Evaluation of the American Stop Smoking Intervention Study (ASSIST): A Report of Outcomes

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Background: **The National Cancer Institute funded an 8-year, nonrandomized demonstration project for tobacco prevention and control, the American Stop Smoking Intervention Study (ASSIST). To evaluate ASSIST, we compared changes in adult smoking prevalence, *per capita* cigarette consumption, and tobacco control policies between the 17 ASSIST states and the 33 non-ASSIST states and the District of Columbia.** ***Methods:*** **The strength of tobacco control index was used to measure state-level program elements directed at tobacco control, and the initial outcomes index (IOI) was used to measure states' tobacco control policy outcomes. Prevalence data were obtained from the Tobacco Use Supplement to the Current Population Survey, and consumption data were obtained from the Tobacco Institute's bimonthly sales figures for cigarette packs moved from wholesale warehouses. Two-stage regression and mixed-effects linear modeling were used to analyze the various outcomes. Statistical analyses for testing individual regression coefficients were one-sided.** ***Results:*** **ASSIST states had a greater decrease in adult smoking prevalence than non-ASSIST states, with an adjusted difference of −0.63% ($P = .049$). *Per capita* cigarette consumption was not statistically significantly different between ASSIST and non-ASSIST states. However, an increase in the IOI of a state from the 25th to the 75th percentile was associated with a reduction in *per capita* cigarette consumption by 0.57 packs per person per month. State IOI was also inversely, albeit not statistically significantly, associated with smoking prevalence (regression coefficient = −0.11; $P = .06$).** ***Conclusions:*** **The reduction in adult smoking prevalence associated with ASSIST could have translated into approximately 278 700 fewer smokers nationwide if all states had implemented ASSIST. Investment in building state-level tobacco control capacity and promoting changes in tobacco control policies are effective strategies for reducing tobacco use. [J Natl Cancer Inst 2003;95:1681–91]**

The National Cancer Institute's (NCI's) long-standing role in supporting research to prevent cancer by reducing tobacco use has spanned the continuum from basic biomedical research to large-scale public health interventions and demonstration projects *(1–5)*. In 1991, the NCI awarded contracts to 17 state health departments—Colorado, Indiana, Maine, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New Mexico, New York, North Carolina, Rhode Island, South Carolina, Virginia, West Virginia, Washington, and Wisconsin—to undertake the American Stop Smoking Intervention Study (ASSIST) and formed a partnership with the American Cancer Society to implement the project.

All 50 states and the District of Columbia were eligible to compete for the NCI contracts; 35 states applied for the contracts and 23 states were deemed eligible for funding based on published selection criteria *(6,7)*, although only 17 states were awarded contracts because of budgetary constraints. ASSIST was a phase V demonstration project of the NCI's cancer control research sequence *(8)* and was not a randomized experiment. Therefore, the states chosen for ASSIST funding represented a wide range in terms of their ability and experience in developing and implementing tobacco control programs and constituted a purposeful sample. ASSIST can be considered to be a large-scale natural experiment in which the observational unit was the state (i.e., its entire population and environment), and the goal was to change the state's social, cultural, economic, and environmental factors that influence smoking behavior. This goal was accomplished primarily through interventions in four policy areas: 1) promoting smoke-free environments, 2) countering tobacco advertising and promotion, 3) limiting tobacco access and availability, and 4) increasing tobacco prices through new excise taxes.

The ASSIST states implemented the project in two phases: a 2-year planning phase (October 1991 through October 1993) and a 6-year implementation phase (November 1993 through September 1999). NCI funding was, on average, $1.14 million per year per state during the implementation phase (ranging from $752 000 in West Virginia to $1 851 000 in New York), with a total of $114 million in federal funds originally being allocated for the ASSIST project. The ASSIST project was the first major federal investment in creating state tobacco control infrastructures.

Complicating the ASSIST evaluation was the strategy of diffusion of materials and interventions from ASSIST states to non-ASSIST states, with no restriction on the free flow of knowledge and technical assistance. In addition, during the 1990s, tobacco control activities and issues were receiving more media attention than ever before in most states. Concurrently, the tobacco industry, more forcefully than ever, was opposing tobacco control policy interventions.

In this article, we provide the results of this large-scale demonstration study. The ASSIST evaluation compared changes in tobacco control policies, state *per capita* cigarette consumption, and adult smoking prevalence in the 17 ASSIST states with

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those in the 33 non-ASSIST states and the District of Columbia. We also analyzed the effect of program components and tobacco control policies on reducing smoking prevalence and *per capita* cigarette consumption.

METHODS

Overview

The ASSIST evaluation assumes that cigarette smoking is driven by a complex set of environmental factors and that change in smoking behavior from tobacco control policy initiatives occurs incrementally and at a modest pace. With these assumptions, multiple outcome points (i.e., initial, intermediate, and final) were needed for tracking changes in policy, behavior, cigarette consumption, and smoking prevalence as it occurred over the 8-year span of the ASSIST project. This time span is reasonable, given the expectation that reduction in smoking prevalence would lag behind changes in policy and social norms and reductions in cigarette consumption but that, over time, an effect of ASSIST on smoking behavior should be measurable. Therefore, early signs of change, such as change in policy for states (e.g., amount of tax and new clean–indoor air legislation), could serve as an initial outcome of the effect of the intervention. This article considers only the initial and final outcomes because these were considered to be the primary focus of the evaluation effort. Descriptions of the evaluation model that guided the development of the ASSIST evaluation as well as the data sources, measures, and analytic approaches have been previously described *(9)*. Fig. 1, A, shows the ASSIST evaluation model and Fig. 1, B, shows a timeline of the ASSIST project.

