Examining a Quarter-Century of Smoking Cessation Trials: Is the Target Becoming Harder to Treat?*

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INTRODUCTION Are tobacco smokers becoming harder to treat? Anecdotal reports by smoking-cessation providers would suggest that they are. The notion is that as the prevalence of smoking in the United States has declined, those smokers who have not yet quit represent the "hardcore" recalcitrant subset of the historical smoking population. Between 1974 and 1995, the prevalence of smoking dropped from 43.1% to 27.0% among men and from 32.1% to 22.6% among women (U.S. Bureau of the Census 1998). This decline in smoking prevalence can be attributed to factors such as increased knowledge about the health consequences of smoking, the deleterious effects of secondhand smoke on nonsmokers, antismoking public health campaigns, antismoking legislation (e.g., limitations on smoking in public places), and the availability of relatively effective behavioral and pharmacological smoking cessation interventions. Moreover, the last two decades were characterized by a dramatic decline in the social acceptance of smoking, which has led to increased social pressure to quit smoking. Indeed, approximately half of all ever-smokers have now quit (U.S. DHHS 1989).

Those who believe that smokers are becoming increasingly recalcitrant argue that those individuals who continue to smoke or who initiate smoking, despite the health warnings and the social pressure, are probably different from those who have already quit; that is, because of selective quitting and initiation, the current population of smokers is likely to be comprised of individuals more entrenched in their smoking behavior than would be found in earlier years. Although this is a frequent clinical observation, there has been little direct evidence to support this hypothesis, and the hypothesis is controversial. Based on data that such characteristics are associated with poorer cessation rates and greater initiation rates, Hughes (1996) offered indirect evidence that today's smokers are more likely to be highly nicotine-dependent and to have comorbid psychiatric and substance abuse disorders than in the past. Similarly, Fagerström and colleagues (1996) found that ex-smokers had lower nicotine dependence levels (when they were smokers) than current smokers, and that the typical dependence level of smokers in the United States is higher than that found

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in countries in which smoking is more prevalent. Hughes (1996) also noted that the prevalence of smoking is declining slowest among the poor and less educated. Other evidence suggesting that the population of smokers might be becoming more dependent is that an intensive community-based tobacco control intervention—the Community Intervention Trial for Smoking Cessation (COMMIT)—led to increased cessation among light to moderate smokers but not among heavy smokers (COMMIT 1995). If this result is representative of other tobacco control efforts, the remaining population of smokers should be becoming increasingly nicotine-dependent. In contrast to this perspective, indirect evidence that the population of smokers is *not* changing is provided by epidemiological evidence that indicates that the average smoking rate (cigarettes per day) in the population has not changed in recent years. This evidence is presented in other chapters of this monograph (see Chapters 7 and 8).

If the smoking population has been changing, we would expect that smoking cessation interventions should have become progressively less successful at producing abstinence within it. This would be expected because smokers who are highly nicotine-dependent, of low socioeconomic status, or who suffer from comorbid psychopathology or substance abuse tend to have poorer outcomes from clinical interventions. To the degree that these characteristics have become more common among smokers in recent years, this should be reflected in declining success rates of smoking interventions. However, Shiffman (1993) conducted a historical analysis of outcomes from published smoking cessation interventions and concluded that cessation rates have been stable since the mid-1970s. It is possible, though, that the increasing recalcitrance of smokers during this period was masked by the concurrent development of new and improved smoking cessation aids that were employed in the published trials. Thus it is important that the type of intervention be held relatively constant over a historical analysis for changes in recidivism to be revealed.

