

PATH Study: A survey of Ecig use in the US

A US FDA and NIH program, PATH, is studying tobacco use and health in the United States by means of a longitudinal population survey. The first wave of data (2013) have been shown during a scientific meeting in Chicago. A tobacco expert gives her opinion in the light of the results.

By **Jérôme Harlay** - April 6, 2016

The US Food and Drug Administration (FDA) and National Institute of Health's Population Assessment of Tobacco and Health (PATH) Study is a large, national, representative longitudinal cohort study of tobacco use and health in the United States which measures tobacco use behaviors and related health effects. The PATH Study will provide an evidence base for informing **FDA's current and future regulatory actions** in meeting its mandate under the Family Smoking Prevention and Tobacco Control Act (FSPTCA).

The cohort has been followed annually for three data collection waves. PATH researchers announced last week that the study will be extended four years and will now include **7 waves**, with the final wave set to be completed in 2022. The baseline data collection, 59,600 individuals, started in Fall 2013 with a cohort of never, current, and former users of tobacco products ages 12 years and older.

The Society for Research on Nicotine and Tobacco Conference was held in Chicago, last month, and hosted numerous talks among which those dedicated to the analysis of the first wave of data obtained through the PATH Study. Ms Vivien Azer, managing director and senior research analyst for the tobacco sector for the Cowen group, wrote a research note on the first wave (2013). She reports:

- Regular use of electronic cigarettes is low (5.5% of adults, 3.1% of 12- to 17-year-olds having used e-cigs in the past month,
- 8.5% of daily e-cigarette users had not previously used tobacco,
- 63% of the 25-year-olds and above reported using flavors and 85% of users aged 12 to 17,
- 15.9% of adult current e-cigarette users were “nicotine naive”.

The research note points out that **daily users constitute a**

“In fact, among current adult e-cig users, more than 40% had only used an e-cig less than three times in the past 30 days,” -V. Azer.

tobacco categories, not only e-cigarettes.

very small percentage of these 30-day users and its author believes that it indicates the products had not been embraced by consumers at the time of the survey (2013). Ms Azer also notices the **gateway effect to other tobacco products is not supported by the data since the majority of users were already consumers of other tobacco products**. Finally, the expert also notices that the youngest exhibited a strong flavor preference across all

The term “nicotine naive” used by the expert strongly suggests that more effort should be made to inform users on the composition of the products, especially with regard to the active substance, nicotine. This also calls for standardized and more visible labels on nicotine products.

“Are e-cigarettes a step toward a cigarette smoker getting off of cigarettes? Or are e-cigarettes a crutch so they can get nicotine in places and times when they wouldn’t normally be allowed to smoke cigarettes?” -Dr A.Hyland

PATH is a landmark collaboration between the National Institute on Drug Abuse (NIDA)/National Institutes of Health (NIH) and the Center for Tobacco Products (CTP)/ Food and Drug Administration (FDA). **Roswell Park Cancer Institute** is the scientific lead for the Westat team, the prime contractor for the study.

The primary investigator for the government study of trends in smoking and tobacco use, Dr Andrew Hyland, explained that his program is expected to provide a wealth of data about smoking behavior that **could shape regulations ranging**

from warning labels and advertising restrictions to new-product approvals.

Wave 1 database is still confidential, but the full dataset will be available by the end of 2016. The second wave of data is under review, and Wave 3 is 40% complete.

Some **experts are afraid the PATH study may not be able to capture crucial details** about the use of electronic cigarettes, vapor tanks and other devices as tastes and technology are evolving so rapidly. They can be reassured, an expert view already noticed from the earliest results, without going into the details of the whole dataset, that **the published studies assimilating a 30-day use as a regular use of e-cigarette are misleading.**

The extension of the program over 4 additional waves of data collection up to 2022 will increase the chances of capturing interesting details. An expert view on these datasets will hopefully help refining existing literature to discard misleading studies to re-focus the debate on the most important aspects of Public Health and Smoking reduction.



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