

Copenhagen[®] Snuff Fine Cut

Tobacco Products Scientific Advisory Committee

February 6 & 7, 2019



Altria
Altria Client Services

Introduction

Jose Luis Murillo, J.D.

Senior Vice President, Regulatory Affairs
Altria Client Services



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Proposed Modified Risk Claim

**IF YOU SMOKE,
CONSIDER THIS:**

Switching completely to this product from
cigarettes reduces risk of lung cancer.



SMOKELESS TOBACCO
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**WARNING: This product can
cause mouth cancer.**

Almost Two Centuries in Market

- **Copenhagen[®] Snuff Fine Cut**
has been in market since 1822

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Presents a Dilemma and an Opportunity

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Scientific Evidence Supports Risks Reduction

Global, regional, and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016

Summary
Background The Global Burden of Diseases, Injuries, and Risk Factors Study 2016 (GBD 2016) provides a comprehensive assessment of risk factor exposure and attributable burden of disease. By providing estimates over a long time series, this study can monitor risk exposure trends critical to health surveillance and inform policy debates on the importance of addressing risks in context.

Methods We used the comparative risk assessment framework developed for previous iterations of GBD to estimate levels and trends in exposure, attributable deaths, and attributable disability-adjusted life-years (DALYs), by age group, sex, year, and location for 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks from 1990 to 2016. This study included 481 risk-outcome pairs that met the GBD study criteria for convincing or probable evidence of causation. We extracted relative risk (RR) and exposure estimates from 227 randomised controlled trials, cohorts, pooled cohorts, household surveys, census data, satellite data, and other sources, according to the GBD 2016 source counting methods. Using the counterfactual scenario of theoretical minimum risk exposure level (TMREL), we estimated the portion of deaths and DALYs that could be attributed to a given risk. Finally, we explored four drivers of trends in attributable burden: population growth, population ageing, trends in risk exposure, and all other factors combined.

Findings Since 1990, exposure increased significantly for 30 risks, did not change significantly for four risks, and decreased significantly for 51 risks. Among risks that are leading causes of burden of disease, child growth failure and household air pollution showed the most significant declines, while metabolic risks, such as body-mass index and high fasting plasma glucose, showed significant increases. In 2016, at level 3 of the hierarchy, the three leading risk factors in terms of attributable DALYs at the global level for men were smoking (141.1 million DALYs [95% UI 111.2–209.0]), high systolic blood pressure (122.2 million DALYs [110.3–133.3 million]), and low birthweight and short gestation (83.0 million DALYs [75.3–90.7 million]). For women, the three leading risks were high systolic blood pressure (89.9 million DALYs [80.0–100.0 million]), high body-mass index (84.8 million DALYs [74.4–100.0 million]), and 113 countries, the leading risk factor drivers of change were 9.3% (4.9–11.0) of deaths and 10.1–14.9% of disability-adjusted life-years (DALYs) in 2006 and 2016 can be attributed to these risks.

Interpretation This study provides insight into global disease burden and risk exposure trends. The GBD 2016 findings show that a small part in the total burden of disease is due to a few risks.

Funding The Bill & Melinda Gates Foundation, Wellcome Trust, and the UK Medical Research Council.

The Strategic Dialogue on Tobacco Harm Reduction: a vision and blueprint for action in the US

Mitchell Zeller, Dorothy Hatsukami, and the Strategic Dialogue on Tobacco Harm Reduction Group

ABSTRACT
 The issues related to tobacco harm reduction continue to challenge the tobacco control research and policy communities. The potential for combining tobacco products to reduce exposure and risk remains largely unknown, but this has not stopped manufacturers from offering such products making these claims. The role of oral tobacco products in a harm reduction regimen has also been a source of debate and dispute. Within the last few years, major cigarette manufacturing companies have begun selling smokeless products for the first time, claiming to target current cigarette smokers. Other cigarette manufacturers are also offering smokeless products in markets around the world. The harm-reduction debate has at times been divisive. There has been no unifying set of principles or goals articulated to guide tobacco control efforts. In particular, the research needs are extraordinarily high in order to drive evidence-based policy in this area and avoid the mistakes made with "light" cigarettes. This paper discusses recommendations from a strategic dialogue held with key, mostly US-based tobacco control researchers and policy makers in developing a strategic vision and blueprint for research, policy and communications to elaborate the harm from tobacco for the

American Journal of Preventive Medicine

Volume 23, Issue 6, Supplement, December 2007, Pages 837F-838F

Effect of Smokeless Tobacco Product Marketing and Use on Population Harm from Tobacco Use: Policy Perspective for Tobacco-Risk Reduction

Lynn T. Kozlowski PhD R 837F
<https://doi.org/10.1016/j.amepre.2007.08.015>

Abstract
 This article presents policy perspectives on the marketing of smokeless tobacco products to reduce population harm from tobacco use. Despite consensus that smokeless tobacco products as sold in the United States are less dangerous than cigarettes, there is no consensus on how to proceed. Diverse factions have different policy concerns. While the tobacco industry is exempted from U.S. Food and Drug Administration (FDA) oversight, the pharmaceutical industry whose nicotine replacement therapy (NRT) medicines compete with



Scientific Committee on Emerging and Newly Identified Health Risks
 SCENIHR

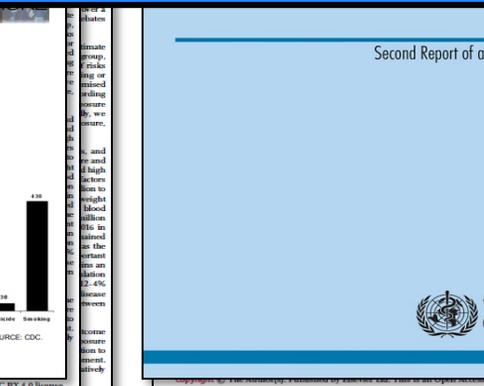
Smokeless tobacco use presents less risk of lung cancer

BACKGROUND
 Tobacco use is projected to kill 1 billion people during the 21st century. While the majority will likely be killed by their use of cigarettes, tobacco use in other forms also contributes to worldwide morbidity and mortality.¹ Table 1 lists a selection of different classes of non-cigarette forms of tobacco use, including smoked products, smokeless products and also non-tobacco delivery of nicotine.² Such products have historically been treated differently from cigarettes for tax and regulatory purposes, and often have longer histories of use than manufactured cigarettes. All forms of tobacco use have negative health consequences, though the severity of those consequences can vary substantially among products.³ There is evidence that some tobacco and nicotine products may pose less of

PRODUCTS
 Use of other forms of tobacco can be divided into three broad categories: other smoked products, smokeless products and nicotine products. Each will be discussed in turn below.

Smoked tobacco products
 Smoked forms of tobacco other than cigarettes include cigars, pipes, koreeds, bidis and waterpipes. Their use is characterized by the burning of tobacco, and the smoke may be inhaled or may be held in the mouth. In some regions, a phenomenon known as "reverse smoking" is sometimes observed, wherein the lit end is placed in the mouth.

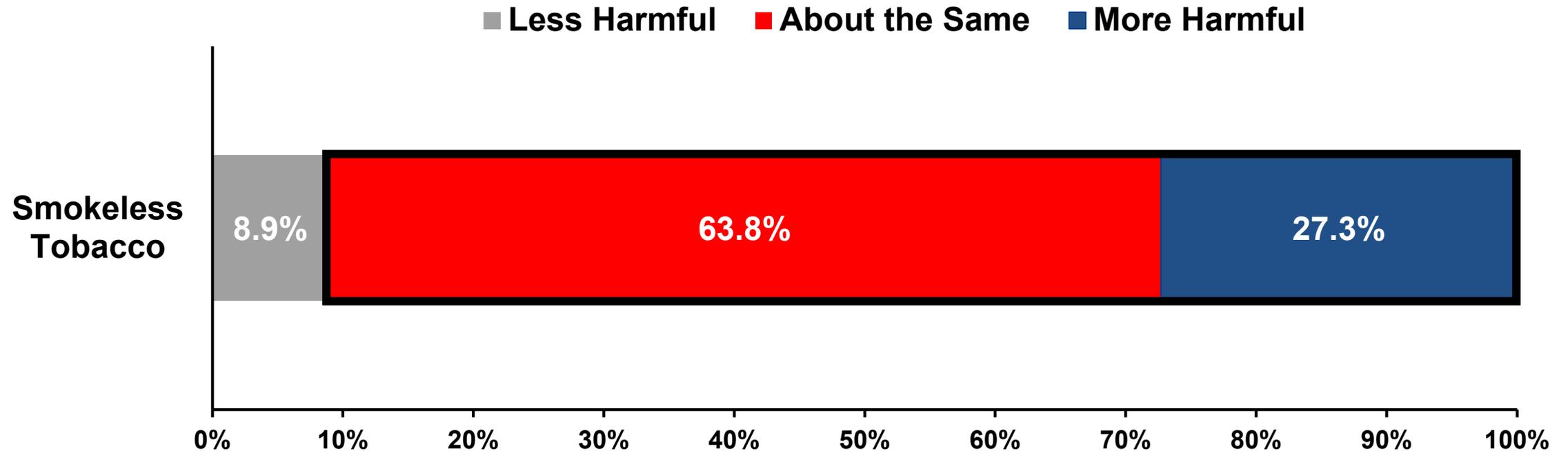
Cigars and pipes
 Cigars are traditionally comprised of shredded tobacco wrapped in tobacco leaf, though modern mass-produced products often employ reconstituted tobacco sheet in wrappers.⁴ Subvarieties of cigar vary by size, from cigarette-like little cigars (which often have a filter) to cigarillos to large cigars (which themselves vary tremendously). Cigar smoking enjoyed resurgence in the US in the 1990s, particularly among adolescents and those believing it to be less hazardous than cigarettes.^{5, 6, 7, 8, 9} The use of cigars and wrappers (flutes) to administer marijuana and other drugs also has generated concern.¹⁰ Pipes are traditionally composed of a bowl (made of clay or other non-combustible material) where the tobacco is placed for burning, attached to a stem through which the smoke is drawn. The tobacco used in pipes may sometimes be flavoured. Data on characteristics on cigars and pipes are less commonly



- Senior Lecturer in General Practice, University of Nottingham
 - Linda Cuthbertson
 Press and PR Manager, Royal College of Physicians
 - Richard Edwards
 Senior Lecturer in Public Health, University of Manchester
 - Christine Godfrey
 Professor of Health Economics, University of York
 - Konrad Jamrozik
 Professor of Primary Care Epidemiology, Imperial College of Science, Technology and Medicine
 - Martin Jarvis
 Professor of Health Psychology, University College London
 - Ann McNeill
 Honorary Senior Lecturer, St George's Hospital Medical School
 - Dawn Milner
 Tobacco Control Consultant
 - Ashley Woodcock
 Professor of Respiratory Medicine, University of Manchester
- Additional background information was supplied by Professor Graint Howells

Adult Smokers Don't Understand the Relative Risk of Smokeless Tobacco Products

- **More than 90%** in FDA's PATH survey say that smokeless tobacco products are just **as harmful** or **more harmful** than cigarettes



The Opportunity

- Providing accurate information to Adult Smokers results in a net benefit to the population as a whole, including users and nonusers
- The real-world impact could be much larger with sustained exposure over time

**IF YOU SMOKE,
CONSIDER THIS:**

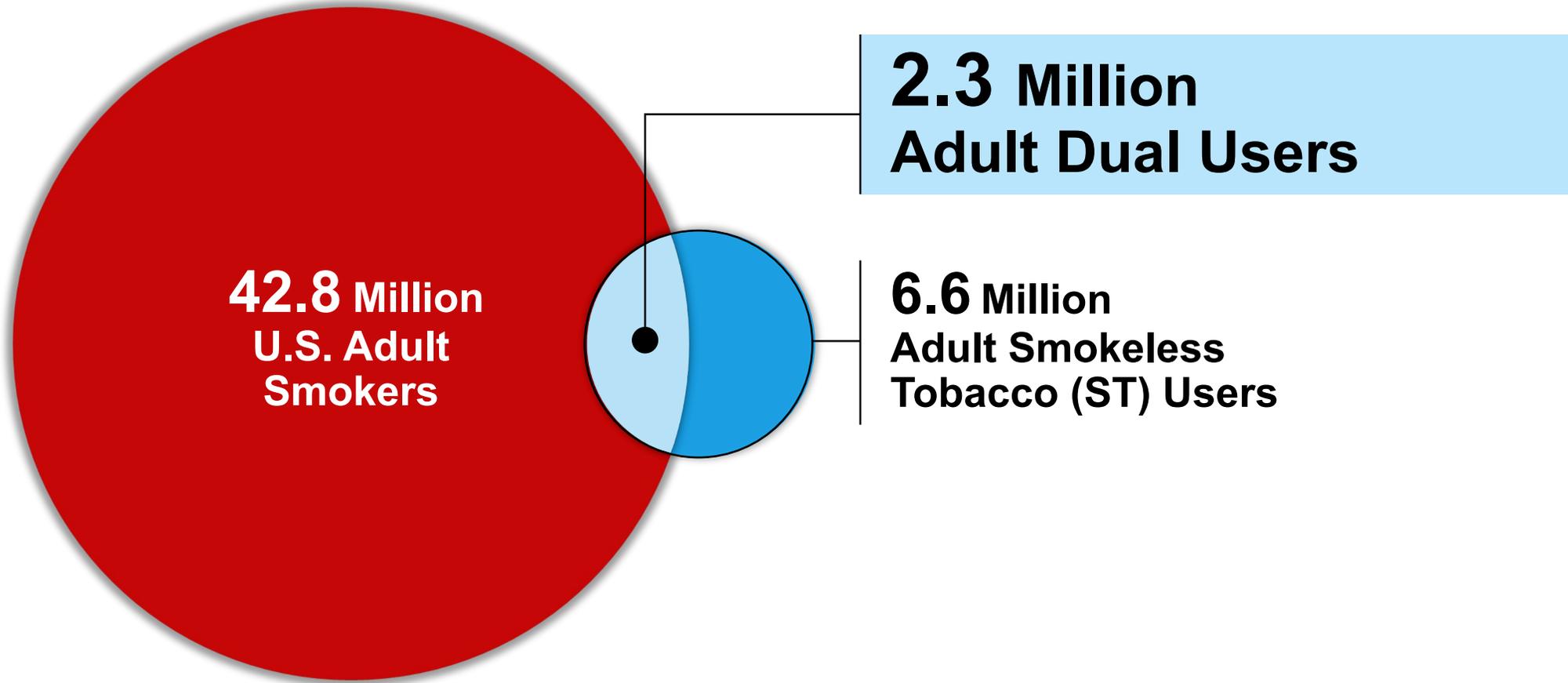
Switching completely to this product from cigarettes reduces risk of lung cancer.



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WARNING: This product can cause mouth cancer.

Adult Dual Users Present Logical Harm Reduction Opportunity

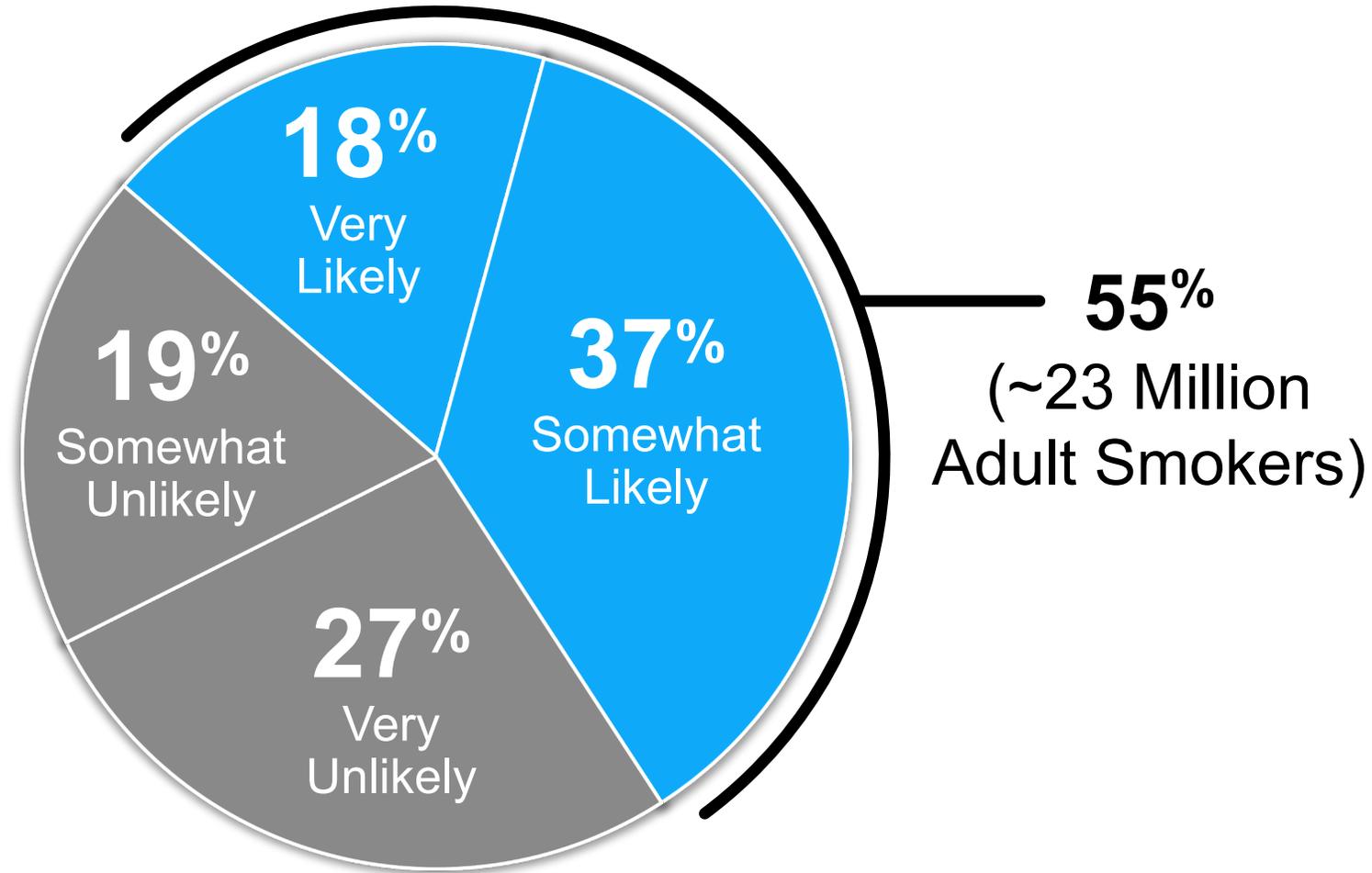


Based on ALCS analysis of PATH Wave 1 data Sep 12, 2013 – Dec 14, 2014.

Cigarette smokers include those who report having smoked at least 100 cigarettes in their lifetime and now smoking every day or some days.

Smokeless Tobacco users include those who report having used ST at least 20 times in their lifetime and now using ST every day or some days.

Over Half of All Adult Smokers Are Interested in Reduced-Risk Tobacco Products



Based on ALCS analysis of PATH Wave 1 data Sept 12, 2013 – Dec 14, 2014; Response to question – “If a tobacco product made a claim that it was less harmful to health than other tobacco products, how likely would you be to use that product?”

Numbers may not foot due to rounding.

MRTPA Addresses Statutory Requirements (§911(g)(1))

- **The candidate product, as it is actually used by consumers, will:**
 - A. Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and
 - B. Benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

Consumer Communications Standard

- **The information provided to consumers must be:**
 - ▶ Accurate
 - ▶ Not misleading
 - ▶ Supported by scientific evidence

Agenda

Jose Luis Murillo, J.D. Senior Vice President, Regulatory Affairs Altria Client Services	Introduction
Mohamadi Sarkar, M. Pharm, Ph.D., FCCP Fellow, Regulatory Affairs Altria Client Services	Scientific Evidence
Gary Harvey Vice President and Principal Consultant William E. Wecker Associates, Inc	Health Risk
Stephanie Plunkett, Ph.D. Senior Director, Perception and Behavior Research Altria Client Services	Claim Development and Testing
Ryan Black, Ph.D. Director, Regulatory Affairs Altria Client Services	Population Impact
Jose Luis Murillo, J.D. Senior Vice President, Regulatory Affairs Altria Client Services	Conclusion

Claim Complements Public Health Prevention and Cessation Strategies

Under FDA oversight, informing adult smokers about reduced-risk products will *complement, not compete* with, proven public health strategies focused on prevention and cessation

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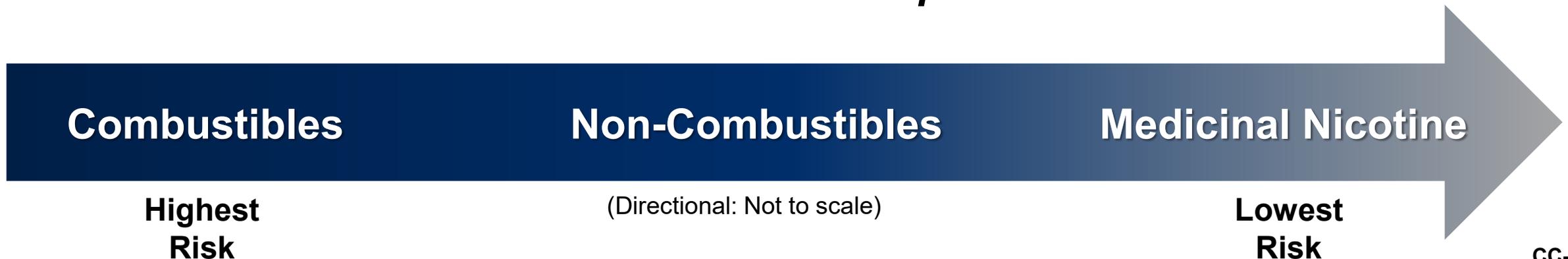
FDA Recognition of Continuum of Risk

Dr. Scott Gottlieb
FDA Commissioner

“[W]e must acknowledge that there’s a continuum of risk for nicotine delivery. That continuum ranges from combustible cigarettes at one end, to medicinal nicotine products at the other.”

“[W]e must also take a new and fresh look at the noncombustible side.”

“[P]olicies should account for changes that will move addicted smokers down that continuum of risk to...less harmful products.”



Proposed Claim

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**WARNING: This product can
cause mouth cancer.**

1

**Draws the attention of
adult smokers**

2

Single disease focus

Neither states nor implies that the product presents no risk of lung cancer or other disease

3

Desired single use behavior

Claim is for Adult Smokers

Adult Never-Users and Adult Smokers Planning to Quit did not show increased interest in the product

**IF YOU SMOKE,
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**WARNING: This product can
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Claim is for Adult Smokers

- **Correcting misperceptions will take time**
- **Comprehensive campaign directed to adult smokers**

**IF YOU SMOKE,
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WARNING: This product can cause gum disease and tooth loss.

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WARNING: This product can cause mouth cancer.

Claim is for Adult Smokers

- **Correcting misperceptions will take time**
- **Comprehensive campaign directed to adult smokers**
 - ▶ Print advertising
 - ▶ Direct mail
 - ▶ Copenhagen[®] branded website

**IF YOU SMOKE,
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WARNING: This product can cause mouth cancer.

Consumer Communications

Print Advertisements

Accompanied by the required rotational warnings

Limited to publications that meet the criteria of an “adult publication” under FDA’s definition

Federally Mandated Warnings

WARNING: This product can cause mouth cancer.

WARNING: This product can cause gum disease and tooth loss.

WARNING: This product is not a safe alternative to cigarettes.

WARNING: Smokeless tobacco is addictive.

Consumer Communications

Print Advertisements

Accompanied by the required rotational warnings

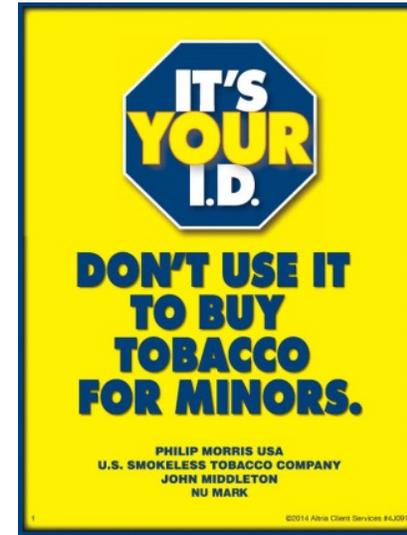
Limited to publications that meet the criteria of an “adult publication” under FDA’s definition

Direct Communications

- ✔ **We verify consumers’ age
*and***
- ✔ **Certify that they are smokers
and/or smokeless tobacco
users before they can receive
the communications**

UST Trade Programs and Youth Access Prevention

- Limit display of products to non-self-serve locations
- Train store personnel who sell tobacco products using We Card® or equivalent training
- Place retail signage that prohibits underage sales and tells adults not to buy tobacco products for underage use



Long History of Product Use



Description of Copenhagen[®] Snuff

- **Blend of 100% American-grown tobacco**
- **Water**
- **Salts**
- **Flavors**



Copenhagen[®] Snuff Use Patterns



- **“Pinch” between lip and gum for ~ 30-40 minutes**
- **Average consumption about one half of a can per day**

Copenhagen[®] Snuff Consumers



- **Consumers of Copenhagen[®] Snuff are, by and large:**
 - ▶ Adult white males
 - ▶ 35 years of age and older

Overview of Support for Authorization of Claim

- **Claim is supported by the scientific evidence**
- **Meets statutory standard for a claim**
- **Represents an important first step towards solving the dilemma faced by adult smokers**

Authorizing the Proposed Claim

- Provides adult smokers a reason to switch
- Offers facts to make an informed decision

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Scientific Evidence

Mohamadi Sarkar, M. Pharm, Ph.D., FCCP

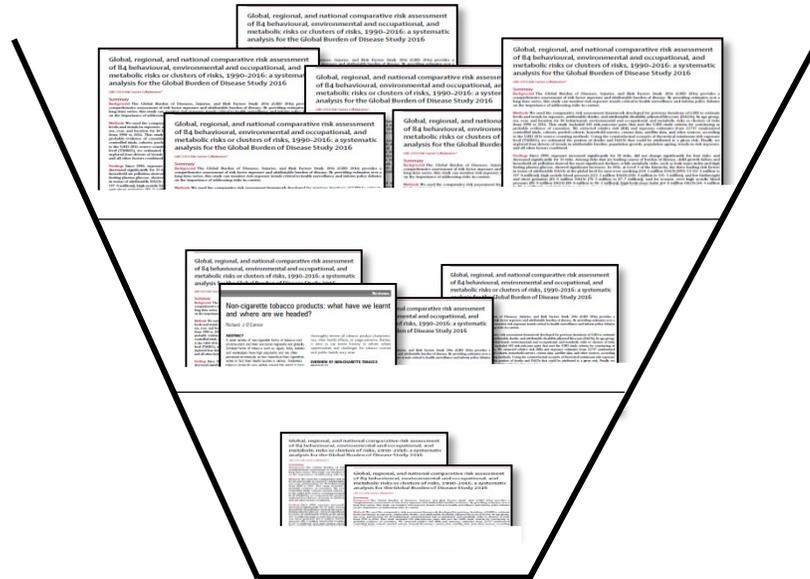
Fellow, Regulatory Affairs
Altria Client Services



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Comprehensive Scientific Review

~6,500 publications



~1,000 publications

Literature Review Protocol included inclusion/exclusion criteria based on published best practices¹

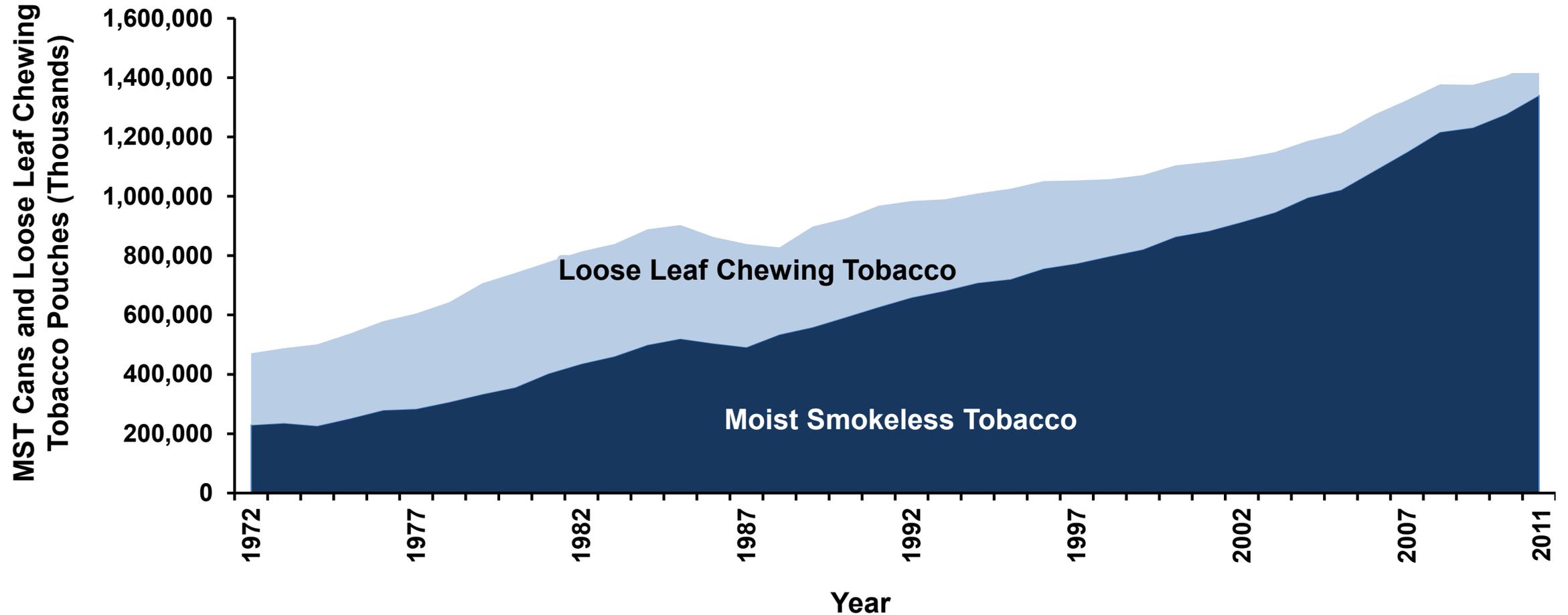
Inclusion	Original research, including secondary analyses and meta-analyses
	Reports from authoritative bodies (e.g., U.S. Surgeon General, IARC, etc.)
	Studies of smokeless tobacco products sold in the U.S.
Exclusion	Published in the English language
	Studies of smokeless tobacco products sold in other countries than the U.S.
	Studies of non-U.S. populations (e.g., Swedish snus epidemiology)
	Published in a foreign language

1. IOM Report “Finding What Works in Health Care: Standards for Systematic Reviews” (IOM, 2011), the Cochrane Handbook for Systematic Reviews of Interventions (Cochrane Collaboration, 2011), and the PRISMA Statement (Moher et al., 2009).