For the present analysis, we searched for smoking cessation trials published between 1975 and 1998. In order to maximize the historical range available for comparison, it was necessary to examine a treatment that has remained relatively constant over that time span. Very few treatments were available throughout this entire historical period. For example, pharmacotherapies were not available during the early portion of the period, and aversive therapies (i.e., rapid smoking) had fallen into disuse by the latter portion of the period. A treatment that did remain relatively constant was cognitive-behavioral coping skills training, which is defined below. This treatment was used as the constant treatment, and reported outcome data was examined based on year of the publication of the research report. It was hypothesized that we would find a trend in which end-of-treatment and follow-up abstinence rates have been declining over the years under study. Such a finding would support the notion that smokers presenting for treatment over the past quarter-century have become progressively more difficult to treat, consistent with the hypothesis of a changing population of smokers.

METHOD A search of the smoking cessation treatment literature was conducted to identify all relevant studies. Keyword searches (e.g., smoking cessation, multicomponent smoking treatment) of the computerized databases *Psyc Lit*, *PsycINFO*, and *MedLine*, and manual searches of bibliographies of smoking cessation reviews (e.g., Glasgow and Lichtenstein 1987; Lichtenstein and Glasgow 1992; Shiffman 1993; Fiore et al. 1996; Silagy et al. 1998), were conducted. We searched for studies published between 1975 and 1998 that met the inclusion criteria. To limit the variability of treatments compared over this 24-year period, the inclusion criteria were strictly defined. We limited the analyses to studies that used multicomponent smoking cessation treatments provided in a group format, emphasizing the training of cognitive and behavioral coping skills. Additionally, studies were required to have been conducted in the United States, and articles must have reported point-prevalence abstinence rates for at least one of the following time points: end-of-treatment, 3 months, 6 months, or 1 year post treatment. Treatment approaches that used purely behavioral techniques (e.g., desensitization, cue exposure, rapid smoking) were not included. We also excluded studies in which smoking interventions were provided to special or captive populations, such as worksite- or hospital-based treatments. Nicotine replacement therapies became available and dominant during the period under study, so we included studies both with and without nicotine replacement.

Table 4-1 lists the 23 studies identified by our search of the literature as meeting inclusion criteria and reporting relevant abstinence rates. Publication dates of the selected articles ranged from 1977 to 1996. Several studies compared highly similar interventions, often with the difference between treatments being the intensity of the intervention or whether nicotine replacement therapy was used. Because of this, 15 studies provided more than 1 treatment that met the inclusion criteria. We therefore conducted two separate sets of analyses. An initial set of analyses was conducted using only one treatment from each study (n = 23). When more than one treatment in a study met inclusion criteria, we selected for these analyses the treatment that most closely fit the prototype of coping skills training plus nicotine replacement. For example, we selected treatments that included nicotine replacement over those that did not, yet we were unlikely to select treatments that included additional elements, such as spousal involvement. To increase statistical power and to ensure the inclusion of all appropriate interventions, a second set of analyses was conducted based on all treatments that met the inclusion criteria (n = 44), allowing for multiple treatments from a single study. No study contributed more than four treatments to the analyses.

