



PATH

Population Assessment
of Tobacco and Health

A collaboration between the NIH and FDA

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

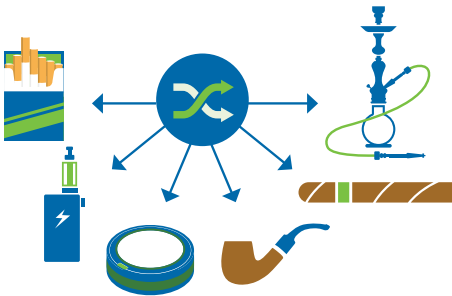
<https://www.drugabuse.gov/research/nida-research-programs-activities/population-assessment-tobacco-health-path-study>

<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 use and addiction
- 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)



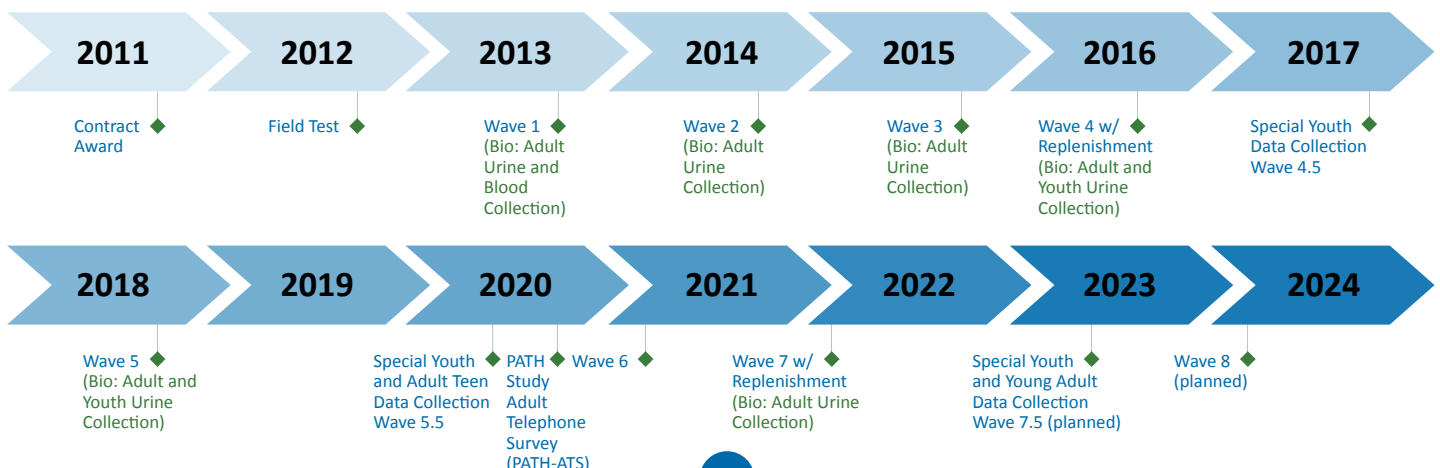
Biospecimens collected—urine, blood

*2020 (telephone only) and 2021-2023 (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 and 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, Wave 4 and Wave 7 to be interviewed at later waves.
- Waves 4 and 7 were “replenishment” waves in which additional samples were recruited.
- 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. Urine was collected from this core group and analyzed at each primary wave for biomarkers of exposure and a biomarker of potential harm.
- A subset of adult respondents who completed the Wave 7 interview were asked to provide urine specimens. These respondents and some of the adult respondents in the existing Wave 1 and Wave 4 Biomarkers Cores were sampled to form the Wave 7 Biomarker Core. Their urine was analyzed for biomarkers of exposure and a biomarker of potential harm.
- Data were collected during the COVID-19 pandemic using telephone interviews (2020; Wave 5.5 and the Adult Telephone Survey [PATH-ATS]) and telephone or ACASI interviews (2021; Wave 6).
- Wave 7 data (2022-2023) are also being collected using telephone or ACASI interviews.

PATH Study Timeline: The Start of Each Data Collection Wave



Data Collection

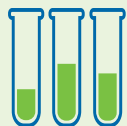
Interviews

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 PATH-ATS (adults), interviews were conducted via telephone due to the COVID-19 pandemic. Wave 6 and Wave 7 interviews were conducted in-person and via telephone due to the COVID-19 pandemic.

Adult 18 years or older (Wave 5.5 young adults: 18–19 years old; PATH-ATS adults: 20 years or older)

Youth 12–17 years old (Wave 5.5 youth: 13–17 years old; Wave 6 youth: 14–17 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 & PATH-ATS Special Collection: Adult & Youth Wave 5.5: Jul. Dec. 2020 PATH-ATS: Sep. Dec. 2020 Adult (PATH-ATS): 8,874 Young Adult (W5.5): 3,628 Youth (W5.5): 7,129		Wave 6 Mar. Nov. 2021 Adult: 30,516 Youth: 5,652	Wave 7 Jan. 2022 – Apr. 2023 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
7	xx,xxx	N/A	N/A

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

Biological Specimens

- Adult urine collected in Waves 1–5 and 7
- Youth urine collected in Wave 4 and 5
- Adult blood collected in Wave 1
- Replenishment adult blood collected in Wave 4
- Aged-up adult blood collected in Waves 2–5

Note: No biological specimens were collected in Wave 6 due to the COVID-19 pandemic.

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 & 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 waves where biospecimens were collected. 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: <http://bit.ly/2wBF0tc>

Researchers' Use of Data



PUF downloads as of 12/31/22:

5,592

Number of RUF documentation downloads:*

15,057

Number of BRUF documentation downloads:*

3,503

*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)
- Waves 4.5, 5.5 and PATH-ATS Special Collection Restricted-Use Files (SCRUF)
- Waves 4.5, 5.5 and PATH-ATS Special Collection Public-Use Files (SCPUF)
- Waves 1-5 Online Data Tables: <https://www.icpsr.umich.edu/web/pages/NAHDAP/path-study-tables-home.html>

[†] Wave 6 RUF data available Spring 2023. Wave 6 PUF data available Fall 2023.

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

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

PATH-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; and 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

600+*

*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 conceptual framework for the PATH Study's 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.



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