

Introduction

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The decline in U.S. smoking prevalence since the publication of the first Surgeon General's Report in 1964 has been hailed as one of the greatest public health accomplishments of the past century (Warner 2001). Forty-four million Americans—almost half of those who ever smoked—have quit, and lung cancer death rates have decreased greatly as a result. As a nation, we've launched wide-reaching tobacco control programs in worksites, schools, communities, and all 50 states, and we've witnessed enormous shifts in social norms, policies, and public attitudes. Growth in clean indoor-air laws and smoking restrictions have made quit-smoking cues "persistent and inescapable" (Glynn, Boyd, and Gruman 1990), and new data shows that tobacco price increases and mass media cessation campaigns can significantly increase population quit rates (CDC 2001). Over the last three decades, we have developed effective clinical treatments—psychosocial and pharmacological—and seen the publication and update of authoritative practice guidelines recommending evidence-based treatments that, if universally applied, could double our national annual quit rate in a highly cost-effective way (Cromwell et al. 1997; U.S. DHHS 2000). Prospects for preventing and treating tobacco use and addiction have never been better.

Yet the papers in this monograph, *Those Who Continue to Smoke: Is Achieving Abstinence Harder and Do We Need to Change Our Interventions?*, raise important questions about what it will take to build on the successes of the last century and, in particular, on the last few decades of research and practice. While efforts to promote tobacco cessation need to be part of a much broader national tobacco control strategy that emphasizes prevention, it is clear that the greatest gains in reducing tobacco-caused morbidity, mortality, and health care costs in the next 30 to 40 years will come from helping addicted smokers quit (Orleans 1997). Further declines in adult smoking are likely to strengthen prevention efforts as well, since adult smoking is a critical determinant of social norms and a vector for youth initiation.

In this context, the findings presented in this monograph have important implications for the next generation of research and practice to help addicted smokers quit. Specifically, these papers and the findings they present indicate that helping more smokers quit will require: (1) developing more powerful treatments that can break through the 25% to 30% quit-rate ceiling achieved with our best existing treatments; (2) refining, targeting and tailoring treatments for high-risk populations; (3) greatly improving surveillance of quitting patterns and determinants; (4) developing combined

clinical-public health approaches that harness synergies between evidence-based clinical treatments, and macrolevel policy and environmental cessation strategies; and (5) improving the use of and demand for treatments that work.

**IS THE TARGET HARDENING?
ARE SMOKERS LESS LIKELY TO
QUIT NOW THAN IN THE PAST?**

This is the central question addressed in different ways by each of the papers in this monograph. Surprisingly, none of the papers presents compelling evidence that this is the case. But each paper offers unique insights into what it will take to raise success rates of individually oriented and population-based approaches.

Burns and Warner (see Chapter 1) approach this question by carefully operationalizing the hardening construct and then testing the hardening hypothesis against available national Current Population Survey (CPS) and National Health Interview Survey (NHIS) data, 1964 to 1999, as well as against data from the California Tobacco Survey (CTS), 1990 to 1999, and the Community Intervention Trial for Smoking Cessation (COMMIT). Their thoughtful paper asks clear questions and gives us mostly clear answers:

- Is there epidemiological evidence that the nation's annual quit rate is falling? No, not at present.
- Is there epidemiological evidence in the United States for decreased cessation rates among groups in which more ever-smokers have quit? No.
- Is there epidemiological evidence that levels of dependence, estimated by cigarettes per day or score on the Fagerström Tolerance Questionnaire (1994), have increased in the United States as prevalence has decreased? No.
- Is there epidemiological evidence among current smokers for increased psychiatric comorbidity among current smokers? The answer here is uncertain, given the lack of systematic surveillance. However, new data from the National Co-morbidity Study (Lasser et al. 2000) shows that patients with diagnosed psychiatric disorders—ranging from anxiety disorders, phobias, and dysthymia to other chemical dependencies to major depressive disorder and schizophrenia—are twice as likely to smoke and currently consume approximately 50% of the cigarettes sold in America. However, Lasser et al. (2000) point out that lifetime quit rates for these smokers are also fairly respectable (ranging from 27% to 34% compared with 43% for smokers with no history of mental illness).

