

E-cigarettes in the US: Use By Physicians, Prevalence, Intentions to Quit, and Findings from Several Trials Investigating Methods for Quitting

MUSC Medical University of South Carolina

Hollings Cancer Center

An NCI-Designated Cancer Center

Benjamin Toll, Ph.D. @bentollphd Professor of Public Health Sciences & Psychiatry Vice Chair of Public Health Sciences Associate Director, Hollings Cancer Center Medical University of South Carolina

Conflicts of Interest in the Past 10 Years

• Testify (since 2015) on behalf of plaintiffs who have filed litigation against the tobacco industry

• Worked as a paid consultant on an Advisory Board about e-cigarettes for Pfizer in 2018



Hollings Cancer Center An NCI-Designated Cancer Center

Professional Perspective

- Direct operations for tobacco treatment services for over 10,000 tobacco users per year in a large health system
 - Usually, tobacco treatment medications are provided
 - Over half of these medically compromised patients died or will die from tobacco related illnesses
- Fierce advocate for patients all of whom need our/your help with quitting tobacco use and other health issues
- Passionate advocate for trainees and colleagues



Hollings Cancer Center An NCI-Designated Cancer Center

Acknowledgements

 Funded by the MUSC Hollings Cancer Center Core Center Support Grant from the National Cancer Institute (P30 CA138313) and startup funds for this presentation

• Multiple other NCI/NIDA/NHLBI/NIAAA grants over the past 20 years – all publicly available on NIH Reporter (reporter.nih.gov)

• The content of this presentation are not the official views of the Society for Research on Nicotine & Tobacco (SRNT)



Hollings Cancer Center An NCI-Designated Cancer Center

Outline

- Review of considerations for healthcare providers regarding nicotine ecigarettes
- Discussion of importance of 18–24-year-olds and e-cigarette use prevalence
- Review of data regarding intentions to quit e-cigarette use from PATH
- Review of pilot study of nicotine replacement therapy (NRT) for ecigarette use
- Review of pilot study of varenicline vs placebo for e-cigarette use



"If I have seen further it is by standing on the shoulders of giants."

- Isaac Newton



Mark Sobell, Ph.D. Professor of Psychology



Stephanie O'Malley, Ph.D. Professor of Psychiatry



Peter Salovey, Ph.D. Professor of Psychology & Immediate Past President

My Mentors & Sponsors



Roy Herbst, M.D., Ph.D. Professor of Medical Oncology

Mike Cummings, Ph.D. Professor of Psychiatry

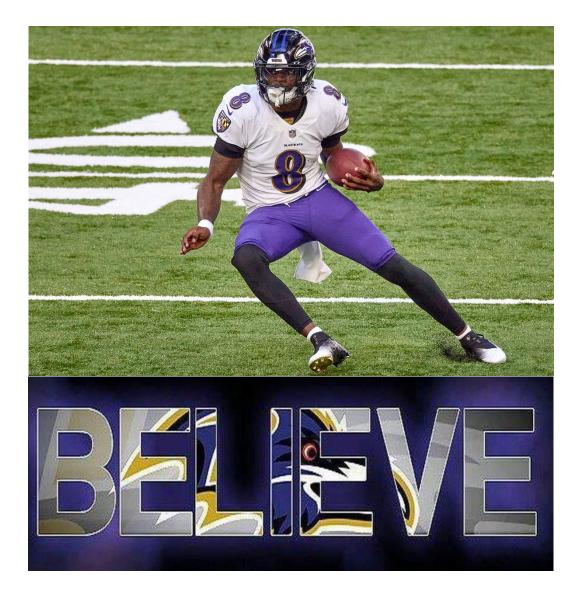


Hollings Cancer Center An NCI-Designated Cancer Center

My teammates have my back. I have theirs.

