Unequal risk for tobacco-related stroke in Black adults

Jelena Mustra Rakic, PhD

"It's About a Billion Lives" Symposium January 26, 2023

Acknowledgment

John Kane, MD, PhD Clive Pullinger, PhD Erin Van Blarigan, ScD Eveline Stock, MD Mary Malloy, MD

CTCRE group:

Pamela Ling, MD, MPH Dorie Apollonio, PhD Maya Vijayaraghavan, MD, MAS Matthew Springer, PhD Gideon St Helen, PhD **Funding:** TRDRP (T32 FT 4767) NCI (T32 CA 113710) Read Family Foundation

Background & Research Question



Stroke: one of the top causes of death in U.S.

- Every 40 seconds someone has a stroke
- Every 3.5 minutes someone dies of stroke
- Fifth leading cause of death and leading cause of long-term disability





Black smokers have uniquely high risk for stroke

• Black people: the highest risk for stroke compared to all other races

Cigarette Smoking and Incident Stroke in Blacks of the Jackson Heart Study Arrican American/Black people = Black people

Adebamike A. Oshunbade, Wondwosen K. Yimer, Karen A. Valle, Donald ClarkIII, Daisuke Kamimura, Wendy B. White, Andrew P. DeFilippis, Michael J. Blaha, Emelia J. Benjamin, Emily C. O'Brien, Robert J. Mentz, Ervin R. Fox, Charles S. O'Mara, Javed Butler, Adolfo Correa and Michael E. Hall

Originally published 10 Jun 2020 | https://doi.org/10.1161/JAHA.119.014990 | Journal of the American Heart Association. 2020;9:e014990

Smoker vs Nonsmoker: Black people (HR = 2.5) White people (HR = 1.5)

Oshunbade, A. A., et al. (2020). J Am Heart Assoc 9 (12): e014990.



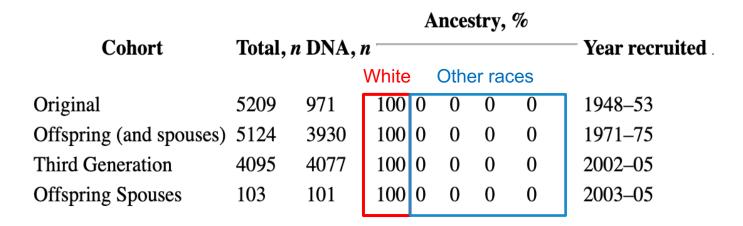
Framingham Heart Study defined risk factors

- Long-term ongoing cardiovascular (includes stroke) cohort study
- Defined traditional risk factors for stroke (blood pressure, smoking..)





Framingham Heart Study conducted in White people





Apolipoprotein L1 (APOL1)

The JOURNAL OF BIOLOGICAL CHEMISTRY @ 1997 by The American Society for Biochemistry and Molecular Biology, Inc.

Vol. 272, No. 41, Issue of October 10, pp. 25576–25582, 1997 Printed in U.S.A.

Apolipoprotein L, a New Human High Density Lipoprotein Apolipoprotein Expressed by the Pancreas

IDENTIFICATION, CLONING, CHARACTERIZATION, AND PLASMA DISTRIBUTION OF APOLIPOPROTEIN L*

(Received for publication, April 21, 1997, and in revised form, July 21, 1997)

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Apolipoprotein L gene family: tissue-specific expression, splicing, promoter regions; discovery of a new gene

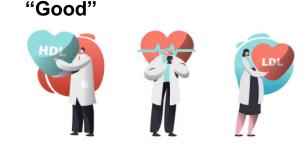
Philippe N. Duchateau,^{1,2,*} Clive R. Pullinger,^{1,*} Min H. Cho,* Celeste Eng,* and John P. Kane^{†,§}

Cardiovascular Research Institute,* Department of Medicine,[†] and Department of Biochemistry and Biophysics,[§] University of California, San Francisco, CA 94143-0130

APOL1: part of the "good" cholesterol

APOL1:

- Component of high-density lipoprotein (HDL)
- Protects against African sleeping sickness (Parasite *Trypanosoma brucei*)







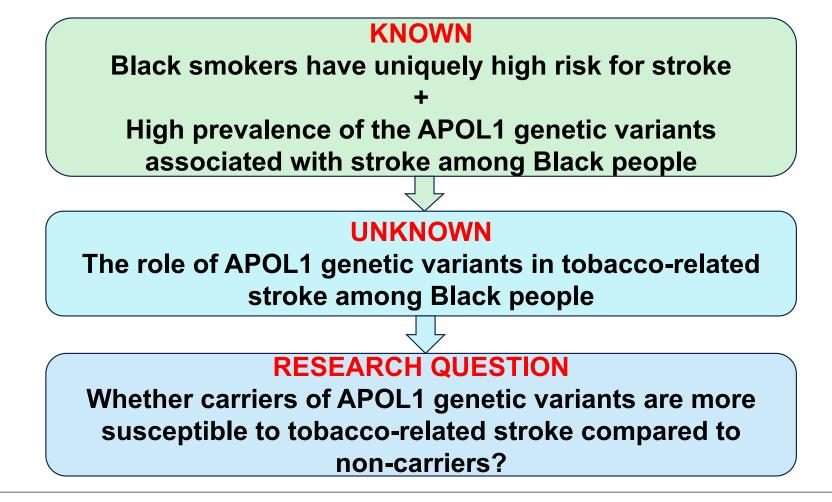
APOL1 genotypes

- The most common: G0 (reference sequence)
- Two genetic variants: G1 & G2

Carriers of APOL1 genetic variants:

- ↑ risk of stroke

In the U.S., ~ 50% of Black people carry APOL1 G1 and/or G2 variants





Methods



Study Design

Cross-sectional study

• Collect data at a single point in time, without intervention on participants

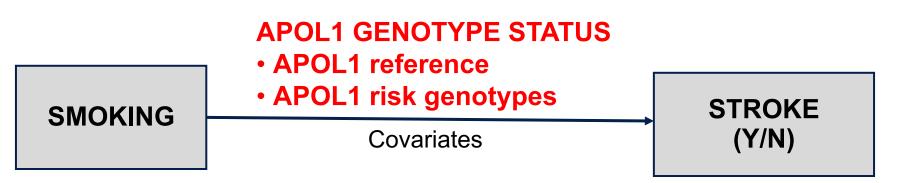
Study population

• 527 Black people, recruited through the UCSF Lipid Clinic (1999-2019)