And finally, Burns and Warner highlight the growing concentration of smokers in low socioeconomic status (SES) groups. However, in the absence of evidence that low-SES smokers are any less likely to quit than those in higher income groups when offered proven treatments or exposed to effective cessation policies and environmental influences, it is difficult to conclude support for the hardening hypothesis from these findings.

Hence Burns and Warner conclude that the hardening hypothesis should continue to be tested, and evidence that hardening is actually occurring should be required before it is used as a justification for changing current tobacco control strategies.

Burns' and Warner's paper also raises some important questions about language. They wisely cite John Slade's caution about the use of hardening as a term that could be construed to be demeaning or dismissive of people's quit attempts. Moreover, their findings suggest that a better question for understanding and addressing the challenges of increasing our national quit rate might be "is the target *changing?*" Substituting the word "changing" for "hardening" immediately brings a wider range of solutions into view, pointing not only toward future treatments that might be more intensive but also toward those that might be more effective or better tailored, packaged, promoted, and priced to reach their target populations.

Irvin and Brandon (see Chapter 4) offer another creative and rigorous approach to testing the hardening hypothesis: reviewing published cessation trials conducted in the United States to examine whether success rates have declined. For cognitive-behavioral multicomponent treatments published between 1977 and 1996, they found significant declines in reported end-of-treatment, 3-month, and 6-month (but not 12-month) abstinence rates—with mean 6-month quit rates declining about 10 percentage points, from over 40% to about 30%. Somewhat similar patterns were observed for trials of nicotine gum (1984 to 1996), transdermal nicotine (1990 to 2000), and varied placebo treatment conditions (1983 to 1999).

However, while they carefully examined and attempted to control for a range of potentially confounding and mediating variables (e.g., mean age, years smoked, daily smoking rate, Fagerström Tolerance Questionnaire scores), Irvin et al. point out that they may have missed key mediating variables (especially those related to nonspecific treatment effects) and had limited statistical power to detect mediation effects. In fact, it is quite possible that early adopters of these treatments (both smokers and clinicians) brought higher treatment expectations than later adopters, and that those smokers who were among the first to try each of these treatments had higher treatment-related self-efficacy based on fewer past, unsuccessful quit attempts or treatment experiences. Moreover, while these trials were conducted during periods of significant decline in national adult smoking prevalence, participants represented a very small subset of all U.S. smokers who tried to quit. The 1986 Adult Use of Tobacco Survey (AUTS) found, for instance, that only 30% of smokers tried to quit that year, and that only 10% to 15% of them used any formal treatment (2% to 4% counseling, 3% to 12% nicotine gum) (Fiore et al. 1990). Hence these published treatment studies provide limited insight into national quitting patterns and practices. Irvin and Brandon conclude that they cannot establish that their findings are consistent with the "population target hardening" theory.

**ARE WE SEEING A
HARDENING OF THE
POPULATION? OR A
HARDENING OF OUR
INTERVENTIONS?**

The clear look we get from Irvin and Brandon (see Chapter 4) at the performance of the same basic (essentially unchanged) treatments in published reports dating back 25 years, and over periods of time ranging from 10 to 19 years, begs a more fundamental question: is it our *smokers*, or our *treatments*, that have hardened? As Shiffman pointed out in his landmark 1993 paper (Shiffman 1993), behavioral intervention quit rates plateaued in the 1980s after a period of rapid innovation and improvement in the 1970s. Shiffman concluded in 1993 that behavioral cessation research “was in a rut” and challenged the field to renewed innovation. A few years later, Rimer (1997) pointed out that behavioral medicine research in general was suffering from “a hardening of the theories”—reflecting a growing tendency to abandon both formal theory testing and new theory development. And Piasecki and Baker (2001) recently reached a very similar conclusion, noting that not much had changed since Shiffman’s review and concluding that “the rut had deepened.”

Each of these reviews makes it clear that we will need to reinvigorate the science base driving treatment research if we are to develop new clinical treatments that can break through current 25% to 30% quit-rate ceilings. This will require new theory and more creative application of existing theory to expand beyond reliance on the handful of cognitive behavioral theories and models on which most recent tobacco dependence treatment research has been based (Orleans 1997). Progress also is likely to come from examining new combinations of pharmacologic and behavioral treatments, developing treatments that are biologically and developmentally tailored as well as environmentally and culturally tailored, and making tobacco dependence treatments more holistic by addressing related lifestyle risks and comorbid conditions. A return to the study of how today’s smokers actually quit and how they use existing treatments could furnish important new insights.

