1. The ASSIST Evaluation Project: An Overview

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1. The ASSIST Evaluation Project: An Overview

This chapter presents an overview of the American Stop Smoking Intervention Study for Cancer Prevention (ASSIST)[*] evaluation and its historical context. It reviews the key points of ASSIST and describes the conceptual framework that guided the ASSIST evaluation, as well as the key constructs of the conceptual framework, the rationale for their inclusion, and the research questions that established the linkages between these conceptual constructs.

ASSIST presented a unique challenge for evaluating tobacco control[†] program effectiveness. The ASSIST program guidelines included a focus on broad social and environmental change and recommended that interventions be delivered at the highest structural level (i.e., state or region) to ensure the greatest impact on tobacco use (see Monograph 16, chapter 2, pp. 21–23). As a result, one of the aims of the ASSIST evaluation was to show that this approach to tobacco control would reduce cigarette consumption and smoking prevalence. In the past, tobacco control interventions were often delivered in isolation or were aimed at specific groups and tested under controlled circumstances. In contrast, ASSIST was a demonstration project that combined capacity building and policy-focused interventions to change how tobacco control was delivered in 17 states. This focus on capacity development and policy interventions represented a more upstream approach to tobacco control, and evaluating it required identifying constructs or components and measures that went beyond those used to assess more traditional interventions that focused on changing individual behavior.

The ASSIST evaluation team developed a conceptual framework around a set of constructs including state tobacco control functioning, policy development, and state-level demographics and conditions that were used to help understand the process of change resulting from statewide tobacco control efforts. The initial outcomes were changes in policy, and the final outcomes were changes in smoking prevalence and cigarette consumption. Additional components of this model, such as tobacco industry interference tactics and print media coverage, were also studied. In some cases, measures were developed but were not ultimately included in the

[*]The official name for ASSIST was the American Stop Smoking Intervention Study for Cancer Prevention. The title was often shortened to the American Stop Smoking Intervention Study, and it is this shortened form that is used in this monograph. For a more extensive description of the ASSIST conceptual framework, model, interventions, and case studies, and discussion of how ASSIST contributed to the development of a national tobacco control program, please see NCI Tobacco Control Monograph 16—*ASSIST: Shaping the Future of Tobacco Prevention and Control.*

[†]The phrase "tobacco use prevention and control" was emphasized in the development and dissemination of ASSIST materials. In this monograph, the phrase has frequently been shortened to "tobacco control."

final evaluation model. These measures are described in this monograph because they formed part of the knowledge base of population-level tobacco control that was developed for the overall ASSIST evaluation effort.

By developing and validating a conceptual framework that reflects the complexity inherent in tobacco control, and by developing measures that are strongly related to tobacco control outcomes, this effort serves as a model for evaluations of public health interventions with components that are diffused throughout an entire population. Moreover, such an approach fits a growing systems view of the world where the interrelationships and feedback across factors more closely mirror real-world behavior and outcomes.

Introduction

This chapter introduces the model used for the evaluation of ASSIST—one of the largest government-sponsored tobacco control initiatives ever undertaken. In addition, and perhaps more important, this chapter explores the historical context and trends that led to a unique and forward-thinking approach to evaluation. In this and subsequent chapters, the underlying theoretical perspective, the development and measurement of the evaluation components, and the analysis methods and outcomes are described.

While tobacco has played an important role in U.S. history, efforts to curtail its use have an equally long history. Thomas Jefferson noted that "[Tobacco] is a culture productive of infinite wretchedness. . . . The cultivation of wheat is the reverse in every circumstance."[1] However, the past half-century marks a unique period in which organized public health efforts, particularly at the policy level, have contributed to changes in social norms that have made cigarette smoking less socially acceptable to the public. This success is attributable to a complex and interdependent mosaic of interventions delivered through multiple channels.

Against this backdrop, ASSIST represented a major initiative to address tobacco use through high-level, policy-based interventions delivered at the state and community levels. Unlike prior efforts, ASSIST was a demonstration project and not a randomized trial, focusing instead on multiple interventions, many with indirect long-term outcomes, without the benefit of randomized control groups. Moreover, ASSIST implemented interventions at the level of a broad population group, through means such as capacity building, policy advocacy, legislative change, and media interventions, rather than measures such as individual smoking cessation assistance.

The challenge of evaluating ASSIST resulted in a sophisticated and statistically validated model, developed with multidisciplinary input. The evaluation assessed not only the effectiveness of the ASSIST intervention in the 17 intervention states but also overall tobacco control efforts across all U.S. states and the District of Columbia. The evaluation introduced a new and more ecological

approach, including an assessment of the upstream or more short-term indicators of tobacco control efforts and outcomes. The ultimate and long-term hypothesized outcomes were changes in smoking prevalence (the number of people who smoke) and per capita cigarette consumption. Change in prevalence across all states was assessed with multiple linear regression that adjusted for potential confounding factors. In addition, per capita consumption was examined using mixed effects linear modeling that accounted for the consumption rates in each state during the time when the ASSIST intervention began and incorporated the state factors associated with cigarette consumption and each state's seasonal pattern of consumption. The evaluation effort demonstrated that ASSIST was a success, and both this project and its evaluation can serve as models for how large-scale public health efforts must continue to evolve in the future.

The ASSIST Evaluation: A Historical Context

The ASSIST evaluation presented a unique challenge, formed by the confluence of numerous trends within both tobacco control and public health in general—trends toward more complex interventions that were aimed at broader population groups and took place in complex environments that were increasingly less amenable to randomized trials or controls.

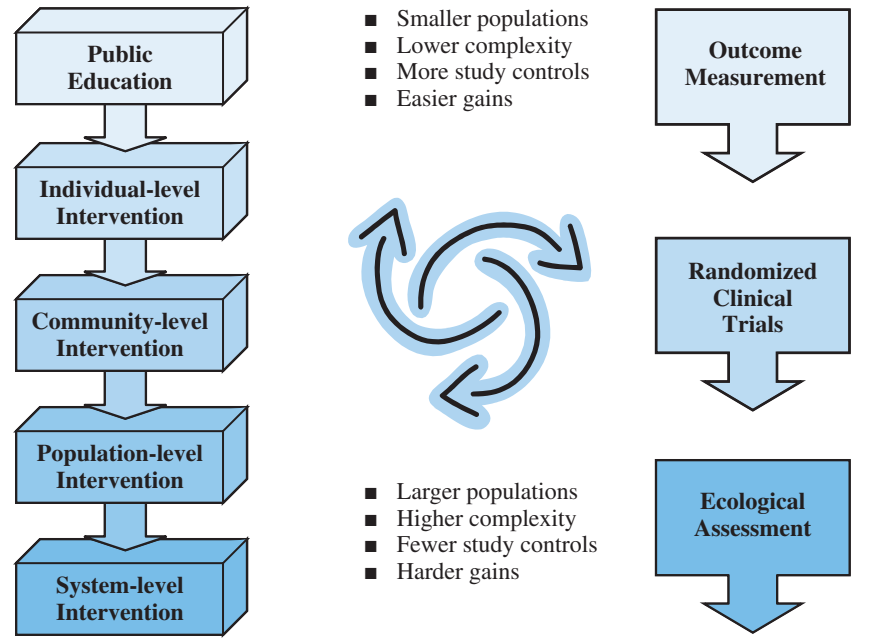
To put the ASSIST evaluation in its proper context, one should first look at the broader trends in tobacco control that framed this project. Half a century ago, cigarette smoking was an ingrained part of American culture, with an adult prevalence rate of nearly 60% for males and 44% overall, and a concomitant burden of premature disease and death.[2] By 2004, overall tobacco prevalence had declined by nearly a factor of two from these levels, ranking as one of the great success stories of public health.[3]

