

Quitlines and Nicotine Replacement for Smoking Cessation: Do We Need to Change Policy?

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Abstract

In the past 20 years, public health initiatives on smoking cessation have increased substantially. Randomized trials indicate that pharmaceutical cessation aids can increase success by 50% among heavier smokers who seek help, and use of these aids has increased markedly. Quitlines provide a portal through which smokers can seek assistance to quit and are promoted by tobacco control programs. Randomized trials have demonstrated that telephone coaching following a quitline call can also increase quitting, and a combination of quitlines, pharmaceutical aids and physician monitoring can help heavier smokers to quit.

While quit attempts have increased, widespread dissemination of these aids has not improved population success rates. Pharmaceutical marketing strategies may have reduced expectations of the difficulty of quitting, reducing success per attempt. Some policies actively discourage unassisted smoking cessation despite the documented high success rates of this approach. There is an urgent need to revisit public policy on smoking cessation.

NRT: nicotine replacement therapy

INTRODUCTION

For more than 50 years, reducing morbidity and mortality from cigarette smoking has been a high public health priority (64, 79). The 1989 review of the first 25 years of the public health campaign against smoking (82) noted that there was a consistent gradual increase in successful quitting through 1987. It identified that the reduction in smoking could have been faster if the very high rate of relapse after quit attempts could be reduced. That almost 90% of quit attempts were unassisted (28) suggested that developing effective assistance programs could have a major tobacco control impact.

The 1990s saw a number of innovations to increase the effectiveness of tobacco control. Following the success of a mass media tobacco control program in Australia (24, 58), California introduced the world's first comprehensive tobacco control program (6). The compelling logic of a funded public health effort coordinating tobacco control led to dissemination of this approach even before it had been shown to be effective (56, 60). During this period, pharmaceutical companies developed nicotine replacement therapy (NRT) (initially available in the United States by prescription) that tested well in trials (68) and appeared to have a positive impact on population cessation (57). In 1996, NRT was approved to be generally available as an over-the-counter (OTC) purchase. It was widely marketed and use during quit attempts increased, leading an earlier *Annual Review* article to publish high expectations for a major effect on population behavior (67). Following demonstrations that telephone coaching by quitlines could increase quitting (95), quitlines were rapidly incorporated into tobacco control programs to assist smokers who responded to mass media advertising on quitting. This article reviews the development of these initiatives and presents evidence from population studies that address how they have influenced population cessation. Finally, we address a series of critical questions related to public health effectiveness.

THE CESSATION PROCESS

Many published randomized trials have tested interventions to help smokers successfully quit (71–73). Across numerous studies, the probability of relapse has been inversely related to the duration of the quit attempt (81). For those who have been quit continuously for 12 months, the relapse rate is ~5% (35), leading one year to be used as a marker of successful cessation. In the United States, the average successful quit rate (1+ year) was a low 3.4% per year across the 1990s (45).

The earliest texts in psychology include chapters on breaking habits, sometimes modeled after experience with opium dependence. In 1890, William James (39) laid out a series of maxims for dependent behavior that were widely recognized then and that still hold today. Success requires that the smoker (*a*) make a strong resolution to change, (*b*) act quickly on that resolution, (*c*) make a personal commitment to another to be successful, and (*d*) understand the danger that a single lapse will seriously diminish chances of success.

Meta-analyses have shown that a 50–100% increase in successful quitting can be achieved with cognitive behavioral therapy interventions, most of which include the above maxims (65) and interventions involving nicotine replacement (72), other pharmaceutical aids (12), and quitlines using telephone coaching (73). Variables known to reduce success include (*a*) heavier consumption/higher dependence levels and (*b*) presence of another smoker in the home, particularly when the home is not smoke-free (34).

NICOTINE REPLACEMENT THERAPY

Very early relapse has been associated with nicotine withdrawal symptoms (81) such as anxiety, anger, difficulty concentrating, mood disturbance, sleep disruption, and weight gain (2). These effects may occur because of abrupt vacating of nicotinic receptors that had been continuously occupied during chronic

smoking (52). NRT has reduced nicotine self-administration by animals as well as craving and withdrawal symptoms in humans (38).

In the early 1980s, the U.S. Food and Drug Administration (FDA) approved nicotine gum as a physician-prescribed cessation aid to be used in conjunction with a behavioral program (27). The nicotine patch was added to this list in the early 1990s and allowed for sale without a prescription in 1996. Many of the early trials included at least one and often multiple brief telephone coaching calls along with the pharmaceutical aid (44). Although there has been debate about bias in different trial designs and the role of the funder as an influence on trial outcomes (25), investigators generally agree that the evidence from NRT trials indicates that cessation can be improved by at least 50% in heavy smokers who seek assistance to quit (72). When NRT went OTC in 1996, it was accompanied by a significant pharmaceutical company mass media marketing campaign; the proportion of smokers using it as a cessation aid more than doubled, and this new level of usage was maintained over time (67).

