PATH
Population Assessment of Tobacco and Health

A collaboration between the NIH and FDA

NIH National Institute on Drug Abuse

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NIDA Council, May 2016
Bethesda, Maryland

Overview of the Population Assessment of Tobacco and Health (PATH) Study and Highlighted Findings From Wave 1

Presented by Kevin Conway on behalf of the PATH Study Team

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National Institute on Drug Abuse

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Objectives

- Overview of the PATH Study design
- Highlight select findings from Wave 1
  - Flavored tobacco product use among youth (*JAMA*, 2015)
  - Prevalence estimates by tobacco product in youth and adults *(Society for Research on Nicotine and Tobacco: Presidential Plenary, 2016*)
  - Associations among tobacco use, substance use, and mental health problems in youth and adults (*in progress*)
- Describe how to access Wave 1 data
- Discussion, questions, and answers

Population Assessment of Tobacco and Health (PATH) Study

PATH Study Overview

- A nationally representative longitudinal study of tobacco use, its determinants, and its impacts
- Funded by the FDA Center for Tobacco Products
- Administered by the NIH National Institute on Drug Abuse
- Developed by FDA and NIH with assistance from:

Westat and the Westat Scientific Partners

Project Director **David Maklan, Westat**

Principal Investigator **Andrew Hyland, Roswell Park Cancer Institute**

Roswell Park Cancer Institute
Medical University of South Carolina
University of California San Diego
Rutgers University
Geisel School of Medicine at Dartmouth
Truth Initiative
University of Waterloo
University of Minnesota

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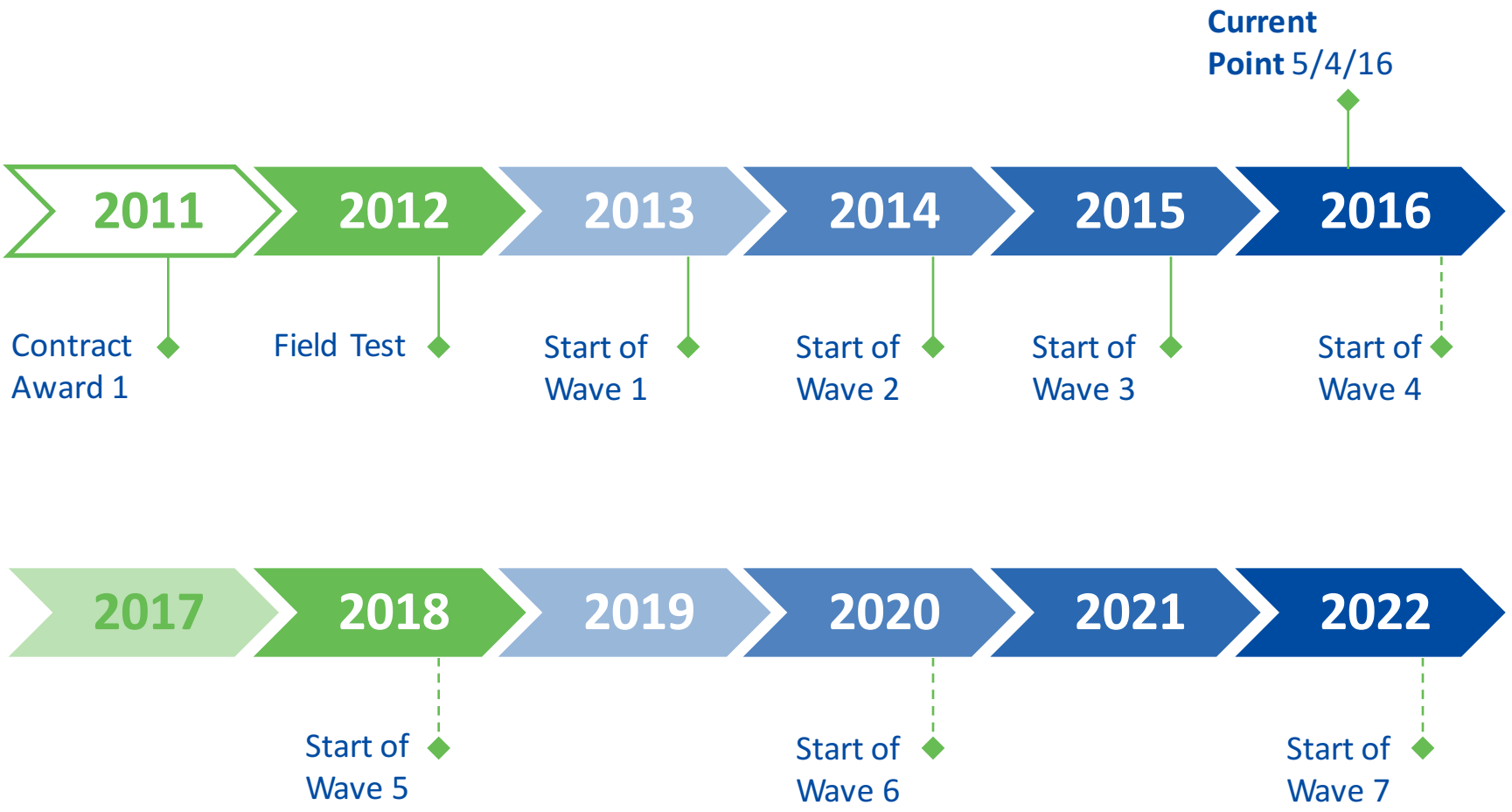
PATH Study Timeline



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Wave 1 Design Features

Longitudinal cohort design

Nationally representative sample of U.S. civilian, non-institutionalized population ages 12 years and older

Sample size: N=45,971 (N=32,320 adults 18+ years; N=13,651 youth 12-17 years)

Baseline data collection: September 2013 – December 2014

Sample includes **never, current, and former tobacco users**

Four-stage, stratified probability sample design

Up to two adults (oversampled for tobacco users, African Americans, and young adults ages 18-24) and **up to two youths** (at random) per household

The weighted response rate for the Household Screener was **54.0%**.

Among screened households, the overall weighted response rate was 74.0% for the Adult Interview and 78.4% for the Youth Interview.

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Tobacco Products Assessed in Wave 1

Cigarette

E-cigarette

Traditional cigar, cigarillo, little filtered cigar

Pipe

Hookah

Dissolvable tobacco

Smokeless (snus pouches, chewing tobacco, dip, moist snuff)

Bidis and kreteks (youth)

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Wave 1 Questionnaire and Biospecimen Collection

Instruments

- Household Screener
- Adult Extended Interview
- Youth Extended Interview
- Parent Interview

Instrument Methodology

- Audio Computer-Assisted Self-Interviewing (ACASI) for adults and youth
- Computer-Assisted Personal Interviewing (CAPI) for Household Screener, Parent Interview, ancillary

Biospecimens (urine, blood, buccal cells) from adults

- CDC is performing some of the biospecimen lab work

Participants Eligible to Provide Biospecimens

	Participant	Wave 1	Wave 2	Wave 3	Wave 4[a]	Wave 5	Wave 6[a]	Wave 7
		Completed		**Ongoing**	**Planned**			
Urine	Adult	All	Core [b] 18 yr olds	Core [b] 18 yr olds	Core [b] 18 yr olds New [a]	Core [b] 18-19 yr olds	Core [b] 18-19 yr olds New [a]	Core [b] 18-19 yr olds
	Youth	--	--	--	All	Core [b] 12-13 yr olds	Core [b] 12-13 yr olds	Core [b] 12-13 yr olds
Blood	Adult	All	18 yr olds	18 yr olds	18 yr olds New [a]	18-19 yr olds Gave blood at W1	18-19 yr olds New [a]	18-19 yr olds
Buccal	Adult	All [c]	--	--	--	--	--	--

[a] Includes replenishment sample to approximate Wave 1 final sample size; [b] Core (Adult): comprised of adult tobacco-user groups of high interest including cigarette users, non-cigarette product users, former users, and never users; Core (Youth): comprised of 50 percent of continuing youth who gave a sample in previous wave; [c] Discontinued midway through wave; __ Indicates a longitudinal subsample

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Planned Biospecimen Analyses of "Core Adults"

Analyte	Matrix	Indication
Nicotine and nicotine metabolites: cotinine, trans-3'-hydroxycotinine, cotinine N-oxide, norcotinine, nicotine N-oxide, nornicotine, anatabine, anabasine	Serum Urine	Exposure
Tobacco specific nitrosamines (TSNAs): NNAL, NNN, NAT, NAB	Urine	Exposure
Polycyclic aromatic hydrocarbon (PAH) metabolites: 1-naphthol, 2-naphthol, 2-hydroxyfluorene, 3-hydroxyfluorene, 1-hydroxyphenanthrene, 3-hydroxyphenanthrene, 1-hydroxypyrene, naphthalene, phenanthrene, fluorene	Urine	Exposure
Metals: cadmium, cobalt, uranium, lead, strontium, beryllium, manganese, thallium	Urine	Exposure
Speciated arsenic: arsenous acid, arsenic acid, dimethylarsinic acid (DMA), monomethylarsonic acid (MMA)	Urine	Exposure
Volatile organic compounds (VOC) metabolites: 22 total	Urine	Exposure
Creatinine	Urine	Validation
F2-isoprostane / 8-epi-prostaglandin F2a*	Urine	Harm (oxidative stress)
High sensitivity C-reactive protein (hsCRP)	Serum	Harm (inflammation, cardiovascular disease)
Interleukin 6 (IL-6)	Serum	Harm (inflammation)
Soluble intercellular adhesion molecule (sICAM)	Serum	Harm (cardiovascular disease)
Fibrinogen	Plasma	Harm (cardiovascular disease)

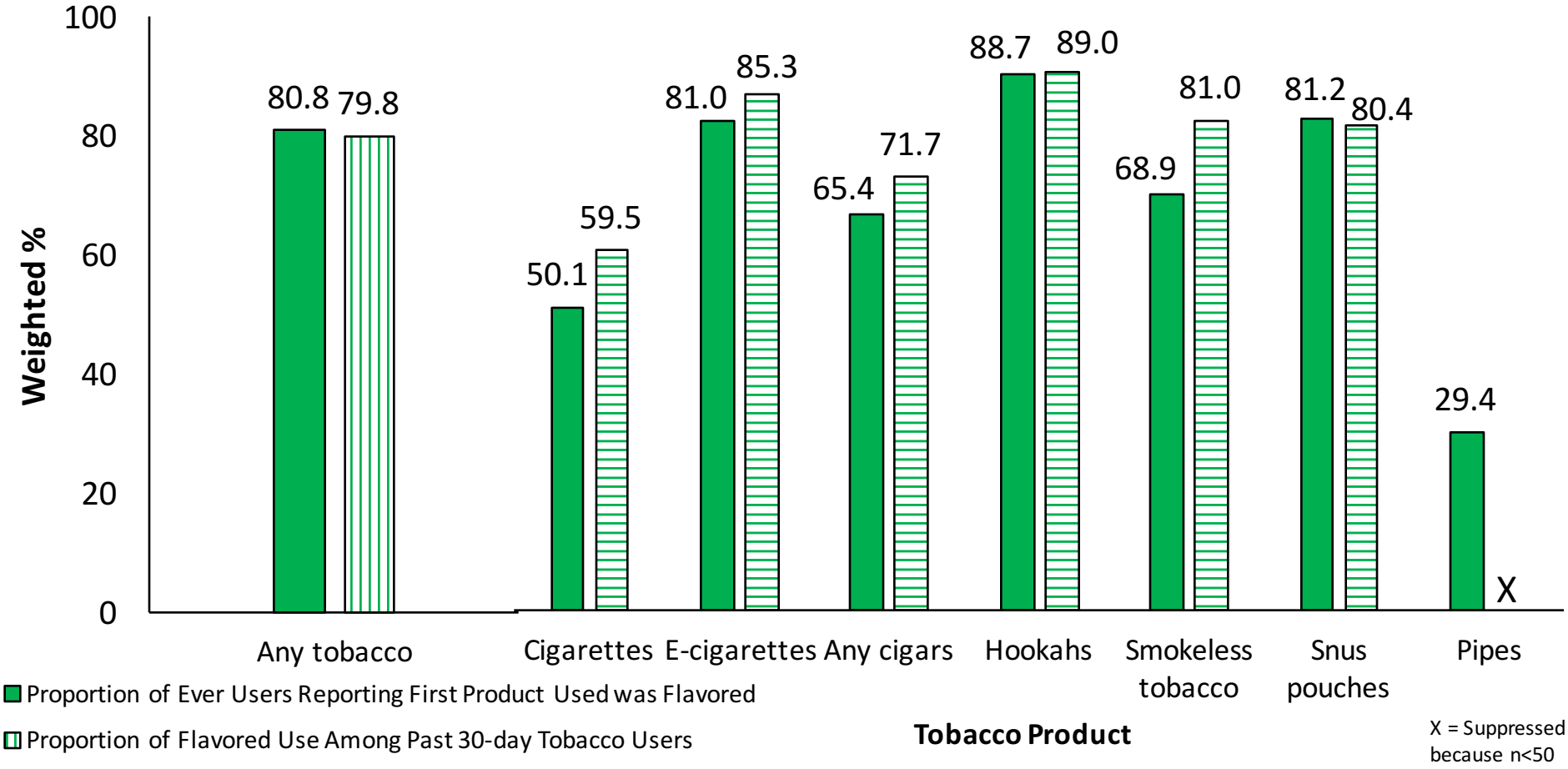
Wave 1 PATH Study Data

Flavored Tobacco Use Among Youth (Ambrose et al., JAMA, 2015)

From: **Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014**

JAMA. Published online October 26, 2015.1-3 doi:10.1001/jama.2015.13802

Prevalence of Ever and Past 30-Day Use of Tobacco Products, Proportion of Ever Users Reporting That the First Product Used Was Flavored, and Proportion of Past 30-Day Users Reporting Use of a Flavored Product, by Product—Population Assessment of Tobacco and Health Study Youth Respondents Aged 12-17 Years, 2013-2014