Figure 1.1 depicts the evolution of tobacco control interventions and evaluation of those interventions between 1964 and the ASSIST evaluation. The trajectory between these two points in time encompasses five general phases in the evolution of tobacco control efforts:

Phase 1: Education. The first surgeon general's report on smoking and health,[4] a massive school-based smoking prevention program, and extensive public service advertising and education about the dangers of smoking yielded a measurable reduction in tobacco prevalence and cigarette consumption. The first National Cancer Institute (NCI) tobacco control monograph, *Strategies to Control Tobacco Use in the United States: A Blueprint for Public Health Action in the 1990's,* notes that despite this initial drop, it quickly became clear that information alone would not be sufficient to effect major changes in tobacco use.[5(p ix)]

Phase 2: Individual-level Intervention. In the years following the mid-1960s, numerous resources became available to promote smoking cessation among individuals. These resources included clinics and classes to help smokers quit smoking, self-help and behavioral strategies for smoking cessation, and interventions to educate the general population about the dangers of smoking. Most

Figure 1.1. Trends over Time in Tobacco Control Projects and Their Evaluation



cessation strategies focused on teaching individual smokers how to quit smoking. Other cessation approaches included physician advice and counseling, mass media campaigns, and the beginnings of on-demand resources such as telephone quit lines.[6]

Phase 3: Community-level Intervention. From the 1970s through the 1980s, an era in which early gains in smoking cessation began to plateau, there was a growing recognition that tobacco use was a public health problem with epidemiological implications. This recognition led to community-based interventions to address tobacco use. Early community-based intervention studies included the 1972 Stanford Three Community Study[7] and the North Karelia demonstration project in Finland.[8] These interventions were followed by larger-scale projects such as the Community Intervention Trial for Smoking Cessation (COMMIT), funded by NCI from 1986 through 1992.[9–12] A randomized community trial comparing the effects of interventions in paired U.S. cities, COMMIT focused on areas such as cessation resources, education, and health-care interventions, and also on broader areas such as community mobilization and workplace smoking, laying the groundwork for a coalition model of tobacco control.

Phase 4: Population-level Intervention. Projects such as COMMIT began to sow the seeds of intervention through means

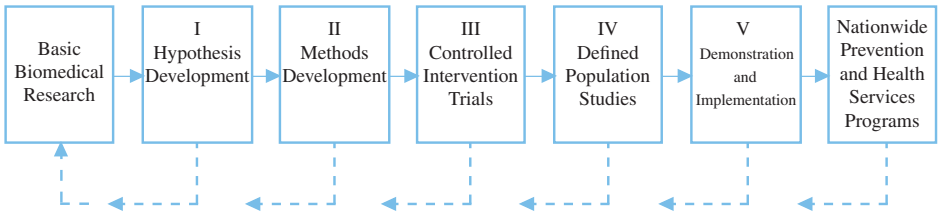
such as worksite smoking policies and community mobilization, which naturally led to efforts that addressed tobacco health issues through large-scale population-level interventions. By the close of the 1980s, numerous such initiatives took shape, ranging from efforts promoting clean air laws and increased taxation to media interventions—and social norms about smoking began to change. As a result of these early successes, the need for comprehensive approaches to tobacco control was recognized. A comprehensive approach required employing multiple channels and sectors, including political, economic, education, communication, health professional, and health voluntary sectors.[5(p52)] It was against this backdrop that the hypothesis behind ASSIST, that smoking behavior could be changed through sociopolitical means, was ultimately formed and tested.

Phase 5: System-level Intervention. Today, the epidemiological model of tobacco control continues to evolve toward a broader systems view that incorporates the multiplicity of factors and stakeholder groups behind patterns of tobacco use and public health. Recent initiatives in tobacco control, such as the NCI-funded Initiative for the Study and Implementation of Systems[13] and the Global Tobacco Research Network,[14] are now exploring tobacco control issues at systems and network levels, while broader efforts, such as the Syndemics initiative funded by the Centers for Disease Control and Prevention (CDC),[15] show promise for examining the interrelationship of tobacco use prevention and control and other population-level health issues.

This progression represented more than just simple evolution—it was also part of a strategic objective on the part of NCI to implement population-level tobacco control on a framework of proven science. Figure 1.2 illustrates five phases of cancer control defined in the early 1980s under the leadership of Dr. Peter Greenwald and Dr. Joseph Cullen, Director and Deputy Director, respectively, of NCI's Division of Cancer Prevention and Control.

In practice, this framework helped guide the science from COMMIT, a randomized community trial aimed at

Figure 1.2. NCI's Five Phases of Cancer Control Research



Sources: Greenwald, P. G., and J. W. Cullen. 1984. The scientific approach to cancer control. *CA-A Cancer Journal for Clinicians* 34 (6): 328–332. National Cancer Institute. 1990. *Smoking, tobacco, and cancer program: 1985-1989 status report* (NIH publication no. 90-3107). Bethesda, MD: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health (p. vi).

defined community groups, to ASSIST, a demonstration project with much larger target groups and more complex interventions, while at the same time defining a clear trend toward larger-scale tobacco control efforts. This science-based model for tobacco control also helped lay the groundwork for a fundamental shift in tobacco control philosophy during the 1990s, which in turn led to equally fundamental changes in how society as a whole viewed the use of tobacco products.

The 1990s: A Turning Point for Tobacco Control

Through the beginning of the 1990s, the story of modern tobacco control in the United States was marked by a transition from public education to one of individual and community-level interventions. While these methods did achieve substantial reductions in tobacco use, at a broader social level these gains took place in a society in which smoking remained an accepted part of the fabric of life. Cigarette advertising, smoke-filled bars, and a doctrine of personal choice all remained part of the landscape of public life, as had been the case for decades before.

By comparison, the decade that followed marked a critical juncture in how society viewed tobacco. By the beginning of the new millennium, cigarettes had become an increasingly expensive, legislated, and socially unacceptable product—and tobacco manufacturers began to be held much more accountable for the health consequences of their products. This environment was a direct result of policy-level interventions promoted by a broad coalition of government, health-care, and community stakeholders—guided by a strong voice from the population itself, as expressed through their elected officials.

