The Case for Hardening of the Target*

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INTRODUCTION Tobacco control efforts increased smoking abstinence up until 1990; however, in the mid-1990s, smoking prevalence rates and the U.S. per capita consumption leveled off and remained constant (CDC 1999b; Taylor 2001; see Chapter 8). Per capita consumption again declined in 1999 following the Master Settlement Agreement (MSA) and a subsequent increase in the cost of cigarettes. However, it is unclear whether this decline is a resumption of the previous trends or a one-time drop due to the increase in cost (see Chapter 8). The percent of ever-smokers who have quit (the quit ratio) increased from 1965 to the early 1990s but has changed little since then (Figure 2-1).

One explanation for this plateauing is that a selection bias is operating such that those smokers who found it easy to quit did so, leaving a more hardcore or hardened group of smokers (Hughes 1993) who had more difficulty achieving abstinence. The argument for such a selection bias is that since high dependence predicts low rates of cessation (Fagerström and Schneider 1989), the inevitable consequence is that, over time, remaining smokers will be those who are highly dependent. The only way this would not be true is if those new persons recruited to smoking were the same as those leaving smoking; i.e., if those recruited were destined to become the less dependent smokers. What is noteworthy is that the hardening hypothesis assumes that the level of dependence varies across smokers. Many politicians, public health advocates, and scientists have acted as if all smokers are victims of a ubiquitous addiction that occurs completely and immediately upon smoking initiation. In reality, adult smokers do, in fact, vary from no dependence to heavy levels of dependence (Giovino et al. 1995).

Two tests of the hardening hypothesis support it. One test involved a comparison of smoking prevalence and degree of dependence across European countries (Fagerström et al. 1996). In this study, those countries with a lower prevalence of smoking had higher nicotine dependence scores among remaining smokers than did countries with higher rates of smoking. The other test examined quit rates in published treatment outcome studies and found that quit rates decreased over time (Irvin and Brandon 2000; Irvin, Hendricks, and Brandon 2001) (see Chapter 4).

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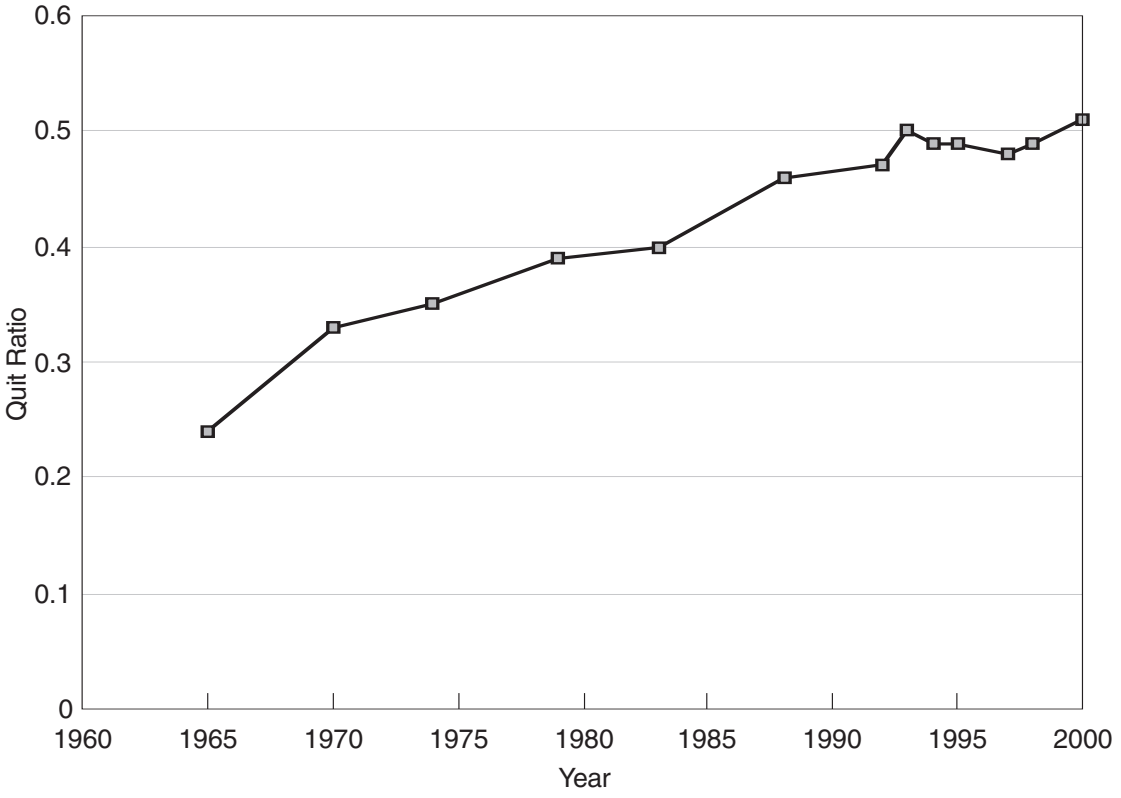
Figure 2-1
Quit Ratio by Calendar Year, 1965–2000



