

Cost-Effectiveness of Intensive Tobacco Dependence Intervention Based on Self-Determination Theory

Irena Pesis-Katz, PhD; Geoffrey C. Williams, MD, PhD; Christopher P. Niemiec, PhD;
and Kevin Fiscella, MD, MPH

Tobacco dependence is the leading cause of death in the United States and carries an estimated cost of \$183 billion in US dollars per year in direct medical care and lost productivity.^{1,2} Interventions for smokers who want to stop within 30 days are cost-effective, requiring less than \$2500 per quality-adjusted life-year (QALY) saved.³⁻⁶ This estimate compares favorably with other medical services, such as screening for hypertension among men aged 45 to 54 years (\$5200 per QALY). Tobacco dependence treatments can also help prevent costly chronic conditions, such as heart and pulmonary disease, cancer, and various infectious diseases.⁷ However, there are few data on the cost-effectiveness of interventions that target all smokers, including those who do not want to stop within 30 days.

The objective of this effectiveness (ie, real world) study was to evaluate the cost-effectiveness of an intensive tobacco dependence intervention that targeted all smokers, both those who did and did not want to stop smoking within 30 days. The intervention was based on self-determination theory (SDT) and consistent with the Public Health Service (PHS)-sponsored Clinical Practice Guideline for Treating Tobacco Use and Dependence.⁸⁻¹¹ Previous findings from this trial have documented the effectiveness of the intervention, relative to community care (CC), in facilitating tobacco abstinence at 6, 18, and 30 months postrandomization.¹²⁻¹⁴ The current analysis presents data on the cost-effectiveness of the intervention and, in doing so, advances the extant literature in 2 ways. Specifically, it provides the first cost-effectiveness analysis of an intensive tobacco dependence intervention that was intended to support autonomy and perceived competence and which was thus consistent with the principles of biomedical ethics.¹⁵ Also, it provides the third-party payer's perspective on the cost-effectiveness of an intensive intervention that targeted all smokers, not only those who wanted to stop within 30 days.

METHODS

Participants, Study Design, and Conditions

Data for the current cost-effectiveness analysis were obtained from a randomized cessation-induction trial of an SDT-based intervention intended to support autonomy and perceived competence. Cessation-induction trials differ from aid-to-cessation studies in that they include smokers

Objectives: To evaluate cost-effectiveness of a tobacco dependence intervention based on self-determination theory (SDT) and consistent with the Public Health Service (PHS)-sponsored Clinical Practice Guideline for Treating Tobacco Use and Dependence.

Study Design: Adult smokers were recruited into a randomized cessation-induction trial of an intensive intervention versus community care. Seven-day point prevalence (7dPP) tobacco abstinence and cost-effectiveness of the intervention were examined using 737 participants with health insurance.

Methods: Community care (CC) participants received smoking-cessation pamphlets and information on local treatment programs. Intervention participants received those materials and were asked to meet 4 times over 6 months with study counselors to discuss their health in a manner that supported autonomy and perceived competence. The third-party payer's perspective was used for this analysis, and the primary outcome was cost-effectiveness using self-reported 7dPP tobacco abstinence at 6 months. Sensitivity analyses were performed using costs of generic medications, biochemically validated tobacco abstinence, actual rates of tobacco abstinence, life-years saved (not adjusted for quality of life), and costs in 2011 US dollars. A subgroup analysis was conducted using smokers who did not want to stop within 30 days.

Results: Smokers in the intervention, relative to CC, were more likely to attain 7dPP tobacco abstinence at 6 months. The overall incremental cost-effectiveness ratio was \$1258 per quality-adjusted life-year saved, in US dollars. The sensitivity and subgroup analyses yielded similar results.

Conclusions: An intervention based on SDT and consistent with the PHS Guideline facilitated tobacco abstinence among insured smokers and was cost-effective compared with other tobacco dependence and medical interventions.

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In this article

Take-Away Points / e394

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see end of text.

Take-Away Points

This study evaluated cost-effectiveness of an intensive tobacco dependence intervention based on self-determination theory and consistent with the Public Health Service-sponsored Clinical Practice Guideline for Treating Tobacco Use and Dependence.

■ Findings suggested that the intervention was highly cost-effective (about \$1300 per quality-adjusted life-year in US dollars) among insured smokers, both for those who did and did not want to stop smoking within 30 days.