However, a cautionary note came from two studies: One demonstrated that the population rate of relapse following quitting did not change in the six years following the widespread dissemination of NRT as an OTC medication (55), and the other followed smokers who were offered free nicotine patches if they participated in the health department's "Stop Smoking for Life" group behavioral cessation program (1). As hoped, the addition of free NRT resulted in a significant increase in quit attempts (38% to 65%); however, this initial increase in product reach did not result in increased sustained abstinence, suggesting that the success per attempt might be the opposite of that observed in the randomized trials. This evidence raised the possibility that the increased usage of NRT may have come from recruitment of a population of smokers who were not involved in the clinical trials—such as less-dependent smokers (68)—or that there had been a change in the population willingness to persevere with a quit attempt.

THE DEVELOPMENT OF TOBACCO CONTROL PROGRAM QUITLINES

Starting in 1983, the first tobacco control program in Australia used paid antismoking television commercials tagged with a quitline number. Following Dubren (23), this quitline provided a prerecorded motivational message and information on local cessation services (54). In the United States throughout the 1980s, the Office on Smoking and Health tagged public service announcements with the 1-800-4-Cancer number, where the smoker could access a health professional for brief advice (5). Both programs showed that television advertisements could effectively motivate large numbers of smokers to call for help (53, 54).

Both Shiffman (66) and Ossip-Klein et al. (51) reported significant increases in abstinence rates when a cessation program involved a live telephone coach. The first randomized trial of more than 2,000 smokers was reported by Orleans and colleagues (50). Following Lando's recommendation (42), this "Free and Clear" program used lay coaches to provide four proactive motivational calls scheduled at 6, 16, 32, and 64 weeks after quitting. A 50% increase in cessation was observed at the 8-month follow-up (after only two calls), and this persisted through the 16-month follow-up. At 16 months, 18% of the telephone coaching group reported being abstinent for at least 6 months.

Initially, the California Tobacco Control Program funded a randomized trial proposal by Pierce to test the effectiveness of lay telephone coaches in promoting successful cessation among smokers who called a quitline in response to a media message. A California protocol, which focused on self-regulation (7) and framing of decisions (76), was developed (96). The study compared a self-help control group with single and multiple contact interventions. The single-call intervention was a 40-min call that used a client-centered counseling approach (63) to review smoking and quitting history. A critical component was to build motivation and

to obtain a commitment to make a near-term quit attempt, as suggested by James's maxims (39). The intensive intervention group received five additional calls in the first month following quitting using a relapse-sensitive schedule (94). These calls emphasized goal-setting, positive reframing of attempts to quit as successes rather than failures, and identification of strategies to resist future cues to smoke. Theory suggested that such a protocol would increase self-efficacy and perseverance with the change attempt (8). Using 12-month continuous abstinence, Zhu et al. (95) demonstrated that, compared with the self-help control group, the intensive intervention group was 83% more successful, and the single-call intervention group was 39% more successful. As a result, the California Smokers' Helpline became a core service of the California Tobacco Control Program. Zhu et al. (92) subsequently embedded a randomized trial within the English- and Spanish-language California Smokers' Helpline service. The protocol called for six counseling calls over the first month of quitting. The coaching protocol was provided to 72% of the treatment group; however, 32% of the control group also received an average of 3 coaching calls. At 12 months, continuous abstinence was 32% higher for the intervention group compared with the control group (9.1% versus 6.9%). The efficacy of this California protocol has been demonstrated for African Americans (93) and culturally and linguistically adapted versions have been demonstrated to be effective with Chinese, Korean, and Vietnamese speakers (91). These results have provided empirical support for quitlines as an appropriate intervention for underserved U.S. populations.

A recent Cochrane review (73) identified 65 trials of telephone coaching and focused on the effectiveness of different numbers of coaching calls in interventions. Many studies used repeated short motivational interviews following a modified version of the "Free and Clear" 1991 study. Some used the California protocol, whereas others mainly promoted the use of pharmaceutical aids in the cessation

attempt. Although such diversity of approach made meta-analysis difficult, this review determined that, overall, telephone coaching was helpful to smokers who wanted to quit, with some evidence of a dose response. Quitlines that provide assistance to smokers who call for help appear to have been more effective than those that used direct recruitment strategies or contacted a patient following a health-provider referral received by fax (77).