ASSIST Evaluation Questions

The ASSIST evaluation addressed two types of questions. The first was designed to address program effectiveness, i.e., to determine whether ASSIST states increased their tobacco control policies and had greater decreases in smoking prevalence and *per capita* cigarette consumption than non-ASSIST states. The second was designed to address whether state tobacco control activity and changes in tobacco control policy were related to change in tobacco use over time, i.e., did states with strong tobacco control efforts and polices, reflecting an idealized model of ASSIST (ASSIST-like), have lower tobacco use? This article addresses four specific research questions: 1) Was ASSIST associated with an increase in the initial outcomes index (IOI), which measures the percentage of smokers covered by 100% smoke-free work sites, cigarette price, and legislative ratings? 2) Was ASSIST associated with a decrease in adult smoking prevalence and adult *per capita* cigarette consumption? 3) Did states with higher strength of tobacco control (SOTC) scores (a measure of resources, capacity, and program efforts [*see* below]) have lower adult smoking prevalence and adult *per capita* cigarette consumption than states with lower SOTC scores? and 4) Did states with higher IOI scores have lower adult smoking prevalence and adult *per capita* cigarette consumption than states with lower IOI scores?

Intervention Measures

ASSIST indicator. States were identified as either ASSIST (17 states) or non-ASSIST (33 states plus the District of Columbia.).

SOTC. The SOTC index was developed to provide additional information on which components of ASSIST or ASSIST-like programs might be associated with lower smoking prevalence or *per capita* cigarette consumption *(10)*.

The SOTC index is a multi-element measure that assesses the combined amount of three variables in each state: tobacco control resources, capacity, and program efforts focused on policy and environmental change. Tobacco control resources include states' budgetary expenditures for tobacco control and the number of full-time tobacco program personnel. The capacity to

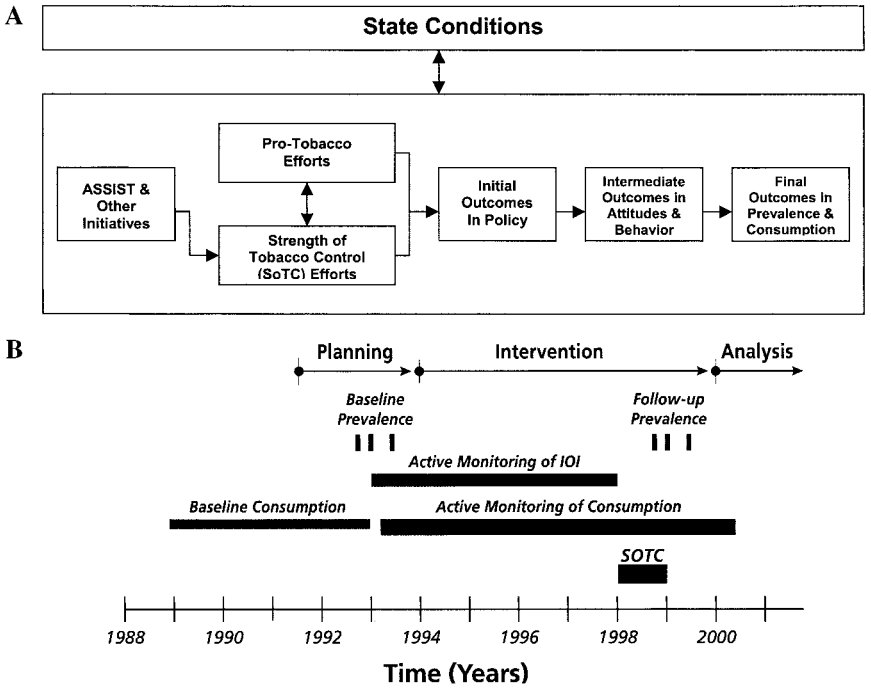

Fig. 1. A) American Stop Smoking Intervention Study (ASSIST) evaluation model. **Arrows** show the hypothesized relationships between the different components of the ASSIST evaluation, where State Conditions are the baseline person- and state-level variable values prior to the intervention, ASSIST & Other Initiatives are the intervention and other tobacco control programs that occurred during the intervention period, Strength of Tobacco Control (SOTC) Efforts are the level of tobacco control activity in the states, Pro-Tobacco Efforts are the countervailing efforts on the part of the tobacco industry, Initial Outcomes in Policy are the states' tobacco control policies, Intermediate Outcomes in Attitudes and Behavior are the person-level behaviors and attitudes about tobacco use, and Final Outcomes in Prevalence and Consumption are the states' smoking prevalence and *per capita* cigarette consumption. **B**) The ASSIST timeline of events showing the different periods and activities of the intervention and evaluation.

implement tobacco control activities in the ASSIST evaluation includes health department infrastructure, staff experience, interagency relationships, and the number and coverage of statewide coalitions *(11,12)*. Tobacco control program efforts are the percentage of effort focused on socio-environmental and policy interventions.

The SOTC index can be used to compare the different tobacco control programs in the various states. Budget data were available to assess the amount of federal and state money committed to tobacco control for all years from 1991 through 1999. No consistent or complete data were available on number of staff, capacity, or program efforts, so a new data collection method was designed and implemented in 1998–1999 to collect this information. To obtain these data, a structured survey was conducted with key informants (i.e., all tobacco control organizations, including state health departments, voluntary health organizations, advocacy groups, and coalitions; n = 353) from state-level tobacco control organizations in all 50 states and the District of Columbia. *(13)*. These data were used to determine whether states with more resources, better infrastructure, and greater capacity to deliver tobacco control programs achieved lower smoking prevalence and *per capita* cigarette consumption than states with fewer resources and lower capacity.

Structural equation modeling was used to validate the SOTC index. The three major variables of the SOTC index—tobacco control resources, capacity, and program efforts focused on policy and environmental change—were found to make statistically significant contributions to the overall SOTC index. The SOTC index was also validated externally *(10)*.

State Conditions (Controlled Factors)

Person-level factors. Demographic characteristics of individuals (Table 1) were used as independent factors (variables) in the regression analysis for adult smoking prevalence. Adjusting the analysis at the person level makes use of the approximately 480 000 participant responses to the Tobacco Use Supplement to the Current Population Survey (TUS-CPS, an NCI-sponsored survey of tobacco use that is part of the U.S. Census Bureau's Current Population Survey) and allows for removal of individual variability accounted for by the demographic variables before moving to the state-level analysis.

State-level factors. State-level factors include both demographic and economic factors that are measured for each state and may confound the relationships between intervention measures and outcomes (Table 1); these factors are controlled for in the regression analyses *(14,15)*. For example, the value of the tobacco industry to a state's economy, which was measured by assessing the multiple sectors of the state economy that benefit from growing, manufacturing, and processing tobacco *(16)–18)*, may confound the relationship between SOTC index and *per capita* cigarette consumption outcomes.

