were based on scanning of purchases. NRT products could have been purchased and used but not scanned; however, we saw no evidence of bias resulting from under scanning, as inferred from the retail value of scanned merchandise. We analysed the incidence of monthly purchase, but did not delve into details about the amount purchased or how long each supply would last, which would have required difficult inferences about the rate of use. In any case, the sensitivity analysis (in which a whole month could pass without a recorded purchase while still being counted as continuous purchase) should account for these sources of under counting.

We also could not tell when what appeared to be a run of NRT purchase was due to two distinct quit efforts, either by two different members of the household, or two efforts in quick succession by a single individual. Our analysis was limited because we analysed household data, rather than individual data. This may be misleading if multiple individuals within a household were buying or using NRT. The above limitations may have caused us to overestimate the incidence of persistent use; thus, we believe our estimates likely represent the upper bound of the incidence.

Another limitation is that our study did not assess whether NRT users consulted their physicians. NRT labelling permits use for longer than the recommended period under a physician's guidance. Some of the individuals using NRT for long periods may be doing so under physician direction or supervision. We also had no data on motives for use, amount

‡The estimated prevalence would be 16.5% if one assumes the 2.3% incidence of persistent use based on the analysis of continuous patterns (table 2, top panel), without allowing one month gaps in purchase. Also, an estimate obtained by simply overlaying the distribution displayed in fig 1, to model the experience of successive cohorts of new nicotine gum users, results in a very similar estimated prevalence of 35.8%. Several factors not taken into account in either estimate may cause the prevalence to be underestimated: the censoring of the use patterns in this analysis, the existence of some gum users who may persist for more than 24 months, and the unknown carryover of persistent users from the prescription NRT era (before OTC sales).

What this paper adds

Some smokers who use nicotine gum for smoking cessation progress to persistent use of the gum, beyond its recommended period of use. The availability of nicotine gum in unsupervised over-the-counter sales could potentially increase the incidence of persistent gum use. However, all the data to date have been either anecdotal or based on small clinical trial populations.

This study presents a population based estimate of persistent use, based on objective measures of nicotine gum and patch purchases over time. The data show that the incidence of persistent use is low.

of use, concomitant smoking, or smoking history, and thus could not thoroughly explore patterns of persistent use. Finally, our data cover only the first few years of OTC availability of patch and gum. It is possible that who purchases OTC NRT or how they use it have shifted or will shift over time, as OTC NRT becomes even more established in the market.

At the same time, this study and method had unique advantages. It examined NRT use in a large and reasonably representative population based cohort, where most prior studies have looked at small clinical samples, often from single clinical settings. The demographic profile of households in this sample was similar to that of NRT users in NHIS, and weighting to match the NHIS profile did not affect the estimates. Also, the measures used were relatively objective, and did not depend on recall or verbal self reports of use patterns in a clinical context, where respondents might be inclined to under report proscribed behaviour. Participants in this study had not been identified or recruited based on smoking or NRT use, but had agreed to scan all their retail purchases over many months, and were thus unlikely to be self conscious about their NRT use.

In summary, this study suggests that persistent use of NRT is rare, even under OTC conditions without mandatory medical supervision. For those who do use NRT beyond the recommended period, persistent use carries few health risks,[31] even among those with cardiovascular conditions,[46 47] and even when used for periods of years by smokers with compromised health.[7] Conversely, longer use of NRT may help some smokers achieve permanent abstinence.[43] Our data also suggest that most users of OTC NRT actually terminate their NRT use before the indicated period. Smokers should be encouraged to use NRT in the amounts and for the duration indicated in the FDA approved directions, without concern for persistent use of or dependence on NRT medications.

FINANCIAL DISCLOSURE

This study was supported by GlaxoSmithKline Consumer Healthcare (GSKCH) which markets nicotine replacement medications for smoking cessation. The data were provided by ACNielsen, a commercial research data vendor.

Drs Shiffman and Pillitteri serve as consultants to GSKCH on an exclusive basis regarding matters relating to smoking cessation. Dr Shiffman also has an interest in a new nicotine replacement product.

Dr Hughes has received honoraria, consulting fees, or research grants from the following organisations that support tobacco research or market tobacco cessation/prevention product/services/information: American Academy of Addiction Psychiatry, American Council on Science and Health, Association for Medical Education and Research in Substance Abuse, Bioscience Communications, BL Seamon, Edelman Public Relations, Genatics, Maine Medical Center, Massachusetts Department of Health, Pacific Pharmaceuticals, Pfizer Inc, Pharmacia, Pinney Associates, Sanofi Pharmaceuticals, Society for Research on Nicotine and Tobacco, Stanford Research Institute, University of Minnesota, University of Mississippi, University of Wisconsin, US Food and Drug Administration, US National Institutes of Health, US Veterans Administration, and Vermont Area Health Councils. He has not received funds from alcohol or tobacco companies.

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