The Current Status of Quitlines

Quitlines are now available throughout North America, Europe, and Asia. As of November 2004, U.S. tobacco users could access their state quitline through a single national portal (1-800-QUITNOW), which is promoted widely across the nation (4, 43). The quitlines in the United States, Canada, and Mexico participate in the North American Quitline Consortium, which states its mission is to "maximize the access, use, and effectiveness of quitlines; provide leadership and a unified voice to promote quitlines; and offer a forum to link those interested in quitline operations" (48).

All the European Union countries and many of the accession countries have quitlines, and 27 countries participate in the European Network of Quitlines. Representatives from quitlines in Australia, New Zealand, Hong Kong, Taiwan, Korea, Singapore, and Thailand have recently formed the Asia Pacific Quitline Network to share lessons learned and to provide a forum for research related to quitlines.

In the United States, more than 500,000 tobacco users called state quitlines in fiscal year (FY) 2009, an increase of almost 130% from FY 2005 (9). Calls to the quitline represent a population response to a tobacco program's cessation initiatives. The number and mix of callers can indicate how well the program has communicated its message. Quitlines can have broad appeal to tobacco users, and callers have relatively high representation from populations that are traditionally underserved such as tobacco users from ethnic and linguistic minority groups (93). Similar results were found from

quitlines in California, Texas, Louisiana, and Washington, DC (93, 61).

Potential Developments with Quitlines

A recent review (37) identified a number of Internet and mobile phone text-messaging interventions (29, 30, 36) aimed at assisting smokers to quit. Many are focused on teens or young adults, subpopulations who are heavy users of these technologies. Brendryen (11) recruited via Internet advertisements and randomized participants to an intensive 54-week intervention that consisted of more than 400 contacts by email, Web pages, interactive voice response, and short message service (text-messaging) technology. Although the intensive intervention encouraged NRT use, it was not associated with more smokers using NRT, only with longer use by those who did use NRT. However, in this study, NRT usage did not mediate the treatment effect, which was a 60% increase in quitting for at least 7 days at 12-month follow-up. Another trial, Txt2stop, enrolled 5,800 U.K. smokers who were randomly assigned to the text-messaging program (motivational messages and behavior change support over a 26-week period) or who received text messages unrelated to quitting smoking (30). Results confirmed the utility of mobile phone messaging. At six months, the text program condition had double the biochemically verified success rates compared with the control condition. The U.S. Department of Health and Human Services recently recommended the use of text messaging and mobile phone applications as a way to improve public health. The National Cancer Institute has launched two mobile smoking cessation services to augment their Web site (<http://www.smokefree.gov>). One program, SmokeFreeTXT, is for teens and young adults. Enrollees receive text messages related to quitting and staying quit. The other program, QuitNowTXT, is an interactive text-based program for adults; it provides for automated text messages but also includes personalized

advice if participants respond to periodic assessment questions. Text services are also being used as a way to extend the telephone-based counseling service. A recently announced partnership of the largest U.S. quitline operation (Alere Wellbeing, Inc.) and the mobile technology company (Voxiva) that created Text2Quit provides one model for the integration of mobile and telephone coaching services. Whittaker et al. (88) are also exploring another interesting mobile phone technology: whether the addition of video messages can enhance success rates through observational learning.

COMBINATIONS OF NICOTINE REPLACEMENT THERAPY AND QUITLINE FOR HEAVILY DEPENDENT SMOKERS

One large randomized trial provides strong evidence that a combination of pharmaceutical aid and telephone coaching can be a very effective approach for heavily dependent smokers (3). In a sample of Minnesota veterans (mean age = 57 years), almost half had their first cigarette within 5 min of waking and 38% woke during the night to smoke (average consumption 26 cigarettes per day). Thus, this population was much more dependent than the average smoker who calls a quitline (59). More than one-third of these participants reported that they were in poor/fair health.

The intensive intervention used the California protocol and included a physician participating in weekly case-management reviews and lay coaches who strongly encouraged adjuvant use of pharmacologic therapy in conjunction with their behavior therapy. A total 94% of enrollees completed the initial call, and 72% completed 3 or more coaching calls (average 7.7 calls). Among the usual care group, 64% visited their primary care physician within 3 months, and 90% went within 12 months. Almost all physician visits included cessation advice. Because all Veterans Administration patients have access to referral-based coaching, control group participants could request such telephone coaching.

At 12 months, 43% of the control group had not used either a pharmaceutical aid or coaching, and 18% had used both. Among the intensive intervention group, 86% had used a pharmaceutical aid as well as coaching in the first 3 months. The intensive intervention achieved a 6-month continuous abstinence rate of 13% compared with 4% in the usual care group, more than a threefold effect. Importantly, the authors noted that continuous abstinence rates were similar between participants who used both medications and coaching, regardless of group assignment.