Table 4-1
Studies Included in the Historical Analyses

Study	Tx. Condition	*n*	NRT	Biochemical Verification	Abstinence Rates (%)			
					End of Tx.	3 Months	6 Months	12 Months
Lando, 1977	Broad Spectrum Behavioral Tx.	17	no	yes	100	—	76	—
Elliott and Denny, 1978	Cognitive-Behavioral Tx. Package	15	yes	no	65	—	45	—
Lando, 1981	Two-Stage, Intensive Contact Behavioral Tx.	21	no	yes	88	63	58	46
	Two-Stage, Minimal Contact Behavioral Tx.	12	no	yes	60	30	30	17
	Three-Stage, Intensive Contact Behavioral Tx.	19	no	yes	83	35	22	19
	Three-Stage, Minimal Contact Behavioral Tx.	22	no	yes	67	52	42	19
Brown et al., 1984	Nicotine Fading + Relapse Prevention	16	no	yes	—	—	25	19
Rabkin et al., 1984	Behavior Modification	34	no	yes	—	—	24	—
Hall et al., 1984	6 s. Aversive Smoking + Skills Training	29	no	yes	90	—	55	52
	30 s. Aversive Smoking + Skills Training	28	no	yes	89	—	50	39
Killen et al., 1984	Skills Training + Nicotine Gum	22	yes	yes	86	—	—	—
	Skills Training Only	20	yes	yes	55	—	—	—
Hall et al., 1985	Intensive Behavioral Tx. + Nicotine Gum	35	yes	yes	—	73	59	44
	Behavioral Tx. Only	36	yes	yes	—	47	31	28
Lando and McGovern, 1985	Nicotine Fading + Maintenance	32	no	yes	62	36	21	19
	Oversmoking + Maintenance	32	no	yes	62	46	42	46
	Nicotine Fading/Smoke-holding + Maintenance	32	no	yes	85	63	51	44
Davis and Glaros, 1986	Basic Tx. + Relapse Prevention	15	no	yes	73	20	7	13
	Discussion of Relapse Situations Control	14	no	yes	21	29	21	21
McIntyre-Kingsolver et al., 1986	Basic Program	32	no	yes	48	36	19	32
	Basic Program + Spousal Support	32	no	yes	73	42	27	36
Molgienecki et al., 1986	Behavior Modification Clinic	89	no	yes	—	—	20	—
	Behavior Modification Clinic + Media Campaign	38	no	yes	—	—	37	—
Hall et al., 1987	Intensive Behavioral Tx. + 2 mg Nicotine Gum	35	yes	yes	—	43	43	34
	Intensive Behavioral Tx. + Placebo Gum	34	yes	yes	—	35	21	21
Curry et al., 1988	Group-Based Relapse Prevention Tx.	~ 24	no	yes	47	28	—	28
Stevens and Hollis, 1989	Relapse Prevention	184	no	yes	—	—	—	48

continued

Table 4-1 (continued)

Study	Tx. Condition	*n*	NRT	Biochemical Verification	Abstinence Rates (%)			
					End of Tx.	3 Months	6 Months	12 Months
Goldstein et al., 1989	Behavioral Tx. + Fixed Nicotine Gum Schedule	25	yes	yes	52	—	32	—
	Behavioral Tx. + Ad lib Nicotine Gum Schedule	24	yes	yes	58	—	42	—
Lando et al., 1990	Freedom From Smoking Clinic	331	no	yes	—	24	24	22
	Fresh Start Clinic	363	no	yes	—	29	27	25
	Laboratory Clinic	347	no	yes	—	37	29	29
McGovern and Lando, 1992	Freedom From Smoking Clinic + Nicotine Gum	146	yes	yes	86	40	—	35
	Freedom From Smoking Clinic Only	127	no	yes	—	40	—	32
Hill et al., 1993	Behavioral Training Only	22	no	yes	46	—	—	—
	Behavioral Training + Nicotine Gum	22	no	yes	46	—	—	—
	Behavioral Training + Exercise	18	no	yes	33	—	—	—
Cincirpini et al., 1994	Cognitive-Behavioral Tx. + Scheduled Smoking	17	no	yes	59	—	53	41
Fiore et al., 1994	High Contact Cognitive-Behavioral Tx. + 22 mg Nicotine Patch	44	yes	yes	59	—	34	—
	High Contact Cognitive-Behavioral Tx. + Placebo Patch	43	no	yes	40	—	21	—
Jorenby et al., 1995	Cognitive-Behavioral Tx. + 22 mg Nicotine Patch	87	yes	yes	59	26	—	—
	Cognitive-Behavioral Tx. + 44 mg Nicotine Patch	80	yes	yes	49	25	—	—
Cincirpini et al., 1996	Behavior Therapy Only	32	no	yes	63	22	22	22
	Behavioral Therapy + Patch	32	yes	yes	79	48	39	38

RESULTS Pearson correlations were calculated between year of publication and abstinence rates for four assessment points ranging from treatment end to 12 months post treatment. Because of differences across studies in the particular assessment points reported, analyses of the four assessment points were based on different subsets of the total sample of studies. One-tailed significance tests were used because the strong a priori directional hypothesis was that negative correlations would be found.

