9. Final Outcomes: Analytical Methods and Results

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9. Final Outcomes: Analytical Methods and Results

This chapter describes the analytical methods and findings for the American Stop Smoking Intervention Study (ASSIST). The primary evaluation question was whether the ASSIST program reduced adult smoking prevalence and per capita cigarette consumption. The evaluation model implied additional secondary research questions that were also tested. These analyses investigated the association between ASSIST, the Strength of Tobacco Control (SoTC), the Initial Outcomes Index (IOI), and the longer term outcomes (adult smoking prevalence and per capita cigarette consumption).

Multiple linear regression was used to evaluate the effect of ASSIST on adult smoking prevalence, and a mixed effects linear model was used to analyze per capita consumption. A detailed discussion of these methods and the rationale for selecting them are provided in appendices to this chapter.

ASSIST was shown to reduce the prevalence of adult smoking, at a level that would be projected to result in more than 1.2 million fewer smokers if ASSIST had been implemented nationwide. However, analyses accounting for between-states variation using random effects modeling showed no effect of ASSIST in reducing per capita consumption of cigarettes. Among secondary results, adjusted IOI was associated with decreased prevalence, while SoTC and the cigarette price component of IOI were associated with decreased per capita cigarette consumption.

Introduction

This chapter presents the methods and results from the formal ASSIST evaluation.[1]

The aim of ASSIST was "to demonstrate that the application of statewide tobacco prevention and control programs and policies would reduce cigarette consumption and smoking prevalence."[2(p261)] As detailed in Monograph 16, ASSIST sought to change the social and environmental influences that affect individuals' use of tobacco, primarily through interventions in four policy areas: (1) smoke-free environments, (2) tobacco advertising and promotion, (3) youth access to tobacco, and (4) tobacco price. Seventeen states with staffs with a wide range of abilities and experience in developing and implementing tobacco control programs were chosen for ASSIST funding. These states also differed in type and number on baseline (preintervention) factors (such as demographics and economic dependence on tobacco) that have documented relationships with smoking prevalence and cigarette consumption rates. It was important to take these factors into consideration when comparing ASSIST and non-ASSIST states because any changes observed could potentially be attributable to these differences and not to the effects of ASSIST.

At the start of the intervention, 1992–93, there were no statistically significant differences between the smoking prevalence and per capita cigarette consumption rates in ASSIST and non-ASSIST states[1] (see table 9.1). By the end of the intervention, 1998–99, overall smoking prevalence rates in the United States had decreased by 2.4%. Subsequent statistical analysis, therefore, focused on whether the decreases in smoking prevalence during the intervention period were greater in ASSIST states than in non-ASSIST states to ensure that this difference was not simply attributable to other factors. Regression analyses adjusting for potential confounding factors (see table 9.1 for a list of the factors considered) showed that there was a greater decrease of smoking prevalence in ASSIST states than there was in non-ASSIST states. Further analyses investigated whether the intervention had a greater effect on people of particular ages or gender. These analyses found that the decreased prevalence effect of ASSIST mainly affected women.

Per capita consumption was also examined via a statistical analysis that took into account the consumption rates in each state during the time when ASSIST began, incorporated the state factors associated with cigarette consumption, and illustrated each state's seasonal pattern of consumption. This analysis did not show any differences in consumption rates over time.

Table 9.1. Baseline Characteristics of ASSIST and Non-ASSIST States

Variable	ASSIST states (*N* = 17)	*SE*	Non-ASSIST states + DC (*N* = 34)	*SE*	*p*[a]
Adult smoking prevalence (%)	25.19	0.64	24.41	0.48	.35
Initial Outcomes Index (IOI)	0.20	0.60	–0.10	0.39	.65
Per capita tobacco consumption (packs per month)	10.64	0.48	10.54	0.41	.88
Sex					
Female (%)	52.22	0.16	51.76	0.24	.21
Race/ethnicity					
Black–non-Hispanic (%)	8.57	1.86	10.28	2.17	.61
Hispanic (%)	5.54	2.10	4.78	1.04	.72
Metropolitan area resident (%)	70.52	4.46	62.76	4.28	.26
Below poverty line (%)	13.85	0.88	14.36	0.78	.69
Economic value of tobacco × 10^3 (fraction)	5.24	3.58	1.46	1.02	.20
With education above high school (%)	44.63	1.71	45.67	0.96	.57
Mean state population (million)	4.10	0.74	3.54	0.79	.65
Mean age of state population	41.18	0.23	41.03	0.26	.71

Note: Data in tables 9.1, 9.3, 9.6, and 9.7, and in figures 9.2 and 9.3, were published in an earlier analysis in Stillman, F. A., A. M. Hartman, B. I. Graubard, E. A. Gilpin, D. M. Murray, and J. T. Gibson. 2003. Evaluation of the American Stop Smoking Intervention Study (ASSIST): A report of outcomes. *Journal of the National Cancer Institute* 95 (22): 1681–91.

[a]Two-sided *p* values are based on *t* tests.

Questions to be Addressed in the ASSIST Evaluation

The primary questions of the ASSIST evaluation are whether the ASSIST program reduced smoking prevalence and whether it reduced per capita cigarette consumption.[a] However, the evaluation conceptual model suggests a number of secondary questions about the relationships between SoTC (see chapter 2), IOI (see chapter 4), smoking prevalence, and per capita cigarette consumption. These primary and secondary questions raised in the original evaluation model[b] and reported on by Stillman and colleagues[c] are as follows:

Primary Questions

- Was ASSIST associated with a decrease in adult smoking prevalence?
- Was ASSIST associated with a decrease in adult per capita cigarette consumption?

Secondary Questions

- What was the relationship between ASSIST and SoTC?
- Was ASSIST or SoTC associated with an increase in IOI?
- Did states with higher SoTC scores have lower adult smoking prevalence?
- Did states with higher IOI scores have lower adult smoking prevalence?
- Did states with higher SoTC scores have lower adult per capita cigarette consumption?
- Did states with higher IOI scores have lower adult per capita cigarette consumption?

[a]Manley, M., W. Lynn, R. Payne Epps, D. Grande, T. Glynn, and D. Shopland. 1997. The American Stop Smoking Intervention Study for Cancer Prevention: An overview. *Tobacco Control* 6 (Suppl. 2): S5–S11.

[b]Stillman, F. A., A. M. Hartman, B. I. Graubard, E. A. Gilpin, D. Chavis, J. Garcia, L-M. Wun, W. Lynn, and M. Manley. 1999. The American Stop Smoking Intervention Study: Conceptual framework and evaluation design. *Evaluation Review* 23 (3): 259–280.

[c]Stillman, F. A., A. M. Hartman, B. I. Graubard, E. A. Gilpin, D. M. Murray, and J. T. Gibson. 2003. Evaluation of the American Stop Smoking Intervention Study (ASSIST): A report of outcomes. *Journal of the Nation Cancer Institute* 95 (22): 1681–1691.

The sidebar “Questions to be Addressed in the ASSIST Evaluation” describes the conceptual framework that guided the evaluation of ASSIST and the primary and secondary research questions. The next section (“Overall Considerations for Analysis”) describes the overall considerations that applied to both the primary and secondary analyses.

The three sections that follow describe the analytical methods used and present the results from the analysis of (1) adult smoking prevalence, (2) per capita cigarette consumption, and (3) the various secondary outcomes for the ASSIST evaluation. The last section summarizes the main results and places them in context with respect to tobacco control in the United States during the intervention period.

Additional background information about the selection of analytic methodologies is contained in two appendices to this chapter, “Issues Related to Selection of Methods for Analyzing Smoking Prevalence” (appendix 9.A) and “Approaches to Analyzing per Capita Cigarette Consumption Data” (appendix 9.B).

Overall Considerations for Analysis

This section outlines, with respect to the ASSIST evaluation, several decisions that apply to all of the analyses that were conducted for both the primary and secondary questions.

Units of Selection/Observation

Although states were not assigned randomly to ASSIST or non-ASSIST status,[3] the state was the unit of selection for ASSIST sites; therefore, the state was the unit of analysis for the evaluation. In the evaluation models, each of the 51 units (50 states plus the District of Columbia) is treated as an equal unit, regardless of population size. With only 51 units of observation, the number of variables that can be included in a regression analysis is limited. Consequently, the ASSIST evaluation relied heavily on developing summary indices (see chapters 2 and 4).

One-tailed Tests and Statistical Power

Decisions related to the initial design of the ASSIST evaluation included the use of one-tailed statistical tests for hypotheses that could be formulated directionally.[2] It was assumed that ASSIST would lead to lower prevalence and to lower per capita cigarette consumption. There was no basis for suspecting that this intervention would increase prevalence or per capita consumption. Tests of means, proportions, and single coefficients from regression models were, therefore, from one-tailed t tests at the .05 level of significance when the hypotheses were directional. For ease of understanding, two-sided 90% confidence intervals are presented so that the reader may focus on the appropriate upper or lower confidence limit corresponding to the implied direction of the hypothesis. However, when simultaneous inferences about several regression coefficients were being made, two-tailed F tests at the .05 level of significance were used, because the hypotheses involved were multidirectional.

A priori power computations based on a one-tailed test for unadjusted smoking prevalence indicated that with the 17 ASSIST states and 34 non-ASSIST states, such an analysis would have a power between 63% and 76% to detect a difference of 1.5 percentage points and between 95% and 99% to detect a difference of 2.5 percentage points.[2] No a priori power computation was performed with respect to differences in per capita cigarette consumption.

Preliminary Analyses

A number of preliminary analyses were conducted to explore potential methods for the evaluation. These analyses used prebaseline and baseline data. The analysis approach was selected on the basis of these preliminary analyses and before any additional analyses were conducted. In this way the researchers ensured that the method selection was not unduly influenced by the results. An additional feasibility analysis was performed using interim data through mid-1996. This allowed for verification that the methods selected were sound without adding to the number of statistical tests performed on the final data and potential Type I error.

Two appendices at the end of this chapter document the issues addressed in this decision-making process. Appendix 9.A describes issues related to the analysis of adult smoking prevalence, including the treatment of baseline prevalence and the options for adjusting for factors or state conditions that might differ among the states. Appendix 9.B addresses some of the possible ways to analyze the per capita consumption data. It also addresses the importance of accounting for the state-specific variability in the data; these differences had a substantial effect on the analysis results (and, in particular, on the size of the confidence intervals) that related ASSIST to per capita consumption. The interested reader should consult these appendices if there are questions concerning why the analytic approaches described below were used.