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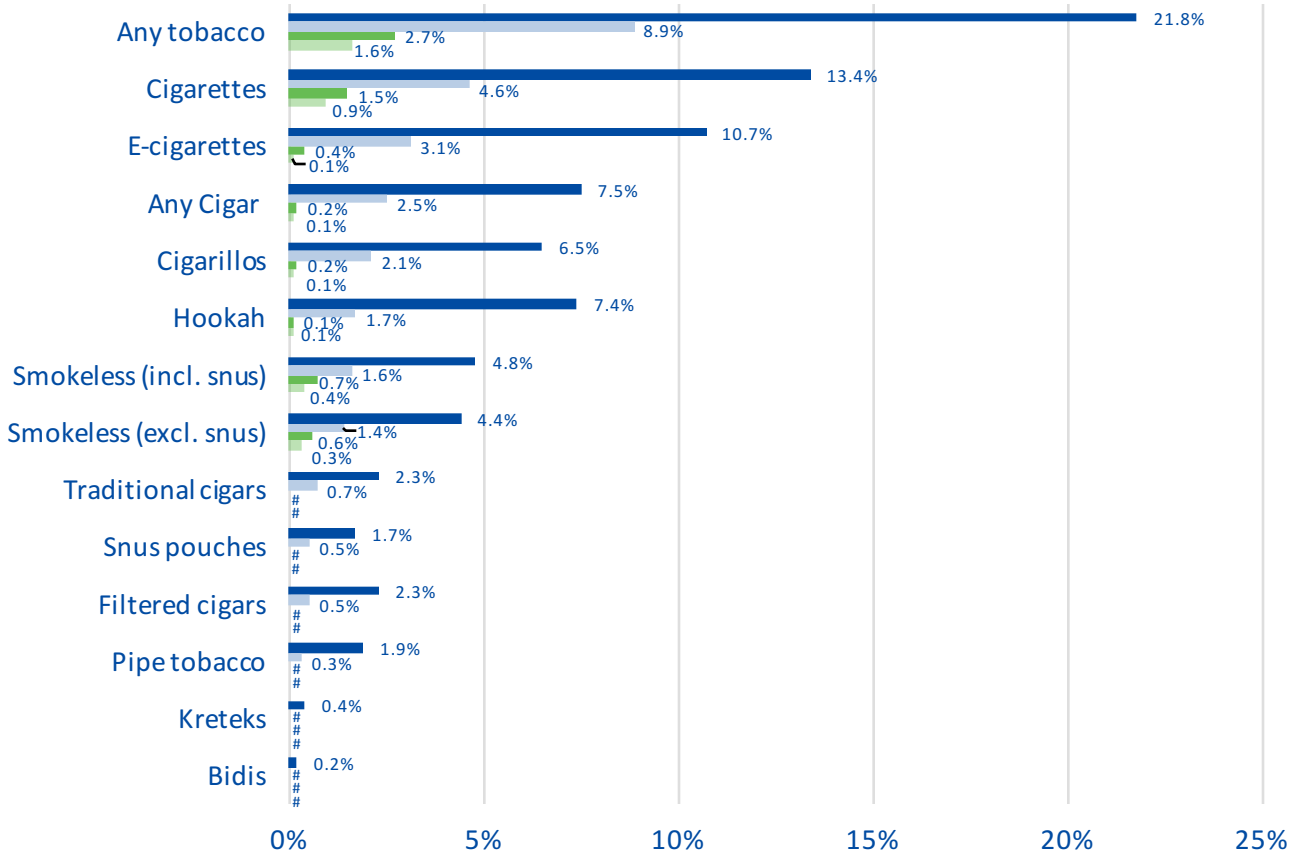
Wave 1 PATH Study Data

Society for Research on Nicotine and Dependence (Chicago, 2016)
Presidential Plenary

The PATH Study Wave 1 – Youth Reporting

Percent of Youth Reporting Ever, Past 30-Day, Frequent,* and Daily Use, by Product



* Frequent use is defined as: use of a product on 20 or more of the past 30 days; for hookah, frequent use is defined as: use at least 20 times per month on average; frequent use of "any tobacco" product reflects only those who used a particular product on 20 or more of the past 30 days; daily use of "any tobacco" product reflects only those who used a particular product daily.

\# Estimate suppressed because it is statistically unreliable; it is based on a sample size of less than 50, or the coefficient of variation of the estimate is larger than 30 percent.

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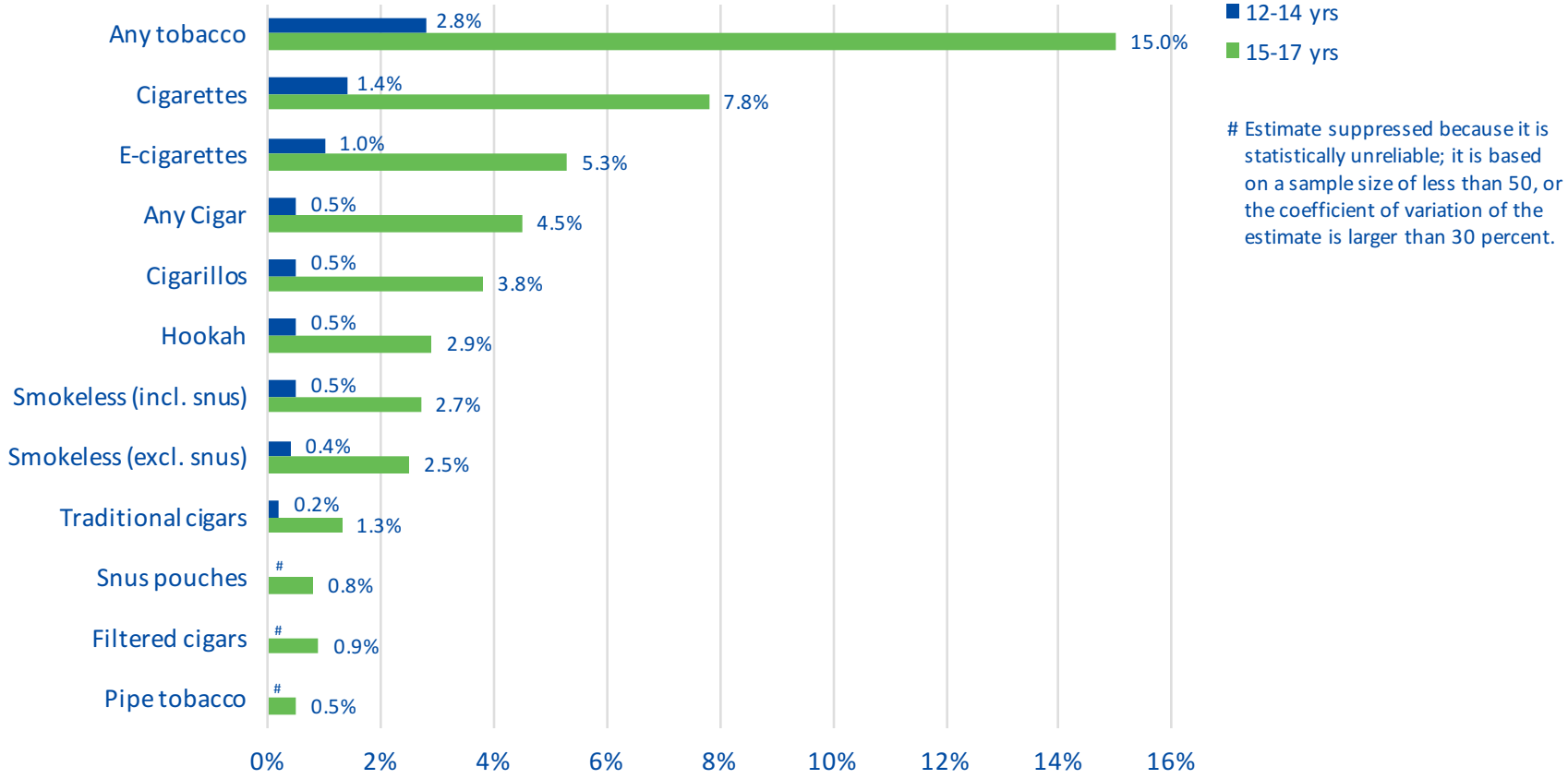
The PATH Study Wave 1 – Youth Reporting

Percent of Youth Reporting Past 30-Day Use, by Age



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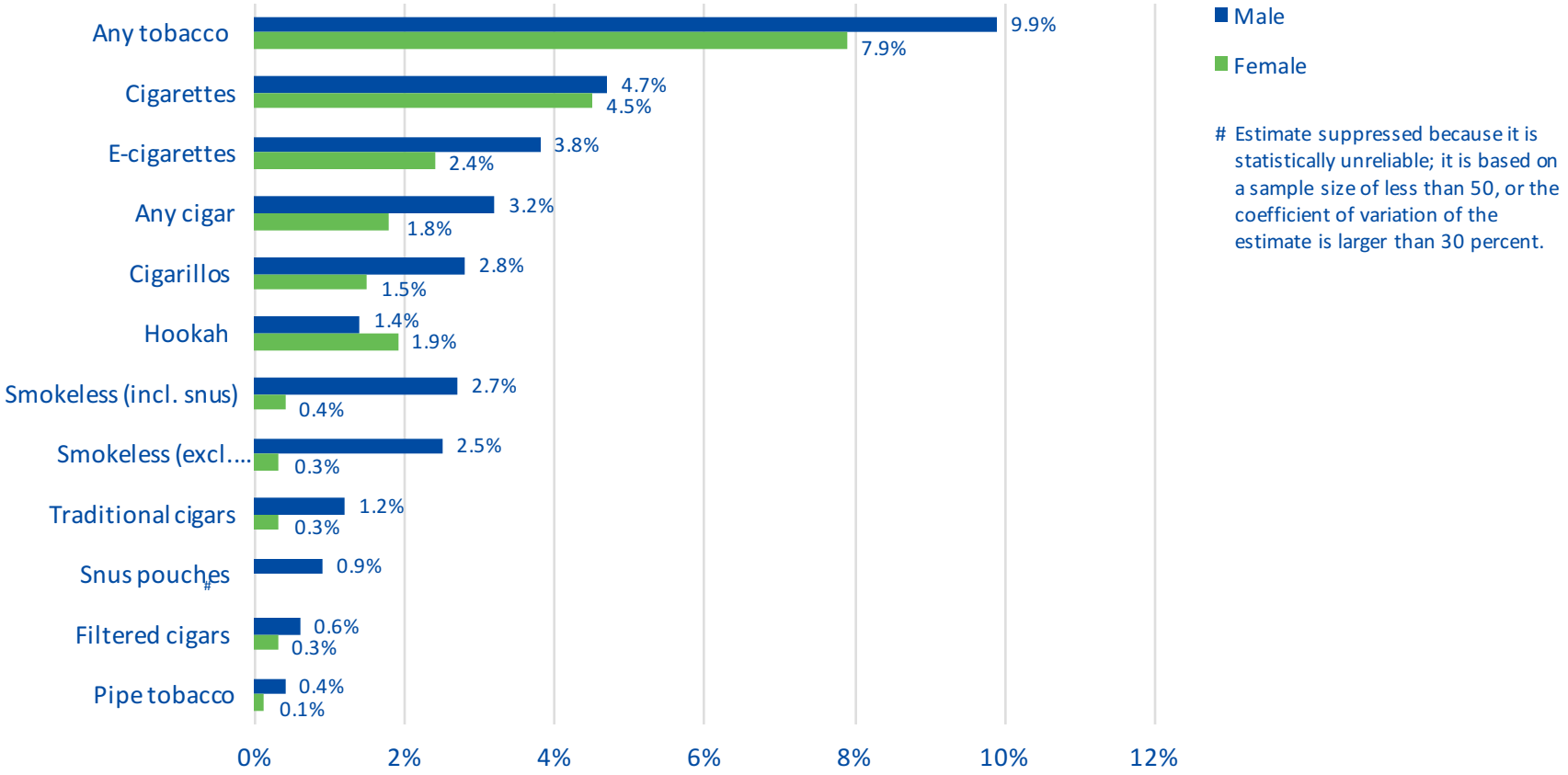
The PATH Study Wave 1 – Youth Reporting

Percent of Youth Reporting Past 30-Day Use, by Sex



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2013–2014 PATH Study Youth

Percent of Youth Reporting Past 30-Day Use: Comparisons with 2014 National Survey on Drug Use and Health (NSDUH),* by Age

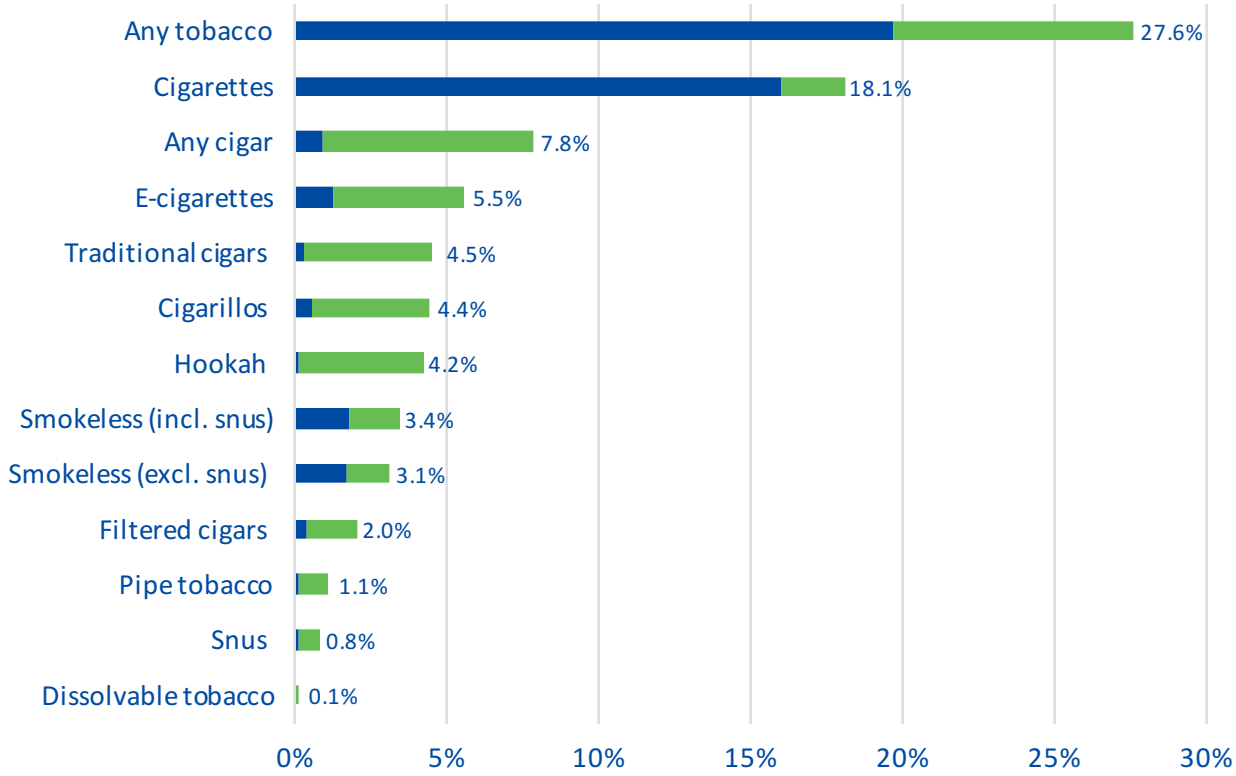
Tobacco Product	Data Source	12- to 13-Year-Olds	14- to 15-Year-Olds	16- to 17-Year-Olds
Cigarettes	**2013–14 PATH Study**	**1.0 (0.7, 1.4)**	**3.3 (2.9, 3.9)**	**9.5 (8.6, 10.5)**
	2014 NSDUH	0.7 (0.4, 1.0)	3.4 (2.8, 4.0)	10.2 (9.3, 11.1)
Any cigar	**2013–14 PATH Study**	**0.3 (0.1, 0.4)**	**1.7 (1.4, 2.2)**	**5.6 (4.9, 6.4)**
	2014 NSDUH	0.3 (0.1, 0.5)	1.5 (1.1, 1.9)	4.4 (3.8, 5.0)
Smokeless tobacco**	**2013–14 PATH Study**	**0.3 (0.2, 0.5)**	**1.2 (0.9, 1.7)**	**3.2 (2.7, 3.8)**
	2014 NSDUH	0.3 (0.1, 0.5)	1.6 (1.2, 2.0)	3.9 (3.3, 4.5)

* PATH Study and NSDUH are both conducted in households.