Innovative transdisciplinary research efforts, like those supported through the new Tobacco Use Transdisciplinary Research Centers (TUTRCs), cofunded by the National Cancer Institute, the National Institute on Drug Abuse, and the Robert Wood Johnson Foundation, are promising incubators for discovering more powerful approaches to tobacco dependence treatments and public health cessation strategies. Research that bridges the clinical and public health domains, connecting the science of individual behavior change (i.e., individually oriented tobacco dependence treatment) with the science of population-based cessation (i.e., policies and environmental influences that promote cessation in organizations, communities, or larger populations), could be equally transformative—pointing us not only toward more effective treatments and cessation interventions but also toward more effective dissemination strategies to spread their use and application.

WHAT CAN WE LEARN FROM AND ABOUT SPECIAL POPULATIONS? HOW CAN BETTER SURVEILLANCE HELP US TO DESIGN BETTER TREATMENTS AND DISSEMINATION EFFORTS?

At the 2002 Society for Research on Nicotine and Tobacco meeting, Gary Giovino presented a systematic overview of the epidemiology of quitting in America, based on analysis of trends from 1965 to the present in several national data sets (CPS, NHIS, National Household Survey on Drug Abuse, and Monitoring the Future), which

confirms a slow but continuing rise in our national annual quit ratio for most adult smoker populations. Trend analyses (national and state) of cigarettes per day and some-day smoking do not indicate hardening. And, despite suggestive evidence for a slight increase in indicators of addiction from 1985 to 1994, trends in measures of dependence do not support the view that U.S. tobacco control efforts have led to proportionately more quitting among less dependent smokers or left behind a population of proportionately more dependent smokers (see also Giovino 1996).

Perhaps most provocative, however, are NHIS data showing much higher quit ratios for some groups than others. Adults aged 18 to 24 and 25 to 44 have the highest rates of current smoking prevalence and lowest quit ratios, while those aged 65 and over and 45 to 64 have the lowest rates of current smoking prevalence and highest quit ratios. Similarly, smoking prevalence is highest and quit ratios are lowest among Americans with fewer than 12 years of education compared with those having a college education or higher. Similar findings have been reported for racial/ethnic minority adult populations (e.g., Boyd et al. 1998; Gilpin et al. 2001). These stark contrasts underscore the need to target and tailor our interventions better to these high-risk groups.

The contrast most germane to the target-hardening hypothesis is that between older adults (65 and over) and young adults (aged 18 to 24):

- Older adults represent a population in which the prevalence of smoking has declined to a very low level (10.6% in 2000) and thus comprises a group in which the most “hardening” should have occurred, a group with the greatest potential recalcitrance to standard treatment approaches. However, with access to in-depth national surveillance data from the 1986 AUSTS (Fiore et al. 1990)—which clarified how older adults tried to quit, thought about quitting, what their misconceptions were (e.g., “it’s too late to quit”), and identified covariates of successful quitting—we were able to develop population-targeted self-help and primary care treatments designed specifically for them that produced quit rates as high, if not higher, than those seen with the same general approaches in younger populations (e.g., Orleans et al. 1994; Rimer et al. 1994). A strict target-hardening theory would have predicted poorer outcomes.
- In contrast, younger adult smokers, with the highest smoking prevalence (27.9% in 2000), represent the group in which, by definition, the least hardening has occurred. Yet quit rates with standard treatment approaches (counseling, pharmacotherapy)

effective for most adult populations have proven ineffective and unappealing with these younger smokers (Sussman 2002), likely reflecting the different determinants of quitting motivation and success in this population. Unfortunately, given the dearth of national survey data on youth quitting determinants and practices, we are handicapped in developing treatments to better assist them.