Percent of ever-smokers who had quit by the time of the survey (quit ratio) over time. Data from the National Health Interview Survey @ **www.cdc.gov/tobacco/research_data/adults_prev/tab_3.htm**

Changes in success rates per quit attempt over time have not been published. Data from the U.S. Current Population Survey (CPS) and the California Tobacco Survey (CTS) (Burns et al. 2000) was used to calculate the proportion of quit attempts in the last year that resulted in abstinence of 3-plus months. The success rate per quit attempt is calculated using the percent quit 3-plus months in the numerator and the percent who made a quit attempt in the denominator. This measure does not include either quit <3 months or occasional smokers, but the results are the same when these measures are included. This success rate hovers between 13.6% and 16.3%, with no discernable time trend between 1992 and 1999 for the CPS data.

In the CTS, success rate per quit remained stable from 1990 to 1996 (17% versus 16%). If the number of quit attempts among those who tried to quit has increased over time, this would mask a decline in success rates, but this effect is unlikely to be large enough to mask a meaningful decline. This evidence does not support a decline in the success rate per quit, but limitations on the length of time over which the rates are calculated means that it remains unclear whether success rates per quit attempt have changed over time.

The plateauing of smoking prevalence could possibly be due to a decline in the prevalence of quit attempts. The CPS data reports a decline in the prevalence of quit attempts in the year prior to the survey from 37% in 1992/93 to 32% in 1995/96 (Burns et al. 2000), but they rose again in 1998/99 (see Chapter 8). In California and Massachusetts where tobacco control programs were in effect, quit attempts declined slightly in California (33% in 1990 versus 31% in 1996) and were unchanged in Massachusetts (48% in 1993 and 1997) (Burns et al. 2000). Once again, a clear trend over time is not evident.

In this chapter, there are three points to be discussed: (1) why it is important to continue to test the hardening hypothesis; (2) why one must distinguish between indirect, inadequate tests of the hypothesis and direct, adequate tests of the hypothesis; and (3) why, even though this monograph focuses on dependence, the most important factors in any hardening may be psychosocial factors.

WHY IT IS IMPORTANT TO TEST THE HARDENING HYPOTHESIS

To understand the importance of the hardening hypothesis to tobacco control, it is helpful to first outline the role of cessation in tobacco control. Tobacco control has traditionally focused on prevention; e.g., the U.S. Centers for Disease Control and Prevention (CDC) recommends that only 21% to 33% of tobacco control money be spent on cessation (CDC 1999a). In the past, when tobacco control plans have focused on cessation, they have usually focused on motivating quit attempts and not on providing treatment.

In contrast, plans for the control of alcoholism or illicit drug use make providing for treatment a central component (NIDA 1999). In addition, these plans for controlling alcohol or illicit drug use clearly state that simply increasing motivation is insufficient; rather, drug-dependent individuals need treatment and some will need intensive treatment (NIDA 1999).

One of the reasons that tobacco control has avoided treatment is the myth that treatment is not efficacious and not cost-effective (Hughes 1999b). In terms of efficacy, several meta-analyses have concluded that many treatments for smoking double quit rates (Hughes 1996). Importantly, meta-analyses have found that, unlike alcohol dependence treatment, the efficacy of treatments for smoking cessation is dose-related; i.e., more intensive treatments do, in fact, result in higher quit rates (Fiore et al. 2000).

In terms of cost-effectiveness, therapies such as brief advice (with or without medications), telephone counseling, and over-the-counter (OTC) medications have all been shown to be cost-effective (Cromwell et al. 1997). In fact, provision of smoking cessation has been called the gold standard of cost efficacy as no other treatment in medicine has been able to match it (Eddy 1992).

A corollary myth among many tobacco control advocates is that even though cessation treatment may be cost-effective, prevention is more so. Empirical data to support this belief is lacking. Treatment is likely to be as cost-effective if not more cost-effective than prevention. If one induces a

smoker to stop smoking, the benefit of cessation begins within a year, whereas, if one induces a teenager not to start smoking, the benefit may not occur for 30 or more years. Economists observe that, due to discounting, $100 spent to obtain a given benefit next year is much more cost-effective than $100 spent to obtain the identical benefit 30 years from now (Warner and Luce 1983).

In contrast to tobacco control programmatic efforts, research on smoking behavior has adopted a much broader approach to the problem. Research efforts have examined clinical treatment as well as prevention and public policy interventions, and future directions include examining the interactions of genetic, biologic, psychologic, and sociologic factors in smoking behavior and resultant disease (NCI 1998, 2001).

Given this background on tobacco control and cessation, now let us assume the hardening hypothesis gathers sufficient evidence to become believable. The main implication would be that tobacco control should focus more on cessation; that is, tobacco control would need to reallocate program delivery funds from just motivating smokers to quit to actually providing treatment, including intensive treatment.