Outcome Measures

IOI. ASSIST and other state-level comprehensive tobacco control programs set goals to change the tobacco control policy environment, such as increasing cigarette prices or passing more restrictive clean–indoor air legislation, in addition to promoting changes in individual smoking behavior. For the ASSIST evaluation, the IOI (a summary measure) was developed to assess states' tobacco control policy outcomes. A description of the general methodology used to construct the IOI, which is calculated as a *z*-score, has been previously described *(19)*. A modification to this *z*-score was performed by adjusting subsequent *z*-scores (i.e., after baseline) to the baseline *z*-score to reflect index changes over time within and between states. The IOI variables used in this evaluation were 1) yearly state-specific estimates of the population percentages of indoor workers in smoke-free workplaces from the TUS-CPS; 2) average state cigarette price, as obtained from yearly tobacco industry reports *(20);* and 3) yearly rating of state clean–indoor air legislation (taking into consideration state preemption laws), combined with the percentage of the state's population covered by equally restrictive or more restrictive local legislation. Data for the state and local ratings were obtained from the NCI's State Cancer

Table 1. American Stop Smoking Intervention Study (ASSIST) evaluation components

Measure	Variables
	Intervention measures
ASSIST indicator	Identification of states as either ASSIST or non-ASSIST
Strength of tobacco control index	Resources committed to tobacco control (staff and funds) Capacity to deliver state-level tobacco control (infrastructure) Program efforts focused on policy and socio-environmental change
State conditions (controlled factors)	
Person-level (demographic factors)	Age: 18–29, 30–49, 50–64, 65 years or older
	Sex: male, female Education: less than 9th grade, 9th–12th (no high school diploma), high school diploma, some college or associate's degree, 4-year college degree or higher Family income: in dollars Race/ethnicity: black non-Hispanic, Hispanic, white non-Hispanic, other Household size: number of residents Census region: Midwest, West, South, Northeast Employment status: employed, unemployed
State-level (socio-demographic factors)	Sex: % female
	Education: % above high school degree Income: % below poverty level Race/ethnicity: % black non-Hispanic, % Hispanic Metropolitan residency: % living in metropolitan area Census region: Midwest, West, South, Northeast State population: 18 years of age or older Economic value of tobacco: fraction of gross state product from growing, manufacturing, and processing tobacco
	Outcome measures
Initial outcomes index	% of workers covered by 100% smoke-free workplace Cigarette price (including tax) Rating of local and state clean–indoor-air policies
Final outcomes	Adult smoking prevalence (18 years of age or older) *Per capita* cigarette consumption

Legislative Database *(21)* and the American Nonsmokers' Rights Foundation's Local Database *(22–24)*.

Final outcomes. Final outcomes of this evaluation were adult smoking prevalence and adult *per capita* cigarette consumption at the end of the intervention period. Smoking prevalence was obtained from adults interviewed in the TUS-CPS in September 1992, January 1993, and May 1993 (baseline) and in September 1998, January 1999, and May 1999 (follow-up). An adult smoker (≥18 years of age) was defined as an individual using cigarettes on a current, everyday, or occasional basis who had smoked at least 100 cigarettes in his/her lifetime. *Per capita* cigarette consumption was calculated bimonthly for each state from sales data for the total number of cigarette packs moved from wholesale warehouses divided by the state's adult population. The sales data were obtained from the Tobacco Institute's monthly reports *(20)*.

Statistical Analyses

The unit of selection for the ASSIST sites was the state; therefore, the unit of analysis in the evaluation was also the state *(9)*. Using the state as the unit of analysis properly accounts for any interclass correlations of smoking behavior among persons living in the same state because they are more likely to be similar, on average, in their smoking behavior than persons living in different states. If this within-state correlation is not properly accounted for in the analysis, it can lead to inflated type I errors. Each state was treated as an equal unit, regardless of population size. Therefore, with only 51 units of analysis (i.e., 50 states and the District of Columbia), the number of variables included in the analytic regression model is limited. Hence, the analysis in this evaluation relied on the development of indices that summarize multiple independent variables, that is, the SOTC index and the IOI.

ASSIST versus Non-ASSIST states. ***IOI analysis.*** We compared the IOI score between the ASSIST and non-ASSIST states over the intervention period using mixed-effects linear modeling *(25)*. The intercept was treated as a state-varying random effect. Polynomial terms for time were included to reflect nonlinear trends in the IOI. Stepwise regression was used to select state-level conditions as independent variables.

Smoking prevalence analysis. We compared the prevalence of adult smoking between the ASSIST and non-ASSIST states using a two-stage regression analysis *(26)*. The first stage of the regression analysis was used to adjust for differences in person-level demographic factors (Table 1) that exist among states and are associated with smoking. At this stage of the regression analysis, we predicted current smoking at the person level using a logistic regression model that was fit to the combined TUS-CPS data from the baseline (1992–1993) and follow-up (1998–1999) periods. The logistic regression was weighted by TUS-CPS sample weights and included person-level variables and the interactions between sex and age and between sex and race/ethnicity. Residuals obtained from the logistic regression were averaged within each state to form adjusted state-level smoking prevalences for each of the baseline and follow-up periods to be used in the second stage of the regression analysis.

Multiple linear regression was used for the second stage of the regression analysis to adjust for state-level factors (Table 1) and baseline smoking prevalence (using the adjusted baseline state-level prevalences from the first-stage regression) and to evaluate the relationship between an exposure (e.g., ASSIST, SOTC, or IOI) and adult smoking prevalence. State-level factors were selected for inclusion as independent variables in the regression analysis using an all-possible-subsets procedure *(27)*. However, after the analysis, none of the state-level factors were statistically significant, indicating that adjustment at the person level was sufficient for explaining variability in the state-level smoking prevalences. State-level factors were therefore not included as independent variables in the regression model.

An estimate of the reduction in the number of smokers if ASSIST had been implemented nationwide was obtained by multiplying the estimated total number of smokers at baseline (44 238 000) by the adjusted difference in smoking prevalence between the ASSIST and non-ASSIST states.