CESSATION ASSISTANCE WITHIN THE MEDICAL CARE SYSTEM

In the United States, health care providers have been more likely to advise older and heavier smokers to quit compared with younger, lighter smokers (71). Training of health care professionals increased intervention rates with all their patients who smoked, and rates were further improved with the addition of clinician prompts and reminders in the medical records (41). Rigotti et al. (62) found 33 trials of cessation counseling that began during hospitalization. They concluded that counseling was associated with a 65% increase in successful cessation among all types of hospitalized smokers but only when it included continued supportive contacts for more than 1 month after discharge (similar to telephone coaching). Recently, Steinberg et al. (74) were able to enroll only 79 smokers admitted to a university-based hospital between 2007 and 2009. Although provision of a pharmaceutical cessation aid did not produce improvement in cessation rates, the 40% of patients who utilized postdischarge behavioral treatment had significantly higher abstinence rates at 24 weeks (53% versus 9%).

Curry et al. (21) have advocated for a health care system approach in the United States that requires implementing changes at the practice, organizational, and financial levels, similar to that undertaken in 1999 in the National Health

Service (NHS) in England (49). The NHS Stop Smoking Service provides free, tailored support to all smokers who wish to stop, offering a combination of recommended pharmaceutical cessation aids and behavioral support. In 2010–2011, the service assisted almost 800,000 smokers who were prepared to set a quit date. This reach of cessation services in England was much greater than in the United States; this number of 800,000 smokers was 60% higher than the total number of callers to all U.S. quitlines in the same period, although the population in the United States is over 6 times that of England. Of these smokers, the NHS service provided NRT to 64% and other medication (mainly varenicline) to an additional 27%. Fewer than 10% received behavioral counseling without pharmaceutical aids. Quitting for at least 4 weeks (early marker of potential success) was 45% for those who received NRT and 59% for those who received varenicline compared to 50% of those who did not use any pharmaceutical aids. However, the effectiveness of this program over at least the past 5 years in getting much higher proportions of smokers assistance to quit has not resulted in any noticeable change in smoking prevalence (70). Smoking prevalence declined rapidly in England from 1970 through the mid-1990s (13). The decline was much slower through 2007. Although the NHS system has been fully operational since 2007, there has been no further decline since then (70). Even though the United States provided much less cessation assistance, it has reported a similar stagnation in prevalence (14).

The emergence of electronic medical records (EMR) in hospitals and health care systems in the United States has opened up additional possibilities (87). Sarah Moody Thomas (personal communication) led a team that implemented a tobacco use assessment on the EMR within Louisiana's 11 public hospitals, which allows smoking status to be updated every quarter for patients in the system. By mid-2010, more than 1,000 health care providers had been trained. Approximately 2,000 of more than 10,000 patients were identified as ready to

quit. More than 50% of these patients indicated that they would like a pharmaceutical cessation aid, and two-thirds indicated that they wanted behavioral counseling.

WHAT HAS HAPPENED TO POPULATION CESSATION RATES IN THE UNITED STATES?

Smoking is well known to be a chronic relapsing condition (21). From their long-term study of British doctors, Doll & Peto (22) noted that the level of reversibility of health risk depended on the age of successful cessation: the risk of mortality from smoking was (a) almost completely avoided if successful quitting occurred before age 35, (b) halved if successful quitting occurred before age 50, and (c) reduced by one-third if successful quitting occurred by age 65. Accordingly, we use these ages to discuss population patterns of cessation.

Comprehensive Programs Increased Cessation but Only in Young Adults

The California Tobacco Control Program is the only one to report effectiveness in promoting smoking cessation. Since its inception, this program used mass media advertisements to lead other interventions aimed at changing the social norms around smoking. Messer et al. (45) compared quitting in the 1980s and 1990s in California with quitting in New York/New Jersey (states with similar high cigarette prices in the 1990s but without a comprehensive tobacco control program) and with quitting in the seven tobacco-growing states (low cigarette price, no program). Among 20- to 34-year-olds, the California program was associated with higher successful quitting than in either of the other jurisdictions. Among 35- to 49-year-olds, successful quitting in California was no different to New York/New Jersey, although it was higher than that in the tobacco-growing states. There was no difference in quitting by region among those over the age of 50 years. Thus, the changing social norm approach used in California would appear to be particularly effective in

promoting cessation among younger smokers. Because the quitline in California has consistently provided service to 1–2% of smokers annually (93), the effect of the television advertisements on successful quitting in these young adults cannot be solely attributed to calls to the quitline.