Study Design

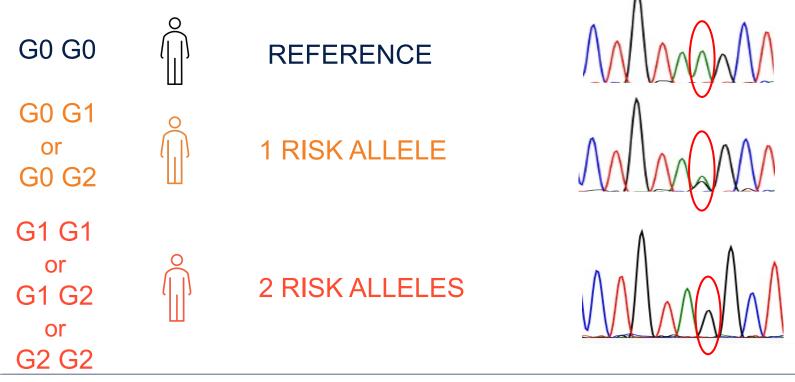


•EVER smokers (Past + Current) •NEVER smokers



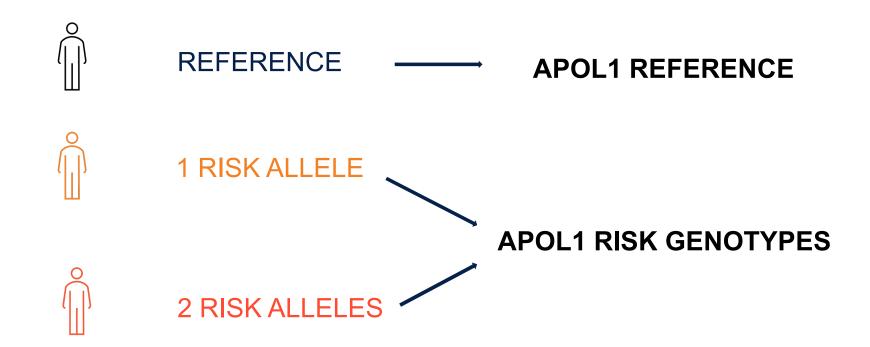
APOL1 genotype status

• Sequencing: the terminal exon of APOL1 gene





APOL1 groups: APOL1 reference or risk genotypes





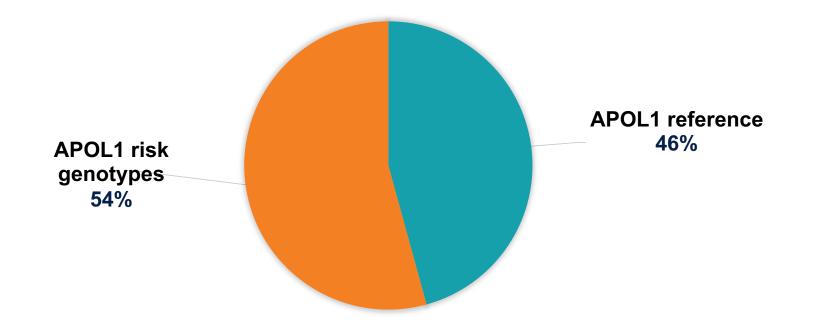
Results



Participants' characteristics

- Median age in years: 58 [18 88]
- 52% are female
- 42% ever smokers (current and past smokers)
- Diabetes (28%)
- High blood pressure (56%)
- High lipid levels (28%)

Prevalence of the APOL1 genotypes (N=527)



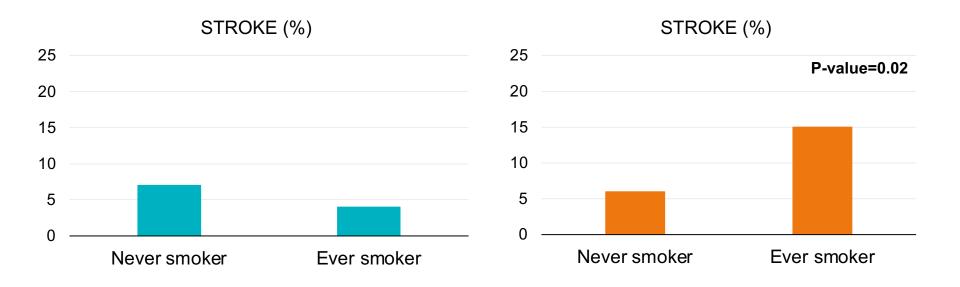


Participants in smoking groups differ

- Age
- Sex
- Diabetes
- High blood pressure
- High lipid levels

More stroke in smokers with APOL1 risk genotypes

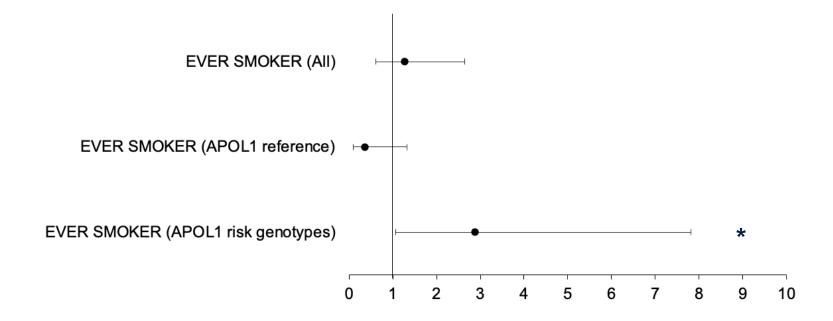
APOL1 reference APOL1 risk genotypes





APOL1 variants increase tobacco-related stroke

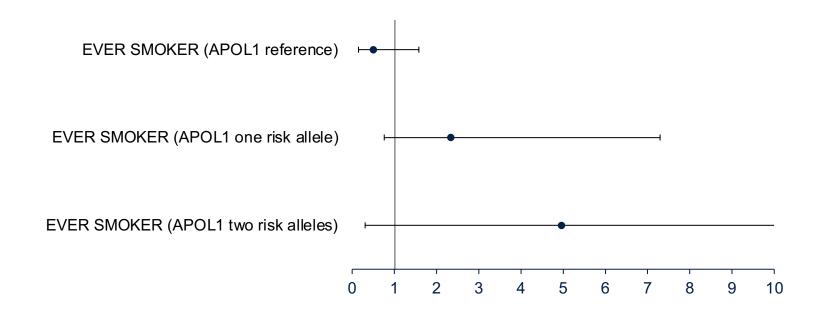
Odds ratio (OR)



Logistic regression (ADJUSTED model: age, sex, high lipid levels, diabetes, high blood pressure) *P<0.05



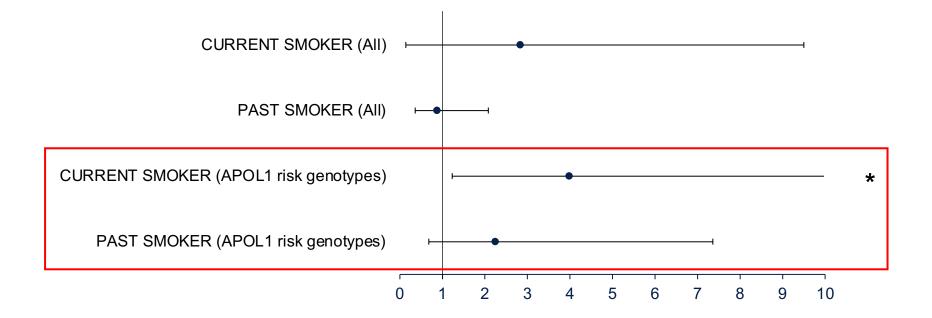
Exploratory: dose-response of APOL1 risk alleles



Logistic regression (ADJUSTED model: age, sex, high lipid levels, diabetes, high blood pressure)



Exploratory: Current and Past smoking status



Logistic regression (ADJUSTED model: age, sex, high lipid levels, diabetes, high blood pressure) *P<0.05



Conclusions & Implications



CONCLUSIONS

- Ever smokers CARRIERS of APOL1 risk variants are more susceptible to stroke
- Carriers of TWO APOL1 risk alleles may be more likely to have stroke than carriers of ONE APOL1 risk allele
- Carriers of APOL1 risk variants who QUIT smoking may be less likely to have stroke

IMPLICATIONS

- Screening for the APOL1 genetic variants can help identify people at especially high risk for tobacco-related stroke
- Policies, like the recent menthol ban that affects Black smokers, may address the susceptibility of the carriers
- Smoking cessation programs may address this susceptibility



Reference

Limou, S., et al."APOL1 kidney risk alleles: population genetics and disease associations." *Adv Chronic Kidney Dis*. (2014)

Tsao CW, Vasan RS. "Cohort Profile: The Framingham Heart Study (FHS): overview of milestones in cardiovascular epidemiology." *Int J Epidemiol*. (2015)

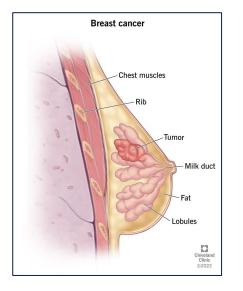




Industry Influence Over Scientific Information on Breast Cancer: Exploring the UCSF Industry Documents Library

Cristin Kearns, DDS, MBA, PhD(c) Assistant Professor **Philip R. Lee Institute for Health Policy Studies** Preventive and Restorative Dental Sciences School of Dentistry, UCSF

Breast Cancer – Key Facts





- Most common form of cancer in women, except for skin cancer
- Over 42,000 women and 500 men die each year
- Family history accounts for only 10% of breast cancer diagnoses
- A large and growing body of evidence indicates that toxic chemicals may increase the risk of developing





<u>Ce</u>

RFP to Explore UCSF Industry Documents Library – January 2021

//// INDUSTRY DOCUMENTS LIBRARY

- ✔ Tobacco Collections (all tobacco collections selected)
- Chemical Collections (all chemical collections selected)
- Solution Collections (all drug collections selected)
- ✓ Food Collections (all food collections selected)
- ✔ Fossil Fuel Collections (all fossilfuel collections selected)

- "None of the over 800 journal articles published to date relate directly to breast cancer."
- "Bibliography of publications that have used the Industry Documents Library for the keyword "breast" returned a single newspaper article, and no scientific or other publications."