Table 4-2 displays the results from these two sets of analyses. The pattern of negative correlations between publication year and abstinence rates suggests that rates have declined over the 20 years represented by the sampled studies. The greatest effect was found at the first two assessment points (end-of-treatment and 3-month follow-up). By 12 months post treatment, the correlations had disappeared.

We considered several potential moderator variables. First, because biochemical verification (i.e., breath carbon monoxide, thiocyanate, cotinine) may have become more commonly used in later studies, the declining abstinence rates could reflect the use of these more objective measures of smoking status. However, only 1 of the 23 studies did not use biochemical verification, and exclusion of this study did not substantively change the results. Second, nicotine replacement products became available in the 1980s, so they were more likely to be used in the later studies. Of the 44 total treatments used in the analyses, 11 included nicotine replacement. Given that nicotine replacement is intended to enhance treatment outcomes, this possible confound should, if anything, attenuate the effect of declining abstinence rates over time. Indeed, as seen in Table 4-2, controlling for nicotine replacement yielded negative partial correlations of greater magnitude than the corresponding zero-order correlations reported above.

Three additional methodological variables were examined: whether or not an intent-to-treat analysis was used (reported for 20 studies, 41 treatments), time interval used to determine point-prevalence abstinence (13 studies, 29 treatments), and treatment sample size (all 23 studies and 44 treatments). Additionally, we examined four subject variables that were reliably reported: gender proportions, mean age (22 studies, 43 treatments), mean years of smoking (15 studies, 31 treatments), and mean daily smoking rate (20 studies, 41 treatments). Of these seven variables, three were significantly correlated with year of publication: mean daily smoking rate ($r = -0.46$, $p < 0.01$), and the highly redundant ($r = 0.96$) variables of age and years of smoking (both r's = 0.67, $p < 0.001$); that is, over the period of analysis, subjects in the more recent clinical trials tended to be older, have longer smoking histories, and smoke fewer cigarettes per day. Smoking rate was not related to any of the four outcome measures, but both age and years of smoking were negatively correlated with abstinence rates at treatment end ($r = -0.47$, $p < 0.01$, and $r = -0.40$, $p < 0.05$) but not at the later assessment points. Controlling for mean age reduced the association between publication year and abstinence rates at the four assessment points below statistical significance (pr's = –0.21, –0.27, –0.13, 0.12, respectively).

Table 4-2
Correlations Between Year of Publication and Reported Point-Prevalence Abstinence Rates at Treatment End and Follow-Up for Three Analyses: (1) Including Only a Single Treatment per Study, (2) Including All Treatments That Met Inclusion Criteria, and (3) Partial Correlations Including All Treatments, but Controlling for the Use of Nicotine Replacement Therapy (NRT)

	Assessment Point			
	End of Treatment	3 Months	6 Months	12 Months
One treatment per study	–0.48* (n = 16)	–0.55* (n = 11)	–0.31 (n = 17)	–0.03 (n = 14)
Multiple treatments per study	–0.45** (n = 31)	–0.32† (n = 25)	–0.32* (n = 33)	0.09 (n = 28)
Multiple treatments, controlling for NRT	–0.49** (n = 31)	–0.44* (n = 25)	–0.45** (n = 33)	–0.01 (n = 28)

*p <0.05, one-tailed.

**p <0.01.

†p <0.1.

Because of severely restricted statistical power due to the cumulative effects of missing data, similar analyses could not be performed using years of smoking or smoking rate as covariates.

DISCUSSION Findings indicate a robust downward trend in abstinence rates since the mid-1970s among multicomponent cognitive-behavioral smoking cessation interventions, as measured immediately following treatment and at 3- and 6-month follow-up. These results are consistent with the notion that the target has been hardening; that is, as more and more smokers quit, the population of remaining smokers may be changing and becoming progressively more difficult to treat. Because the prevalence of smoking is again increasing among adolescents (CDC 1995), it is possible that this trend will soon reverse.