Per capita cigarette consumption analysis. Bimonthly *per capita* cigarette consumption in the ASSIST states was compared with that in the non-ASSIST states by using a mixed-effects linear modeling analysis in which the intercept was treated as a state-varying random effect *(25)*. Polynomial and trigonometric terms for time were included in the model to reflect the nonlinear trend and periodicity in *per capita* consumption over the period beginning in December 1988 and ending in May 1999. Stepwise regression was used to select state-level conditions as independent variables. The estimate of the ASSIST effect was modeled by interacting the ASSIST indicator variable with the variables for time trend. This model showed the trend in *per capita* cigarette consumption for the ASSIST states to be different from that for the non-ASSIST states during the pre-intervention period (1988–1993).

IOI and SOTC analyses. We analyzed the association between the IOI and bimonthly *per capita* cigarette consumption using mixed-effects linear modeling *(25)*. This analysis was restricted to the implementation phase of the intervention period (November 1993 through May 1999) because both the IOI, which was measured annually, and the SOTC index, which was measured only once, were measured only during this period. The IOI analysis estimated the association between the change in IOI over the intervention period and *per capita* cigarette consumption, as well as the association between each state's specific mean IOI and *per capita* cigarette consumption.

Therefore, for each state, the model included main effects for the state-specific mean IOI and the difference between IOI at each time point during the intervention and the mean IOI; it is the latter regression coefficients that are of interest because they show how change in IOI within a state relates to change in tobacco consumption. The SOTC analysis estimated the association of the SOTC index with *per capita* cigarette consumption over the intervention period. The model included a main effect for the SOTC index.

We analyzed the simple relationship between IOI and smoking prevalence and SOTC and smoking prevalence using a Pearson correlation coefficient. We analyzed the association between IOI and adult smoking prevalence and the SOTC index and adult smoking prevalence using the two-stage regression modeling analyses described above. For each state, mean IOI was included in the second stage of the regression analysis to estimate the adjusted regression coefficient. For the SOTC analyses, the single SOTC index measure was included in the second stage of the regression analysis to estimate the adjusted regression coefficient.

Subset analyses. Selected analyses of smoking prevalence were conducted for sex and age subgroups because of interest in how ASSIST might differentially affect smoking within these groups and because these factors are important predictors of smoking. The first- and second-stage regression analyses were repeated using only data from the appropriate subgroup.

Model diagnostics. In an analysis of a limited number of states in which all states are treated equally, individual states can strongly influence the findings. Standard regression diagnostics were therefore conducted for the smoking prevalence models in which one state at a time was left out to identify states that had an unusually strong influence on the results. In addition, covariates used in the regression models to adjust for state-level factors were examined for unusually high correlations with the exposures (e.g., ASSIST, SOTC, and IOI) to determine whether these factors were unduly inflating variances. The District of Columbia appears to be a prime example of such an influence. Because the District of Columbia lacks the jurisdictional infrastructure of a state, the tools used to measure SOTC and policy change (i.e., IOI) do not accurately assess the actual political structure of the District of Columbia. As a result, we conducted analyses both with and without data from the District of Columbia. We also examined *per capita* cigarette consumption models, with IOI or cigarette price as exposures, by adjusting for state cross-border differentials in price *(28)*. The cross-border adjustments did not change our overall results (data not shown).

Tests of statistical significance. As described in the ASSIST evaluation plan *(9)*, tests of statistical significance for single regression coefficients are based on one-tailed *t* tests at the .05 level. The tests are one-tailed because we were interested in only one-sided alternative hypotheses—that is, is ASSIST associated with a reduction in adult smoking prevalence or not? However, instead of presenting 90% confidence intervals (CIs), which would be consistent with the one-tailed .05 level hypothesis tests, we have presented 95% confidence intervals to comply with the Journal of the National Cancer Institute publication requirements. Thus, the reader should be alerted to, and not confused by, the fact that a regression coefficient could be statistically significantly different from zero based on the one-tailed hypothesis test while, at the same time, the 95% confidence interval could contain zero. *t* tests of statistical significance were used to analyze statistical significance of differences between two variables. *F* tests of statistical significance were used for simultaneous inference of more than one regression coefficient (e.g., testing for interactions between ASSIST and time). The denominator degrees of freedom for the *t* and *F* tests were based on the number of states, with appropriate reduction in degrees of freedom for the number of covariates in the analysis *(25)*. All analyses were conducted with SAS/STAT software (release 6.12; SAS Institute, Cary, NC) *(29)*.

RESULTS

Baseline State Conditions

At baseline, the ASSIST states had an average prevalence of adult smoking (for ages 18 or older) that was less than one percentage point higher than that for the non-ASSIST states (25.19% and 24.41%, respectively; difference = 0.78%, 95% CI = −0.86% to 2.41%; $P = .35$). Table 2 lists other key baseline variables, none of which was statistically significantly different between the ASSIST and non-ASSIST states *(9)*.

Was ASSIST Associated With Increased IOI?

ASSIST states had a greater unadjusted increase in policy outcomes (i.e., IOI) than non-ASSIST states. By the end of the intervention period, the mean (standard deviation) IOI increase for all 50 states and the District of Columbia was 4.05 (1.26) points (Table 3). Of the 17 ASSIST states, 12 (71%) achieved this level of increase (i.e., approximately 4.1 points) in the IOI, but only 10 (29%) of the 34 non-ASSIST states did so. ASSIST states had a greater increase in IOI than non-ASSIST states only from 1993 through 1994. During this time period, the average unadjusted IOI was higher in the ASSIST states than in the non-ASSIST states (Fig. 2). Thereafter, both groups increased their IOI scores each year. In addition, although the ASSIST states gained a 1.1-point lead in 1994 and maintained this lead in IOI over time, they did not accrue a greater lead by the end of the project in 1999.