Preliminary IDL Search: "breast cancer"

//// INDUSTRY DOCUMENTS LIBRARY
Tobacco Collections (all tobacco collections selected)
Chemical Collections (all chemical collections selected)
Drug Collections (all drug collections selected)
Food Collections (all food collections selected)
Fossil Fuel Collections (all fossilfuel collections selected)

Documents Returned 54,283 169 549 842 15



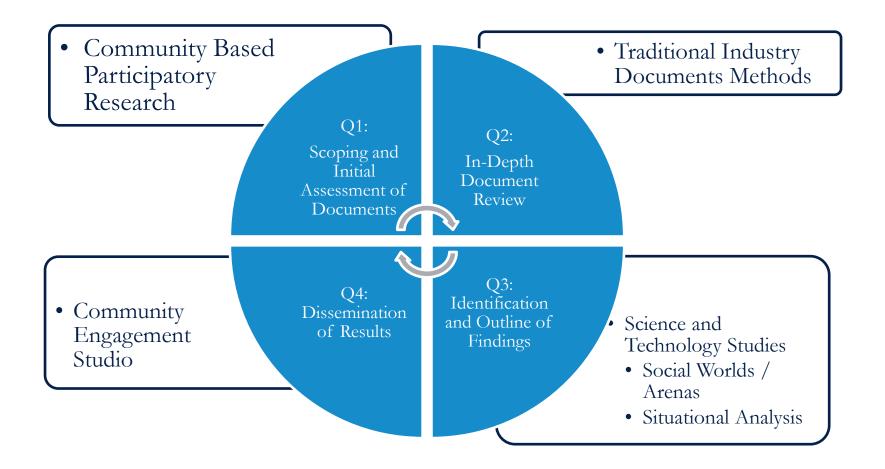
Our Transdisciplinary Team



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- Hannah Khan, MPH, MD(c)
- Kate Tasker, MLIS
- Rachel Taketa, MLIS



Project Timeline and Methodology

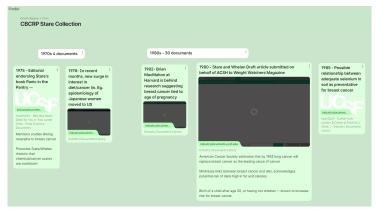




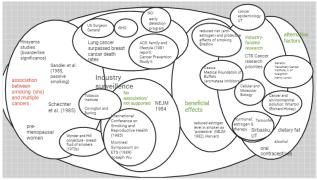
Research Tools

Document Characteristics

 Timelines of Key Events -Padlet Most Frequent Chemicals, Drugs

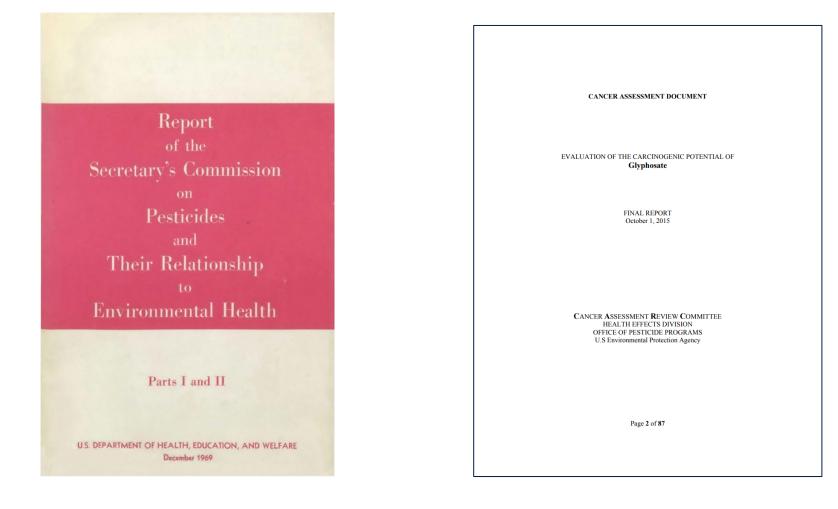


 Social Worlds / Arenas Mapping – Google Jamboard





Over 50 Key Threatening Events Related to Breast Cancer Identified (1969-2015)





Topics Selected for Further Review

Risk of Breast Cancer Related to:

- Smoking
- Environmental Tobacco Smoke
- Hormonal Replacement Therapy
- Glyphosate
- Benzene
- DDT
- Recombinant Bovine Somatotropin
- Dietary Fat





Key Tobacco Industry Findings-Council for Tobacco Research

Breast Cancer Research (at least 13,186 documents) At least 38 research publications



1970s-1990

- Non-tobacco related explanations for breast cancer risks: genetics and estrogen metabolism
- Smoking's positive effects on breast cancer due to the aromatase inhibitor content of smoke
- Aromatase inhibitor extraction for therapeutic purposes
- Epidemiological studies of breast cancer mortality in contrast to lung cancer
- Cellular and molecular biology research
- Methodological critiques of epidemiological studies
- Genetic causes (BRCA-1, BRCA-2)
- Hormonal therapy
- Vitamin D, protein protease therapeutics





1990s-

Key Tobacco Industry Findings – Philip Morris / RJ Reynolds

California Environmental Protection Agency Reports on Health Effects of Environmental Tobacco Smoke (at least 1,067 documents)



1997

- Key strategy: Deflection and Misdirection
 - published research
 - · attended scientific conferences
 - highlighted other studies that emphasized other breast cancer causes including alcohol use, body mass index, premenopausal and postmenopausal status, reproductive effects



- Key strategy: Denial and Suppression of Evidence
 - published research
 - attended scientific conferences
 - Criticized other studies that found a link between ETS and breast cancer, scrutinized validity of research design, sample size, etc.



Key Drug, Chemical and Fossil Fuel Industry Findings

Wyeth-Ayerst (at least 175 documents) – Monsanto (at least 250 documents) – Oil Industry (at least 350 documents)



2002



2015



1984

- Wyeth developed a PR campaign in response to evidence that Premarin increase breast cancer risk
- Monitored new evidence, presented positive evidence to professionals, targeted women's health providers
- Women's Health Research Institute
- Monsanto hired Sustainalytics to mitigate impact of 2015 IARC report
- Monitored news media, NGO reports, press releases regulatory announcements
- Monsanto's "GMO Answers" PR program criticized studies linking glyphosate to breast cancer
- Shell Oil and others hired Environ Corp. to undermine generalizability of animal models to humans related to benzene exposure and mammary/ovarian tumors
 - Shifted blame from benzene to dietary fat
 - Exxon contributions to Susan G. Komen Foundation



Key Food Industry Findings

DDT (at least 102 documents) – rBST (at least 143 documents) – Dietary Fat (at least 10,000 documents)

