



PATH

Population Assessment of Tobacco and Health

A collaboration between the NIH and FDA

CY2021

The PATH Study is a nationally representative, longitudinal study of tobacco use, its determinants, and its impacts.

Funded by the Food and Drug Administration (FDA), Center for Tobacco Products (CTP)

Administered by the National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA)

Developed by NIH/NIDA and FDA/CTP with assistance from Westat and Westat Scientific Partners

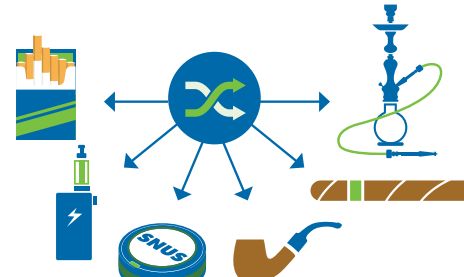
<https://www.drugabuse.gov/research/nida-research-programs-activities/population-assessment-tobacco-health-path-study>

<https://www.fda.gov/tobacco-products/research/fda-and-nih-study-population-assessment-tobacco-and-health>

<https://pathstudyinfo.nih.gov>

Designed to Assess

- Tobacco product use behaviors and associated factors
- Tobacco product addiction and dependence
- Exposures and potential harm from tobacco use and their related biomarkers
- Co-morbid conditions
- Poly-tobacco use and switching between tobacco products



Tobacco Use



Initiation



Dependence



Cessation



Relapse



Health Conditions

caused by or associated with tobacco use



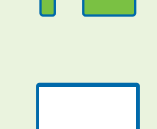
Changes

in awareness, knowledge, attitudes, and beliefs

Study Design Features



In-home data collection* annually or biennially



Questionnaires administered via Audio Computer-Assisted Self-Interviewing (ACASI)



Biospecimens collected—urine, blood

*2020 (telephone only) and 2021 (telephone option)

Can track changes between waves, including frequency of tobacco product use, among subgroups such as youth, young adults, people reporting daily and non-daily use, racial/ethnic minority groups, and people who use various types of tobacco products.

- Nationally representative sample of U.S. civilian, non-institutionalized individuals, age 12 years and older
- Four-stage, stratified probability sample design selected by primary sampling units (e.g., counties), segments (e.g., census tracts), residential addresses, and individuals
- Sample includes:
 - people reporting never, current, and former tobacco use
 - up to two adults aged 18+ per household (oversampled for people reporting tobacco use, African Americans, and young adults aged 18-24)
 - up to two youths aged 12-17 (at random) per household
- An additional "shadow sample" of youth ages 9-11 was selected at Wave 1 and Wave 4 to be interviewed at later waves.
- Wave 4 was a "replenishment" wave in which additional sample was recruited.
- In each wave, youth who turn age 18 and are eligible for the adult interview are considered aged-up adults.
- A subset of adult respondents who completed the interview and provided biospecimens at Wave 1 were sampled to form the Wave 1 Biomarker Core, and had their urine and blood analyzed for biomarkers of tobacco exposure and biomarkers of potential harm. Urine was collected from this core group and analyzed at each subsequent wave for biomarkers of exposure and biomarkers of potential harm. At Wave 4, all youth respondents were asked to provide urine specimens for the first time and a subset were sampled to form the Wave 4 Biomarker Core.
- Data were collected during the COVID-19 pandemic using telephone interviews (2020) and telephone or ACASI interviews (2021).

Data Collection

Interviews

Waves 1-5 interviews were conducted entirely in-person. Wave 4.5 (the first "special collection;" youths only) interviews were entirely in-person. In the second "special collection," Wave 5.5 (youth and young adults) and the Adult Telephone Survey (adults), interviews were conducted via telephone. Wave 6 interviews were conducted in-person and via telephone.

Adult 18 years or older **Youth** 12–17 years old (Wave 5.5 youth: 13–17 years old)

Wave 1

Sep. 2013–Dec. 2014

Adult: **32,320**

Youth: **13,651**

Wave 2

Oct. 2014–Oct. 2015

Adult: **28,362**

Youth: **12,172**

Wave 3

Oct. 2015–Oct. 2016

Adult: **28,148**

Youth: **11,814**

Wave 4

Dec. 2016–Jan. 2018

Adult: **33,822**

Youth: **14,798**

Wave 4.5 Special Collection: Youth Only

Dec. 2017–Nov. 2018

Youth: **13,131**

Wave 5

Dec. 2018–Nov. 2019

Adult: **34,309**

Youth: **12,098**

Wave 5.5 & ATS Special Collection: Adult & Youth

Wave 5.5: Jul.–Dec. 2020
ATS: Sep.–Dec. 2020

Youth (W5.5): **7,129**

Young Adults (W5.5): **3,628**

Adults (ATS): **8,874**

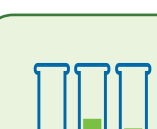
Wave 6

Mar.–Nov. 2021

Data not yet available

Adult: **xx,xxx**

Youth: **xx,xxx**



Biological Specimens

Total number of biological specimens collected*

Wave	Adult Urine	Youth Urine	Adult Blood
1	21,801	N/A	14,520
2	13,696	N/A	908
3	14,979	N/A	835
4	21,046	13,097	3,608
5	12,102	10,584	2,040

Biological Specimens

- Urine Waves 1–5 adults
- Urine Waves 4 and 5 youth
- Blood Wave 1 adults
- Blood Wave 4 replenishment adults
- Blood Waves 2–5 aged up adults

*A subset of samples were analyzed for inclusion in the Wave 1 and Wave 4 biomarker cores.