Model Diagnostics

Because the unit of analysis was the state, and there were a limited number of states, an individual state could strongly influence the results. Standard regression diagnostics were therefore conducted for the smoking prevalence analyses in which one state at a time was left out to identify states that had an unusually strong influence on the results.[4] Also, with respect to the prevalence analyses, covariates used in the regression analyses to adjust for state conditions were examined for unusually high correlations with the exposures (e.g., ASSIST, SoTC, and IOI) to determine whether these covariates were unduly inflating variances.[4]

Separate analyses omitting the District of Columbia are presented because some measures developed for the evaluation (SoTC and IOI) require information from local jurisdictions that are not present in the District of Columbia.* For example, the District of Columbia has an inflated IOI score; states that preempted local clean indoor air legislation had points deducted from the state and local clean indoor air rating (see chapter 3), a component of the IOI score. However, preemption at any level below the unit of analysis is not an option in the District of Columbia, so no points could be deducted. In addition, the District of Columbia IOI score is artificially inflated due to strong enforcement of a weak clean indoor air law. These factors, along with easy access to less expensive cigarettes in Virginia, render the District of Columbia an influential outlier for the smoking prevalence-IOI relationship.

Additional analyses that exclude California are presented. California is an influential outlier because it had established a comprehensive, well-funded tobacco control program prior to ASSIST and the funding for its tobacco control program far exceeded funding in any other state during the ASSIST period.

*Although the District of Columbia is obviously not a state, it was treated as a "state" in these analyses because it was part of the Centers for Disease Control and Prevention's Initiatives to Mobilize for the Prevention and Control of Tobacco Use (IMPACT) and it was a SmokeLess States grantee during the ASSIST period.

Adult Smoking Prevalence

Methods

Data Source

Smoking prevalence data are from the Tobacco Use Supplement to the Current Population Survey (TUS-CPS; see chapter 5).[5] From the survey data on individuals, the percentage or prevalence of current smokers can be computed within each state and the District of Columbia. The TUS-CPS was conducted at baseline in 1992–93, at an interim point in 1995–96, and at the end of the program in 1998–99. However, only the baseline and end of the program data were included in the final analyses.

Analytic Approach

The prevalence data were analyzed using a two-stage regression model. At the first stage, a single logistic regression model was fit to the TUS-CPS data from baseline (1992–93) and from last follow-up (1998–99) to model current smoking status (1 = current smoker, 0 = nonsmoker) at the individual level. This logistic regression used the TUS-CPS sample weights; it included the variables listed in table 9.2 as individual-level covariates; and it included interactions between sex and age and between sex and race/ethnicity. Residuals obtained from the logistic regression were averaged within each state for the baseline and follow-up period to be used in the second stage of the regression analysis. These state-level mean residuals represent adjusted prevalences for the states that remove state-to-state differences for the individual-level covariates.

Multiple linear regression was used for the second stage of the analysis to adjust for state-level covariates (see table 9.2). The model for this analysis is described by equation 9.1 where $\mathbf{R_{Bs}}$ and $\mathbf{R_{Fs}}$ represent the mean residuals for a state *s* from the first-stage logistic regression of the baseline and the follow-up, respectively; $\mathbf{E_s}$ represents the exposure variables of interest for a state *s*; and ε_s is the random error. The exposure variable could have been ASSIST status, IOI, SoTC, and/or selected interaction(s) between these exposures.

$$R_{Fs} = \beta_0 + \beta_1 R_{Bs} + \beta_2 E_s + \varepsilon_s \qquad (9.1)$$

State-level covariates (see table 9.2) were considered for inclusion as independent variables in equation 9.1, using an all-possible-subsets procedure based on the minimum Mallows Cp statistic.[6] This stepwise procedure was applied by fixing the baseline mean residual as a covariate in the model, omitting the exposure variable(s) (e.g., ASSIST), and evaluating the possible subsets of state-level covariates. None of the state conditions was statistically significant when this procedure was used. This indicated that the first stage of the analysis effectively removed these sources of variation at the individual level, so that no further variation need be explained by state-level covariates.

Separate sets of models for smoking prevalence were estimated for adult men and women and by age group (18–29, 30–49, 50–64, 65+).

Table 9.2. Covariates at Individual and State Levels

Source	Covariate
Individual-level	
CPS–CORE	▪ Age: 18–29, 30–49, 50–64, 65+ ▪ Education: <9th grade, 9th–12th (no high school degree), high school degree, 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 ▪ Sex: male, female ▪ Census region: Midwest, West, South, Northeast ▪ Employment status: employed, unemployed
State-level	
Census population data	▪ Sex: % female ▪ State population: 18 years of age or older ▪ Income: % below poverty level ▪ Race/ethnicity: % black–non-Hispanic, % Hispanic
CPS–CORE	▪ Education: % above high school degree ▪ Metropolitan residency: % living in metropolitan area ▪ Census region: Midwest, West, South, Northeast
USDA Economic Research Service & Department of Commerce's Bureau of Economic Analysis	▪ Economic value of tobacco: fraction of gross state product from growing, manufacturing, and processing tobacco

Note: CPS indicates Current Population Survey. CORE indicates CPS basic monthly survey questions. USDA indicates U.S. Department of Agriculture.

Results

Unadjusted Descriptive Results

Table 9.1 compares ASSIST states with non-ASSIST states at baseline for selected demographic and state conditions. Smoking prevalence rates in ASSIST states were not significantly different from prevalence rates in non-ASSIST states (25.19% vs. 24.41%, $p = .35$). There were also no differences between ASSIST and non-ASSIST states for IOI at baseline (0.20 vs. –0.10, $p = .65$) or for any of the other measures evaluated at baseline.[1]

The mean change in smoking prevalence in the entire United States from 1992–93 to 1998–99 was –2.4% (SE = 0.20%). Appendix 9.C presents baseline and outcome (unadjusted) prevalence data for all states. (See also appendix 11.A for the ASSIST and non-ASSIST crude prevalence rates by state.) Of the 17 ASSIST states, 12 (71%) equaled or exceeded the national mean change, compared with only 15 (44%) of the 34 non-ASSIST states (including the District of Columbia). Among the ASSIST states, Maine and Virginia achieved the largest decrease in mean adult smoking prevalence (–5.01%, *SE* = 1.68%, and –4.70%, *SE* = 1.36%, respectively), while Indiana and New York had the smallest decreases (–0.78%, *SE* = 1.79%, and –0.98%, *SE* = 0.63%, respectively). Among non-ASSIST states, Georgia and Nevada had the greatest decreases in mean adult smoking prevalence (–4.43%, *SE* = 1.57%, and –4.31%, *SE* = 1.52%, respectively), whereas Delaware, the District of Columbia, and Oklahoma had slight increases in prevalence (0.04%, *SE* = 1.74%; 0.31%, *NA;* and 0.78%, *SE* = 1.51%, respectively). Taken together, ASSIST states achieved a somewhat greater decrease in adult smoking prevalence than non-ASSIST states (*M* = –3.02% vs. –2.11%, respectively; a difference of –0.91%, *p* = .015).

Results from Adjusted Two-stage Model

Table 9.3 presents the results of the multiple linear regression analysis for prevalence (adjusted for baseline prevalence and individual-level demographics) between ASSIST and non-ASSIST states at the end of the intervention period (1998–99). The adjusted difference (regression coefficient) in prevalence was –0.63% (90% confidence interval [CI]: –1.25, –0.01, *p* = .049). This relationship was slightly weakened when the District of Columbia was removed from the analyses (–0.53%; 90% CI: –1.12, 0.07, *p* = .076, data not shown). However, without California in the analyses, the relationship was similar to the overall results (–0.66%; 90% CI: –1.28, –0.04, *p* = .044, data not shown). Table 9.3 also shows subgroup analyses for the exposure effects of ASSIST on prevalence, by sex and age. ASSIST had a significant effect on prevalence rates among females: –0.96% (*p* = .023). However, ASSIST's effect was not statistically significant among males. No differences in effect on prevalence by age were found.

Per Capita Cigarette Consumption

Methods

Data Sources

Bimonthly estimates of per capita cigarette consumption for each state were the data to be modeled. The sources of these data are described elsewhere (see chapter 5). Figure 9.1 shows the raw bimonthly data for ASSIST and non-ASSIST states in the top and bottom panels, respectively. The variability with respect to the states in the consumption data over time, particularly in the non-ASSIST states, was substantial, and it is not difficult to imagine that it might obscure any signal (e.g., effect of ASSIST) to be found in the noise (variability).

Analytic Approach

The analytic model of per capita consumption that was implemented is a mixed effects linear model,[7] given by equation 9.2.

Table 9.3. Results of Regression Analysis of Smoking Prevalence for ASSIST Status, by Sex and Age

	ASSIST versus non-ASSIST			
Exposure/ Subgroup[a]	ß	90% CI	p[b]	R^{2}[c]
Total	–0.63	–1.25, –0.01	.049	.68
Sex				
Male	0.09	–0.46, 0.64	.42	.50
Female	–0.96	–1.73, –0.19	.023	.65
Age				
18–29	–0.60	–1.92, 0.71	.23	.38
30–49	–0.57	–1.50, 0.36	.15	.42
50–64	0.45	–0.46, 1.40	.21	.37
65+	–0.65	–1.56, 0.25	.12	.54

Note: Non-ASSIST states include the District of Columbia. CI indicates confidence interval.