1993-94	 ACSH / ILSI secretly engaged leaders at Mount Sinai Medical School and Harvard to disseminate claims critical of evidence linking DDT residues in foods to breast cancer Harvard's Nutrition Program conducted public relations activities for ILSI and other industry organizations in exchange for sponsorship 	
	 Monsanto recruited experts at Mass. General Hospital and Harvard to counter proposed state legislation to require labelling of milk from cows treated with rBST 	
rBST FREE	 Monsanto subsequently donated \$100K to Harvard's Department of Nutrition 	
2015	 ACSH instrumental in opposing efforts to ban rBST in NY 	
BUTTER arter columne BUTTER	 Food, chemical, fossil fuel, and tobacco industry – all involved in influencing dietary recommendations related to dietary fat and breast cancer 	
BUTTER NETWI-OC (1949)	 Key events include the 1974 National Cancer Act, formation of the National Cancer Institute Diet, Nutrition, and Cancer Program, agency reports that 	
1984	published conflicting conclusions on dietary fat and cancer in the 1970s and 1980s	



Opportunities and Lessons Learned

- Rich opportunities for future research and public health action
- New methodological approaches and research tools applied to documents research – high-level scoping
- Dissemination is ongoing: 2023 Annual Tobacco Industry Docs Workshop
- Many other areas of potential interest unexplored:
 - 1483 documents: U.S. Brewers Association, Alcohol Beverage Medical Research Foundation
 - 1121 documents: Synthetic Estrogen
 - 4829 documents: Physical Activity
 - 8980 documents: American Council on Science and Health
 - 3029 documents: Chemical Manufacturers Association
 - 10262 documents: International Life Sciences Association
 - 4478 documents: American Petroleum Institute







Tobacco Cessation in Substance Use Treatment:

Research and Policy Efforts to Reduce Tobacco-Related Health Inequity

Caravella McCuistian, PhD

January 26th, 2023

Supported by: California Tobacco Control Program (CTCP 18-10025) NIDA Training Grant (NIDA T32DA007250) Tobacco-Related Disease Research Program (TRDRP T32KT5241)



Collaborators and Partners

Research Team	Communit	ty Partners
Joseph Guydish	Smoking Cessation Leadership Center UCSF	Champions Recovery Hanford
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Valerie Gruber	Amity Foundation Los Angeles, San Diego	Van Ness Recovery Los Angeles
Carmen Masson	Center Point Napa San Rafael	Project Pride Oakland
Anna Pagano	Progress House Camino/Garden Valley	LA CADA Los Angeles
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Jennifer Le	Fred Brown Recovery San Pedro	Chabad Rehab Los Angeles
Elliott Chaney	Janus of Santa Cruz Santa Cruz	Yolo Community Care Woodland

Substance Use Disorder

In the United States in 2019

- 165.4 million people reported any substance use in the past month
- 20.4 million people reported substance use disorder
- 4.2 million received any form of substance use treatment

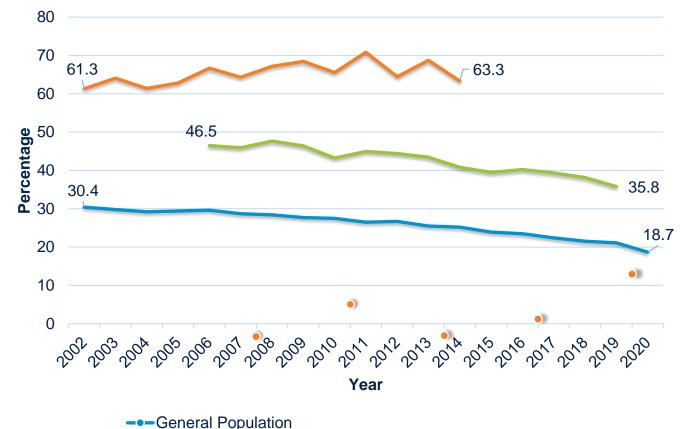


SAMHSA, 2020



Smoking Prevalence Among People with Substance Use Disorder

Smoking Prevalence



---Substance Use Disorder without Cannabis Use Disorder

--- People with Substance Use Disorder

SAMHSA 2020 Decrease in smoking prevalence among general population from 2002 – 2020

Han et al., 2022 Significant decrease in smoking prevalence among

people with substance use disorder from 2006-2019

Weinberger et al. 2018 When excluding cannabis use disorder, smoking prevalence among people with substance use disorder increased from 2002-2014



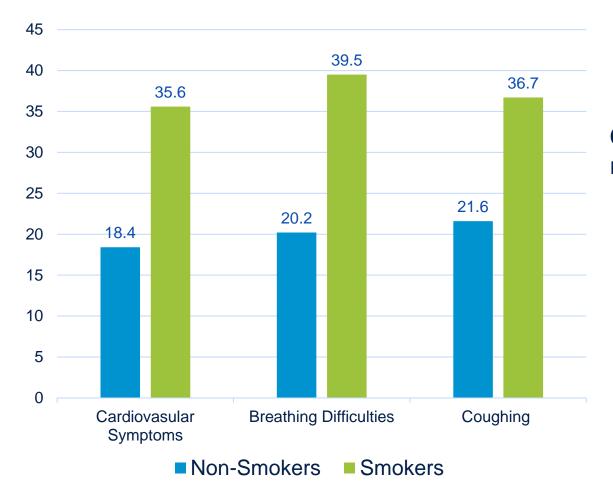
Smoking Prevalence in Substance Use Disorder Treatment in California



CDC 2020 Guydish et al. 2020



Health Symptoms Related to Smoking among People with Substance Use Disorder



Compared to non-smokers, California smokers report more:

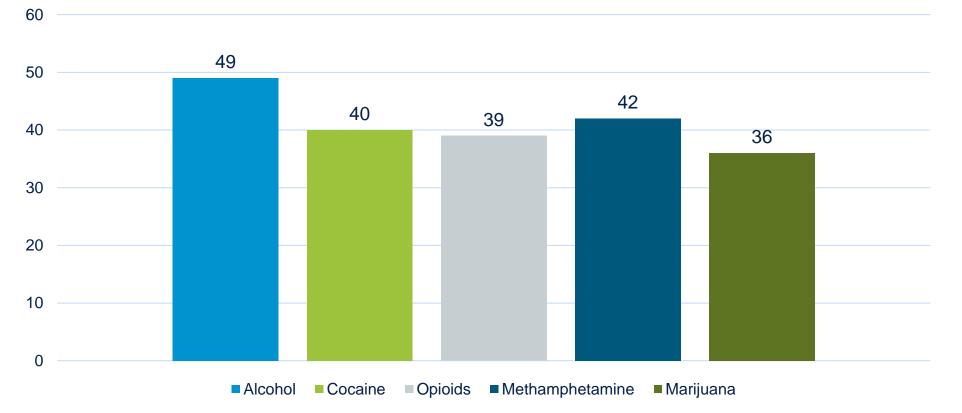
- Days of poor mental health in past month
 - 1 among non-smokers, 3 among smokers (p = 0.05)
- Sugary beverage consumption
 - 5 among non-smokers, 9 among smokers (p < .0001)

Patkar et al, 2002 Pagano et al 2022



Tobacco-Related Deaths Among People with Substance Use Disorder

Rates of Deaths Due to Smoking-Related Conditions in California 1990-2005



Callaghan et al., 2018



Tobacco Cessation and Substance Use Treatment Outcomes

- Continued smoking is associated with increased relapse
- Smoking contributes to economic hardship
- Smoking cessation is not associated with negative treatment outcomes
- Smoking cessation is associated with a 25% increase in abstinence from other drugs



Schroeder & Morris, 2010 Weinberger et al. 2017 Prochaska et al., 2004 McKelvey et al. 2017



Smoking Cessation Services in Substance Use Disorder Treatment

- Substance use disorder treatment is wellpositioned to offer smoking cessation services
- Gaps in treatment exist

California			
Screening	52%		
Counseling	42%		
Tobacco-free grounds	22%		
NRT	20%		
Pharmacotherapy	16%		

Marynak et al., 2018



Perceived Pros/Cons to Offering Tobacco Services in Substance Use Disorder Treatment

"We try to encourage people to stop smoking, but when staff's outside smoking, it's kind of hard."