ASSIST. ASSIST, launched in 1991, was a major policy-level tobacco control initiative that became a vanguard of the tobacco use prevention and control efforts that followed. During the same period as the COMMIT intervention, NCI published its first monograph on tobacco control, which became known as the "blueprint."[5] The blueprint synthesized 40 years of research on effective tobacco control strategies. This document identified the need for comprehensive tobacco control interventions, primarily through policy-based approaches that could alter the sociopolitical environment of tobacco use. Along with the COMMIT findings, this document became the basis for ASSIST.

ASSIST was a macro-level policy approach to tobacco control.[16,17] NCI made the first substantial monetary investment to accomplish its stated tobacco control objectives by releasing a Request for Proposal to fund state tobacco control programs. In 1991, NCI partnered with the American Cancer Society to implement ASSIST through contracts to 17 state health departments; the contracts incorporated the recommendations that were in the blueprint. These 17 states were funded to implement upstream interventions in three core areas: policy, media, and program services, to be delivered across several population channels. (For a more extensive discussion of the ASSIST intervention areas, see Monograph 16, chapter 2, pp. 26–28.)

NCI Tobacco Control Monograph 16: ASSIST

Tobacco Control Monograph 16, *ASSIST: Shaping the Future of Tobacco Prevention and Control,* is a companion volume to this monograph. Monograph 16 provides the background and history of ASSIST. This history includes not only the program components but also a detailed look at how the initiative was implemented. The case studies and detailed descriptions of the "complexities, politics, and outright opposition encountered by the ASSIST team"[a] afford the reader a better understanding of state-level tobacco control programs and a recognition of how far we have come since the 1950s, when tobacco use was a well-accepted social behavior. Monograph 16 also leaves the reader with an appreciation for the challenges faced by the ASSIST evaluation team.

[a]National Cancer Institute. 2005. *ASSIST: Shaping the future of tobacco prevention and control* (Tobacco control monograph no. 16, NIH pub. no. 05-5645). Bethesda, MD: National Cancer Institute (p. viii).

ASSIST was the first major federal investment in state tobacco control infrastructure, and its program standards formed the foundation of two other nationally-based programs, SmokeLess States and Initiatives to Mobilize for the Prevention and Control of Tobacco (IMPACT), during the 1990s.[18] As the largest public-private partnership in tobacco control ever implemented, ASSIST invested about $22.5 million per year in tobacco control programs. Although this amount was substantial, it represented only about 0.03% of the $5.7 billion that the tobacco industry spent on average per year to market its products each year during the same period (1991–99). The NCI investment allowed states to establish strong infrastructures to support comprehensive state tobacco control programs. Moreover, ASSIST provided states with the guidance they needed to implement strong, evidence-based tobacco control practices.

SmokeLess States. During the same period, in 1993, the Robert Wood Johnson Foundation in partnership with the American Medical Association funded the SmokeLess States National Tobacco Policy Initiative.[19] This complementary private-sector initiative initially funded coalitions in 19 states and a youth-specific project in Tucson, Arizona. Two years later, additional funding brought in 13 new grantees, and by the time the program ended in 2004, almost all of the states had been funded.[20] Much like ASSIST, the SmokeLess States project focused on policy-level initiatives for tobacco control, concentrating on clean air ordinances, increasing tobacco taxes, and providing insurance coverage for tobacco dependence treatment. It also fostered a similar coalition model for the implementation of its interventions.

IMPACT. In 1994, through IMPACT, CDC funded the remaining 32 non-ASSIST states and the District of Columbia (California had its own well-developed tobacco control program and was not included in IMPACT) to implement tobacco control programs, providing technical assistance with limited funding support (average annual awards were $360,000) to build the states' capacity to sustain broad-based tobacco control programs. CDC provided technical assistance and training on planning, developing, implementing, and evaluating

SmokeLess States Versus ASSIST

The SmokeLess States project differed from ASSIST in two important ways.

- First, SmokeLess States funding did not go through state health departments as did the funding for ASSIST. Therefore, SmokeLess States grantees, who were mainly health voluntary agencies and other coalition partners, did not have to contend with state governmental restrictions and bureaucratic limitations. They were freer to engage in media and policy advocacy to promote specific policy changes, which was severely limited under the government funding of ASSIST. Funding from the Robert Wood Johnson Foundation could be used for advocacy (educating policy makers and the public about tobacco-related policies) but not for lobbying. However, funds for lobbying were provided through partnerships with voluntary agencies (American Cancer Society, American Heart Association, American Lung Association), which did allow SmokeLess States grantees to advocate for specific legislation, an activity in which state health departments could not engage.[a]
- Second, while ASSIST was a demonstration project designed to employ policy interventions within 17 specific funded states, SmokeLess States eventually funded 42 state coalitions. Although there was no a priori evaluation plan for SmokeLess States, it is currently being evaluated using the ASSIST evaluation framework.

Projects such as SmokeLess States also benefited from the knowledge base that evolved from ASSIST. A unique component of ASSIST was the ASSIST Coordinating Center, which provided technical assistance to the ASSIST states but also helped diffuse ASSIST-like interventions to other states. This dissemination was done primarily through a national tobacco control conference to which all states, not just the 17 ASSIST states, were invited.

[a]Gerlach, K. K., and M. A. Larkin. 2005. The SmokeLess States Program. In *The Robert Wood Johnson Foundation anthology: To improve health and health care,* vol. 8, 29–46. San Francisco: Jossey-Bass. www.rwjf.org/files/publications/books/2005/chapter_02.pdf.

tobacco control programs.[21] While SmokeLess States and IMPACT had very beneficial effects on national smoking policy, they also presented a challenge for the ASSIST evaluation: the ASSIST influence had now spread beyond the 17 states under study, necessitating a fresh approach to the ASSIST evaluation.

Individual States. Concurrently, the efforts of individual states in the 1990s began to demonstrate the potential impact of policy initiatives. In California, Proposition 99 raised over $150 million for tobacco control education and research via the imposition of an additional tax of 25¢ per pack, and the resulting advertising and outreach efforts helped reduce California's smoking prevalence from 26% to 18%.[22] In Massachusetts, successive 25¢ cigarette tax increases in 1992 and 1996 helped fund an aggressive campaign of advertising, education, and cessation resources within a coalition environment. As a result, smoking prevalence decreased from 23.5% to 19.4% during the 1990s, a decline almost four times the national average during this period.[23] The successes of state-level programs like these furthered the scientific support for larger-scale initiatives such as ASSIST and SmokeLess States.

Turning Point for the Tobacco Industry. The tobacco industry, whose marketing expenditures have always far outstripped the sums invested in tobacco control, responded to these measures with numerous counterefforts. These ranged from spending tens of millions of dollars on efforts to defeat policy initiatives such as the ones outlined above, to moments such as April 14, 1994, when the CEOs of seven major tobacco companies appeared before the U.S. House of Representatives Subcommittee on Health and the Environment chaired by Rep. Henry Waxman and claimed that nicotine was "not addictive."[24]

However, the tide of both public opinion and legislation turned substantially against the tobacco industry during the 1990s. In particular, a 1994 lawsuit by the state of Mississippi to recover the costs of treating sick smokers under Medicaid unleashed a flood of similar lawsuits from other states, culminating in settlements with four individual states and, ultimately, the $300+ billion Master Settlement Agreement between the tobacco industry and state attorneys general in 1998.[25] This settlement, which provided monetary payments to states as well as funding for numerous tobacco cessation resources, put the industry in the unique position of subsidizing tobacco control efforts at the same time it was aggressively marketing its products. Of equal importance, this agreement also negotiated the conditions under which internal tobacco industry documents that revealed the scope of industry efforts to promote its products and to counter tobacco control efforts should be made and remain accessible to the public.