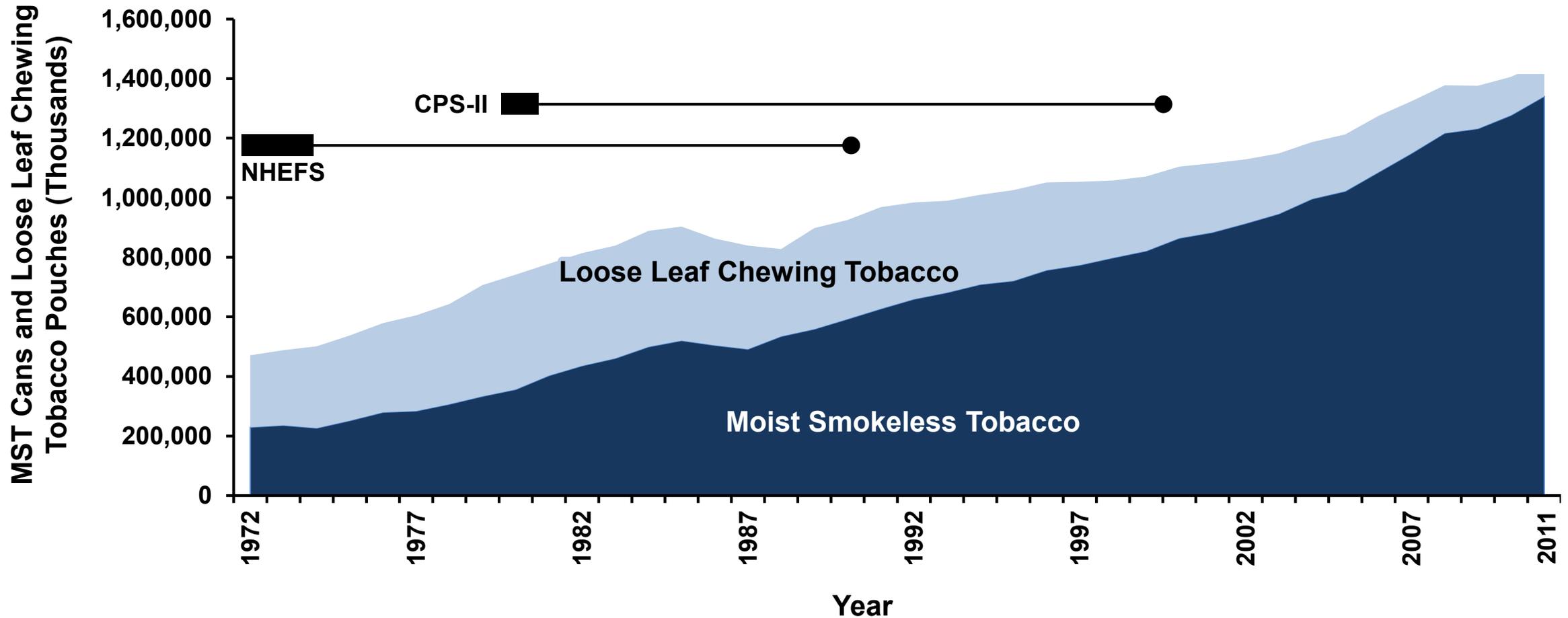
Review Covered Diverse Array of Health Topics

- **Epidemiology**
- **Clinical**
- **Nonclinical**
 - ▶ Tobacco or tobacco extracts
 - ▶ Specific tobacco constituents

Applicability of Epidemiology



Moist Smokeless Tobacco Was the Predominant Form During Epidemiology Studies

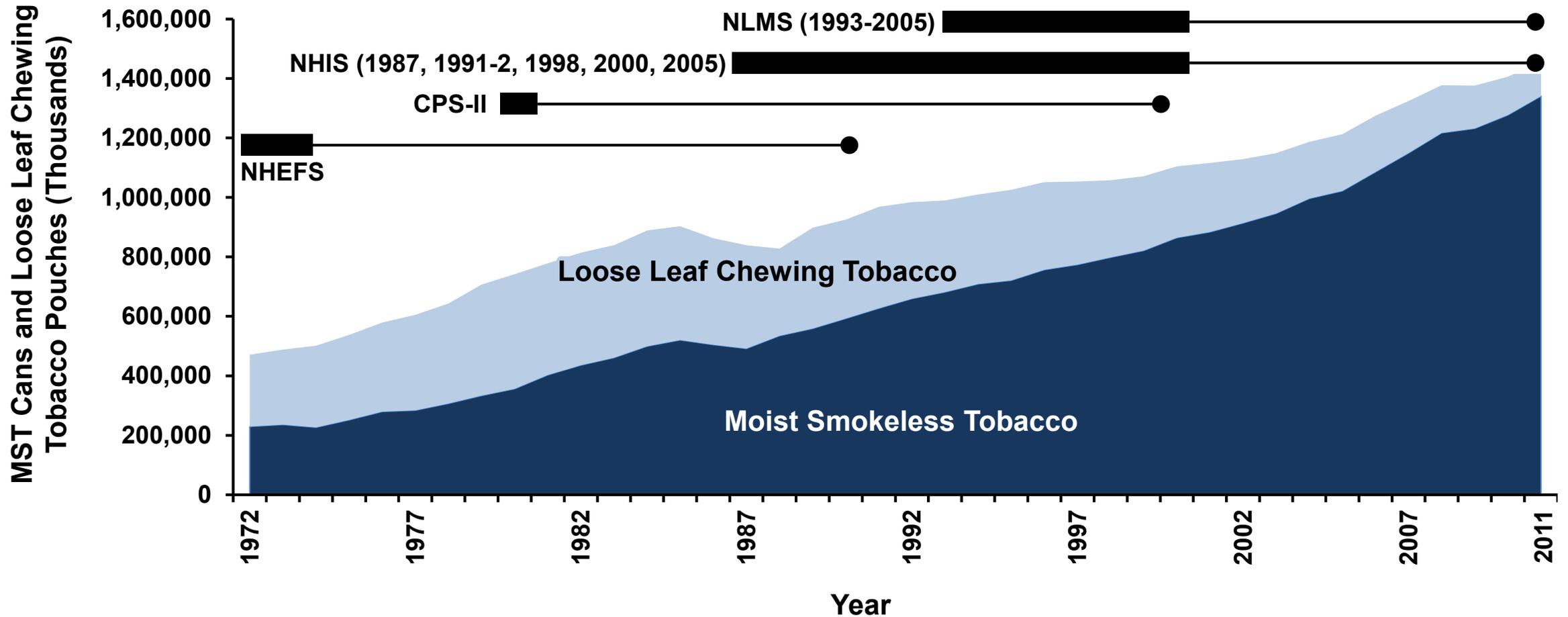


Unit volume of moist smokeless tobacco and loose leaf chewing tobacco derived from Maxwell Reports 1972-2011

CPS-II = Cancer Prevention Study - II; NHEFS = NHANES-I Epidemiologic Follow-up Study

Black boxes represent the baseline periods for studies and black circles represent the end of follow-up period

Moist Smokeless Tobacco Was the Predominant Form During Epidemiology Studies

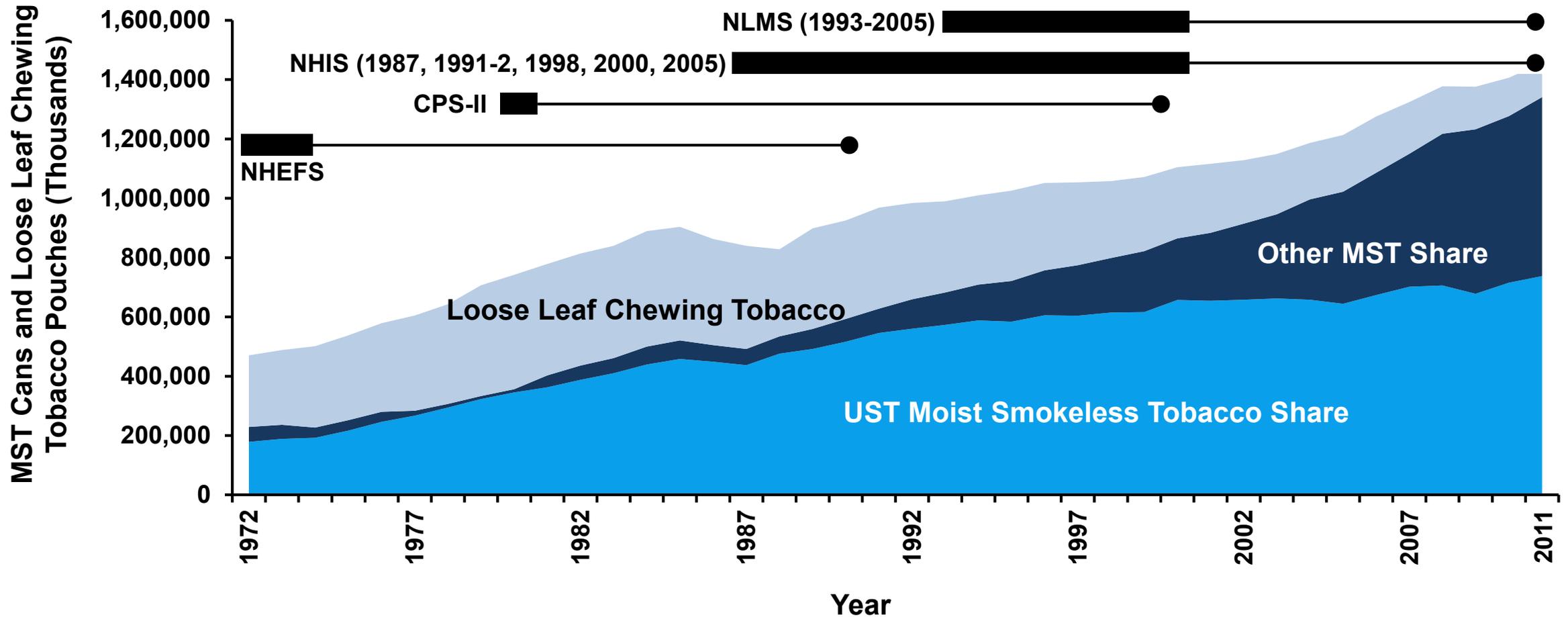


Unit volume of moist smokeless tobacco and loose leaf chewing tobacco derived from Maxwell Reports 1972-2011

NHIS = National Health Interview Survey; NLMS = National Longitudinal Mortality Study; CPS-II = Cancer Prevention Study – II; NHEFS = NHANES-I Epidemiologic Follow-up Study

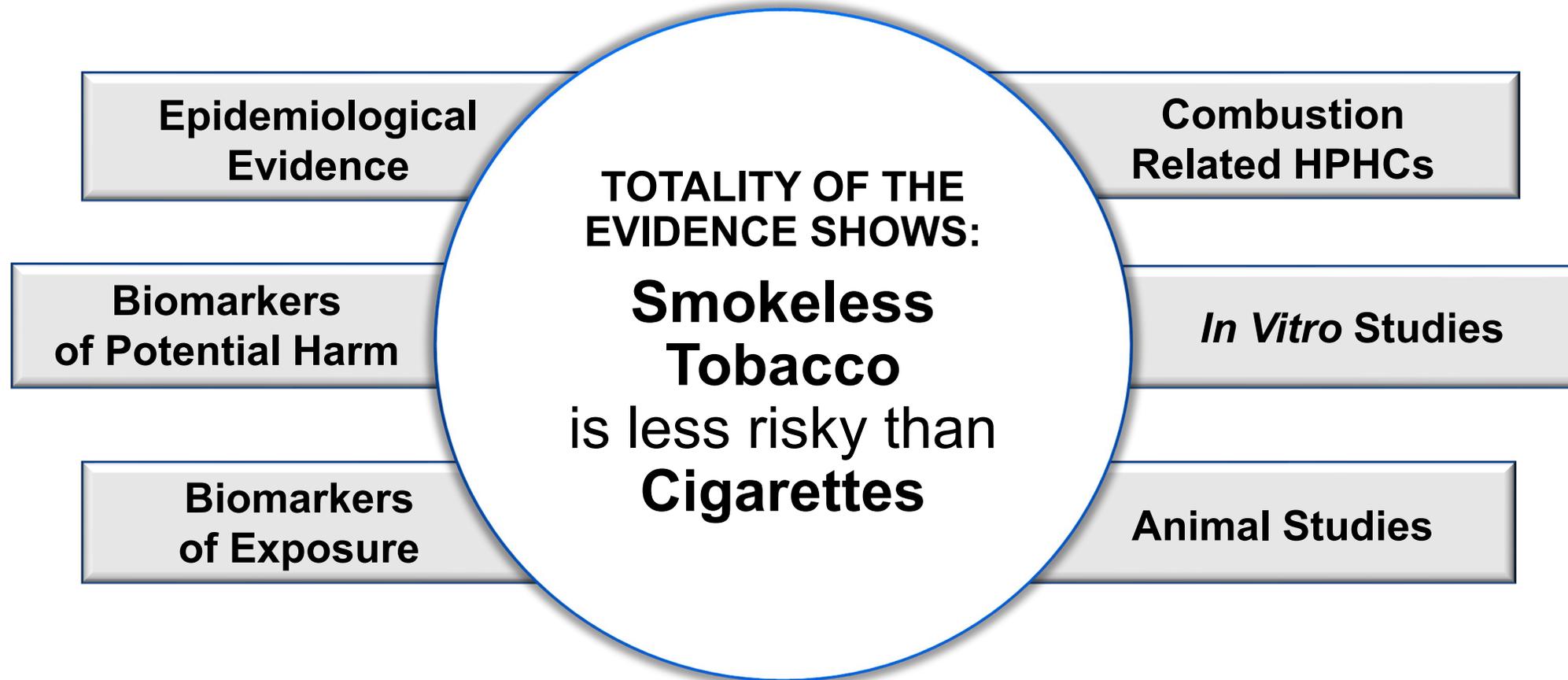
Black boxes represent the baseline periods for studies and black circles represent the end of follow-up period

Copenhagen[®] Snuff Was One of the Major Products Consumed During Epidemiology Studies



Unit volume of moist smokeless tobacco and loose leaf chewing tobacco derived from Maxwell Reports 1972-2011; UST volumes based on historical shipment data
 NHIS = National Health Interview Survey; NLMS = National Longitudinal Mortality Study; CPS-II = Cancer Prevention Study – II; NHEFS = NHANES-I Epidemiologic Follow-up Study
 Black boxes represent the baseline periods for studies and black circles represent the end of follow-up period

Multiple Lines of Evidence



Smokeless Tobacco is Less Hazardous than Cigarettes – *Public Health Consensus*

“On the continuum of risk, non-combustible tobacco products are more likely to reduce harm than a smoked form of tobacco for individuals who would otherwise be using conventional cigarettes.”

Source: Zeller, Hatsukami *et al.*, *The Strategic Dialogue on Tobacco Harm Reduction: a vision and blueprint for action in the US*. Tobacco Control, 18(4), 324-332, 2009

“Spit or smokeless tobacco is a less lethal, but still unsafe, alternative to smoking.”

Source: American Cancer Society Website. “Health Risks of Smokeless Tobacco” (Last accessed Feb. 4, 2019)

“[U]sers of smokeless tobacco products generally have lower risks for tobacco-related morbidity and mortality than users of combustible tobacco products such as cigarettes.”

Source: WHO Study Group on Tobacco Product Regulation (TobReg), *The Scientific Basis of Tobacco Product Regulation*, 951 WHO Technical Reports Series (2008)

Health Risk of Copenhagen® Snuff

Gary Harvey

Vice President and Principal Consultant
William E. Wecker Associates, Inc.



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Key Questions

- Do smokeless tobacco users have the same or lower lung cancer risks compared to current smokers?
- Do smokeless tobacco users have the same or lower all-cause and all-cancer mortality risks compared to current smokers?

Linked Mortality Analysis: Based on Nationally Representative Epidemiology



National Health Interview Survey

National Longitudinal Mortality Study

Based on the Current Population Survey

1987 – 2005
(intermittent)

Survey Years

1993 – 2005

154,391

Total Respondents

210,090

3,006

Smokeless Tobacco Users

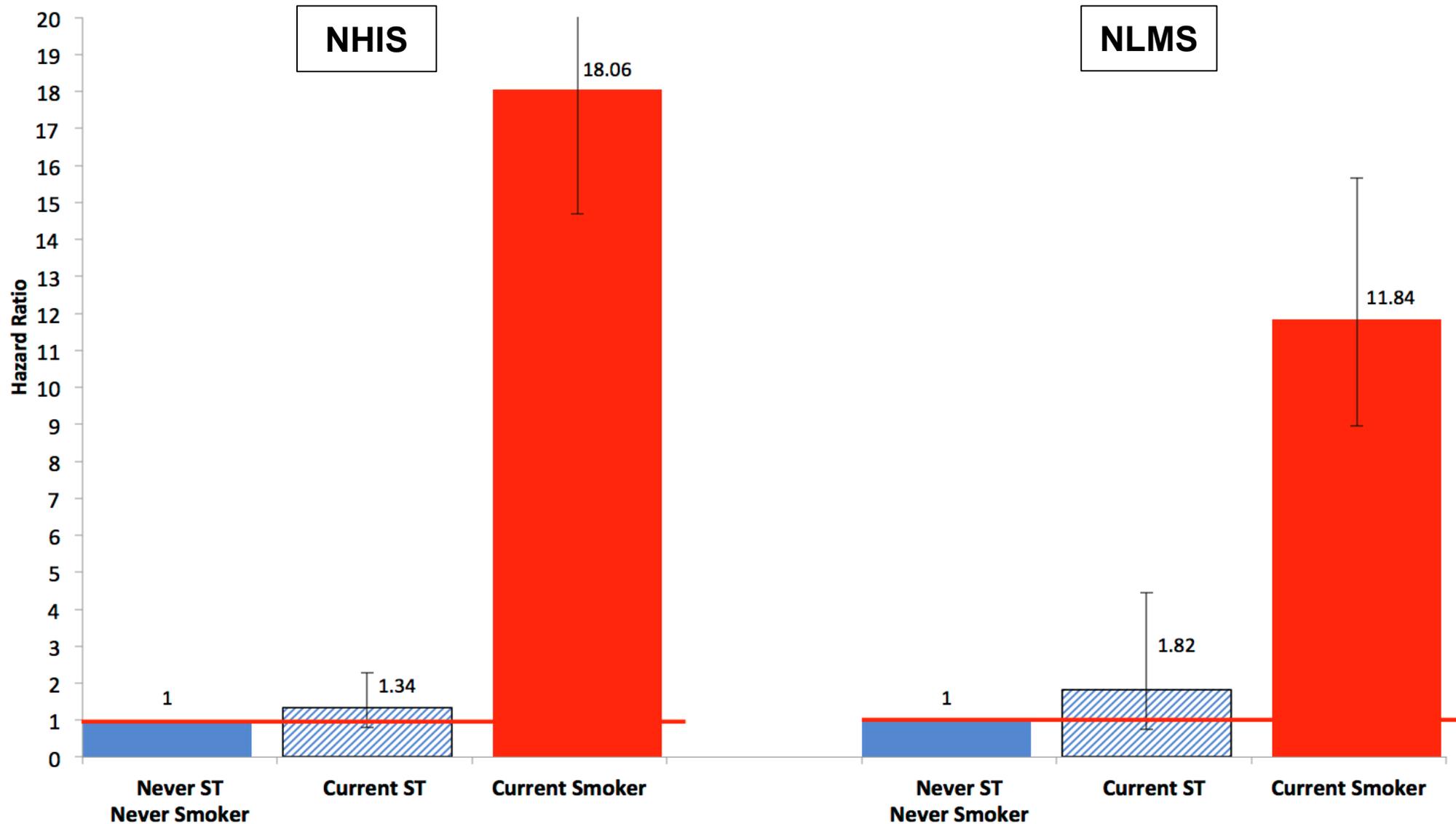
3,492

Two nationally representative public health surveys linked to the National Death Index (2011 update)*

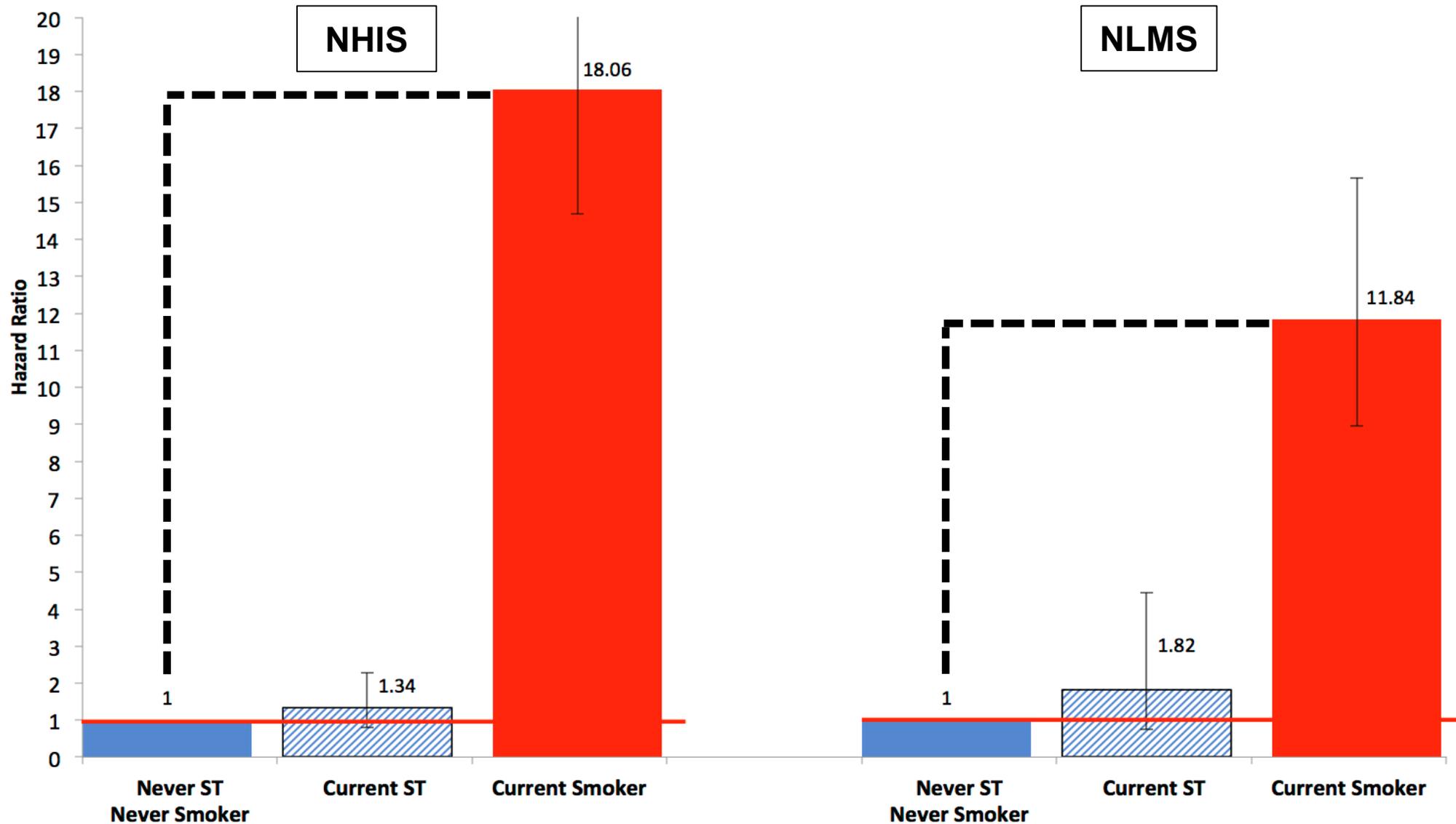
*Mortality outcomes available through linkage to the National Death Index (NDI) available from the National Center for Health Statistics

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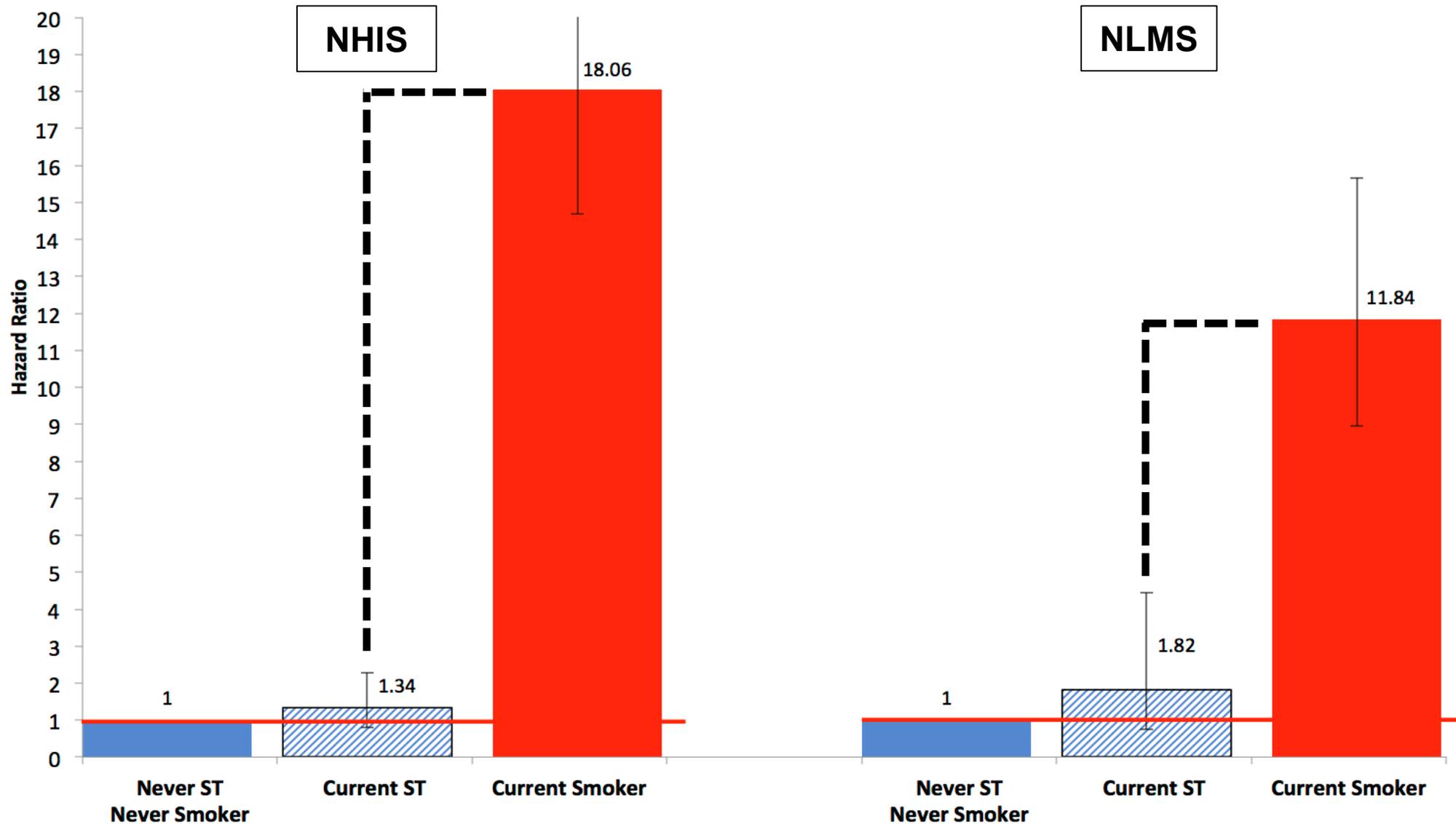
Lung Cancer Mortality Risks