** PATH Study smokeless tobacco estimate includes snus for comparison to NSDUH

The PATH Study Wave 1 – Adult Reporting

Percent of Adults Reporting Current (Every Day and Some Day) Tobacco Product Use*, by Product



* Current use for cigarettes is defined as smoking at least 100 cigarettes in lifetime and currently smoking every day or some days.

Current use for other products is currently using every day or some days with no minimum threshold.

Distribution of everyday vs. someday use does not consider the 100 cigarette threshold.

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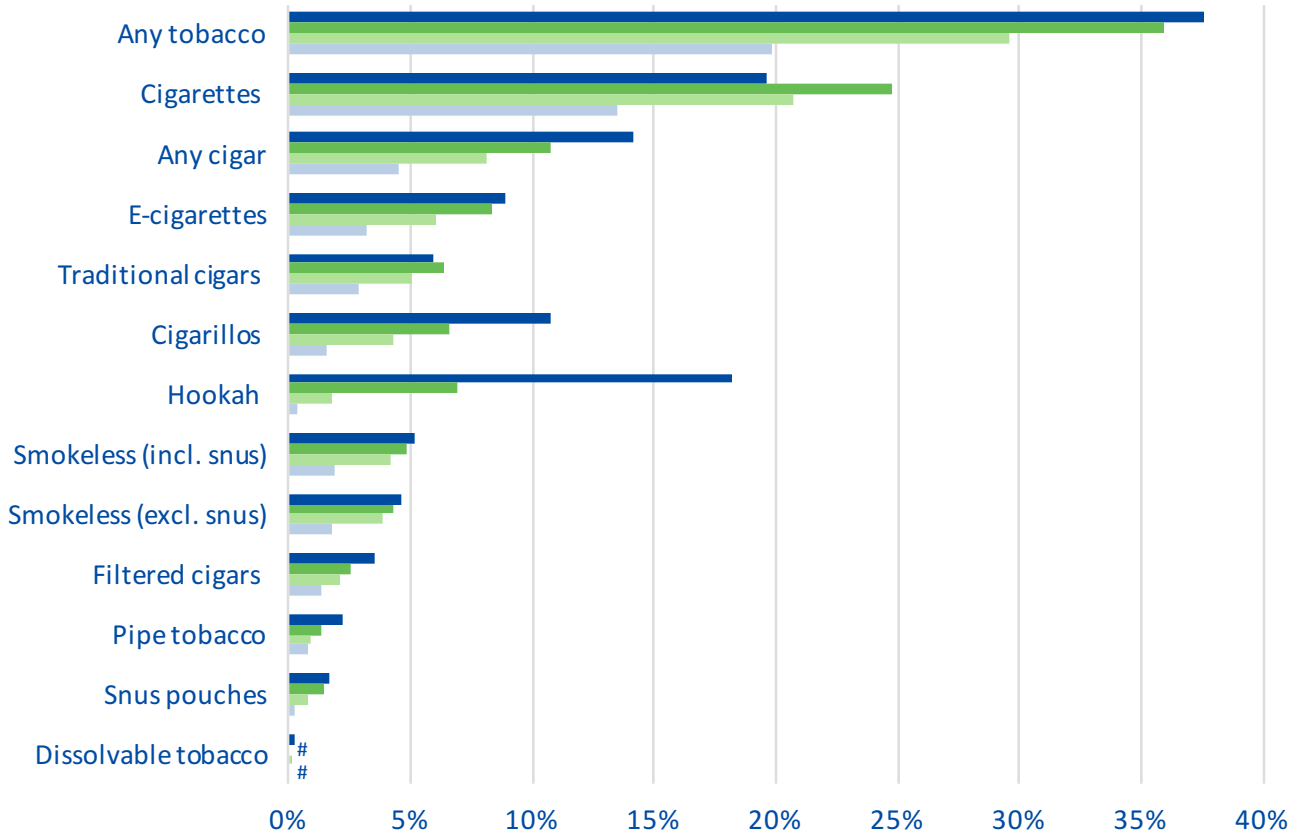
The PATH Study Wave 1 – Adult Reporting

Percent of Adults Reporting Current Tobacco Product Use,* by Age



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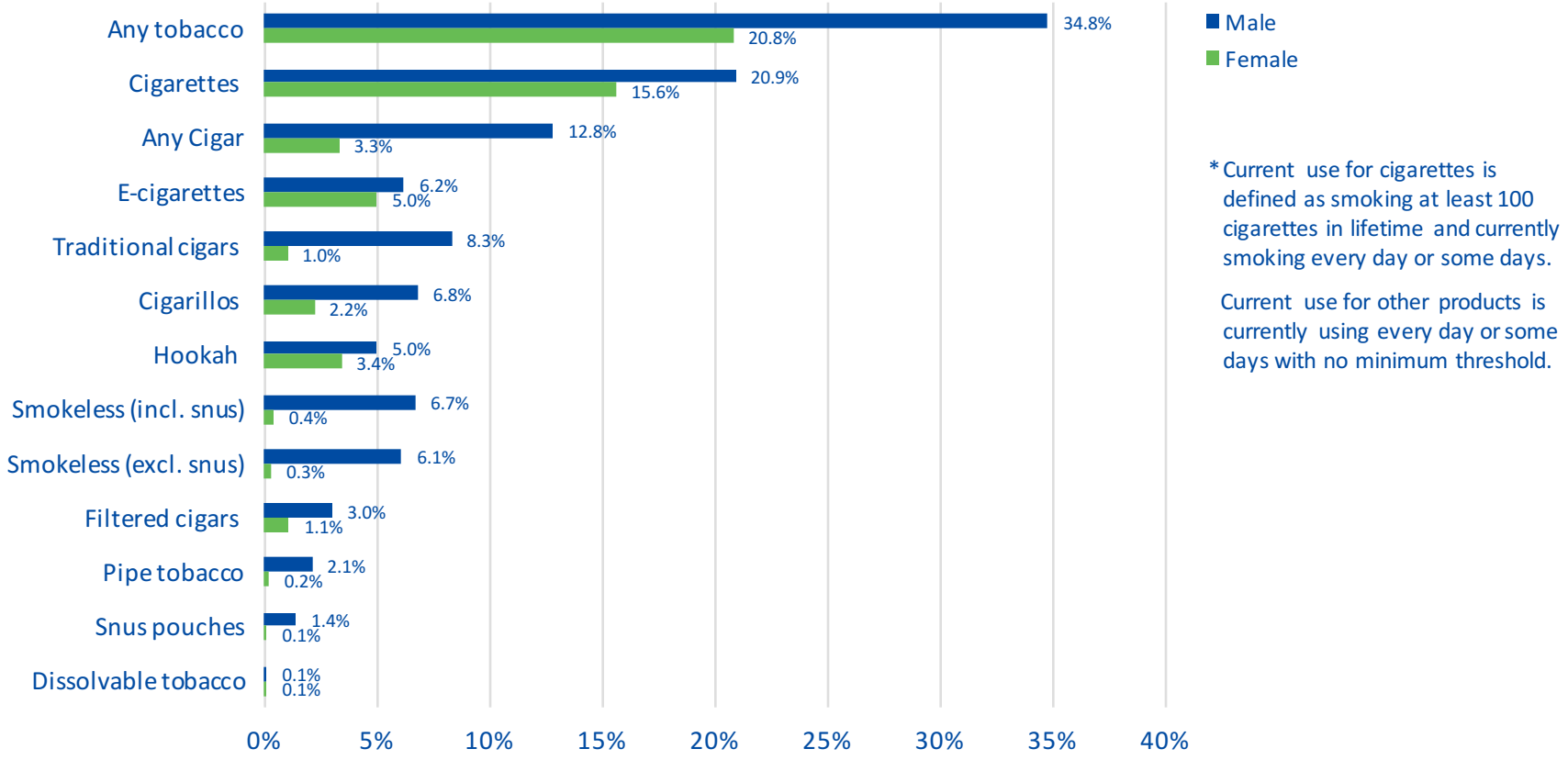
The PATH Study Wave 1 – Adult Reporting

Percent of Adults Reporting Current Tobacco Product Use,* by Sex



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Current use for other products is currently using every day or some days with no minimum threshold.

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2013–2014 PATH Study Adults

Percent of Adults Reporting Current Tobacco Use*: Comparisons With 2014 National Health Interview Survey (NHIS) and 2014 National Survey on Drug Use and Health (NSDUH)

Tobacco Product	Data Source	Past 30-Day Use
Cigarettes	**2013-2014 PATH Study**	**22.5 (21.9-23.2)**
	2014 NSDUH	22.5 (21.9-23.1)
Any cigar	**2013-2014 PATH Study**	**7.2 (6.9-7.5)**
	2014 NSDUH	4.8 (4.6-5.0)
Smokeless tobacco**	**2013-2014 PATH Study**	**3.3 (3.1-3.5)**
	2014 NSDUH	3.4 (3.2-3.6)

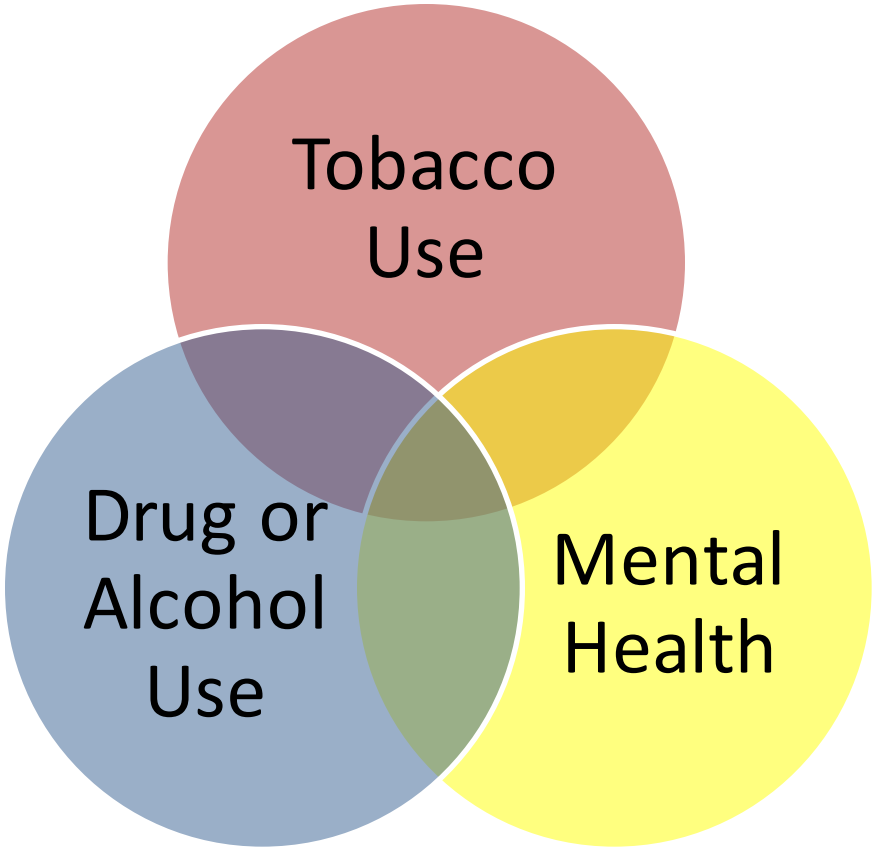
Tobacco Product	Data Source	Current Use
Cigarettes	**2013-2014 PATH Study**	**18.1 (17.6-18.7)**
	2014 NHIS	16.8 (16.1–17.4)
E-cigarettes	**2013-2014 PATH Study**	**5.5 (5.3-5.8)**
	2014 NHIS	3.7 (X)

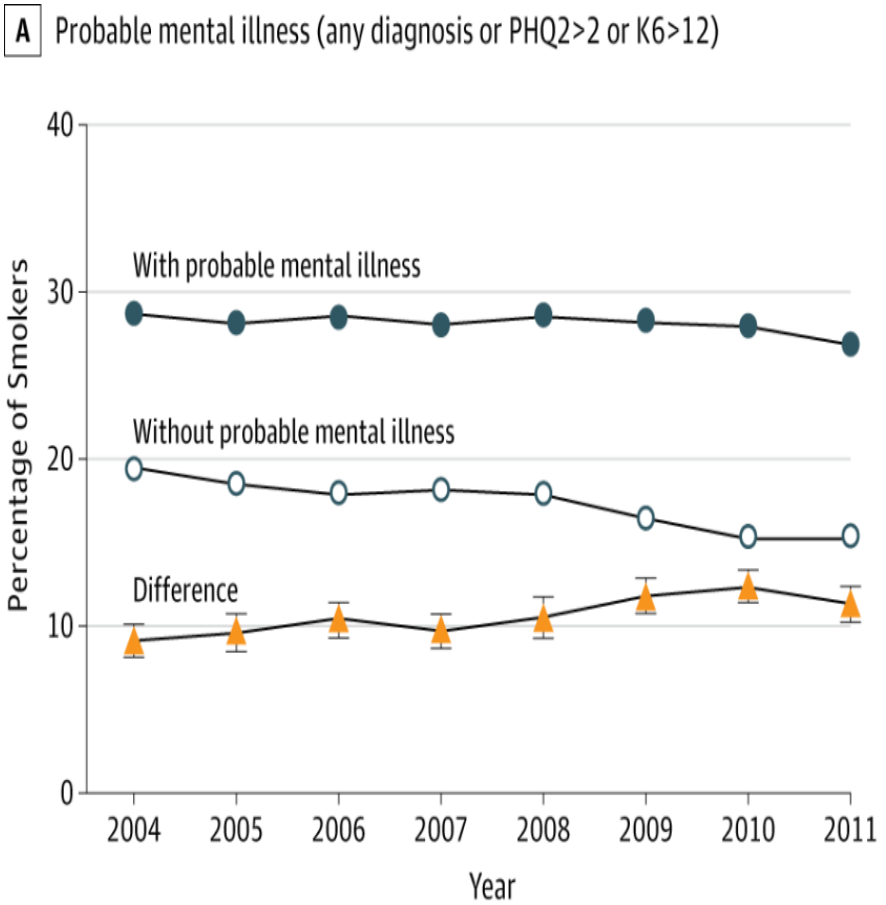
* NSDUH and PATH Study define current use for cigarettes, any cigar, and smokeless tobacco as use within the past 30 days. NHIS and PATH Study define current use for cigarettes as smoking at least 100 cigarettes in lifetime and currently smoking every day or some days; NHIS and PATH Study define current use for e-cigarettes as currently using every day or some days with no lifetime threshold