All of these factors combined to create both great progress and great challenges in tobacco control by the end of the 1990s. Tobacco use in the United States is now lower than it has been in over half a century, and there is a strong and growing evidence base that shows that population-based strategies are effective. In the process, the public's perception of tobacco use has changed and is now viewed as a social as well as an individual problem.

Tobacco Control Today

On September 30, 1999, the ASSIST contracts ended and on October 1, 1999, CDC funding for the National Tobacco Control Program (NTCP) began. Chapter 10 in Monograph 16 describes the transition from ASSIST and IMPACT to NTCP. As of 2005, the field of tobacco control encompassed a broad mosaic of efforts spanning the entire spectrum from the individual, to the community, to national and even global populations. The evolution of those efforts over time points to a number of trends that have influenced the direction of the evaluation of ASSIST:

- **Increasing complexity.** A generation ago, tobacco control specialists looked at the effectiveness of individual interventions. Today, they are also likely to be examining interrelated social, political, and economic factors that relate to the root causes of tobacco use—interventions in which causes and effects must be quantified by increasingly sophisticated and often indirect means.
- **Larger sample sizes.** There is a clear trend toward interventions aimed at

larger populations, in keeping with a growing epidemiological and systems view of tobacco use and health issues. Factors behind this trend include the spread of policy interventions and dissemination of best practices to growing stakeholder networks. In a world where a highly competitive tobacco industry seeks growth in overseas markets and targets population groups, future efforts to reduce tobacco use will become global as well as national.

- **More stakeholders.** Tobacco control has evolved over the past several decades from an ancillary public health issue to a field unto itself. Today, stakeholders range from practitioners and activists at the community level, to an extensive and transdisciplinary network of researchers, to thought leaders and organizations at the highest levels of government.
- **Tougher gains over time.** As of 2004, adult smoking prevalence rates over the preceding 15 years had declined at approximately half the rate of the 15 years following the release of the 1964 surgeon general's report.[26] While today's continuing rates of decline remain a positive trend, it is clear that further gains in tobacco-related health increasingly lie beyond simple interventions.

Trends such as these can be seen clearly by doing a side-by-side comparison of the two most recent large-scale government tobacco control efforts, COMMIT and ASSIST. Table 1.1 illustrates many of the factors that influenced the design of the ASSIST evaluation. (For a more extensive comparison of COMMIT and ASSIST, see Monograph 16, chapter 1, p. 10.)

These differences underscore the natural evolution that occurred in tobacco control and, by corollary, other issues in public health. As a result, the ASSIST evaluation represents an important first

Table 1.1. Comparison of COMMIT and ASSIST

COMMIT	ASSIST
Focus on community-level interventions	Focus on state- and community-level interventions
Interventions to directly change smoking behavior	Interventions to change the social and cultural environment and attitudes toward smoking. These environmental changes, in turn, create an environment that changes tobacco use behavior.
Clinical trial model, tracking a cohort within city pairs with and without intervention	Ecological model applied to statewide populations
Focus on developing intervention channels	Focus on policy change, program implementation, and capacity building
Focus on research and data collection with less funding to direct services or interventions	Demonstration project with less focus on research or evaluation and most funding directed toward interventions
Incorporated a community-level coalition model	Incorporated a state-level coalition model

step in how to assess future population-level efforts that address tobacco use and, potentially, other behaviors that cause preventable death and disease. It represents a fundamental change in evaluation methodology, as well as a base from which future public health and evaluation efforts will continue to evolve.

The ASSIST Evaluation

Because ASSIST was a demonstration project, the original evaluation plan was for a very limited assessment, based on a comparison of final outcomes (e.g., tobacco use) between ASSIST and non-ASSIST states. The rationale for this was that ASSIST interventions were based on known science, its influence was initially limited to specific states, and its focus was on implementation. However, as NCI efforts increasingly focused on identifying and disseminating *evidence-based approaches* into practice across the cancer control continuum to increase the likelihood of improved intervention outcomes,[27] it became clear that evaluating ASSIST was crucial.

- This project represented a rare opportunity to measure the effectiveness and cost-effectiveness of upstream interventions, particularly as they related to other accepted public health interventions (such as mammography, diet and exercise approaches to obesity prevention, and injury and violence prevention) and public education.
- ASSIST interventions were expanding to other states, amidst other modalities for tobacco control, and a mechanism was needed to assess how effective these measures were at a population level.
- The science of evaluation itself needed to evolve beyond the bounds of randomized clinical trials and single disciplines toward methods and measures to evaluate complex public health initiatives.

Fundamental differences between COMMIT and ASSIST precluded adapting the COMMIT evaluation methodology to ASSIST. COMMIT was a randomized community trial, and its purpose was to test the effectiveness of an intervention and the dissemination of successful strategies through a demonstration project. The protocol for COMMIT was fixed across all sites, whereas the protocol for ASSIST varied across sites. In addition, COMMIT was implemented only in communities whose populations ranged in size from 50,000 to 170,000, whereas ASSIST was implemented across entire states whose mean population size was approximately four million.

Evaluating ASSIST, therefore, required a new approach. ASSIST was a large-scale, multisite demonstration project (Phase V) designed to reduce smoking prevalence through the development and implementation of a comprehensive tobacco prevention and control intervention. It was a natural experiment rather than a randomized experiment and was not comprehensive in the scope of its interventions, which meant that ASSIST was not amenable to a standard evaluation of processes or outcomes. Instead, this effort required an evaluation paradigm that could measure the impact of program interventions on public health

outcomes in an environment with substantial diffusion of these interventions.

What factors ultimately defined the methodology for evaluating ASSIST? Four key principles underscored the design and implementation of this evaluation:

Use an Ecological Approach. This evaluation was not a simple cause-and-effect study, but rather an observation of numerous factors interacting toward an outcome. There were multiple levels of activity; these levels interacted synergistically over time; and they formed elements of an overall approach in which the sum of the parts was expected to be greater in terms of success than each individual program component alone.

Measure the Impact of Social Rather Than Individual Change. The classic randomized experiment measures the effectiveness of a single intervention on a defined outcome. By comparison, ASSIST sought to change the social environment surrounding tobacco use and, in turn, effect long-term changes in individual behavior.

Seek to Measure Capacity for Change. In the clinical model, an intervention has a specific effect. In the ecological model, interventions create capacity (in the form of resources, coalitions, and policy) that, in turn, creates environmental change and continues to adapt to the conditions of this environment.