- Lamar Jackson







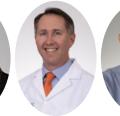


Our Larger Team at MUSC Hollings Cancer Center

Robust Tobacco Research Group



M. Carpenter J. Dahne **M.** Cummings





A. Palmer E. McClure

A. Rojewski

M. Saladin

B. Sanford

T. Smith B. Toll

R. Tomko G. Warren



K. Armeson



B. Hill



K. Gray

J. Obeid

Biostatistics & Bioinformatics

X. Li





Dissemination & Implementation







M. Ford

A. Deshmukh

Outstanding Leadership



Nicotine e-cigarettes: considerations for healthcare providers

Benjamin A. Toll^{1,2,3}, Tracy T. Smith^{2,3} & Brian A. King⁴

nature medicine



Tracy Smith, Ph.D. MUSC



Brian King, Ph.D. Director FDA Center for Tobacco Products



Hollings Cancer Center

Nicotine e-cigarettes: considerations for healthcare providers

- Clinicians should provide behavioral counseling and FDA-approved medications as a first line treatment
- For adults who continue to smoke, healthcare professionals may consider discussing the relative risks of tobacco products and educate patients that exclusive use of e-cigarettes instead of cigarettes would reduce exposure to known toxicants and carcinogens
- Providers should reinforce the importance of complete transitioning away from combusted products to realize the full health benefits
- If patients choose to use an e-cigarette to transition away from cigarettes, providers should make patients aware of the 23 e-cigarette products and devices authorized by FDA





- Vermin:
 - from the Latin word vermis, which means "worm" - originally used to describe the worm-like larvae of certain insects that infest food
- Defecate & urinate all over your residence
- Spread illness and death
- Eat your food
- Disturb your sleep





- MUCH more attractive than mice **BUT**
- Defecate and urinate in a litter box
- Cause allergies
- Scratch up and destroy furniture
- Bite and scratch you, leading to illness















etristă near alt april 19 restear transferit (

Importance of Young Adults to Tobacco Industry

- Young adults aged 18-24 are important to the tobacco industry as a time when people who use tobacco often transition to established use and brand loyalty
- Philip Morris called this group "Young Adult Male Smokers" or "YAMS" & "Young Adult Female Smokers" or "YAFS" & studied them, noting they foreshadow future performance
 - The only segment who would not fill out any of the surveys are YAMS especially for unmotivating rewards like free pack coupons or free lighters.
- Share decline led by severe erosion among YAFS, followed by softening among 25-34
 - YAFS were of particular importance given they represented they foreshadowed the brand's long-term performance

Accessed from UCSF Tobacco Documents Library: <u>https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=sxkf0109</u> & <u>https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=tfhf0157</u>



Methods – Studying Young Adult E-cigarette Use

- Waves 1-6 of the FDA Population Assessment on Tobacco and Health (PATH) study, a nationally representative longitudinal cohort survey conducted in the United States between 2013 and 2021
- Primary outcomes:
- **PATH Defined Current Established Smoking:** Those who report smoking 100 or more cigarettes in their lifetime and currently smoke every day or some days
- **PATH Defined Current Established Vaping:** Those who report ever use of any electronic nicotine product, have ever used them fairly regularly, and currently use them every day or some days



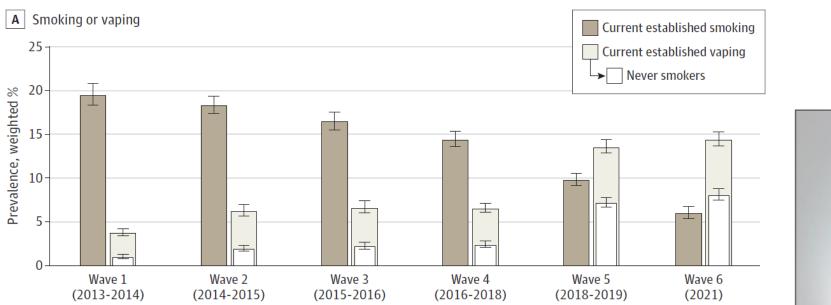
Brandon Sanford, Ph.D. & Naomi Brownstein, Ph.D. MUSC



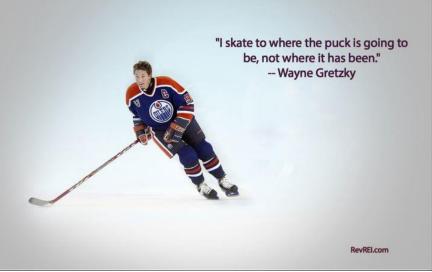
Hollings Cancer Center An NCI-Designated Cancer Center

JAMA Internal Medicine

Figure. Prevalence of Current Established Smoking and Vaping Among US Young Adults Aged 18 to 24 Years



Brandon T. Sanford, PhD Naomi C. Brownstein, PhJ Nathaniel L. Baker, MS Amanda M. Palmer, PhD Tracy T. Smith, PhD Alana M. Rojewski, PhD Benjamin A. Toll, PhD



JAMA Internal Medicine, 184, 106-108. DOI: 10.1001/jamainternmed.2023.5239



Hollings Cancer Center An NCI-Designated Cancer Center

JAMA Open...