** PATH Study smokeless tobacco estimate includes snus for comparison to NSDUH

X = Confidence interval for estimate is unavailable

Areas of Particular Interest to NIDA





JAMA. 2014;311(2):172-182. doi:10.1001/jama.2013.284985

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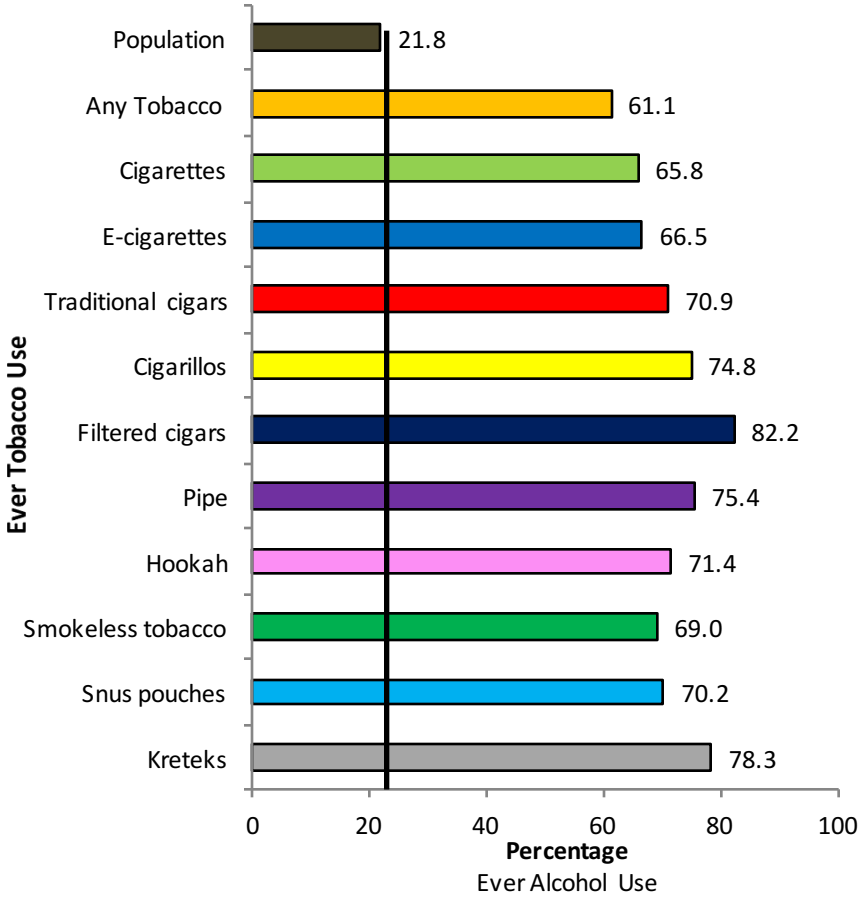
Wave 1 PATH Study Data (IN PROGRESS)

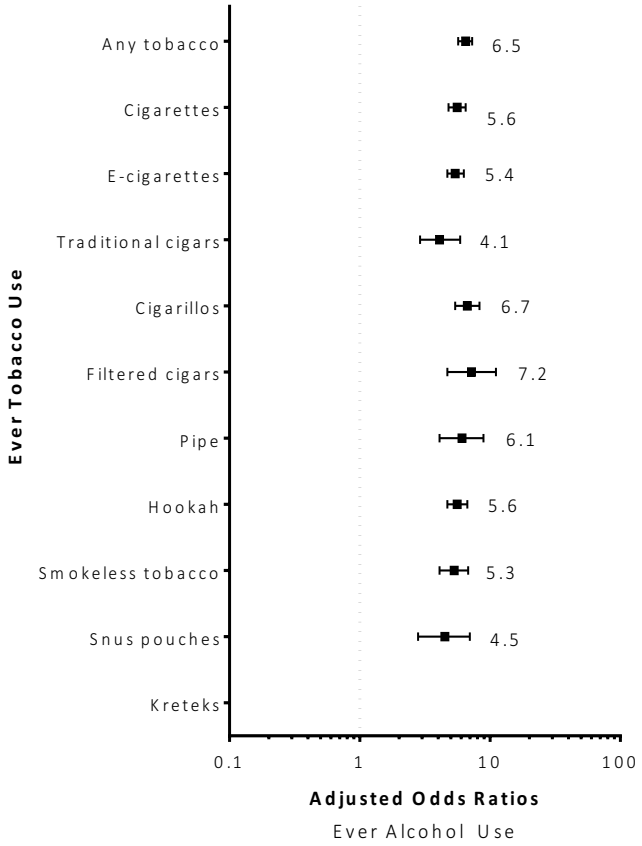
Co-occurrence of Tobacco, Substance, and Mental Health Problems -- YOUTH

Co-occurrence of Tobacco Product Use, Substance Use, and Symptoms of Mental Health Problems

- **Independent variables**
  - Self-reported ever and current use of tobacco products (cigarettes, e-cigarettes, traditional cigars, cigarillos, filtered cigars, pipe, hookah, snus pouches, other smokeless tobacco, dissolvable tobacco, and bidis and kreteks)
- **Dependent variables**
  - Ever and past-year use of alcohol, marijuana, other drugs
  - Ever and past-year internalizing, externalizing, and substance use problems

2013-2014 PATH Study Youth: Proportions and Odds of Ever Alcohol Use According to Ever Tobacco Use





Adjusted odds ratios (AOR)s and 95% confidence intervals from multivariable logistic regression analyses adjusted for age, gender, race/ethnicity, lifetime mental health (internalizing and externalizing) problem symptoms, and sensation seeking

Bidis and dissolvable proportions, as well as kreteks, bidis, and dissolvable AORs were suppressed when n < 50 or relative standard error > 30%

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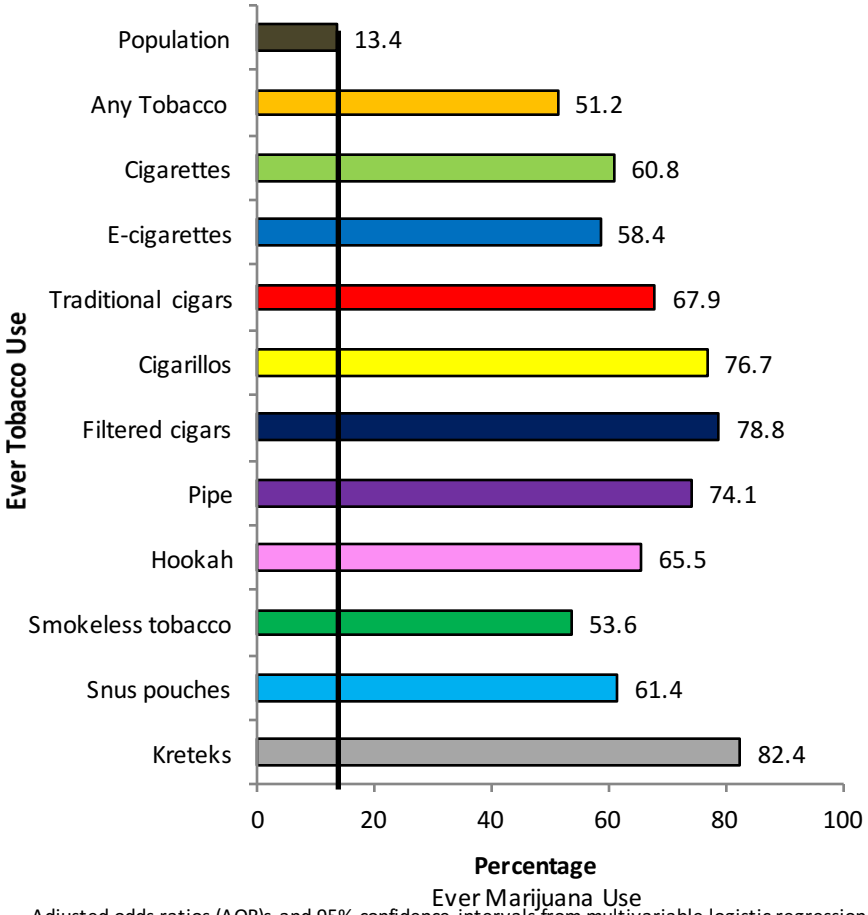
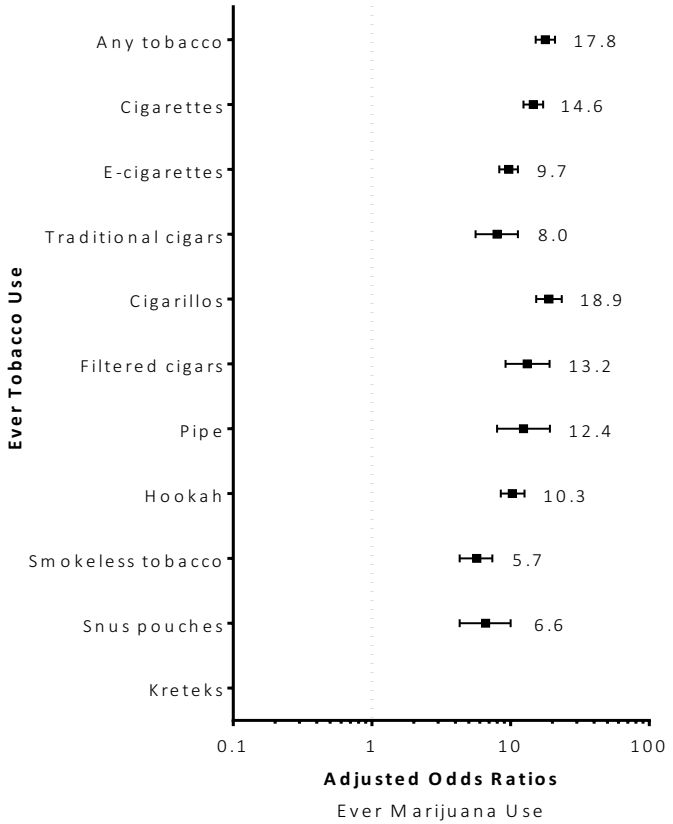
2013-2014 PATH Study Youth: Proportions and Odds of Ever Marijuana Use According to Ever Tobacco Use





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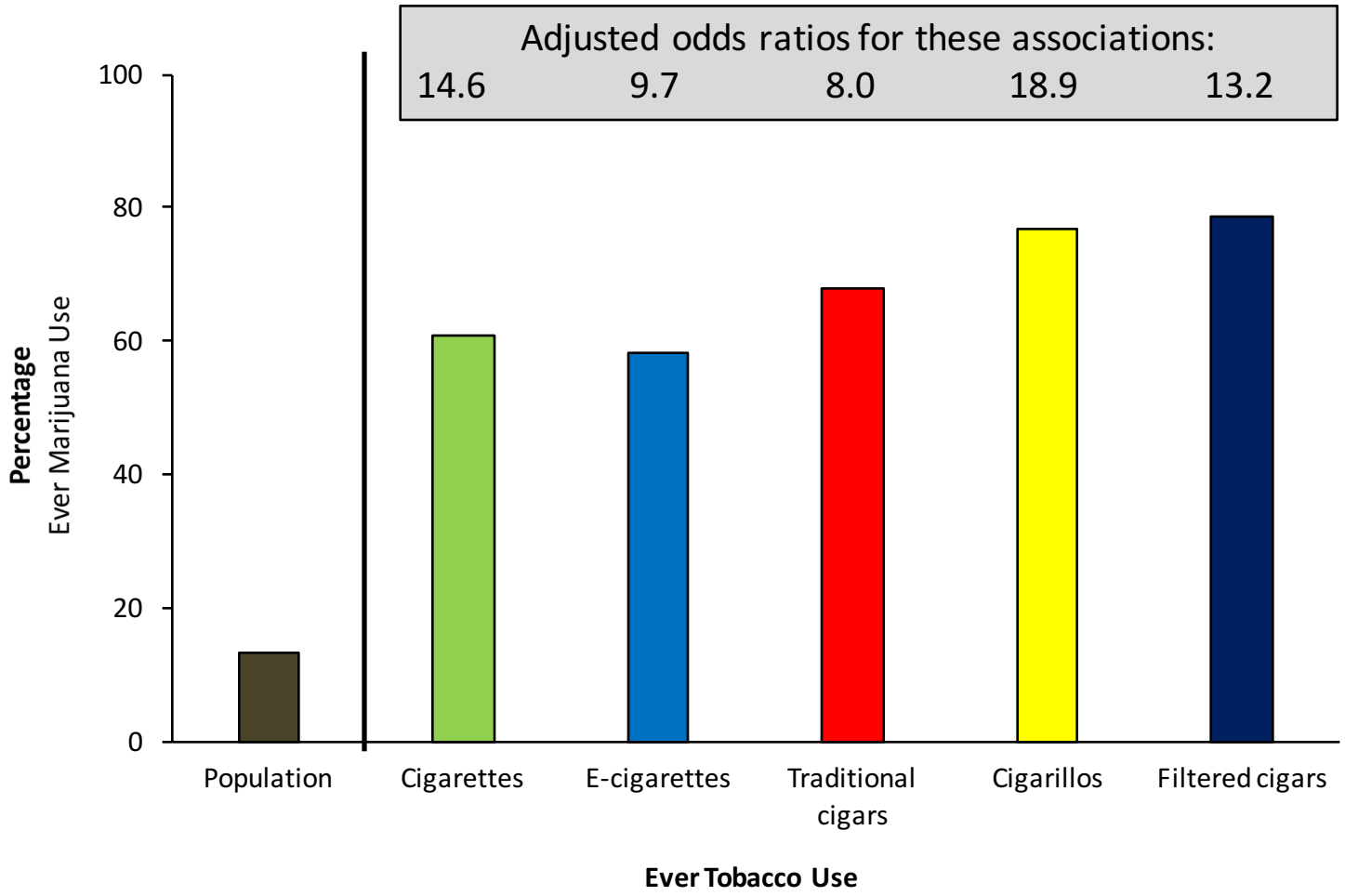
2013-2014 PATH Study Youth: Proportions and Odds of Ever Marijuana Use According to Ever Tobacco Use



Global Appraisal of Individual Needs-Short Screener (GAIN-SS)

GAIN-SS Subscales in the PATH Study	No. of Items	Severity Category		
		No/Low	Moderate	High
Substance Use Problems	7	0-1	2-3	4+
Internalizing Problems	4	0-1	2-3	4
Externalizing Problems	7	0-1	2-3	4+