The declining trend in treatment outcome was not found when one-year post treatment follow-up was used as the outcome index. Smoking relapse is no doubt influenced by multiple factors such as personality, level of nicotine dependence, exposure to cigarettes and other conditioned stimuli, environmental stressors, and so on. With the passage of time since quitting, there is greater opportunity for a variety of factors to influence whether or not an individual relapses. It is therefore not surprising that abstinence rates at later follow-up points will show weaker relationships with any single predictor variable—including year of cessation. In addition to such "noise" affecting the correlations, it is also likely that later assessment points suffer from greater measurement error due to subject attrition, repeated quit attempts, and the like. At the very least, however,

our findings suggest that smokers in clinical trials are relapsing more quickly than they have in the past, even if the eventual, long-term outcomes have not changed much over time.

The observed declining trend in successful outcome was particularly noteworthy given that the average smoking rate (cigarettes per day) among study participants also declined during the period of analysis. Epidemiological studies tend to find that smoking rate is inversely related to the probability of smoking cessation (e.g., Hymowitz et al. 1997); that is, lighter smokers are more likely to quit than heavier smokers. In this study, smoking rate was unrelated to outcome. This leads us to question the validity of smoking rate as an index of nicotine dependence. We believe that smoking rate is an imperfect measure of dependence for two reasons. First, because of variability in smoking topography (e.g., frequency, strength, and duration of inhalations), smoking rate is only modestly associated with actual level of nicotine delivery. Second, factors other than nicotine delivery—such as vulnerability to negative affect, cognitions, and culture—influence nicotine dependence (Shadel et al. 2000).

The present findings may initially appear to contradict the conclusions from Shiffman's (1993) analysis of historical trends (1957 to 1989) in treatment outcomes. Shiffman found that treatment outcomes improved during the early 1970s and remained stagnant thereafter. However, he acknowledged that the apparent lack of improved outcomes since the mid-1970s may have been a product of more heavily addicted smokers being seen in smoking cessation clinics; that is, improvements in cessation technology may have been masked by the counterforce of more difficult clients. The present findings are consistent with this explanation, because treatment outcomes actually *declined* when we held treatment constant in the historical analysis—especially when we controlled for the use of nicotine replacement therapies.

In drawing conclusions based on this historical analysis, certain methodological limitations should be considered. First, our findings are based on only one general type of treatment. It was necessary to select a prototype treatment that has been in use over the entire time period under investigation and for which there were enough published studies to conduct meaningful correlational analyses. Nevertheless, the possibility that the observed declining success rates are somehow limited to this particular treatment approach should be addressed. It may be that over time the better therapists or more motivated clients became attracted to newer treatments, and they became less likely to participate in the fairly standard treatment considered in this analysis. Given that nicotine replacement was the major innovation during the period under study, and that many of the studies included in our analyses used nicotine replacement, this scenario seems unlikely. In fact, it is interesting that nicotine replacement, which is considered an empirically supported treatment (Fiore et al. 1996), was found to be no more effective than placebo in two recent studies (Jorenby et al. 1999; Joseph and Antonnucio 1999). This suggests that other interventions may be experiencing a declining efficacy similar to that found in the

current study. Nevertheless, historical outcome analyses similar to the present one should be conducted for other smoking cessation approaches, and perhaps for the control conditions of clinical trials as well.

An alternative explanation for our findings is that, over time, less dependent smokers have become more likely to elect treatment options that do not require attending a formal cessation clinic. In particular, our findings may have been affected by the recent availability of over-the-counter nicotine replacement. Thus it is possible that our findings reflect a trend in which the subset of smokers seen in research clinics has become more challenging, whereas the general population of smokers has not changed. It may also be that participant recruitment strategies changed over the period under study. For example, in recent years there has been greater emphasis placed on recruiting research samples that are representative of the ethnic, racial, gender, and socioeconomic diversity of the population at large. Thus it may be that more recent studies have included a greater proportion of smokers from subpopulations that have greater difficulty quitting smoking or maintaining abstinence.