[a]Tests of statistical significance were performed for interactions of sex by ASSIST status (two-sided), $p = .18$, and age group by ASSIST status, $p = .30$. [b]One-sided p values are based on t tests. [c]R^2 was calculated using a standard formula for linear regression.

$$C_{st} = \mu + \beta_1 t + \beta_2 t^2 + \beta_3 t^2 + \beta_4 t^4 + \beta_5 \sin(t\,\pi/3) + \beta_6 \cos(t\,\pi/3) + \gamma X_{st} + \alpha_1 A_s + \alpha_2 A_s \times t + \alpha_3 A_s \times t^2 + \alpha_4 A_s \times t^3 + \alpha_5 A_s \times t^4 + m_s + b_s t + \varepsilon_{st}. \quad (9.2)$$

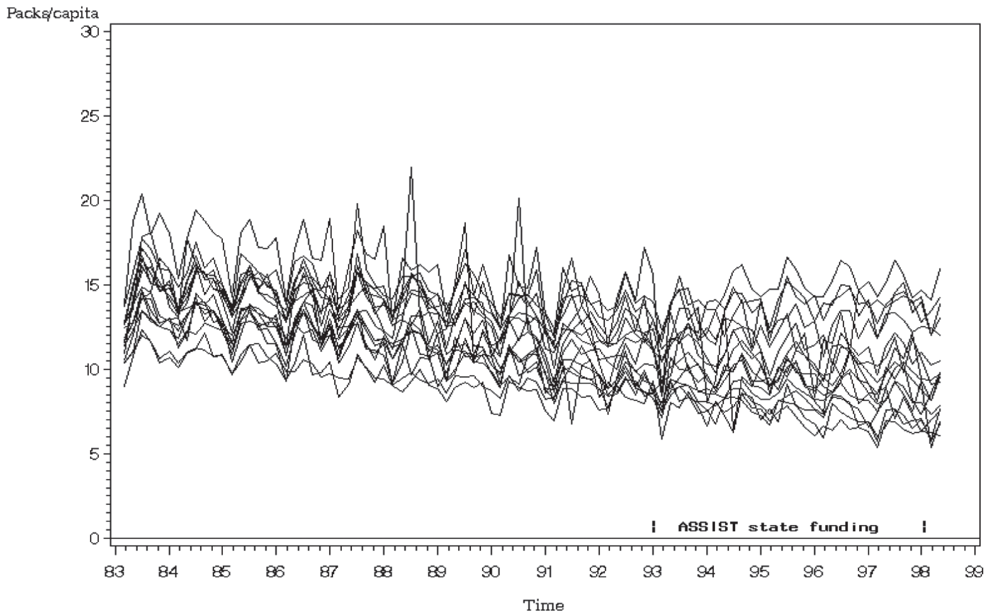
The dependent variable is bimonthly consumption, denoted by $\mathbf{C_{st}}$ for state s at time t. Independent variables include time (bimonthly time, **t**) and powers of time ($\mathbf{t^2}$, $\mathbf{t^2}$, $\mathbf{t^4}$), which account for a nonlinear trend, and sine and cosine functions of time, **sin(t π/3)**, **cos(t π/3)**, which account for seasonal periodicity in the consumption data, and ASSIST status, $\mathbf{A_s}$.

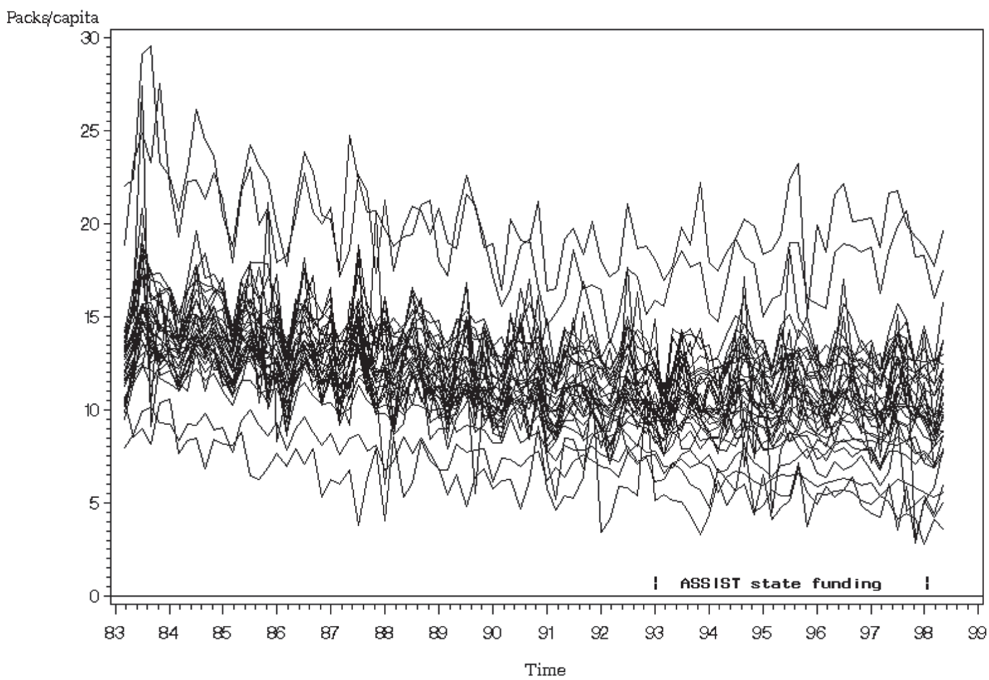
This model has a state-varying random intercept, $\boldsymbol{m_s}$, a random regression coefficient, $\boldsymbol{b_s}$, for the time variable, and an ARIMA(1) autoregressive correlation structure for the error terms, $\varepsilon_{\mathbf{st}}$, across time within state.

Forward stepwise regression was used to select the time-varying and non–time-varying state-level covariates (table 9.2) to be added to an initial model with only the terms involving time and without interactions with $\mathbf{A_s}$. The stepwise regression resulted in a final model that included statistically significant state-level covariates ($\mathbf{X_{st}}$), independent variables for ASSIST status, interactions between ASSIST status and time, powers of time, and the sine and cosine of time.

In the modeling approach that was used, the interactions between ASSIST status and time were over the entire period (December 1988–May 1999). After adjusting for the state conditions, this model permits the trend in cigarette consumption for the ASSIST states to be different from the trend for the non-ASSIST states during the preintervention period (December1988–October 1993)

Figure 9.1. Bimonthly per Capita Cigarette Consumption in ASSIST (top) and Non-ASSIST (bottom) States





as well as the intervention period (November 1993–May 1999).

It should be mentioned that the time-varying covariates used in the analysis were not available at each bimonthly time point. Some were available annually, and those derived from the TUS-CPS had only three distinct values corresponding to the three surveys. Therefore, interpolated values from the TUS-CPS for each year were generated. The yearly values were used for six adjacent bimonthly periods. Per capita consumption models with IOI or cigarette price as exposures, $\mathbf{E_s}$, adjusting for state cross-border differentials in price, were also examined.[8]

Primary Results

Unadjusted Results

The ASSIST and non-ASSIST states did not show a significant difference in baseline per capita cigarette consumption (table 9.1: 10.64 vs. 10.54 packs/month, $p = .88$).

Figure 9.1 shows the state-specific, unadjusted, bimonthly per capita consumption rates by ASSIST status. There appears to be a common periodic seasonal pattern in these rates, which was the motivation behind including the cosine and sine time relationships in equation 9.2. Figure 9.2 shows the difference in the aggregated unadjusted mean consumption rates (jagged line) between the ASSIST and non-ASSIST (ASSIST minus non-ASSIST) states over time. ASSIST states tended to have higher per capita consumption before the intervention period but lower consumption during the intervention period.

Results from Adjusted Analyses

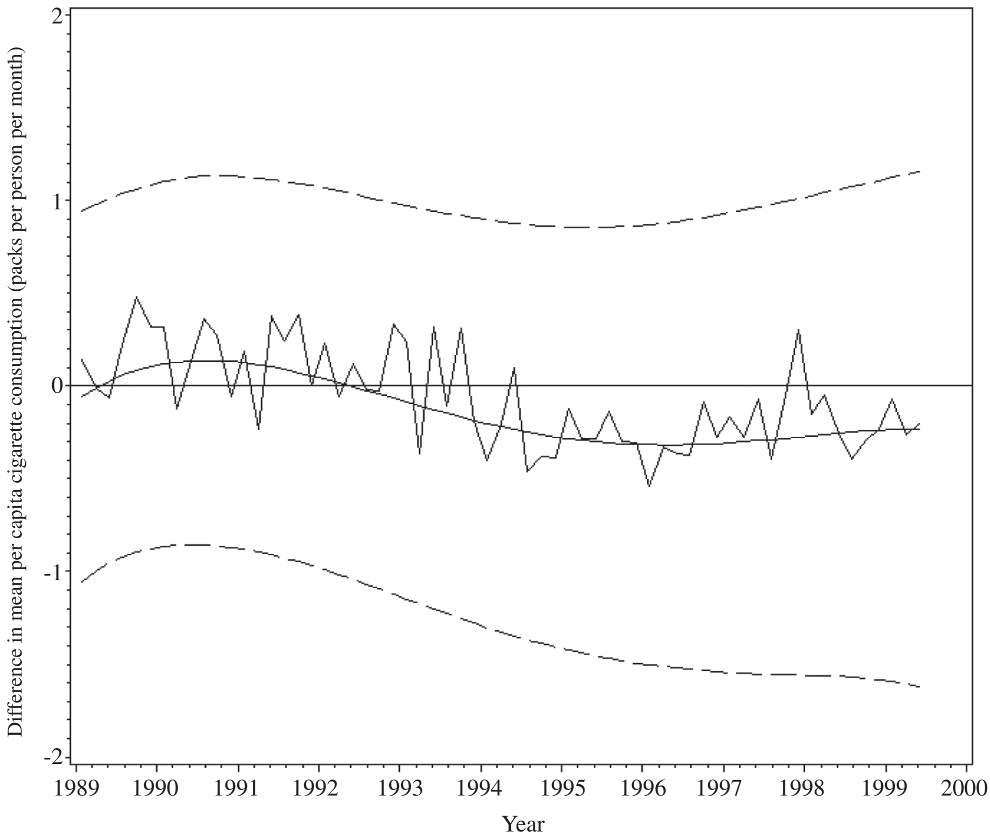
Figure 9.2 also shows the difference in consumption (smooth line) as calculated by the fitted model given by equation 9.2 together with 90% confidence intervals for the difference (dashed lines). The adjusted differences between the ASSIST and non-ASSIST states in consumption for each year as estimated by the mixed-effects model (equation 9.2) are presented in table 9.4. After adjusting for the significant state conditions (percentage Hispanic, economic value of tobacco, and percentage with income below poverty level), ASSIST had no statistically significant effect on consumption ($p = .22$).

These results did not differ substantially when the District of Columbia or California was removed from the analyses or when the analysis time was extended to include data as far back as 1985. Adding terms to the model to account for cross-border smuggling did not change the overall ASSIST-effect result (e.g., not significant), but these terms were significantly related to consumption.

Secondary Results (SoTC and IOI Analyses)

This section addresses the secondary questions related to SoTC and IOI. (See “Secondary Questions” section in the sidebar on page 271.)