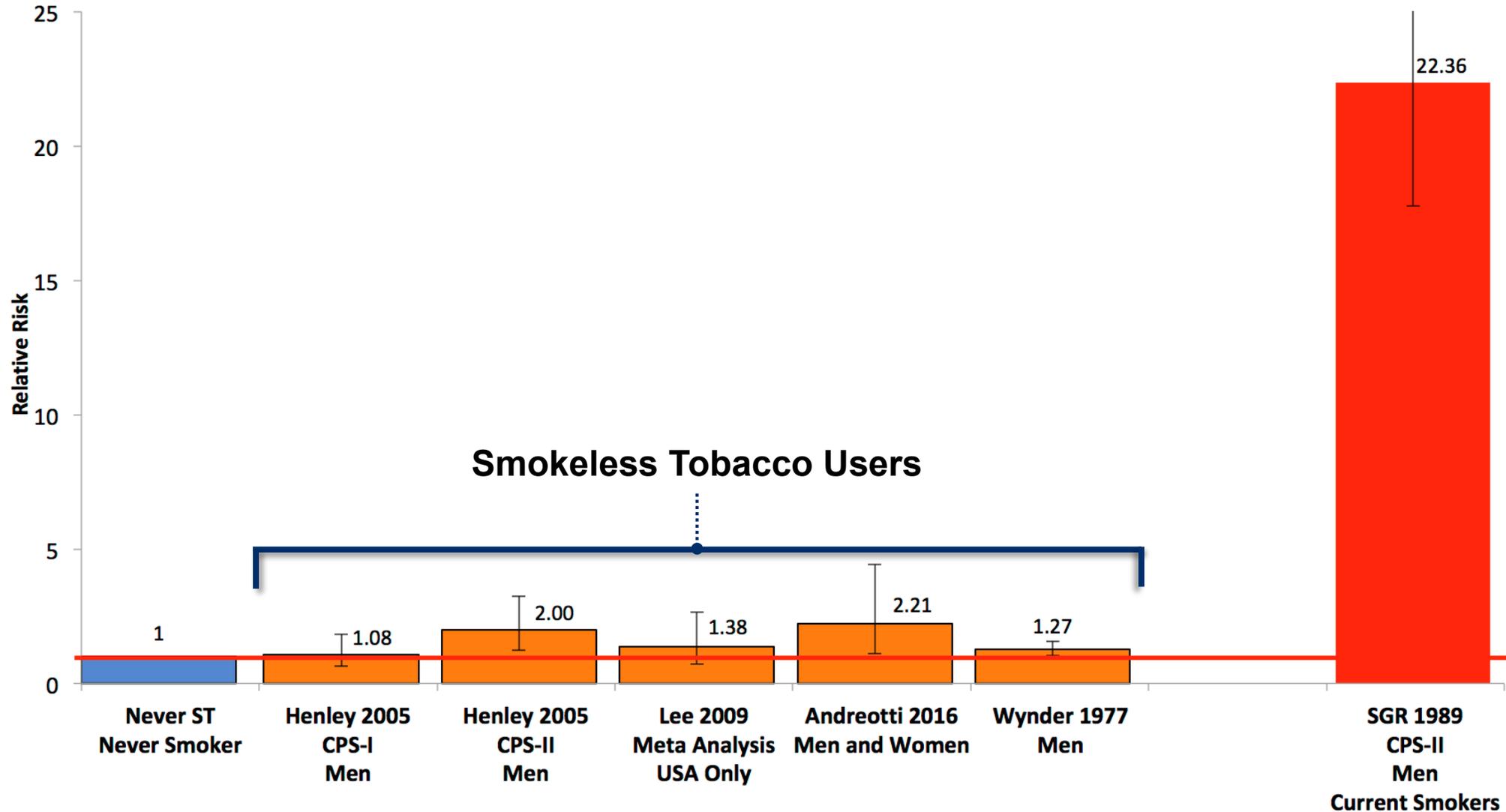
Lung Cancer Mortality Risks



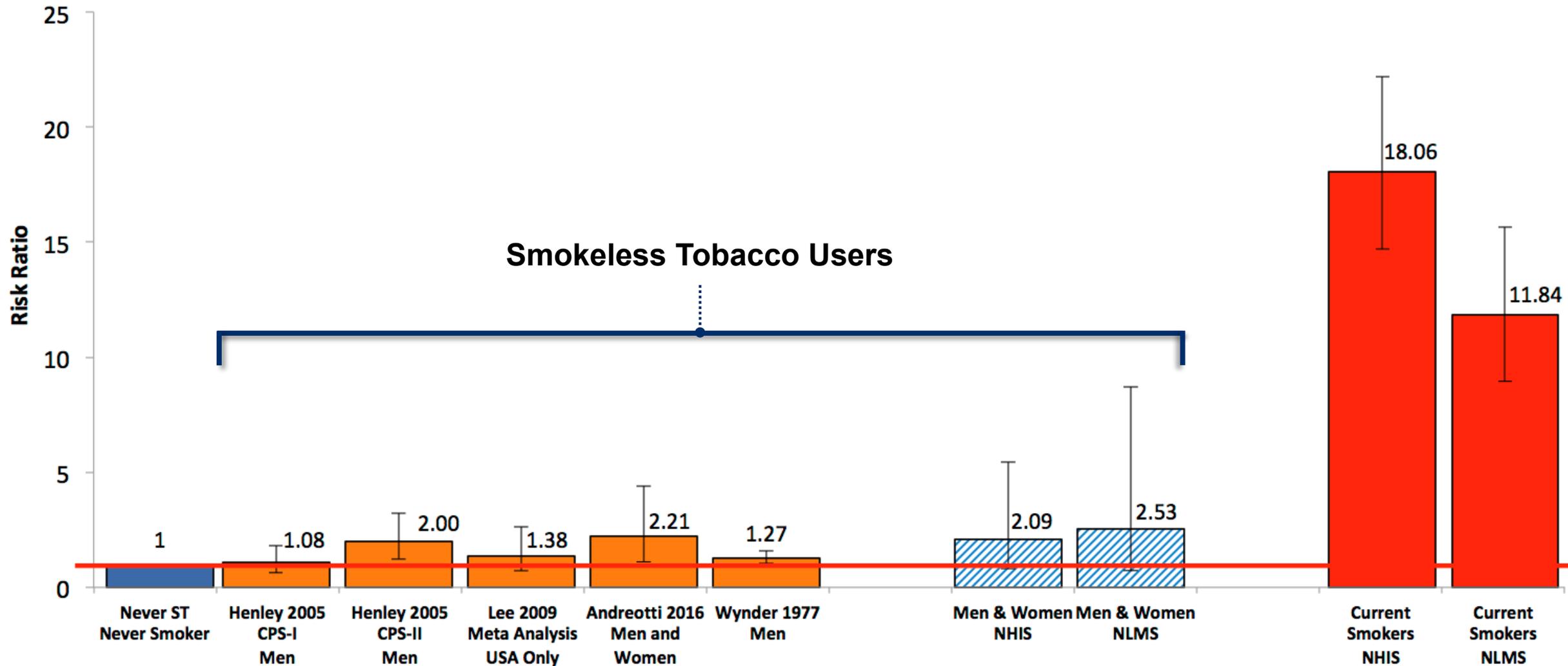
Lung Cancer Mortality Risks



Lung Cancer Mortality Risks

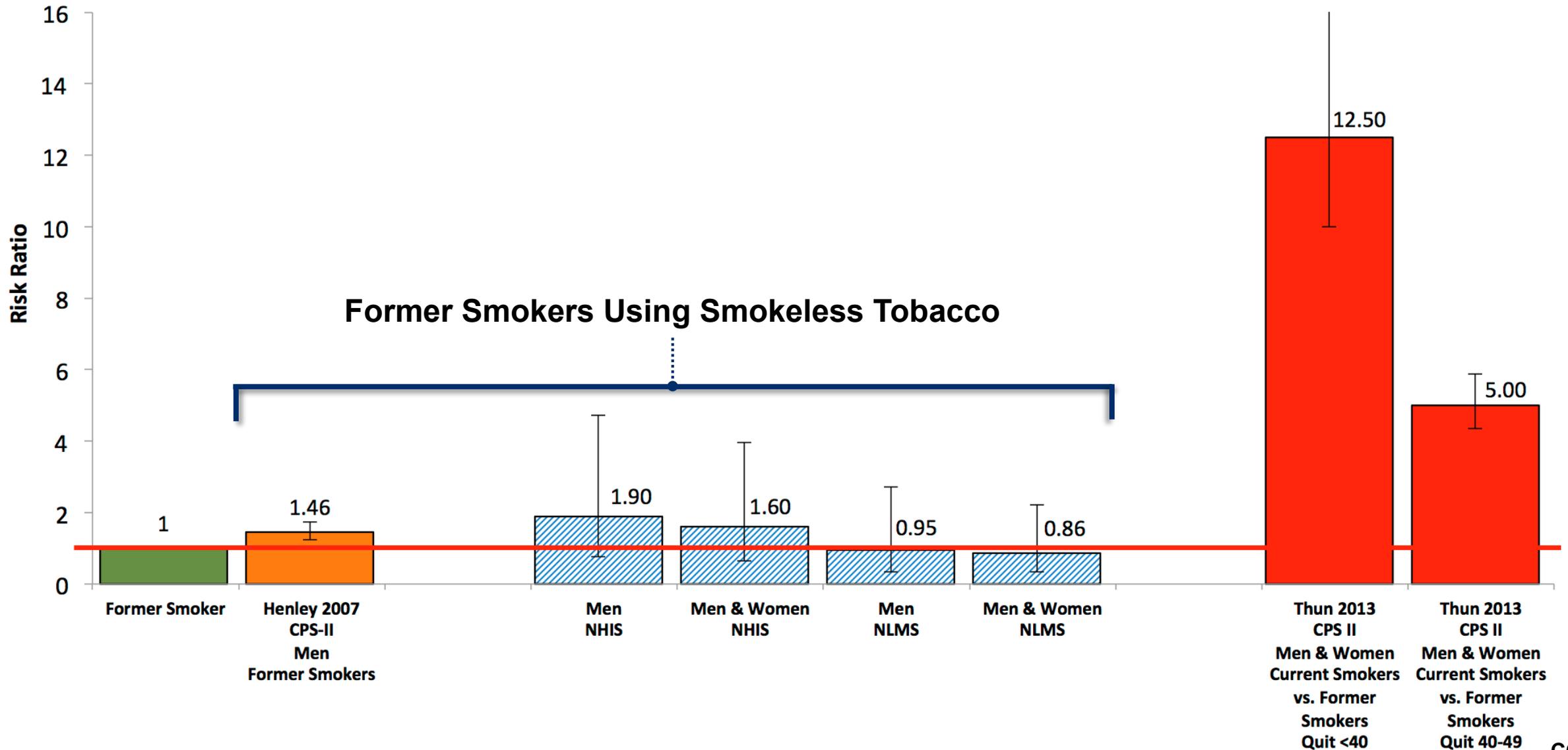


Lung Cancer Mortality Risks

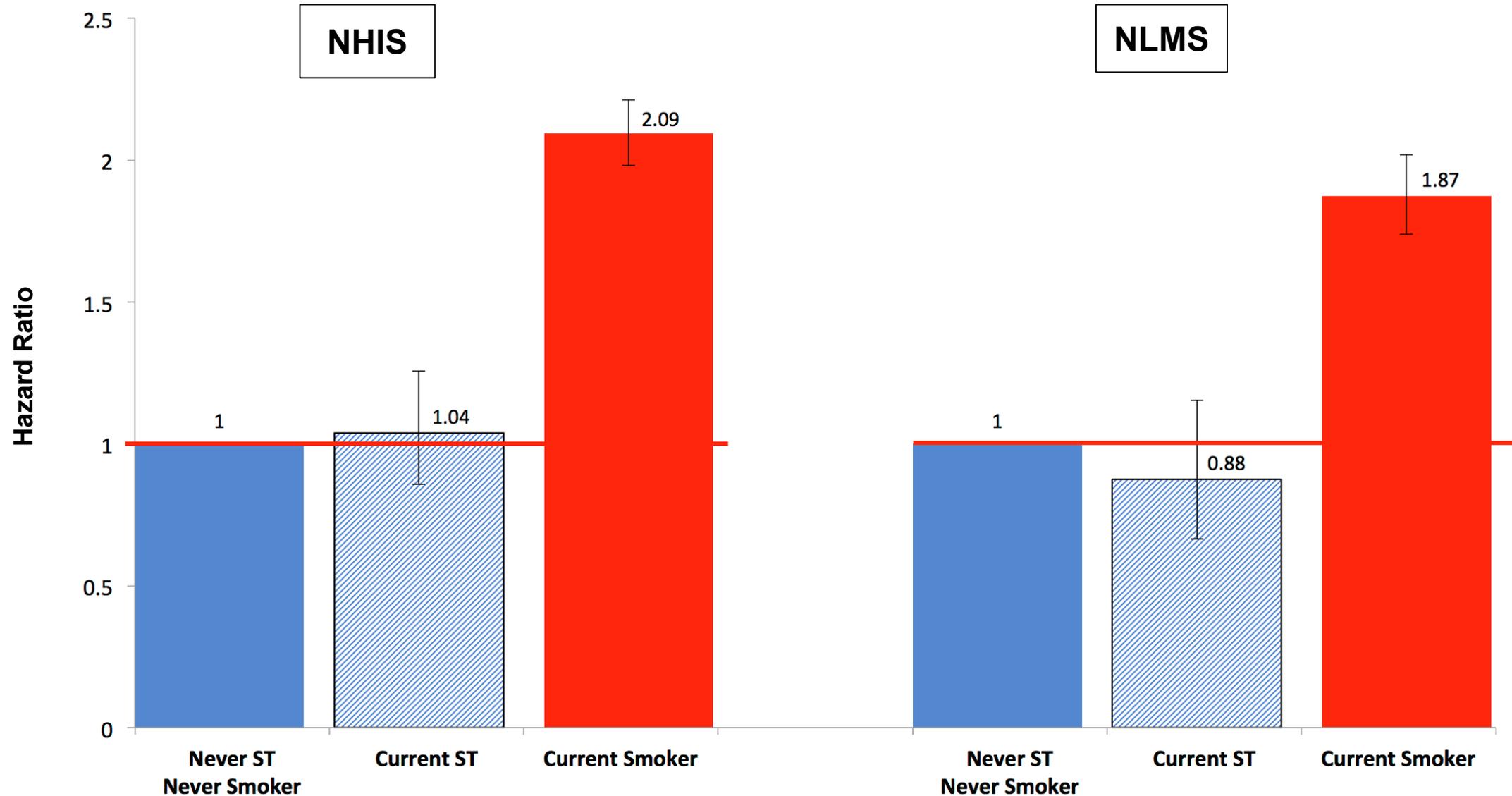


Andreotti 2016 and Wynder 1977 included mortality and lung cancer "incidence".

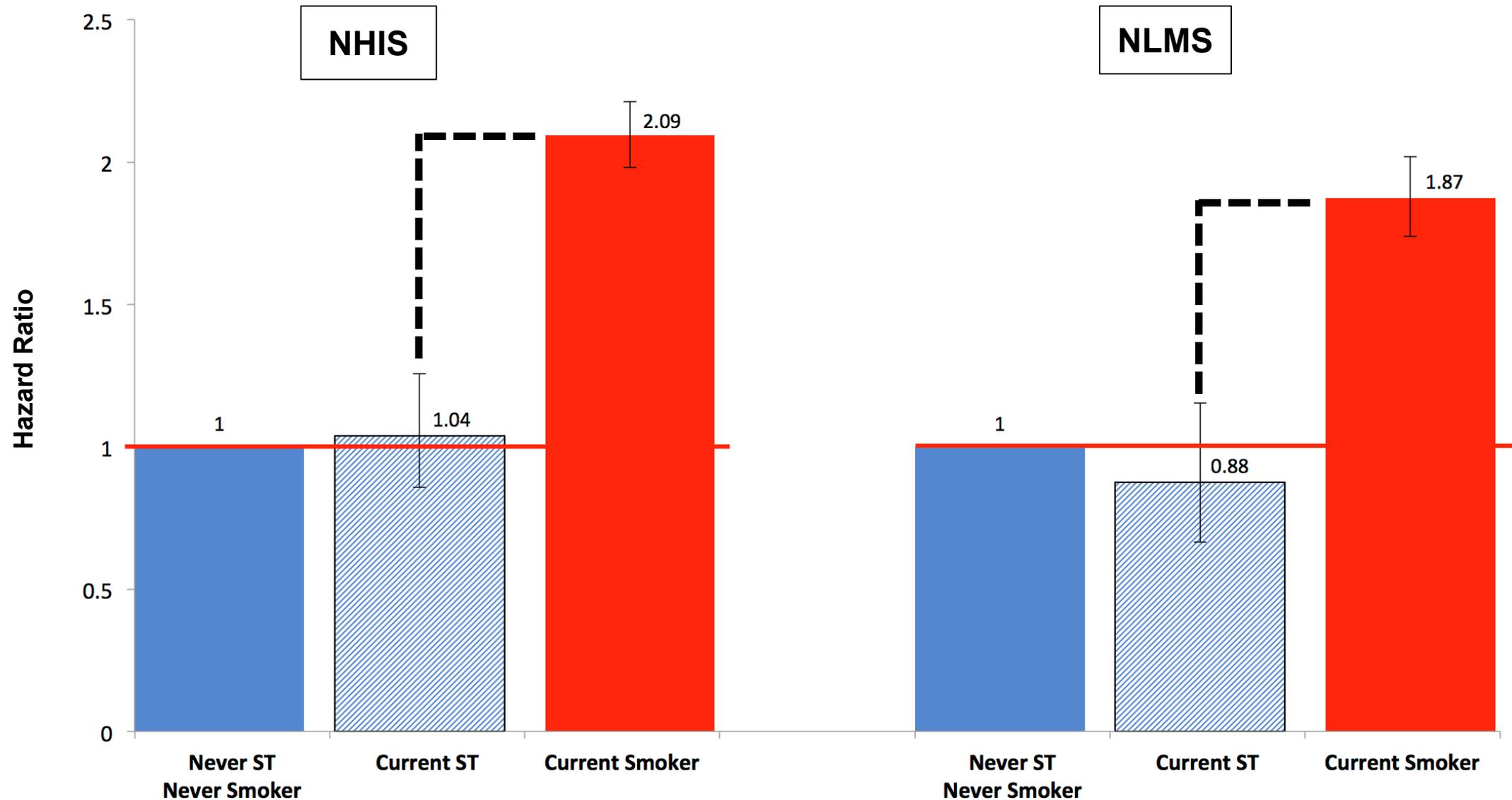
Lung Cancer Mortality Risks Among Former Smokers



All-Cause Mortality Risks



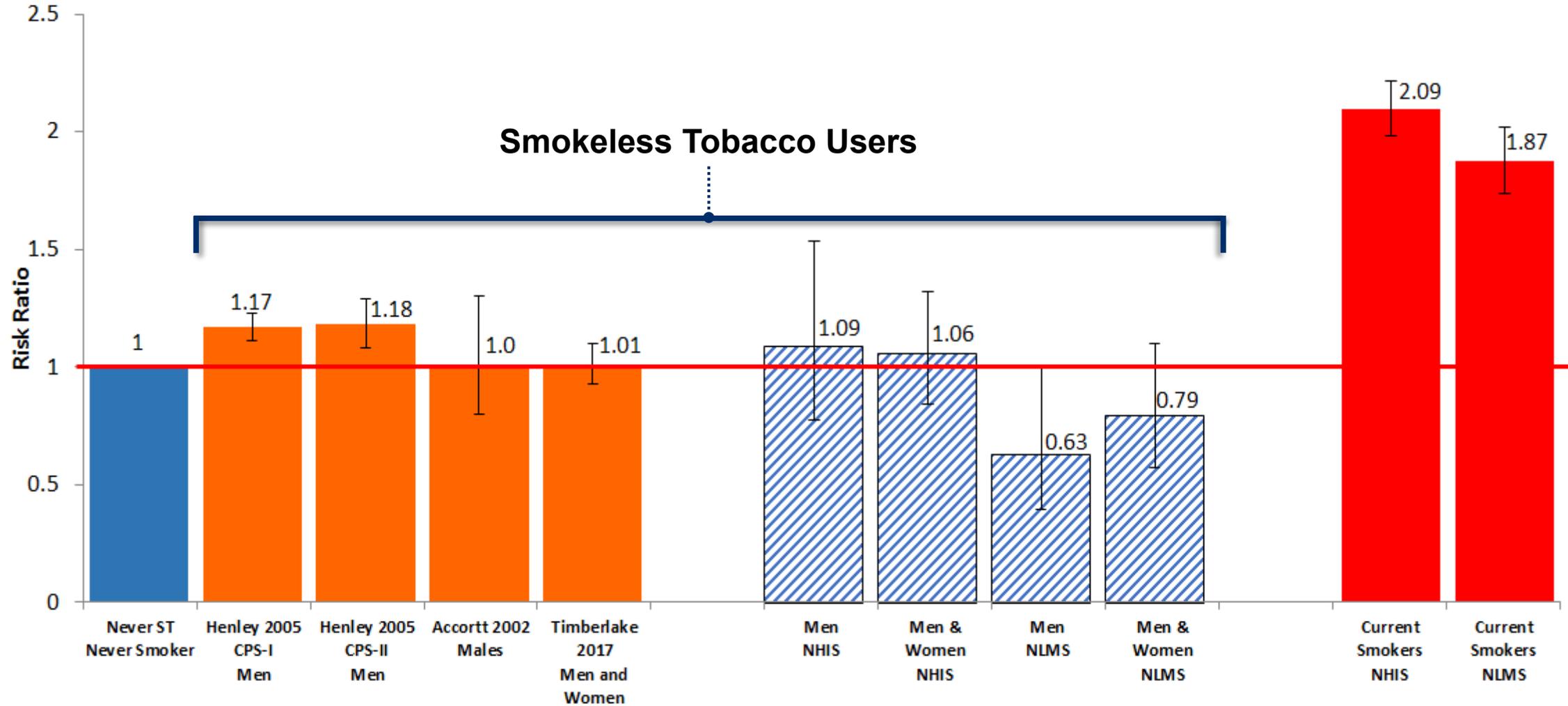
All-Cause Mortality Risks



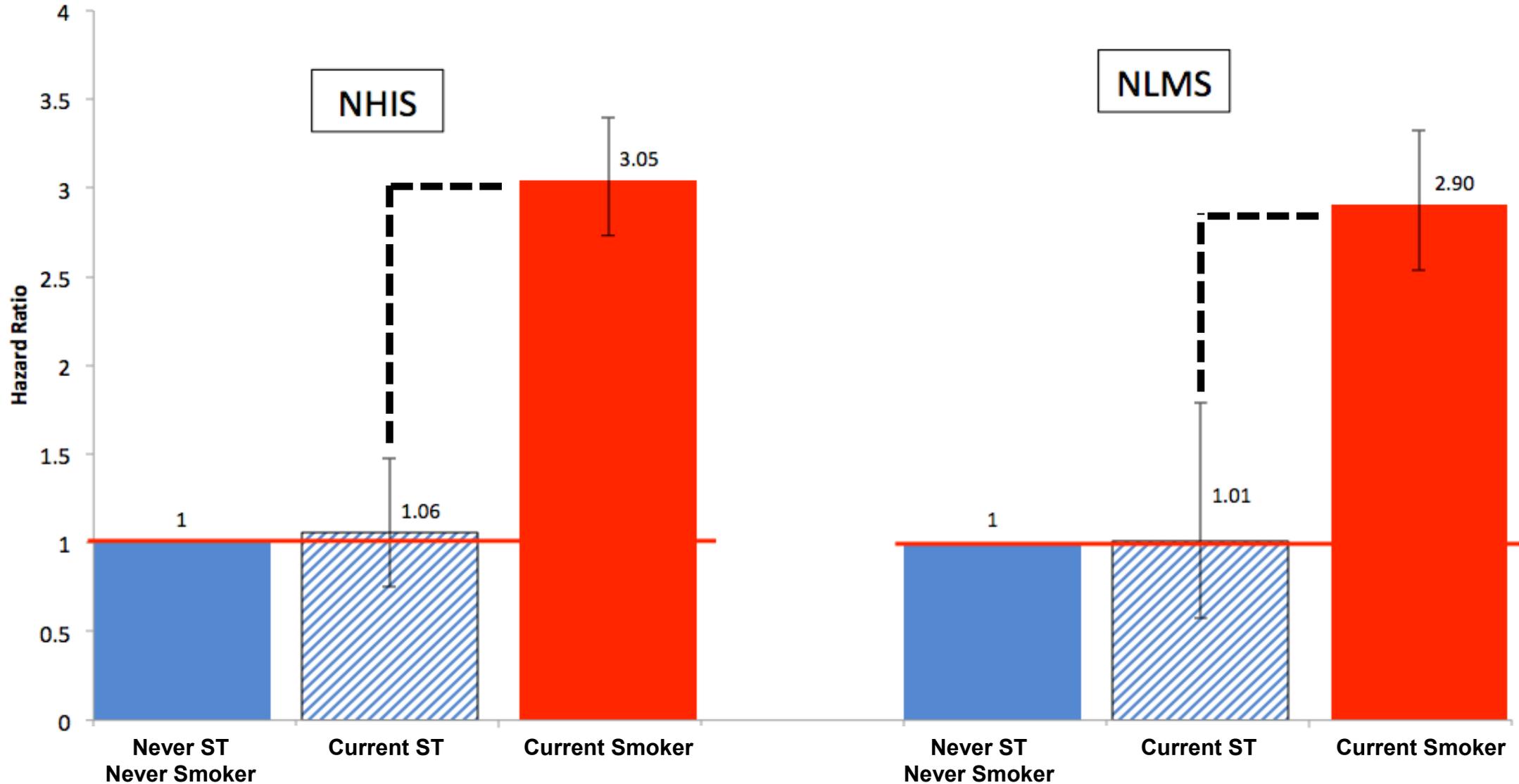
Linked Mortality Sensitivity Analyses

- **Men and women**
- **All races and white only**
- **Other causes of death beyond lung cancer, all-cause, and all-cancer**
- **Alternative model specifications and control variables**
- **None of these sensitivity analyses importantly impacted the conclusions**

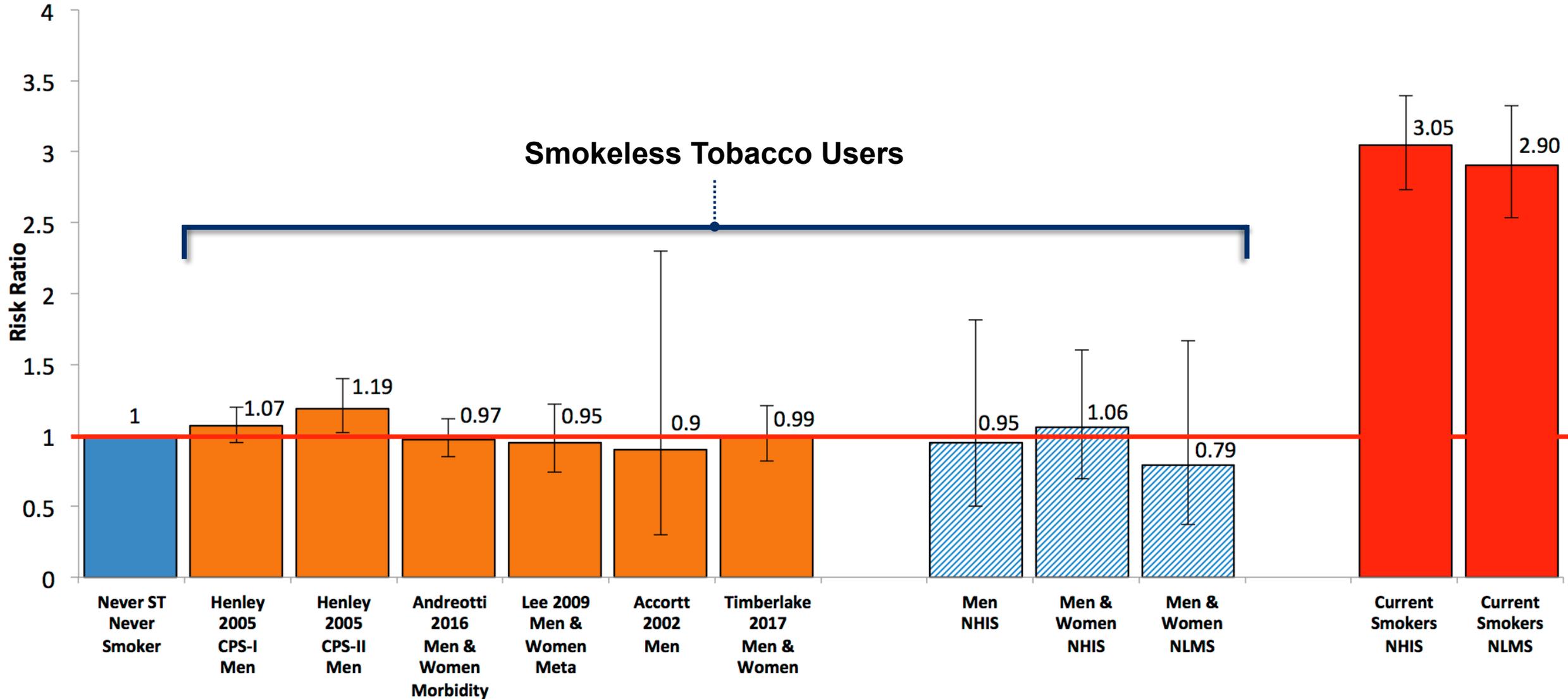
All-Cause Mortality Risks



All-Cancer Mortality Risks



All-Cancer Mortality



Andreotti 2016 includes "Cancer incidence", Lee 2009 includes "death" and "incidence".

Key Takeaways – Health Risk

- **Smoking cigarettes dramatically increases the risks of lung cancer, all-cause mortality and all-cancer**
- **If current smokers quit smoking, then their risks are dramatically reduced**
- **Smokeless tobacco users' risk of lung cancer is statistically significantly lower than that of current smokers**

Copenhagen[®] Snuff Claim Development and Testing

Stephanie Plunkett, Ph.D.