Table 2. Baseline characteristics of American Stop Smoking Intervention Study (ASSIST) and non-ASSIST states*

Characteristic	ASSIST (95% CI) (N = 17)	Non-ASSIST (95% CI) (N = 34)	P†
Adult smoking prevalence, %	25.19 (23.83 to 26.55)	24.41 (23.44 to 25.38)	.35
Initial outcome index	0.20 (−1.06 to 1.48)	−0.10 (−0.90 to 0.69)	.65
Per capita tobacco consumption, packs per mo	10.64 (9.62 to 11.66)	10.54 (9.71 to 11.37)	.88
Sex, %			
Female	52.22 (51.98 to 52.56)	51.76 (51.27 to 52.25)	.21
Race/ethnicity, %			
Black non-Hispanic	8.57 (4.63 to 12.50)	10.28 (5.86 to 14.70)	.61
Hispanic	5.54 (1.10 to 9.98)	4.78 (2.67 to 6.89)	.72
Metropolitan area resident, %	70.52 (61.07 to 79.97)	62.76 (54.05 to 71.48)	.26
Below poverty line, %	13.85 (11.99 to 15.71)	14.36 (12.78 to 15.95)	.69
Economic value of tobacco × 10^3‡, fraction	5.24 (−2.35 to 12.82)	1.46 (−0.61 to 3.53)	.20
Education above high school, %	44.63 (41.00 to 48.25)	45.67 (43.71 to 47.63)	.57
Mean state population, millions	4.10 (2.53 to 5.66)	3.54 (1.92 to 5.15)	.65
Mean age of state population, y	41.18 (40.69 to 41.67)	41.03 (40.51 to 41.55)	.71

*Non-ASSIST states include the District of Columbia; CI = confidence interval.

†Two-sided *P* values are based on *t* tests.

‡Economic value of tobacco was measured by assessing the multiple sectors of the state economy that benefit from growing, manufacturing, and processing tobacco.

Table 3. Crude prevalence, initial outcome index (IOI), and strength of tobacco control (SOTC) index scores for American Stop Smoking Intervention Study (ASSIST) and non-ASSIST states and overall United States*

Variables	ASSIST (N = 17)	Non-ASSIST (N = 34)	Overall United States (N = 51)
Mean prevalence, % (SD)			
Baseline	25.19 (2.64)	24.41 (2.79)	24.67 (2.74)
Final	22.17 (2.33)	22.30 (3.02)	22.26 (2.79)
Change†	−3.02 (1.37)	−2.11 (1.36)	−2.41 (1.42)
Mean IOI (*z*-score)‡, (SD)			
Baseline	0.20 (2.47)	−0.10 (2.27)	0.00 (2.32)
Final	4.68 (2.99)	3.74 (2.75)	4.05 (2.84)
Change†	4.47 (1.34)	3.85 (1.18)	4.05 (1.26)
Mean SOTC, % (SD)			
Final	0.06 (0.84)	−0.03 (1.35)	0.00 (1.20)

*Non-ASSIST states include the District of Columbia. SD = standard deviation.

†Change = final estimate minus baseline estimate. Two-sided *P* values are less than .001 (based on paired *t* tests).

‡IOI is calculated as a *z*-score, according to previously published methods (*19*).

However, after adjustment for state-level factors (i.e., education above high school, metropolitan residency, and southern census region), we found that ASSIST was not statistically significantly associated with change in IOI over time ($P = .13$). Thus, ASSIST was not associated with a differentially greater increase in the IOI throughout the entire intervention period.

Was ASSIST Associated With Reduced Adult Smoking Prevalence and *Per Capita* Cigarette Consumption?

Prevalence. The mean (standard error) state-specific change in adult smoking prevalence in the entire United States from 1992–1993 to 1998–1999 was –2.4% (0.20%). Of the 17 ASSIST states, the change in prevalence in 12 (71%) states equaled or exceeded the national mean change, compared with only 15 (44%) of the 34 non-ASSIST states (including the District of Columbia; data not shown). Among the ASSIST states, Maine and Virginia achieved the largest decrease in mean adult smoking prevalence (–5.01% [1.68%] and −4.70% [1.36%], respectively), whereas Indiana and New York had the smallest decreases (−0.78% [1.79%] and −0.98% [0.63%], respectively). Among the non-ASSIST states, Georgia and Nevada had the largest decreases in mean adult smoking prevalence (−4.43% [1.57%] and −4.31% [1.52%], respectively), whereas Delaware and Oklahoma had slight increases in prevalence (0.04% [1.74%] and 0.78% [1.51%], respectively).

As shown in Table 3, ASSIST states had a statistically significantly larger decrease in adult smoking prevalence than non-ASSIST states (mean of –3.02% versus –2.11%, respectively; difference = −0.91%, 95% CI = –1.72% to −0.09%; $P = .015$). The two-stage regression analysis that adjusted for person-level factors also showed a statistically significantly larger decrease in adult smoking prevalence in ASSIST states compared with non-ASSIST states (adjusted difference = −0.63%, 95% CI = –1.38% to 0.12%; $P = .049$) (Table 4). Subset analyses of smoking prevalence by sex and age (Table 4) showed that ASSIST was statistically significantly associated with a decrease in smoking prevalence among women (adjusted difference = −0.96%, 95% CI = –1.90% to −0.02%; $P = .023$) but not among men (adjusted difference = 0.09%, 95% CI = −0.80% to 0.97%; $P = .42$); the interaction between sex and ASSIST status was not statistically significant ($P = .18$). The association of ASSIST with adult smoking prevalence by age was not statistically significant.

Consumption. Fig. 3 shows the unadjusted difference in mean *per capita* cigarette consumption between the ASSIST and non-ASSIST states over time. The mixed-effects model, which adjusts for the statistically significant state-level factors (i.e., percentage Hispanic, economic value of tobacco, and percentage with income below poverty level), found that ASSIST states tended to have higher *per capita* consumption than non-ASSIST states before the intervention period and lower *per capita* consumption during the intervention period. However, ASSIST was not statistically significantly associated with the decrease in *per capita* cigarette consumption over time ($P = .22$), as indicated by the wide confidence intervals. To examine the sensitivity of our results to the length of the time period before the ASSIST intervention, we adjusted for *per capita* consumption data back to 1985 in a reanalysis. The results of the reanalysis were not different from those of the original analysis, which goes back to December 1988 (*see* "Methods").

Did States With Higher SOTC Scores Have Lower Adult Smoking Prevalence and *Per Capita* Cigarette Consumption?

Prevalence. In unadjusted analyses, the SOTC index had an inverse association with smoking prevalence in 1998–1999 (Pearson correlation coefficient = −0.42; $P = .001$). However, this relationship was not maintained after adjusting for baseline prevalence and person-level factors (regression coefficient = −0.19, 95% CI = −0.49 to 0.11; $P = .11$) (Table 4). In addition, the SOTC component variables (i.e., resources, capacity, and efforts) were not statistically significantly associated with smoking prevalence after adjustment for person-level factors.