Figure 9.2. Crude Difference in Bimonthly per Capita Consumption of Cigarettes between ASSIST and Non-ASSIST States



Notes: The jagged line shows the crude difference in bimonthly mean per capita consumption of cigarettes between ASSIST and non-ASSIST states (ASSIST minus non-ASSIST). The smooth solid line shows the predicted bimonthly per capita consumption from the mixed-effects model. The dashed lines are the pointwise 90% confidence intervals for the predicted bimonthly per capita consumption derived from the model.

Methods

Data Sources

The data used in these analyses are described in chapter 2 ("Strength of Tobacco Control") and chapter 4 ("Initial Outcomes Index").

Models

Effect of ASSIST on SoTC. The basic form of the model presented in equation 9.1 was the basis for this analysis. SoTC was the dependent variable. Explanatory variables included in the model were baseline level of funding (this was the

Table 9.4. Adjusted Differences in per Capita Cigarette Consumption between ASSIST and Non-ASSIST States during the Intervention Period

Year	ASSIST–non-ASSIST adjusted difference[a]	90% CI
1993	–0.19	–1.28, 0.90
1994	–0.27	–1.40, 0.86
1995	–0.31	–1.49, 0.87
1996	–0.31	–1.54, 0.92
1997	–0.27	–1.55, 1.01
1998	–0.24	–1.58, 1.10
1999	–0.23	–1.61, 1.15

Note: CI indicates confidence interval.

[a]The units are in packs per month per person. None of the differences was statistically significant; all *p* values were greater than .32. The interactions between ASSIST status and time and powers of time (Wald test) were not statistically significant ($p = .22$).

only component of SoTC collected at baseline), ASSIST status as the exposure variable, and covariates selected using the Mallows Cp procedure (as described previously). Besides SoTC as a composite index, its individual components (see chapter 2) were examined in separate analyses.

Effect of SoTC or ASSIST on IOI. The analysis of IOI as an outcome variable was restricted to the baseline and intervention period (September/October 1992 through April/May 1999); IOI was measured (annually) during this period only. The IOI models examine the relationship between ASSIST and IOI and between SoTC and IOI, using the mixed-effects linear model given by equation 9.3:

$$\mathrm{IOI}_{st} = \mu + \beta_1 t + \beta_2 t^2 + \beta_3 t^3 + \gamma X_{st} + \alpha_1 E_s + \alpha_2 E_s \times t + \alpha_3 E_s \times t^2 + \alpha_4 E_s \times t^3 + m_s + \varepsilon_{st} \quad (9.3)$$

The annual IOI measurement, denoted by $\mathbf{IOI_{st}}$ for state *s* at time *t,* is the dependent variable, and independent variables include time (annual time, **t**) and powers of time ($\mathbf{t^2}$, $\mathbf{t^3}$), which account for a nonlinear trend in IOI. The model also includes a random intercept, $\mathbf{m_s}$, which allows for state-varying random intercepts, and an ARIMA(1) autoregressive correlation structure among the error terms ε_{st}, across time within state. Because the dependent variable IOI is measured annually, there is no need for sine and cosine terms to adjust for seasonal periodicity. Time-varying and non–time-varying state-level covariates were added to a model that included only the terms involving time as independent variables. A forward stepwise approach was used to select state-level covariates. The final model included the significant state-level covariates and independent variables for exposure status, $\mathbf{E_s}$, indicating either ASSIST status or level of SoTC.

Effect of SoTC or IOI on Prevalence. Equation 9.1 was used for these analyses, with the exposure variable of interest either SoTC or IOI. When the exposure variable was SoTC, the final 1999 value (only one available) for each state was used, and when exposure was IOI, the average IOI over the intervention period for each state was used. In addition to the evaluation of the composite indices, separate analyses were conducted using each of their components.

Table 9.5. IOI Analyses of the Impact of SoTC, as a Main Effect, on IOI and the Components of IOI

Outcome	SoTC ß[a]	90% CI	p[b]
IOI[c]	0.27	–0.10, 0.64	.12
Components			
Cigarette price	2.95	–1.03, 6.93	.11
Smoke-free workplaces	0.87	–0.12, 1.86	.07
Clean indoor air legislative score[c]	0.44	–0.47, 1.35	.21

Note: IOI indicates Initial Outcomes Index. SoTC indicates Strength of Tobacco Control. CI indicates confidence interval.

[a]The units are standard deviation of IOI (or IOI components) per standard deviation of SoTC. [b]*p* tests of significance are two-sided. [c]The clean indoor air legislation score reflects both the strictness and coverage of clean air ordinances within each state. The score includes a preemption penalty and a further adjustment for local ordinance strength (see chapter 3).

Effect of IOI on per Capita Consumption. The analysis relating IOI to per capita consumption was again restricted to the intervention period (see above section on "Effect of SoTC or ASSIST on IOI"). Because of this restricted time period, a new mixed-effects linear model was fit to the consumption data and is described by equation 9.4.

$$C_{st} = \mu + \beta_1 t + \beta_2 t^2 + \beta_3 t^3 + \beta_4 \sin(t\,\pi/3) + \beta_5 \cos(t\,\pi/3) + \gamma X_{st} + \alpha_1 \mathrm{MIOI}_s + \alpha_2 (\mathrm{IOI}_{st} - \mathrm{MIOI}_s) + m_s + b_s t + \varepsilon_{st}. \quad (9.4)$$

The model includes a state-varying random intercept, $\boldsymbol{m_s}$, and a random regression coefficient for time, $\boldsymbol{b_s}$. This model includes the following as independent variables: $\mathbf{MIOI_s}$, the within state mean IOI (the average of the annual IOI measurements for a state); and $\mathbf{IOI_{st} - MIOI_s}$, the difference between the annual IOI and the average IOI for a state. The regression coefficient for $\mathbf{IOI_{st} - MIOI_s}$, $\boldsymbol{\alpha_2}$, is the one of interest because it describes how change in IOI within a state relates to change in per capita consumption.[9] This model also includes an ARIMA (1) autoregressive correlation structure for correlation between the error terms, $\boldsymbol{\varepsilon_{st}}$, within state. The state-level covariates in table 9.2 were rescreened using forward stepwise regression, starting with a model that included only the terms involving time as independent variables, without the main effects and interactions with $\mathbf{MIOI_s}$ and $\mathbf{IOI_{st}}$. Additional models including ASSIST status and interactions between ASSIST status and IOI were examined to determine how ASSIST might have modified the effect of IOI on consumption.

Relation of SoTC to per Capita Consumption. The analysis of the effect of SoTC on per capita consumption was restricted to the intervention period because only a single value of SoTC, measured at the end of the intervention (1999), was available to represent tobacco control during the entire intervention period. The model used for the SoTC analysis is given by equation 9.5.

$$C_{st} = \mu + \beta_1 t + \beta_2 t^2 + \beta_3 t^3 + \beta_4 \sin(t\,\pi/3) + \beta_5 \cos(t\,\pi/3) + \gamma X_{st} + \alpha_1 \mathrm{SoTC}_s + m_s + b_s t + \varepsilon_{st} \quad (9.5)$$

This model is the same as the one relating IOI to consumption (equation 9.4); it included the same state conditions and independent variable for SoTC (denoted by $SoTC_s$), which replaced the IOI terms.

Results

Did ASSIST Affect SoTC?

As in chapter 2, where the mean SoTC scores did not differ by ASSIST status, ASSIST status was not significantly related to SoTC in the regression analysis that adjusted for baseline funding, metropolitan residency, age, and education above high school (ASSIST regression coefficient, β = .062, 90% CI: –0.445, 0.569, p = .42). Excluding the District of Columbia or California from the analyses did not change the results. ASSIST was also not related to the separate components of SoTC (capacity, resources, effort), with or without the District of Columbia or California in the analyses. (See appendix 11.A for state-level crude SoTC estimates.)

Did SoTC Affect IOI?

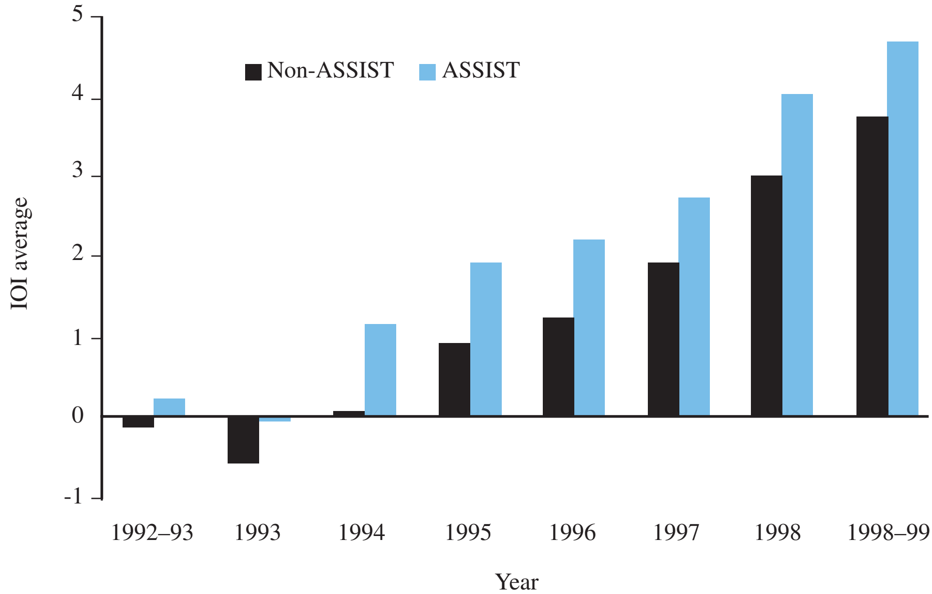
Using a mixed model analysis based on equation 9.3 with SoTC as only a main effect, SoTC was not found to be related to IOI (β = .27, standard deviation of IOI per standard deviation of SoTC, 90% CI: –0.10, 0.64, p = .12), after adjusting for state conditions (education above high school, metropolitan residency, and southern census region) (table 9.5). Also, SoTC was not related to the components of IOI (clean indoor air legislation, cigarette price, smoke-free workplaces), and omitting the District of Columbia or California had no effect.

Did ASSIST Affect IOI?

The overall mean change in IOI in the United States from 1993 to 1999 was 4.05. (Appendix 11.A shows baseline and final time points for unadjusted IOI by state.) Of the 17 ASSIST states, 12 (71%) achieved this level of increase in IOI, compared with 10 (29%) of the 34 non-ASSIST states (see chapter 4, table 4.5).