■ Sensitivity analyses indicated little variation in cost-effectiveness using generic medications, biochemically validated tobacco abstinence, actual rates of tobacco abstinence for each gender and age group, life-years saved (not adjusted for quality of life), and costs in 2011 US dollars.

low-density lipoprotein cholesterol.¹⁸ Because previous analysis of these data indicated no effect of the dietary intervention on tobacco outcomes, the dietary and tobacco conditions were collapsed and the current analysis focused only on the tobacco intervention and outcomes.¹³ About 70% of the insured participants (n = 526) were randomized to a 6-month SDT-based intervention, whereas the rest (n = 211) were random-

regardless of whether they want to stop and, because smokers are not assigned a specific stop date, study outcomes are reported based on time from randomization.

Participants were recruited from the greater Rochester, New York area between January 2000 and July 2002 using newspaper advertisements and signs in physicians' offices, and were enrolled in the study for 18 months (until January 2004). Although participants were enrolled in the study for 18 months, the intensive intervention was provided only during the first 6 months of the study and accordingly, the current analysis presents the 6-month costs and outcomes. Eligibility criteria were designed to yield a fairly representative sample of smokers, and included having smoked at least 100 cigarettes in their lifetime and 5 or more cigarettes per day during the week prior to enrollment, being at least 18 years of age, having the ability to read and speak English, having no history of psychotic illness (anxiety and depression were allowed), having a minimal life expectancy of 18 months, and planning to live in the greater Rochester, New York area for at least 18 months. Notably, having an intention to stop smoking was not an inclusion criterion and, thus, the study sample represented a broad population of smokers that varied in their intention to stop. The original sample included 1006 adult smokers with different insurance coverage, including private insurance, public insurance, and no insurance. Those without insurance were excluded from this analysis because we were interested in cost-effectiveness from the third-party payer's perspective and because utilization of smoking-cessation services varies by existence and extent of health insurance.¹⁶ The final sample included 737 participants with health insurance.

A detailed description of the study design, recruitment procedures, treatment approach, and primary outcome results has been presented elsewhere.^{12-14,17} All study participants signed an informed consent form at the time of enrollment, received parking passes, and were paid \$30 after completing the 6-month questionnaire (honoraria were prorated if participants withdrew from the study before completing it). Randomization was stratified by whether participants met the National Cholesterol Education Program guideline for

ized to CC. This ratio for random assignment was used to minimize harm to the CC condition, as the intervention was expected to have a more pronounced effect on tobacco abstinence.¹¹ All CC participants were offered intensive treatment after completing the study. This protocol was approved by the University of Rochester's Research Subjects Review Board.

Participants in the CC condition received the *You Can Quit Smoking* and *Clearing the Air: Quit Smoking Today* smoking-cessation pamphlets, the results of their cholesterol tests, and a list of all local smoking-cessation resources, including the New York State Quit Line.¹⁹ They were also encouraged to enroll in a smoking-cessation program and to consult with their physician about their smoking and cholesterol. Thus, this study examined whether the intervention facilitated improvement in tobacco outcomes compared with typical care available in the community.

Participants in the intervention condition received the same materials and advice as those in CC, and were asked to meet 4 times over 6 months with study counselors to discuss their health. The initial visit lasted 50 minutes, and follow-up visits lasted 20 minutes each. The intervention involved taking a medical and smoking history, eliciting and acknowledging participants' perspectives on their smoking and its health risks, and discussing how stopping might improve health. Counselors presented participants with their 10-year absolute risk for developing coronary artery disease and the expected risk-reduction if they stopped smoking completely, and asked how they felt about that information.^{20,21} Participants discussed life aspirations and were asked how smoking helped and/or hindered them in attaining those goals.²² Finally, participants were asked whether they wanted to stop using tobacco. If yes, counselors provided competence support, and those participants who wanted to use medication were given the option of obtaining it from their own healthcare provider or from a study prescriber. Available medications included all first-line smoking-cessation medications approved at the time of this trial (ie, nicotine replacement, bupropion SR). Those who were not ready to stop were asked to return in 2 months to

Cost-Effectiveness of Intensive Tobacco Dependence Intervention

discuss smoking cessation again. There was no limit on the number of contacts within the 6-month intervention period.

Smoking Status

At 6 months postrandomization, participants responded either “yes” or “no” to having smoked a cigarette, even a puff, in the past 7 days and to having currently used a pipe, cigars, snuff, or chewing tobacco. To be classified as having attained 7-day point prevalence (7dPP) tobacco abstinence at 6 months, participants must have responded “no” to having used each form of tobacco listed above.