DID QUIT ATTEMPTS INCREASE IN THE UNITED STATES AFTER THE EARLY 1990s?

The best estimate of population trends in quitting behavior comes from large-scale repeated cross-sectional surveys designed to provide precise population estimates at a particular point in time. **Figure 1** presents analyses from the nationally representative Tobacco Use Supplements to the Current Population Surveys (TUS-CPS) (78) since 1992. Although studies show that recall of quit attempts in the past year underestimates actual attempts made (33), trends in this measure over time should not be biased. A weighted average was calculated for those who reported having stopped smoking intentionally for 1+ days in the previous year, and a Loess smoother was used to construct the general pattern. Across the past 20 years, attempts to quit are highest in the youngest smokers and attempts decrease slightly with each age studied. Prior to the influx of monies to state tobacco control programs in 1999, the quit attempt rate for 30- to 35-year-old smokers had been relatively stable at ~30% per year, and the rate for 60- to 65-year-olds was ~23% per year. Quitting increased between 1999 and 2004 before leveling off again with the 30- to 35-year-olds at ~35% per year and the 60- to 65-year-olds at ~28% per year. Thus, the large increases in cigarette prices, tobacco control expenditures, and media coverage that followed the Master Settlement Agreement in the United States (60) were not associated with a large increase in the level of self-reported quit attempts. Importantly, these rates appear to decline after 2007.

DID SUCCESSFUL CESSATION IN THE UNITED STATES INCREASE AFTER THE EARLY 1990s?

The cumulative proportion of successful quitters among ever-smokers can be estimated from the national surveys by considering the proportion of the population at each age who indicate that they have been former smokers for at least one year. **Figure 2** was generated by using the weighted means from the National Health Interview Survey (NHIS) and TUS-CPS for each age group, and a piecewise linear regression was fitted with break points at 1980, 1990, and 2000, as in Pierce et al. (59). The cumulative proportion of successful quitters by ages 30–35 years was ~10% in 1965; this proportion increased to ~25% by the mid-1980s and has remained relatively unchanged ever since. For those aged 45–50 years, the cumulative proportion of successful quitters was just under 20% in 1965, and it increased with each year through the early 1990s to ~40%. It has remained at this same level since the early 1990s. For those aged 60–65 years, the cumulative proportion who had successfully quit in 1965 was 30%; this proportion increased with each year through 2000 when the proportion was 60%. However, no increases have been observed since then.

DID WE LOSE EFFECTIVENESS BECAUSE OF THE WAY WE PROMOTE CESSATION PRODUCTS?

Pharmaceutical companies have produced television advertisements promoting use of NRTs since 1992; since then, they have been by far the most prevalent source of cessation advertising (85). From the beginning, NRT was priced to require the same expenditure that a moderately heavy smoker would pay for his/her cigarettes. However, although most tobacco products are packaged so the moderately heavy user can buy a one-day supply of nicotine (e.g., pack of cigarettes), the smallest purchase possible of NRT is a one-week supply, thus increasing the initial out-of-pocket cost (18). Between

1992 and 2005, pharmaceutical companies were the heaviest purchasers of advertising related to cigarette smoking cessation; they bought more than double the television advertisements per month compared with the combined tobacco control programs (84). By 2001, nicotine medications were almost universally known in the United States (18).

On the other hand, it is not clear that NRT marketing efforts have focused on maximizing cessation. Pharmaceutical advertising has rarely indicated that quitlines could help increase success as an adjunct to medication. Furthermore, the marketing strategies used have been described as belonging to a classification called “remedies,” where the marketing product offers a solution to consumer problems that has been characterized as providing a “get out of jail free” card (10) as opposed to focusing on the need to persevere in the quit attempt. After exposure to NRT remedy advertisements, Frosch et al. (31) noted that smokers had reduced perceptions of risk and undervalued the difficulty of quitting. This might be a problem particularly for the younger population.

A content analysis noted that very few advertisements described either the quitting process or risk factors for relapse. Many advertisements emphasized using medication as a way to regain control of one’s life and as a way to obtain social approval. In 2001, 39% of a national sample of smokers indicated that the introduction of stop-smoking medications had made it easier for smokers to quit (18), a belief not supported by the population cessation rates.

What Is the Effect of Providing Free Nicotine Replacement Therapy to Encourage Smokers to Call the Quitline?

Most tobacco control programs have used mass media, particularly television commercials, to encourage smokers to call their quitlines. In an analysis of the effectiveness of types of advertising promoting calls to the New York Tobacco Control Program quitline, Farrelly et al. (26) noted that television, radio, and print media were all effective in increasing calls.