Figure 9.3 shows that for each year, starting in 1992–93 through 1994, the unadjusted (for state conditions) mean IOI in the ASSIST states was higher than it was in the non-ASSIST states. 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. Nevertheless, when adjusted for state conditions (education above high school education, metropolitan residency, and southern census region), ASSIST status was not significantly related to change in IOI over the intervention period (p = .13). This adjusted analysis further confirmed that ASSIST did not differentially increase IOI during most of the intervention period. Excluding the District of Columbia or California from the analyses did not change these results. Similar analyses of the separate components of IOI (clean indoor air legislation, cigarette price, smoke-free workplaces) did not reveal significant relationships between the components and ASSIST, with or without the District of Columbia or California in the analyses.

Figure 9.3. Yearly Initial Outcomes Index Average for ASSIST and Non-ASSIST States



Did SoTC Affect Prevalence?

SoTC had an inverse association (unadjusted) with smoking prevalence in 1998–99 ($r = -.42$). However, this relationship was not maintained after adjusting for baseline prevalence and individual-level factors ($\beta = -.19$, change in prevalence [%] per standard deviation of SoTC, 90% CI: –0.43, 0.06, $p = .11$) (table 9.6). In addition, the SoTC components (i.e., resources, capacity, efforts) were not statistically significantly associated with smoking prevalence after adjustment for individual-level factors. Results remained the same without the District of Columbia or California in the analyses, and the analyses within gender or age group also showed no association between SoTC and smoking prevalence. Because of these statistically nonsignificant results, the interaction between SoTC and ASSIST was not explored.

Did IOI Affect Prevalence?

Unadjusted IOI had a moderately strong negative correlation with smoking prevalence in 1998–99 ($r = -.52$; see chapter 4). Analyses that adjusted for baseline prevalence and individual-level factors found that IOI was inversely associated with prevalence, although the association was not statistically significant ($\beta = -.11$, prevalence [%] per standard deviation of IOI, 90% CI: –0.22, 0.01, $p = .063$; table 9.7). When the District of Columbia was removed from the analysis, IOI was statistically significantly inversely associated with smoking prevalence ($\beta = -.15$, 90% CI: –0.26, –0.04, $p = .015$). Without California, the results were similar to the overall analysis (β = –.11, 90% CI: –0.22, 0.01, p = .07). Again, because the adjusted main effects did not reach statistical significance, interactions with ASSIST were not explored.

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), when analyzed separately, was statistically significantly associated with smoking prevalence, when adjusted for baseline smoking prevalence. However,

Table 9.6. Results from Regression Analysis of Smoking Prevalence for Strength of Tobacco Control (SoTC)

Exposure/Subgroup	Prevalence/SoTC[a]	90% CI	p^b	R^{2c}
Total	–0.19	–0.43, 0.06	.11	.67
Sex				
Male	–0.17	–0.45, 0.11	.16	.51
Female	–0.23	–0.54, 0.08	.12	.63
Age				
18–29	–0.22	–0.73, 0.29	.24	.38
30–49	–0.15	–0.52, 0.22	.25	.41
50–64	–0.31	–0.66, 0.05	.08	.39
65+	–0.05	–0.40, 0.31	.41	.52

Note: CI indicates confidence interval.

[a]The units are percent prevalence per standard deviation unit in SoTC. [b]One-sided p values are based on t tests. [c]R^2 was calculated using a standard formula for linear regression.

Table 9.7. Results from Regression Analysis of Smoking Prevalence for Initial Outcomes Index (IOI)

Exposure/Subgroup	Prevalence/ IOI ß[a]	90% CI	p^b	R^{2c}
Total	–0.11	–0.22, 0.01	.063	.67
Sex				
Male	–0.02	–0.16, 0.11	.40	.50
Female	–0.20	–0.35, –0.06	.012	.65
Age				
18–29	–0.13	–0.37, 0.11	.18	.39
30–49	–0.04	–0.22, 0.14	.36	.41
50–64	–0.17	–0.35, 0.01	.06	.39
65+	–0.11	–0.29, 0.08	.17	.53

Note: CI indicates confidence interval.

[a]The units are percent prevalence per standard deviation unit in IOI. [b]One-sided p values are based on t tests. [c]R^2 was calculated using a standard formula for linear regression.

when the District of Columbia was removed from the model, all of the IOI components individually were statistically significantly associated with lower smoking prevalence. This finding emphasizes the difference between the District of Columbia and states in their mechanisms for implementation of tobacco control policy (see subsection in this chapter on "Model Diagnostics" in the section on "Overall Considerations for Analysis," page 273). With the District of Columbia removed, a higher percentage of smoke-free work-site policies was statistically significantly associated with lower smoking prevalence (β = −.046, CI: –0.08, –0.01, p = .022); higher cigarette price was statistically significantly associated with lower smoking prevalence (β = −.013, CI: –0.025, –0.001, p = .047); and higher clean indoor air local and state legislation ratings were statistically significantly associated with lower smoking prevalence (β = −.053, 90% CI: –0.105, –0.002, p = .049). Table 9.7 also indicates that states with higher IOI scores have significantly lower prevalence rates among females (p = 0.012) but not among males. No age effect was found.

Did SoTC Affect per Capita Consumption?

After adjustment for state-level factors, the SoTC index was found to be statistically significantly inversely associated with per capita cigarette consumption (β = −.39, packs per person per month per standard deviation of SoTC, 90% CI: –0.01, –0.77, p = .046). States with higher SoTC scores had lower per capita consumption. In all states combined, per capita consumption decreased by 0.61 per person per month (90% CI: 0.02, 1.20), 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 (β = −.64, 90% CI: –0.28, –1.00, p = .003). States with higher levels of capacity had lower per capita consumption, regardless of their ASSIST

Table 9.8. Results from Regression Analysis of per Capita Cigarette Consumption for Strength of Tobacco Control (SoTC)

Exposure	Per capita cigarette consumption/ SoTC ß[a]	90% CI	p^b	Adjusted effect size 75th–25th percentile difference in exposure	90% CI
Total SoTC	–0.39	–0.776, –0.003	.046	–0.61	–1.215, –0.005
Components					
Resources	–0.11	–0.53, 0.31	.32	–0.039	–0.180, 0.102
Capacity	–0.64	–1.00, –0.27	.003	–1.270	–2.009, –0.531
Effort	–0.04	–0.39, 0.31	.43	–0.077	–0.749, 0.595

Note: CI indicates confidence interval.

[a]The units are packs per person per month per standard deviation of SoTC or of components of SoTC. [b]p tests of significance are one-sided.

status. Results were unchanged without the District of Columbia or California (see table 9.8).

Analyses were also conducted to determine whether the effect of SoTC (and its individual components) on per capita consumption differed between the ASSIST and non-ASSIST states. This analysis was based on a mixed-effects model that tested interactions between SoTC (or its components) and ASSIST status. Table 9.9 shows no statistical difference between the effect of SoTC or its components by ASSIST status. These results remained unchanged without the District of Columbia or California.

Finally, analyses were conducted to determine if SoTC affected the temporal pattern of bimonthly per capita consumption over the intervention period. Table 9.10 shows no significant interaction between SoTC and time.

Did IOI Affect per Capita 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 ($\beta = -.32$, packs per person per month per standard deviation of IOI, 90% CI: –0.39, –0.25, $p < .001$). For a state, per capita consumption was estimated to decrease by 0.57 packs per person per month as the IOI values increased from the 25th to the 75th percentile over the intervention period (90% CI: 0.45, 0.69). 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 ($\beta = -.023$, 90% CI: –0.020, –0.026, $p < .001$). States with higher cigarette prices and larger changes in cigarette price during the ASSIST period had lower per capita consumption. Results remained unchanged without the District of Columbia or California in the analyses (see table 9.11).

The interaction of change in IOI with ASSIST status was also examined. The mixed effects model for this analysis was similar to equation 9.4 but included an

Table 9.9. Results from Regression Analysis of per Capita Cigarette Consumption for Interactions of Strength of Tobacco Control (SoTC) and ASSIST Status

Exposure	Interaction with ASSIST ß[a]	90% CI	*p*[b]
Total SoTC	–0.71	–1.73, 0.31	.13
Components			
Resources	–0.66	–1.65, 0.33	.14
Capacity	–0.17	–1.03, 0.69	.36
Effort	0.10	–0.76, 0.96	.42

Note: CI indicates confidence interval.

[a]The units are packs per person per month per standard deviation of SoTC or of components of SoTC. [b]*p* tests of significance are one-sided.

Table 9.10. Results from Regression Analysis of Temporal Pattern of per Capita Cigarette Consumption for Strength of Tobacco Control (SoTC)

Model terms	ß for interaction	*SE*	$p^{a,b}$
Interactions with total SoTC			
SoTC × time	–0.0128	0.0161	.19
SoTC × time^2	0.0001	0.0009	
SoTC × time^3	0.0000	0.0000[c]	
Components			
Resources × time	–0.0051	0.0166	.44
Resources × time^2	–0.0002	0.0009	
Resources × time^3	0.0000	0.0000[c]	
Capacity × time	–0.0243	0.0165	.10
Capacity × time^2	0.0008	0.0009	
Capacity × time^3	–0.0000	0.0000[c]	
Effort × time	0.0026	0.0151	.67
Effort × time^2	–0.0004	0.0008	
Effort × time^3	0.0000	0.0000[c]	

[a]*p* for simultaneous inference for all interactions with time. [b]*p* tests of significance are two-sided. [c]Numbers shown to four significant figures and were less than 0.0001.

Table 9.11. Results from Regression Analysis of per Capita Cigarette Consumption for Initial Outcomes Index (IOI)

Exposure	Per capita cigarette consumption/ IOI ß[a]	90% CI	p^b	Adjusted effect size 75th–25th percentile difference in exposure	90% CI
Change in IOI[c]	–0.32	–0.39, –0.25	<.001	–0.57	–0.69, –0.45
Components					
Change in cigarette price	–0.023	–0.026, –0.020	<.001	–0.420	–0.494, –0.346
Change in smoke-free workplaces	0.015	–0.007, 0.037	.14	0.190	–0.096, 0.476
Change in clean indoor air legislative score[c]	–0.017	–0.047, 0.013	.17	–0.004	–0.011, 0.003

Note: CI indicates confidence interval.