Cost Estimates

We adopted the third-party payer’s perspective for this analysis. All costs were estimated in 2003 US dollars (adjusted when appropriate) using the Consumer Price Index inflation tables provided by the US Department of Labor.²³ Variable costs included the type and amount of personnel time (in-person and over-the-phone contact minutes with each participant), wages (including overhead), and self-reported purchase of recommended medications. The medication costs were based on contract pricing for brand-name and generic medications provided by the largest private insurer in the greater Rochester, New York area. Fixed costs were attributed across all participants and included program promotion, lab tests (lipid analysis), parking passes, computers (only applicable depreciation value), software, supplies, copying and printing, and postage. Rent, utilities, janitorial expenses, and taxes were included as fixed costs and attributed based on their relative use in the intervention. For those who received smoking-cessation consultation from their own physician, we included participants’ self-reported contact time in the cost estimates. Nonrecurring costs (eg, program start-up, including staff training, devel-

■ **Table 1.** Fixed and Variable Costs Incurred per Study Participant

Fixed Costs	Cost per Participant, \$	Total Cost, \$	
Supplies	10.7	7893.8	
Software	0.7	524.7	
Copy charges	1.0	755.6	
Computers	10.9	8041.9	
Program promotion	9.7	7109.2	
Rent	38.6	28,420.6	
Taxes	0.2	178.8	
Utilities	4.7	3455.0	
Postage	9.2	6782.5	
Janitorial expenses	2.5	1807.8	
Parking	3.0	2091.0	
Lipid profile blood test ^a	38.0	44,809.6	
Total fixed costs		111,870.2	
		Total Cost (by Study Condition), \$	
Variable Costs	Cost per Unit, \$	Community Care (n)	Intervention (n)
Consultation	19.5/hour (counselor) 74.5/hour (physician)	2590.9	33,199.6
Medication (brand name):	Cost per 30-day Supply, \$		
Nicotrol inhaler	30.5	91.4 (2)	3928.3 (57)
Nicotine gum	15.4	153.8 (7)	723.0 (18)
Nicotine patch	106.0	4028.3 (19)	29,788.1 (103)
Nicotine nasal spray	398.2	0 (0)	12,342.5 (9)
Bupropion (Zyban)	106.2	5202.8 (18)	24,952.3 (86)
Total variable costs		12,067.2	104,933.8

^aTwo tests performed per participant.
Note: (n) = number of participants who used each medication.

opment, research, and evaluation) were not included in the cost estimates. **Table 1** provides all fixed and variable costs incurred per study participant.

Quality-Adjusted Life-Years Saved

Six-month rates of tobacco abstinence, stratified by gender and age for each group, were converted to QALYs using published estimates of the long-term benefits of smoking cessation.²⁴ In that study, QALYs for gender and age were derived from Markov chain modeling using data from US national cohorts. Estimates were discounted at 3% and assumed a 35% relapse rate.

Cost-effectiveness Calculations

Incremental cost-effectiveness ratios were calculated for each gender and age group. The numerator was the difference in overall costs between the intervention and CC conditions. Fixed costs were equally distributed among all participants and variable costs were attributed to each par-

Table 2. Descriptive Statistics at Baseline for the 737 Insured Smokers in the Intervention and Community Care Conditions

Baseline Variable	Intervention Mean (SD)	Community Care Mean (SD)	P
Age	45.79 (11.98)	44.55 (11.39)	.20
Socioeconomic status (1-9)	4.54 (2.42)	4.60 (2.41)	.76
Cigarettes per day	20.18 (9.95)	19.92 (9.69)	.75
Fagerström Addiction Severity Scale	4.91 (2.36)	4.74 (2.33)	.37
	Intervention N (%)	Community Care N (%)	
Want to stop within 30 days	261 (49.6)	100 (47.4)	.43
Female	329 (62.5)	138 (65.4)	.47
Married	210 (39.9)	84 (39.8)	.98
Ethnicity (white)	432 (82.1)	171 (81.0)	.71
Commercial insurance (vs government)	460 (87.5)	183 (86.7)	.65
Lost to follow-up at 6 months	181 (34.4)	65 (30.8)	.35

SD indicates standard deviation.
 Note: Intervention condition (n = 526); Community care condition (n = 211). Socioeconomic status was measured as annual family income, where: 1 = \$0-\$9,999; 2 = \$10,000-\$19,999; 3 = \$20,000-\$29,999; 4 = \$30,000-\$39,999; 5 = \$40,000-\$49,999; 6 = \$50,000-\$59,999; 7 = \$60,000-\$69,999; 8 = \$70,000-\$79,999; 9 = \$80,000+.