The interesting contrast in treatment recalcitrance between these two groups, older and younger smokers, not only challenges the hardening hypothesis but also points strongly to the need for much better surveillance of current quitting motives, barriers, and practices among all smoker populations in the United States. Such survey data could be systematically used to develop more appealing treatments and more effective methods for promoting their use in the targeted populations (Boyd et al. 1998). Without such data, we are working very much in the dark to help more smokers quit.

Systematic longitudinal, nationally representative surveys could help us to engineer more effective treatments and public health cessation strategies and systematically evaluate impacts of varying public policy and environmental interventions. Such surveillance is especially critical now, given the emergence of new so-called reduced-harm tobacco products. Marketed as safe alternatives to quitting, these products may lure many would-be quitters away from serious quit attempts and existing treatments. Monitoring these trends nationally is essential. Improved cessation surveillance should include a special focus on high-risk populations—including youth, racial/ethnic minorities, low-SES groups, as well as smokers with psychiatric comorbidity (Lasser et al. 2000). It is not reasonable to assume that one size fits all when it comes to motivating and assisting smokers to quit, and these populations continue to merit special targeting.

To begin to address neglected surveillance needs, the Robert Wood Johnson Foundation, the Centers for Disease Control and Prevention, and the National Cancer Institute (NCI) are cofunding a youth cessation panel study that will, beginning in 2003, longitudinally follow smokers aged 16 to 20 over two years, and the NCI has identified the need for prospective observational studies of quitting and relapse processes in its 2004 bypass budget. However, more extensive efforts are needed. Comprehensive sustained surveillance would provide the compass we now lack to reach the 2010 quitting goals we have set for the nation (U.S. DHHS *Healthy People 2010*).

**IMPORTANCE OF
WIDENING THE LENS—
COMBINING CLINICAL
AND BROADER
POLICY-BASED AND
PUBLIC HEALTH
APPROACHES AND
BUILDING CONSUMER
DEMAND**

Hughes' paper (see Chapter 2) underscores the need for broad-spectrum approaches that combine effective clinical treatments with effective policy and environmental approaches. The past three decades of research have given us vital resources, two sets of evidence-based tobacco intervention guidelines on which we can draw to find new and better ways to help addicted smokers quit: (1) clinical practice guidelines for treating tobacco use and dependence (U.S. DHHS 2000),

and (2) public health guidelines for policy and macrolevel environmental strategies that can help spur quitting by changing the larger social and political contexts in which smokers live and work (e.g., tobacco price increases, smoking bans and restrictions, mass media campaigns, policies that reduce smokers' out-of-pocket treatment costs) (CDC 2001).

Hughes (see Chapter 2) proposes that raising tobacco prices, cessation-oriented media campaigns, and provider advice may have primary impacts on smokers' quitting motivation and attempt rates, while improving treatment efficacy and access may primarily affect quitting success rates among those who make attempts. Unfortunately, without systematic and ongoing cessation surveillance, it is difficult to test these hypotheses, to assess the differential effects of policy and treatment advances on our national quitting profile, or to understand the mechanisms through which these different strategies exert their influence.

As a nation, we have only just begun to understand how to implement these clinical or public health strategies fully or to capitalize on the synergy between them. Lessons learned from states with comprehensive tobacco control policies and programs (e.g., California, Massachusetts, and Oregon) offer vital clues and inspiration. California provides one of the nation's most important laboratories for these kinds of studies (Warner 2000) and serves as a model for the nation.

Elements of California's comprehensive 12-year Tobacco Control Program have included: a statewide smokers' telephone helpline, antitobacco media campaigns (including those designed specifically to motivate quitting and helpline use), local smoking cessation programs, increases in insurance coverage for nicotine pharmacotherapy, clean indoor-air laws, campaigns educating smokers about the dangers of environmental tobacco smoke, tobacco tax increases and enforcement of youth access laws (Fichtenberg and Glantz 2000; Gilpin et al. 2001). These initiatives led to a spontaneous grassroots movement supporting voluntary in-home smoking bans across the state. In fact, 25% of smokers in California now live in smokefree homes, and they report higher quit attempts and quit rates (Gilpin et al. 2001).