Senior Director, Perception and Behavior Research
Altria Client Services



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Presentation Overview

- **Behavioral theory**
- **Claim development and testing**
- **Claim comprehension and risk perception findings**
- **Impact of the claim on behavioral intentions**

Presents a Dilemma and an Opportunity

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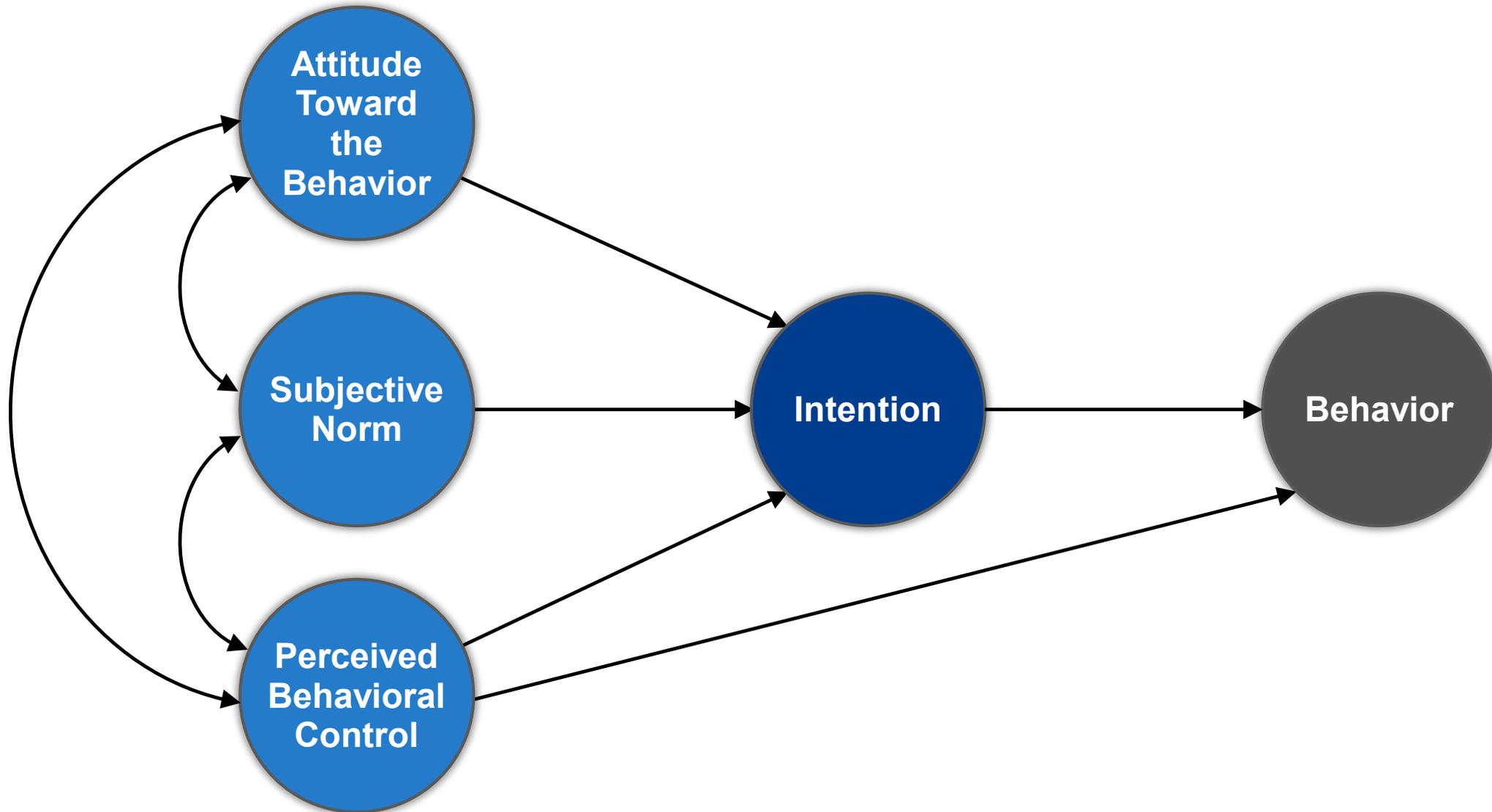
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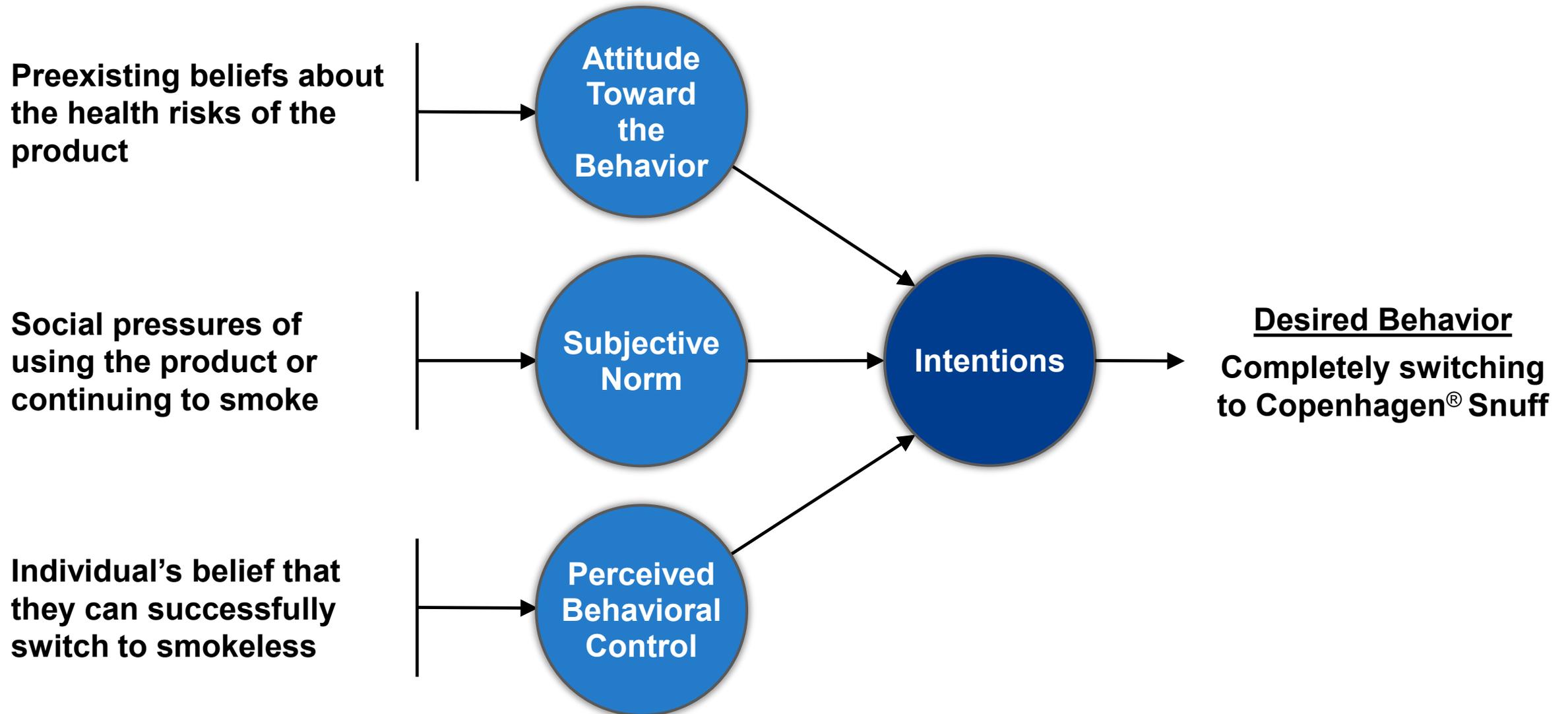
Presentation Overview

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Ajzen's Theory of Planned Behavior



Applied Theory of Planned Behavior and Switching



Misperceptions of Smokeless Tobacco Health Risk Published Literature

Borland et al. *Harm Reduction Journal* 2012, 9:19
http://www.harmreductionjournal.com/content/9/1/19



RESEARCH Open Access

Effects of a Fact Sheet on beliefs about the harmfulness of alternative nicotine delivery systems compared with cigarettes

Ron Borland^{1,2*}, Lin Li¹, K Michael Cummings², Richard O'Connor³, Kevin Mortimer⁴, Tom Wikmans⁵, Lars Ramstrom⁶, Bill King¹ and Ann McNeill⁷

Abstract

Background: This study examined the effects of a fact sheet on beliefs about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes. The fact sheet was developed to address common misperceptions about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes. The fact sheet was distributed to 1000 smokers in Australia, Canada, the United Kingdom, and the United States. The fact sheet was found to be effective in reducing misperceptions about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes. The fact sheet was found to be effective in reducing misperceptions about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes. The fact sheet was found to be effective in reducing misperceptions about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes.

Borland et al. *Harm Reduction Journal* 2011, 8:21
http://www.harmreductionjournal.com/content/8/1/21



RESEARCH Open Access

Trends in beliefs about the harmfulness and use of stop-smoking medications and smokeless tobacco products among cigarettes smokers: Findings from the ITC four-country survey

Ron Borland^{1*}, Jae Cooper¹, Ann McNeill², Richard O'Connor³ and K Michael Cummings³

Abstract

Background: This study examined the trends in beliefs about the harmfulness and use of stop-smoking medications and smokeless tobacco products among cigarettes smokers. The study was conducted in Australia, Canada, the United Kingdom, and the United States. The study was found to be effective in reducing misperceptions about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes. The study was found to be effective in reducing misperceptions about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes. The study was found to be effective in reducing misperceptions about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes.

Nicotine & Tobacco Research Volume 9, Number 9 (September 2007) 977-982



Brief report

Harm perception of nicotine products in college freshmen

Stephanie Y. Smith, Barbara Curbow, Frances A. Stillman

Received 9 February 2006; accepted 9 October 2006

Abstract

This study examined the association of sociodemographic characteristics and smoking behaviors (i.e., cigarette, cigar, and waterpipe) with nicotine product harm perception in college freshmen. Students were asked to compare the perceived harmfulness of 11 nicotine-delivering products with that of a regular cigarette. Data were from a survey of 1,000 college freshmen in the United States. The study was found to be effective in reducing misperceptions about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes. The study was found to be effective in reducing misperceptions about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes. The study was found to be effective in reducing misperceptions about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes.

Communicating accurate risk information is key

Background: The majority of harm from tobacco use comes from combusted forms; that is, from the dirty delivery system, not the nicotine. Some forms of smokeless tobacco (ST) are less harmful than others [1,2], with some existing smokeless products still very harmful (albeit less harmful than smoking) such as oral tobacco products used in South Asia and Sudan [3]. This is because they contain high levels of toxicants, often produced during the manufacturing, curing and storage process. However, when concerted efforts to reduce the levels of known carcinogens in smokeless tobacco (ST) are made, the products can be much less harmful [4,5]. If it seems plausible that such products could be even less harmful [5], it is important to know what tobacco users believe about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes. The fact sheet was developed to address common misperceptions about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes. The fact sheet was distributed to 1000 smokers in Australia, Canada, the United Kingdom, and the United States. The fact sheet was found to be effective in reducing misperceptions about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes. The fact sheet was found to be effective in reducing misperceptions about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes. The fact sheet was found to be effective in reducing misperceptions about the relative harmfulness of alternative nicotine delivery systems compared with cigarettes.

Background

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Original Article

Evaluation of modified risk claim advertising formats for Camel Snus

Brian V Fix^a, Sarah E Adkison^a, Richard J O'Connor^b, Maansi Bansal-Travers^a, K Michael Cummings^a, Vaughan W Rees^c and Dorothy K Hatsukami^d

Abstract

Objectives: The US Food and Drug Administration (FDA) has regulatory authority for modified risk tobacco product advertising claims. To guide future regulatory efforts, we investigated how variations in modified risk claim advertisements influence consumer perceptions of product risk claims for Camel Snus. **Methods:** Young people and adults (15-65), including current, never, and former smokers, were randomised to view one of five Camel Snus print advertisements as part of a web-based survey. Four of the advertisements presented information related to nitrosamine content of snus using four formats: (1) text, (2) a bar chart, (3) a text/testimonial and (4) a bar chart/testimonial. The fifth format, used as a control, was a current advertisement for Camel Snus without the explicit claims made about nitrosamine content. After viewing advertisements for all products, participants were asked which product they would be most interested in trying. **Results:** Participants exposed to advertisements that contained an explicit reduced risk message agreed the advertising claim for that product posed fewer health risks than cigarettes. However, advertisements containing the reduced risk messages were also viewed as containing less truthful information and respondents

Nicotine & Tobacco Research Volume 9, Number 10 (October 2007) 1033-1042



Original Article

Smokers' beliefs about the relative safety of other tobacco products: Findings from the ITC Collaboration

Richard J. O'Connor, Ann McNeill, Ron Borland, David Hammond, Bill King, Christian Boudreau, K. Michael Cummings

Received 19 May 2006; accepted 26 November 2006

Abstract

Most tobacco control efforts in western countries focus on the factory-made, mass-produced (FM) cigarette, whereas other tobacco products receive relatively little attention. Noncombusted tobacco products (i.e., referred to as smokeless tobacco), particularly Swedish-style snus, carry lower disease risks, compared with combusted tobacco products such as cigarettes. In this context, it is important to know what tobacco users believe about the relative harmfulness of various types of tobacco products. Data for this study came from random-digit-dialed telephone surveys of current smokers aged 18 or older in Australia, Canada, the United Kingdom, and the United States. Three waves of data, totaling 13,322 individuals, were assessed. Items assessed use of and beliefs about the relative harms of cigars, pipes, smokeless tobacco, and FM and roll-your-own cigarettes, as well as sociodemographics and smoking behaviors. Cigars (2.8%–12.7%) were the other tobacco products most commonly used by current cigarette smokers, followed by pipes (0.3%–2.1%) and smokeless tobacco (0.0%–2.3%). A significant minority of smokers (12%–21%) used roll-your-own cigarettes at least some of the time. About one-quarter of smokers believed that pipes, cigars, or roll-your-own cigarettes were safer than FM cigarettes, whereas only about 13% responded correctly that smokeless tobacco was less hazardous than cigarettes. Multivariate analyses showed that use of other tobacco products was most strongly related to beliefs about the reduced harm of these other products. Use of other tobacco products was low but may be growing among smokers in the four countries studied. Smokers are confused about the relative harms of tobacco products. Health education efforts are needed to correct smoker misperceptions.

The current marketplace offers a diverse and delivering products. The promotion of a "harm reducing" nicotine product may provide incentives for experimentation and initiation (Hughes, 1998). A consumer's decision to use a particular product is influenced by perceptions of the product's perceived harm and safety (Stratton et al., 2001). Typically information about product safety and harmfulness is relayed to consumers through marketing. Based on these marketing efforts, consumers formulate correct and incorrect beliefs about the product that affect their decision-making process (McGuire, 1972). Tobacco industry documents reveal that persons aged 18-24 years constitute the largest segment of targeted tobacco marketing efforts (Katz & Lavack, 2002; Ling & Glantz, 2002a, 2002b; Sepe, Ling, & Glantz, 2002). Evidence shows associations between

Robert Wood Johnson Princeton, NJ; Barbara Stronegger, FL; Frances A. Stillman School of Public Health, Boston, MA; Richard J. O'Connor, Ph.D., M.P.H., Program Director, 3555 Market Street, Philadelphia, PA; Fax: 215-998-6895; Email: rjohp.edu

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Presentation Overview

- Behavioral theory
- **Claim development and testing**
- Claim comprehension and risk perception findings
- Impact of the claim on behavioral intentions

Claim Development Process and CCI Study Design

Phase 1

Modified Risk Claim DEVELOPMENT

DEVELOPMENT of Promotional Material

Round 1

Qualitative study to **develop proposed claim**

Round 2

Qualitative study to **further develop proposed claim**

Claim Requirements

- Communicated that consumers knew they needed to stop smoking in order to reduce lung cancer risk
- Consumers understood that there is risk with the use of Copenhagen[®] Snuff

Claim Development Process and CCI Study Design

Phase 1

Modified Risk Claim DEVELOPMENT

DEVELOPMENT of Promotional Material

Round 1

Qualitative study to
**develop proposed
claim**

Round 2

Qualitative study to
**further develop
proposed claim**

Phase 2

Modified Risk Claim TESTING

TESTING of Promotional Material

CCI Study

Quantitative study
**to assess the
comprehension and the
effect of the claim on
behavioral intentions**

Claim Development Process and CCI Study Design

Phase 2 Key Questions

- Do participants correctly understand the claim?
- Do participants understand that using Copenhagen[®] Snuff still poses a health risk?
- Do participants change their behavioral intentions?

Phase 2

Modified Risk Claim TESTING

TESTING of Promotional Material

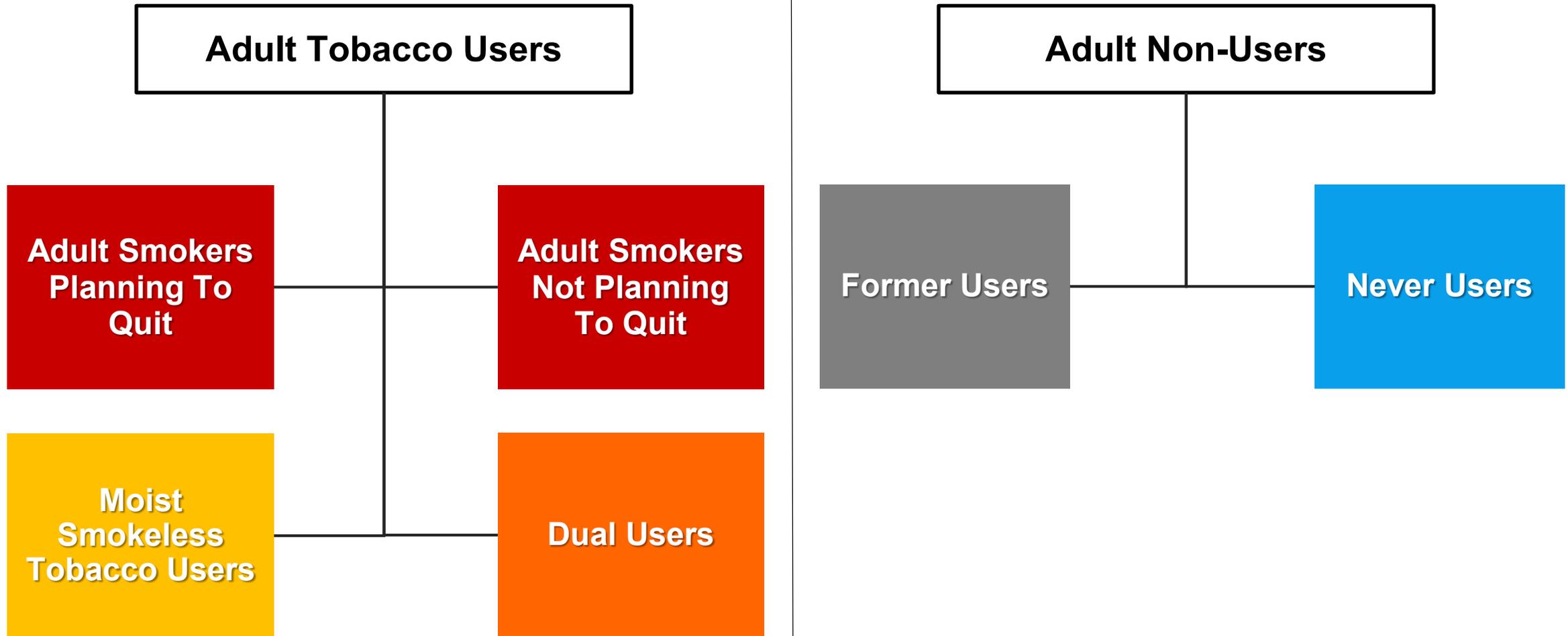
CCI Study

Quantitative study
**to assess the
comprehension and the
effect of the claim on
behavioral intentions**

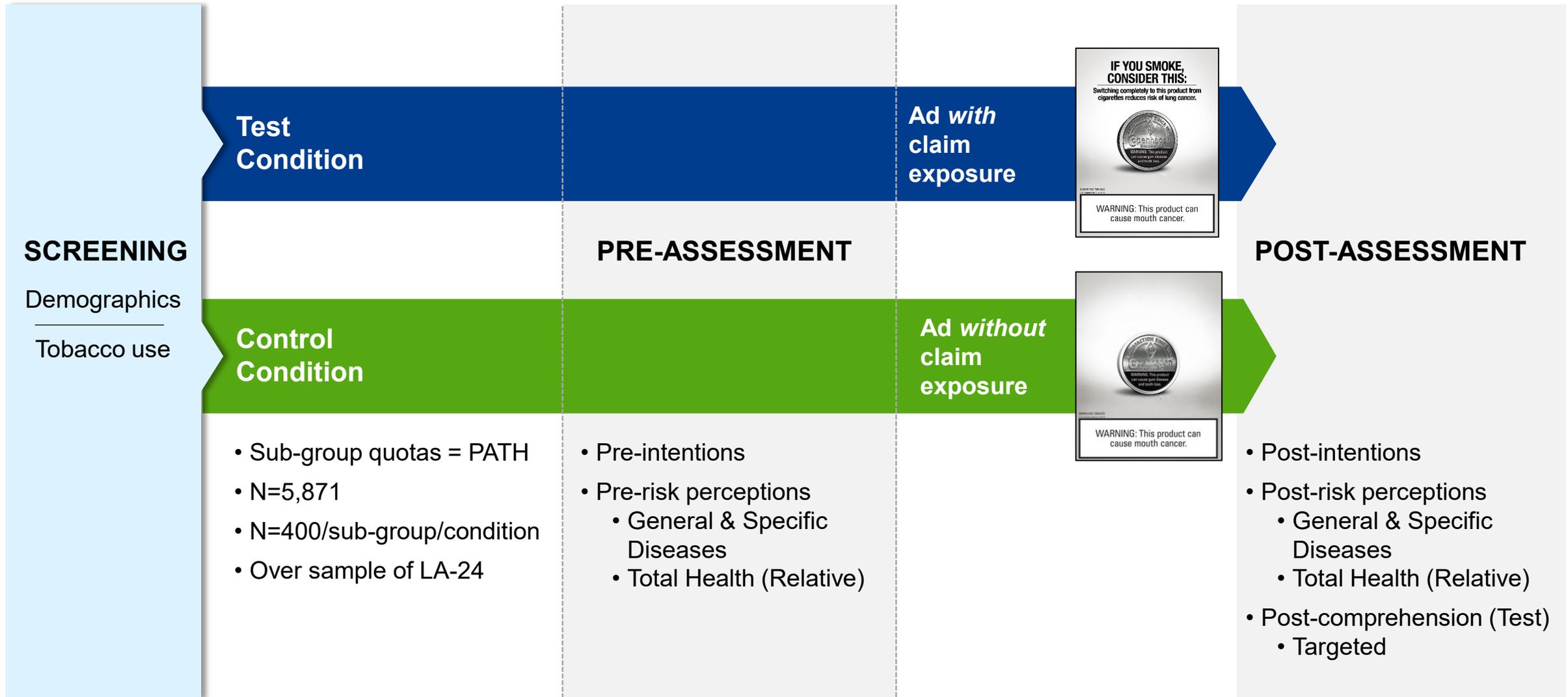
CCI Study Overview

- **Quasi-randomized, controlled study design**
- **5,871 adult tobacco users and non-users from across the U.S.**
- **Participants matched to the U.S. population using major demographic variables based on PATH study quotas**
- **Oversampled legal age to 24-year-old population**

CCI Study Subgroups



CCI Study Design



Presentation Overview

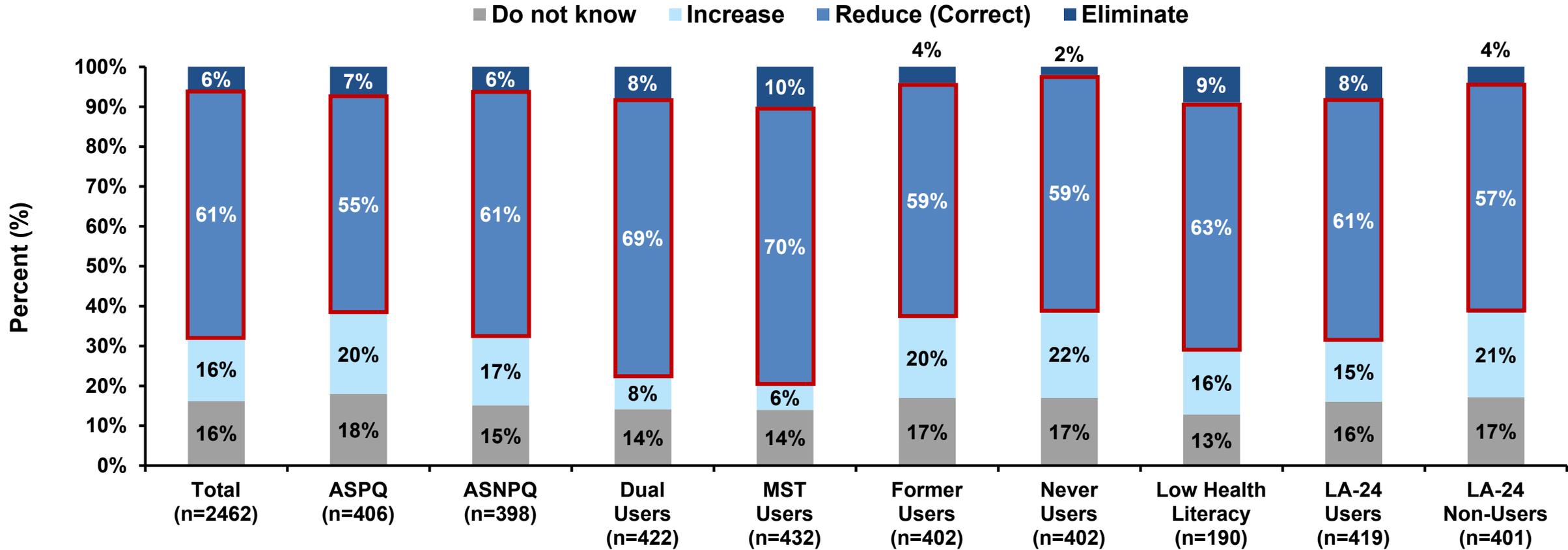
- Behavioral theory
- Claim development and testing
- **Claim comprehension and risk perception findings**
- Impact of the claim on behavioral intentions

Comprehension Question

Based only on the information shown in this ad, smokers who switch completely from cigarettes to Copenhagen[®] Snuff:

- Increase the risk of lung cancer**
- Reduce the risk of lung cancer**
- Eliminate the risk of lung cancer**
- Do not know**

Participants Comprehend the Claim



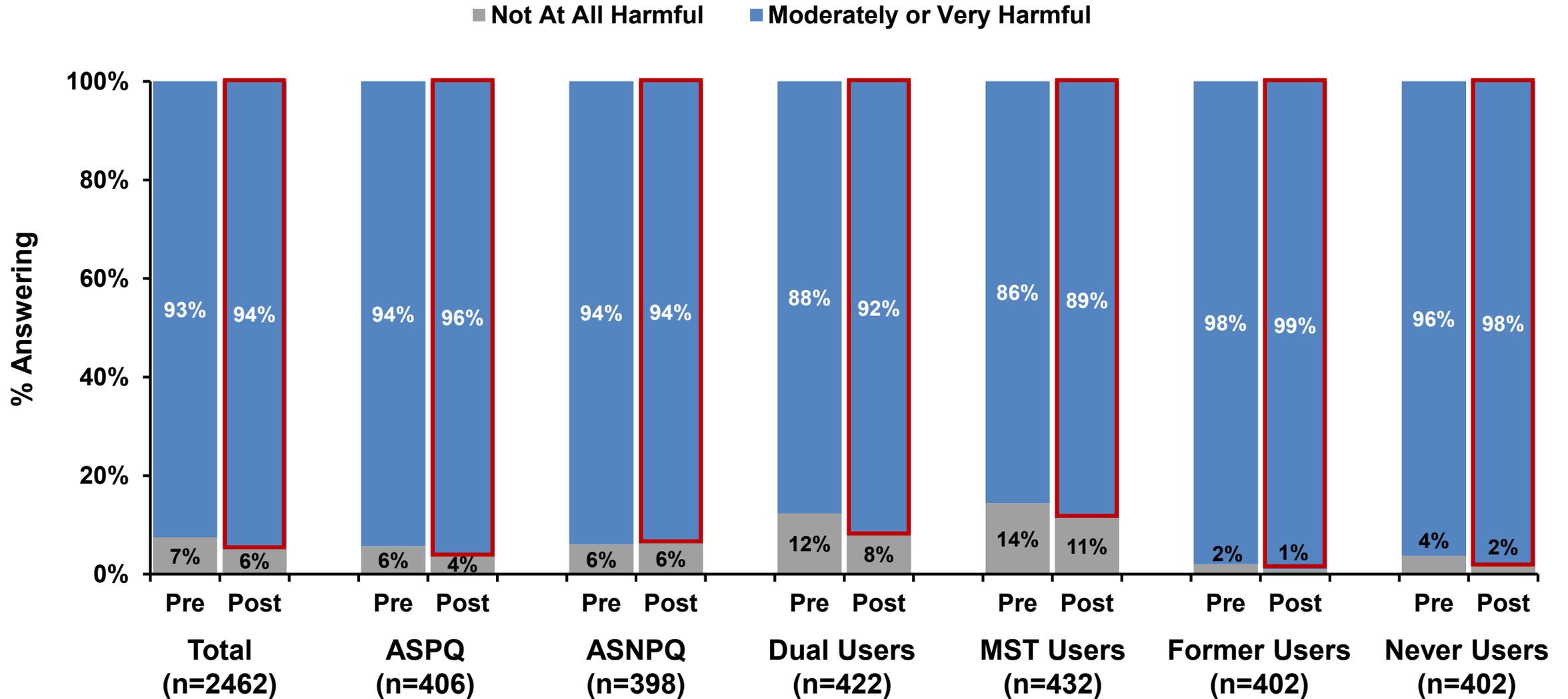
Based only on the information shown in this ad, smokers who switch completely from cigarettes to Copenhagen® Snuff: Increase the risk of lung cancer, Reduce the risk of lung cancer, Eliminate the risk of lung cancer, Do not know.

General Harm Question

How harmful do you think using Copenhagen[®] Snuff is to a person's health?

- Very harmful**
- Moderately harmful**
- Not at all harmful**

Participants Understand Copenhagen[®] Snuff is Not Risk-Free



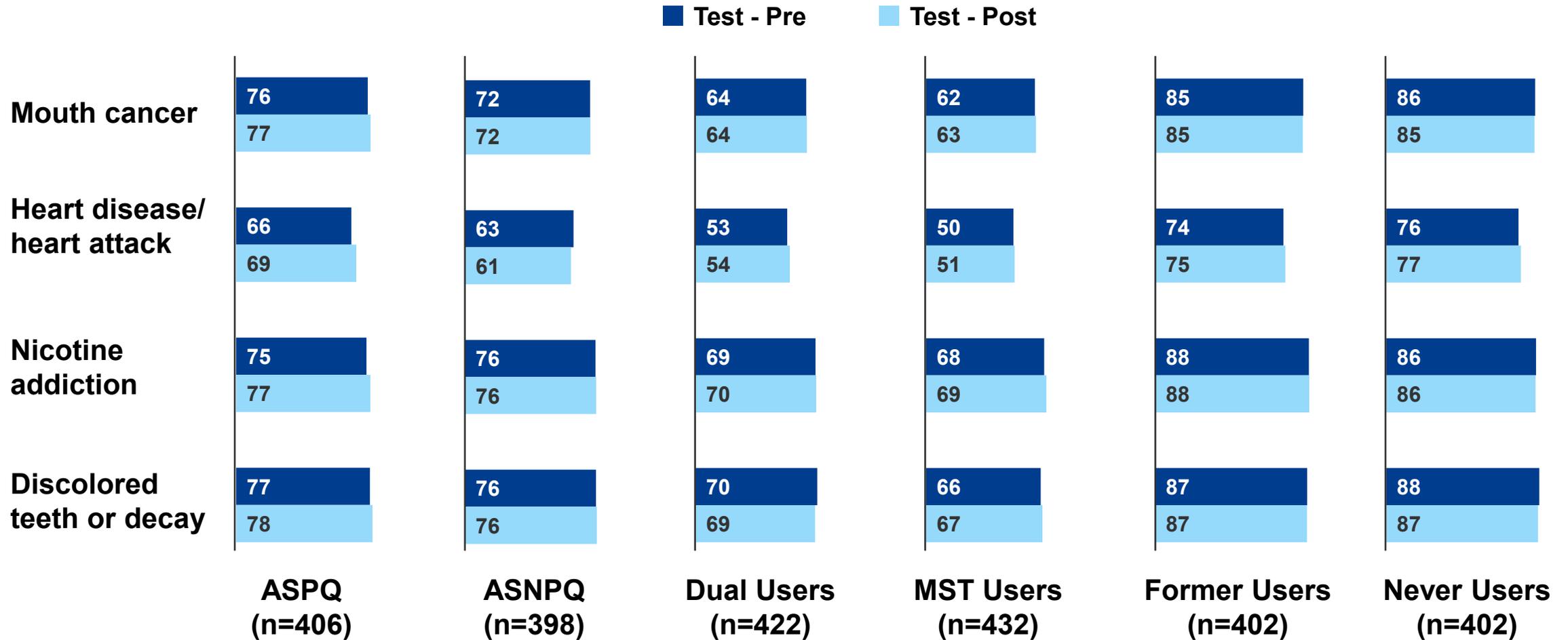
General and Specific Diseases Risk Question

How likely is it that these things will happen to a person who only uses Copenhagen[®] Snuff daily?