Access to PATH Study Data



Questionnaire Public-Use Files (PUF), Questionnaire Restricted-Use Files (RUF), and Biomarker Restricted-Use Files (BRUF) are available to researchers. Access to the RUF and BRUF is restricted and requires application and approval. Access to the PUF is available for download with an account.

Data, instruments, and codebooks are maintained by the Inter-University Consortium for Political and Social Research (ICPSR), National Addiction and HIV Data Archive Program (NAHDAP).

Available online at: <https://doi.org/10.3886/Series606>

Other available data include **State Identifier Restricted-Use File (SIRUF)**, **Special Collection Restricted-Use Files (SCRUF)** and **Tobacco Universal Product Code Restricted-Use Files (TUPCRUF)**. These require applications and approvals.

Biospecimen Access Program

The PATH Study Biospecimen Access Program provides the research community with access to urine, serum, plasma and genomic DNA (gDNA) collected from PATH Study participants in Wave 1 through Wave 5. Investigators proposing meritorious and feasible studies consistent with PATH Study objectives and/or research priorities for tobacco regulatory science will be given highest priority for access to these biospecimens.

Policies and procedures to access biospecimens are available online at: <https://doi.org/10.3886/Series606>

Researchers' Use of Data



PUF downloads as of 12/31/21:

4,903

Number of RUF documentation downloads*:

5,669

Number of BRUF documentation downloads*:

878

*RUF and BRUF data downloads are not captured as these datasets are accessed on a secure server.

Data available to researchers:

- Waves 1–5 Questionnaire Public-Use Files (PUF)
- Waves 1–5 Questionnaire Restricted-Use Files (RUF)
- Waves 1–5 Biomarker Restricted-Use Files (BRUF)*
- Waves 1–5 State Identifier Restricted-Use Files (SIRUF)
- Waves 1–5 Tobacco Universal Product Code Restricted-Use Files (TUPCRUF)
- Wave 4.5 Special Collection Restricted-Use Files (SCRUF)*
- Wave 4.5 Special Collection Public-Use Files (SCPUF)*

*BRUF are initially released when some panels are available and updated as more panels become available.

*W5.5/ATS data will be available in Spring 2022.

Selected Changes to PATH Study Questionnaire

Wave 5.5 (2020) questions added on:

- awareness and ever use of IQOS
- perceived proportion of peers that use ENDS and smoke cigarettes and whether respondent has seen anyone using ENDS or smoking cigarettes in or around their school
- impact of COVID-19 including social distancing practices, impacts on tobacco use, perceptions of COVID-19 severity for people who smoke cigarettes or use ENDS, impacts on stress, receiving a COVID-19 diagnosis, and experiencing COVID-19 related symptoms

ATS (2020) was a new special collection survey with a subset of questions included from the full questionnaire. Questions selected for inclusion on:

- tobacco use prevalence
- purchasing behaviors
- use of flavors and brand information
- nicotine dependence and cessation for cigarettes and ENDS
- diagnosis of health conditions related to respiratory, cardiovascular, and other health outcomes
- use of alcohol and other drugs
- Questions were added on the impact of COVID-19 including employment; testing; receiving a positive test; the severity of COVID-19.

Wave 6 (2021) questions added on:

- IQOS including current use, use of menthol HeatSticks, purchasing location, exposure to marketing, perceived harm, and susceptibility for use
- disposal locations for cigarette butts, cigarette packaging, and ENDS devices, including product components, and e-liquids
- use of ENDS as a cessation tool; use of mint and menthol flavors captured separately
- time spent on social media and exposure to tobacco-related content on social media
- whether respondent has ever been evaluated or treated for a respiratory condition related to use of nicotine and marijuana in ENDS
- perceived stress and social support
- impact of COVID-19 including employment; testing; receiving a positive test; the severity of COVID-19

Wave 7 (2022) questions added on:

- awareness, use, and brands used for nicotine pouches and other types of oral nicotine products.
- IQOS including use (lifetime, regular, every day), age of initiation, purchasing, dependence, disposal, reasons for use and discontinued use, flavored use, dual use, HeatSticks use, exposure to health warnings and advertisements, perceptions of harm, and rules for using IQOS in the home
- secondhand exposure to ENDS and/or tobacco products in a vehicle, indoor public place, and outdoor public place
- exposure to ENDS and tobacco-related content on social media
- COVID-19 vaccination status including receipt of booster

Publications



Number of PATH Study-Related Publications

440+*

*Includes papers published using PATH Study data or methods

Examples of PATH Study papers are available at: <https://www.icpsr.umich.edu/web/ICPSR/search/publications?q=PATH+Study>. Note: this list does not include all publications using PATH Study data.

Highlighted Methods Papers

[Longitudinal Uses of the Population Assessment of Tobacco and Health Study. Tobacco Regulatory Science, 7\(1\), Jan. 2021.](#)

Prior work described the methods of the first wave of the PATH Study. In this paper, the authors describe the methods of the subsequent 2 waves and provide recommendations for how to conduct longitudinal analyses of PATH Study data.

[Design and methods of the Population Assessment of Tobacco and Health \(PATH\) Study Tobacco Control, 26\(4\), Jan. 2017.](#)

This paper describes the methods and pathways of the PATH Study Wave 1 data collection. The paper concludes that cumulative, population-based data, generated over time by the PATH Study, will contribute to the evidence base to inform FDA's regulatory mission under the Family Smoking Prevention and Tobacco Control Act and efforts to reduce the Nation's burden of tobacco-related death and disease.