In tobacco control, growing evidence shows the impact capacity has to change behaviors and outcomes: for example, according to recent CDC best practices, recommended levels of funding could have substantial positive impact on tobacco sales;[28] however, successful implementation of these resources requires adequate infrastructure, such as numbers of staff and levels of staff experience, and the strength of agency and community coalitions.[29,30] That infrastructure was conceptualized and subsequently quantified as capacity, a concept for which there are multiple models in the extant literature (W. Trochim, F. Stillman, P. Clark, and C. Schmitt, 2003, "Empirically-Developed Conceptual Model," unpublished work).

Focus on Intermediary as well as Final Outcomes. The ASSIST evaluation focused not only on the long-term goals of a tobacco control program—namely, reduced tobacco prevalence and cigarette consumption levels—but also identified, assessed, and in some cases measured the relationship between the intervention, interim outcomes, and long-term outcomes. A formal measure of some of these outcomes, the Initial Outcomes Index, was part of the ASSIST evaluation analysis, based on measures of total cigarette price, a rating of local and state clean indoor air policies, and the percentage of workers covered by 100% smoke-free workplaces.

Before ASSIST, no evaluation methodology had been developed to measure the outcomes of such a complex program. The ASSIST evaluation was designed to determine if multiple, community-based, statewide efforts could accelerate the reduction of smoking prevalence; the evaluation was not designed to compare any single tobacco control intervention or combination of interventions. Measures of program effectiveness included individual-level outcomes (e.g., reductions in cigarette

Randomized Clinical Trials Versus ASSIST

The requirements of the ASSIST evaluation were not unique to tobacco control. A growing evidence base to guide clinical practice, such as the Cochrane Collaboration, is being increasingly applied to public health interventions. However, clinical practices do not necessarily translate well to public health settings. For example, randomized clinical trials are often inappropriate or infeasible in public health settings, where it is often impossible or undesirable to limit interventions across population groups. In addition, randomized clinical trials frequently do not account for the complexity of effect modification of the interventions and comorbidity factors found in the real world—a fact illustrated by the growth of public health efforts that use a systems approach to model the interplay between linked epidemics and related phenomena.[a] Finally, randomized clinical trials may have limited generalizability outside the restricted interventions and populations used in the trials.

Using Cochrane-style meta-analysis efforts to drive future advances in evidence-based public health requires a fresh approach to program evaluation. The size and scope of the ASSIST effort made it an ideal test case for developing such an evaluation methodology.

[a]Centers for Disease Control and Prevention. 2004. Syndemics Prevention Network. http://www.cdc.gov/syndemics.

consumption and smoking prevalence) as well as macro-level environmental changes (e.g., enactment of policies and legislation, and increase in the coverage of tobacco-related issues in the media). Because ASSIST was a demonstration project, the proportion of evaluation dollars to program dollars was quite low—less than 5%. The rationale behind this lack of investment in a comprehensive evaluation of ASSIST was that as a Phase V project, ASSIST was supposed to implement strategies whose effectiveness had already been documented, not break new ground or test the effectiveness of new methods. Thus, the original plans to evaluate ASSIST relied on a very simple methodology that required little additional data collection—comparing tobacco use and environmental changes in ASSIST and non-ASSIST states.

However, the ASSIST evaluation evolved into an integrated and comprehensive analysis of ASSIST and of state-level tobacco control program effectiveness in general. The ASSIST evaluation compared changes in tobacco control policies, state per capita cigarette consumption, and adult smoking prevalence in ASSIST and non-ASSIST states and the District of Columbia. Smoking prevalence was obtained from adults interviewed in the NCI-sponsored Tobacco Use Supplement to the U.S. Census Bureau's Current Population Survey (TUS-CPS) in 1992–93 and 1998–99. Per capita cigarette consumption was calculated every two months for each state from sales data for the total number of cigarette packs moved from wholesale warehouses, divided by the state's adult population. This analysis represented a major advance in the evaluation of comprehensive state-level tobacco control programs and, by corollary, of complex multifactor public health interventions.

The development of the ASSIST evaluation conceptual framework helped redirect the evaluation effort to a more comprehensive look at overall tobacco control development and effectiveness.

On the basis of this model, a series of research questions were formulated to establish linkages between the complex program components and outcomes. In addition to examining whether the 17 ASSIST states achieved lower cigarette consumption and lower smoking prevalence than the other 33 states and the District of Columbia, the evaluation design provided for an in-depth evaluation of state tobacco control program components. The evaluation allowed a determination of whether states with more tobacco control resources and infrastructure and those that focused more effort on changing the policy environment produced greater change in tobacco-related policies (initial outcomes) and achieved lower tobacco prevalence and cigarette consumption rates (final outcomes).

Conceptual Design

ASSIST represents an ecological systems model (sometimes referred to as "the new public health")—an approach that focuses on changing the social, cultural, economic, and physical environmental factors that influence health behaviors.[31,32]

The ASSIST evaluation model is based on the assumption that cigarette smoking is driven by a complex set of environmental factors and that changes in smoking that result from tobacco control policy initiatives occur incrementally and at a modest pace. Testing these assumptions required multiple outcome points (initial, intermediate, and final) to track change as it occurred over the 8-year span of ASSIST. This span accommodated the expectation that a measurable reduction in smoking prevalence would lag behind changes in policy and social norms and would also lag behind reductions in cigarette consumption. Therefore, early signs of change, such as change in policy for states (for example, the amount of tax or new clean indoor air legislation), could serve as an initial indicator that the intervention had an effect.

The ASSIST Evaluation Model

Evolution

In 1992, an evaluation group was convened to develop and implement an evaluation methodology for ASSIST, as originally designed—as a simple comparison of smoking prevalence between ASSIST and non-ASSIST states. An early plan also included matching ASSIST states with non-ASSIST states. However, this methodology lacked adequate statistical power to assess change.

Some components of the early evaluation design included

- Measures such as the TUS-CPS, an extensive tobacco use questionnaire, tied in with the U.S. Census and tobacco use information from the Behavioral Risk Factor Surveillance System (BRFSS) developed by NCI but implemented by the CDC.
- An ASSIST Coalition Assessment designed as a qualitative measure of state-level tobacco control coalitions, in areas such as environmental, structural, and functional characteristics. This assessment, a case study approach based on document reviews, one-on-one interviews, direct observations, and a written survey instrument, was

pilot tested but never implemented across all ASSIST states. Ultimately, the Strength of Tobacco Control (SoTC) measure, discussed in more detail in chapter 2, was developed and implemented to gather data on program components and functioning across all U.S. states.

- A rating system for the ASSIST evaluation using the State Cancer Legislative Database.

In the second phase of the ASSIST evaluation, a Technical Expert Panel was convened and the final conceptual framework was developed. This section describes its key constructs, assessment techniques, and the analytical methods used for prevalence and consumption analyses.