0% Extremely Unlikely to 100% Extremely Likely

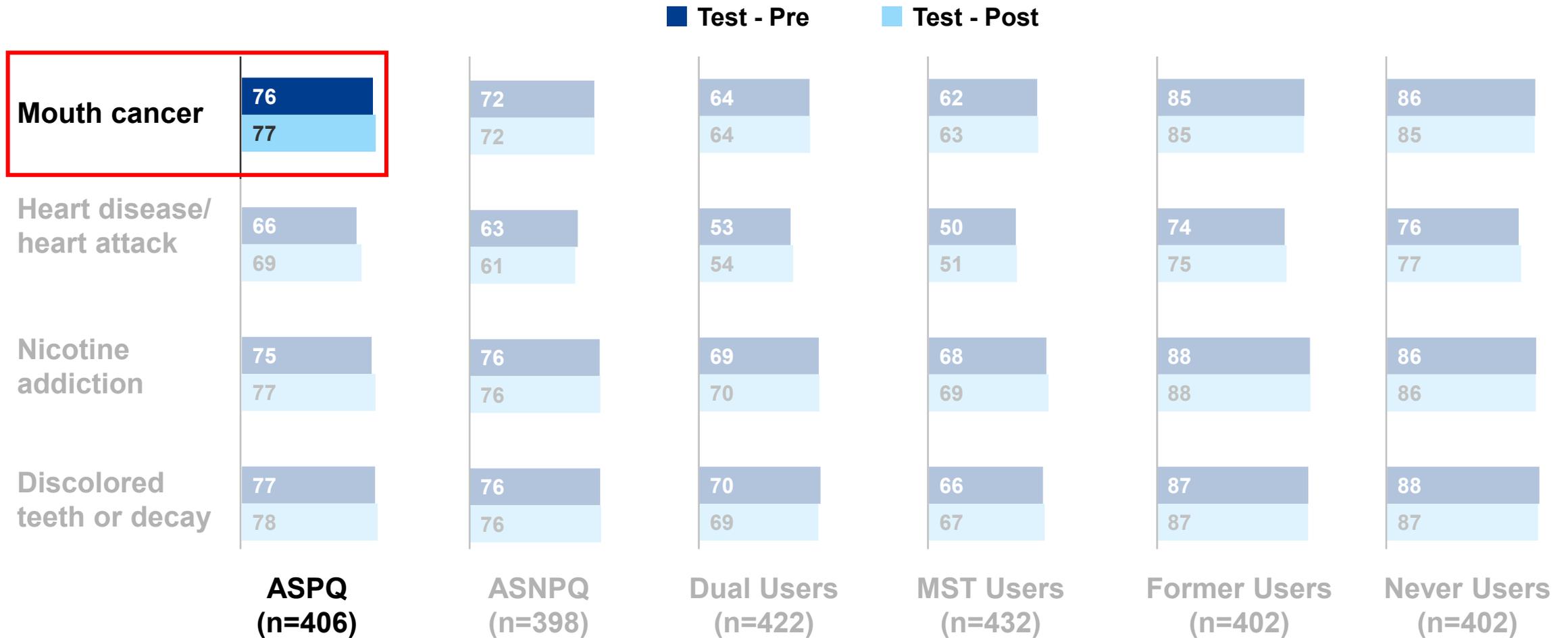
- Negatively impacts health**
- Mouth cancer**
- Hearth disease/heart attack**
- Lung cancer**
- Nicotine addiction**
- Discolored teeth or decay**

Likelihood of Health Risks



We realize you may not know the answer to each question, but please give your best answer.
 Looking at the same list, how likely is it that these things will happen to a person who only uses Copenhagen® Snuff daily?
 0% Extremely Unlikely 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% Extremely Likely.

Likelihood of Health Risks



We realize you may not know the answer to each question, but please give your best answer.
 Looking at the same list, how likely is it that these things will happen to a person who only uses Copenhagen® Snuff daily?
 0% Extremely Unlikely 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% Extremely Likely.

Proposed Modified Risk Claim

**IF YOU SMOKE,
CONSIDER THIS:**

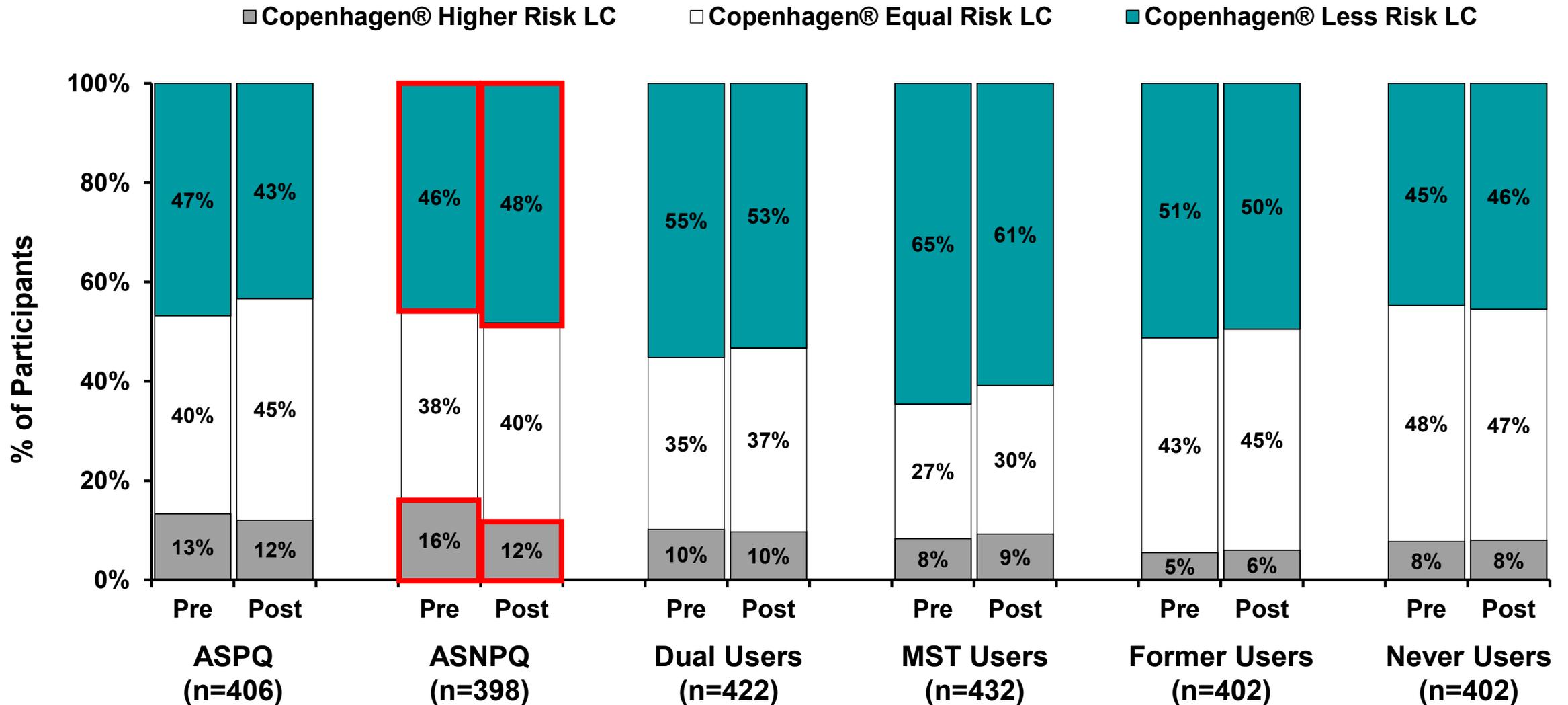
Switching completely to this product from
cigarettes reduces risk of lung cancer.



SMOKELESS TOBACCO
© U.S. Smokeless Tobacco Co. 2017-A1

**WARNING: This product can
cause mouth cancer.**

Likelihood of Lung Cancer (Test) Copenhagen[®] Snuff vs. Smoking Cigarettes



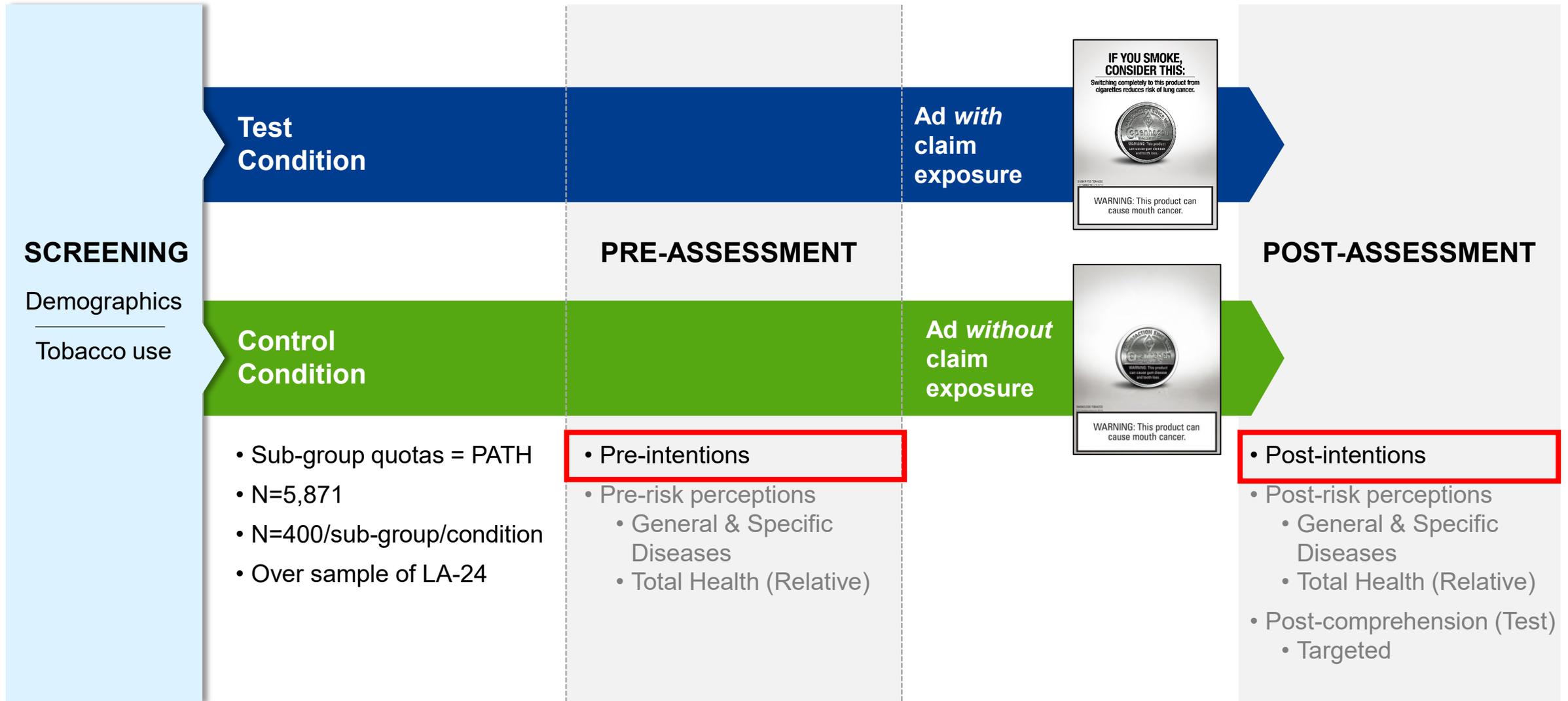
Key Takeaways – Comprehension and Perceptions

- **Tobacco users and non-users correctly understand the claim**
- **After viewing the claim, users and non-users continue to believe Copenhagen[®] Snuff poses risk to health**
- **The claim shows potential to help correct misperceptions of lung cancer risk in Adult Smokers Not Planning to Quit**

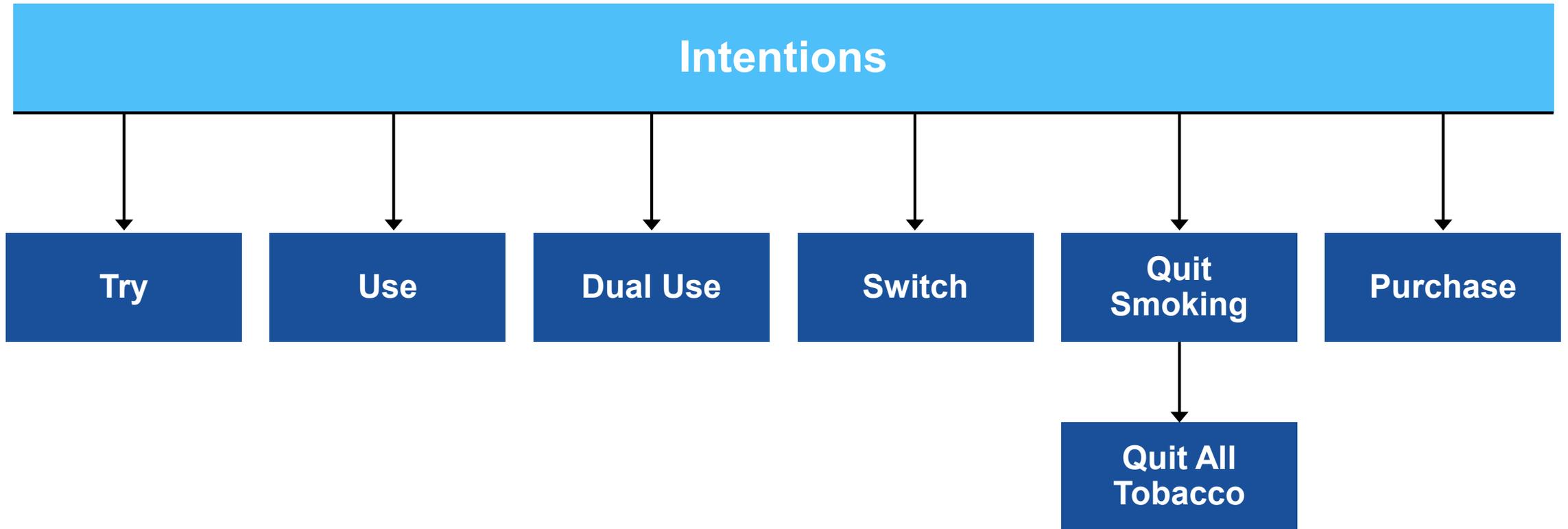
Presentation Overview

- Behavioral theory
- Claim development and testing
- Claim comprehension and risk perception findings
- **Impact of the claim on behavioral intentions**

CCI Study Design



Behavioral Intentions Assessed



Intention to Use Measure

Strongly disagree (1)	Disagree (2)	Somewhat disagree (3)	Somewhat agree (4)	Agree (5)	Strongly agree (6)
---------------------------------	------------------------	---------------------------------	------------------------------	---------------------	------------------------------

I would consider using Copenhagen[®] Snuff more than once.

I expect to use Copenhagen[®] Snuff.

It is likely that I will regularly use Copenhagen[®] Snuff in the next 6 months.

Copenhagen[®] Snuff will be my regular brand of dip/snuff in the next 30 days.

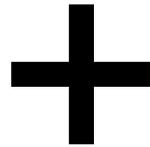
Behavioral Intentions Results

- **Significant difference in Intention to Use among Adult Smokers Not Planning to Quit**
- **No other significant differences in behavioral intentions were observed**

Likelihood of Behavior Measure



**Positive
Behavioral Intent**

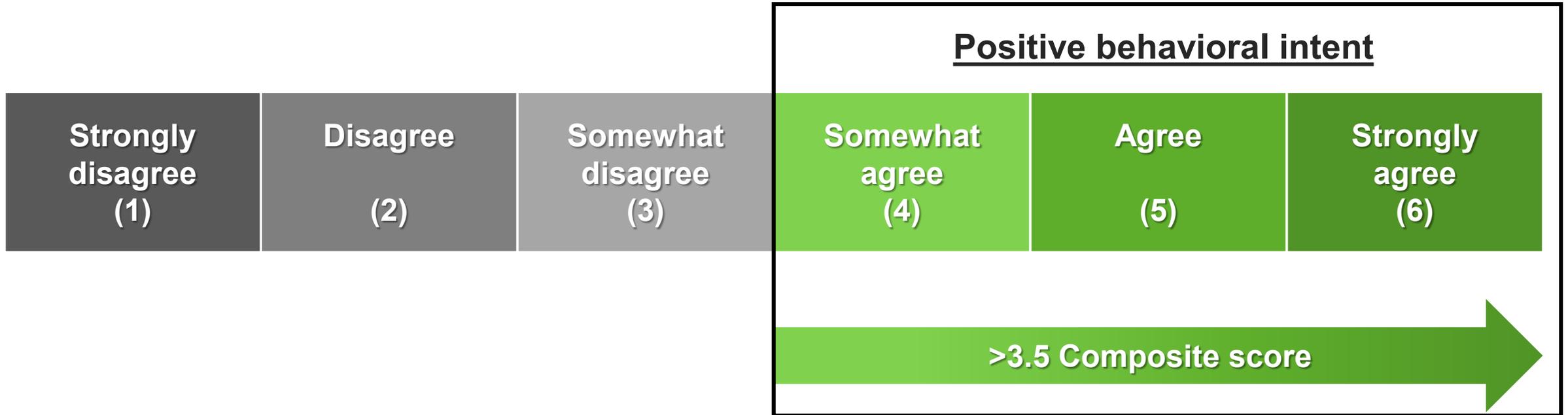


**Intention to
Purchase
Right Now**



**Future Behavior
Measure**

Likelihood of Behavior Metric



and

**Intention to purchase right now
(Yes/No scale)**

Relative Impact

Adult Tobacco Use Behavior	Change in Likelihood of Behavior* (Relative Impact Factor)
Cigarette Smokers Switching to Copenhagen [®] Snuff	1.21
Cigarette Smokers Transitioning to Dual Use	1.16
Dual Users Switching to Copenhagen [®] Snuff	1.06
Former Smokeless Tobacco Users Relapsing to Copenhagen [®] Snuff	1.00
Never Users Initiating with Copenhagen [®] Snuff	0.80

*Results not statistically significant.

Key Takeaways

- **Consumers understand that using Copenhagen[®] Snuff poses risks to health and are not misled**
- **Data indicate a favorable response to the claim**
- **It will take time and repeated reinforcement of this message for adult smokers to switch completely to Copenhagen[®] Snuff**

Population Impact

Ryan Black, Ph.D.

Director, Regulatory Affairs
Altria Client Services



Altria
Altria Client Services

Presentation Overview

- **Gateway**
- **Youth use**
- **Population modeling**
- **Postmarket surveillance**

Presentation Overview

- **Gateway**
- Youth use
- Population modeling
- Postmarket surveillance

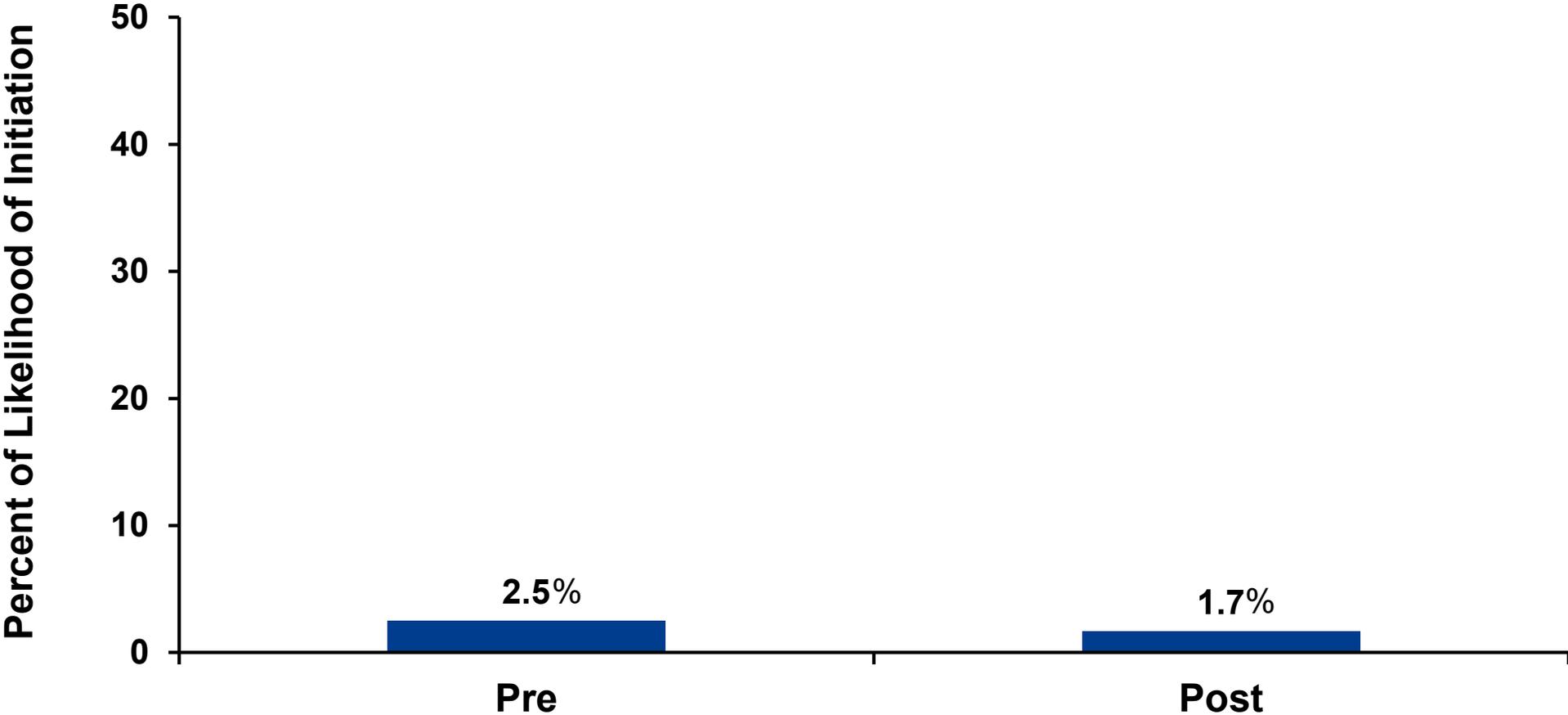
Gateway Effect

- **Concern that individuals who do not already use tobacco will start using a less hazardous tobacco product, like Copenhagen[®] Snuff, and switch to a more harmful tobacco product, like cigarettes**



Claim Did Not Increase Likelihood of Use

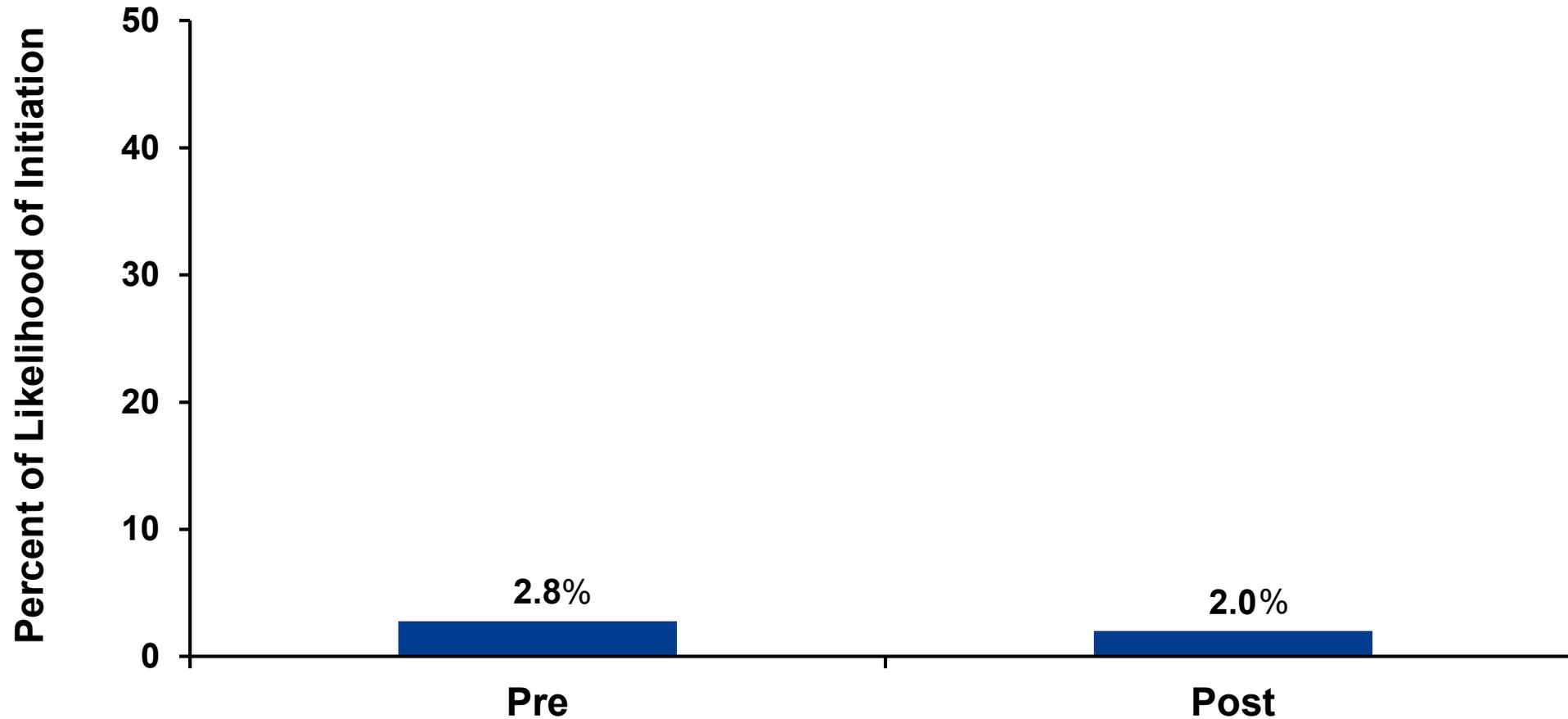
Adult Never Users



Pre Post scores for test group only.
No statistically significant difference

Claim Did Not Increase Likelihood of Use

Adult Never Users Legal Age to 24



Pre Post scores for test group only.
No statistically significant difference

Presentation Overview

- Gateway
- **Youth use**
- Population modeling
- Postmarket surveillance

Youth Use

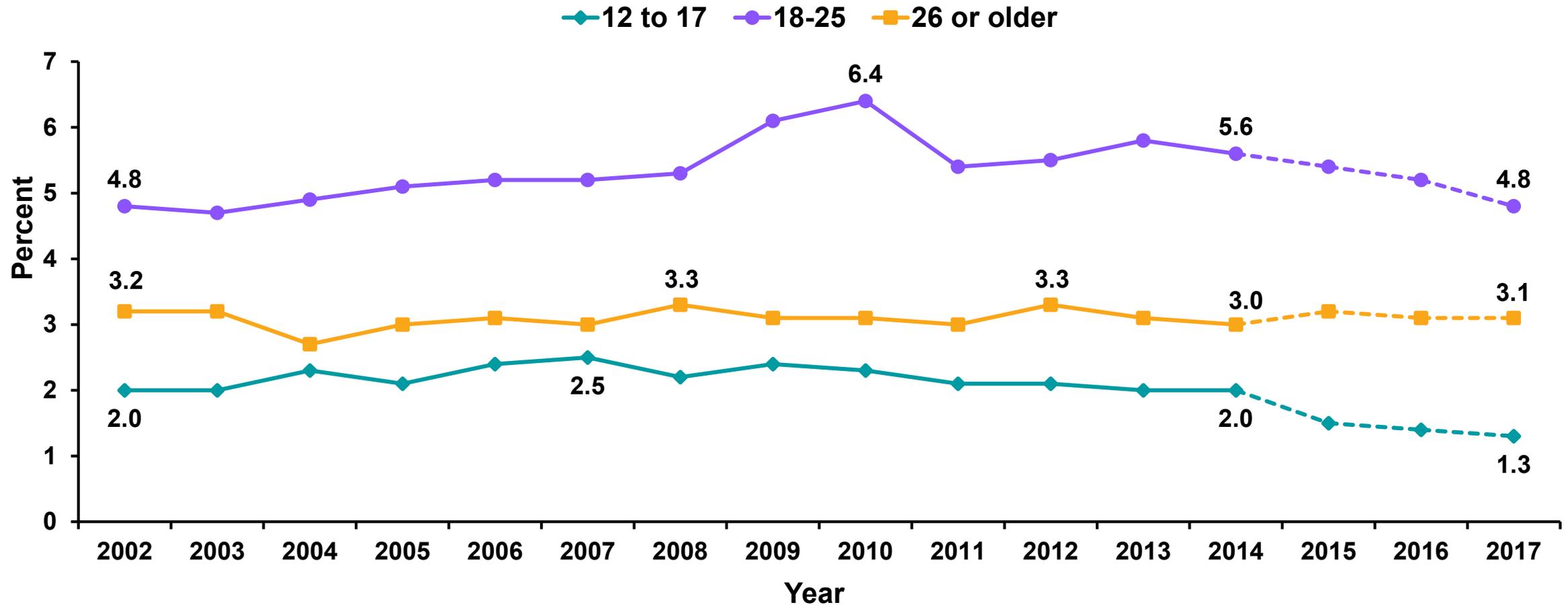
**Youth should not use any tobacco product.
Reduced-risk messages should not influence
youth to use Copenhagen[®] Snuff
or any other tobacco product.**

Understanding Youth Use

- **Relied on publically available resources including:**
 - ▶ Government data
 - National Survey on Drug Use and Health
 - Monitoring the Future
 - FDA's PATH Study
 - ▶ Published literature

Prevalence of Youth ST Use Stable to Declining

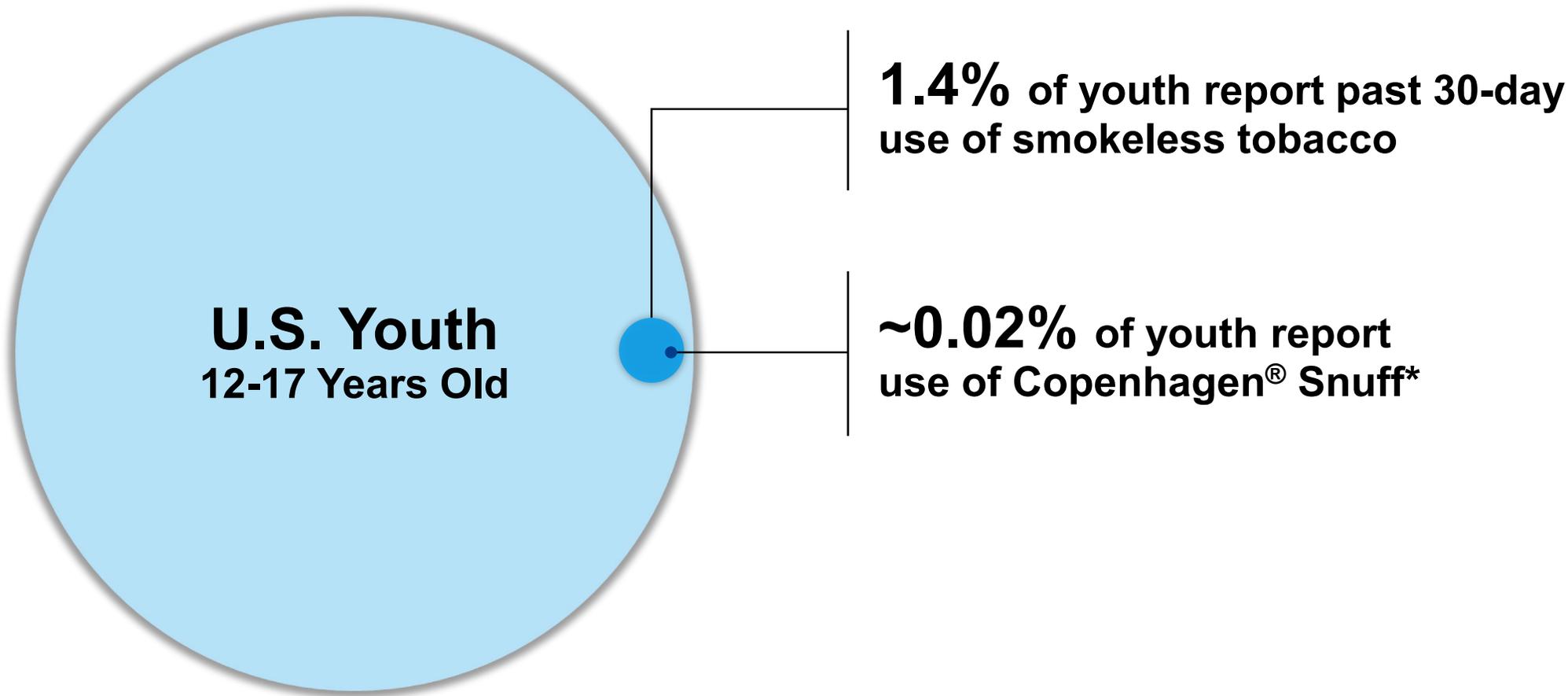
Percentages Reporting Past 30-Day Smokeless Tobacco Use by Age Group (NSDUH)



As represented by the dotted line, smokeless tobacco use question modified with the inclusion of snus in the definition of smokeless tobacco in 2015.