participant as incurred. The denominator was the difference in QALYs between the intervention and CC conditions. Rates of tobacco abstinence were estimated for each gender and age group based on intention-to-treat, in which all participants who were lost to follow-up were assumed to be smoking. Overall cost-effectiveness was calculated by multiplying each group's rate of tobacco abstinence by the expected QALYs due to smoking cessation, discounted at 3%, using estimates from previous research.²⁴ The incremental cost-effectiveness ratio was calculated as:

$$\frac{\text{individual costs (intervention)} - \text{individual costs (CC)}}{\text{QALYs saved (intervention)} - \text{QALYs saved (CC)}}$$

Sensitivity Analysis

To test the robustness of the results, the following parameters were varied: costs of generic medications, biochemically validated tobacco abstinence, actual rates of tobacco abstinence for each gender and age group (for groups larger than 5), and life-years saved (not adjusted for quality of life). Further, because this study used data that were collected in 2003, we performed an additional sensitivity analysis by estimating all costs in 2011 US dollars and using generic medications when available to determine current cost-effectiveness implications. Finally, a subgroup analysis was conducted using smokers who did not want to stop within 30 days (n = 370).

RESULTS

Descriptive Statistics at Baseline

Table 2 presents descriptive statistics at baseline for the 737 insured smokers across the 2 conditions. There were no statistically significant group differences in the baseline variables or percentage of participants who were lost to follow-up at 6 months.

7dPP Tobacco Abstinence at 6 Months

Table 3 presents the total number and percentage of smokers who attained 7dPP tobacco abstinence at 6 months across the 2 conditions. Participants in the intervention, relative to the CC group, were more likely to attain both self-reported (15.59% vs 4.74%; $\chi^2(1) = 16.23, P < .01$) and biochemically validated (12.74% vs 3.32%; $\chi^2(1) = 14.79, P < .01$) measures of 7dPP tobacco abstinence at 6 months. Among those who did not want to stop smoking within 30 days, participants in the intervention, relative to the CC group, were more likely to attain self-reported 7dPP tobacco abstinence at 6 months (13.79% vs 4.59%; $\chi^2(1) = 6.61, P < .05$).

Incremental Costs per Participant and Incremental Cost-effectiveness Ratios

Total study costs averaged \$145 per participant in the CC group and \$377 per participant in the intervention group (this difference was due to higher variable costs in the intervention). The incremental costs per participant in the intervention ranged from \$161 to \$432. The overall incremental cost-effectiveness ratio, discounted at 3%, was \$1258 per QALY, and ranged from \$645 to \$2674 per QALY. Examination of the gender and age breakdown showed that the cost-effectiveness ratios were slightly better (ie, lower ratio) for younger men. The incremental cost-effectiveness ratio, discounted at 3%, for the subgroup who did not want to stop within 30 days at baseline was \$1242 per QALY, and ranged from \$586 to \$3828 per QALY.

Sensitivity Analyses

Sensitivity analyses confirmed the robustness of our findings. By changing all medication costs from brand name to generic, the overall incremental cost-effectiveness ratio was reduced by about 10% to \$1144 per QALY, and ranged from \$699 to \$2616 per QALY. By classifying only those with biochemically validated 7dPP as having attained tobacco

abstinence, the overall incremental cost-effectiveness ratio was increased by about 34% to \$1692 per QALY, and ranged from \$749 to \$5668 per QALY. By using actual rates of tobacco abstinence for each gender and age group, the overall incremental cost-effectiveness ratio was increased by about 1% to \$1267 per QALY, and ranged from \$542 to \$2670 per QALY. By using life-years saved (not adjusted for quality of life), the overall incremental cost-effectiveness ratio was \$498 per life-year saved, and ranged from \$294 to \$2343 per life-year saved. By estimating all costs in 2011 US dollars, the overall incremental cost-effectiveness ratio was increased by about 6% to \$1332 per QALY, and ranged from \$814 to \$3047 per QALY.