AN ADEQUATE TEST OF THE HARDENING HYPOTHESIS IS NEEDED

The major issue in assessing evidence for or against the hardening hypothesis is the validity of the measure of nicotine dependence used. Contrary to what many believe, there are widely accepted criteria of dependence; i.e., those recommended by the American Psychiatric Association's (APA) *Diagnostic and Statistical Manual: Fourth Edition (DSM-IV-R)* (APA 2000), and the almost identical criteria of the World Health Organization's (WHO) *International Classification of Diseases: 10th Edition (ICD–10)* (WHO 1992). These criteria focus on two aspects: physical dependence (i.e., tolerance and withdrawal) and psychological dependence (i.e., impaired control over drug use). Although the DSM/WHO criteria have been widely used in alcohol and illicit drug dependence research and practice, they have been used in only a few studies of nicotine dependence (Giovino et al. 1995). Thus data on their reliability and predictive validity in smokers is limited.

The most widely used measures of nicotine dependence are the Fagerström tests, i.e., the Fagerström Tolerance Questionnaire and the newer Fagerström Test for Nicotine Dependence (Fagerström and Schneider 1989). These measures combine queries about consumption and some indices of psychological dependence, and they predict the success of quit attempts and compensatory smoking (Fagerström and Schneider 1989). The item of the Fagerström scales that carries the most predictive power is time to the first cigarette of the morning, and this single item has been shown to have predictive validity (Kozlowski et al. 1994).

Cigarettes per day (CPD) is often used as a proxy measure for nicotine dependence, as evidenced by many of the chapters in this monograph. Such consumption measures are correlated with the probability of alcohol and other drug dependencies, but this correlation is much smaller than most believe (Mendelson and Mello 1985). In fact, it is noteworthy that the

amount of drug consumption is not part of the DSM/WHO criteria for dependence on any drug.

One major problem with CPD is that it actually is a nonspecific measure of the dose of nicotine (and smoke) received by the smoker (e.g., the correlation between CPD and nicotine levels is usually $r < 0.50$) (Benowitz 1983). This is because the way a smoker smokes a cigarette (number of puffs, puff volume, for example) is as important as CPD in determining nicotine consumption. Another problem with CPD is that currently in the United States many variables other than dependence have large effects on CPD (Evans, Farrelly, and Montgomery 1999). For example, there may be many highly dependent smokers who would like to smoke 40 CPD but can only smoke 15 CPD due to increasing cost and worksite and home restrictions on smoking. There is some evidence that social policy changes, such as tax increases, may be accompanied by compensation in the way individual cigarettes are smoked such that declines in CPD do *not* produce a proportional decrease in nicotine intake (Evans and Farrelly 1998), again suggesting CPD may be an imprecise measure of intake or dependence.

Currently, only Fagerström scores, and perhaps the time to the first cigarette, are adequately validated measures of nicotine dependence. The problem is that the majority of data sets one could use to examine the hardening hypothesis only include CPD. It could be argued that CPD is still an adequate measure to test the hypothesis because, with large data sets, a very accurate measure of dependence is not needed, and a measure somewhat related to dependence would be adequate. However, in reality, CPD is poorly correlated to nonconsumption measures of dependence. For example, the correlation between CPD and Fagerström scores (minus CPD) is only $r = 0.33$, and the correlation of CPD with the number generated by the DSM/WHO criteria is only $r = 0.23$ (Riggs and Hughes 1999). Thus, when tests of the hardening hypothesis use CPD and give negative results, one must entertain the real possibility of false negative results due to measurement error.

DEPENDENCE MAY NOT BE THE MOST RELEVANT CAUSE OF ANY HARDENING

Several variables other than the variable of dependence predict lower rates of cessation: lower income, psychological comorbidity, younger age, lower education, alcohol/drug problems, stress, certain occupations, and other smokers in the household, for instance (U.S. DHHS 1990). Thus it is probable that future smokers are more likely to be the poor or those with minor or major psychological or other problems (Hughes 1999a), and it may be changes in these factors, not dependence, that account for hardening. Thus it is important to include these factors, as well as dependence, when testing the hardening hypothesis. Also, if psychosocial factors are driving the hardening, then instead of providing treatments tailored for heavily dependent smokers, we may need to provide treatments focusing on the special problems of the poor (e.g., improving access to treatment), on problems with other smokers in the household (e.g., how to handle a smoking spouse), or on more effective and tailored prevention.

SUMMARY Tobacco control advocates should be proud that they have dramatically changed society's view of smoking. But every businessman knows that as the society changes, the characteristics and needs of their clients change. It would be quite foolish for tobacco control advocates to assume the same is not true for their clients, i.e., smokers. Thus, in reality, the question is not whether the target is hardening but rather, how the remaining smokers are changing and whether they changed enough to necessitate changes in our tobacco control efforts. We should not rely on imprecise measures of dependence (e.g., studies using CPD as a measure of dependence) to prematurely make what has a good chance of being a false negative or false positive decision. Rather, new studies with good measures of dependence and those other factors that might be changing over time are needed. Marketers do this type of "characterizing the changing market" all the time. Why shouldn't those in tobacco control do the same?

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