Cut point

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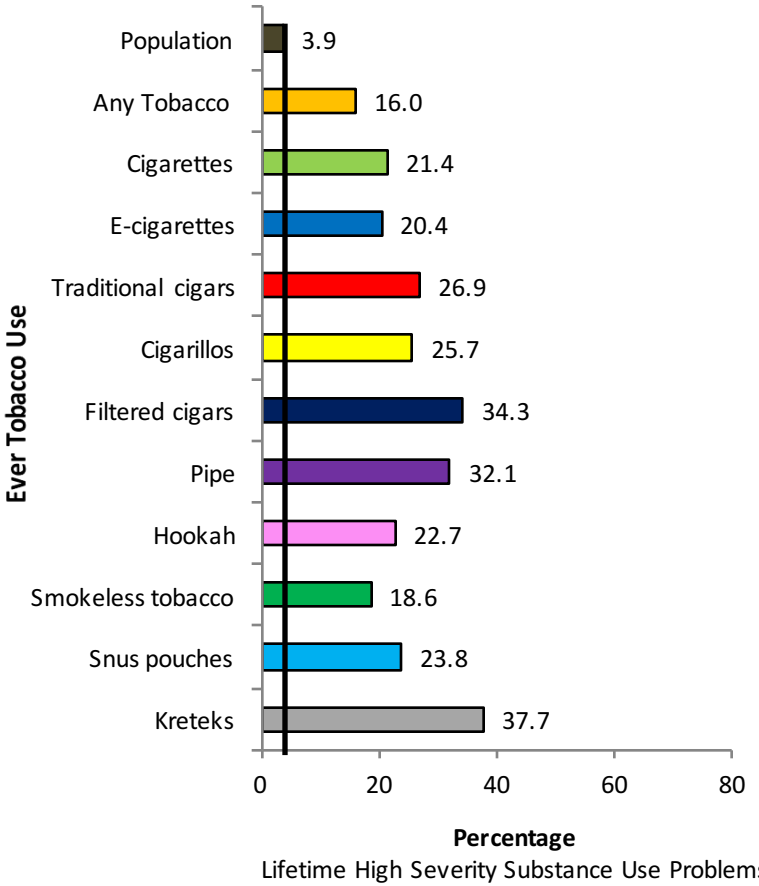
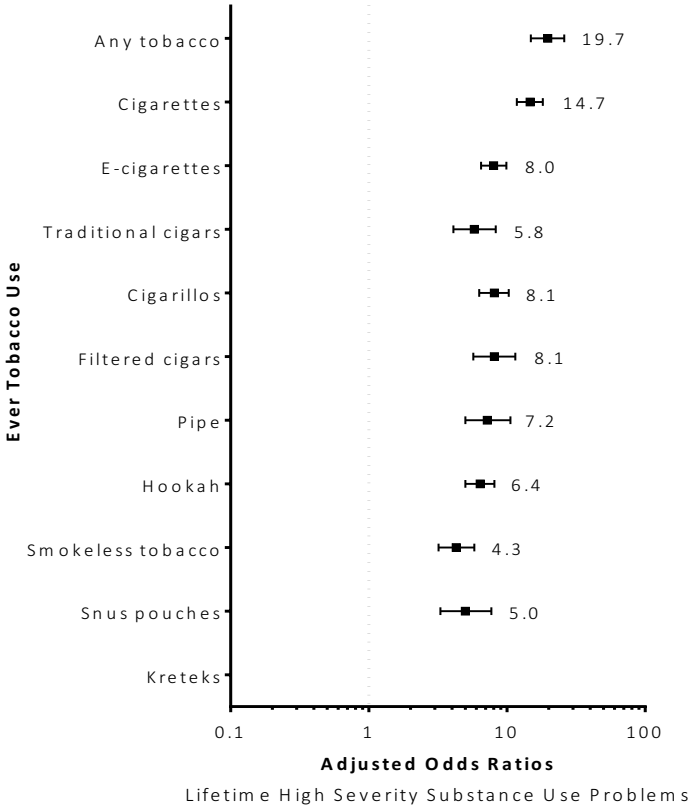
2013-2014 PATH Study Youth: Proportions and Odds of Lifetime Substance Use Problems According to Ever Tobacco Use





Adjusted odds ratios (AOR)s and 95% confidence intervals from multivariable logistic regression analyses adjusted for age, gender, race/ethnicity, and sensation seeking; model the odds of high severity versus combined moderate and low severity levels

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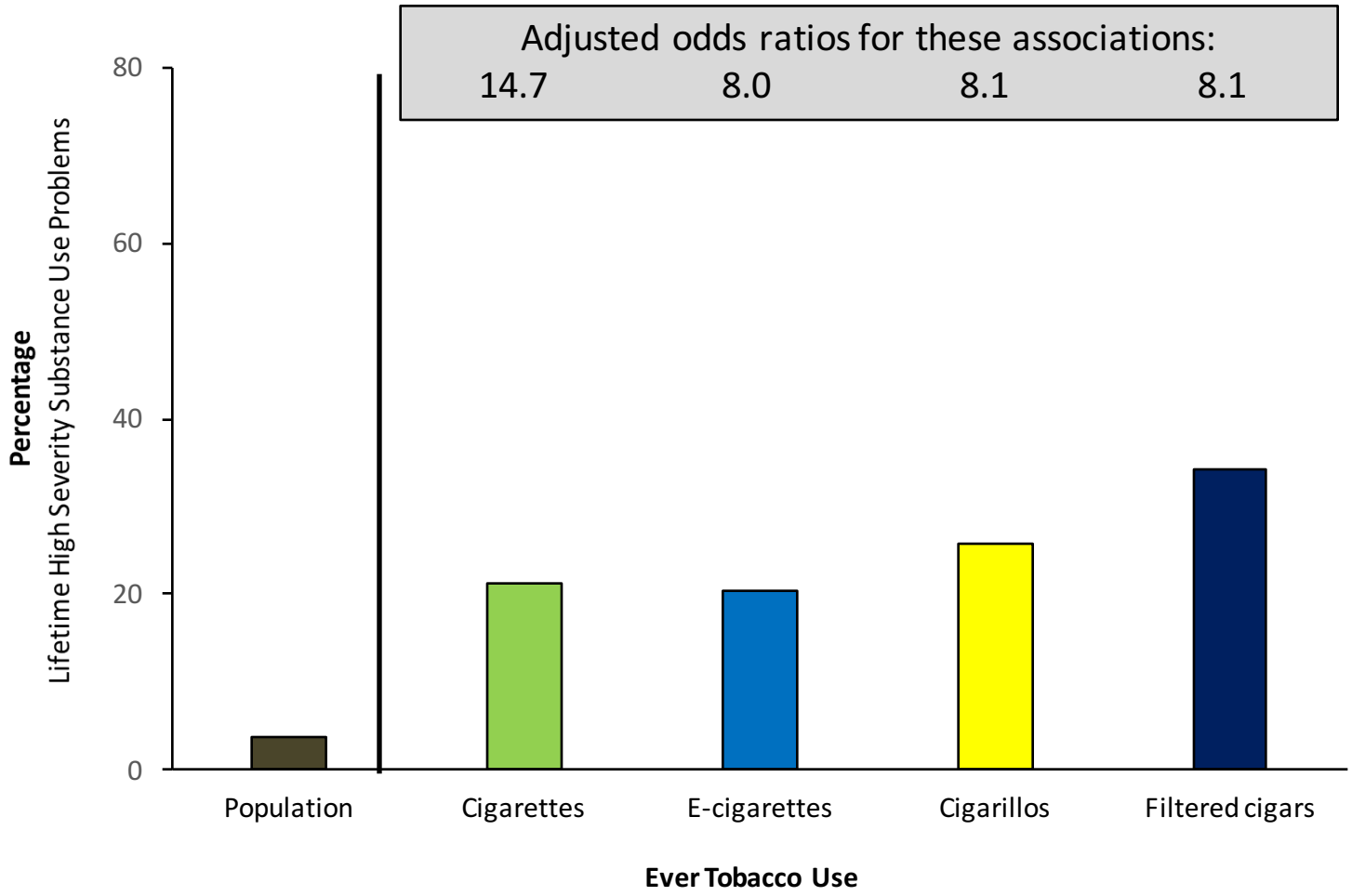
2013-2014 PATH Study Youth: Proportions and Odds of Lifetime Substance Use Problems According to Ever Tobacco Use



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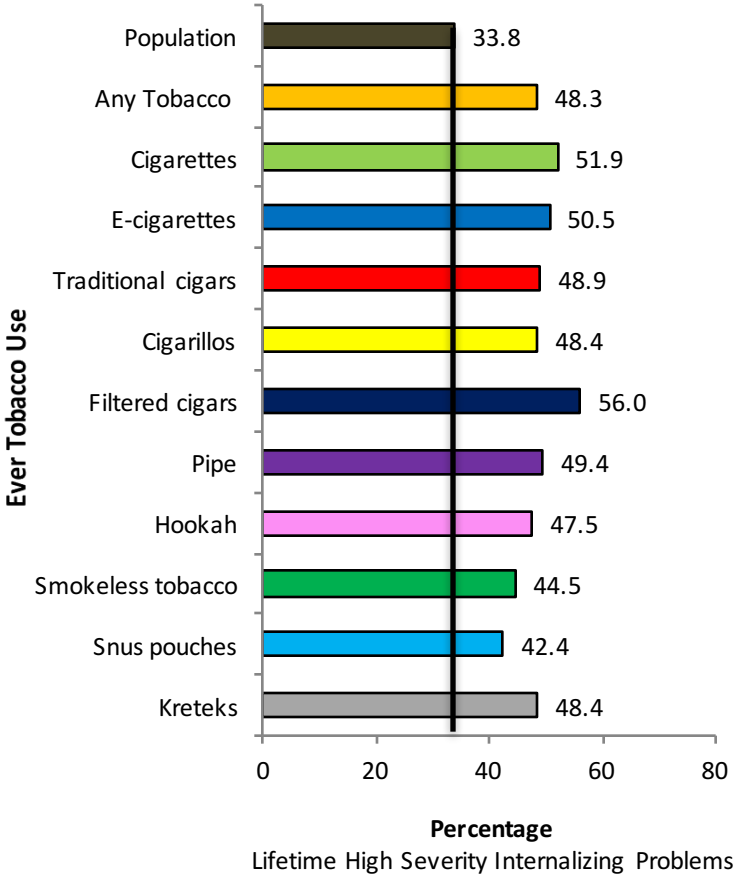
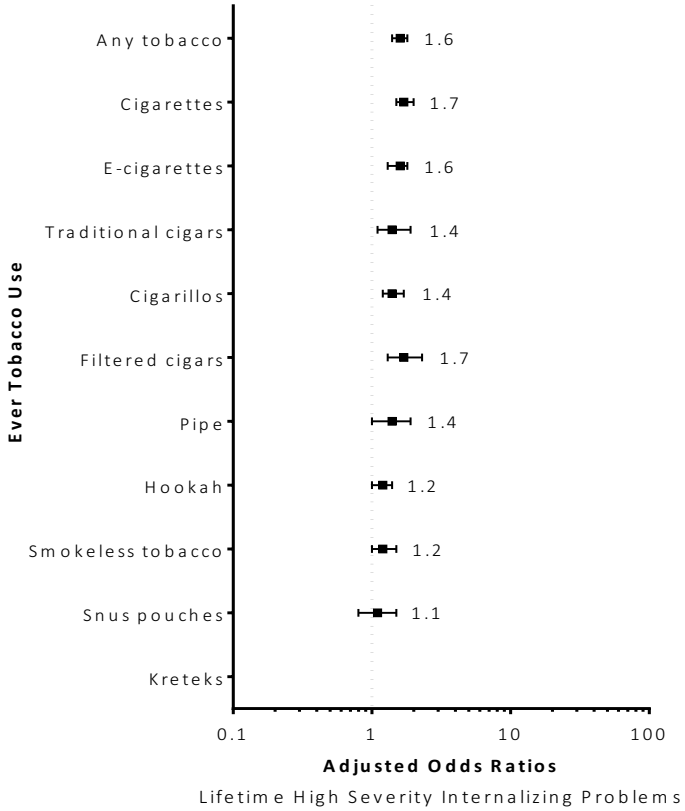
2013-2014 PATH Study Youth: Proportions and Odds of Lifetime Internalizing Problems According to Ever Tobacco Use





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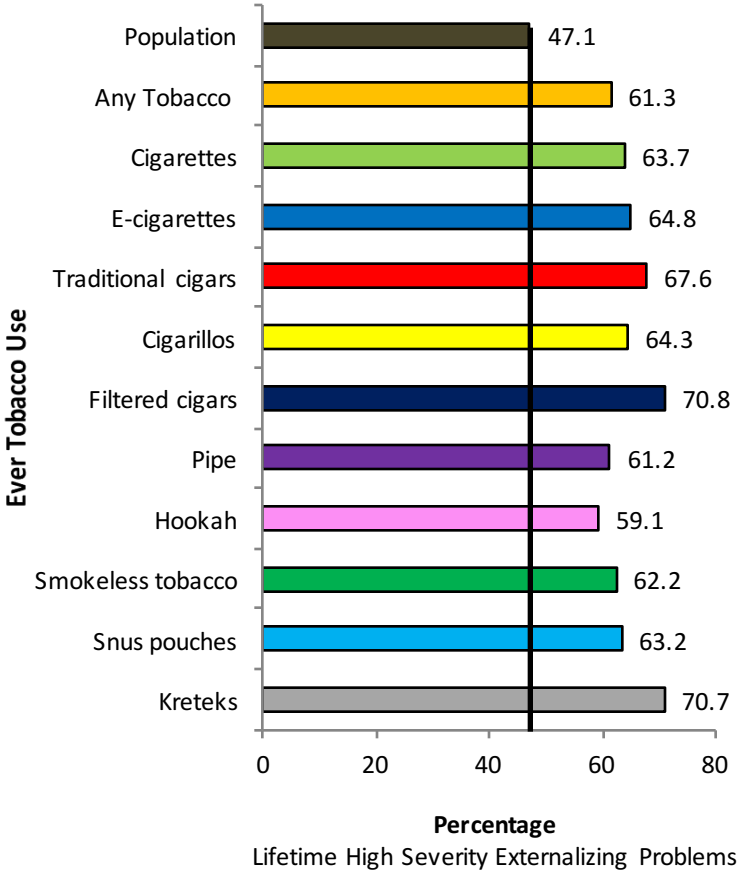
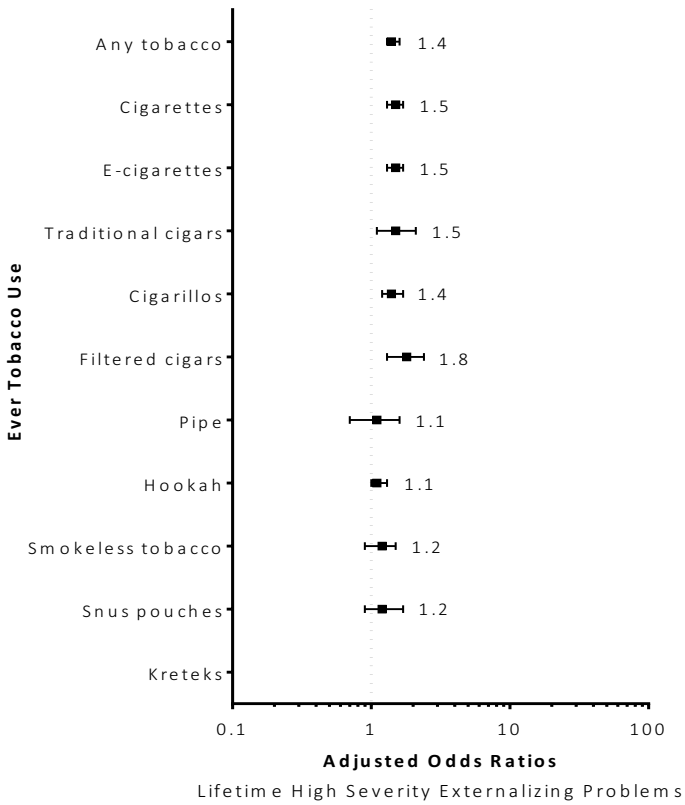
2013-2014 PATH Study Youth: Proportions and Odds of Lifetime Externalizing Problems According to Ever Tobacco Use