[a]The units are packs per person per month per standard deviation of IOI or of components of IOI. [b]*p* tests of significance are one-sided. [c]The clean indoor air legislation score reflects both the strictness and coverage of clean air ordinances within each state. The score includes a preemption penalty and a further adjustment for local ordinance strength (see chapter 3).

Table 9.12. Results from Regression Analysis of per Capita Cigarette Consumption for Interactions of Change in Initial Outcomes Index (IOI) and Its Components with ASSIST Status

	Interaction with ASSIST			Adjusted effect size	
Exposure	**ß[a]**	**90% CI**	***p*[b]**	**75th–25th percentile difference**	**90% CI**
Change in IOI[c]	–0.001	–0.103, 0.101	.49	–0.0022	–0.1870, 0.1826
Components					
Change in cigarette price	0.006	–0.001, 0.013	.05	0.110	0.001, 0.219
Change in smoke-free workplaces	–0.010	–0.032, 0.012	.23	–0.120	–0.389, 0.149
Change in clean indoor air legislative score[c]	–0.066	–0.143, 0.011	.08	–0.015	–0.032, 0.002

Note: CI indicates confidence interval.

[a]The units are packs per person per month per standard deviation of IOI or of components of IOI. [b]*p* tests of significance are one-sided. [c]The clean indoor air legislation score reflects both the strictness and coverage of clean air ordinances within each state. The score includes a preemption penalty and a further adjustment for local ordinance strength (see chapter 3).

interaction between ASSIST status and the within-state change in IOI and an interaction between ASSIST status and the mean state IOI; the first interaction was the one of interest (table 9.12). The association of the change in IOI and consumption did not vary between the ASSIST and non-ASSIST states ($p = .49$), but there was a small effect in change in price between ASSIST and non-ASSIST states (β = .006, 90% CI: –0.001, 0.013).

Summary

Our analyses demonstrate that ASSIST states had statistically significant 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 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 were one of several priority populations for interventions in the ASSIST project.[10]

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. However, changes in per capita consumption and smoking prevalence

The Importance of State Variations

With the state as the fundamental unit of measure, these per capita consumption results underscored the importance of accounting for variations between states within the analysis. An earlier study by Manley and colleagues[a] showed that ASSIST states had lower per capita consumption than non-ASSIST states at the midpoint of the intervention; however, this conclusion was incorrect because the analysis was flawed, having failed to properly account for between-state variability in per capita consumption of cigarettes. Further details on this analysis are provided in appendix 9.B.

Source: Davis, W. W., B. I. Graubard, A. M. Hartman, and F. A. Stillman. 2003. Descriptive methods for evaluation of state-based intervention programs. *Evaluation Review* 27 (5): 506–34.

[a]Manley, M. W., J. P. Pierce, E. A. Gilpin, B. Rosbrook, C. Berry, and L-P. Wan. 1997. Impact of the American Stop Smoking Intervention Study on cigarette consumption. *Tobacco Control* 6 (Suppl. 2): S12–S16.

do not always occur together, as was the case for the prevalence analysis, which showed a statistically significant decrease over the intervention period. In California, per capita cigarette consumption continued to decline significantly during a period of unchanged smoking prevalence.[11] Also, the extensive between-states 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 (figure 9.2). 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 (table 9.4).

IOI was only marginally related to adult smoking prevalence ($p = .063$) when the District of Columbia was included in the analysis. However, when the District of Columbia was removed, IOI was significantly and negatively related to smoking prevalence. IOI was significantly and negatively related to per capita cigarette consumption. In addition, IOI was higher in ASSIST states and changed more in ASSIST states over the intervention period; however, a multivariate analysis that was adjusted for state conditions did not show a significant main effect or interaction between IOI and ASSIST status. That is, there was not a statistically significant differential effect of ASSIST on increasing IOI during most of the intervention period. However, there was a suggestion of an ASSIST interaction on the association between change in price and per capita consumption.

SoTC was significantly negatively related to prevalence but not when adjusted for baseline prevalence and individual-level covariates. SoTC was significantly negatively related to per capita consumption after adjustment for state-level covariates. However, SoTC was not related to IOI over the intervention period. Finally, ASSIST was not related to SoTC, after adjustment for important state-level covariates. The SoTC measure was available only at one point in time (1999); if it had been measured consistently before and during the intervention period, the results might have been different. For example, if SoTC had been measured at baseline, one would have expected to see increases over time.

Since the analysis treated all states and the District of Columbia equally, it is not surprising that removing the District of Columbia from the analysis increased the impact of policy on smoking prevalence. IOI and SoTC were constructed to capture state effects, and since the District of Columbia is not a state and does not have the same infrastructure and governmental jurisdictions as a state, the District of Columbia data were artificially increased and of questionable accuracy for those analyses.

It must be remembered that ASSIST was not a randomized trial, and the evaluation was restricted to 51 units of observation, assessed during a period of tremendous nationwide changes affecting tobacco control. Many non-ASSIST states instituted tobacco control programs. Some of these programs were initiated pre-ASSIST, and others were initiated during the intervention period. In addition to initiation of state-level tobacco control programs, litigation between the states' attorneys general and the tobacco industry resulted in considerable attention to tobacco issues, including negative publicity for the tobacco industry from the release of their previously confidential internal documents. During this same time, the U.S. Food and Drug Administration attempted but failed in its bid to regulate tobacco.

Finally, the tobacco industry appears to have actively allocated effort and resources to counter tobacco control efforts generally and ASSIST specifically at the state level. For example, Slater et al. found more pervasive Marlboro promotional offers and advertisements in states with comprehensive tobacco control programs.[12] White and Bero[13,14] identified multiple tactics and coordinated efforts that the tobacco industry used to attack ASSIST. Had the evaluation successfully measured and accounted for these efforts in the analyses described in this chapter, we might have seen a greater ASSIST effect on the primary outcomes of smoking prevalence and per capita cigarette consumption.

Despite these challenges, the ASSIST evaluation did successfully answer some of the primary and secondary questions addressed in the conceptual framework. ASSIST status was associated with decreased smoking prevalence, and higher IOI was associated with lower prevalence. In addition, SoTC and IOI were associated with lower per capita consumption.

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.[15,16] Indeed, if all 50 states and the District of Columbia had implemented ASSIST among the baseline population 18 years of age or older (i.e., 192,322,966),[17] the decrease in adult smoking prevalence would represent approximately 1,213,000 (95% CI: −235,200, 2,661,300) fewer smokers nationally.

The methods used to evaluate ASSIST were necessarily very complex. However, many of the challenges encountered in the ASSIST evaluation will also be present in the evaluation of state-level tobacco control programs. The units of observation (counties or jurisdictions where interventions are administered and applied) will likely be limited so that summary measures or indices (e.g., SoTC, IOI) will be required. The effects observed over time may be attributable to influences from national programs (e.g., American Legacy Foundation's TRUTH campaign) or spillover from other states' programs, rather than interventions within the state. It will be appropriate to account for secular trends occurring even before the interventions took place and to account for demographic and other differences among the observational units.

Conclusions

1. Change in prevalence across all states was analyzed using multiple linear regression that adjusted for potential confounding factors. Per capita cigarette consumption was examined using mixed effects linear modeling incorporating initial consumption rates and state factors associated with cigarette consumption.
2. Primary analysis results showed that ASSIST states exhibited statistically greater decreases in smoking prevalence for women. ASSIST states also exhibited lower per capita cigarette consumption over the course of the intervention period; however, ASSIST status was not significantly related to per capita cigarette consumption when these results were adjusted for state conditions.
3. Secondary results were as follows:
   - **ASSIST Status.** The ASSIST status of a state was not significantly related to the Strength of Tobacco Control index or to the Initial Outcomes Index after adjusting for state conditions.
   - **Strength of Tobacco Control.** Strength of tobacco control was significantly related to decreased per capita cigarette consumption. However, strength of tobacco control and its components (i.e., resources, capacity, or efforts) were not statistically significantly associated with smoking prevalence after adjustment for individual-level factors. Strength of tobacco control was also not found to be significantly related to the Initial Outcomes Index.
   - **Initial Outcomes Index.** The Initial Outcomes Index was significantly associated with reduced smoking prevalence among women as well as with overall smoking prevalence when the District of Columbia was removed from the analysis. Initial Outcomes Index and its cigarette price component were also significantly related to decreased per capita cigarette consumption. While the Initial Outcomes Index was not significantly related to ASSIST status, there was a relationship between its cigarette price component and ASSIST status.
4. Combining these results shows that if ASSIST had been implemented nationwide, projections indicate that there would have been over 1.2 million fewer smokers in the United States.

Appendix 9.A. Issues Related to Selection of Methods for Analyzing Smoking Prevalence

This appendix presents background material about how the methods used to analyze smoking prevalence were selected. The authors made decisions about how to account for baseline prevalence in the analytic model and how to adjust for state factors, such as inequalities in demographics, that affect adult smoking prevalence. The details of the models used are presented in the main body of the chapter.

Baseline Prevalence

One of the first issues to be addressed in formulating the model is how to treat the baseline and final prevalence estimates. The simplest approach would be to ignore the baseline data and assume that the mean prevalence for the ASSIST and non-ASSIST states was similar at baseline. This assumption may or may not be valid. It might also be more appropriate to use an analysis of covariance approach to adjust for the baseline value, because states with high initial prevalence rates could exhibit a different degree of change than states with low initial prevalence rates. Another choice would be to use the change score (difference) in smoking prevalence from baseline to the end of the program as the dependent variable in the analyses.

This issue is not unique to the ASSIST evaluation, and a discussion of the advantages of the baseline as covariate over the other approaches is presented in Bonate.[18] Because the correlation between baseline and outcome is less than 1, the correlation between baseline and change score is negative. Thus, an observed difference between groups at baseline is predictive not only of a difference in raw outcomes but also of a difference in change scores in the opposite direction. If the intervention group is at an unfair disadvantage compared with the control group when its effects are measured in raw outcomes (due to an imbalance at baseline), change scores will maintain that unfair advantage. In contrast, the baseline-as-covariate method produces a result that is uncorrelated with the baseline; it essentially subtracts a fraction of the baseline from the outcome. Further, the variance of parameters of interest is generally lower with the baseline as covariate approach than would be obtained with the other approaches.