Consumption. After adjustment for state-level factors, the SOTC index was found to be statistically significantly inversely associated with *per capita* cigarette consumption (regression coefficient = −0.39, 95% CI = −0.86 to 0.07; $P = .047$; data not shown). States with higher SOTC scores had lower *per capita* consumption. In all states combined, *per capita* consumption decreased by 0.61 packs (95% CI = −0.11 to 1.34 packs) per person per month, with a change from the 25th percentile to the 75th percentile of SOTC over all states. In separate analyses, the capacity component of the SOTC index was found to be inversely and statistically significantly associated with *per capita* consumption level (regression coefficient = −0.64, 95% CI = –1.08 to −0.19; $P = .003$; data not shown). States with higher levels of capacity had lower *per capita* consumption, regardless of their ASSIST status.

Did States With Higher IOI Scores Have Lower Adult Smoking Prevalence and Did States With Larger Changes in IOI Scores Have Lower *Per Capita* Cigarette Consumption?

Prevalence. The IOI score had a moderately strong negative correlation with smoking prevalence in 1998–1999 (Pearson correlation coefficient = −0.52; $P < .001$). Analyses adjusted for baseline prevalence and person-level factors found that the IOI was inversely associated with prevalence, although the associa-

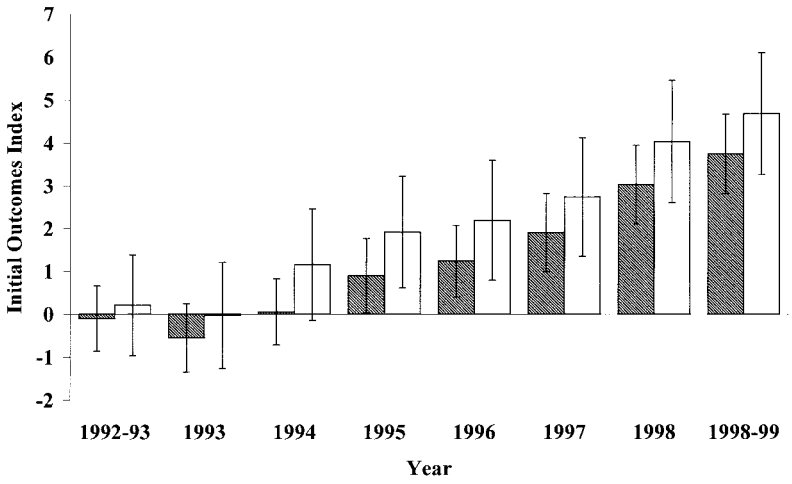

Fig. 2. Mean initial outcomes index (IOI) (*z*-scores) and 95% confidence error bars for the American Stop Smoking Intervention Study (ASSIST) (**open bars**) and non-ASSIST (**hatched bars**) states by year. The IOI is a *z*-score that measures the level of the states' tobacco control policies.

tion was not statistically significant (regression coefficient = −0.11, 95% CI = −0.25 to 0.03; $P = .06$) (Table 4). However, when the District of Columbia was removed from the analyses, the IOI was statistically significantly inversely associated with smoking prevalence (regression coefficient = −0.15, 95% CI = −0.28 to −0.02; $P = .015$; data not shown).

With all states and the District of Columbia in the model, none of the IOI component variables (i.e., smoke-free workplace, cigarette price, or state and local ratings for clean–indoor air legislation) was statistically significantly associated with smoking prevalence, when adjusted for baseline smoking prevalence or when each component was analyzed separately. However, when the District of Columbia was removed from the model, all of the IOI components individually were statistically significantly associated with lower smoking prevalence. Higher percentage of smoke-free work site policies was statistically significantly associated with lower smoking prevalence (regression coefficient = −0.046, 95% CI = −0.091 to −0.001; $P = .022$; data not shown); higher cigarette price was statistically significantly associated with lower prevalence (regression coefficient = −0.013, 95% CI = −0.028 to 0.002; $P = .047$; data not shown); and higher clean–indoor air local and state legislation ratings were statistically significantly associated with lower prevalence (regression coefficient = −0.053, 95% CI = −0.116 to 0.010; $P = .049$; data not shown).

Subset analyses were performed separately within sex and age subgroups (Table 4). States with higher IOI scores were statistically significantly associated with lower smoking prevalence among women (regression coefficient = −0.20, 95% CI = −0.38 to −0.03; $P = .01$) but not among men. However, the interaction between IOI score and sex was not statistically significant ($P = .19$). No statistically significant association of state IOI scores with smoking prevalence was found by age group.

Consumption. After adjusting for state-level factors (i.e., percentage Hispanic, economic value of tobacco, and percentage with incomes below poverty level), states with larger changes in IOI score over time were associated with lower *per capita* cigarette consumption than states with smaller changes in IOI (regression coefficient = −0.32, 95% CI = −0.40 to −0.24; $P<.001$; data not shown). For a state, *per capita* consumption was estimated to decrease by 0.57 packs per person per month (95% CI = 0.43 to 0.72 packs per person per month) as the IOI values increased from the 25th to the 75th percentile over the intervention period. When analyzed separately, the only component of the IOI score with a statistically significant association with consumption was cigarette price, which was statistically significantly inversely associated with consumption (regression coefficient = −0.023, 95% CI = −0.028 to −0.018; $P<.001$; data not shown). States with higher cigarette prices and larger changes in cigarette price during the ASSIST intervention period had lower *per capita* consumption (data not shown).

Discussion

Our analyses demonstrate that ASSIST states had statistically significantly lower adult smoking prevalence than non-ASSIST states at the end of the intervention period. Our data also suggest that much of the decrease in adult smoking prevalence may be associated with decreases in smoking prevalence among women. However, this finding needs to be interpreted with caution because this was a subset analysis and because the result of the statistical test of interaction between sex and ASSIST status for a difference in the association of ASSIST on smoking prevalence was not statistically significant. Nevertheless, this finding is still of interest to the general health community, because women are one of several priority populations for interventions in the ASSIST project *(30)*.