Research Letter | Substance Use and Addiction

Interest in Quitting e-Cigarettes Among Adult e-Cigarette Users With and Without Cigarette Smoking History

Amanda M. Palmer, PhD: Tracy T. Smith, PhD: Georges J. Nahhas, PhD: Alana M. Rojewski, PhD: Brandon T. Sanford, MS: Matthew J. Carpenter, PhD: Benjamin A. Toll, PhD

Introduction

MUSC

Medical University

of South Carolina

Approximately 2.8% to 3.2% of US adults are current e-cigarette users, with a majority being current cigarette smokers or former cigarette smokers.¹ The most common use for e-cigarettes is to quit smoking, but e-cigarette use may continue even after discontinuation of combustible cigarettes.² Furthermore, those who initiate e-cigarettes to quit smoking may not be successful, leading to dual use of both tobacco cigarettes and e-cigarettes, which increases potential health harms.³

Previous studies have shown that people who use e-cigarettes, also called vaping, are interested in quitting.^{4,5} No published randomized clinical trials for e-cigarette discontinuation exist, and evidence on how to aid e-cigarette users in stopping is limited. It is important to understand interest in quitting among e-cigarette users, including dual users. The purpose of this study was to provide the most up-to-date estimate of interest in e-cigarette discontinuation among US adults.





TOBACCO CONTROL

Brief report

Interest in guitting e-cigarette use by device type and smoking history in US adults

Amanda M Palmer [©], ¹ Alana M Rojewski, ^{1,2} Matthew J Carpenter, ^{1,2,3} Elias M Klemperer, ⁴ Nathaniel L Baker, ^{1,2,3} Brandon T Sanford, ^{1,5} Benjamin A Toll^{1,2,4}

ABSTRACT Additional supplemental material is published online

only. To view, please visit the

journal online (http://dx.doi.

¹Department of Public Health

of South Carolina, Charleston,

Sciences, Medical University

South Carolina, USA

Carolina, USA

²Hollings Cancer Center,

Medical University of South

Carolina, Charleston, South

³Department of Psychiatry and

Behavioral Sciences, Medical

University of South Carolina,

⁴Department of Psychiatry,

Burlington, Vermont, USA

Medical University of South

Carolina, Charleston, South

Dr Amanda M Palmer, Medical

University of South Carolina,

Charleston, SC 29425, USA;

Received 24 August 2022

Accepted 5 January 2023

Correspondence to

palmeram@musc.edu

University of Vermont,

Carolina, USA

'n

Background The use of e-cigarettes has been increasing, especially since the introduction of 'pod' devices to the marketplace since 2018. Most adults org/10.1136/tc-2022-057710). who vape report interest in guitting. The present study examined level of interest in e-cigarette cessation between users with varving cigarette smoking histories and device types.

Methods Data obtained from wave 5 (2018–2019) of the Population Assessment of Tobacco and Health study (n=34 309). Analyses were conducted on adult current established e-cigarette users, categorised on cigarette smoking history (current, former or never) and device type (disposable, cartridge/pod, tank or Charleston, South Carolina, USA mod). Participants reported if they planned to ever quit e-cigarettes, attempted to quit in the past year and attempted to guit by cutting back in the past year. Results Of the 2922 established e-cigarette users, ⁵Department of Family Medicine, 68.21% reported plans to guit vaping; 17.27% reported attempting to guit e-cigarettes in the past year; and 29.28% reported attempting to guit by cutting back in the past year. Cartridge users had higher odds of interest in guitting than tank and mod users. Disposable and cartridge users had higher odds of reporting a past year guit attempt than tank and mod users. Individuals with no smoking history had higher odds of reporting a past year guit attempt or cutting back relative to those reporting dual use (of both e-cigarettes and cigarettes)

> and former smoking. Conclusions Tobacco control should consider the type of e-cigarette device that is being used, alongside users' cigarette smoking history, when developing interventions and other resources for vaping cessation.

WHAT IS ALREADY KNOWN ON THE TOPIC

⇒ E-cigarette use prevalence is constantly shifting as new devices are introduced into the marketplace. Adults may use e-cigarettes for a variety of reasons, such as to guit smoking, as an alternative to smoking or as a result of experimentation. Prior research has shown that many adult e-cigarette users report symptoms of dependence and a desire to guit vaping.

