Tobacco Policy & Regulation

Since Westat’s founding in 1963, our research and technical support capabilities have helped to inform and support policymakers, regulators, and program officials in developing, implementing, and monitoring public health policy, regulations, and programs.

Our work in this area sometimes comes through mining the rich sources of data about health conditions and behaviors that Westat has collected over the years, such as the many rounds of the National Health and Nutrition Examination Survey (NHANES), for which Westat has been responsible since 1971. Our various national and state tobacco surveillance activities likewise support the needs of policymakers, dating as far back as 1986, when we conducted the Centers for Disease Control and Prevention (CDC) Office on Smoking and Health’s Adult Use of Tobacco Survey, among whose purposes was measuring the impact of various Surgeon General’s Reports on the Health Consequences of Smoking.

Over the past 15 years, we have been directly supporting the needs of tobacco policy making, regulation, implementation, and monitoring by applying combinations of various disciplines and methodologies, such as:

- Epidemiologic and surveillance surveys
- Biospecimen collection and analysis
- Analytical and technical support
- Database design and management
- Program evaluation
- Content analysis
- Focus groups
- Cognitive interviews

Our support for tobacco policy, regulation, and legislation includes the following projects.

**Population Assessment of Tobacco and Health (PATH) Study**

On June 22, 2009, the landscape changed dramatically for tobacco use prevention and control in the U.S. when the Family Smoking Prevention and Tobacco Control Act was signed into law, giving the Food and Drug Administration (FDA) broad regulatory authority over the manufacturing, marketing, and distribution of tobacco products to protect the Nation’s health. In contrast to other Centers within the FDA that review therapeutic products using a “safe and effective” standard, the FDA’s Center for Tobacco Products (CTP) was charged with regulating tobacco products through standards based on population health, weighing potential benefits and harm to current, former, and never users of tobacco products. The PATH Study was launched to collect longitudinal epidemiologic data on tobacco use behaviors, including patterns of use, attitudes, beliefs, exposures, and health among the U.S. population to inform FDA’s regulatory actions to reduce tobacco-related death and disease. The PATH Study is a research study that assesses within-person changes and between-person differences in a large national cohort of participants ages 12 years and older over time. As such, the aims of the PATH Study center on research questions that enhance the evidence base to inform FDA’s tobacco regulatory activities.
Scientists at the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) lead the PATH Study. Westat is the survey contractor for the PATH Study, supporting it with capabilities in survey design, questionnaire development, statistical design, data collection, biospecimen collection, and data analysis. Westat manages a team of partner organizations with additional expertise in tobacco research, including tobacco use behaviors, health conditions, and research methods. Our scientific partners are Roswell Park Cancer Institute, Truth Initiative (formerly Legacy), UC San Diego Moores Cancer Center, Geisel School of Medicine at Dartmouth, Medical University of South Carolina, Rutgers University, University of Minnesota, and University of Waterloo. Westat also works closely with the Centers for Disease Control, Division of Laboratory Sciences, which supports the PATH Study through an inter-agency agreement with FDA.

The PATH Study is a national longitudinal cohort study of almost 46,000 adults and youth 12 years of age and older. Wave 1 data collection began on September 12, 2013 and ended on December 14, 2014. Wave 1 of the PATH Study includes the following features:

- An initial, nationally representative household sample of 45,971 persons (including 32,320 adults ages 18 and older, and 13,651 youths ages 12 to 17), using an area-probability, address-based sample design;
- The oversampling of tobacco users, young adults ages 18 to 24, and African Americans (due to higher rates of menthol cigarette use compared to other races);
- The use of audio computer-assisted self-interviewing (ACASI) and computer-assisted personal interviewing (CAPI) administered questionnaires, including the extensive use of images of tobacco products to help respondents accurately report which tobacco products they use;
- Bilingual (English and Spanish) field interviewers and versions of questionnaires and other survey materials for participants;
- The collection of biospecimens from adults who consented to provide them, with urine and blood requested from all adults during the entire field period and buccal cells requested from adults during a portion of the field period.
- Preparation of weighted analytical files of questionnaire and laboratory data, including restricted-use and public-use files for use by researchers and the general public; and
- Production of a wide range of detailed data tabulations, special analyses, and scientific papers.

The current contracts for the PATH Study cover seven annual waves of behavioral data and biospecimen collection through 2024. Data collection for Wave 2 and Wave 3 began October 2014 and October 2015, respectively. After each wave, Westat will produce new weighted files and manage the production of an increasing number of analytical products. As future waves of data are collected, longitudinal weights will be created that allow data from multiple time periods to be analyzed. Longitudinal data gathered by the study can be used to explore mediational models assessing temporal relationships between “exposure” and “outcome” variables.