> "Clients may choose not to come here for treatment or leave treatment"

"People who quit smoking have a better chance of staying quit from other drugs and alcohol. And that's what we do here. Treatment."

"We want outdoor space for alternative activities – walking paths...to allow folks to participate in alternatives to smoking."

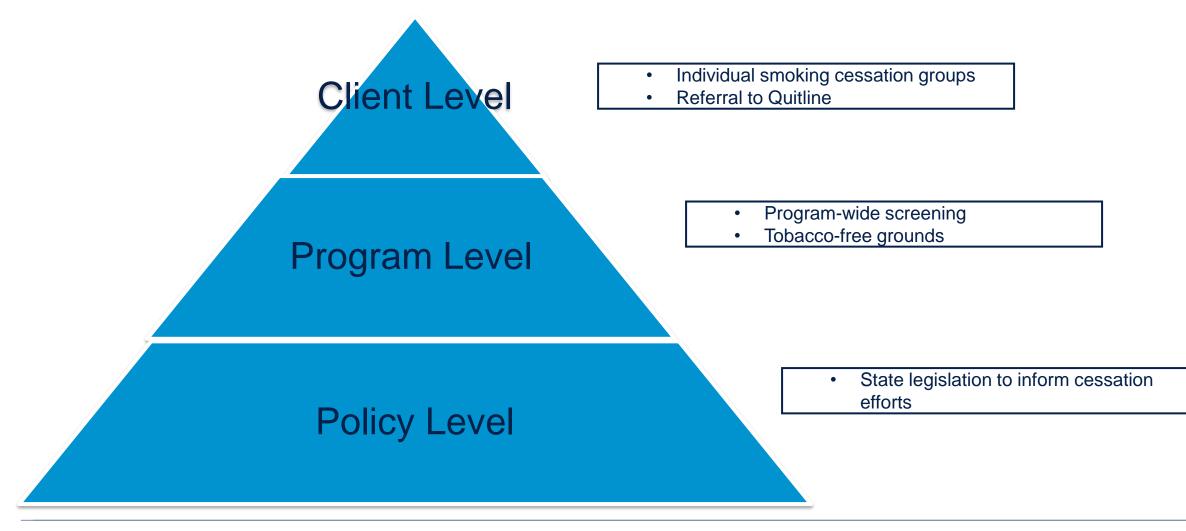
"You don't want them to quit everything at the same time, because It just puts too much stress [on clients]"

"If we're working on wholeperson education...we really need to figure out how we can assist them in quitting [tobacco] too."

Fokuo, et al. 2022, Pagano et al., 2016

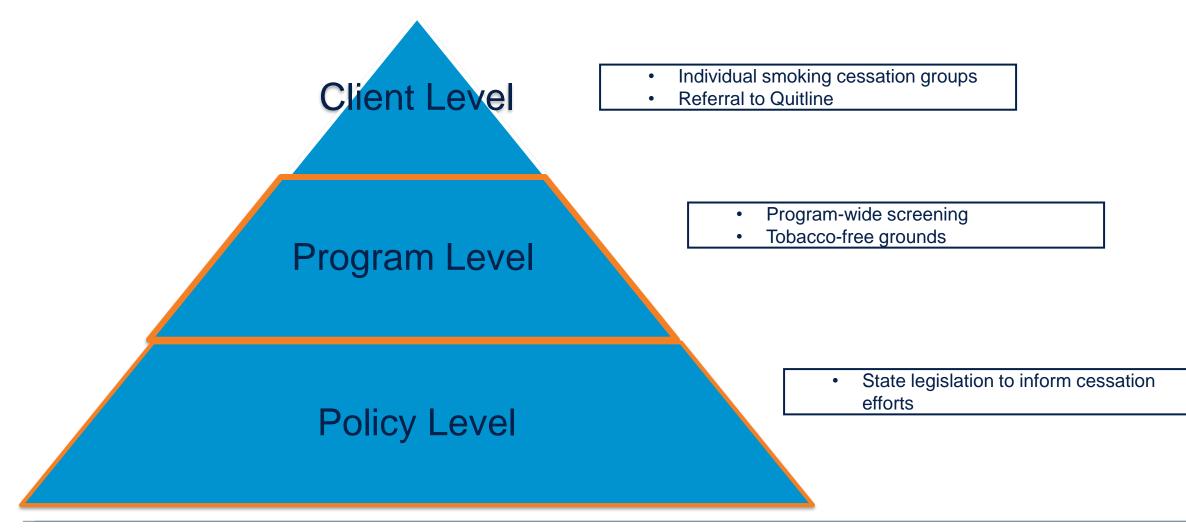


Interventions for Tobacco Cessation in SUD Treatment





Interventions for Tobacco Cessation in SUD Treatment





California Tobacco Control Program Tobacco Free for Recovery Initiative

- Substance use disorder treatment programs received 18-month contract (\$36,000) to develop an individualized tobacco-free policy
- Activities to Support Policy Development
 - Completed needs assessment
 - Evaluated current tobacco policies
 - Identified barriers/facilitators to policy implementation
 - Met monthly with UCSF Smoking Cessation Leadership Center
 - Attended SCLC-sponsored training for program representatives and key staff
 - Attended monthly learning collaboratives



UCSF

University of California San Francisco



Policy Requirements

- Create an individualized policy that:
 - Prohibit tobacco use on program grounds for clients, staff, and visitors
 - Details specific enforcement plan
 - Outlines details for screening, education, and treatment
 - Describes in detail how the policy will be communicated
 - Assessed and treats client tobacco use
 - Implemented other wellness activities that support a tobacco-free environment