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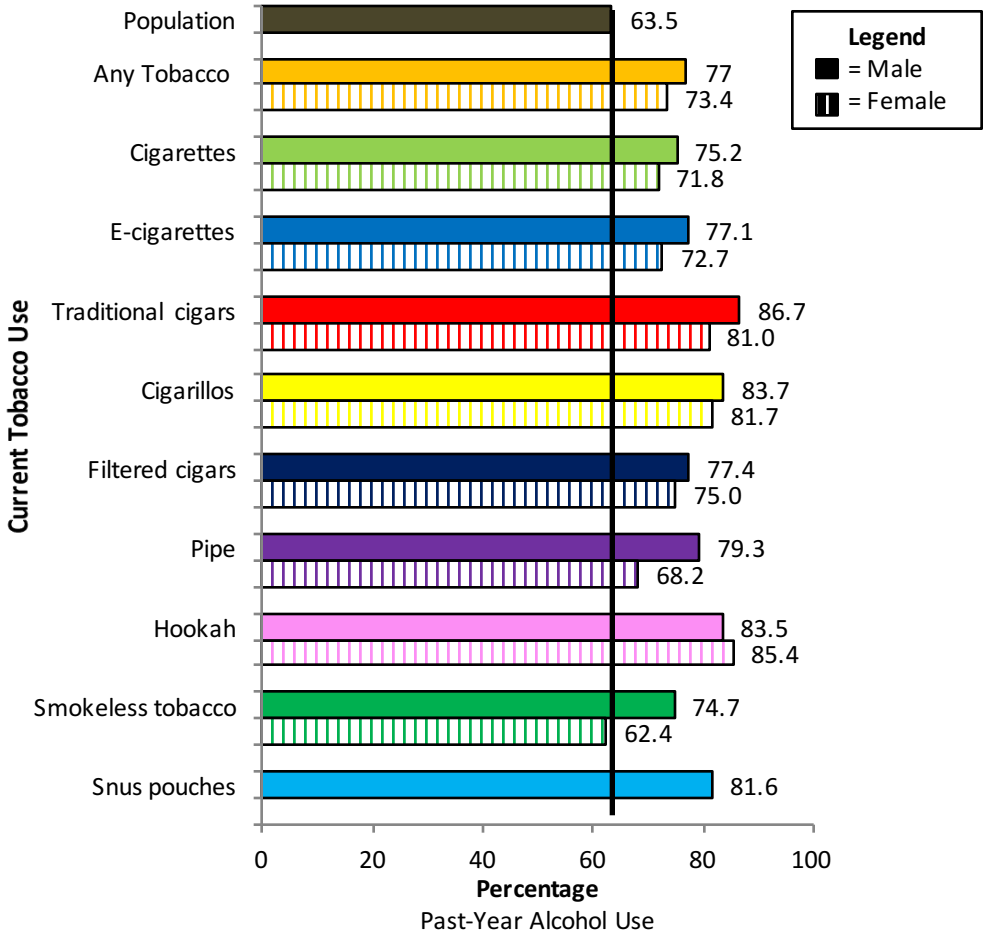
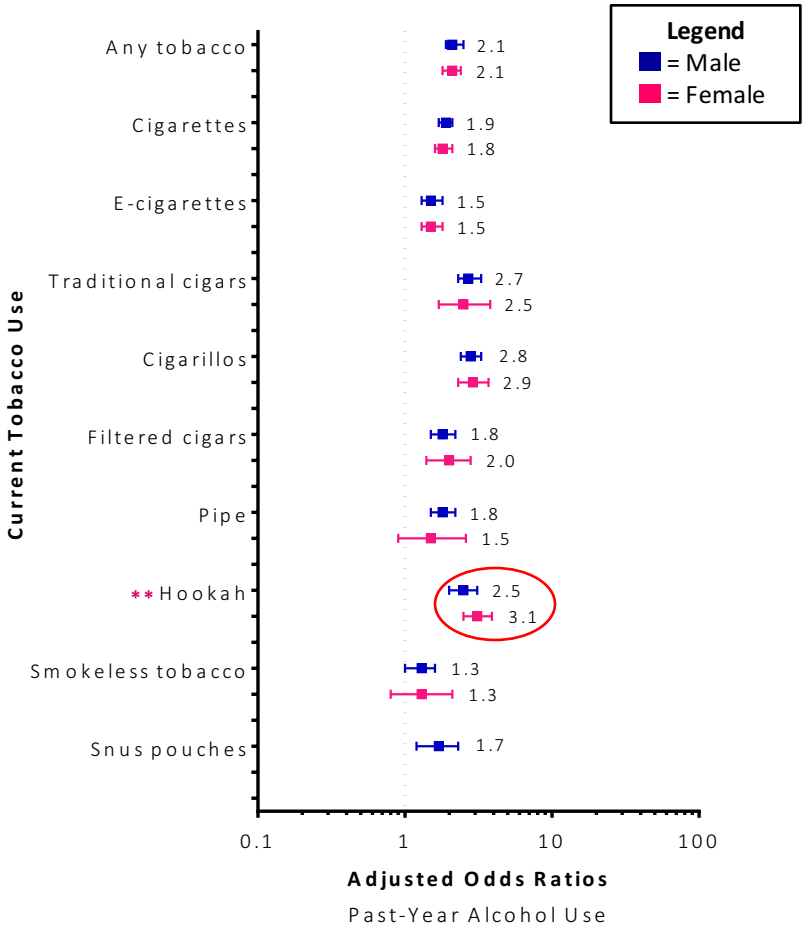
Wave 1 PATH Study Data (IN PROGRESS)

Co-occurrence of Tobacco, Substance, and Mental Health Problems -- ADULTS

2013-2014 PATH Study Adults: Proportions and Odds of Past-Year Alcohol Use According to Current Tobacco Use by Gender





Adjusted odds ratios (AOR)s and 95% confidence intervals from multivariable logistic regression analyses adjusted for age, race/ethnicity, and past-year mental health (internalizing and externalizing) problem symptoms
Snus female proportion and AOR and Dissolvable proportions and AORs were suppressed when n < 50 or relative standard error > 30%

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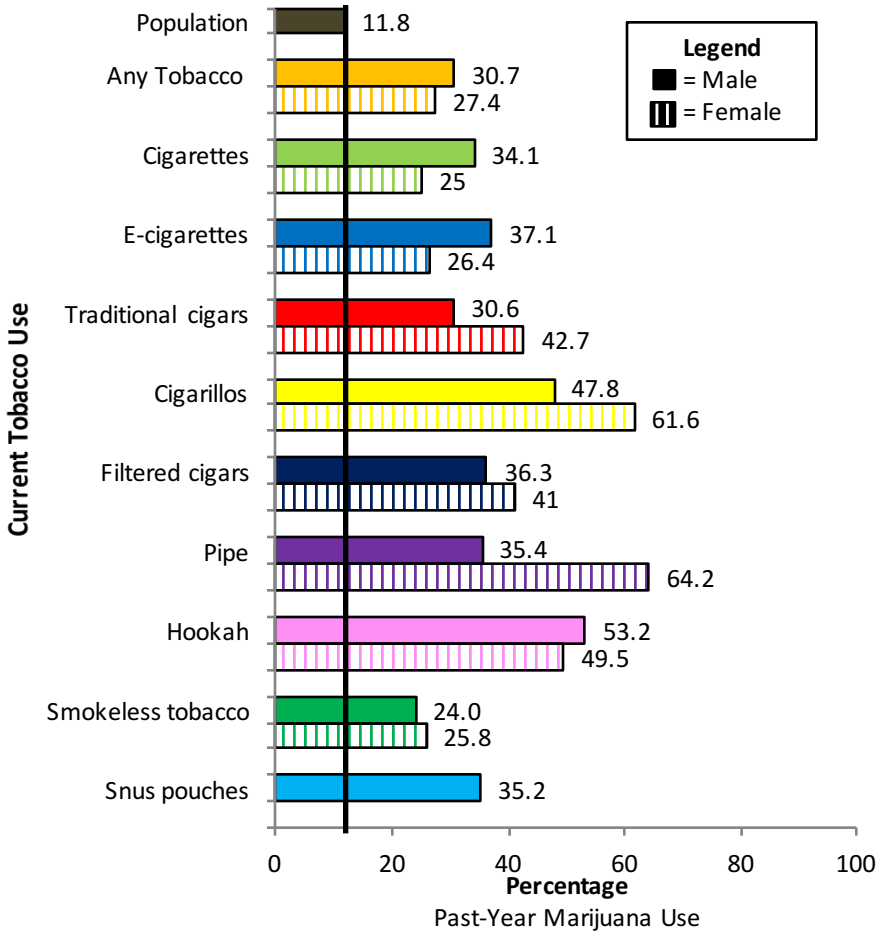
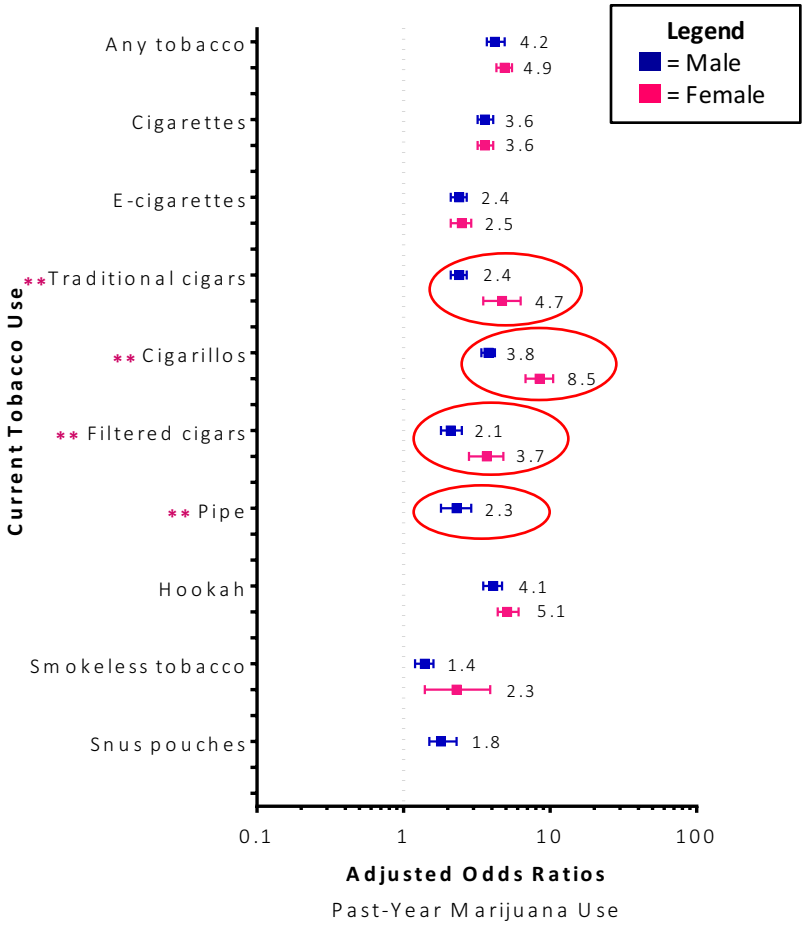
2013-2014 PATH Study Adults: Proportions and Odds of Past-Year Marijuana Use According to Current Tobacco Use by Gender





Adjusted odds ratios (AOR)s and 95% confidence intervals from multivariable logistic regression analyses adjusted for age, race/ethnicity, and past-year mental health (internalizing and externalizing) problem symptoms
Pipe female AOR, Snus female proportion and AOR, and Dissolvable proportions and AORs were suppressed when n < 50 or relative standard error > 30%

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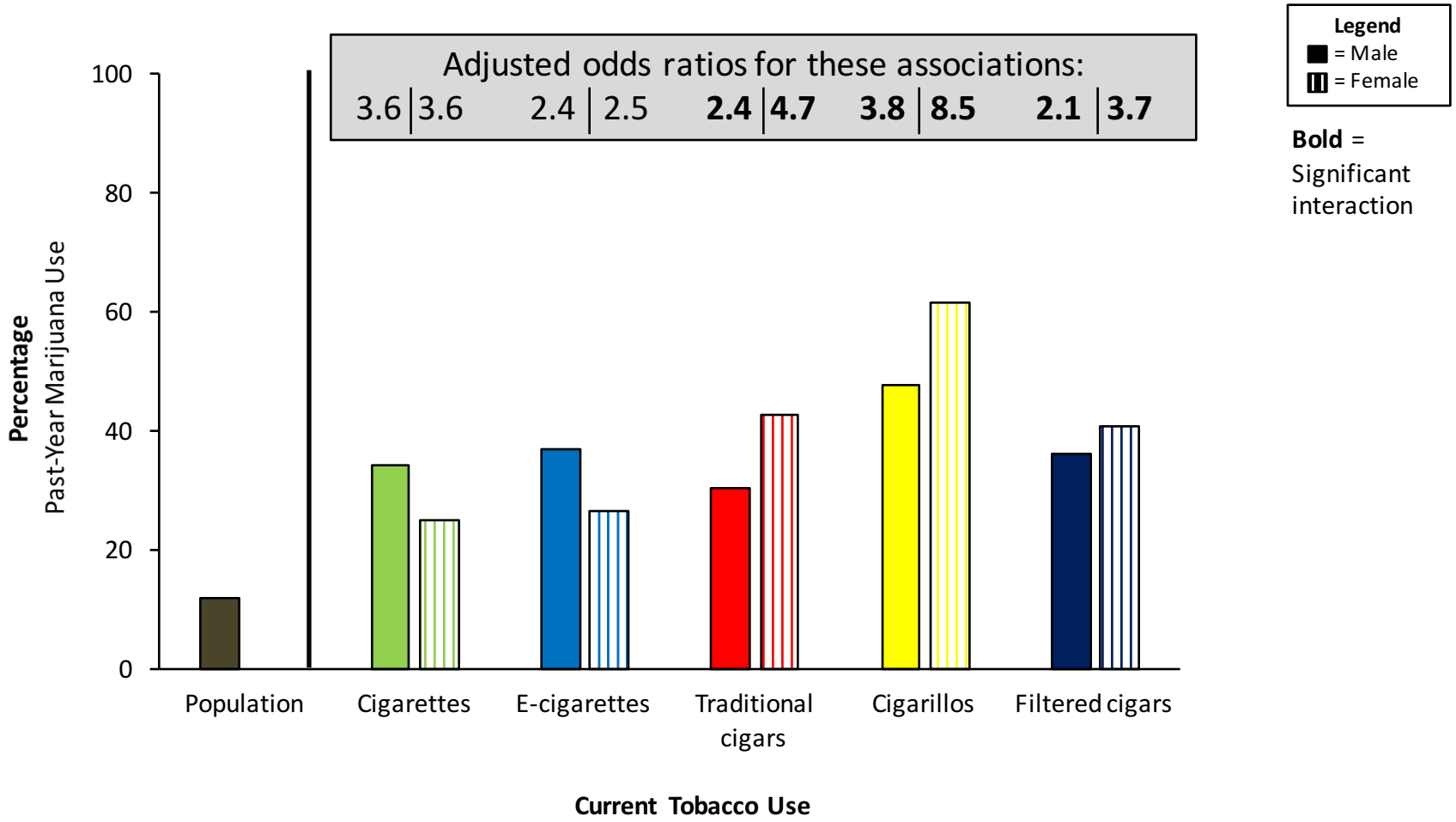
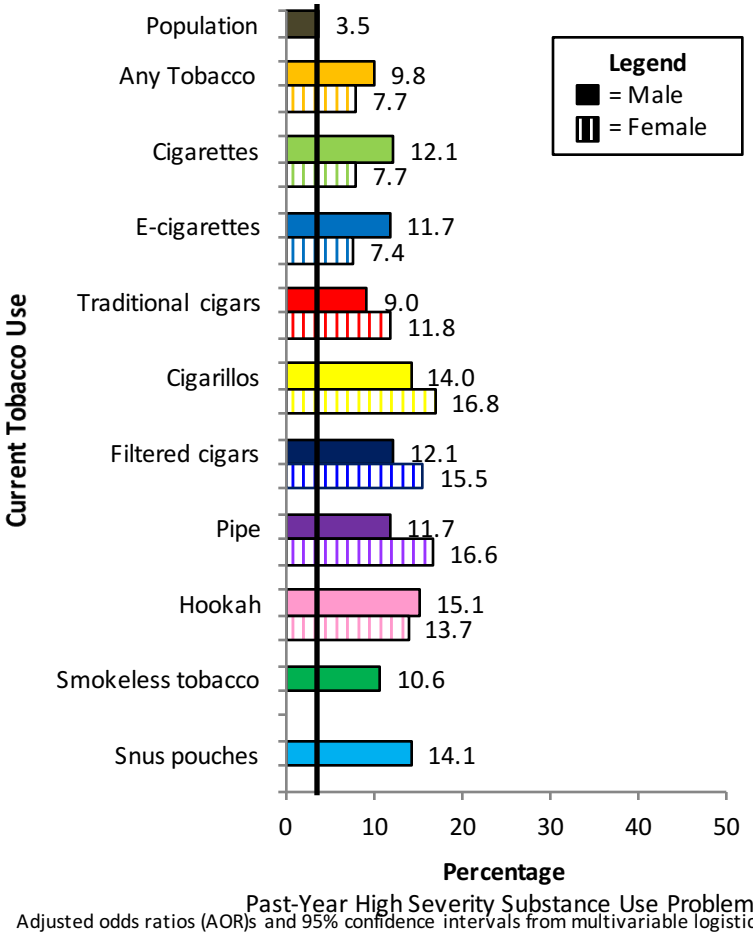
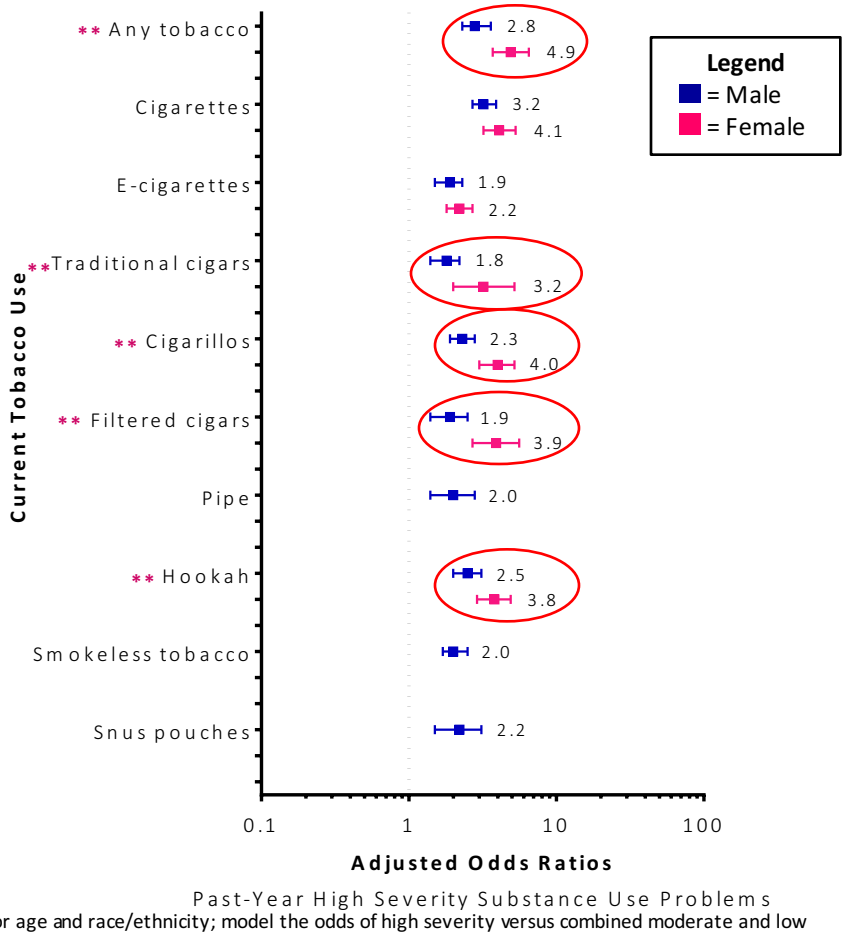
2013-2014 PATH Study Adults: Proportions and Odds of Past-Year Marijuana Use According to Current Tobacco Use by Gender