Adapted from National Survey on Drug Use and Health Behavioral Health Trends Report (2015), Detailed Tables (2016-18)

Youth Use of Copenhagen[®] Snuff is Very Low



Exposure To Claim Did Not Impact Youth Susceptibility To Use (El-Toukhy et al., 2018)

- 480 youth (13-17 year olds) randomized to receive one message by risk claim and by product type

Risk Claim

- Less harmful than cigarettes
- As harmful as cigarettes, or
- No statement (control)

Product Type

- Heat-not-burn
- E-vapor
- Snus

- Researchers found that the lower risk claim had no effect on susceptibility to use among youth

Presentation Overview

- Gateway
- Youth use
- **Population modeling**
- Postmarket surveillance

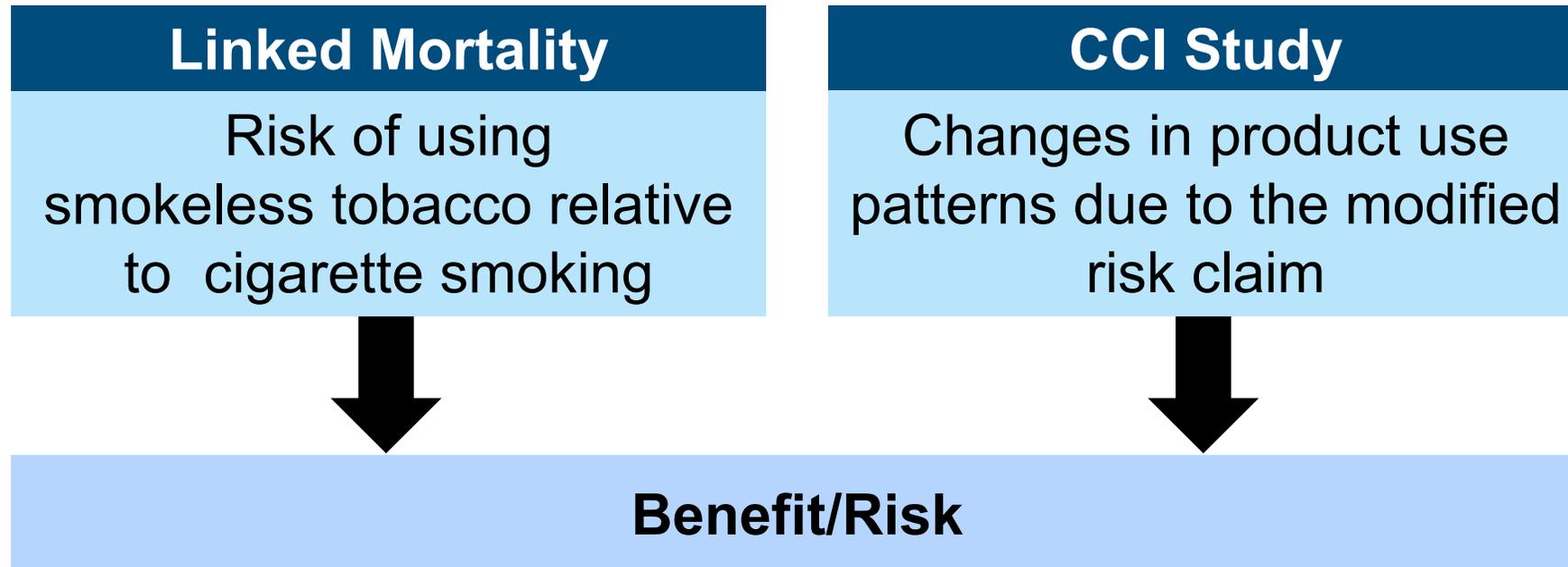
Population Models

- **Predict outcomes within a population under changing dynamics**
- **Rely in part on empirical data in addition to estimates and assumptions, informed by evidence**
- **Shed light on trends, not intended to predict future outcomes with numerical precision**

Model Validation

- **Developed and validated the cohort model**
 - ▶ Used best practices as described by
 - Institute of Medicine (IOM)
 - International Society of Pharmacoeconomics and Outcomes Research (ISPOR)
 - Society for Medical Decision Making (SMDM)

Modeling the Impact on the Population

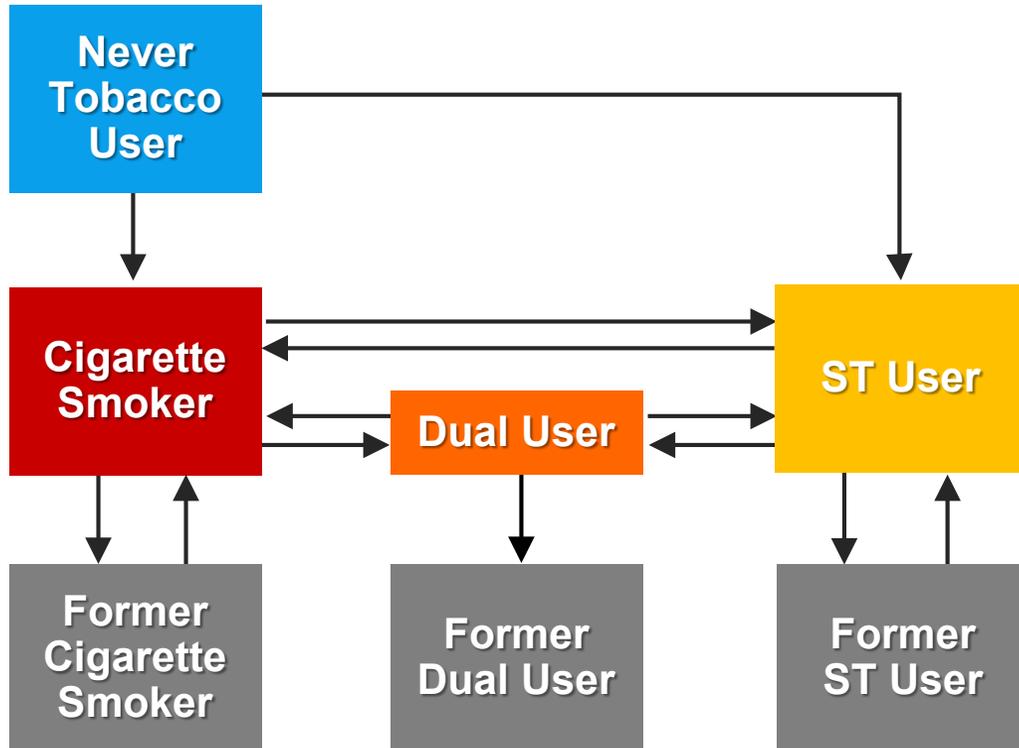


Model Inputs

- **Male population defined by the U.S. Census data**
- **Tobacco use patterns informed by systematic literature review published by public health scientists including FDA research scientists**
- **Risk of exclusive smokeless tobacco use relative to cigarette smoking estimated from the Linked Mortality Analyses**

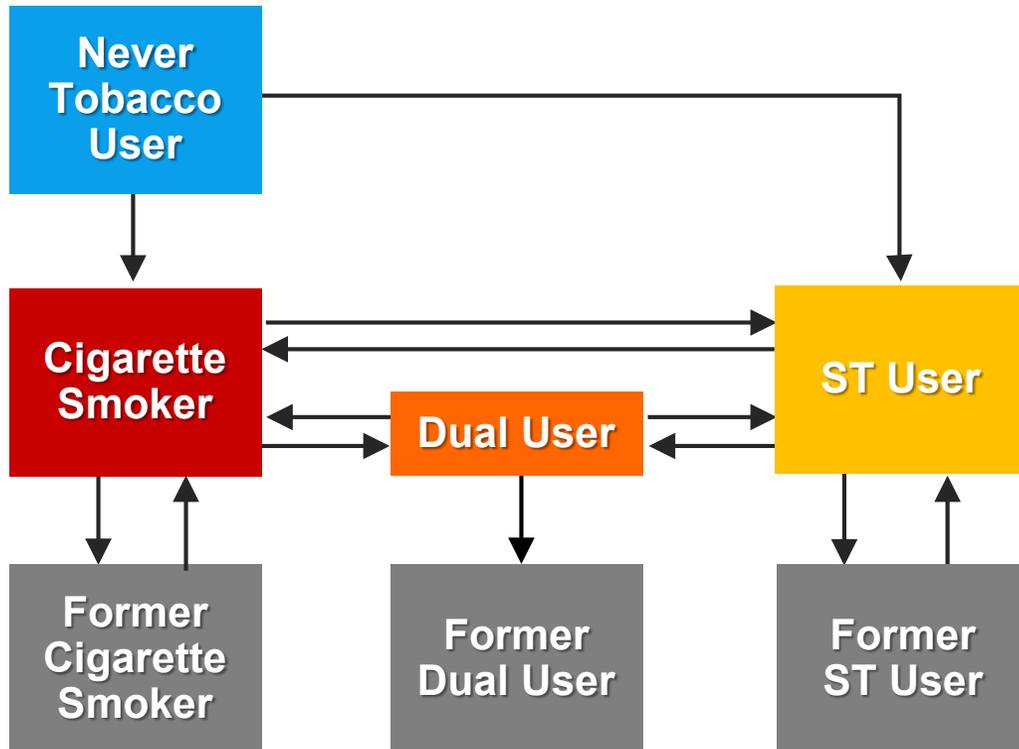
Modeling Framework: Multiple Cohort Approach

Base Case – World As Is Today

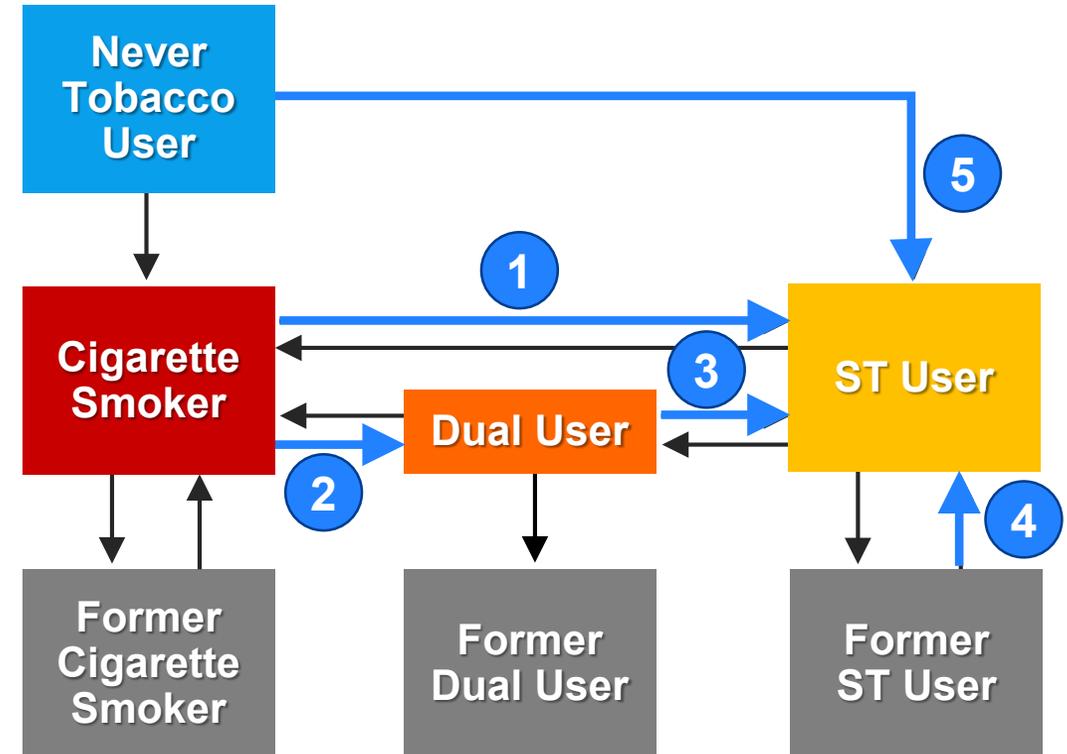


Modeling Framework: Multiple Cohort Approach

Base Case – World As Is Today



Modified Case – Future World



Blue Arrows = Modified Transitions

Adult Male Transition Rates

Tobacco Use Transition	Base Case Transitions* (From the Literature)	Modified Case Transitions* (Adjusted from CCI Study)
1 Current smoker → ST	1.4%	1.7%
2 Current smoker → Dual user (ST + cigarettes)	3.2%	4.0%
3 Dual user → ST	17.4%	18.4%
4 Former ST → ST	1.8%	1.8%
5 Never user → ST	1.6%	1.5%

*Five year transition rates

Base case transition rates largely informed by Tam J., Day H.R., Rostron B.L., Apelberg B.J. A systematic review of transitions between cigarette and smokeless tobacco product use in the United States. BMC Public Health. 2015;15:258

Adult Male Transition Rates

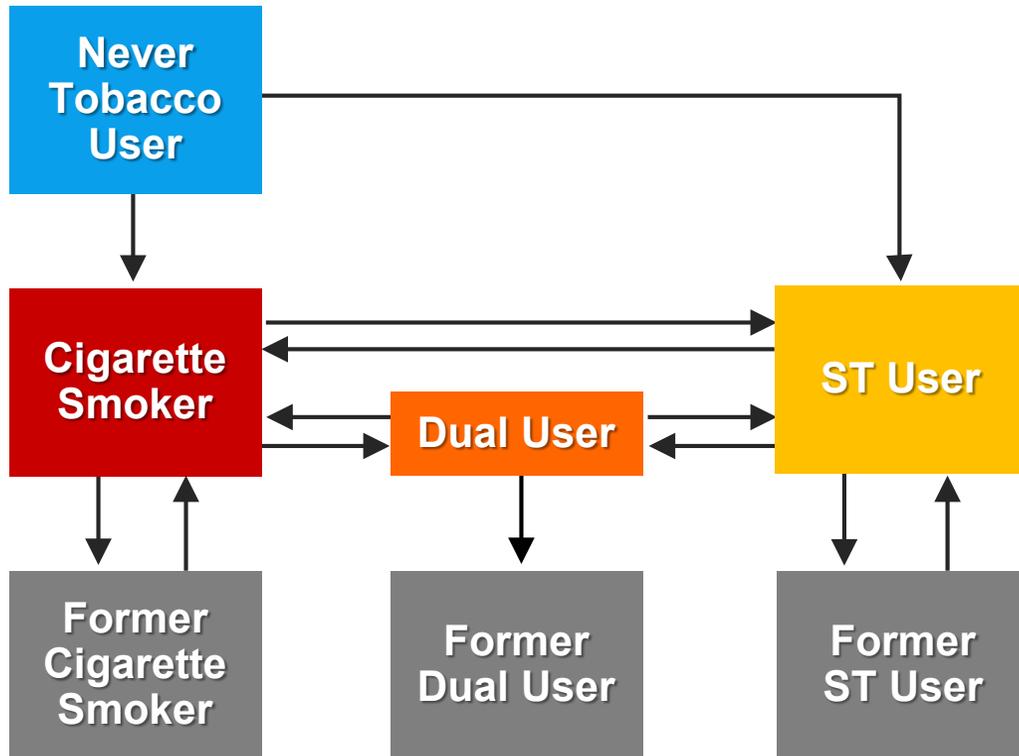
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*Five year transition rates

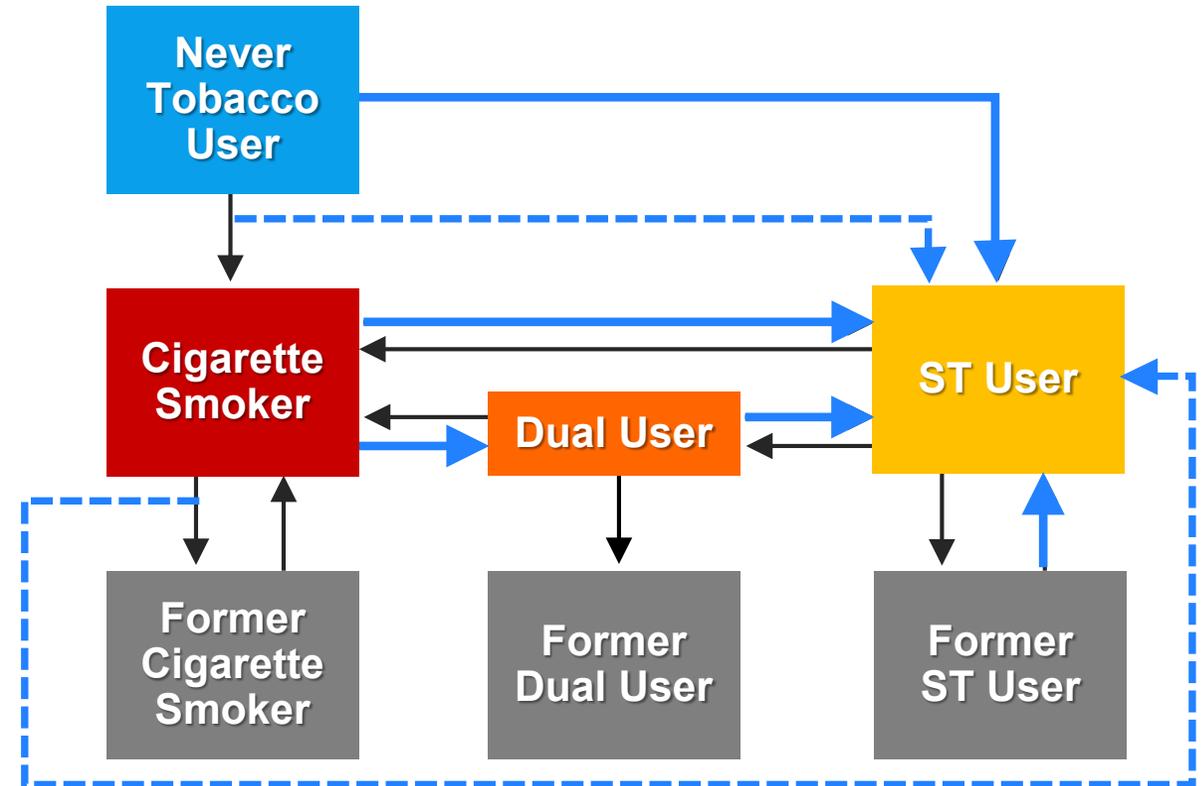
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Modeling Framework: Multiple Cohort Approach

Base Case – World As Is Today



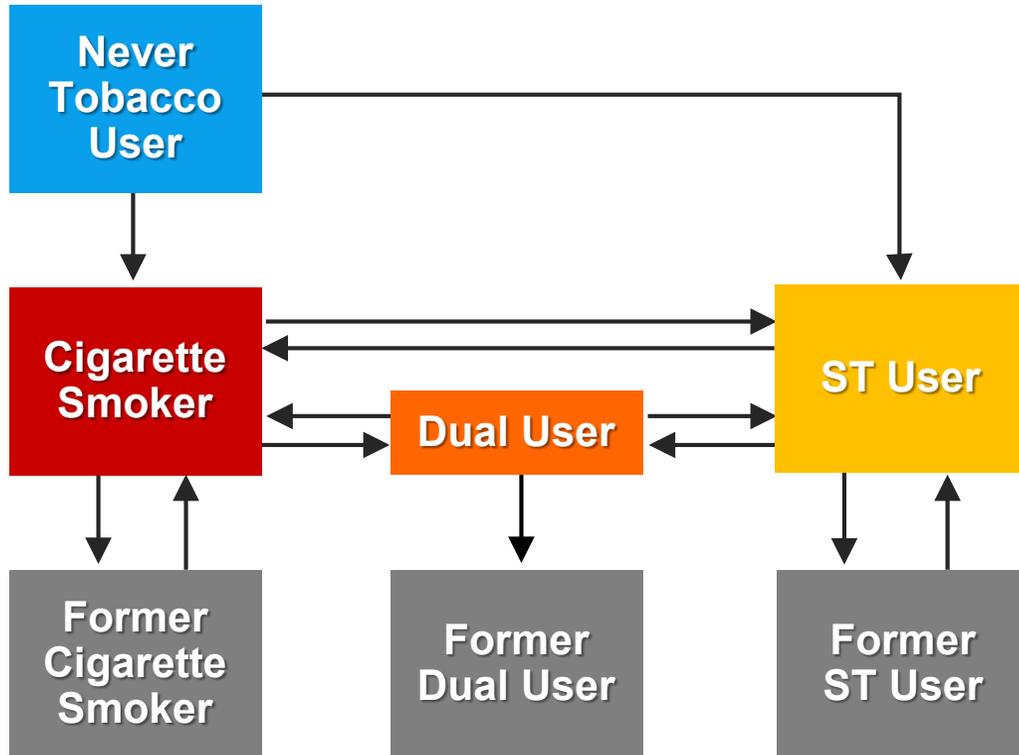
Modified Case – Future World



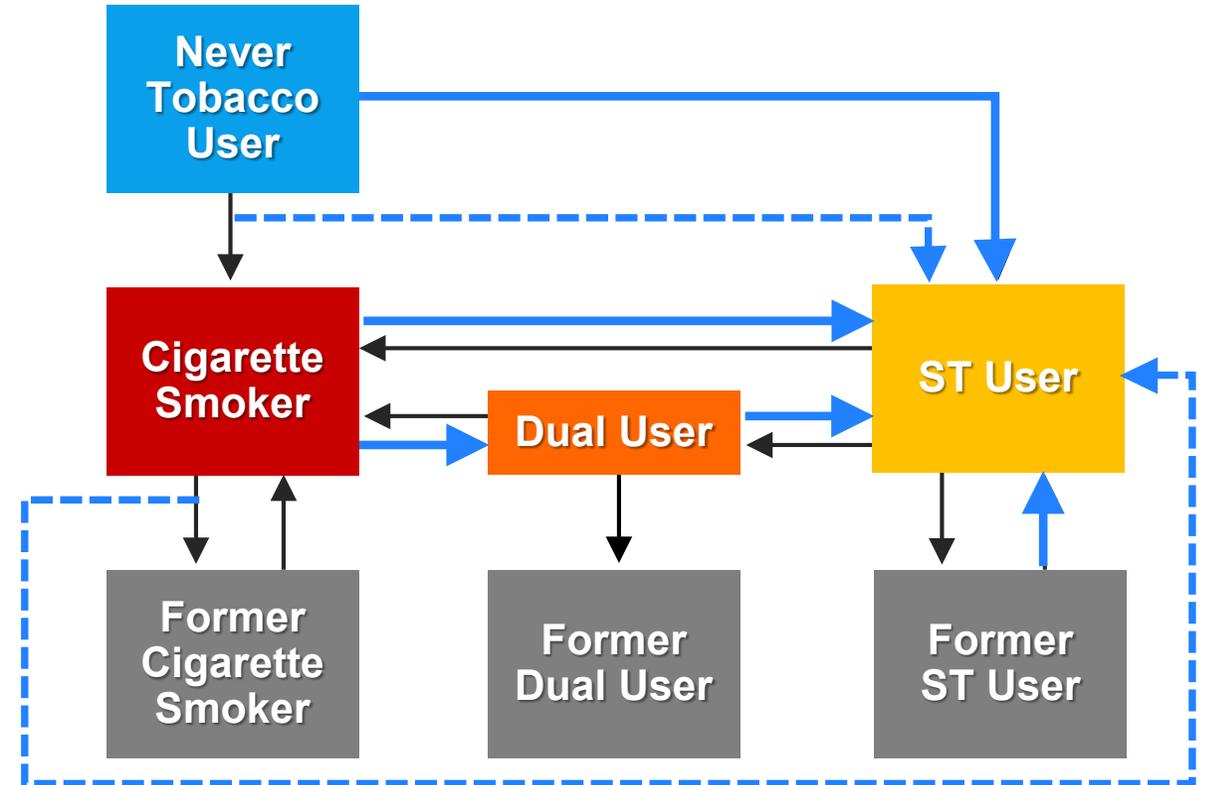
Blue Arrows = Modified Transitions

Modeling Framework: Multiple Cohort Approach

Base Case – World As Is Today



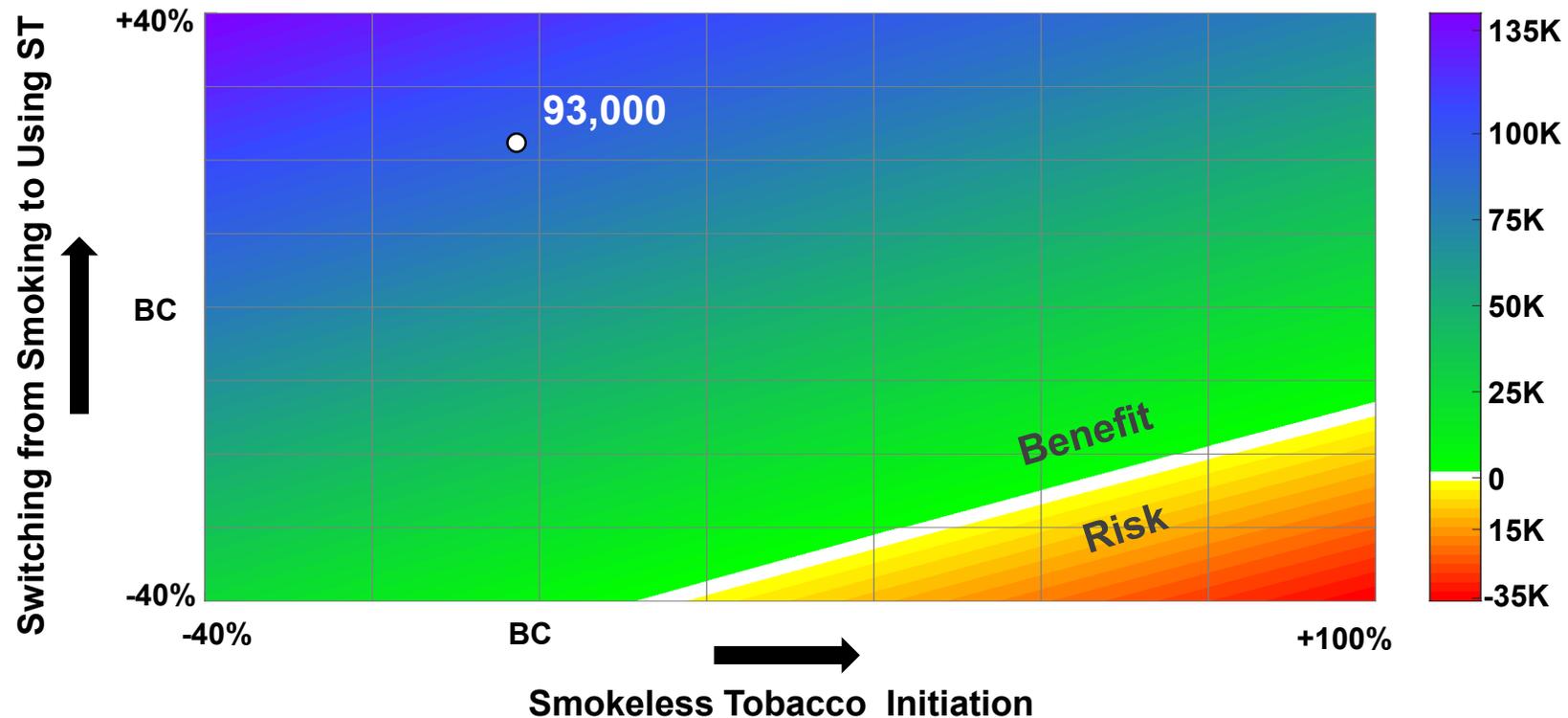
Modified Case – Future World



Approximately 93,000 premature deaths prevented over the 60 years following claim authorization

Robust Findings from Sensitivity Analyses

- **Concurrently vary:**
 - Change in rate of Never Tobacco Users initiating on smokeless tobacco (*Initiation*)
 - Change in rate of Cigarette Smokers switching to smokeless tobacco (*Switching*)
- **All other transition rates kept the same as those in the Modified Case scenario**



Presentation Overview

- Gateway
- Youth use
- Population modeling
- **Postmarket surveillance**

Proposed Postmarket Surveillance Program Scope

Surveillance

- **Postmarket studies (e.g., cross-sectional and longitudinal cohort studies)**
 - ▶ Transitions among tobacco users
 - ▶ Initiation/cessation
 - ▶ Risk perceptions
 - ▶ Awareness of modified risk communication

Proposed Postmarket Surveillance Program Scope

Surveillance

- **Postmarket studies (e.g., cross-sectional and longitudinal cohort studies)**
 - Transitions among tobacco users
 - Initiation/cessation
 - Risk perceptions
 - Awareness of modified risk communication
- **Refining population modeling input parameters**

Proposed Postmarket Surveillance Program Scope

Surveillance

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 - ▶ Transitions among tobacco users
 - ▶ Initiation/cessation
 - ▶ Risk perceptions
 - ▶ Awareness of modified risk communication
- **Refining population modeling input parameters**
- **Adverse event reporting**
 - ▶ Consumer Response Center
 - ▶ Clinical studies
 - ▶ Literature reviews
 - ▶ FDA Adverse Events Reporting System/
Health and Human Services Safety Portal

Proposed Postmarket Surveillance Program Scope

Surveillance

- **Postmarket studies (e.g., cross-sectional and longitudinal cohort studies)**
 - Transitions among tobacco users
 - Initiation/cessation
 - Risk perceptions
 - Awareness of modified risk communication
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- **Adverse event reporting**
 - Consumer Response Center
 - Clinical studies
 - Literature reviews
 - FDA Adverse Events Reporting System/ Health and Human Services Safety Portal
- **Literature reviews**
 - Health effects
 - Risk perceptions
 - Patterns of use
 - Misuse/abuse/tampering

Proposed Postmarket Surveillance Program Scope

Surveillance

- **Postmarket studies (e.g., cross-sectional and longitudinal cohort studies)**
 - Transitions among tobacco users
 - Initiation/cessation
 - Risk perceptions
 - Awareness of modified risk communication
- **Refining population modeling input parameters**
- **Adverse event reporting**
 - Consumer Response Center
 - Clinical studies
 - Literature reviews
 - FDA Adverse Events Reporting System/ Health and Human Services Safety Portal
- **Literature reviews**
 - Health effects
 - Risk perceptions
 - Patterns of use
 - Misuse/abuse/tampering
- **Monitoring and secondary analyses of national survey data**

Conclusion

Jose Luis Murillo, J.D.