It is interesting to note that the Minnesota Heart Health Program (MHHP) found similar results in terms of changes in smoking prevalence among women *(31)*. MHHP was a community-based heart disease prevention project that compared three intervention communities with three comparison communities. The MHHP investigators reported a statistically significant decline in adult smoking prevalence among women totaling 8.4% over 6 years (1.4% per year) in the intervention communities compared with the comparison communities, but no statistically significant decline was observed among men *(32)*. However, the results from ASSIST were not consistent with those reported earlier by the Community Intervention Trial for Smoking Cessation (COMMIT) *(33)*. COMMIT reported no statistically significant intervention effect on smoking prevalence among either men or women, although the relative reduction in smoking prevalence was greater among women than among men. A possible reason for the difference in results between ASSIST and COMMIT could be in the nature of the intervention. ASSIST was initiated to prevent and reduce to-

Table 4. Results from regression analysis of smoking prevalence for the American Stop Smoking Intervention Study (ASSIST), initial outcomes index (IOI), and strength of tobacco control (SOTC) index exposures by sex and age*

Exposure/subgroup†	Regression coefficient (95% CI)	P‡	R^2§
	ASSIST vs. non-ASSIST		
Total	−0.63 (−1.38 to 0.12)	.05	.68
Sex			
Male	0.09 (−0.80 to 0.97)	.42	.50
Female	−0.96 (−1.90 to −0.02)	.02	.65
Age, y			
18–29	−0.60 (−2.21 to 1.01)	.23	.38
30–49	−0.57 (−1.70 to 0.57)	.16	.42
50–64	0.45 (−0.66 to 1.56)	.21	.37
≥65	−0.65 (−1.76 to 0.46)	.12	.54
	Initial outcomes index		
Total	−0.11 (−0.25 to 0.03)	.06	.67
Sex			
Male	−0.02 (−0.19 to 0.14)	.40	.50
Female	−0.20 (−0.38 to −0.03)	.01	.65
Age, y			
18–29	−0.13 (−0.43 to 0.16)	.18	.39
30–49	−0.04 (−0.26 to 0.18)	.36	.41
50–64	−0.17 (−0.39 to 0.05)	.06	.39
≥65	−0.11 (−0.33 to 0.12)	.17	.53
	Strength of tobacco control index		
Total	−0.19 (−0.49 to 0.11)	.11	.67
Sex			
Male	−0.17 (−0.52 to 0.17)	.16	.51
Female	−0.23 (−0.61 to 0.15)	.12	.63
Age, y			
18–29	−0.22 (−0.84 to 0.41)	.24	.38
30–49	−0.15 (−0.61 to 0.30)	.25	.41
50–64	−0.31 (−0.74 to 0.13)	.08	.39
≥65	−0.05 (−0.48 to 0.39)	.41	.52

*Non-ASSIST states include the District of Columbia. CI = confidence interval. Two-stage regression analysis was used for the total and subgroup analyses. In the first stage, smoking prevalence was adjusted for the person-level variables listed in Table 1, including interactions between sex and age and between sex and race/ethnicity. These same first-stage adjustments were used for the smoking prevalence in sex and age subgroup analyses with the exception that sex and age adjustments at the person level were not used in the corresponding sex and age subgroup analyses. Selected state-level covariates, along with adjusted baseline prevalence, were included as covariates in the second stage of the regression analyses. The second-stage analyses of the total data included the baseline-adjusted smoking prevalence as their only covariate, but different sets of state-level covariates that were selected through stepwise regression were included in models used for the subgroup analyses.

†Tests of statistical significance were performed for interactions of 1) sex by ASSIST status (two-sided), $P = .18$; 2) age group by ASSIST status, $P = .30$; 3) sex by IOI, $P = .19$ and age group by IOI, $P = .60$; and 4) sex by SOTC, $P = .98$; and age group by SOTC, $P = .84$.

‡One-sided P values are based on t tests.

§R^2 was calculated using a standard formula for linear regression.

bacco use primarily through the application of policy-based approaches to alter the sociopolitical environment. Although COMMIT recognized the importance of working with the community to change attitudes and environmental factors, the primary objective of the COMMIT study was to encourage behavioral change through the application of individually focused activities as well as some community mobilization. Another possible explanation of the difference between the ASSIST and COMMIT results is that women have been found to be more sensitive to higher cigarette prices and may respond more to policy interventions than men because women allocate more importance to social norms, accept the values of prevention to a greater degree, and are more likely to respond to authority and legislative acts *(34–36)*.

Although the *per capita* cigarette consumption rates were lower in ASSIST states than in non-ASSIST states at the end of the intervention period, these differences were not statistically significant. We had hypothesized that an ASSIST effect would be more easily detected for *per capita* consumption than for smoking prevalence because consumption data were available for the entire time period and for more frequent time points. However, the extensive between- and within-state variability in *per capita* consumption data appears to have overshadowed any small difference in *per capita* consumption rates between ASSIST and non-ASSIST states. A *post hoc* power analysis indicated that there was only an 11% power to detect the largest difference in *per capita* consumption rate observed between ASSIST and non-ASSIST states during the intervention period (data not shown). An earlier study found that ASSIST states had lower consumption rates than non-ASSIST states at the midpoint of the intervention *(37)*. However, the approach used for computing standard errors for the predicted difference in *per capita* consumption underestimated the standard error by failing to properly account for the between-state variation in consumption *(38)*. Hence, when the between-state variation was included in the analysis, the differences in *per capita* consumption between ASSIST and non-ASSIST states were not statistically significant.

The focus of the ASSIST project was on policy change, which was assessed with the IOI measure. The finding that states with larger increases in IOI score during the intervention period had larger decreases in *per capita* cigarette consumption, regardless of their overall IOI level during the intervention, suggests a causal relationship between tobacco control policy change and tobacco consumption. Indeed, these findings imply that policy-focused interventions have a strong and sustained effect on *per capita* cigarette consumption. Our findings add to the body of similar findings from other studies and expert reports *(39–45)* documenting the importance of a comprehensive approach to tobacco control.