2013-2014 PATH Study Adults: Proportions and Odds of Past-Year Substance Use Problems According to Current Tobacco Use by Gender





Adjusted odds ratios (AOR)s and 95% confidence intervals from multivariable logistic regression analyses adjusted for age and race/ethnicity; model the odds of high severity versus combined moderate and low severity levels

Snus and smokeless female proportions, pipe, smokeless, snus female AORS and dissolvable proportions and AORs were suppressed for n < 50 or relative standard error >30%

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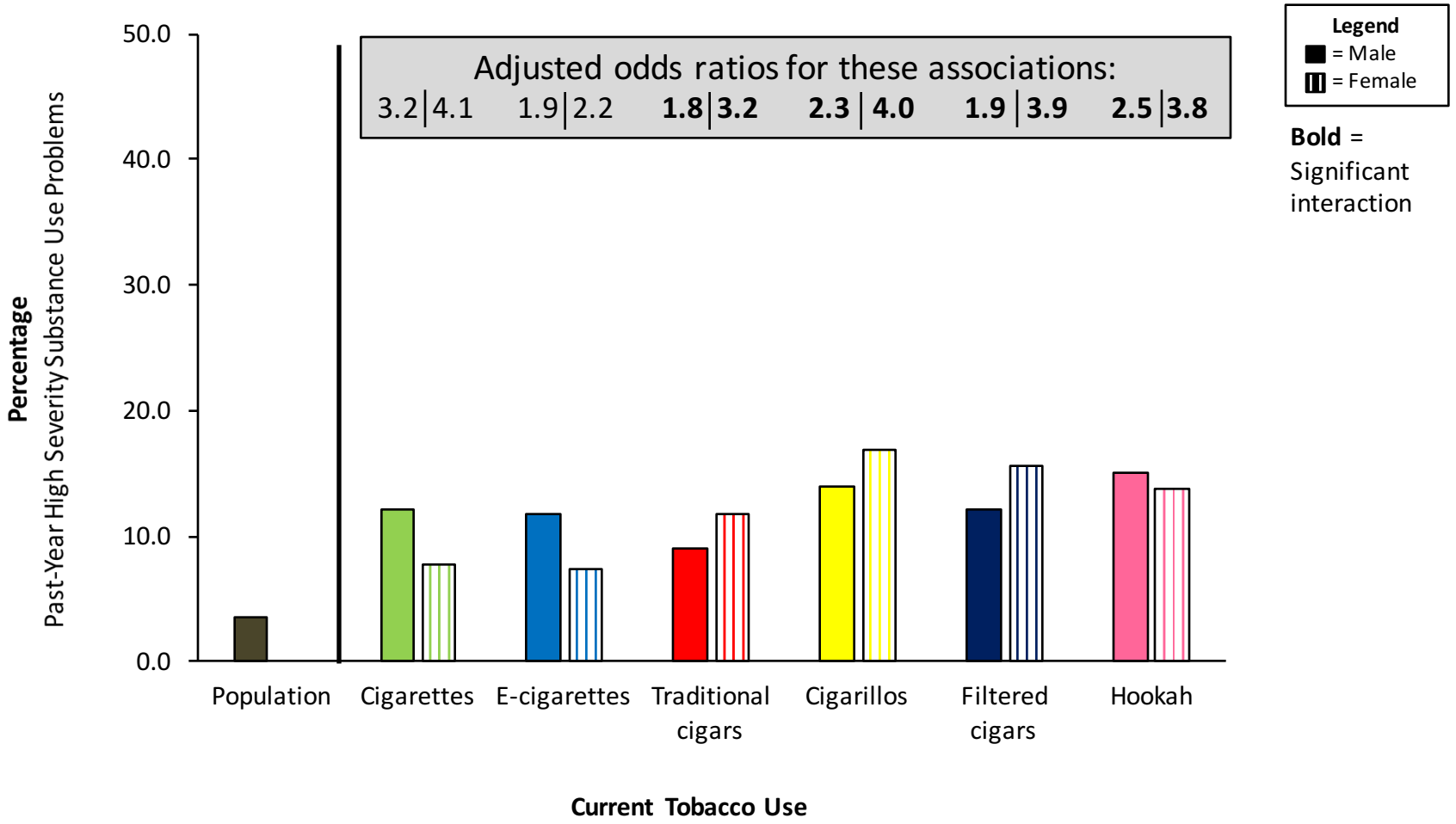

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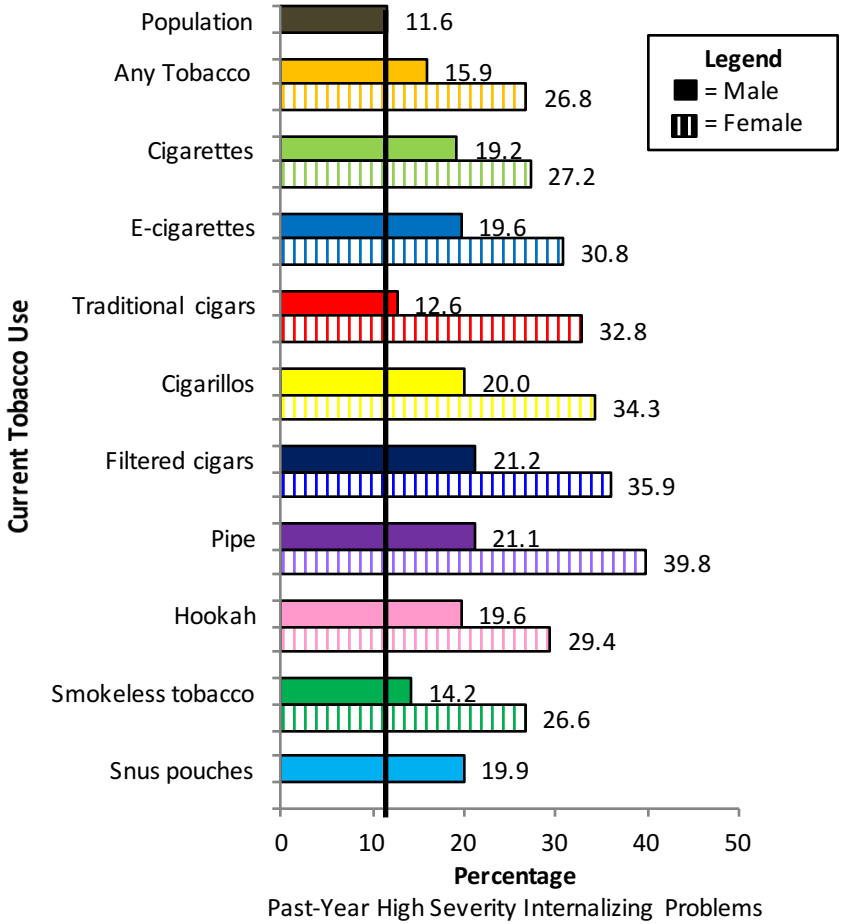
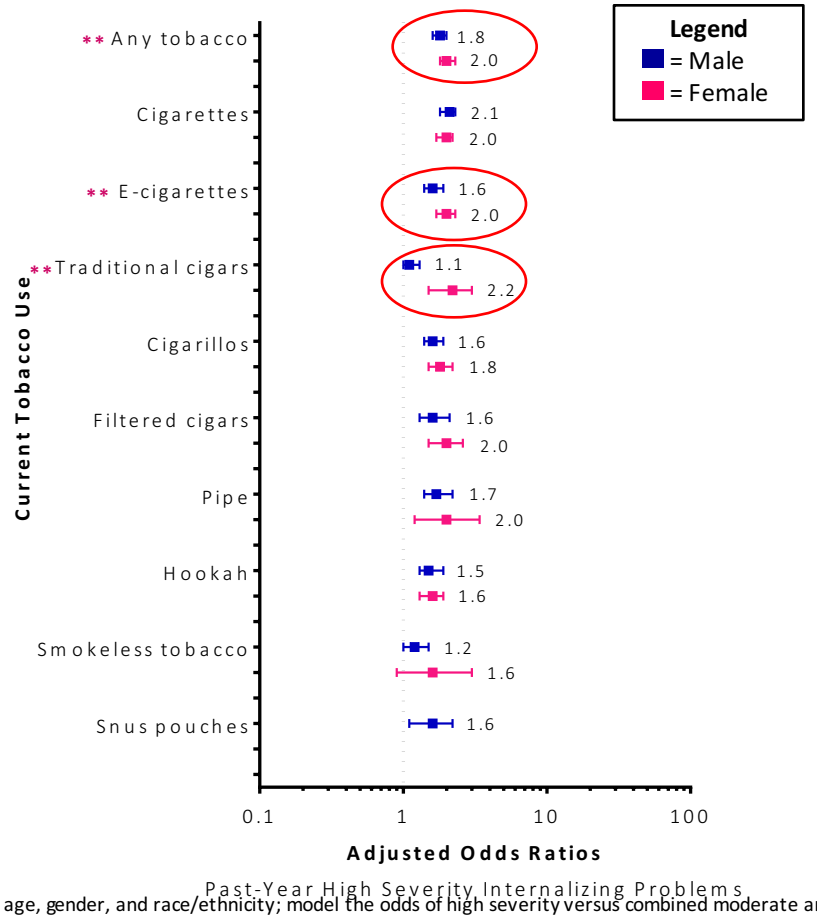
The analyses/manuscript is in preparation and published results may differ from those reported here. This is not a formal dissemination of information and the views and opinions expressed in this presentation/poster are those of the authors only and do not necessarily represent the views, official policy or position of the U.S. Department of Health and Human Services or any of its affiliated institutions or agencies.