Senior Vice President, Regulatory Affairs
Altria Client Services



Altria
Altria Client Services

Copenhagen[®] Snuff MRTPA Summary

- **Proposed claim is truthful, accurate and substantiated by scientific evidence**
- **Copenhagen[®] Snuff is significantly less harmful than cigarettes**
- **Switching completely from cigarettes to Copenhagen[®] Snuff reduces the risk of lung cancer**
- **Tobacco users and non-users understand Copenhagen[®] Snuff is not risk-free**
- **Population benefit is expected with authorization of the claim**

Presents a Dilemma and an Opportunity

**IF YOU SMOKE,
CONSIDER THIS:**

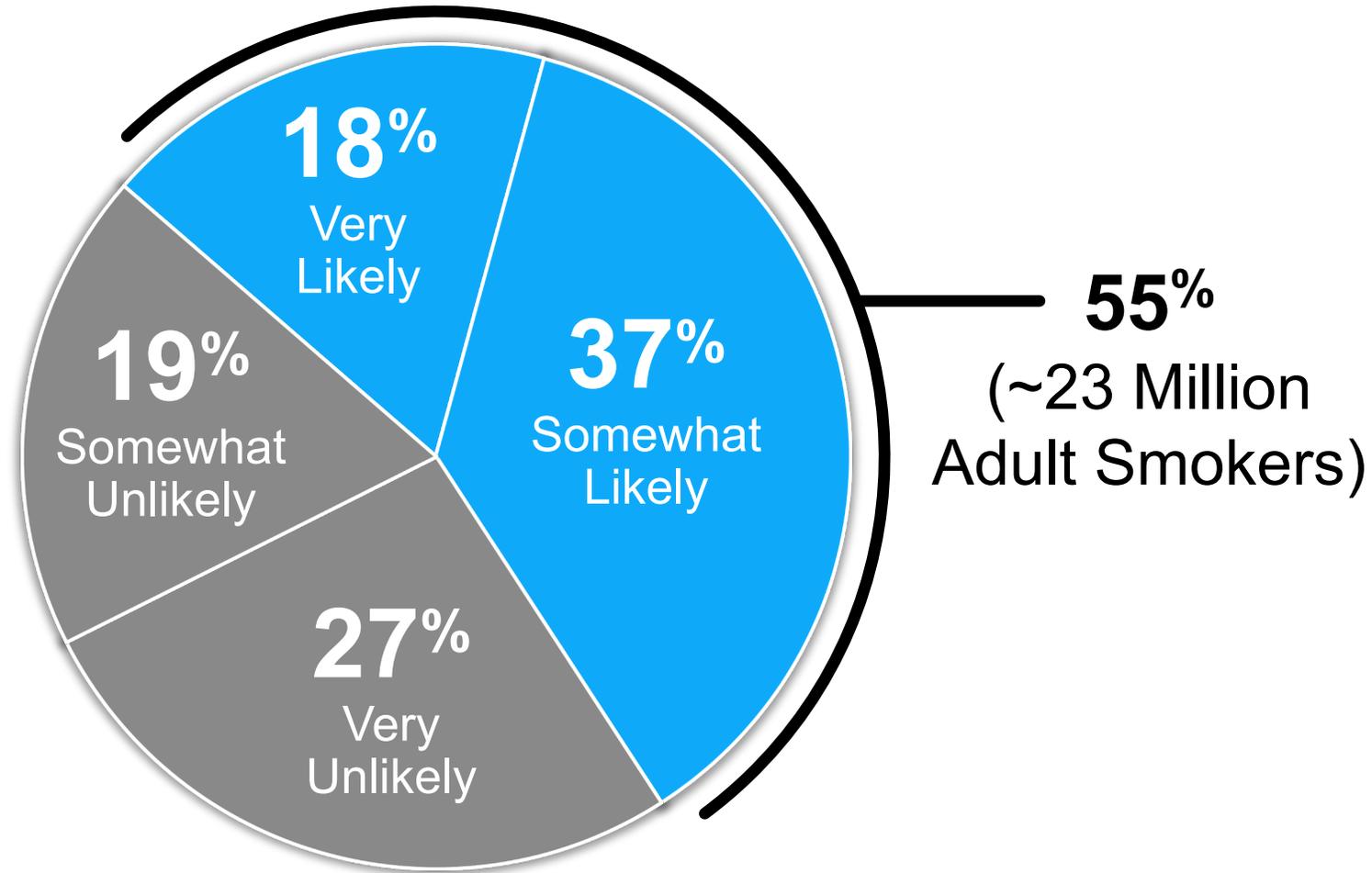
Switching completely to this product from
cigarettes reduces risk of lung cancer.



SMOKELESS TOBACCO
© U.S. Smokeless Tobacco Co. 2017-A1

**WARNING: This product can
cause mouth cancer.**

Over Half of All Adult Smokers Are Interested in Reduced-Risk Tobacco Products



Based on ALCS analysis of PATH Wave 1 data Sept 12, 2013 – Dec 14, 2014; Response to question – “If a tobacco product made a claim that it was less harmful to health than other tobacco products, how likely would you be to use that product?”

Numbers may not foot due to rounding.

Proposed Claim Can Begin Correcting Misperceptions

**IF YOU SMOKE,
CONSIDER THIS:**

Switching completely to this product from
cigarettes reduces risk of lung cancer.



SMOKELESS TOBACCO
© U.S. Smokeless Tobacco Co. 2017-A1

**WARNING: This product can
cause mouth cancer.**

Additional Experts Available for Questions

Michael Fisher, Ph.D.	Senior Principal Scientist Altria Client Services
Simeon Chow, Ph.D.	Vice President Altria Client Services
Kenya Blake	Senior Director U.S. Smokeless Tobacco Co.
Yezdi Pithawalla, Ph.D.	Senior Director Altria Client Services
Ed Largo, Ph.D.	Director Altria Client Services
Tim Danielson, Ph.D.	Senior Principal Scientist Altria Client Services

Copenhagen[®] Snuff Fine Cut

Tobacco Products Scientific Advisory Committee

February 6 & 7, 2019



Altria
Altria Client Services

Applicant Backup Slides Shown

Tobacco Products Scientific Advisory Committee

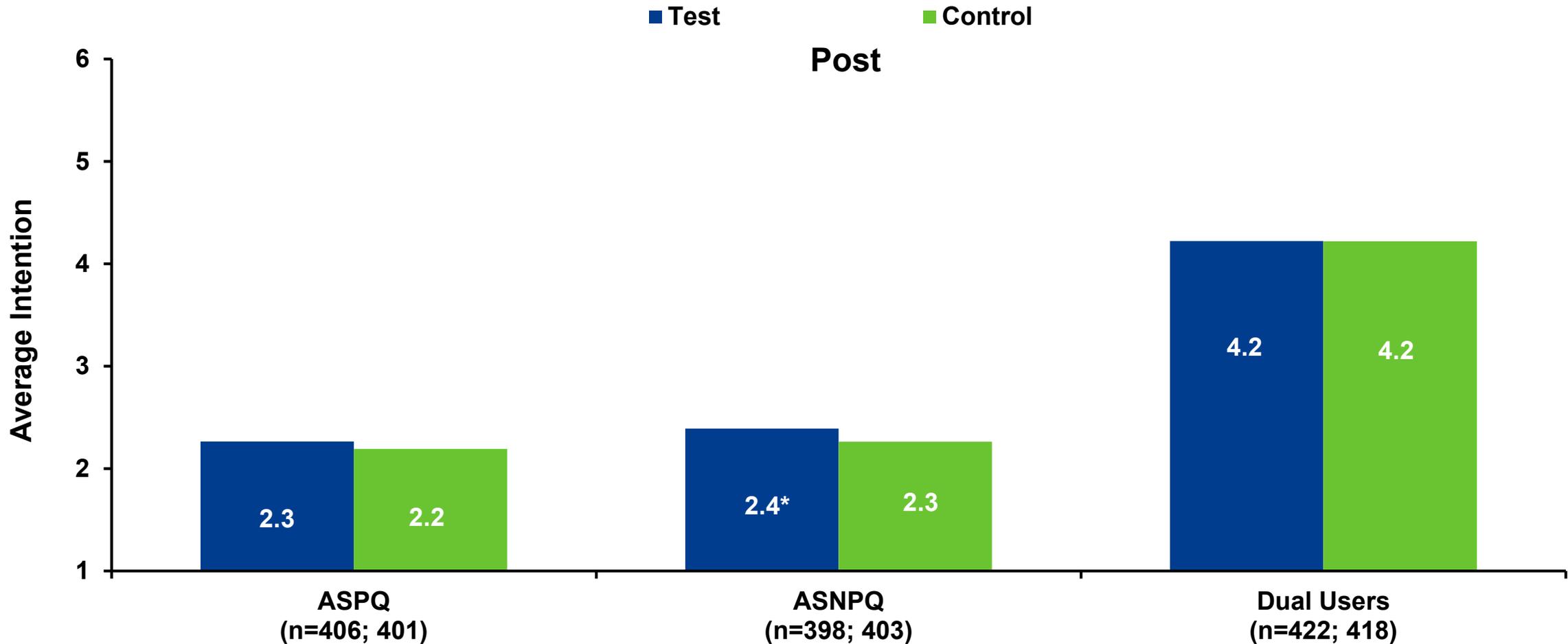
February 6 & 7, 2019



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Intention to Use Copenhagen® Snuff

Adult Tobacco Users

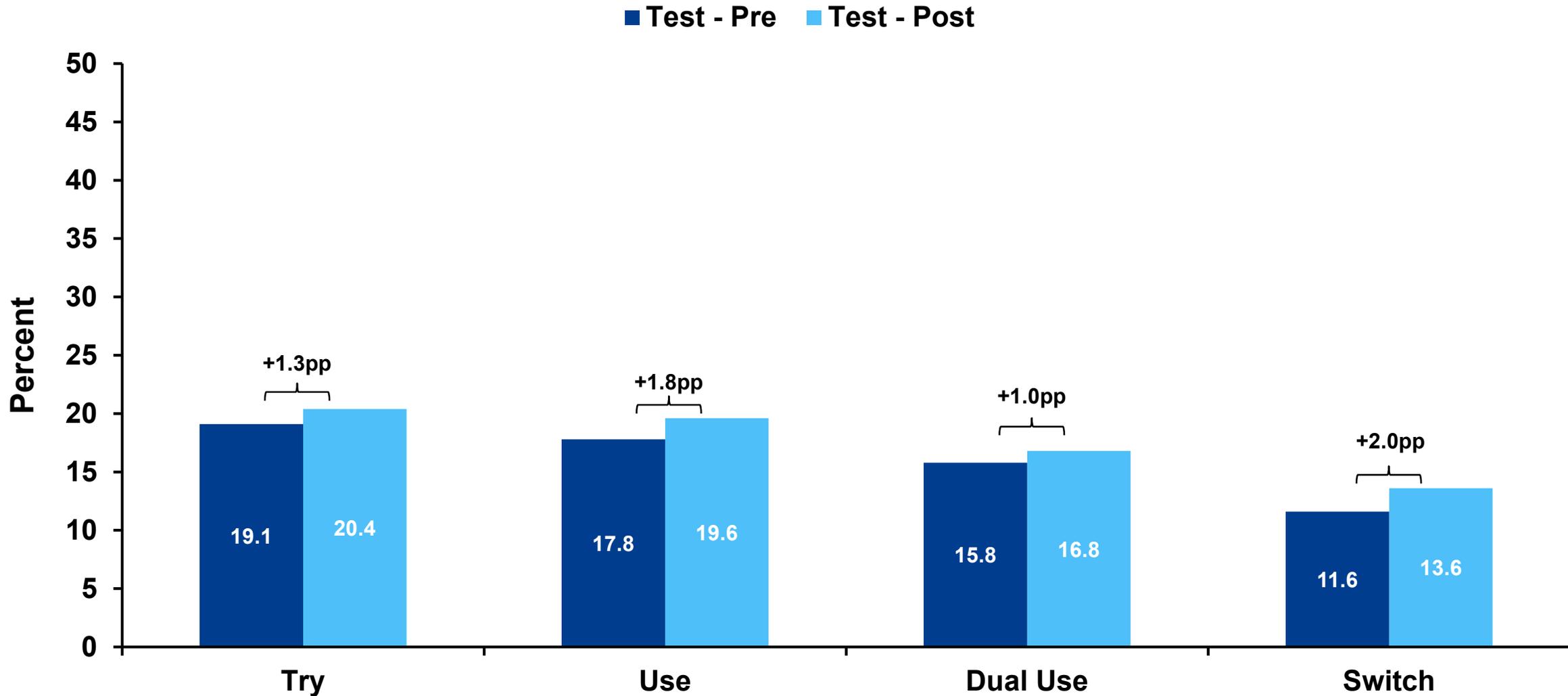


I would consider using Copenhagen® Snuff more than once. I expect to use Copenhagen® Snuff. It is likely that I will regularly use Copenhagen® Snuff in the next 6 months. Copenhagen® Snuff will be my regular brand of snuff/dip/smokeless tobacco in the next 30 days. 6=Strongly Agree, 5=Agree, 4=Somewhat Agree, 3=Somewhat Disagree, 2=Disagree, 1=Strongly Disagree. Composite Score calculated by averaging across the four measures, at the individual level.

*p=.003

*Statistically significant difference between test and control (ANCOVA)

Likelihood Behavior Measures - ASNPQ



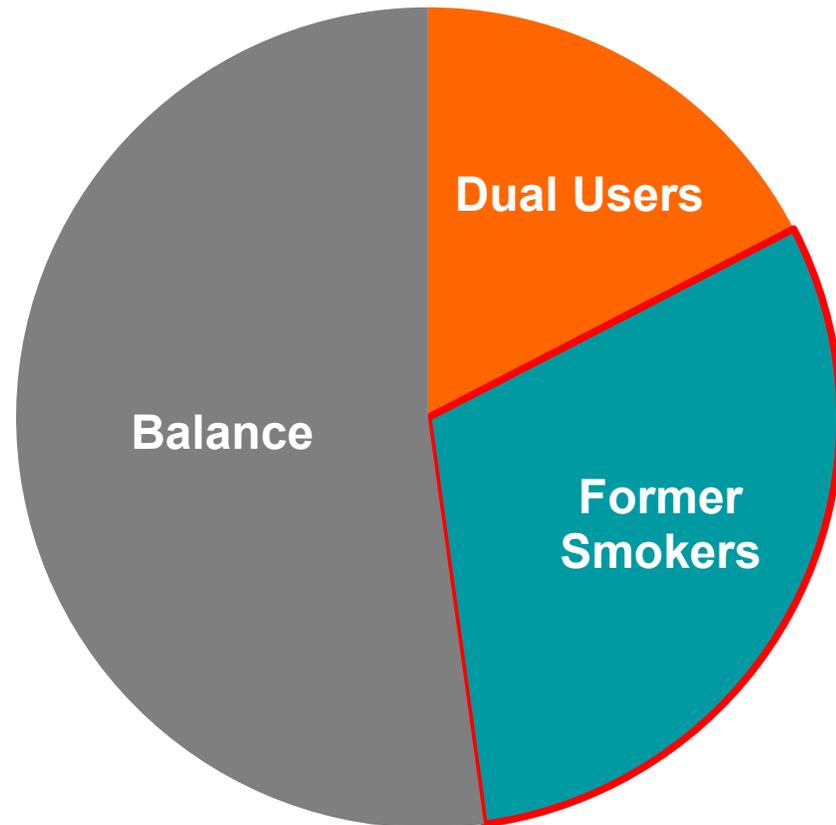
Intention to Use, Switch & Dual Use Copenhagen® Snuff

Table of P-Values

	ASPQ	ASNPQ	Dual Users	MST Users	Former Users	Never Users	Tobacco Users LA-24	Tobacco Non-Users LA-24
Intention to use	0.133	0.002	0.742	0.460	0.243	0.149	0.803	0.533
Intention to switch	0.553	0.049	0.281	-	-	-	0.972	-
Intention to dual use	0.635	0.109	0.563	-	-	-	0.789	-

Copenhagen[®] Snuff is Relevant to Adult Smokers

Copenhagen[®] Snuff Users



- **Among the 460K Copenhagen[®] Snuff users:**
 - ▶ 380K were exclusive users
 - 140K were former adult smokers*
 - ▶ 80K were dual users

Based on ALCS analysis of PATH Wave 1 data Sep 12, 2013 – Dec 14, 2014.

Cigarette smokers include those who report having smoked at least 100 cigarettes in their lifetime and now smoking every day or some days.

Smokeless Tobacco users include those who report having used ST at least 20 times in their lifetime and now using ST every day or some days.

*Former Smokers are defined as having smoked 100+ cigarettes but not currently smoking every day or some days.

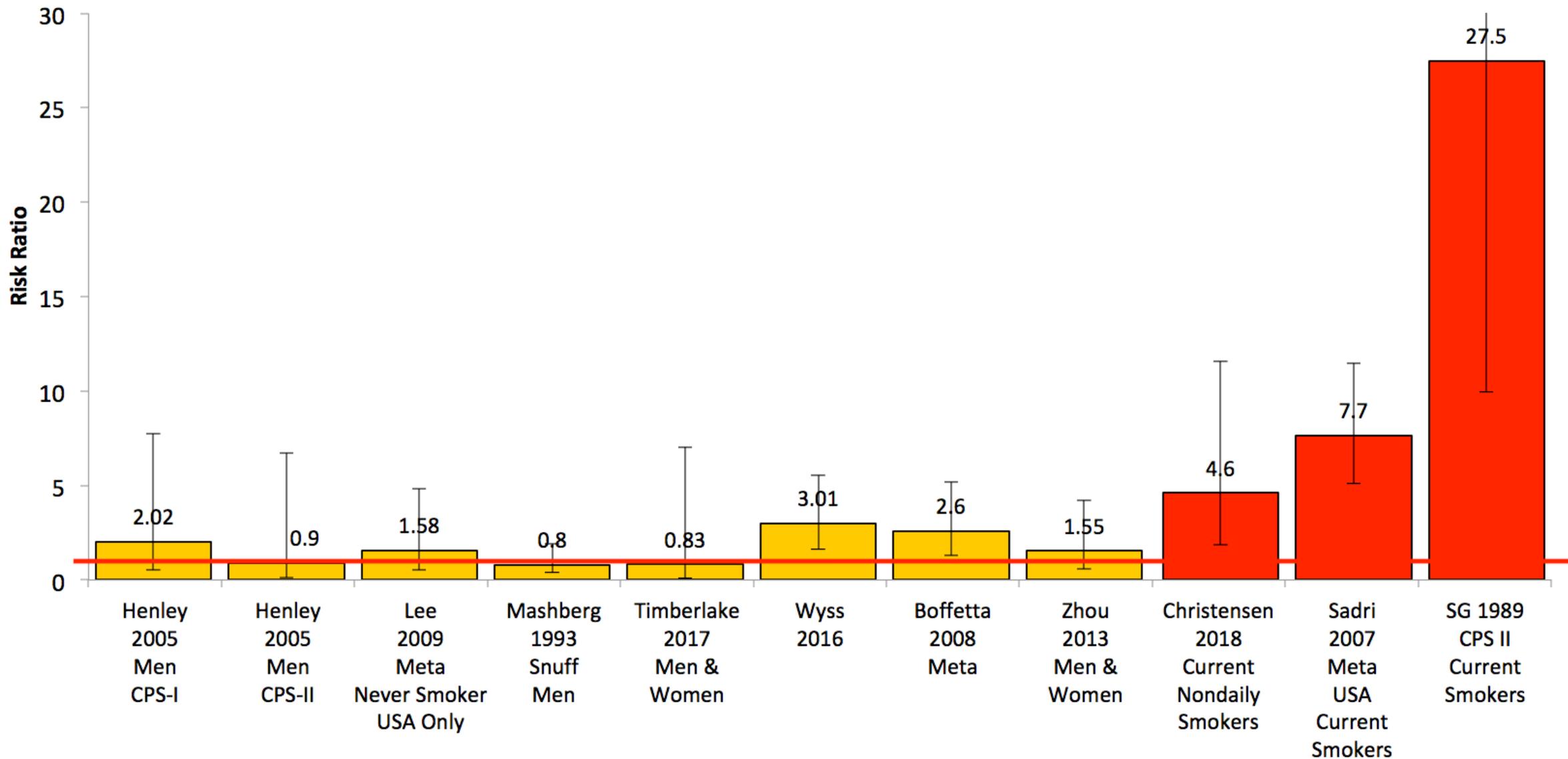
Believability by Incoming Beliefs on Lung Cancer

- The majority (68%) of respondents who did not find the ad believable came in perceiving the risk of lung cancer from using Copenhagen® Snuff to be 100% (Extremely Likely)

		Copenhagen Snuff: Lung Cancer Risk (Pre) and Ad Believability Cross tabulation											
		0% Extremely Unlikely %	10% %	20% %	30% %	40% %	50% %	60% %	70% %	80% %	90% %	100% Extremely Likely %	Total
Q164. This ad is believable	Strongly Disagree	7.3%	2.0%	2.2%	1.8%	5.0%	8.1%	5.6%	4.2%	7.5%	8.3%	48.0%	N=496
	Disagree	5.0%	4.4%	3.3%	6.8%	8.3%	13.6%	7.1%	8.6%	9.8%	10.9%	22.2%	N=338
	Neither Agree Nor Disagree	10.1%	5.9%	7.3%	5.7%	8.3%	15.6%	7.4%	7.7%	6.3%	5.7%	20.1%	N=795
	Agree	13.7%	12.5%	8.7%	9.2%	6.7%	13.6%	6.0%	7.7%	6.1%	5.5%	10.2%	N=963
	Strongly Agree	21.7%	9.1%	6.5%	4.1%	2.3%	9.1%	3.8%	5.6%	5.9%	8.5%	23.5%	N=341
Total													N=2933

Oral Cancer Mortality Risks

Smokeless Tobacco Risk Ratios



HPHC Data vs STP Category – TSNAs

TSNAs	Copenhagen® Snuff Mean (± 95% CI)	2014-2015 MST Market Survey Mean Range (min - max)	2014 MST Market Survey Copenhagen® Snuff Mean	2015 MST Market Survey Copenhagen® Snuff Mean
	ng/gram (as-is)			
NNK	472 (88.3)	97 - 1751	831	381
NNN	1746 (73.8)	552 - 5222	2403	1523

Copenhagen® Snuff Data Source: Section 7.1, N= 35 replicates (5 lots each with 7 replicates)

Market Survey 2014-2015 Data Source: https://digitalmedia.hhs.gov/tobacco/static/mrtpa/RJR/6_RESEARCH/5%20Section%206.1.5%20-%20Chemistry_Redacted.pdf

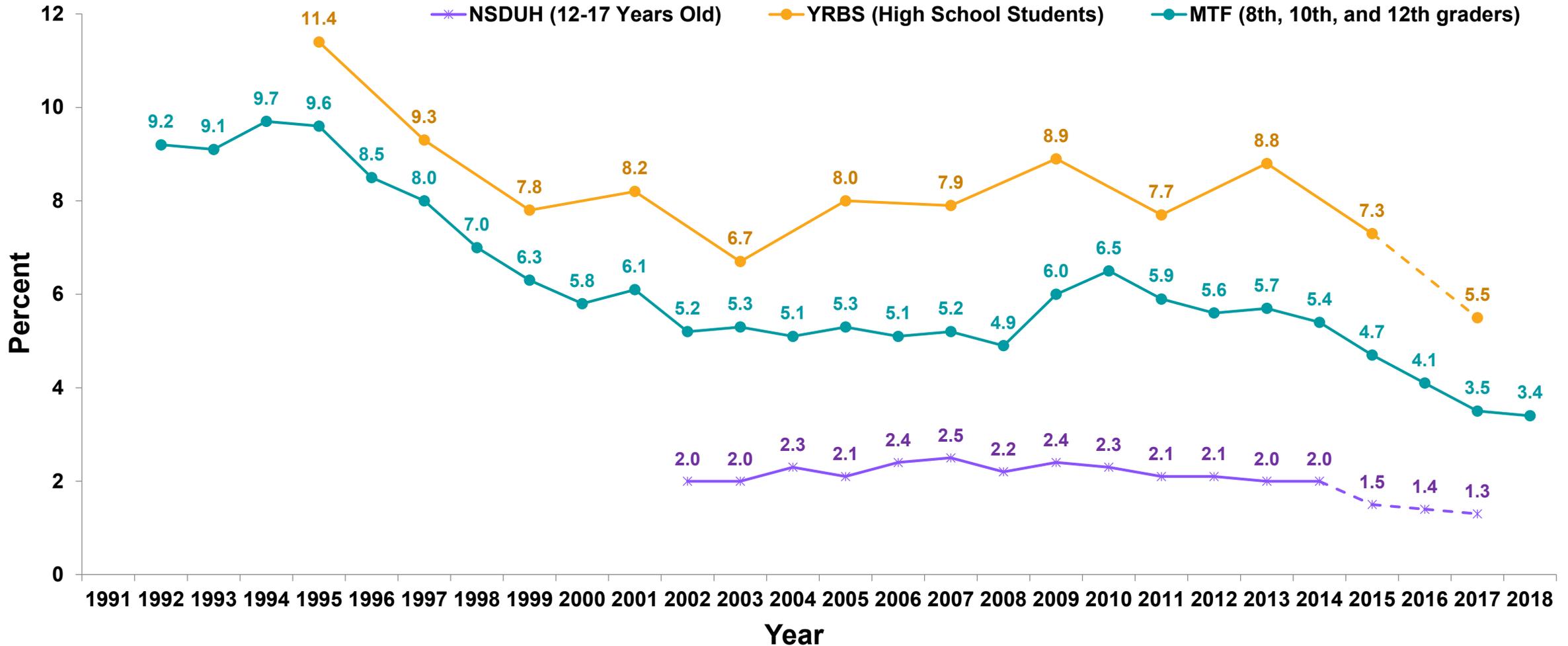
Market surveys to determine the HPHC content of U.S. smokeless tobacco products were conducted in 2014 and 2015

Twenty-two moist snuff products were sampled in 2014 representing a total of 68% of the moist snuff market share.

Twenty-nine moist snuff products were sampled in 2015 representing a total of 72% of the moist snuff market share.

Past 30-Day Smokeless Tobacco Use Among Youth

NSDUH, YRBS, MTF



National Survey on Drug Use and Health (NSDUH): <https://www.samhsa.gov/data/report/2017-nsduh-annual-national-report>

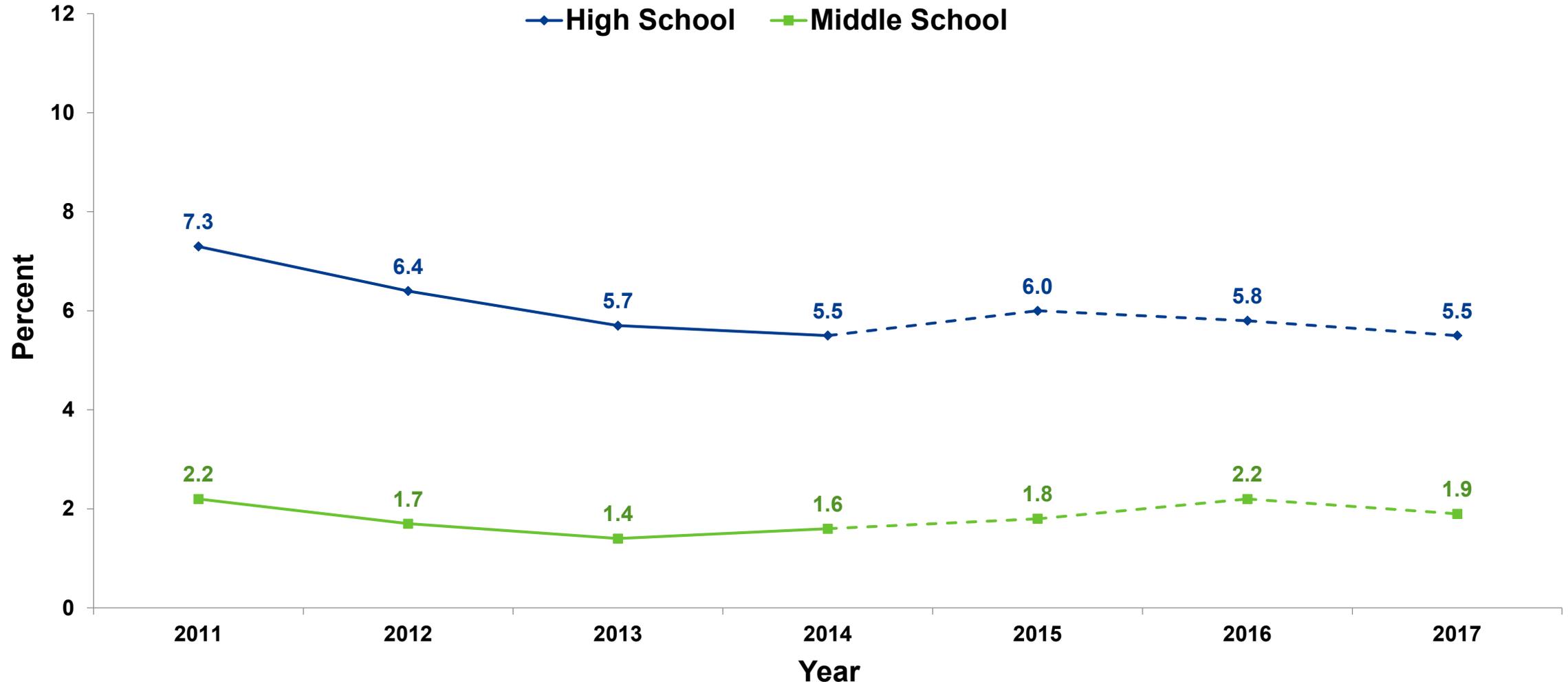
Note: For smokeless tobacco, 2015 and prior years' data are not comparable due to methodological changes in 2015 - snus combined into measure.

Youth Risk Behavior Survey (YRBS): <https://www.cdc.gov/healthyyouth/data/yrbs/pdf/2017/ss6708.pdf>

Note: For smokeless tobacco, 2017 and prior years' data are not comparable due to methodological changes in 2017. Beginning in 2017 snus and dissolvable tobacco were combined into the smokeless measure.