The ASSIST evaluation ultimately compared changes in tobacco control policies, state per capita cigarette consumption, and adult smoking prevalence in the 17 ASSIST states with those in the 33 non-ASSIST states and the District of Columbia. The evaluation also analyzed the effect of program components and tobacco control policies on smoking prevalence and per capita cigarette consumption. The development of the ASSIST evaluation conceptual framework and the research questions that sought to establish linkages between the program components and program outcomes provided a more comprehensive assessment of ASSIST effectiveness and tobacco control functioning across the United States.

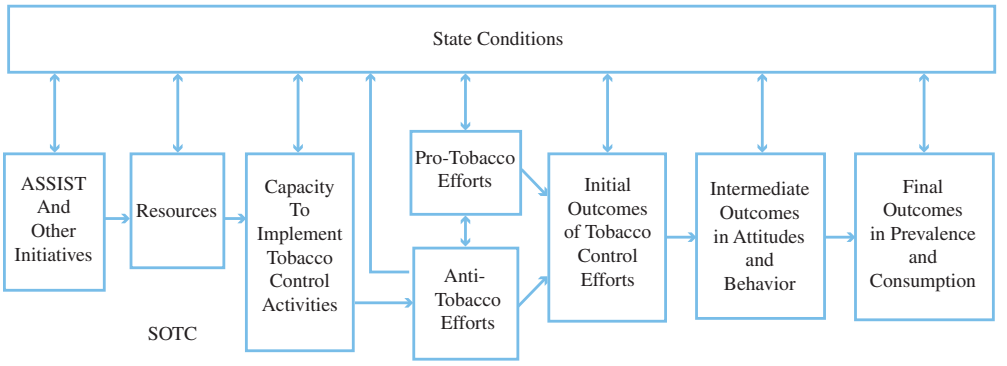
Key Constructs

Figure 1.3 presents the conceptual framework for the ASSIST evaluation, illustrating the sequential process of change resulting from statewide tobacco control efforts. The model consists of key constructs that may impede or promote progress toward the final outcomes of reducing cigarette consumption and smoking prevalence, expressed as groupings of related variables used to index or measure the more abstract concepts behind them.

Figure 1.4 shows the timeline for data collection in the ASSIST evaluation. Per capita cigarette consumption data were collected every two months for each state from sales data for the total number of cigarette packs moved from wholesale warehouses, divided by the state's adult population. Smoking prevalence was collected in the NCI-sponsored TUS-CPS in 1992–93 and 1998–99. For the ASSIST evaluation, only data from baseline (1992–93) and final (1998–99) collections were used. Data for the SoTC measure were collected only once, at the end of the intervention phase, whereas data for the Initial Outcomes Index (IOI) were collected throughout the study. The measurement and computation of indirect indices such as SoTC and IOI required more sophisticated efforts, described in detail in chapters 2 and 4, respectively, in this monograph. Table 1.2 delineates the key constructs and the variables that were proposed for the evaluation.

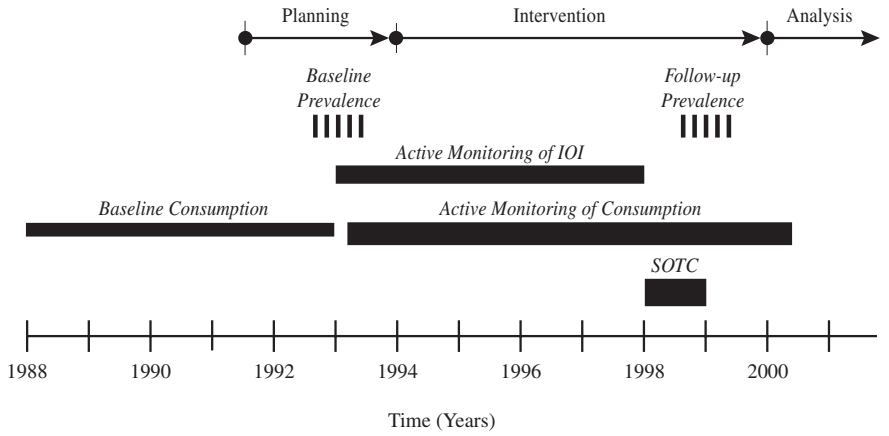
The Strength of Tobacco Control (SoTC) index was developed to measure the components of ASSIST or ASSIST-like programs. The index is a multi-element measure consisting of three major components:

Figure 1.3. The ASSIST Evaluation Model



Source: Stillman, F. A., A. Hartman, B. Graubard, E. 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): 263. Used with permission.

Figure 1.4. ASSIST Evaluation Timeline



Source: 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): 1682. Used by permission of Oxford University Press.

Table 1.2. Key Constructs and Variables Initially Proposed for the ASSIST Evaluation

Measure	Variable
Key constructs	
Resources[a]	■ Dollars expended for tobacco control ■ Source of funds for tobacco control
Capacity to implement tobacco control activities[a]	■ Number of state-level tobacco control personnel ■ Capability of state organization to provide surveillance, training, and technical assistance ■ Number of state organizations involved in tobacco control ■ Frequency and type of contact between organizations ■ Linkages between state and local tobacco control
Antitobacco efforts[a]	■ Quality of state tobacco control plan ■ Comprehensiveness of state tobacco control plan ■ Type of tobacco control strategies ■ Comprehensiveness of state tobacco control effort
Protobacco efforts	■ Advertising dollars ■ Legislative activities ■ Other activities
State conditions	■ Age, education, population size, poverty status, race/ethnicity, sex, urban/rural ■ Economic value of tobacco from agricultural, manufacturing, and processing (% of gross state product)
Outcome measures	
Initial outcomes	■ Rating of local and state tobacco control policies ■ Percentage of workers covered by clean indoor air policies and workplace smoking bans ■ Media advocacy score ■ Cigarette price/tax
Intermediate outcomes	■ Behavior change ■ Attitudes
Final outcomes	■ Prevalence ■ Consumption

Source: Stillman, F., A. Hartman, B. Graubard, E. Gilpin, D. Chavis, J. Garcia, L. M. Wun, W. Lynn, and M. Manley. 1999. The American Stop Smoking Intervention Study (ASSIST): Conceptual framework and evaluation design. *Evaluation Review* 23 (3): 264. Used with permission.

[a]Summarized to form the Strength of Tobacco Control (SoTC) index.

- The first component of SoTC is **resources** committed to state tobacco control efforts. This construct includes state budgetary expenditures for tobacco control and the number of personnel working on tobacco control.
- The second component is the **capacity** to implement tobacco control activities. This construct includes the number of state-level agencies and local coalitions committed to tobacco control. This capacity construct also measures the extent to which specific structures and linkages have developed among key state agencies, coalitions, and advocacy groups. Studies have demonstrated that these linkages can be measured with quantitative indicators.[33,34]
- The third component is tobacco control program **efforts**. This construct includes tobacco control program efforts that focus on socioenvironmental and policy interventions and efforts that focus on changing individual behavior.

These three variables (resources, capacity, and efforts) were summarized to form the overall exposure measure of tobacco control efforts at the state level—SoTC—which in turn served as an indirect measure of ASSIST.

