

ASPO Joseph W. Cullen Memorial Award Lecture

Bridging the Clinical and Public Health Perspectives in Tobacco Treatment Research: Scenes from a Tobacco Treatment Research Career¹

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Abstract

This paper, delivered as the 2000 Joseph W. Cullen Memorial Award Lecture, reviews smoking cessation treatment research conducted over the past 15 years at the Center for Health Studies, Group Health Cooperative. The research program includes assessment, treatment, and health services research that addressed four main questions: (a) What motivates people to quit smoking? (b) Are self-help interventions effective? (c) Can health care benefits impact the utilization of smoking cessation services? and (d) Does smoking cessation impact health care utilization and costs?

In the area of motivation for smoking cessation, an intrinsic-extrinsic model of type of motivation for smoking cessation was used to develop and validate a reasons for quitting scale. Results from administration of the scale across different samples of smokers show that higher levels of intrinsic relative to extrinsic motivation predicts successful cessation. A series of five randomized trials of self-help interventions indicate that self-help interventions accompanied by motivational feedback and/or outreach telephone counseling can be effective. However, the same interventions did not improve long-term abstinence rates in non-volunteer samples of smokers.

With regard to health care benefits, we find that full coverage of smoking cessation services improves the reach of proven interventions into the general population of smokers with no significant reductions in effectiveness. Furthermore, studies of smoking cessation and health care utilization find that, although quitters have higher initial costs, their costs go down at the same time that those of continuing smokers' begin to accelerate. Cessation appears to reverse a trajectory of higher health care costs.

Introduction

Despite declines in smoking prevalence in the United States over the past few decades, cigarette smoking remains the lead-

ing cause of premature death and disability in our country (1). Youth continue to initiate smoking at unacceptable rates, and long-term smoking cessation is an elusive goal for the majority of established adult smokers (2). An important public health challenge is ensuring that proven interventions reach the largest possible proportion of smokers. A combination of broad reach and high rates of treatment effectiveness affords the greatest impact on reducing smoking related disease and mortality.

The health care delivery system is an important channel for achieving these goals. Estimates are that at least 70% of smokers see a physician at least once in a given year (3). In addition, smokers see dentists and other healthcare professionals. The impact of health care delivery on cessation of tobacco use can be leveraged with resources at three levels. At the individual level, effective and disseminable cessation treatments are needed. At the practice level, evidence-based guidelines can outline what providers ought to do, but these need to be accompanied by system-level resources such as automated tracking systems and other system supports that facilitate actual guideline implementation. Finally, at the organizational level, insurers and managed care providers need to provide coverage that gives patients access to effective treatments and to allocate resources for practice level supports (*e.g.*, reimbursement, performance incentives, and clinical information systems) (4, 5).

Over the past 15 years, my colleagues and I have built a research program in tobacco interventions at GHC³ that addresses important conceptual and clinical questions across these levels. GHC is a consumer-governed health maintenance organization that provides health care to >500,000 residents of western Washington. Approximately 70% of GHC enrollees receive their care through a group model system that has 650 physicians, 340 of whom practice in primary care. GHC has 30 medical centers, 1 hospital, 6 specialty centers, and 1 skilled nursing facility. Of particular relevance to some of our research are GHC's extensive automated data systems, including diagnostic and procedure data on all ambulatory and inpatient encounters, prescription and over-the-counter medications, skilled nursing facility care, and radiology and laboratory services. Appointments are logged on a centralized system. Membership files contain age and gender information for all enrollees.