WHAT THIS STUDY ADDS

⇒ Less is known about the role of device type in e-cigarette cessation intentions and actions. Findings from the US Food and Drug Administration's Population Assessment of Tobacco and Health wave 5 adult data suggest that individuals who use cartridge and disposable devices have higher intentions to quit and were more likely to report past quit attempts than individuals who use tank or mod devices. Individuals with history of smoking were less likely to report past guit attempts.

HOW THIS STUDY MIGHT AFFECT RESEARCH. PRACTICE, OR POLICY

⇒ Understanding more about how device type and smoking history relate to interest in cessation will help to inform future treatments and public policy related to vaping cessation.

respondents reported being established e-cigarette users, with 60.7% reporting future interest in quit-



Amanda Palmer, Ph.D. **MUSC**

Wave 4: December 2016 – January 2018

	Analyzed sample		Plan to Quit			Attempted to Quit			
		n	Weighted %	n	Weighted % (95% CI)	р	nª	Weighted % (95% CI)	р
Overall		1988	n/a	1208	60.7% ^c	n/a	302	15% ^c	n/a
	Dual User	1053	54	624	59 (55.2 – 62.8)		177	15.3 (12.8 – 17.8)	
E-cigarette user type	Former cigarette smoker	540	31	357	66.1 (60.4 – 71.8)	<.001	52	7.9 (5.2 – 10.7)	.02
user type	Never cigarette smoker	371	15	213	55.4 (49.2 – 61.6)		69	20.9 (15.2 – 26.6)	

Wave 5: December 2018–November 2019

			Plan to quit (n=2,734)		Attempted to quit (n=2,748)		
	n	Weighted %	n	Weighted % (95% CI)	n	Weighted % (95% CI)	
Overall	2922		1884	68.21% (65.53 – 70.89)	550	17.27% (15.62 – 18.92)	

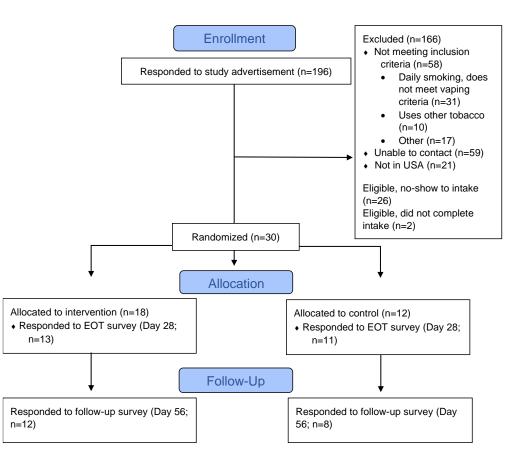






Recruitment and Study Procedures

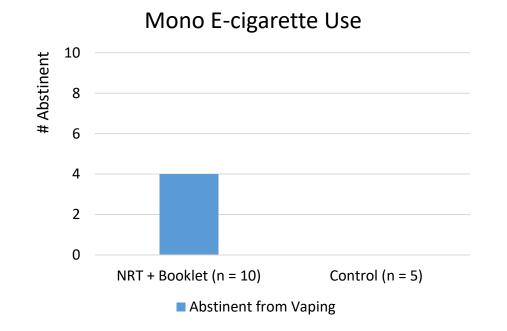
- Adults who used e-cigarettes daily in SC who were motivated to quit (could also be smoking)
- Randomized 2:1 Treatment or Control
 - Treatment: 28-days of NRT patch (21mg) plus lozenges (4mg)
 - Control: Referral to SC Quitline





Nicotine Replacement Pilot Trial Results

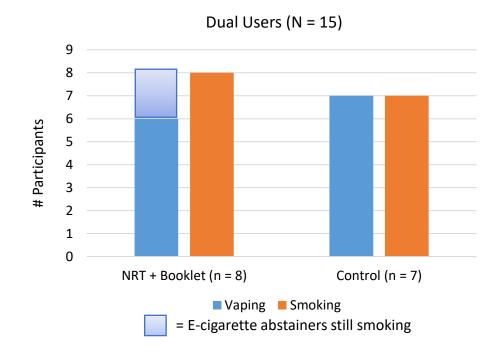
 Following treatment, 40% (4/10) of the people in the intervention group who received NRT quit e-cigarette use whereas 0% (0/5) in the control group quit