Examples of Individualized Policies and Changes









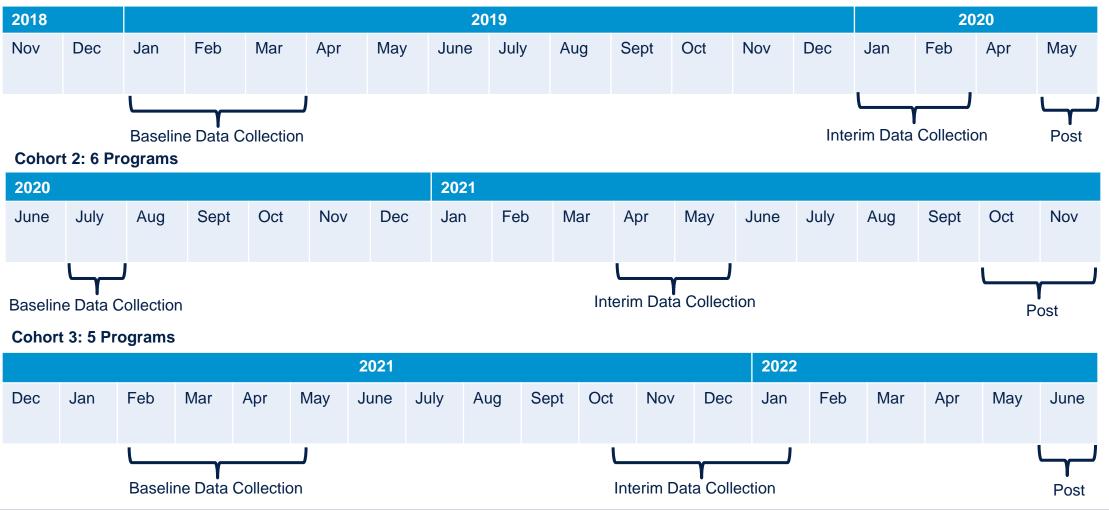






Overview of Tobacco Free for Recovery Cohorts and Evaluation

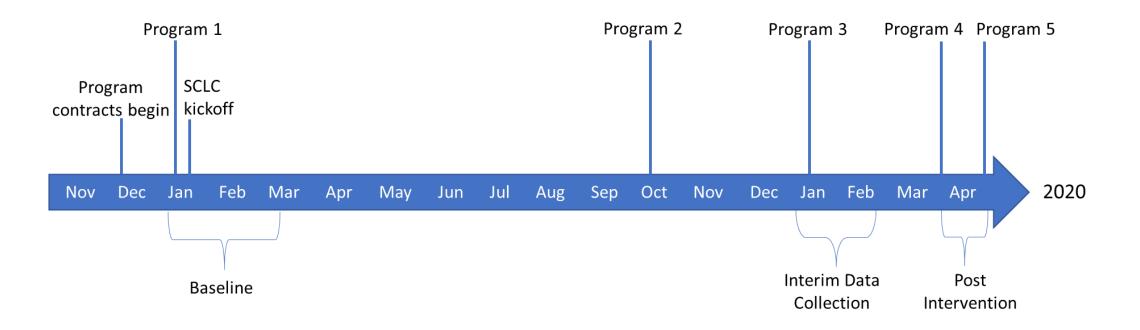
Cohort 1: 7 Programs



Evaluation Metrics for Tobacco Free for Recovery Initiative

Client Survey		Staff Survey	
Smoking Prevalence All participants	Current smoker and 100 cigarette in lifetime	Smoking Prevalence	Current smoker and 100 cigarettes in lifetime
Tobacco Use Behaviors Current smokers	 Cigarettes per day Concurrent Staff/Client Smoking 	Tobacco Free Policy	 Report in change in tobacco policy
		Tobacco Cessation Education	 Attending a training on tobacco cessation
Cessation Services Current smokers and those who quit in treatment	 Asked if you smoke Referral Counseling Nicotine Replacement Therapy or Pharmacotherapy Cessation in treatment plan 	Provision of Cessation Services	 Asked if you smoke Referral Counseling Nicotine Replacement Therapy or Pharmacotherapy Cessation in treatment plan

Timeline of Tobacco Free Grounds Policies in Cohort 1



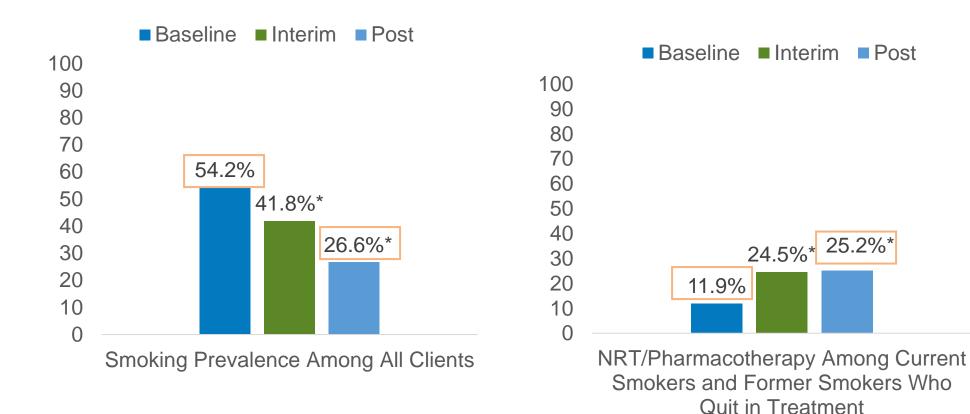
Two programs did not implement tobacco free policies due to county directives requiring a designated smoking area

Figure 1: Timeline for data collection and tobacco-free policy implementation

McCuistian et al. (2022)



Cohort 1 Client-Level Changes

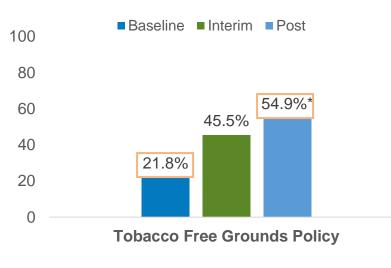


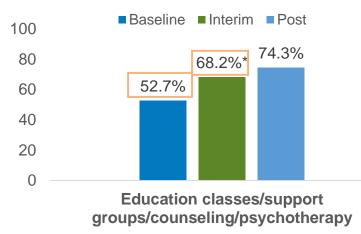
McCuistian et al. (2022)

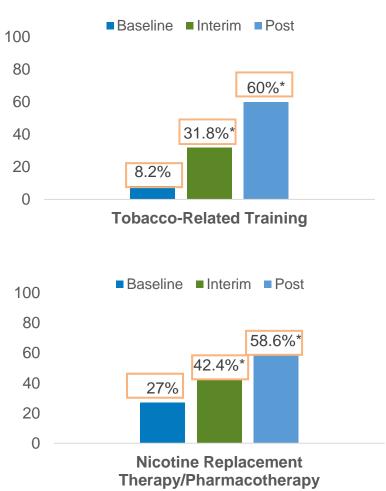


*significantly different from baseline

Cohort 1 Staff Level Changes





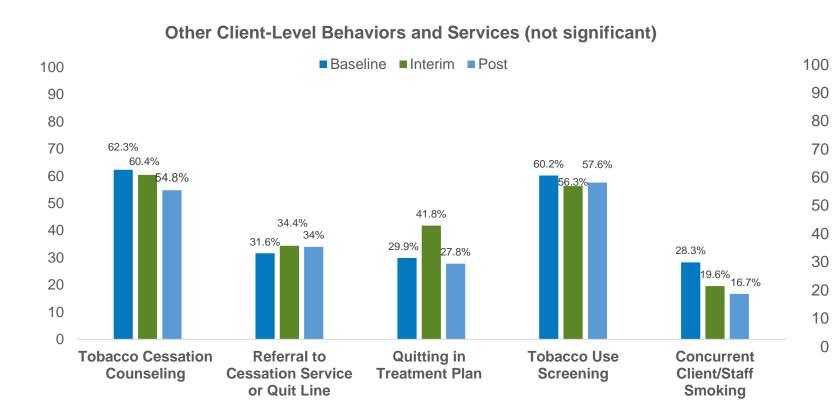


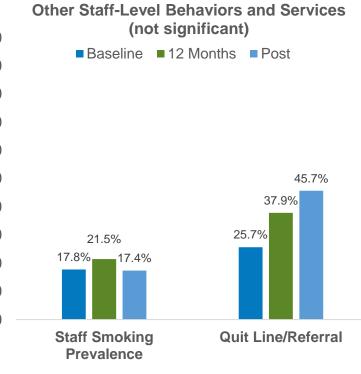
*significantly different from baseline

Campbell et al. (2022)



Areas for Improvement

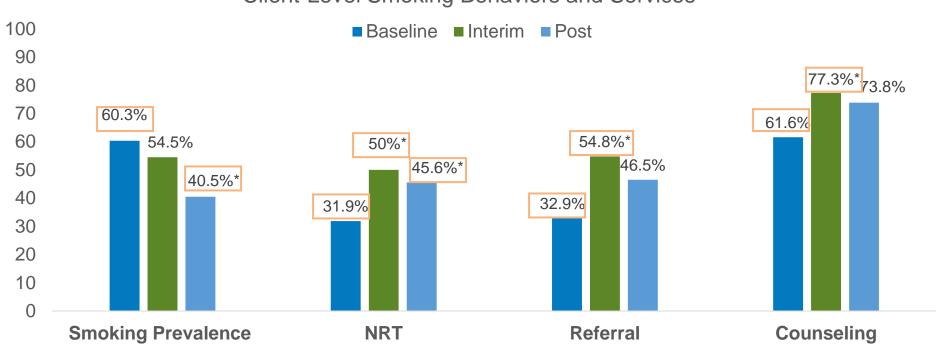




McCuistian et al. (2022) Campbell et al. (2022)