Our work bridges the clinical and public health perspectives in tobacco treatment research. As described by Lichtenstein and Glasgow (6) nearly a decade ago, these perspectives can be thought of as two ends of a continuum. Treatment outcome research at the clinical end of the continuum includes component studies of intensive treatments that are conducted

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³ The abbreviations used are: GHC, Group Health Cooperative; RFQ, Reasons for Quitting; NRT, nicotine replacement therapy; BP, behavioral program; CDS, chronic disease score; NPV, net present value.

primarily with self-referred, highly motivated smokers. Baseline and follow-up data from comprehensive assessments of study participants are used to study factors associated with successful cessation and with relapse after initial cessation. This research is vital for developing an in-depth, conceptually based understanding of the smoking cessation process at the individual level. At the public health end of the continuum are studies of less intensive treatments, conducted in community settings (e.g., health care systems and worksites), often with non-volunteer, population-based samples of smokers. Baseline and follow-up data from smokers in these studies help to expand our understanding of the smoking cessation process beyond those smokers who are motivated to quit. Also relevant to the public health end of the continuum are treatment studies that evaluate more “upstream” interventions, such as the impact of different levels of insurance coverage for smoking cessation treatments on program utilization.

Our studies have addressed four main questions: (a) What motivates people to quit smoking? (b) Are self-help interventions effective? (c) Can health care benefits impact the utilization of smoking cessation services? and (d) Does smoking cessation impact health care utilization and costs?

What Motivates Smokers to Quit?

Motivation is one of the key elements in the smoking cessation process. Although a vast majority of smokers will state that they are motivated to quit smoking at some point in the future, population-based studies indicate only ~20% of smokers are prepared to make an active quit attempt in the immediate future (i.e., within 30 days). An additional 40% are seriously considering quitting in the near future (i.e., within 6 months). However, fully 40% of smokers are not seriously considering quitting in the near future (7).

Motivation for smoking cessation refers both to the strength or level of smoker’s desire to quit and to the why or type of motivation. We set out to develop and test a conceptual model of type of motivation for smoking cessation and, subsequently, to translate our findings into disseminable interventions. Our conceptual framework derives from an intrinsic-extrinsic model for type of motivation for smoking cessation. Intrinsic and extrinsic motivation refer to the origins of the desire to engage in a particular behavior (8). Intrinsically motivated behaviors are ones for which the rewards are internal to the person. Extrinsically motivated behaviors occur in response to external rewards or punishments. Beginning with studies with volunteer smokers in self-help smoking cessation programs, we developed and validated a RFQ scale that measures two dimensions of intrinsic motivation (health concerns and self control) and two dimensions of extrinsic motivation (immediate reinforcement and social influence) (9). A consistent finding in longitudinal studies is that higher levels of intrinsic relative to extrinsic motivation predicts smoking cessation among self-selected, volunteer samples of smokers seeking assistance in quitting (9) and in a general population sample of smokers (10). Furthermore, in a sample of pregnant smokers, higher intrinsic relative to extrinsic motivation for cessation during the first trimester of pregnancy was associated with lower rates of relapse during the first two months postpartum (11). Among continuing smokers, movement forward in readiness to quit is associated with significant increases in health concerns and self-control motivation (10).

To date, our studies show that health motivation is not the only salient intrinsic motivator. Smokers are also motivated by a desire for self-determination or self-control. It also appears

that not all types of motivation are equally associated with successful cessation. Our clinical aim is to help maximize levels of intrinsic relative to extrinsic motivation.

Are Self-Help Interventions Effective?

Self-help programs for smoking cessation are a promising bridge between clinical and public health interventions. Given a choice, the majority of smokers prefer self-help treatments to more intensive group programs. Because self-help programs have the potential to reach large segments of the smoker population at relatively low cost, effective self-help programs can significantly improve the impact of smoking cessation treatments (12). In the 1980s, randomized trials of self-help interventions were one of four areas of concentration for the National Cancer Institute’s Smoking, Tobacco, and Cancer Program.

Orleans *et al.* (13) conducted a study at GHC that was funded under the Smoking, Tobacco, and Cancer Program self-help initiative. This study recruited >2000 volunteers from the GHC population and randomized them to one of four groups [a control group that received a brief bibliotherapy guide, a comprehensive self-help manual (Free & Clear), the Free & Clear Manual plus social support guide, and the Free & Clear manual, social support guide and four outreach telephone counselor calls]. Results at a 16-month follow-up showed a significantly higher prevalent abstinence rate in the group that received the outreach telephone counseling compared with the other three groups. In this study, the comprehensive manual alone or with a social support guide did not outperform a brief bibliotherapy guide, although post-hoc analyses indicated a higher rate of outside program use among those randomized to the bibliotherapy condition.