The finding that ASSIST was associated with improvement in the policy environment (i.e., increased IOI score) only in the first few years of the intervention may indicate that ASSIST served as an impetus for change. By 1994, the Centers for Disease Control and Prevention was supporting tobacco control programs in all non-ASSIST states, and the Robert Wood Johnson Foundation's SmokeLess States program was being implemented in numerous ASSIST and non-ASSIST states, diffusing ASSIST ideals and making it more difficult to detect differences between ASSIST and non-ASSIST states. In addition to numerous new national and state tobacco control programs, high-attention events, such as state and federal tobacco litigation *(46)*, the release of tobacco industry documents *(47)*, and the failed attempt by the U.S. Food and Drug Administration to regulate tobacco *(48)*, may also have reduced our ability to detect additional ASSIST results.

States that had higher levels overall on the SOTC index, especially states with higher capacity scores, had statistically significantly lower *per capita* consumption rates than states with lower capacity scores, regardless of their ASSIST status. The SOTC is a new and promising measure for tobacco control research and evaluation. Although we developed a conceptual

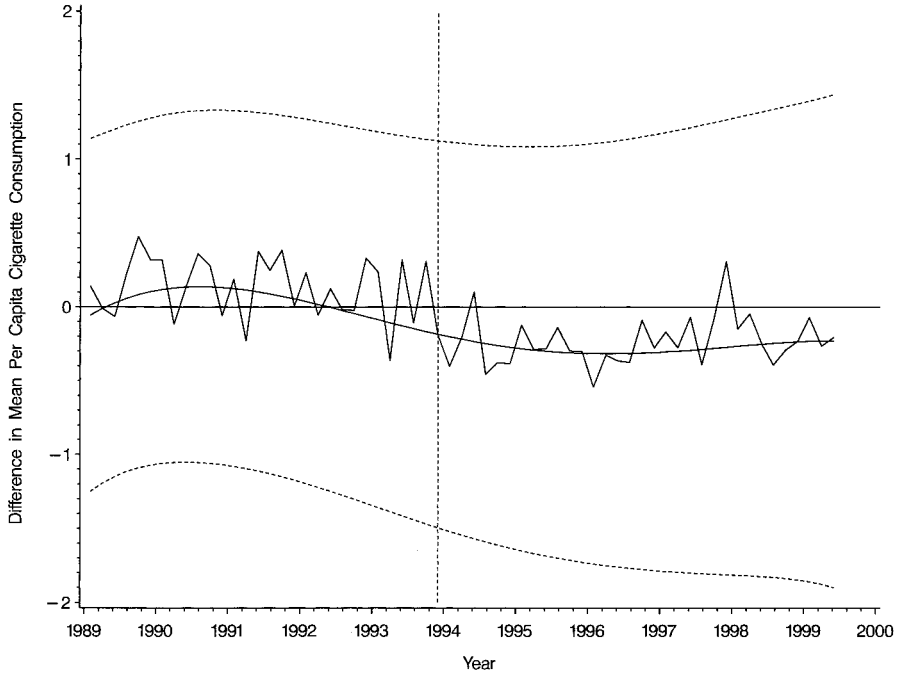

Fig. 3. Difference in mean *per capita* cigarette consumption between the American Stop Smoking Intervention Study (ASSIST) and non-ASSIST states. The **jagged line** shows the crude difference in bimonthly mean *per capita* cigarette consumption between the ASSIST and non-ASSIST states (i.e., value for ASSIST minus the value for non-ASSIST). The **smooth line** shows the adjusted bimonthly mean *per capita* cigarette consumption using mixed-effects modeling. The **dashed curved lines** are the pointwise 95% confidence intervals for the predicted bimonthly mean *per capita* cigarette consumption derived from the mixed-effects modeling. The **dashed vertical line** indicates the start of the ASSIST project.

model to guide the SOTC construction and validated the index *(10),* we have data from only one time point, the end of the intervention phase (1998–1999). Thus, we cannot assess change in the SOTC index and how it is associated with changes in smoking prevalence and *per capita* cigarette consumption. In the future, however, collection of the SOTC data at multiple time points will enhance its potential as an analytical tool for tobacco control program effects.

There are limitations to this study. An evaluation of states restricts the number of observations to 51 and reduces the power to detect small but important changes, particularly with respect to *per capita* cigarette consumption, which is highly variable among states. Although we did find some statistically significant results, these were not particularly robust in light of the multiple comparisons in this evaluation and the fact that the *P* values were not adjusted for the number of comparisons. However, the lack of robustness was not a problem because ASSIST developed a conceptual model and identified, *a priori,* a limited number of hypotheses that were of interest to this evaluation.

Although the conceptual model attempted to identify as many important factors as possible, political, social, and economic factors that went beyond the control of the ASSIST intervention could all cause the delivery of the intervention strategies to be different between states, with some ASSIST states being better able than others to build their infrastructure and focus on policy change as outlined in the ASSIST program plans.

In addition to the limitations discussed above, we should also not overlook the fact that tobacco control efforts have faced constant challenges and that the tobacco industry spends billions of dollars on countereffortsefforts each year in the United States *(49)*. The actual impact of these countervailing forces on program outcomes is unknown. There is documentation of direct actions on the part of the tobacco industry to counter the ASSIST project *(50–53);* however, we were not able to develop an overall measure to assess the strength of the tobacco industry's countervailing effort (*54*). Hence, we can only report the net effects of the public health investment and are unable to determine how the tobacco industry's investment may have affected the success of the ASSIST project.

In conclusion, the small but statistically significant differences in the reduction of adult smoking prevalence in ASSIST states, when applied on a population basis, could be expected to have a large impact on the public *(55, 56*). Indeed, if all 50 states and the District of Columbia had implemented ASSIST, the decrease in adult smoking prevalence would represent approximately 278 700 (95% CI = –54 000 to 611 500) fewer smokers nationally. The opportunities to learn from this natural experiment and to improve public health are too important to be neglected. As more community-based interventions in tobacco and other health arenas, such as obesity, drugs, gun control, and violence, focus on policy change to promote public health, further development of methods for evaluating these large-scale and complex interventions will be needed; the methods used for the ASSIST evaluation can be built on. Although policy efforts take time, they bring about major changes in social norms, affect smoking behavior, save lives and, ultimately, improve public health. More investment (i.e., both time and money) is needed to improve state-level capacity to implement comprehensive tobacco control programs.

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NOTES

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