Outcome Measures

Tobacco control efforts produce many types of change, as noted by the outcome measures listed in table 1.2. Initial outcomes could be measured at both the individual (micro) and state (macro) levels. For example, a workplace tobacco policy (a primary intervention objective) is an initial outcome. Workplace tobacco policies can be self-imposed by employers and measured by individuals responding to a survey, or they can be mandated by state or local legislation and measured by a rating of the state or local legislation. Intermediate outcomes include changes in smoking behavior (quit attempts) and changes in attitudes. Final outcomes include changes in consumption levels and prevalence rates as well as in initiation rates and quit ratios.

The analyses of multiple outcomes (e.g., cigarette consumption, quit ratios, initiation rates, delay in age of initiation, changes in workplace policies, and media exposure at their different levels—initial, intermediate, final—in addition to smoking prevalence outcomes) are critical to understanding the relationships and timing of the various components of the tobacco control model. From the California experience, it is apparent that changes in cigarette consumption can be seen sooner than changes in prevalence.[35] Changes in prevalence attributable to an intervention result from a complex mixture of changes in quitting and initiation, delays in the age of initiation, and changes in the ability to affect these in the entire population examined. Cigarette consumption may also change as a consequence of several factors, such as the number of people beginning to smoke, the number of people quitting completely, and the number of smokers cutting down the number of cigarettes smoked. However, cigarette consumption is a more sensitive measure of tobacco control outcomes than smoking prevalence because it is a continuous measure and is collected frequently over

time, resulting in many more measurements with a better basis for estimating trends in a time-trend analysis.[36]

Research Questions

The ASSIST evaluation was guided by a series of research questions that are summarized in table 1.3. The initial question was whether the 17 ASSIST states would achieve lower cigarette consumption rates and lower smoking prevalence than all other states.[37] However, the evaluation design included questions about the relationship between exposure to tobacco control efforts (i.e., as measured by SoTC) or initial outcomes and levels of cigarette consumption and prevalence across all 50 states and the District of Columbia. In other words, did states with higher SoTC scores or higher initial outcome scores have lower tobacco usage? The practices and approaches that were most likely associated with successful implementation of state-level tobacco control programs were also identified.

Analytic Challenges

When ASSIST began in 1991, the initial plan for its evaluation was a simple ASSIST/non-ASSIST comparison using responses from the BRFSS. However, it was determined that data from the BRFSS were not comparable across states: not all states were using the BRFSS at the beginning of the project; in addition, states used different methodologies, specifically varying sampling strategies. The evaluation ultimately used the TUS-CPS, which was developed by NCI for the ASSIST evaluation and was conducted by the Bureau of the Census. Baseline (1992–93), mid-project (1995–96), and follow-up (1998–99) surveys of smoking and tobacco use prevalence were to be measured in all 50 states and the District of Columbia. The TUS-CPS

Table 1.3. Research Questions Guiding the ASSIST Evaluation

- What is the effect of ASSIST on cigarette consumption and smoking prevalence rates (final outcomes)?
- What is the relationship between ASSIST and the Strength of Tobacco Control index (SoTC: resources, capacity, and antitobacco efforts)?
- What is the relationship between SoTC and cigarette consumption and smoking prevalence rates?
- What is ASSIST's effect on initial outcomes (worksite smoking bans, legislative scores, media advocacy scores, cigarette prices)?
- How are the initial outcomes related to the final outcomes?
- What is the relationship between SoTC and the initial outcomes?
- Did ASSIST modify the effects of the initial outcomes and/or SoTC's effects on the final outcomes?

Source: Stillman, F., A. Hartman, B. Graubard, E. Gilpin, D. Chavis, J. Garcia, L. M. Wun, W. Lynn, and M. Manley. 1999. The American Stop Smoking Intervention Study (ASSIST): Conceptual framework and evaluation design. *Evaluation Review* 23 (3): 267. Used with permission.

provided state-specific estimates as well as overall data on the U.S. population at large.

The primary endpoint planned for ASSIST was the prevalence of cigarette smoking and other tobacco use in the intervention sites. Smoking prevalence in the ASSIST states was to be compared with smoking prevalence in non-ASSIST states. A simple comparison at that time seemed a rational approach because few state health departments had tobacco control programs and ASSIST was therefore relatively unique.

However, this simple evaluation plan could not be used. The size and complexity of this demonstration project resulted in a number of difficult analytic challenges, including diffusion of ASSIST-like activities to other states, variations in state conditions that could affect program implementation or outcomes, site selection bias, and statistical limitations related to the small number of observations (50 states plus the District of Columbia).

Diffusion, Contamination, and Secular Trends

ASSIST was designed as a catalyst for tobacco control efforts, and no effort was made throughout the project to inhibit or prevent the diffusion of tobacco control strategies from ASSIST to non-ASSIST sites. Within the first few years of the project, non-ASSIST states adopted ASSIST program elements. In fact, the spread of activities from ASSIST to non-ASSIST sites was considered a possible indicator of success, and substantial natural diffusion from parallel antitobacco activities was expected to occur throughout ASSIST. ASSIST was considered a precursor to a national tobacco control program with "sustained funding for all states and territories,"[18(p446)] and wide diffusion of ASSIST practice standards would make this transition easier. (As discussed previously, two key initiatives that helped spread the concepts of many ASSIST interventions to other states were the SmokeLess States National Tobacco Policy Initiative and the CDC IMPACT program.)

As a result, at the midpoint of the ASSIST intervention, all states had tobacco control programs. This situation was desirable from a public health perspective, but it made it difficult to characterize non-ASSIST states as control or no-treatment states. In addition, it was expected that it would take an extended period of time for the program to affect consumption and prevalence, making it difficult to separate secular trends in tobacco use from program effects.

Competing Factors and Forces

The evaluation was further complicated by the fact that ASSIST activities were not conducted in a vacuum. State conditions such as demographics (specifically, sex, age, race/ethnicity, poverty status, education, urban/rural, population size) and economic dependence on tobacco (the relative contribution of tobacco growing and manufacturing to each state's economy) were expected to influence the success of tobacco control efforts. In addition, ASSIST represented a considerable economic threat to profits from sales of tobacco. Tobacco industry internal documents reveal that in 1989,

immediately upon announcement of the ASSIST Request for Proposal, the industry began to develop a strategy to counter tobacco control activities in the ASSIST states (see Monograph 16, chapter 8, for more extensive discussion and details of the activities of the tobacco industry in countering ASSIST). The billions of dollars that the tobacco industry spent promoting their products each year between 1991 and 1999 (from over $4 billion in 1991 to over $8 billion in 1999)[38] far exceeded the funding that states received in their contracts from NCI and the American Cancer Society.