In parallel with the Orleans *et al.* (13) trial, we conducted a study to evaluate ways to enhance the use of self-help programs, using the intrinsic/extrinsic framework to operationalize different motivational adjuncts (14). The impetus for this study was an earlier finding that, among smokers who were randomly assigned to receive a smoking cessation program either in face-to-face group sessions or through the mail, 12-month abstinence rates were comparable among those who participated in the programs. However, because participation rates were lower in the group that received the program in self-help format, overall abstinence rates favored the group program (15). Thus, the focus of this initial study was to increase the reach of a self-help program into a sample of motivated volunteers through either an intrinsic (motivational feedback) or extrinsic (financial incentive) strategy. We recruited volunteers from GHC and randomized 1200 smokers in a 2 × 2 design to receive a self-help manual alone, a self-help manual plus written personalized feedback, a self-help manual plus financial incentive for using the manual, or both the feedback and financial incentive. The personalized feedback was designed to increase smokers’ confidence in their ability to successfully use the self-help program. Part of the personalized feedback used smokers’ responses to the intrinsic motivation scale items from the RFQ scale to highlight their strong intrinsic motivators for cessation. Findings from this study were remarkably consistent with the overall intrinsic/extrinsic motivation model. Both the intrinsic and extrinsic motivation strategies increased use of the self-help manual. However, use of the manual was associated with improved outcomes only in the group that received only the intrinsic, personalized feedback strategy. The feedback had no effect on initial cessation or long-term abstinence when it was paired with the extrinsic, financial incentive. Overall, by

the 12-month follow-up, long-term abstinence rates were more than doubled in the intrinsic-only group (14).

Encouraged by these findings, our next study aimed to replicate and extend the intrinsic treatment model as an outreach intervention (16). We identified a random sample of GHC adult enrollees, conducted telephone health behavior surveys to identify a population-based cohort of smokers, and randomly assigned smokers to one of four groups: usual care; self-help manual only; self-help manual plus personalized feedback; and self-help manual, personalized feedback, and outreach telephone counseling. Process measures from this study were encouraging. A large proportion of non-volunteers used the self-help materials. Among participants who were randomized to receive the outreach telephone counseling, over three-fourths of them participated in all three phone calls. The 3-month follow-up results were promising for the group that received the outreach telephone counseling; they had nearly double the abstinence rate of the control group. However, by the 12-month follow-up, prevalent abstinence rates did not differ across the study arms. Abstinence rates held steady in the phone counseling group and improved in the other three groups. Notably, our positive results for the written personalized feedback with our volunteer sample of smokers were not replicated in this non-volunteer sample (16).

The findings from our non-volunteer study suggested that outreach interventions by a health care delivery system may need to occur in more potent "teachable contexts." Our next study involved a relapse prevention trial with pregnant smokers (17). Perhaps our outreach approach that combines self-help materials with written personalized feedback and outreach telephone counseling would work better with a population that has strong motivators for quitting, high spontaneous quit rates, but disappointingly high relapse rates postpartum. In this study, conducted in collaboration with the University of Minnesota and Park-Nicollet, we identified women as they scheduled their first prenatal visit appointment, conducted telephone-based health behavior surveys, and randomized all current smokers and women who had quit for the pregnancy into three groups: (a) a minimal treatment comparison group that received a self-help booklet; (b) a prepartum intervention group that received the self-help booklet and written personalized motivational feedback, three outreach prepartum calls, and a relapse prevention kit mailed late in pregnancy; and (c) a postpartum intervention group that received the prepartum intervention plus three additional outreach counseling calls and three newsletters during the first 4 months postpartum. Once again, we had encouraging results in early postpartum. With regard to overall prevalent abstinence, the prepartum intervention significantly increased 8-week postpartum prevalent abstinence; the postpartum intervention had a significant effect on prevalent abstinence at both 8 weeks and 6 months postpartum. However, there were no significant differences across the three groups in 12-month prevalent abstinence. Results for relapse prevention mirrored those for prevalent abstinence. The prepartum intervention decreased relapse at 8 weeks; the postpartum intervention significantly lowered relapse rates at 8 weeks and at 6 months postpartum. There were no significant differences in relapse rates at 12 months across the three groups (17).