2013-2014 PATH Study Adults: Proportions and Odds of Past-Year Internalizing Problems According to Current Tobacco Use by Gender





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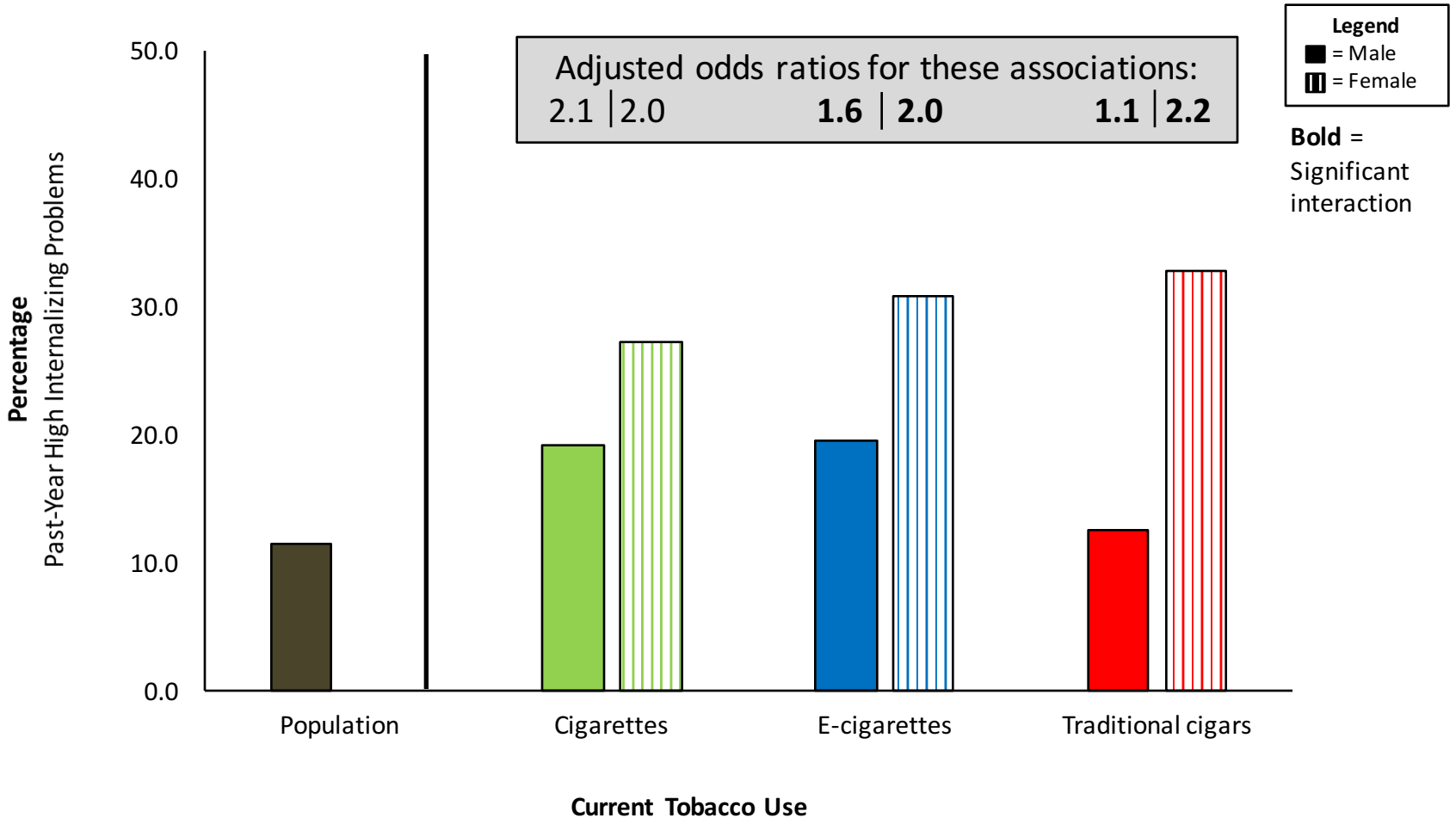
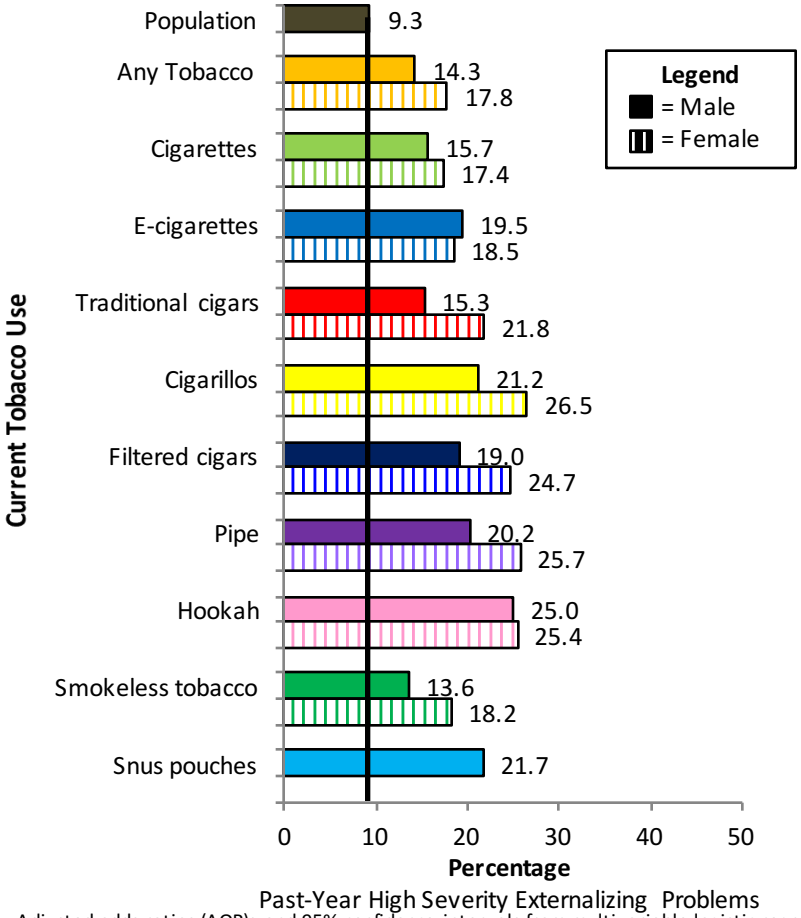
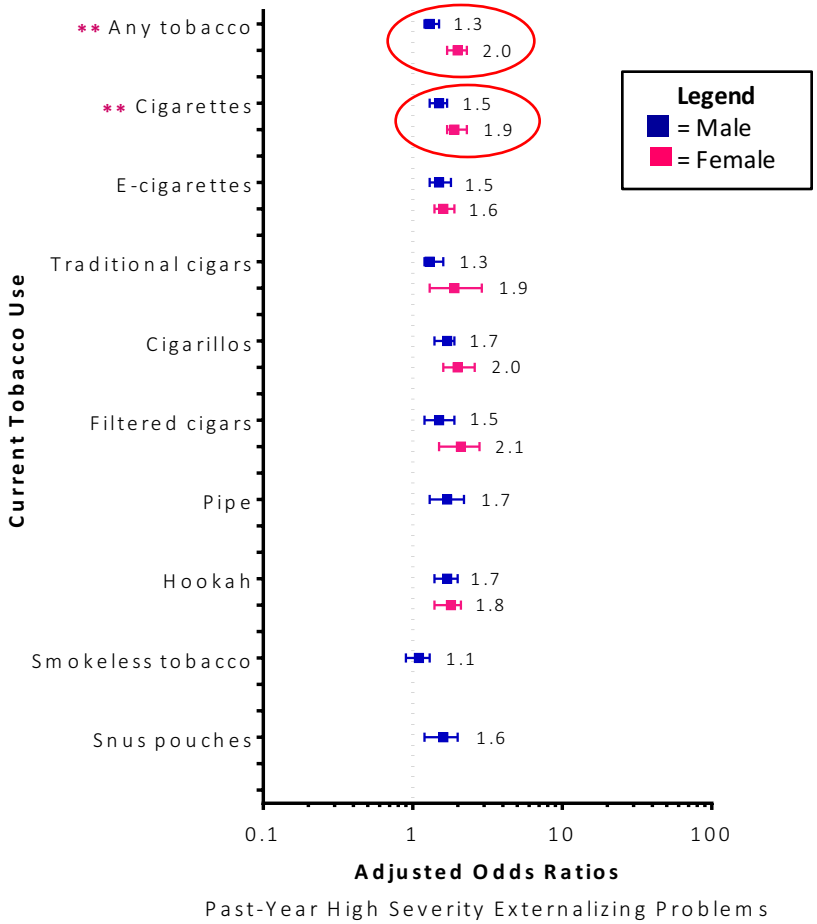


2013-2014 PATH Study Adults: Proportions and Odds of Past-Year Externalizing Problems According to Current Tobacco Use by Gender





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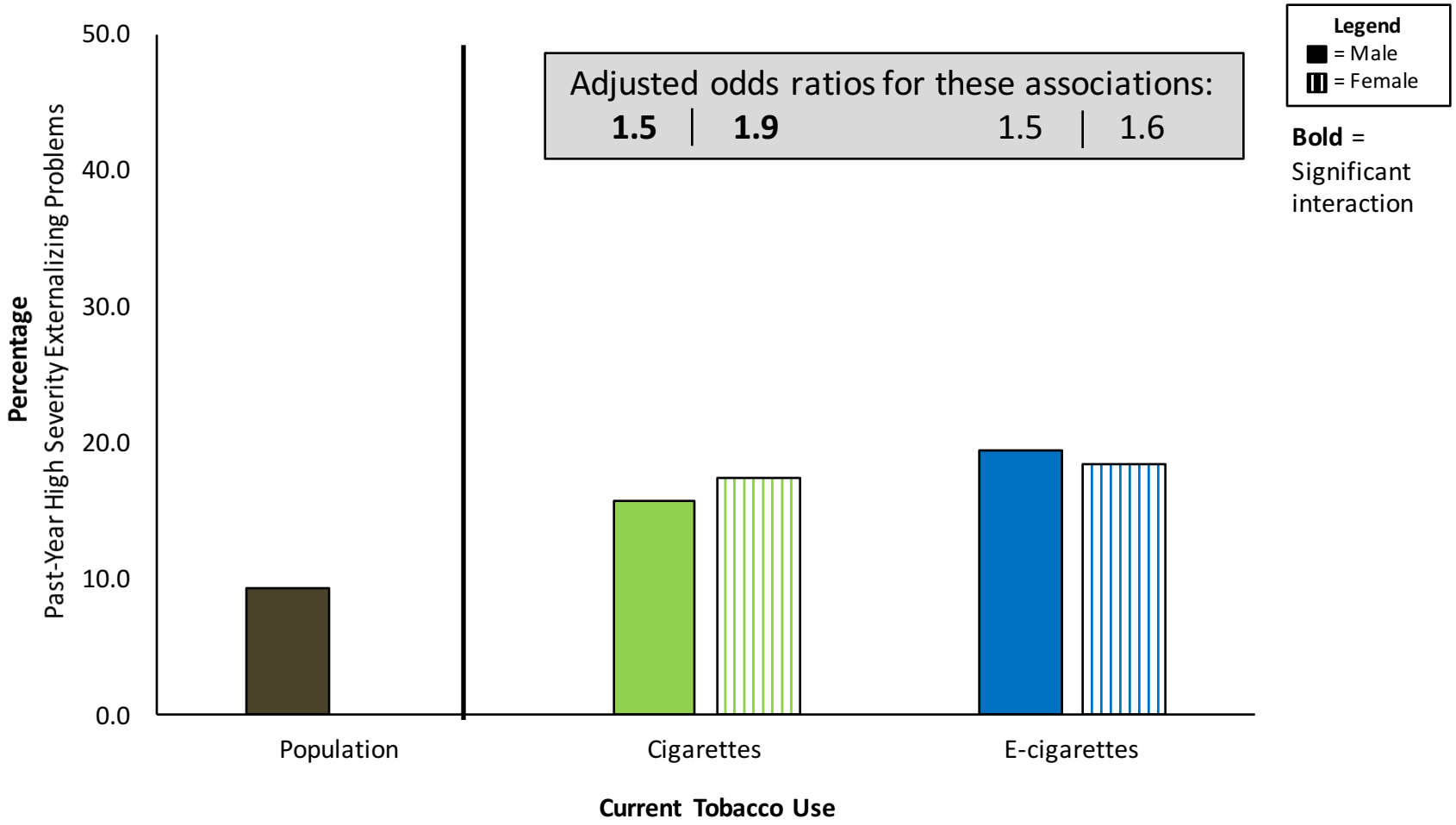
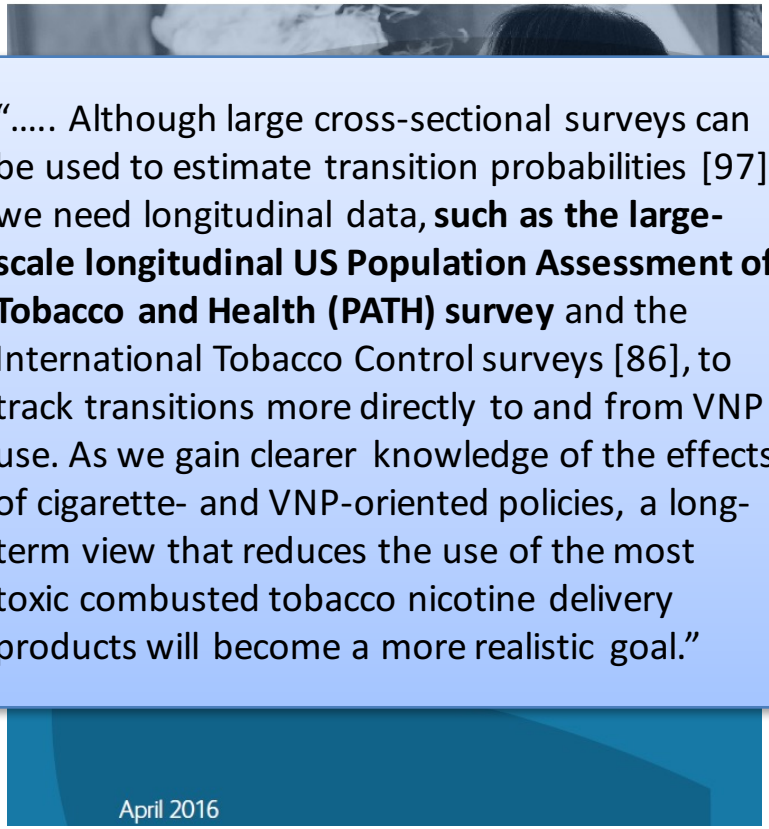


Hot Topic: Electronic Nicotine Delivery

Royal College of Physicians



"….. Although large cross-sectional surveys can be used to estimate transition probabilities [97] we need longitudinal data, **such as the large-scale longitudinal US Population Assessment of Tobacco and Health (PATH) survey** and the International Tobacco Control surveys [86], to track transitions more directly to and from VNP use. As we gain clearer knowledge of the effects of cigarette- and VNP-oriented policies, a long-term view that reduces the use of the most toxic combusted tobacco nicotine delivery products will become a more realistic goal."

ADDICTION
SSA SOCIETY FOR THE STUDY OF ADDICTION
FOR DEBATE
doi:10.1111/add.13394

A framework for evaluating the public health impact of e-cigarettes and other vaporized nicotine products

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ABSTRACT

The use of vaporized nicotine products (VNPs), especially e-cigarettes and, to a lesser extent, pressurized aerosol nicotine products and heat-not-burn tobacco products, are being adopted increasingly as an alternative to smoking combusted products, primarily cigarettes. Considerable controversy has accompanied their marketing and use. We propose a framework that describes and incorporates patterns of VNP and combustible cigarette use in determining the total amount of toxic exposure effects on population health. We begin by considering toxicity and the outcomes relevant to population health. We then present the framework and define different measures of VNP use; namely, trial and long-term use for exclusive cigarette smokers, exclusive VNP and dual (cigarette and VNP) use. Using a systems thinking framework and decision theory we considered potential pathways for current, former and never users of VNPs. We then consider the evidence to date and the probable impacts of VNP use on public health, the potential effects of different policy approaches and the possible influence of the tobacco industry on VNP and cigarette use.

Keywords E-cigarettes, framework, harm reduction, industry response, public health, public policy.

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PATH Study Data Access

Wave 1 Restricted Use Files

The PATH Study: Next Steps

Wave 1 instruments and codebooks available online at the Inter-University Consortium for Political and Social Research (ICPSR) and the National Addiction and HIV Data Archive Program (NAHDAP):

http://www.icpsr.umich.edu/icpsrweb/NAHDAP/studies/36231

The PATH Study: Next Steps

Restricted-use data files can be accessed via the **Virtual Data Enclave (VDE)** upon approval

Public-use data files will be available **later this year**

ICPSR

NAHDAP

The PATH Study: Next Steps

For general inquiries email: PATHInfo@westat.com

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