

Drug Counselor Report of Adolescents Abuse of Nicotine Replacement Therapy

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ABSTRACT. Background. Nicotine replacement products (NRT) are formulated and marketed to reduce their abuse liability among adolescents. Few studies have examined the extent of adolescent abuse. The objective of this manuscript is to describe the youth abuse rate for NRT and other over-the-counter (OTC) abusable substances.

Methods. Two cross-sectional telephone surveys of Safe and Drug Free School Coordinators were conducted in 1996/7 (N = 562) and 1998/9 (N = 501). Abuse of NRT and other OTC drugs and circumstances surrounding NRT abuse was ascertained.

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Andrew Hyland was responsible for analyzing the data, interpreting the findings, and writing the manuscript. David Bradford was responsible for conducting the two surveys and developed the initial analytical plan. Joe Gitchell conceived the project and assisted in the manuscript development. Mr. Gitchell also has a financial interest in a venture to develop a new nicotine replacement product, and the company for which he works, Pinney Associates, provides consulting services on an exclusive basis to GlaxoSmithKline Consumer Healthcare.

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Results. NRT abuse rates were low and did not change significantly between the two surveys (2.7% in 1996/7 to 4.6% in 1998/9). NRT abuse rates were well below those of other OTC abusable substances (e.g., diet pills and inhalants).

Conclusions. Concerns over promotion of youth dependence to nicotine by offering the sale of NRT OTC to adults have not been realized and policymakers should consider reducing barriers to access these products. [Article copies available for a fee from The Haworth Document Delivery Service: 1-800-HAWORTH. E-mail address: <docdelivery@haworthpress.com> Website: <<http://www.HaworthPress.com>> © 2005 by The Haworth Press, Inc. All rights reserved.]

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INTRODUCTION

Approximately 440,000 people die from smoking caused illnesses¹ each year in the United States, and 8.6 million people suffer from a cigarette-attributable morbid condition.² At least 25% of ever smokers will die prematurely from a smoking related illness.¹ Smoking cessation greatly reduces the risk of disease and premature death³ and increasing cessation is the key element to decreasing the tobacco-related disease burden over the next 20 years.⁴

Nicotine replacement products are proven to increase quit rates in adults (Silagy C, Lancaster T, Stead L, Mant D, Fowler G. 2002. Nicotine replacement therapy for smoking cessation. *Cochrane Database Syst Rev* (4): CD000146.). In 1996, the Federal Food and Drug Administration's (FDA) approved over-the-counter (OTC) availability of nicotine gum and two brands of nicotine patch, which increased utilization of these products.⁴ However, nicotine replacement therapies (NRT) have not been approved as safe and effective for adolescents and children; therefore, they are not indicated for use by smokers under 18 years of age.

In an effort to reduce the appeal of NRT to minors, the FDA restricts the marketing and distribution of OTC NRT.⁵ For example, OTC NRT sales to persons under the age of 18 are prohibited unless under the advice of a physician, NRT are only available for purchase packages with product sufficient for several days compared to cigarettes that can be purchased by the pack and lasting a typical smoking about one day, and

NRT marketing and product formulations are intentionally designed to reduce youth appeal. Few studies have examined the extent to which adolescent abuse these products using national data sources.

A study of adolescent use of NRT products done in 1998 among 11th graders in the Memphis School District was recently reported.⁶ About 5% reported ever use of an NRT product, and about 1.7% of never smokers reported ever use of NRT and 0.3% reported past daily use of NRT. Another study from the same research team also recently reported that a teenager was able to purchase OTC NRT products in about 80% of occasions of a sample of retail outlets in Memphis, TN.⁷ The survey of adolescents is one of the few studies on this topic; however, data gaps continue to exist, which include the need for national-level data, the scope of adolescent NRT abuse in conjunction with other OTC drugs commonly abused by adolescents, and research distinguishing between use and abuse of NRT.

To begin to address these issues, we report data from two national cross-sectional surveys of school drug counselors conducted in 1996/7 and 1998/9 to determine the extent to which minors appear to be abusing OTC NRT and other OTC substances.

METHODS

Data Sources

Data for this paper are derived from two national cross-sectional surveys of Safe and Drug-Free Schools Coordinators (SDFSC). IRB was not required or sought for this research.¹ The first cross-sectional survey was conducted between October 1996 and February 1997. State-specific lists of SDFSC were obtained from all states except Hawaii and New York State's list did not include New York City coordinators. States are required to maintain a list of coordinators in connection with Federal grant funding for the Safe and Drug-Free Schools program, and a total of 11,588 SDFSC were enumerated. SDFSC were stratified by state and randomly selected with probability proportionate to the population of the state.

Ten trained interviewers were given training on the data collection instrument and procedures. They used a computer assisted telephone interviewing (CATI) system to administer the questions and record the answers. The CATI system facilitates appropriate branching to relevant questions based on the respondent's answers, and also conducts edit

checks of the responses to ensure that they fall within the pre-determined ranges. Respondents were asked about their knowledge of drug abuse in their school, including abuse of NRT and other OTC substances. Out of the 1,091 SDFSC who were sampled, 562 completed the interview in 1996/7 (response rate = 52%).