A third population-based randomized trial that evaluated a similar intervention strategy with women who had participated in cervical cancer screening also had null findings (18). In this study, we found no significant differences between a usual care control group and a group that received written feedback that linked smoking and cervical cancer risk as well as provided tailored motivational messages, National Cancer Institute's

"Clearing the Air" booklet, and up to three outreach phone counseling calls.

The findings from our series of studies reflect the general state of the science in self-help interventions. Among self-selected motivated smokers, self-help interventions accompanied by motivational feedback and/or outreach telephone counseling can be effective. However, minimal self-help interventions, even with outreach telephone counseling, do not improve long-term abstinence rates in non-volunteer samples of smokers, although some studies have shown short-term gains. What is notable in these studies is the abstinence rates achieved in the interventions groups are consistent with the outcomes that were projected in sample size and power calculations. The null results reflect better-than-predicted quit rates in the control groups. Our non-volunteer studies were conducted against a backdrop of considerable emphasis on addressing tobacco use as a prevention priority at GHC (19). Perhaps the results of these efforts are reflected in the quit rates in the control groups. One could also speculate that we were seeing an intervention effect from the research-related activities of completing a detailed smoking-related survey at three to four time points. In addition, the studies conducted at GHC did not include pharmacotherapy, which may have improved outcomes, and they did not involve face-to-face contact with the health care delivery system or providers. We have not given up entirely on treatment outcome research and have some exciting studies in the field. One study is a randomized trial comparing two doses of bupropion (Zyban) crossed with two different behavioral programs. A second study is evaluating a brief intervention that includes a motivational interview with a clinic nurse, self-help manual, and outreach telephone counseling *versus* usual care for women bringing their children in for treatment at pediatric clinics that serve low-income populations.

Can Health Care Benefits Impact the Utilization of Smoking Cessation Services?

Despite disappointing findings in our trials with non-volunteer smokers, there is evidence in tobacco treatment research that self-help programs with adjuncts such as outreach telephone counseling can significantly improve cessation outcomes among smokers who actively seek treatment (20). Unfortunately, these programs reach only a small percentage of smokers. Estimates are that <5% of smokers ever participate in formal treatment programs; annual rates of program use are <1%.

The experience at Group Health is consistent with these data. In the late 1980s, following the successful evaluation of the Free and Clear program with outreach telephone counseling, Group Health adopted the program and made it available to Group Health patients in either group or self-help plus phone counseling formats for a fee of \$85.00. The program was modified to include NRT as those products became available by prescription. Prevalent abstinence rates among program participants approached 30% at 1-year follow-ups. However, use of the program in either format was quite low. In 1993, in an effort to extend the reach of the program, GHC implemented a smoking cessation services benefit that covered 50% of the cost of the Free and Clear BP and 100% of the cost (exclusive of usual pharmacy copayments) of NRT for patients enrolled in Free and Clear. Patients who wanted NRT without participating in the BP had no coverage and paid the full costs of the NRT.

During the first year of coverage, there was a 10-fold increase in the use of the Free and Clear program (from 175 to >2000 participants). However, there was also a substantial

proportion of patients (30%) who registered for the program but did not pay the fee for the BP and so did not participate in the services (21).