State Selection Bias

Because ASSIST was a demonstration project and not a research study, the award of contracts was not based on random assignment but rather on other considerations that included the competitiveness of the states' proposals.[39,40] All 50 states and the District of Columbia were eligible to compete for the contracts; 35 states applied, and 23 states were deemed eligible for funding based on published selection criteria.[39] In addition, an attempt was made to include states that were unlikely to be able to develop their own tobacco control programs and that were unlikely to reach the prevalence goals set without considerable assistance. Therefore, although the states chosen for ASSIST funding represented a wide range in ability and experience in developing and implementing tobacco control programs, they were a purposeful, not a randomly selected, sample.

At baseline, the average prevalence of adult smoking for ASSIST states was only slightly higher than for non-ASSIST states (25.2% and 24.4%, respectively, $p = .35$). Among the ASSIST states, there were wide variations in state conditions, pre-intervention levels of tobacco control activities, and tobacco control policies. This meant that the evaluation would have to use covariates to control for the nonrandomization and baseline differences of the states and to reduce the variability of estimates. These differences are displayed and discussed in chapter 5 of this monograph.

Limited Number of Available Observations

Since the state was the basis of the ASSIST programs, the unit of analysis was the state. Many constructs in the tobacco control evaluation model were measured only at the state level. However, this provides a maximum of only 50 states and the District of Columbia. As a result, quantitative analyses, such as regression models, were limited to relatively few variables in each analytic model. With only 51 observations, even a modest degree of random variation severely limits the power of the analysis to detect an effect.

Final Conceptual Framework

By the end of ASSIST, its evaluation director had streamlined the conceptual framework discussed earlier in this chapter and finalized the actual variables that would be used to measure all of the constructs. The final conceptual framework for the evaluation, as shown in figure 1.5, aggregated the state-level tobacco control efforts into a single SoTC measure and sought to create a similar measure for the strength of tobacco industry

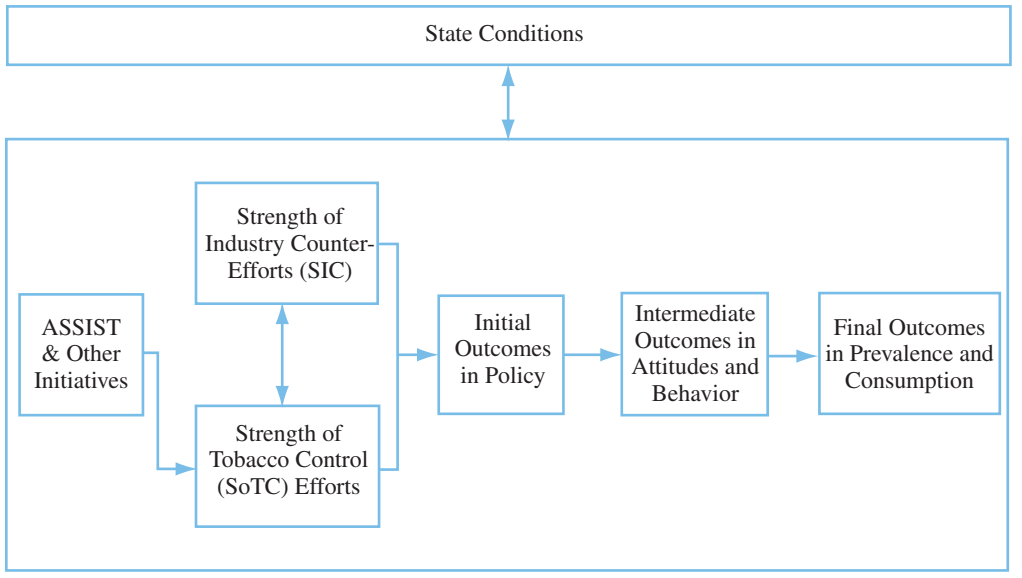
countereffforts. Other measures tracked initial outcomes in policy, intermediate outcomes in attitudes and behavior, and final outcomes in tobacco prevalence and per capita consumption, subsequent to the implementation of ASSIST interventions.

Table 1.4 outlines the actual evaluation measures and variables resulting from this final conceptual framework. Compared with the original constructs and variables outlined in table 1.2, table 1.4 reflects considerably greater aggregation of tobacco control measures, as well as a much broader range of state conditions that served as covariates and/or demographic criteria for the evaluation analyses.

Summary

The remainder of this monograph documents the component parts of the ASSIST evaluation project, starting with its core metrics, SoTC and IOI, as well as a detailed chapter examining policy and legislative changes that helped contribute to IOI. The monograph then discusses the state conditions that were covariates in the analysis, and state economic dependence on tobacco. Next, two ancillary efforts are discussed that did not yield evaluation metrics but provided valuable insights for future work: a database of print media coverage on tobacco and a study of tobacco industry countertactics. Finally, the evaluation

Figure 1.5. Final Conceptual Framework Used for ASSIST Evaluation



Source: 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): 1682. Used by permission of Oxford University Press.

Table 1.4. Final Constructs and Variables Used for the ASSIST Evaluation

Measure	Variables
Intervention measures	
ASSIST indicator	▪ Identification of states as either ASSIST or non-ASSIST
Strength of Tobacco Control (SoTC) index	▪ Resources committed to tobacco control (staff and funds) ▪ Capacity to deliver state-level tobacco control (infrastructure) ▪ Program efforts focused on policy and socioenvironmental change
State conditions (controlled factors)	▪ Age: 18–29, 30–49, 50–64, 65 years or older
Person-level (demographic factors)	▪ 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 (sociodemographic 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 (IOI)	▪ % 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

Source: 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): 1683. Used by permission of Oxford University Press.

and cost-effectiveness of ASSIST are discussed.

The evaluation of ASSIST was an opportunity to generate invaluable information about the delivery and impact of the largest federal tobacco control initiative at that time. It was also a unique research opportunity to investigate the complex relationships inherent in a large-scale public health intervention. The new indices, databases, and analytical methods developed to address the challenges of the evaluation yielded a new model for state-level tobacco control evaluation. The lessons learned can be used to enhance tobacco control program development, as well as other initiatives that seek to change health behavior through a macro-level systems approach.

Conclusions

1. ASSIST was an ambitious public health effort to control tobacco use by building a sustainable, professional infrastructure for tobacco control and by implementing upstream, policy-level interventions. It was the natural extension of earlier interventions at the individual and community levels: an environmental approach to tobacco control that targeted the smoking behavior of populations.
2. The ASSIST evaluation created a conceptual framework that documented the fundamental components of the ASSIST environmental approach to tobacco control. This conceptual framework was used to develop new measures and methods that were used to document the outcomes of this project.
3. Key components of the ASSIST evaluation included intervention measures including the state-level Strength of Tobacco Control metric and demographic factors, and outcome measures including the Initial Outcomes Index, tobacco use prevalence, and per capita cigarette consumption.
4. The ASSIST evaluation faced numerous challenges, including the diffusion of its interventions to other states, competing factors such as demographics and the economic impact of tobacco on states, and limited state-level samples. Addressing these challenges ultimately led to a unique evaluation methodology with lessons for future efforts involving widely diffused, population-level public health interventions. Many population-based health interventions raise similar challenges to evaluation. Because the ASSIST evaluation successfully met those challenges, it remains an exemplar for future evaluations.

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