Adjusting for Differences in Demographics and Other Factors

It is possible that ASSIST states might collectively show a different demographic profile or differ from non-ASSIST states in underlying characteristics related to smoking status at the individual level. The following approaches were considered for adjusting the analyses for differences between the ASSIST and non-ASSIST states in state- and individual-level covariates. These methods were empirically tested using pre-baseline and baseline data so that the selection of the approaches that were used for the evaluation of ASSIST was not influenced by the results of the evaluation.

Propensity Scores

One way to account for these differences is to calculate a propensity score that predicts ASSIST status. This propensity score is subsequently used as a covariate in the model.[19] Accordingly, with ASSIST status as the dependent variable, state-level data (mean values of various demographic characteristics from the CPS or from other sources; see table 9.1 in the main body of this chapter) were subjected to a logistic regression analysis. The resultant probability of being an ASSIST state from this model for each state would become the value of a covariate for the analysis. However, with only 51 units of observation, none of the independent state-level variables were strongly related to ASSIST status.

Matching

Another approach to account for baseline differences among states is to match each of the 17 ASSIST states to a comparable non-ASSIST state. This was done in a previous community intervention study,[20] and matching was suggested[21] and investigated as a possibly superior approach[22] to regression techniques for the ASSIST evaluation.

Using matching would reduce the number of observations to 34. Using power analysis methods developed by Martin et al.,[23] the resulting statistical power to detect a 1.5% difference in prevalence between ASSIST and non-ASSIST was less than 60%. In addition to the overall loss of statistical power, even difficulties in matching states with respect to enough important variables (e.g., preintervention prevalence, cigarette tax rate, demographics) to consider the two states comparable were insurmountable.[21] Thus, matching was abandoned in favor of regression approaches for the ASSIST evaluation.

Another approach related to matching that was considered was to use demographic methods of direct standardization of the smoking prevalence rates for the states using the U.S. distribution of the sociodemographic covariates as a reference population for the standardization. This approach was not used because of limitations on the number of variables that could be used for standardization and because of difficulties in adjusting race and ethnicity categories that were not represented in all states.

Two-stage Regression Model

The prevalence of adult smoking was compared between the ASSIST and non-ASSIST states using a two-stage regression analysis that was similar to the approach used in the analysis of the Community Intervention Trial for Smoking Cessation (COMMIT).[24] The first stage of the regression analysis was used to adjust for differences in individual-level demographic factors (table 9.2) that exist among states and are associated with smoking. At this stage of the regression analysis, current smoking at the individual level was predicted using a logistic regression model that was fit to the combined TUS-CPS data from the baseline (1992–93) and follow-up (1998–99) periods. The logistic regression was weighted by TUS-CPS sample weights and included individual-level variables and the interactions between sex and age and between sex and race/ethnicity. Residuals obtained from the logistic regression averaged (using the TUS-CPS sample weights) within each state for each of the baseline and follow-up periods were 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 9.1) 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. With only 51 units of observation (50 states and the District of Columbia) available for the second stage regression analysis, it was important that the model at this stage be as parsimonious as possible. The task was to select only a few predictors that together explained the most variance in the dependent variable. State-level factors were selected for inclusion as independent variables in the regression analysis using an all-possible-subsets procedure with a minimum Mallows Cp statistic criteria.[6]

Before the two-stage regression analysis was implemented, it was tested and confirmed by a preliminary analysis of prebaseline national smoking prevalence data from 1985 and 1989 Current Population surveys, which served as a test baseline sample, and 1992–93 baseline TUS-CPS data, which served as a test follow-up sample. Further evaluation of the two-stage regression analysis was performed with the 1992–93 TUS-CPS data as the baseline and the 1995–96 TUS-CPS data as the follow-up. These preliminary analyses were useful for demonstrating that the two-stage regression approach could be successfully implemented in the ASSIST evaluation.

How State-level Covariates Were Selected for the Second Stage

With only 51 units of observation used in the second stage of the regression analysis, it was important that the regression model be as parsimonious as possible. The task was to select only a few predictors that together explained the most variance in the dependent variable. The procedure chosen to select the most predictive subset of covariates was an all-possible-subsets regression analysis judged by the minimum Mallows Cp statistic,[6] which worked well in the preliminary analyses.

Model Diagnostics

It was important to determine whether any one individual state unduly influenced the results. The method used computed the DFITS statistic, which allowed for identification of states that altered the prediction of the models, and the DFBETAS statistic to identify states that most influenced the estimates of the regression coefficients.[4] Collinearity diagnostics were also performed to identify state-level covariates with unusually high correlations, which might lead to numerical instability in the estimation of the regression coefficients or inflate the variances associated with the regression coefficients.[4] The collinearity diagnostics computed the eigenvalues for the design matrix times its transpose to obtain a condition index used to check for numerical instability.

Appendix 9.B. Approaches to Analyzing per Capita Cigarette Consumption Data

This appendix describes some of the approaches that were considered for the analysis of the per capita cigarette consumption data and provides more detail regarding the development of the approach used in the final ASSIST evaluation.

Slopes Approach

Linear regression was used to compute a slope for the bimonthly data points in each state before the start of ASSIST. A second slope was computed for data points during the intervention period. The intervention slope was then modeled as a function of the preintervention slope along with the set of covariates (selected as described in appendix 9.A for prevalence) and a variable for ASSIST status (1 = ASSIST, 0 = non-ASSIST). Prior to 1993 and from then until 1996, the linear model provided a reasonable fit to the data. However, as figure 9.B.1 illustrates, in some states trends in per capita cigarette consumption over a longer period were decidedly nonlinear, which implied that another approach was required.

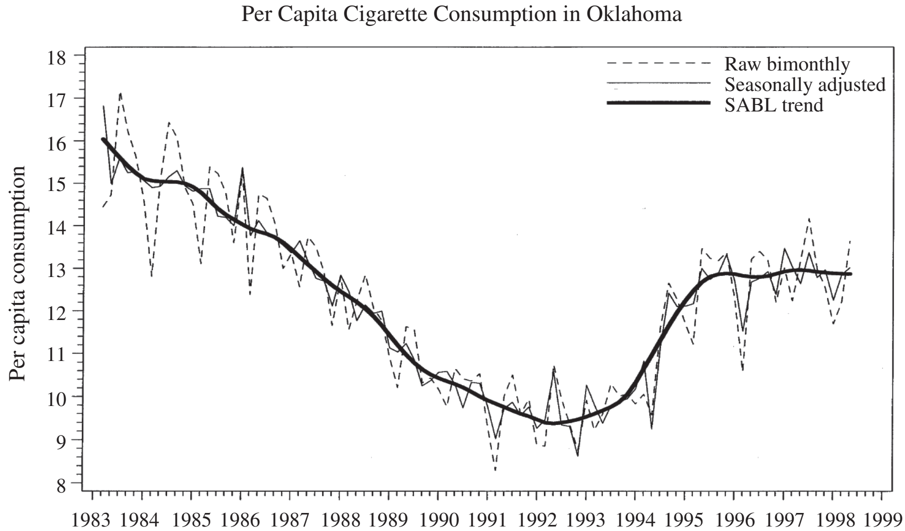
Accounting for State-to-State Variability in Consumption Trends

Because ASSIST and the evaluation design specified state as the unit of observation, it was important that the variability between states be accounted for using appropriate random-effects models. The impact of conducting a fixed versus random effects type of analysis is discussed below.

Manley et al.[25] analyzed per capita cigarette consumption from December 1984 through January 1996 and concluded that there appeared to be an ASSIST effect. In that analysis, bimonthly per capita consumption values were weighted by state population and were then averaged for the ASSIST and non-ASSIST states. Attention centered on the difference in the mean per capita consumption levels for ASSIST and non-ASSIST states over time. A regression-based smoothing technique was then used to compute confidence intervals for the smoothed trend in the difference, and since the lower 95% confidence interval of the smoothed trend in the difference was above zero after 1994, it was concluded that ASSIST had reduced per capita cigarette consumption.

Revisiting this analysis, it was noted that between-states variability was not considered because state was not explicitly the unit of analysis.[26] Also, the variance of the intervention effect can differ greatly depending on whether the states' effects are considered as fixed or random effects. When a random effects model was used to assess the difference and the state variability was taken into account with each state having the same weight, the 95% confidence interval included zero for the entire period considered. However, a weighted analysis produced similar results (figure 9.B.2).

Figure 9.B.1. Examples of States with Nonlinear Trends in Bimonthly per Capita Cigarette Consumption after 1993



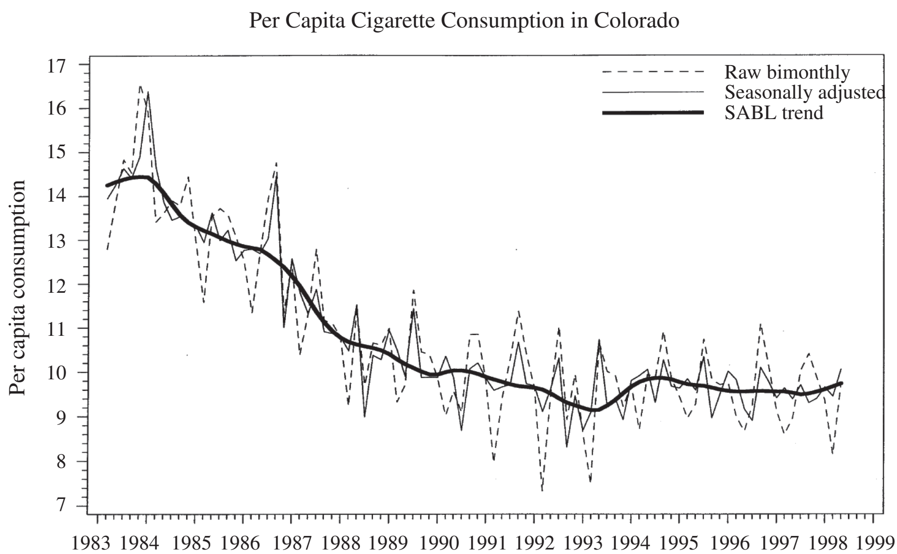
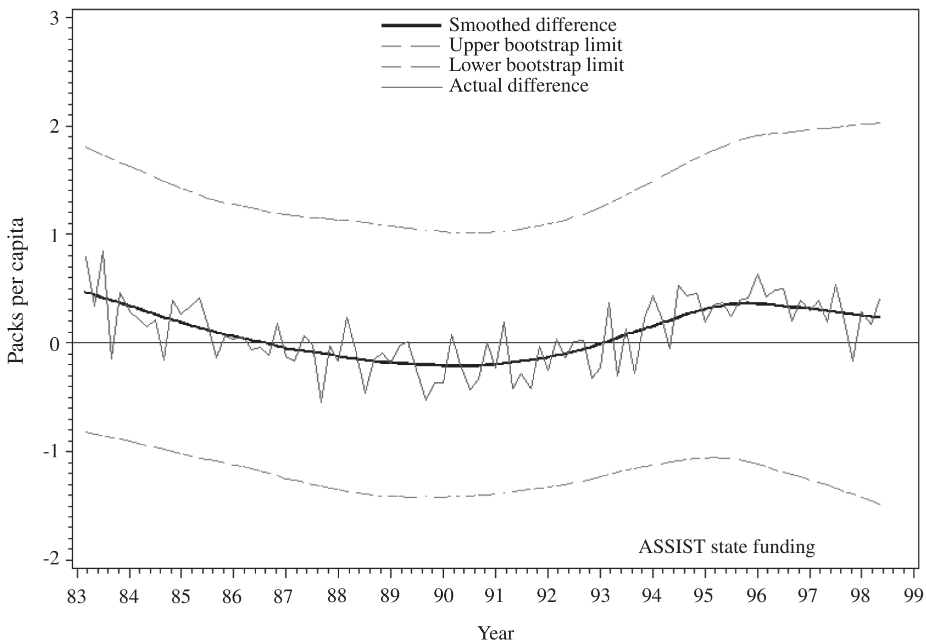