**Center for Evaluation and Coordination of Training and Research (CECTR)**

Westat, in partnership with the Truth Initiative, serves as the coordinating and resource center for the NIH and FDA collaborative Tobacco Regulatory Science Program (TRSP), supporting and evaluating scientific programs funded by the FDA CTP. Through leadership, evaluation, coordination, and facilitation of collaborative efforts, the CECTR can accelerate the advancement of science relevant to the Family Smoking Prevention and
Tobacco Control Act. This will generate new evidence that informs regulatory activities and decisionmaking to positively impact public health and enhance training programs for scientists in tobacco regulatory research. The CECTR performs the following activities:

• Facilitating the development of models, tools, and databases to evaluate the progress of research
• Supporting the development of learning materials, including an online learning center, webinars, and training programs
• Providing analytical and technical expertise, guidance, and tools
• Acting as a central hub to connect CTP-funded research programs to promote engagement and collaboration, across several hundred grants and contracts, including the 14 Tobacco Centers of Regulatory Science (TCORS)

Analytical and Technical Support for Synar Program Activities

Westat supported the Substance Abuse and Mental Health Services Administration’s (SAMHSA) administration of the Synar program. Synar provides oversight and support for the 59 U.S. states and territories, which are required by the Federal Synar regulation to perform annual random inspections of a sample of tobacco retailers and report the rate at which these establishments violate laws prohibiting tobacco sales to minors. The mission of the Synar program is to reduce minors’ access to tobacco products by effective implementation of Federal tobacco control policy at the state and local levels, including state accountability through an annual report on underage tobacco sale violation rates.

Support activities included the following:

• Preparing technical guidance documents for state retailer surveys and reports
• Providing an annual review of each state’s retailer sample designs and inspection protocols
• Processing the states’ annual Synar reports
• Verifying the statistical calculation of each statewide violation rate as estimated from the retailer random sample
• Maintaining comprehensive databases of longitudinal report data and program documents
• Drafting of papers and presentations
• Providing special analyses of quantitative and qualitative historical data
• Tracking of youth tobacco control issues and legislation
• Training and technical support for SAMHSA Synar project officers
• Support for SAMHSA responses to congressional and public inquiries

In addition, Westat collaborated on a one-time general evaluation of the Synar program’s historical performance, structure, methods, and impact to provide guidance and recommendations for the direction of the Synar program, which included a far-reaching redesign of the external and internal processes for submission, review, and support for the states’ Annual Synar Reports. This continuous quality improvement simplified and standardized the reporting process for the states, automated many of the processes, improved feedback to the states, and resulted in the availability of better information about youth tobacco access for SAMHSA. Automation efforts included development of full electronic reporting by the states, development of special-purpose statistical software to simplify the states’ drawing of retailer samples and calculation of annual violation rates, and an interactive and multimedia self-instruction software package for training users of the statistical software.
Evaluation of the HHS National Network of Tobacco Cessation Quitlines Initiative

In 2004, the Secretary of the Department of Health and Human Services (HHS) announced a plan to establish a national network of tobacco cessation quitlines to ensure access to quitline services for all Americans. The National Cancer Institute’s (NCI’s) Cancer Information Service and CDC’s Office on Smoking and Health collaborated with state tobacco control programs and other partners to implement the National Network of Tobacco Cessation Quitlines. This Initiative stemmed from one of six policy recommendations from the Interagency Committee on Smoking and Health, designed to reduce the prevalence of tobacco use. The Initiative provided funding to states to enhance or establish quitlines, and established a single, national access telephone number (1-800-QUIT-NOW) that routes calls to the appropriate state’s quitline service, based on each caller’s area code. The goal was to establish a viable national network in which state-managed quitlines deliver effective cessation services to all Americans in need of quitline services, and to enable the new quitline number to be integrated into all clinics, schools, and community-based tobacco control programs.

The purpose of the evaluation was to assess the implementation of the Initiative and monitor its public health impact. Evaluation information was designed to 1) strengthen key partnerships within cessation research and practice, 2) build and enhance states’ capacity to provide quality quitline services, 3) increase the public use of quitline services, and 4) sustain quality quitline services. Westat conducted the evaluation in partnership with its subcontractors: the University of Illinois at Chicago, Institute for Health Research and Policy, and the University of Wisconsin, Center for Tobacco Research and Intervention. Westat’s activities included an historical case study of the roll-out of the Initiative; developing the process evaluation plan and logic model; identifying primary and secondary data sources; instrument development; collection of primary and secondary data from key informants, reports, databases, and program documents at the state and Federal level; design and implementation of a process to monitor and assess broadcast, print, and web media coverage; an analysis plan and final evaluation report; design and instrumentation for a projected, longer-term outcome study; and technical support to NCI in developing ancillary surveys and Office of Management and Budget packages.