Nicotine Replacement Pilot Trial Results

- Notably, no dual users [0%; 0/8] quit smoking
 - A quarter [25%; 2/8] discontinued their e-cigarette use but continued to smoke
- This suggests that dual users need augmented treatment
- Dr. Palmer is investigating higher doses of NRT with this same protocol (funded by ACS IRG)





Varenicline Vs Placebo Pilot Trial

Lisa Fucito PhD,¹ Stephen Baldassarri MD, MHS,¹ Nathaniel Baker MS,² Amanda Palmer PhD,² Brandon Sanford PhD,² Madilyn Augustine BS,¹ Suchitra Krishnan-Sarin PhD,¹ Stephanie O'Malley PhD,¹ Matthew Carpenter PhD,² Kevin Gray MD,² Benjamin Toll PhD²



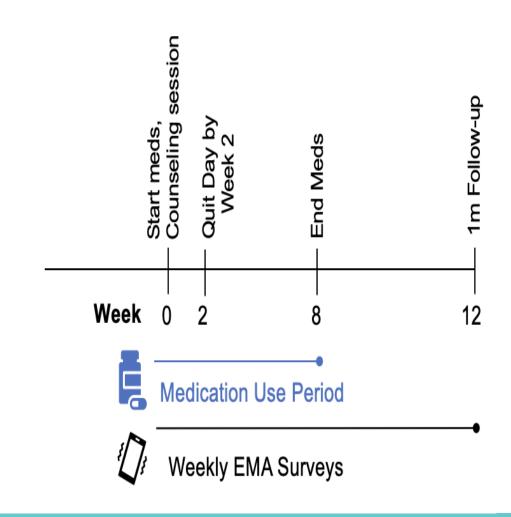


Lisa Fucito, Ph.D. Yale University



Hollings Cancer Center

- 8-week double-blind, 2-site (MUSC, Yale) RCT in treatment-seeking adults who reported exclusive daily e-cigarette use (N=40)
- Randomized to varenicline or matching placebo for 8 weeks & followed to Week 12
- Primary care behavioral support self-directed cessation booklet & single very brief counseling session (5-10 minutes)
- Outcomes via electronic diaries
 - 7-day e-cig PPA & no combusted tobacco use at Week 8 & Week 12





Hollings Cancer Center An NCI-Designated Cancer Center

Characteristic	Overall	Varenicline	Placebo	
		n=20	n=20	
Age	28.2 (8.5)	28.4 (10.3)	28.1 (6.4)	
Gender				
Male	50.0% (20)	50.0% (10)	50.0% (10)	
Female	47.5% (19)	45.0% (9)	50.0% (10)	
Transgender	2.5% (1)	5.0% (1)	0.0% (0)	
Race				
Asian American	12.5% (5)	10.0% (2)	15.0% (3)	
Black	5.0% (2)	5.0% (1)	5.0% (1)	
White	80.0% (32)	85.0% (17)	75.0% (15)	
Other	2.5% (1)	0.0% (0)	5.0% (1)	
Ethnicity				
Hispanic	2.5% (1)	5.0% (1)	0.0% (0)	
Non-Hispanic	97.5% (39)	95.0% (19)	100% (20)	
History of Smoking	52.5% (21)	50.0% (10)	55.0% (11)	
Vaping Continuously All Day ^b	82.5% (33)	75.0% (15)	90.0% (18)	
Years of E-cigarette Use	4.9 (2.4)	4.9 (2.8)	4.8 (1.8)	
E-cigarette Dependence ^c	14.2 (3.3)	13.4 (3.6)	15.0 (2.8)	
E-cigarette Device				
Disposable	50.0% (20)	40.0% (8)	60.0% (12)	
Closed Pod/Cartridge	35.0% (14)	45.0% (9)	25.0% (5)	
Refillable Pod/Cartridge	10.0% (4)	5.0% (1)	15.0%(3)	
Refillable Tank	5.0% (2)	10.0% (2)	0	