While we know little about which of these statewide program elements, alone or in combination, was most responsible for California's rising quit rates, and even less about the mechanisms of change (e.g., exactly how in-home smoking bans are helping more smokers quit), we do have evidence that this comprehensive strategy has worked. From 1989 to 1997, adult smoking prevalence in California dropped 33% compared with 22% in the rest of the country. Rates of lung cancer declined 14% (compared with 4% in the rest of the country), and an estimated 33,000 cardiovascular disease deaths were prevented. Through reduced health care costs, a \$3.62 return was estimated for every \$1.00 invested (Fichtenberg and Glantz 2000). The NCI monograph *Population-Based Smoking Cessation* (NCI 2000) projected that if comprehensive tobacco control programs like California's were implemented nationally, quit rates would increase by one-third every year, creating 500,000 new ex-smokers annually.

Consistent with the data Burns and Warner (see Chapter 1) present for declining addiction levels among California smokers over the last decade, the most recent state survey data (Gilpin et al. 2001) indicate that California's lower smoking prevalence has been accompanied by a softening rather than hardening of the smoker population. The proportion of light smokers (<15 cigarettes per day) increased from 44% in 1990 to 60% in 1999. Smokers reporting serious past-year quit attempts rose from 49% in 1990 to 62% in 1999. The percentages of attempting quitters who succeeded (24%) and of so-called "hardcore" smokers who reported never expecting to quit (10%) were similar in 1990 and 1999.

Finally, California's results, while very encouraging, also demonstrate the need to dramatically widen the reach, use, and appeal of effective treatment services in order to take full advantage of the softening that has occurred. The proportion of quitters using any formal quitting aids rose only 4 percentage points, from 18% in 1990 to 22% in 1999, and rates of physician advice to quit rose only 8 percentage points, from 38% to 46%, during the same period (Gilpin et al. 2001). These rates may in fact be higher than (unknown) national rates, but they are not high enough, especially in underserved low-income and minority populations (Fiore et al. 1990; Gilpin et al. 2001). At the same time that we are investing in research to discover more powerful clinical treatments and public health cessation strategies, we could realize a more rapid return on investment from parallel efforts to improve the reach and appeal of existing treatments and to boost consumer demand for them (Orleans 2001).

In studies and in situations in which we've succeeded in expanding treatment coverage and reducing smoker out-of-pocket costs, we've found that only a minority of smokers come forward (Curry et al. 1998; Mordavsky et al. 2002)—evidence that more can be done to market our treatments effectively or design (or redesign) them for wider use and appeal. Media campaigns to promote quitting or quitline use, both in general populations and in smoker subgroups (African-American smokers, HMO enrollees, and pregnant smokers), have been very successful in getting smokers to call for help. And those who do call quit at predicted rates (Boyd et al. 1998; CDC 2001). In fact, media cessation campaigns are recommended by the Centers for Disease Control and Prevention (CDC) as an effective cessation strategy (CDC 2001). But, to date, we have invested relatively little energy and dollars in these media strategies or in other forms of creative-treatment marketing or packaging to boost consumer demand. In contrast, our competition, the tobacco industry, invests over \$8 billion a year marketing cigarettes and tobacco products (FTC 2001).

Going forward, we need to pursue a two-part strategy—striving both to discover new, more powerful treatments and to get better results from disseminating the proven, science-based interventions we have developed. Just as we need transdisciplinary basic biobehavioral research to discover new quitting approaches, so do we need to bring fresh new perspectives to bear from business, marketing, product design, economics, communications, even new dissemination science to study how quitters actually use our best evidence-based treatments, to reinvent and repackage them for

greater appeal, use, and efficacy. Even small pilot grants to interdisciplinary teams might lead to breakthrough product packaging or delivery improvements that could incorporate what we know to be the most effective treatment elements, comply with U.S. Public Health Service (PHS), CDC, and Food and Drug Administration (FDA) guidelines, and prove to be more widely applicable and cost-effective. These and other dissemination-focused initiatives now being launched or planned by a variety of funders—including the National Partnership to Help Pregnant Smokers Quit (2002) and the *National Blueprint for Disseminating and Implementing Evidence-Based Clinical and Community Strategies to Promote Tobacco Use Cessation* (AHRQ 2002)—could allow us to more fully harvest the fruits of past intervention research and capitalize on the unprecedented potential for social and financial support for smokers' quitting efforts.

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