However, although television advertisements substantially increased the call volume, the investment to generate a call might be as high as the cost to provide the service (44), a particular problem if there are no other goals (such as social norm change) for the mass media advertising. The high cost of advertising has meant that many tobacco control programs are looking for more cost-effective ways to encourage smokers to seek assistance in quitting. Advertising campaigns have generally achieved call rates of ~1–2% of smokers each year in the United States (92). However, during periods of greater marketing and service funding, Australia and the United Kingdom have reported rates as high as 4–6% (75, 90).

If a tobacco control program's goals include maximizing calls to the quitline as well as maximizing the proportion of smokers who use NRT during a quit attempt, then a strong case can be made for providing free NRT to smokers who call a quitline, particularly if the NRT subsidy is focused on smokers of low socioeconomic status (44). Giardina et al. (32) reported that 53% of adult smokers in upstate New York said they would seriously think about quitting if offered free nicotine patches/gum. As of 2010, 76% of U.S. states provided free NRT to smokers who call their quitline, more than double the rate in 2005 (20).

The New York Tobacco Control Program has experimented extensively with providing free NRT to quitline callers. Initially, the program offered a free six-week supply of NRT to smokers who called and were screened by the state quitline. Call volume exceeded 400,000 calls (18). Program staff were able to send NRT to more than 34,000 callers in one month before exhausting their supply of nicotine patches (16, 19, 47, 69). Subsequently, offers of free NRT of different durations were made to entice smokers to call the quitline. Cummings et al. (17) explored 7-day quit rates at 12 months among quitline callers for these incentive packages. No dose-response relationships were evident between free samples of 2-, 4-, 6-, or 8-week supplies, although these incentive packages were offered at different times.

A recent study by Walker et al. (86) randomized 1,410 New Zealand smokers who called the national quitline to receive usual care (coaching) or to receive a box with a choice of NRT products to try for a week followed by a free 8-week supply voucher for their preferred product. Both groups received three 10- to 15-min coaching calls spread evenly over the 8-week supply period. Evaluation did not demonstrate any additional effect of the free NRT over coaching on either continuous abstinence or 7-day abstinence at 6-month follow-up.

What Is the Effect of Promoting the Quitline on Cigarette Packs?

A number of recent studies have suggested that mandating a national quitline number on the cigarette pack could be a cost-effective way to ensure that smokers have access to the number when considering a quit attempt. After the Netherlands introduced this policy, quitline calls gradually increased, peaking at 24 weeks, and then gradually decreased to a steady rate that was 3.5 times the original call volume (from ~200 calls per week to 700 calls per week) (89). Likewise, the introduction of graphic warnings and the quitline number in Australia resulted in a doubling of quitline calls in the first two years before settling down to a steady rate roughly 40% higher than before (46). The U.S. FDA has recently announced that by September 2012, every cigarette pack sold in the United States will be required to include graphic health warnings and the national quitline number. A pending lawsuit by the tobacco industry trying to block this initiative may push back implementation. Canada has also recently approved changes to the use of graphic warning labels on cigarette and small cigar packages. The new labels, which need to be on packages starting March 2012, will need to cover 75% of the front and back and will include a toll-free number that will serve as a portal to provincial quitlines.

Are We Ignoring the Effectiveness of Unassisted Quitting?

In the United States, both the 2008 Update of the Clinical Practice Guideline (83) and the

2011 Joint Commission on Standards on Smoking Cessation for Hospitals recommended that every smoker be treated or offered a pharmaceutical cessation aid unless they belong to the following specific populations for which there is insufficient evidence of the effectiveness and/or safety: pregnant women, smokeless tobacco users, light smokers, and adolescents (40). However, the details outlined in the “Specifications Manual for National Hospital Inpatient Quality Measures Discharges” (implemented the first quarter of 2012) require that the denominator for evaluation purposes should be any patient who has smoked in the past 30 days, ignoring the earlier emphasis on populations with demonstrated efficacy (40). This recommendation is particularly important given the evidence that the majority of smokers may now be light smokers (59). A key federal government fact sheet for all smokers thinking of quitting (80) emphasizes the importance of obtaining a pharmaceutical cessation aid, again a recommendation that goes beyond the available evidence.

Given the above-mentioned research, it would appear that this recommendation is based on questionable science. The many randomized trials of pharmaceutical medications have been undertaken on smokers who seek help to quit. It is not clear how the respective committees rationalize the generalization of these results to the majority of smokers who either do not seek help to quit or who quit without assistance. Chapman (15), for one, has decried the increasing medicalization of smoking cessation. He notes that the majority of successful quitters have achieved that status without assistance and that the majority of current quitters continue to make unassisted quit attempts.