Preliminary Findings for Cohorts 2 & 3



Client-Level Smoking Behaviors and Services

*significantly different from baseline



Potential Health Equity Impact

Across 24 Californian residential SUD treatment programs

- Non-Hispanic Whites smoked at a higher rate (68.7%) than both Hispanics (54.9%) and non-Hispanic Blacks (55.6%)
- Racial/ethnic minorities were accessing more smoking cessation services than Whites, suggesting that SUD treatment could serve as a place to address tobacco-related racial inequities

JOURNAL OF PSYCHOACTIVE DRUGS 2021, VOL. 53, NO. 5, 483–490 https://doi.org/10.1080/02791072.2021.1977874



Check for updates

Racial/Ethnic Differences in Tobacco Use and Cessation Services among Individuals in Substance Use Treatment

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ABSTRACT

Few studies explore racial/ethnic disparities in tobacco use and access to cessation services among people with substance use disorders (SUD). We collected data from Hispanics (n = 255), non-Hispanic Whites (n = 126) across 24 Californian residential SUD treatment programs. Data were analyzed via regression models adjusting for demographics, cigarettes per day, past quit attempts, intent to quit in the next 30 days, and physical health status. Non-Hispanic Whites to receive a night rate (68.7%) than both Hispanic (54.9%) and non-Hispanic Blacks (55.6%) and smoked more cigarettes per day (M = 11.2, 50 = 6.5). Hispanics were more likely than non-Hispanic Whites to receive a referral to a cessation specialist (adjusted odds ratic; AOR = 2.34, 95% CI = 1.15, 4.78) and tobacco-cessation counseling (AOR = 2.66, 95% CI = 1.28, 5.62). Non-Hispanic Blacks were also more likely than non-Hispanic Whites to receive cessation counseling (AOR = 2.61, 95% CI = 1.27, 4.47). Despite their decreased smoking prevalence and severity, REMs were accessing smoking cessation services while in treatment, suggesting that SUD treatment could serve as a place to address tobacco-related racial inequities.

ARTICLE HISTORY Received 21 April 2021

Revised V Accepted 27 August 2021

KEYWORDS Health disparity; tobacco cessation; substance use treatment; racial/ethnic minority

Although smoking prevalence has declined steadily over the past decade in the United States (CDC 2020b; Cornelius et al. 2020), disparities in tobacco use and smoking cessation remain across racial/ethnic minority (REM) groups. For example, specific sub-groups of Hispanic populations smoke at rates 4- 17% higher than the national average (CDC 2019c). Approximately 85% of non-Hispanic Black smokers use menthol cigarettes, surpassing the rates of menthol use among White smokers (28.9%) and smokers from other REM groups (e.g., Hispanics, Asians, and multiracial individuals; Villanti et al. 2016). Menthol cigarettes, marketed directly to African American communities (Gardiner 2004), have been associated with decreased smoking cessation (Delnevo et al. 2011). While there is a tendency toward light or intermittent smoking (Reyes-Guzman et al. 2017; Trinidad et al. 2009), some REM groups, such as African Americans, are less likely than Whites to successfully guit (Bacio et al. 2014; Trinidad

REM groups also experience increased health risks related to tobacco use. African Americans are more likely than Whites to die from smoking related diseases (CDC 2020a). Several smoking-related cancers are the leading cause of death for Hispanics, Native Americans/ Alaskan Natives, Asians, Pacific Islanders, and Native Hawaiians (CDC 2019a, 2019b, 2019c). These health consequences are exacerbated by social determinants of health such as income inequality, housing insecurity, and racial discrimination that disproportionately impact REM communities and contribute to racial health inequity in the U.S. (Braveman, Egerter, and Williams 2011).

Another population with disproportionate rates of smoking prevalence are people with substance use disorders (SUD; Schroeder and Morris 2010). Smoking prevalence among people with SUD has not followed the same pattern noted in the general population, showing no decline from 2002–2014 (CDC 2020b;



State-wide Tobacco Free Grounds Policies



New Jersey (1999)

All programs provided assessment or treatment for tobacco use, 80% had treatment for smoking staff, and 85% used NRT with clients

New York (2008)

Pre-post decrease in client smoking prevalence (69.4% to 62.8%)

Oregon (2012)

Increased tobacco screening (83% vs 92 and referrals to Quit line (32% vs. 51%)



California AB 541

- Assembly Bill (Berman) signed in August 2021
- Went into effect January 2022, slow implementation
- All licensed and certified California SUD treatment programs must:
 - Assess clients for tobacco use
 - Educate clients on the harms of tobacco
 - Include tobacco cessation in treatment plan
 - Offer treatment or referral to services
 - Limited guidance on what services (could vary) or how to implement these changes
 - Does not prohibit smoking, no tobacco free grounds
 - Associated change with smoking prevalence needs to be examined





Reducing Tobacco Use in SUD Treatment: Policy and Legislative Approaches TRDRP T32KT5241– PI: McCuistian

Examine changes associated with AB541	Examine the sustainability of Tobacco Free for Recovery Initiative
 Compare client tobacco prevalence, smoking	 Determine whether client-reported changes in
behaviors, and smoking cessation services	smoking prevalence and receipt of cessation
before and after implementation of AB541	services associated with tobacco free for
among programs not included in Tobacco Free	recovery initiative are maintained 24 months
for Recovery	post implementation



Take Away Message

Providing monetary support, education, and resources allows programs to develop an individualized policy for implementing tobacco free grounds that demonstrates promise for reducing smoking prevalence among people in substance use disorder treatment

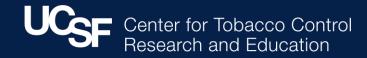
Caravella McCuistian, Ph.D.

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Tobacco Industry Documents: How Looking Through the Keyhole Contributed to Tobacco Control in Brazil

André Luiz Oliveira da Silva, MSc, PhD Briger Family Postdoctoral Fellow





Area - 8,516,000 km² Population - 213 million (estimation 2021)



Brazilian Health Regulatory Agency (ANVISA)

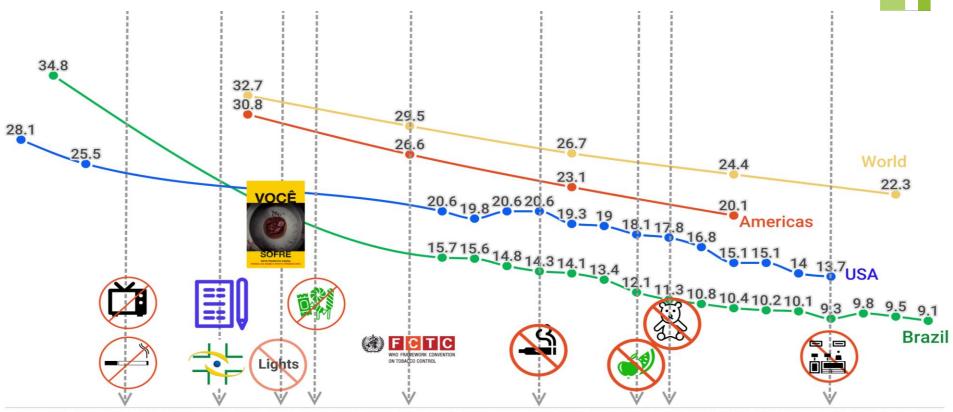
- Health surveillance and sanitary control of products, services, marketing
- Former coordinator regulation, enforcement, and registration activities

Tobacco Control

- Leading regulatory agency in the world
- Global Tobacco Regulators Forum member
- Specialized support to WHO Framework Convention on Tobacco Control



Smoking Rates (%)



1988 1989 1990 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021

Tobacco Industry Documents & Brazilian Regulation

- Anticipate and expose industry strategies
 - Marketing to special groups like kids and women
- Creating and updating regulatory practices
 - Additive ban, pictorial health warnings
- Respond to industry allegations in courts and regulatory processes



Case Study: Tobacco Additive Regulation

Additive ban regulatory process (2010 to 2013)