All school districts which participated in the SDFS program were required to name a program coordinator. In most cases, the nominated coordinators simply added those duties to their other job responsibilities. The level of training and degree of commitment to the program varied across school districts depending on the size of the district, the coordinator's familiarity with and commitment to drug abuse education programs, and the extent of competing job demands. In spite of this variability, they were a logical starting place to get both interview responses and referrals to other knowledgeable informants because of their duties and the availability of contact information.

A second cross-sectional survey of SDFSC identical to the first survey was conducted two years later between October 1998 and January 1999. SDFSC were sampled from the list used for the 1996/7 survey. While individual SDFSC may have changed between the two surveys, the telephone number for the contact generally remained constant. Five hundred one completed interviews were obtained from the 721 SDFSC who were sampled in the 1998/9 interview (response rate = 70%). The response rate was greater in the 1998/9 interview because a more intensive call-back procedure was used.

The original goal of this project was to fulfill a condition of approval of over-the-counter nicotine replacement by assessing how drug counselors perceive NRT abuse in a national sample and to assess how this may have changed over time in the OTC setting. This obligation persisted for three years following the approval of the products, and GSK completed this obligation. It was only recently that other studies (e.g., Klesges et al.⁶) have been published suggesting the need to present additional data on this topic area.

Outcome Variable

Abuse of NRT and other OTC drugs was assessed from responses to the following question: 'What over the counter drugs are abused?' Responses: stay alert pills, cough syrups, diet pills, motion sickness pills, smoking cessation products like nicotine gum or the patch, non-medical chemicals, other.

In addition, respondents were also asked the following question, which specifically addresses the abuse of NRT: 'Are you aware of students abusing smoking cessation products like nicotine gum or nicotine patches?' Responses: yes, no, don't know.

Circumstances surrounding reported student abuse of NRT were assessed from responses to the following open-ended question:

'I would like for you to give me some details about the abuse of nicotine replacement products. I want to get a sense of what's happening.' Interviewer prompts were to inquire if abusers were also tobacco users and what the circumstances of abuse were. The open-ended question was categorized as follows: tobacco users/use while smoking/use while cannot smoke, smokers trying to quit, and other circumstances.

Data Analysis

Means and percentages are reported for both survey years. The z-test was used to test for changes in reported abuse rates over time.

RESULTS

SDFSC had held their positions an average of 4.7 years and worked with an average of 4,500 students each averaged across both survey years. Eighty-five percent of respondents reported their district was predominantly middle class and about 75% of the student population serviced by counselors was Caucasian in both survey years (data not shown).

Reported abuse of NRT relative to other drugs available OTC is presented in Table 1. Diet pills, inhalants, and stay alert pills were the OTC drugs SDFSC most commonly reported awareness of student abuse in both surveys. Abuse of NRT was reported by 2.7% of SDFSC in 1996/7 and 4.6% of SDFSC in 1998/9 (p -value = 0.42). SDFSC reported rates of abuse increased for all specific types of OTC drugs between 1996/7 and 1998/9, except for the 'other' classification; however, inhalants was the only drug category that reached statistical significance at the 5% level.

Among the SDFSC who reported student abuse of NRT, the context of the abuse is reported in Figure 1. The vast majority of adolescents were using NRT while smoking or trying to quit.

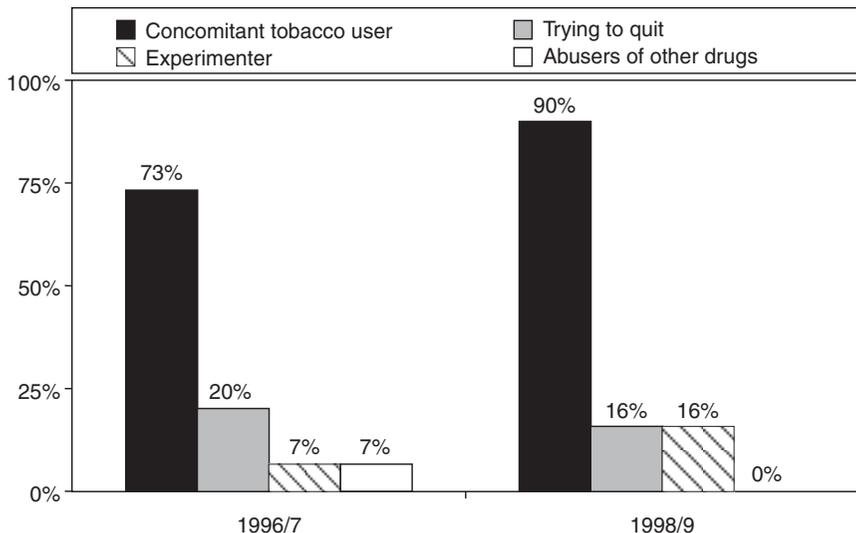
TABLE 1. Reports of abuse of OTC products by survey year.