Figure 9.B.2. Random Effects Analysis with 95% Confidence Interval of Difference in per Capita Cigarette Consumption (Non-ASSIST Minus ASSIST)



Source: Davis, W. W., B. I. Graubard, A. M. Hartman, and F. A. Stillman. 2003. Descriptive methods for evaluation of state-based intervention programs. *Evaluation Review* 27: 522. Used with permission.

These analyses illustrate the importance of accounting for the state-to-state variability in the analysis of the intervention effect.

Mixed Effects Time-dependent Models

Mixed random and fixed effects linear modeling was used to analyze the bimonthly per capita consumption data and the annual IOI data. An alternative modeling approach that was considered was the generalized estimation equation method. However, because there were only 51 states or units of analysis, there was concern that the robust variance estimation and the resulting significance tests that used these robust variances would be inaccurate.[27] Therefore, the likelihood-based approach of mixed effects linear modeling was chosen as the method of analysis.

There were several steps required in deriving the final analytical models for the per capita cigarette consumption data. These were as follows:

- The trend over time in the consumption data for all of the states was modeled by a fourth-order polynomial. A spectral analysis was conducted on the detrended bimonthly consumption data, combining the data from all 50 states and the District of Columbia to determine if there was a periodicity in the data. The analysis was carried out using the SAS time series procedure PROC SPECTRA.[28] A strong annual period component was estimated from the periodogram, which warranted inclusion of a sine and a cosine term in the mixed effects models to account for this periodicity.
- Upon examination of the likelihood ratio test, it was determined that a random intercept and a random slope for time were necessary to properly model the state-to-state variability in the consumption patterns.
- An unstructured correlation (the most general approach, requiring no assumptions) matrix was used to estimate the correlation between the random effects.
- After inclusion of the periodicity terms, trend, and random effects, residual within state correlation remained. This was significantly modeled by an ARIMA(1) variance structure.
- Regarding selection of state-level covariates, the Mallows Cp procedure could not be easily automated for these types of models. Instead, a forward-stepping procedure was used. Without the exposure variable(s) of interest, and after including the terms for time, including periodicity, and the random effects for the intercept and slope, the state condition most significantly related to per capita consumption was selected at each step, and the final model included all those that were significant at the two-sided $p < .05$ level.
- Wald F tests were used to determine the level of statistical significance of the fixed effect regression coefficients in the models. The denominator degrees of freedom depended on the number of state-level time-dependent covariates included in the model, where the degrees of freedom for the variance were reduced by 1 from 50 degrees (1 less than the number of units of analysis) for each of the covariates added to the model. There was also a reduction of 1 degree of freedom for each non–time-dependent variable.
- Finally, the model to evaluate the exposure variable of interest included all of the features indicated above together with the exposure variable of interest. For instance, a dummy variable indicating ASSIST status (1 = ASSIST, 0 = non-ASSIST) and appropriate interaction terms with the polynomial time terms were evaluated in the final model for this exposure. Again, Wald F tests were used to determine statistical significance of the set of exposure variables.

Two versions of the final model were evaluated. In the first version, the interactions between ASSIST status and time and powers of time began only after the implementation of ASSIST (at the end of 1993). After adjusting for the state conditions and other considerations, this model assumes that the trend in cigarette consumption for ASSIST states is the same as the trend for non-ASSIST states during the period before ASSIST was implemented (1988–93).[29] Figure 9.2 in the main body of this chapter suggests that the trends for ASSIST and non-ASSIST states did differ prior to the intervention period, because the difference prior to 1993 diminished (was not constant). Also, results for this model produced predicted differences during the intervention period that were not consistent with the observed data. Thus, another version of the model was adopted. In this version, the interactions of ASSIST and time (and powers of time) were considered over the entire time interval, which allowed the trend for consumption to be different between the ASSIST and non-ASSIST states in both the pre- and postintervention periods.

Appendix 9.C. Outcome Measures: Per Capita Cigarette Consumption (Packs/Month) and Adult (18 Years and Older) Smoking Prevalence (%)

(Shading indicates ASSIST states.)

	Per capita cigarette consumption			Change in per capita cigarette consumption:	Adult smoking prevalence			Change in adult smoking prevalence
State	1992–93	1995–96	1998–99	1992–93 to 1998–99	1992–93	1995–96	1998–99	1992–93 to 1998–99
AK	10.4	11.4	8.2	–2.2	27.61	25.31	26.69	–0.92
AL	11.3	11.0	10.6	–0.7	25.74	23.22	22.29	–3.45
AR	11.9	12.7	11.3	–0.6	28.73	26.57	25.99	–2.74
AZ	8.9	7.7	6.9	–2.0	22.37	22.80	19.86	–2.51
CA	7.2	6.4	5.2	–2.0	18.94	17.92	16.59	–2.35
CO	9.1	9.0	8.7	–0.4	24.16	22.55	20.20	–3.96
CT	8.7	8.3	7.9	–0.8	22.31	19.81	20.56	–1.75
DC	7.0	5.9	5.0	–2.0	23.23	22.25	23.54	0.31
DE	13.0	13.6	14.7	1.7	23.30	24.83	23.34	0.04
FL	9.9	10.0	9.4	–0.5	23.89	22.24	20.66	–0.23
GA	11.5	11.2	10.2	–1.3	24.32	22.79	19.89	–4.43
HI	6.3	5.9	3.5	–2.8	22.18	21.75	18.34	–3.84
IA	10.2	10.3	10.0	–0.2	23.50	23.40	22.37	–1.13
ID	9.4	9.1	8.2	–1.2	23.61	22.32	21.84	–1.77
IL	10.0	9.0	7.9	–2.1	24.47	23.67	22.92	–1.55
IN	13.6	14.8	14.3	0.7	27.81	28.92	27.03	–0.78
KS	9.9	9.9	9.3	–0.6	24.22	25.87	22.45	–1.77
KY	18.0	19.4	17.7	–0.3	31.98	29.69	29.81	–2.17
LA	12.1	12.3	11.2	–0.9	25.37	25.83	22.74	–2.63
MA	9.0	8.2	6.5	–2.5	21.40	20.68	19.34	–2.06
MD	8.9	8.3	7.5	–1.4	23.59	21.07	19.46	–4.13
ME	11.7	10.9	9.1	–2.6	28.52	25.71	23.51	–5.01
MI	11.6	8.9	9.2	–2.4	27.20	25.67	23.36	–3.84
MN	9.0	9.3	8.8	–0.2	25.11	22.85	21.19	–3.92
MO	13.2	13.8	12.7	–0.5	26.24	25.97	23.49	–2.75
MS	11.6	12.2	11.7	0.1	25.46	23.23	21.53	–3.93
MT	9.3	10.1	9.1	–0.2	23.53	23.94	23.29	–0.24
NC	13.9	13.9	12.7	–1.2	26.93	26.21	22.98	–3.95
ND	9.4	8.9	8.2	–1.2	22.18	23.73	20.47	–1.71
NE	9.8	9.6	8.8	–1.0	21.97	21.47	21.18	–0.79
NH	16.6	17.6	18.2	1.6	24.69	23.67	22.04	–2.65
NJ	8.8	8.7	6.8	–2.0	20.38	20.50	19.84	–0.54
NM	7.9	7.6	6.8	–1.1	23.99	23.95	20.93	–3.06
NV	11.0	10.2	10.9	–0.1	28.37	28.09	24.06	–4.31
NY	8.5	7.3	6.8	–1.7	21.52	20.86	20.54	–0.98
OH	11.8	12.1	11.4	–0.4	25.96	26.07	24.01	–1.95
OK	9.4	12.4	12.5	3.1	26.74	25.52	27.52	0.78
OR	10.5	10.4	8.6	–1.9	22.93	22.52	21.16	–1.77
PA	10.2	10.3	9.8	–0.4	23.34	24.08	22.88	–0.46
RI	10.1	9.6	9.4	–0.7	23.20	23.77	19.87	–3.33
SC	12.6	11.0	11.7	–0.9	25.71	25.14	22.73	–2.98
SD	10.1	10.6	9.2	–0.9	25.51	22.73	24.08	–1.43
TN	12.5	13.2	12.2	–0.3	28.53	27.21	25.99	–2.54
TX	9.0	8.6	7.6	–1.4	23.45	23.32	20.89	–2.56
UT	7.4	6.7	5.2	–2.2	16.90	15.04	13.73	–3.17
VA	11.1	11.7	10.8	–0.3	25.47	24.95	20.77	–4.70
VT	12.8	11.9	9.9	–2.9	26.26	24.89	22.34	–3.92
WA	8.4	6.5	5.9	–2.5	24.14	23.28	20.13	–4.01
WI	10.5	10.2	9.3	–1.2	26.15	25.04	24.54	–1.61
WV	11.9	12.2	12.0	0.1	30.25	27.83	26.38	–3.87
WY	12.4	12.7	12.2	–0.2	24.82	25.06	23.70	–1.12

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