Unfortunately, most of these descriptive statistics were not reliably reported, precluding analysis of historical changes in subject characteristics. Of the subject variables examined, only age, years smoking, and smoking rate changed over time, with recent studies including older, more experienced smokers who smoked fewer cigarettes per day. That the remaining pool of smokers willing to participate in clinical trials may be becoming older with a longer history of smoking is consistent with a smoking population who will have more difficulty achieving long-term abstinence. But the dropping rate of number of cigarettes smoked per day appears inconsistent with the notion that remaining smokers should be more nicotine-dependent than in the past. Of course, smoking rate may be influenced by other historical factors such as increasing restrictions on smoking at work, the rising cost of cigarettes, and the growing tendency for smokers to be clustered within lower income groups. Regrettably, other indices of nicotine dependence, such as the Fagerström Tolerance Questionnaire (Fagerström 1978), were reported too infrequently to be analyzed.

Because mean subject age covaried with both publication year and abstinence rates, when we statistically controlled for subject age, the associations between publication year and abstinence rates declined to below statistical significance. There are at least two possible interpretations of this finding. First, the clinical trials included in the analysis may have—for some reason unrelated to the hypothesized changing population of smokers—attracted older, more experienced smokers in the more recent studies. Because older smokers have more difficulty with cessation, subjects' age may be a confound that accounts for the observed association between publication date and outcome. The second interpretation is that subject age, rather than being a confound, is one of the variables that mediates the relationship between year and outcome. That is, over the past 24 years, as fewer adolescents (until recently) began smoking and as the younger, less

experienced smokers may have been the most likely to quit, it is logical that the age of smokers seeking treatment in clinical trials would have increased. The latter interpretation is consistent with the hypothesis that smokers seeking treatment are becoming progressively more recalcitrant, and it is possible that this trend reflects changes in the general population of remaining smokers.

As with any analysis of archived publications, the possibility exists that our findings were influenced by publication bias; that is, studies that did not find significant differences between conditions are less likely to be published; therefore, archived publications may be biased toward studies with significant differences. However, unlike traditional meta-analyses of effect sizes, our analyses were based upon the absolute magnitude of abstinence rates for individual treatment conditions. These statistics should be less susceptible to the problem of publication bias. Moreover, because our analyses focused on changes over time, publication bias could influence the findings only if its effect also changed over time.

A final limitation of the present study is the small sample size necessitated by our desire to hold treatment constant. Even for a fairly common treatment, the number of published studies that met the inclusion criteria (i.e., group treatments that were conducted in the United States and that reported point-prevalence abstinence rates) was small. This may limit the robustness of our findings. In other words, it is possible that our findings are sample-dependent. However, we verified that exclusion of any single data point from the analyses did not appreciably change the results. Moreover, that the negative trend was found for three different assessment points (end-of-treatment, 3 months, and 6 months), based on different subsets of studies, also increases confidence in the robustness of the general trend.

In summary, with the caveat that unknown third variables (e.g., changes in study methodology or subject self-selection) may influence the results of any correlational study, the finding of declining treatment outcomes over the past quarter-century supports the observation that smokers seeking cessation help today are more recalcitrant than in the past. That is, the preliminary answer to the question that began this chapter (are tobacco smokers becoming harder to treat?) appears to be "yes." This may very well reflect the likelihood that today's smokers are more nicotine-dependent, of lower socioeconomic status (SES), and more likely to suffer from comorbid psychopathology and substance abuse, as suggested by Hughes (1996). Or it may simply reflect a change in the subset of smokers who actively seeks behavioral treatments rather than a change in the larger population of smokers. The final answer awaits more direct evidence.

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