Responses to the question, 'What over the counter drugs are abused, not alcohol or tobacco?'

Product	1996-7 (N = 562)		1998-9 (N = 501)		P-value*
	N	Percent	N	Percent	
Diet pills	138	24.6	145	28.9	0.42
Non-medicinal chemicals (inhalants)	111	19.8	167	33.3	0.01
Stay alert pills	125	22.2	140	28.0	0.27
Cough syrup	59	10.5	69	13.8	0.40
Motion sickness pills	44	7.8	48	9.6	0.60
Nicotine patch or gum	15	2.7	23	4.6	0.40
Other	61	10.9	32	6.4	0.18

* P-value for z-test of differences in proportions between the two time periods

FIGURE 1. Circumstances surrounding nicotine product abuse reported by Safe and Drug Free School Counselors, 1996/7 (N = 15) and 1998/9 (N = 19).



Definitions are based on the self-report of open-ended responses of SDFSC's. A concomitant tobacco user is a smoker who is also using NRT simultaneously but not trying to quit. Smokers who are using NRT in a quit attempt are in the 'trying to quit' category. An experimenter is a non-smoker who is using NRT. Those who are using NRT with other drugs are in the 'abusers of other drugs' category.

DISCUSSION

These data suggest that abuse rate of OTC NRT is low and is considerably less than the abuse rate of diet pills and other OTC substances.

This observation is consistent with two reports that estimate the prevalence of youth experimentation with the nicotine skin patch is about 1%^{6,8} and with the argument that increased OTC NRT has not caused widespread abuse of NRT among adolescents.

Few SDFSC reported abuse of NRT among students in their schools and most instances of abuse took place among smokers who used NRT when they couldn't smoke or if they were trying to quit. Furthermore, these data indicate that the availability of NRT OTC has not caused large numbers of non-smoking adolescents to use NRT as a means of obtaining nicotine and potentially initiating tobacco use. These data are in contrast to use of cigarettes in which two-thirds of adolescents experiment with cigarettes and one-third to one-half of these go on to become chronic and dependent smokers.⁹

This study is subject to a number of limitations. The operative measure used in this study was the abuse of NRT. Results may have been different if the use of NRT was queried instead; however, the rationale for using the term abuse is that it is consistent with the goals of the FDA when the switch to OTC was approved, which is to minimize adolescent abuse of NRT. It was apparent from the interviews that SDFSC interpreted abuse differently ranging from the unintended use of NRT to help with smoking cessation (e.g., smoke and use the patch simultaneously) to abuse for reasons other than smoking cessation. Therefore, the rates of NRT abuse reported in this paper are likely to overestimate abuse that is not related to smoking cessation. On the contrary, abuse rates reported in this paper may underestimate current abuse rates because NRT have been available OTC for a longer period of time. Data are reported from a sample of SDFSC and not on the direct report of adolescents, which is an important population to study for this topic. However, we view this as a complementary data collection method, which may have limitations but does offer the advantage of querying adults whose job is to have intimate knowledge of the substance abuse issues in their schools. The response rate to the 1996/7 survey was low; however, given the results were comparable to the 1998/9 data, it is unlikely that the low response rate has spuriously biased the sample.

Given the low rate of OTC drug abuse generally among adolescents and the low abuse potential for NRTs, gathering data directly from teens about their abuse of NRTs would require a very large sample. A sample

the size needed to detect and estimate the rate of such a rare behavior would have been very time-consuming and expensive.

Data presented in this paper from two cross-sectional national surveys of SDFSC suggest that few adolescents are abusing NRT. The important policy questions to be answered with additional research is to what extent should NRT be regulated to prevent misuse among adolescents and to what extent do these regulations inhibit utilization in the broader population of smokers. Relevant future research questions on this topic include more clearly defining the terms 'use' and 'abuse' of NRT and to assess the positive and negative outcomes associated with each, and to investigate the optimal set of FDA regulations that give widespread availability of NRT to those who are indicated for it but restrict access to those who are not.

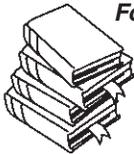
NOTE

1. It was the responsibility of the sponsor of this research, SmithKline Beecham Consumer Healthcare (now GlaxoSmithKline Consumer Healthcare), to determine whether it required an IRB approval. No academic researchers or sites were involved with the conduct of the research, and the research fulfilled a requirement set by FDA as a condition of the approval of OTC NRT products for marketers of such products to conduct surveillance on the possibility of adolescent misuse. FDA thus had oversight over the research. SmithKline Beecham determined that since the research did not involve the distribution of clinical supplies, and that the information being collected was from proxies (not the adolescents themselves but the coordinators), that the research did not require an IRB approval. It should be noted that Dr. Hyland did not participate in the design or conduct of the research, and was only involved with the analyses and interpretation of the results.

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