- Strong opposition from Tobacco Industry
- Tobacco Industry Documents:
 - Supported conceptualization & development of regulation
 - Countered industry arguments in courts and during regulatory process





Fruit/vegetable products

Sweeteners

More than 127,000 letters received

Research pape

The taste of smoke: tobacco industry strategies to prevent the prohibition of additives in tobacco products in Brazil

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CESTEH, Escola Nacional de ABSTRACT

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Received 15 December 2018 Revised 10 April 2019 Accepted 23 April 2019

Background The tobacco industry (TI) uses several strategies to attract new consumers, including using additives in tobacco products, which makes tobacco especially attractive to youth. Based on scientific evidence and the principles of the WHO Framework Convention on Tobacco Control, the Brazilian Health Regulatory Agency (ANVISA, for the name in Portuguese), published the Collegiate Board Resolution (RDC, for the name in Portuguese) 14/2012 in 2012,

prohibiting the addition of substances that enhance the flavour and taste of tobacco products in order to make them more attractive. In response, the TI used various strategies to prevent RDC 14/2012 from entering into force. At the time, the Brazilian additive ban was the most comprehensive in the world as it included a ban on menthol

> Objectives This paper analyses the arguments and strategies used by the TI to prevent the implementation of the additives ban.

> Methods Review of published articles, reports, legislation and legislative activity, internal TI documents, media stories and other documents to describe TI's reaction to the ban

Results The results show that the TI used some wellknown strategies to delay or cancel the entering into force of the resolution. For example, the TI attempted political interference, used litigation and commissioned studies with findings that questioned the resolution's rationale. The TI strategies used in Brazil are similar to those used at the global level to oppose other tobacco control measures.

Conclusions TI successfully delayed the most comprehensive additive ban in the world using its usual tactics, despite the fact that none of the arguments presented by the TI had an acceptable scientific basis or evidence.

Check for updates INTRODUCTION

adulthood. 43

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To cite: Oliveira da Silva AL Bialous SA, Albertassi PGD. et al. Tob Control Epub ahead of print: Iplease include Day Month Year]. doi:10.1136/ tobaccocontrol-2018-054892

Tobacco use is the leading cause of preventable death and disease in the world.1 Efforts to address this global epidemic need to include strategies to ensure that young people do not become addicted to tobacco products. Evidence shows that the younger the person starts smoking, the sooner he or she becomes a regular smoker, and the harder it is for them to quit.2 5 Even smoking chocolate

Estimates indicate that, globally, 82 000 to 99 000 children start smoking every day.64 In Brazil. data indicate (2013-2014) that 18,5% of adolescents between 12 and 17 years of age have tried cigarettes in their lifetime.9 The national Special Tobacco Survey (PETab) conducted by the Brazilian Ministry of Health showed that 17.2% of the population aged 15 years or older used tobacco products in 2008.10 Other surveys showed that the majority of smokers in Brazil started to smoke before they were 20 years of age.^{10 11}

The tobacco industry (TI) uses a variety of strategies to attract new smokers, maintain dependency and prevent tobacco control regulations.11213 These strategies lead to reduced cessation and target young people to start, as the industry needs to replace smokers who stop smoking or die.14-16 Among the strategies used by the TI to maintain addiction and profits, cigarette engineering is perhaps one of the most ingenious. Modern cigarettes are the result of innumerable technological developments where all aspects of their composition are controlled and built to, among other characteristics, optimise the delivery of nicotine to the smoker, facilitate the initiation of new smokers, make the product more palatable and less irritating, mask environmental tobacco smoke and reduce production costs.17-23

One of the technologies used by the TI is the use of additives. The TI's own internal documents point to additives as an important technology for expanding its markets.16 17 19 23-28 The use of additives in tobacco products facilitates tobacco use. enhances the effects of nicotine and allows the TI to use false claims of properties associated with health and well-being.27 29-32

Data from the TI33 show that flavourings are added to cigarettes to improve their flavour and aroma.34 Additionally, TI documents show that these additives are also used to reduce airway irritation caused by smoke.23 33-35 The TI recognises that irritation caused by smoke, unpleasant taste, astringency, dry mouth and other unpleasant tobacco characteristics are effective barriers to the initiation and perpetuation of smoking,16 this the TI considered additives pivotal to market success. Aware of the TI's reasons to use additives, ANVISA, the Brazilian agency empowered, by legislation, to regulate tobacco products, considered the evidence on additives and its public health harms cigarettes in childhood correlates with smoking in and published a resolution, RDC 14/2012, in 2012,

which inter alia prohibited the use of additives that

> Tob Control. 2019 Dec;28(e2):e92-e101. doi: 10.1136/tobaccocontrol-2018-054892. Epub 2019 May 31.

The taste of smoke: tobacco industry strategies to prevent the prohibition of additives in tobacco products in Brazil

Andre Luiz Oliveira da Silva ¹², Stella Aquinaga Bialous ³, Patrícia Gonçalves Duarte Albertassi ², Daniela Aparecida Dos Reis Arquete², Ana Marcia Messeder Sebrao Fernandes². Josino Costa Moreira⁴



Tobacco Industry Arguments

versus

Tobacco Industry Documents



Research paper

Menthol cigarettes and smoking initiation: a tobacco industry perspective

Kim Klausner

This evidence suggests that a ban on menthol in cigarettes would result in fewer people smoking cigarettes. Menthol is a prominent design feature used by cigarette manufacturers to attract and retain new, younger smokers. In addition, not only

CONFIDENTIAL (For Response Only)

Winston introduces "100% First Cut" tobacco blend

General Statement/Q&A

•••

MUST AIRS

- Winston is strengthening its No Bull positioning by introducing a 100% First Cut tobacco blend.
 - The blend, which contains no reprocessed tobacco sheet along with no additives, continues to deliver true tobacco taste – a cornerstone of the brand's No Bull positioning (launched in August 1997).

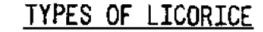
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INGREDIENTS

 If 100% First Cut raises questions about Ingredients in other brands: Reynolds Tobacco's use of cigarette ingredients is guided by the principle of achieving the desired taste characteristics by using the minimum amount of additives. Reynolds Tobacco does not -- and will not -- use any cigarette ingredient if scientific methods and tests indicate that it will increase the inherent toxicity of tobacco smoke.

Tobacco additives have been used in cigarettes throughout the history of cigarette manufacturing. The majority of these ingredients (such as cocoa and sugars) are used to enhance aroma and flavor. Others are used to enhance the sensory aspects, including taste, associated with the smoke (such as menthol), facilitate tobacco processing and cigarette manufacturing (such as carbon dioxide and water), and preserve moisture levels in the finished cigarette (such as water and glycerin).

RJR, 2000



SPRAY-DRIED

liqued

BLOCK

1. IMPARTS DEEP. HEAVY (WOODY) FLAVOR NOTES

LICORICE

2. IMPARTS SLIGHT SWEETNESS

WHAT DOES IT DO?

B&W, 1996

https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=xgkx0138

Current Status



- An injunction allows major companies to keep selling tobacco products with additives
- No discussion whether additives make tobacco products more attractive



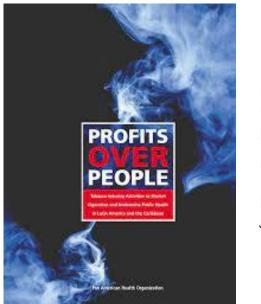
Concluding Remarks

- Industry documents as a powerful tool to support effective regulations
- Lessons learned from Brazil's regulatory success
- More research on industry strategies in developing countries
- Industry documents to identify and regulate "new" technologies
 - Example: flavor capsules, synthetic nicotine





Acknowledgments



Looking Through a Keyhole at the Tobacco Industry

The Brown and Williamson Documents

Stanton A. Glantz, PhD; Deborah E. Barnes; Lisa Bero, PhD; Peter Hanauer, LLB; John Sla JAMA, July 19, 1995–Vol 274, No. 3