Monitoring the Future (MTF): <http://monitoringthefuture.org/data/18data/18drtbl7.pdf>

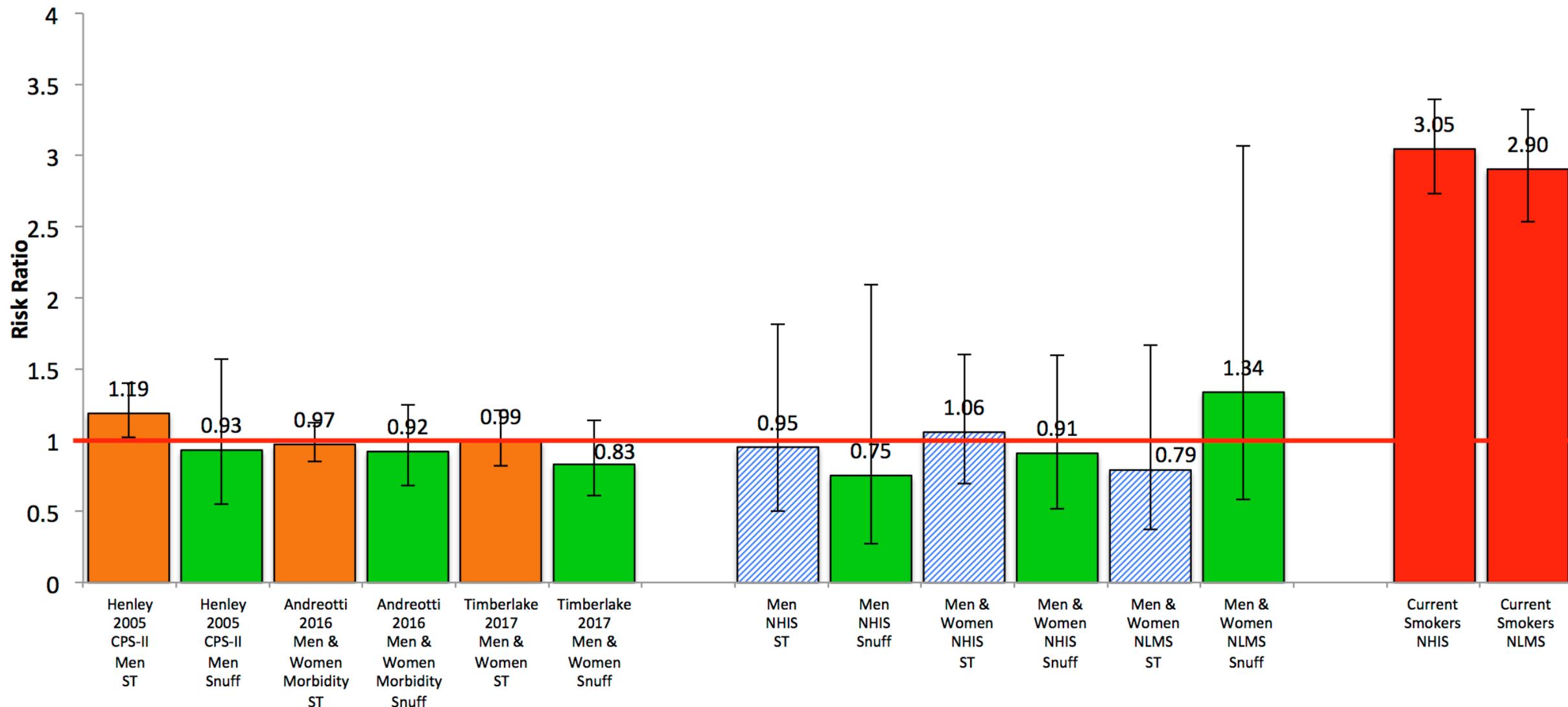
Past 30-Day Smokeless Tobacco Use Among Middle School and High School Students (NYTS)



<https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a3.htm>

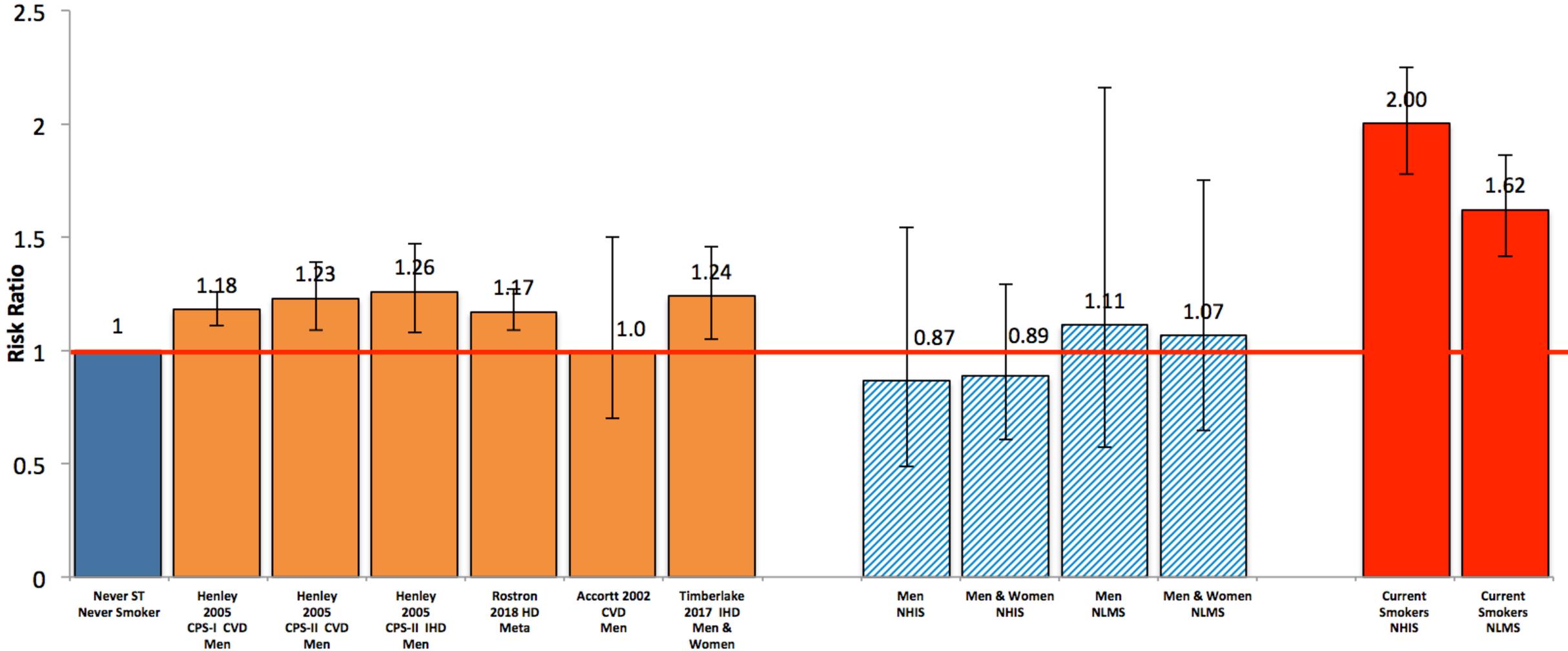
2015 and prior years data are not comparable due to changes in reporting in 2015. In 2015 smokeless tobacco includes chewing tobacco/snuff/dip, snus, and dissolvable tobacco. Prior to 2015, smokeless tobacco included only chewing tobacco/snuff/dip.

All-Cancer Mortality Risks From Smokeless Tobacco and Snuff



Andreotti 2016 includes "Cancer incidence".

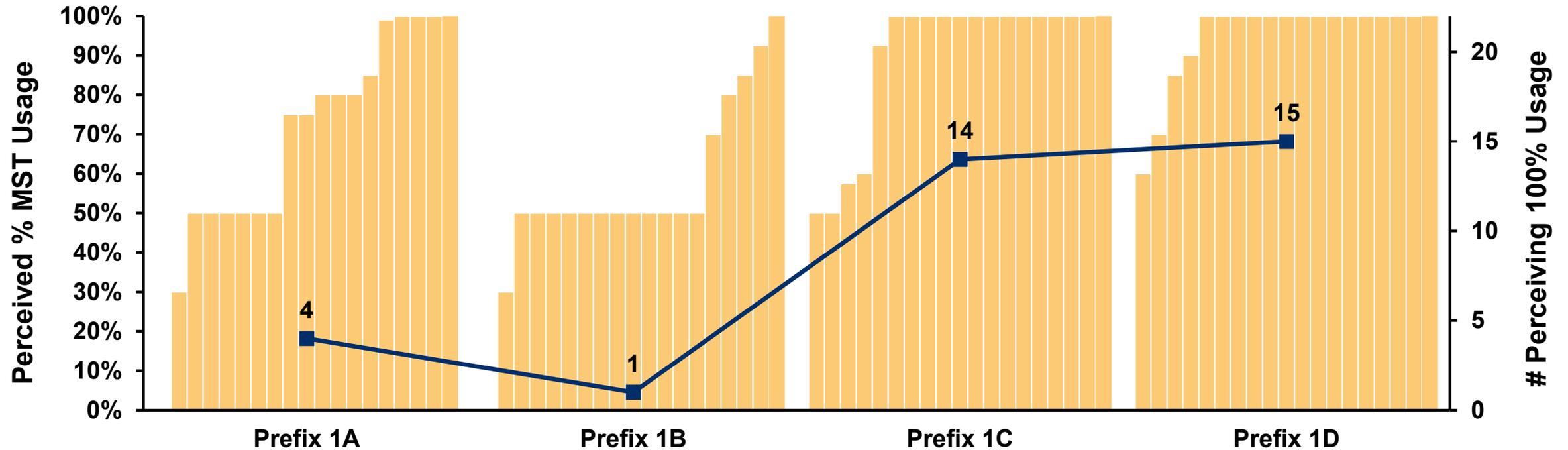
Diseases of the Heart Mortality Risks



Round 2 Specific Language Exploration

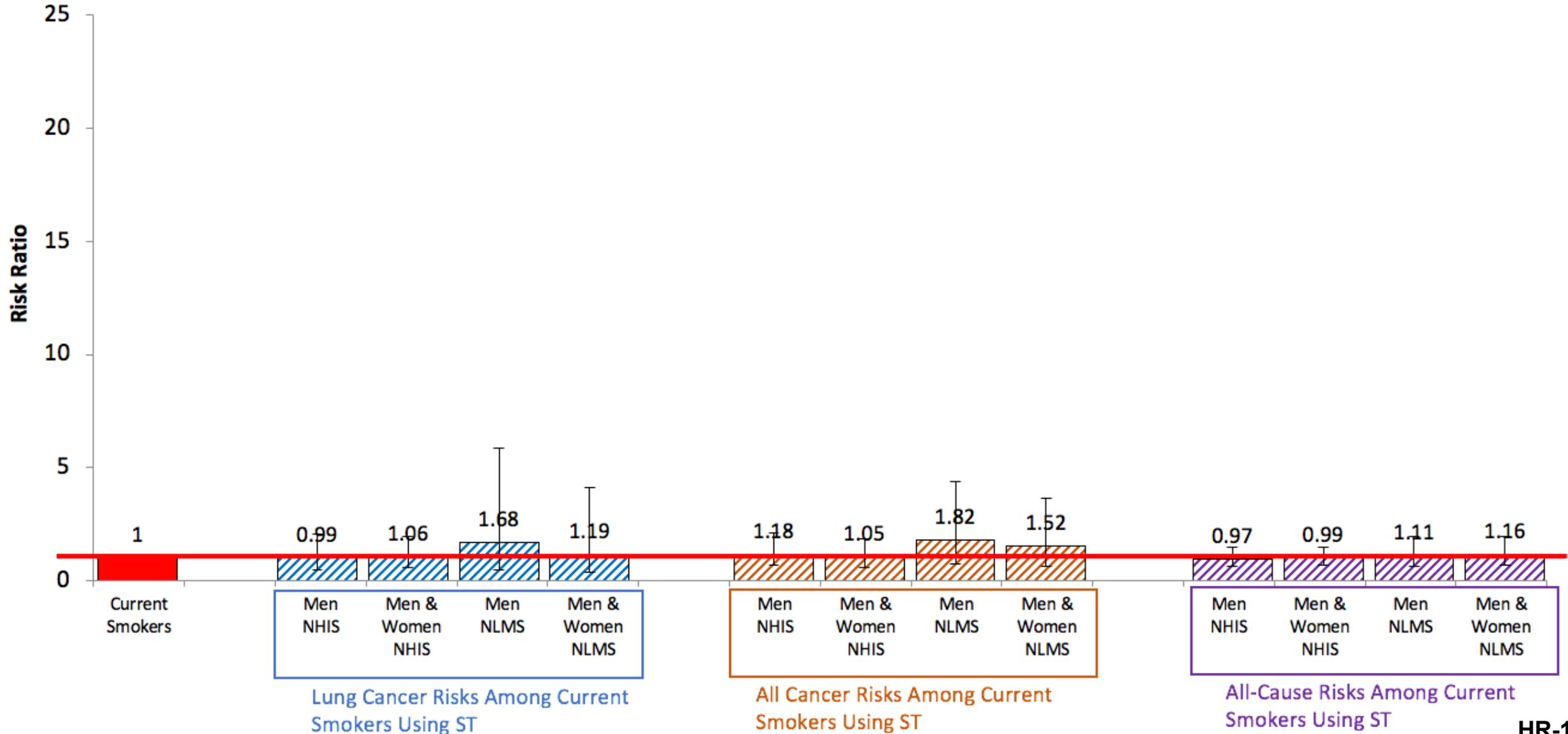
Prefix Phrases:

- 1A Using this product instead of
- 1B Using this product as an alternative to
- 1C Switching completely
- 1D Exclusive use



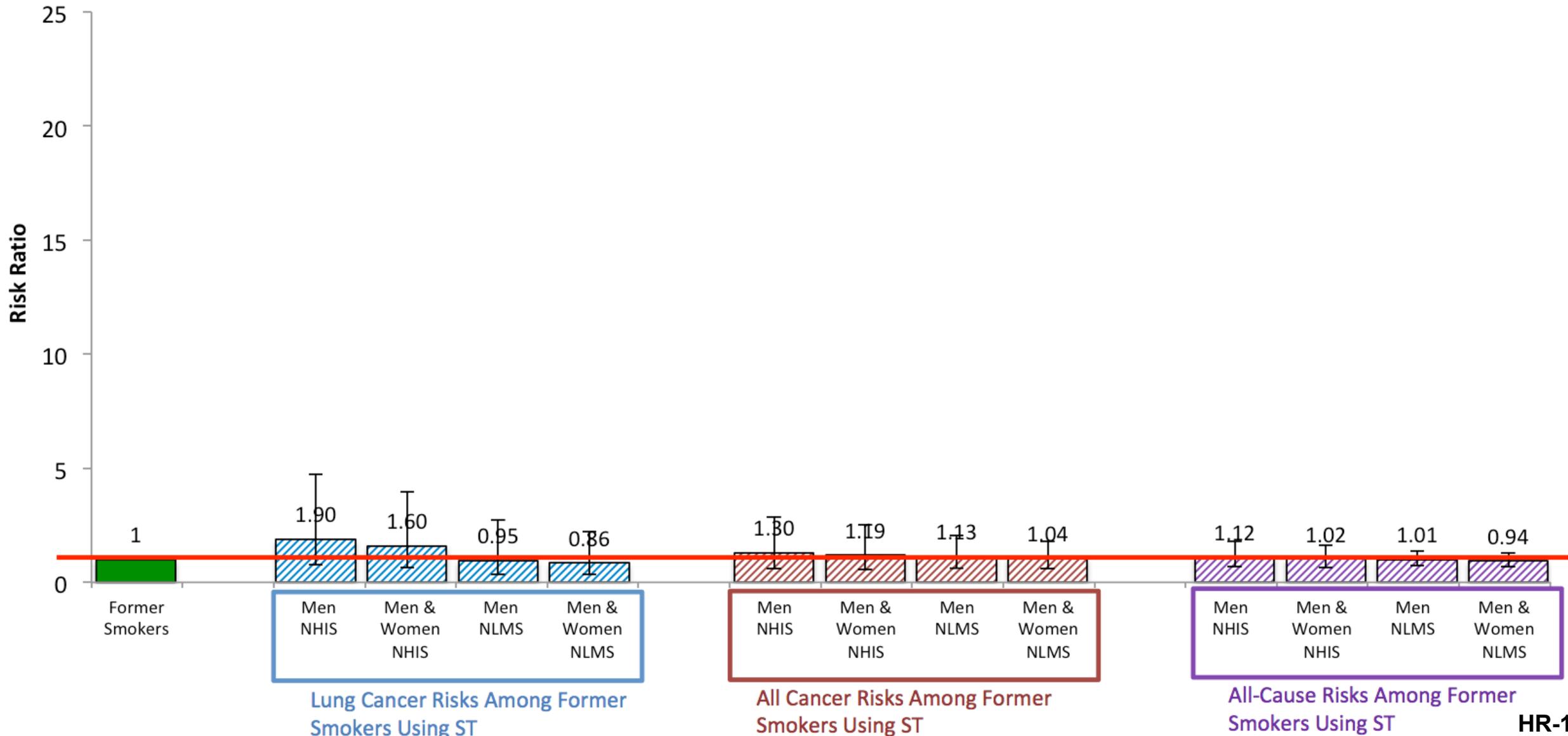
Mortality Risks Among Current Smokers

Lung Cancer, All-Cancer and All Causes in NHIS and NLMS

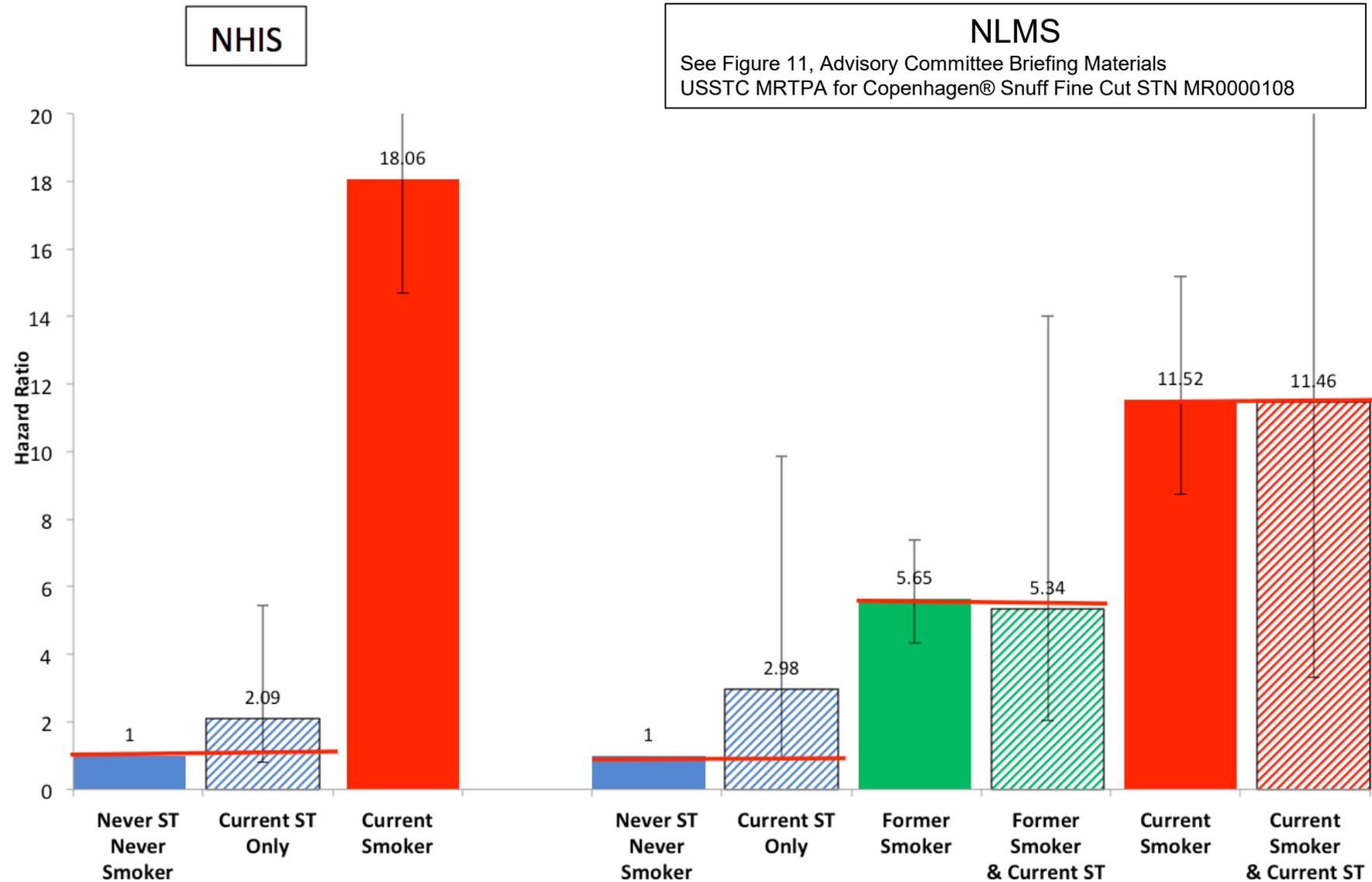


Mortality Risks Among Former Smokers

Lung Cancer, All-Cancer and All Causes in NHIS and NLMS



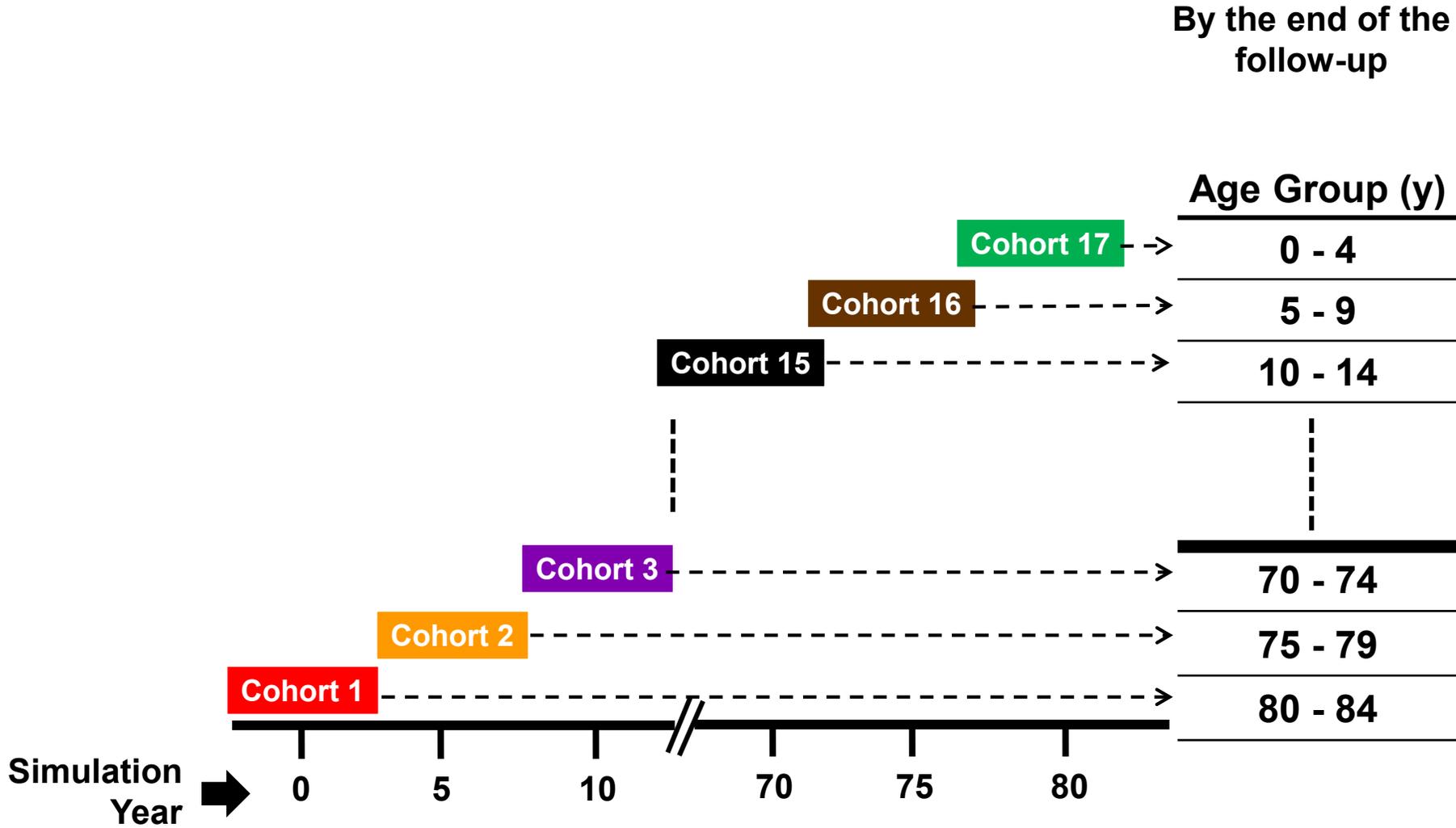
Lung Cancer Mortality Risks



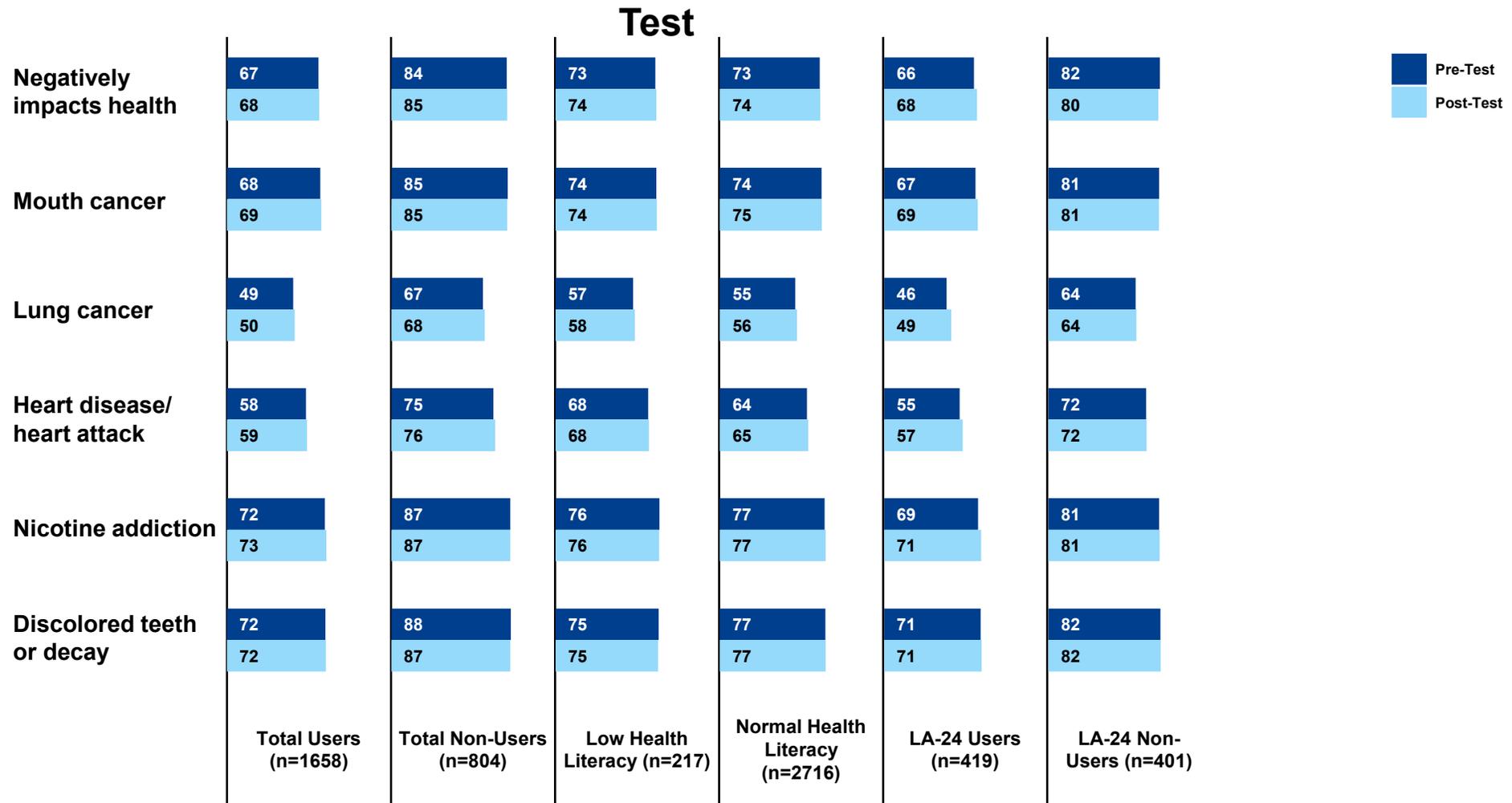
Results: Time-staggered Multiple Cohort

Age Group (y)	Mean Premature Deaths Prevented (Base Case)	Mean Premature Deaths Prevented (Modified Case)	Difference in Premature Deaths Prevented in the Year 2075 (Modified - Base)
0-4 (2075)	11,659,500	11,659,500	0
5-9 (2070)	11,503,227	11,503,227	0
10-14 (2065)	11,343,808	11,343,808	0
15-19 (2060)	11,384,863	11,384,863	0
20-24 (2055)	11,210,354	11,210,354	0
25-29 (2050)	10,975,342	10,975,495	153
30-34 (2045)	10,691,192	10,691,665	473
35-39 (2040)	10,397,394	10,398,367	973
40-44 (2035)	10,099,412	10,101,332	1,920
45-49 (2030)	9,783,564	9,787,295	3,731
50-54 (2025)	9,348,637	9,355,425	6,788
55-59 (2020)	8,747,530	8,757,301	9,771
60-64 (2015)	8,038,615	8,050,922	12,307
65-69 (2010)	7,676,364	7,691,177	14,813
70-74 (2005)	6,873,894	6,889,508	15,614
75-79 (2000)	5,759,539	5,774,009	14,470
80-84 (1995)	4,749,605	4,761,915	12,310
Total Premature Deaths Prevented in the Base vs. Modified Case	160,242,840	160,336,163	93,323

Time-staggered Multiple Cohort Approach



Risk Perceptions – Populations of Interest



We realize you may not know the answer to each question, but please give your best answer. Looking at the same list, how likely is it that these things will happen to a person who only uses Copenhagen® Snuff daily? 0% Extremely Unlikely 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% Extremely Likely.

Would-be Quitter to ST Sensitivity Analysis

(Not Modified by CCIS)

Transition Rate, %	Difference in Premature Deaths Prevented
0	94,680
5 (Modified Case)	93,323
10	91,966
20	89,251
50	81,109
100	67,539