Overview of the Population Assessment of Tobacco and Health (PATH) Study

Presented by Kevin Conway on behalf of the PATH Team

Kevin P. Conway, Ph.D.
Deputy Director, Division of Epidemiology, Services and Prevention Research
Project Officer of PATH
National Institute on Drug Abuse
March 1, 2013

DISCLAIMER: The views and opinions expressed in this presentation are those of the author only and do not necessarily represent the views, official policy or position of the US Department of Health and Human Services or any of its affiliated institutions or agencies.
Contract Mechanism

• The PATH Study is supported by a NIDA contract, led by the Division of Epidemiology, Services and Prevention Research
  – Contracting Officer: Brian O’laughlin
  – Contracting Officer’s Representative (COR): Kevin Conway
  – Alternate COR: Elizabeth Lambert

• FDA-appropriated funds are transferred to NIDA via an Inter-Agency Agreement (IAA)

• Following a competitive process, the contract was awarded to Westat in September of 2011
Study Management Structure

- Executive Committee
  - NIDA, FDA, Westat

- NIDA/FDA Leadership Group

- [External] Data Access Committee

- Scientific Dissemination Committee
  - Data Analysis Team
  - BioSpec Mgmt. Team

- OMB WG

- Bio WG
- Questionnaire WG
- Field Ops WG
- Sampling WG
- Ad Hoc WG

- BioSpec Mgmt. Team

- Existing
- Planned
This project has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, and the Food and Drug Administration, Department of Health and Human Services, under Contract No. HHSN271201100027C.

Other PATH Team Members Involved in Developing This Presentation Include:

- Nicolette Borek, FDA CTP
- Kevin Conway, NIH NIDA
- Larry Corder, FDA CTP
- Bridget Ambrose, FDA CTP
- Nahla Hilmi, NIH NIDA
- Elizabeth Lambert, NIH NIDA
- Genevieve Vullo, NIH NIDA
- Dana Van Bemmel, FDA CTP
- Jonathan Kwan, FDA CTP
- Cathy Backinger, FDA CTP
- Wilson Compton, NIH NIDA
Family Smoking Prevention and Tobacco Control Act (FSPTCA)

FDA was granted the authority to regulate tobacco products under the **Family Smoking Prevention and Tobacco Control Act** which was passed with bipartisan majorities in the House and Senate and signed into law on June 22, 2009.
FSPTCA gave the Food and Drug Administration (FDA) the authority to regulate the manufacture, distribution, and marketing of tobacco products to protect public health.
How can FDA monitor and assess the behavioral, social, and health impact of tobacco use to inform and assess tobacco regulations, such as...

- Tobacco product standards?
- Health warnings?
- Marketing and advertising of new or modified risk products?
- FDA public health campaigns?
This project has been funded with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, and the Food and Drug Administration, Department of Health and Human Services, under Contract No. HHSN271201100027C.

**FDA Communications**
- Warnings, PSAs, Public disclosure

**FDA Product Regulation**
- Performance standards, MRTP, New products, substantial equivalence, product availability

**Industry Product Design Features**
- e.g., Snus, Verve, Blu

**Industry Marketing/Promotion**
- e.g., price promotions, ad campaigns, media channels

**Background Tobacco Control Work**
- Price, Clean air, Public education, Cessation

**POPULATION HEALTH IMPACT**
- Continued exposure to industry marketing and tobacco control

**Policy specific and psychosocial mediator variables**

- Quit Tobacco
- Poly-Use
- Regular Use
- Trial
- Never Use Tobacco

**Continued exposure to industry marketing and tobacco control**
The PATH Study is a NIDA contract, led by the Division of Epidemiology, Services and Prevention Research.

FDA appropriated funds are transferred to NIDA via an Inter-Agency Agreement.

Awarded to Westat in September of 2011.
Principal Investigators and Scientific Partners

- Project Director: David Maklan, Westat
- Principal Investigator: Andrew Hyland, Roswell Park Cancer Institute

- Westat
- Roswell Park Cancer Institute
- Geisel School of Medicine at Dartmouth
- Legacy
- Medical University of South Carolina
- Pinney Associates
- University of California San Diego
- University of Waterloo
Specific Aims of the PATH Study

- Identify trends in tobacco use patterns, including use of new products, dual use, poly use and switching;
- Characterize tobacco use initiation, dependence, cessation, and relapse patterns;
- Monitor change in risk perceptions and other attitudes such as product preferences;
Specific Aims of the PATH Study

- Compare intermediate endpoints and ultimately, short- and long-term incidence/prevalence of health outcomes and cause-specific mortality among users of different types of products;