DISCUSSION

An intensive tobacco dependence intervention based on SDT that targeted all smokers, not only those who wanted to stop within 30 days, was found to be cost-effective compared with other services commonly covered by health plans, including less intensive tobacco dependence treatment and prevention, as well as other medical services. Remarkably, the overall incremental cost-effectiveness ratio was about \$1300 per QALY. Indeed, these findings were based on intention-to-treat data and thus may be conservative estimates. Further, unlike in actual practice, all CC participants in this study were offered a low-intensity intervention. Sensitivity analyses indicated that using: (1) generic medications, (2) biochemically validated tobacco abstinence, (3) actual rates of tobacco abstinence for each gender and age group, (4) life-years saved (not adjusted for quality of life), and (5) costs in 2011 US dollars yielded only small changes in cost per QALY, suggesting that our findings were robust to several plausible variations in the model parameters.

These findings support adoption of intensive tobacco dependence interventions by the US healthcare system for all smokers who are willing to discuss their tobacco use, as the

SDT-based intervention was cost-effective even for those who did not want to stop within 30 days. Although the intervention was provided by a tobacco dependence treatment team, it was integrated with cardiovascular risk information typically discussed in primary care settings, and about half of the participants who used medications received them from their own healthcare provider. Thus, it is feasible for primary care providers to deliver the intervention to smokers who are willing to receive intensive treatment, although we note that within the scope of this study we were not able to measure all costs associated with this form of delivery. Alternatively, a healthcare system could employ counselors at a central location with which primary care providers could collaborate to provide the intervention.

Herein, and in other published articles from this trial, we have emphasized the importance of demonstrating that theoretically consistent mechanisms of change explain the effect of the intervention in facilitating long-term tobacco abstinence. Previous findings from this trial have shown that the intervention was effective in enhancing patient autonomy and perceived competence, and thus consistent with the SDT model of health-behavior change.¹⁴ Interventions, no matter how intensive, that do not address these fundamental aspects of motivation may not yield comparable cost-effectiveness estimates. The proposed explanatory constructs derived from SDT—autonomy and perceived competence—are wholly consistent with the principles of biomedical ethics. Although a focus on mediators of treatment effects is relatively rare among cost-effective interventions, its importance is not to be missed. For instance, if the intervention facilitated tobacco abstinence but undermined patient autonomy, it would not be suitable for translation into medical practice because support for patient autonomy is an outcome that is equivalent to improving patient well-being.^{15,25} That cost-effective interventions support patient autonomy ought to be a benchmark standard for future comparative effectiveness trials and value-based medical studies to attain.²⁶

Several limitations deserve mention. First, the generalizability of our findings may be limited, as they were based on a single study with a modest sample size and participants who were recruited only from the greater Rochester, New York area. Second, medication costs were based on the self-

Table 3. 7dPPTobacco Abstinence at 6 Months in the Intervention and Community Care Conditions

Outcome Variable	Intervention N (%)	Community Care N (%)	χ^2	P
Self-reported 7dPP tobacco abstinence (all participants)	82 (15.6)	10 (4.7)	16.23	<.01
Biochemically validated 7dPP tobacco abstinence (all participants)	67 (12.7)	7 (3.3)	14.79	<.01
Self-reported 7dPP tobacco abstinence (did not want to stop within 30 days)	36 (13.8)	5 (4.6)	6.61	<.05

7dPP indicates 7-day point prevalence.
 Note: All participants (n = 737). Participants who did not want to stop within 30 days (n = 370). Participants with missing information on intention to stop within 30 days (n = 6).

reported amount of medication purchased, as we did not have the amount of medication consumed by each participant, and cost estimates for medications were obtained from the largest private insurer in the greater Rochester, New York, area. Third, we did not estimate the specific QALYs for our participants, but instead used published estimates of the effects of smoking cessation on quality of life and life expectancy within a nationally representative US sample stratified by gender and age.²⁴ The full benefits of smoking cessation take many years to accrue and thus could not be directly derived from our study sample. Indeed, a recent study has demonstrated the improvement in quality of life for non-smokers and those who have stopped relative to those still smoking.²⁷ Fourth, all participants who were lost to follow-up were assumed to be smoking, but this approach yields more, rather than less, conservative estimates, and modifications of relevant model parameters produced similar findings, thus underscoring the robustness of our findings. Future studies might focus on other areas of health-behavior change and evaluate cost-effectiveness based on QALYs for study participants.

Author Affiliations: From School of Nursing (IP-K), Healthy Living Center (GCW), Department of Clinical and Social Sciences in Psychology (CPN), School of Medicine and Dentistry (KF), University of Rochester, Rochester, NY.

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Address correspondence to: Geoffrey C. Williams, MD, PhD, Healthy Living Center, Center for Community Health, University of Rochester, 46 Prince St, Ste 3001, Rochester, NY. E-mail: geoffrey_williams@urmc.rochester.edu.

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