We conducted an observational study to assess the impact of different benefit structures on the use and cost-effectiveness of the smoking cessation services (22). The study used the original benefit design as the “standard” benefit structure (50% coverage of BP, full coverage of NRT) and compared it with three alternatives. The alternatives were: (a) “flipped” coverage (full coverage of the BP, 50% coverage of NRT); (b) “reduced coverage” (50% coverage of BP, 50% coverage of NRT); and (c) “full” coverage (full coverage of the BP, full coverage of NRT). The benefit structures were implemented with employer groups with 15,000–20,000 adult enrollees. Over a 2-year period, we tracked and compared rates of utilization across the benefits. The study also surveyed benefit users to obtain 6-month prevalent abstinence rates and tracked program costs to provide estimates of costs per quit. The methodological details and results have been published; what follows is a general summary of the findings from this study (22).

Estimated annual rates of use of the benefit among smokers ranged from 2.4% (reduced) to 10% (full). Cessation rates at the 6-month follow-up ranged from 28% (full) to 38% (standard). Adding a 50% copayment for NRT, either through flipping or reducing the standard benefit, did not reduce overall use of the BP but did reduce the use of NRT among benefit users (*i.e.*, fewer smokers who entered the BP obtained NRT). Removing the BP copayments, either through the flipped or full benefits, increased use of the BP. Overall, those with full coverage had the highest utilization of the services; it was more than double the rate of use under the standard coverage (10% *versus* 3.5%, respectively). Extrapolating from the quit rates observed in benefit users and the observed rates of use, we estimated that the percentage of smokers who would quit per year as a result of coverage ranged from 0.7% (with reduced coverage) to 2.8% (with full coverage). Per member/per month costs ranged from 7 cents (reduced) to 41 cents (full). Using data from Oster *et al.* (13) with a 3% discount rate, we calculated the cost per year of life saved with the full coverage benefit to be \$883.00, which compares quite favorably to the costs of treatment for moderate hypertension (\$11,300) and treatment of hypercholesterolemia (\$65,511).

Participant satisfaction, measured at the 6-month follow-up surveys varied as a function of level and type of coverage. Smokers with reduced coverage reported significantly lower satisfaction with the cost and quality of the smoking cessation services. Smokers with flipped coverage, in which they had to pay for half of their nicotine replacement but not for the BP, reported significantly lower satisfaction with the cost of the NRT.

Health care benefits can impact utilization of smoking cessation services. Full coverage does improve the reach of proven interventions into the general population of smokers, with no significant reductions in effectiveness. Thus, organizational-level investments to increase patient access to existing smoking cessation services can have a significant impact on smoking prevalence.

Does Smoking Cessation Impact Health Care Utilization and Costs?

The health benefits of smoking cessation are indisputable. Clearly, health insurers, managed care organizations, and health care providers are motivated to reduce smoking in their patient populations to improve health outcomes. Of course, organiza-

tional, practice, and individual-level initiatives for smoking cessation cost money. It is not surprising, then, that there is a great deal of interest in the economic benefits from smoking cessation, particularly in whether and over what time period one sees changes in health care utilization and costs as a result of smoking cessation.

Capitalizing on our large-scale randomized trials, the stability in the Group Health patient population, and GHC’s rich clinical and administrative data resources, we have been able to track health care utilization and costs for smokers, quitters, and never-smokers over several years. Our first study used cohorts of volunteer smokers who participated in two self-help trials (13, 14) to compare outpatient and hospital service use over 5–6 years for quitters and smokers (23). Quitters were defined as study participants who reported abstinence at both the initial and long-term follow-ups in the respective studies. Smokers were defined as those who never reported abstinence at either follow-up. The 5–6 year time frame began in the year before the index quit and continued for 4–5 years postcessation. Results showed that among continued smokers there is a 7–15% increase in outpatient visits and a 30–45% increase in hospital admissions and hospital days/year over time. Among quitters, there is an increase in health care use during the year that they quit and then a progressive decline in health care use over the follow-up period. Quitters’ utilization was significantly lower than smokers’ by the 4th year after quitting. This study did not track health care cost data, nor did it include a cohort of never-smokers for comparison.