WHAT ARE THE POPULATION SUCCESS RATES WITH DIFFERENT APPROACHES TO CESSATION IN THE UNITED STATES?

The best estimate of success following a cessation attempt comes from a study in which the

individual smoker is interviewed on more than one occasion, as in a randomized trial. Again, a precise population estimate requires a study designed to be representative of the population. Such a national longitudinal study was undertaken using the TUS-CPS (78), which interviewed 2,832 smokers both in 2002 and again in 2003. More than half of this sample (56%) smoked 15+ cigarettes per day (heavier smokers). As expected, lighter smokers were more likely than heavier smokers to make a quit attempt during the year (58% versus 42%). Among those who made a quit attempt (Table 1), 59% of heavier smokers and 67% of lighter smokers reported that they quit without any assistance. Approximately one-third of both heavier and lighter smokers reported using a pharmaceutical cessation aid. A much smaller proportion of both heavier and lighter smokers (8% versus 5%) sought help, e.g., from a quitline or cessation clinic.

Using 3 months of continuous abstinence at follow-up as an early marker for successful quitting, lighter smokers were 77% more likely than heavier smokers to be successful (23% versus 13%). Lighter smokers who quit unassisted were 37% more likely to be successful than were those who used help. There was little difference in success between those who sought help whether they used a pharmaceutical aid (19%) or a cessation service such as a quitline (17%). Among heavier smokers, the success rate among those who quit unassisted was 50% higher than those who used help. Again, there was little difference between those who used a pharmaceutical aid (9%) and those who used a cessation service (10%).

SUMMARY

Over the past 20 years, there have been a number of well-disseminated major public health initiatives, including the establishment of population-wide tobacco control programs, widespread use of quitlines, and widespread availability of pharmaceutical aids to quit. Tobacco control programs that target the social acceptability of smoking, such as California’s

Table 1 Quitting success in the United States by method used to quit: 2002–2003. Data from the Tobacco Use Supplements of the Current Population Survey (TUS-CPS)^a

Baseline daily consumption level	Attempted to quit by method used	Reported status at 12-month follow-up			
		Current smoker, made quit attempt	Current former smoker, quit <3 months	Current former smoker, quit 3+ months	% Success (3+ months quit at follow-up)
	<i>N</i> (%)	<i>N</i>	<i>N</i>	<i>N</i>	%
Light smokers (<15 cpd)	576				
Used NRT or prescription medication	159 (29%)	112	17	30	19%
Used quitline, clinic, other organized help	30 (5%)	24	1	5	17%
Unassisted	387 (67%)	248	40	99	26%
Heavy smokers (15+ cpd)	654				
Used NRT or prescription medication	216 (33%)	187	9	20	9%
Used quitline, clinic, other organized help	51 (8%)	42	4	5	10%
Unassisted	387 (59%)	312	18	57	15%

^aAbbreviations: cpd, cigarettes per day; NRT, nicotine replacement therapy.

program, have demonstrated that successful cessation can be increased at least in smokers younger than 35 years.

Quitlines have become widely disseminated and provide access to large populations of smokers who want help to quit. The number of callers to quitlines is used as a process measure for response to cessation motivation messages. Prominent advertising for quitlines on cigarette packages has also doubled the proportion of smokers who seek help to quit. There is also considerable evidence that motivational messages can increase the proportion of smokers seeking help to quit, and developments in using automated targeted messages through electronic media offer significant potential to increase the reach of assistance at markedly reduced cost.

In randomized trials, pharmaceutical aids have significantly increased cessation among heavy smokers who seek help to quit. Indeed, evidence shows that an intensive multicomponent intervention led by an involved physician is effective with heavier smokers with medical problems who seek help to quit. These

results have encouraged governments to recommend strongly that pharmaceutical aids be used in all quit attempts, and many have provided free NRT to smokers who call quitlines. To date, there is no evidence that such policies lead to an increase in successful cessation in the population.

Of particular concern is the leveling off of successful cessation in recent years in the United States and the stabilization of smoking prevalence in England. This has occurred even though the proportion of the population making quit attempts has increased and the proportion using recommended assistance to quit has more than doubled. In seeking to explain why public health initiatives have not been more effective, some have noted that heavy advertising for pharmaceutical aids may be far from optimal, even reducing smokers' willingness to persevere with a quit attempt. Others have pointed to the fact that government policies are associated with overmedicalizing smoking cessation and discouraging the most effective way that smokers in the population quit: by themselves using the maxims laid out more than a century

ago by James (39). That successful smoking cessation has not increased, except for young smokers in California, despite the increased efforts focused on it suggests that there is an urgent need to revisit current tobacco control policy.