- Assess differences between and within critical subgroups including youth, young adults, daily users, racial/ethnic minority groups, and users of new tobacco products; and

- Collect biospecimens to analyze biomarkers of interest.
Office of Management and Budget (OMB) Materials

- Main study design documents, including questionnaires, are available online through OMB until OMB completes its review
  
Selected PATH Design Features

- National representative in-person address-based longitudinal sample of persons 12+ years of age (N~59,600)
- Questionnaires from all; blood, urine, and buccal cell samples from adults
- English and Spanish versions
- Oversample tobacco users, youth, and young adults
- Two-stage screening procedure
Sampling

• Area probability sample
• Address-based sampling
• 150 Primary Sampling Units
• Adult Phase 1 household screening seeks to identify potentially eligible participants through a household informant
• Adult Phase 2 screening seeks to confirm eligibility from the selected participant to launch into the main survey
Some Sample Info

• Youth, 12-17 years old: ~16,900
• Young adults, 18-24 years old: ~10,700
• Adult current tobacco users: ~24,100
• Adult menthol smokers: ~7,000
• Adult dual users of cigarettes and smokeless tobacco products: ~3,300
• Adult daily users: ~19,200
• Users of new tobacco products: TBD
We will be able to track changes in tobacco use every year among...

- Race/ethnicity groups
- Age groups
- SES groups
- Regions
- Lesbian, gay, bisexual, transgender
- Co-morbidities
Behavioral Health Outcomes

- Tobacco Use
- Health Outcomes: Short- and Long-term

- Evaluate all outcomes and changes in behavior for each participant from year-to-year
Tobacco Products Assessed

- Cigarette
- E-cigarette
- Cigar, cigarillo, little filtered cigar
- Pipe
- Hookah
- Smokeless, including snus, chewing tobacco, dip, moist snuff
- Dissolvable tobacco
- Bidis and Kreteks (youth)
Scope of Tobacco Product Information

- First time use
- Current use
- Amount used
- Quitting
- Use in past 12 months (recent quitters)
- Purchase behavior
Scope of Tobacco Product Information

• Brand and variety identification
• Reasons for use, for example...
  – ...costs less
  – ...can use in places where smoking isn’t allowed.
  – ...might be less harmful than cigarettes.
  – ...comes in appealing flavors.
  – ...helps people to quit smoking cigarettes.
Scope of Tobacco Product Information

• Poly-tobacco use
  – Use when couldn’t smoke or to cut down
  – Use as alternative to quitting tobacco altogether
  – Switching between different tobacco products and cigarettes
    • e.g. I have considered switching from smoking cigarettes to using snus.
    • e.g. I have considered switching from using snus to smoking cigarettes.
Regulatory Domains

- Health Education Campaigns
- New and Modified Risk Products
- Product Standards
- Health Warnings
- Product Marketing
Exposure to Tobacco Marketing

• Youth
  – Show specific tobacco product ads and ask about exposure
  – Show web sites for different cigarette brands to assess exposure
  – Receipt and use of coupons and other discounts, promotions/sweepstakes, samples
  – Internet exposure to tobacco messages, ads, videos
Exposure to Tobacco Marketing

• Adult
  – Show specific tobacco product ads and ask about exposure (18-24 year olds)
  – Receipt of e-mails with coupons and promotions
  – Awareness of ads and tobacco product displays in retail environment
Mediators / Moderators

- Demographics
- Knowledge, Attitudes, Beliefs, and Risk Perceptions
- Tobacco Addiction
- Peer, Environmental, Contextual influences
- Mental Health/Substance Abuse Co-morbidities
Timeline

Contract Award 2011
OMB Submission 2012
Field Test 2013
OMB Approval 2014

Wave 1 2015
Wave 2 2016
Wave 3

First Publicly Available Survey Data

Wave 1 Data Release – Restricted Use File
Why a Field Test?

- Goal is to identify improvements that can be implemented for the Baseline PATH Survey.
- The Field Test is one of MANY data sources to answer these questions
  - Are the questionnaires and other data collection instruments giving us the information we expect?
  - Is the biospecimen collection, shipping, processing, and analysis providing us with useable information
  - Are the sampling procedures yielding a sample with the expected characteristics
  - Can the data collection procedures be improved to increase the quality of the data and decrease respondent burden?
  - Are the computer systems for operations, sample management, specimen tracking, quality control, and data processing working seamlessly
  - Can we experiment to determine new ways of getting data more efficiently
More Information

- PATH Public Website: [PATHstudyinfo.nih.gov](http://PATHstudyinfo.nih.gov)
- Email: [PATHstudyteam@mail.nih.gov](mailto:PATHstudyteam@mail.nih.gov)