A recently completed study replicated and extended this work by tracking health care utilization and costs among smokers ($n = 342$), quitters ($n = 381$), and never-smokers ($n = 489$). The sample derived from our first population-based self-help trial (16). With regard to health care utilization, nonsmokers’ utilization remained stable over time and was generally lower than that for former and current smokers. For continuing smokers and quitters, the findings replicated those from the prior study. Among quitters, there is a pattern of increased health care utilization in the period surrounding the quit date, followed by declining utilization over time. Utilization for continuing smokers increases over time. In overall comparisons among the three groups in the sample, we found that the former smokers were significantly older and in poorer health than the never- and current smokers, which likely explains their initially higher use of health care. Health status was compared using a CDS, which is an empirically validated pharmacy-based index of chronic disease status (24). It is notable that higher CDS scores are generally predictive of higher utilization over time. Thus, contrary to the observed decline in health care use among quitters, their CDS scores would have predicted continued increases over time.

Health care costs were assessed using a NPV analysis. The NPV is essentially a cumulative total of the average annual health care costs per current and former smokers, inflation adjusted to 1998 dollars with a discount rate of 5%. Results from these analyses showed that the year 1 costs are higher for quitters compared with continuing smokers, which is consistent with the observed differences in health care utilization. On average, a quitter cost about \$1250 more than a continuing smoker. This difference declines over time, so that by the third year after quitting, the cumulative costs for quitters are only \$160 more than for continuing smokers, and by year six, the average cumulative costs for a smoker exceeds those of a former smoker by \$1400. Thus, the NPV for former smokers equals that for continuing smokers by the 4th year after quit-

ting, and overall initial excess costs for quitters are recovered between the 4th and 5th years after quitting.

We did find associations between health care utilization and smoking cessation in both treatment volunteers and the general population of smokers. Poorer health, reflected in higher use and costs of health care in the index year of quitting, is likely motivating many successful cessation attempts. After their higher initial costs, quitters' costs go down at the same time that those of continuing smokers' begin to accelerate. Cessation appears to reverse a trajectory of higher health care costs. What our data cannot show is what the long-term health care costs would have been, had the quitters not achieved cessation. It would not be unreasonable to assume that their costs would have continued to escalate. Thus, the ultimate savings in health care costs may be greater than what was observed. Our research also has not been able to examine the impact of smoking cessation on health care utilization and costs among potentially "expensive" subpopulations, such as Medicaid and Medicare enrollees.

Summary and Future Directions

It is an immense honor to receive the Joseph W. Cullen Memorial Award as recognition for the contributions that my colleagues and I have made in the area of tobacco intervention research. I was certainly inspired by Joe Cullen's enthusiastic approach to building the evidence base around effective treatment for tobacco cessation and by his vision of moving this evidence from "the ivory tower to the streets." Under his leadership, the National Cancer Institute's grant initiatives in the mid-1980s created a culture of cross-collaboration, collegiality, and productivity in tobacco intervention research that is unparalleled in many research areas. The focus of this presentation on our modest body of research is in no way intended to eclipse the many outstanding contributions of our fellow tobacco researchers.

Over the past 15 years, we have had an opportunity to work in a setting that allowed us to span a wide range of research questions. By leveraging our work in one area (*e.g.*, randomized clinical trials) to address questions in another (*e.g.*, health services utilization), we have moved seamlessly from patient-level clinical trials to population-level health services research. It has been particularly rewarding to see results from tobacco treatment research translated into clinical priorities and practices at GHC.

There is still much important work to be done. Among the key directions for this work are: exploring the use of new technologies such as hand-held computers and the internet both as research tools and to deliver cessation and relapse prevention treatments; developing effective ways to bundle intervention models and methods to address multiple behavioral risk factors; and evaluations of gene-environment interactions in the initiation of tobacco use and in treatment response.

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