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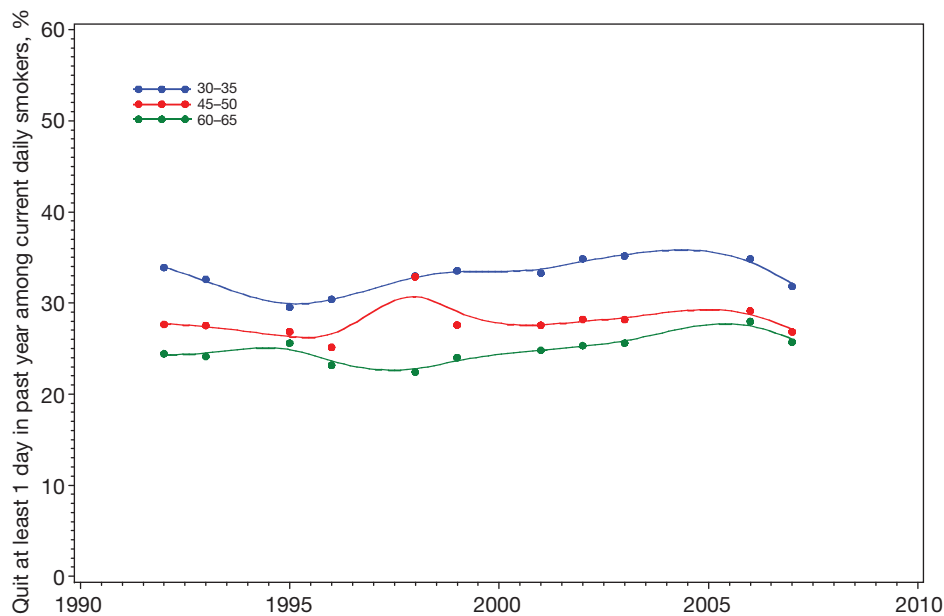


Figure 1

Trends in any self-reported quit attempts in the past year, Tobacco Use Supplements of the Current Population Survey (TUS-CPS), 1992–2007.

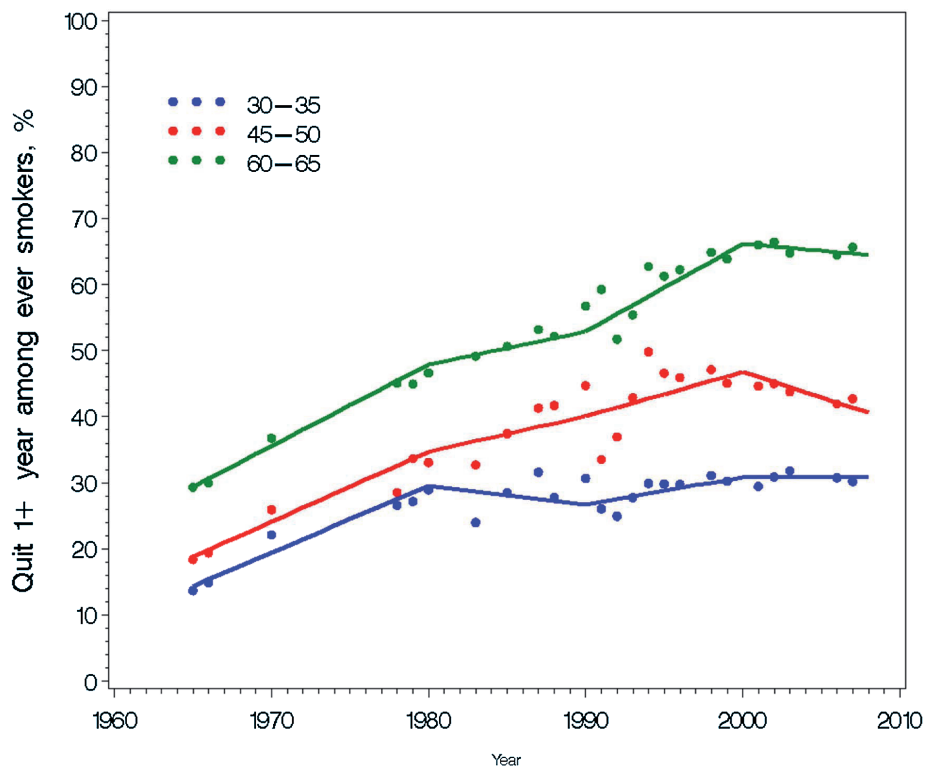


Figure 2

Trends in the cumulative successful quitting (1+ years) in the U.S. population by age; NHIS 1965–1994 and Tobacco Use Supplements of the Current Population Survey (TUS-CPS), 1992–2007.



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