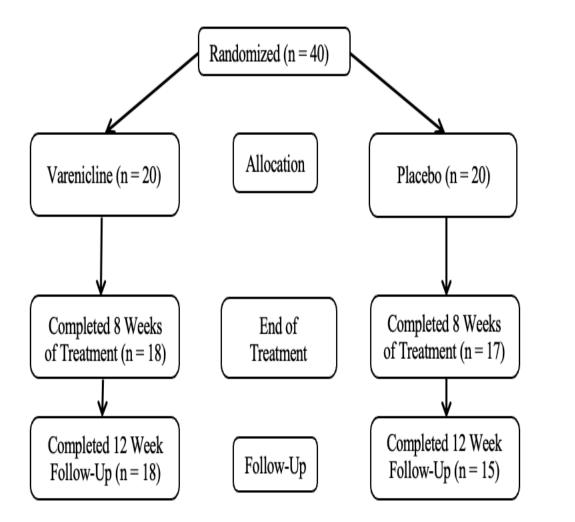
Characteristic	Overall	Varenicline	Placebo
		<u>n=20</u>	<u>n=20</u>
Nicotine Salt-Based E-			
Cigarette	90.0% (36)	85.0% (17)	95.0% (19)
Comorbid Conditions ^d			
Any	40% (16)	45.0% (9)	35.0% (7)
Depression	22.5% (9)	30.0% (6)	15.0% (3)
Anxiety	25.0% (10)	30.0% (6)	20.0% (4)
Other psychiatric	15.0% (6)	25.0% (5)	5.0% (1)
Other substance use disorder	2.5% (1)	0.0% (0)	5.0% (1)

Appendix Table 1. Participant Demographic and Clinical Characteristics Overall and by Group^a



Hollings Cancer Center An NCI-Designated Cancer Center

Results – Feasibility & Acceptability



Adverse Events

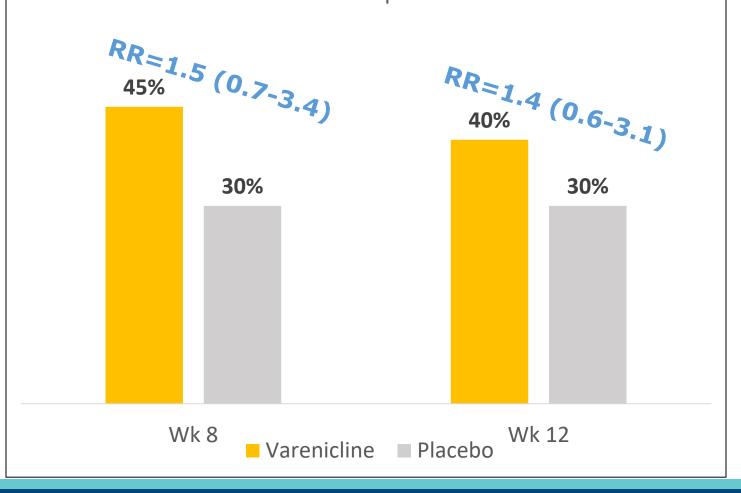
- No serious adverse events
- One VAR participant had a dose reduction due to nausea
- 9 participants (8 VAR, 1 PLA) reported adverse events possibly related to study medication
- E.g., nausea, insomnia, and vivid dreams/nightmares



Hollings Cancer Center An NCI-Designated Cancer Center

Results – Preliminary Efficacy

Self-Reported 7-Day Point Prevalence Quit Rates by Group



Other Outcomes

Participants with Smoking History More Likely to Quit

Week 8 PPA - 47.6% (10/21) vs.
26.3% (5/19) RR=4.9 (1.3,18.5)

Smoking Behavior

- Two participants (1 VAR, 1 PLA)
- VRN participant eventually quit both products
- PLA participant stopped cigarette smoking but not e-cigarette use



Hollings Cancer Center An NCI-Designated Cancer Center

Next Steps

- Drs. Fucito and Toll have a multiple PI grant that proposes a test of varenicline tartrate versus placebo in a group of N=326 mono-vapers at Yale and MUSC
- This will include rigorous examination of several biological markers of oncogenesis (e.g., DNA damage)
- We plan to examine several potential treatment moderators
- Received a fundable score we hope to start by the Spring



Summary Points

- If an adult who smokes does not succeed with a FDA first line treatment, healthcare providers may consider reviewing the relative risks of e-cigarettes, the importance of complete switching, and make patients aware of the 23 FDA authorized e-cigarettes
- E-cigarettes will be the dominant form of tobacco in the US in the relatively near future
- A very high number of people who use e-cigarettes plan to quit



Summary Points

- Dual nicotine replacement therapy (NRT) may have some utility in quitting e-cigarette use but higher doses of NRT may be needed for dual users
- Varenicline tartrate shows preliminary efficacy for quitting ecigarette use
- The field desperately needs high quality large clinical trials to help people who want to quit e-cigarette use to do so





Thank You! @bentollphd

AF MAADNE Everything negative pressure, challenges - is all an opportunity for me to rise. KOBE BRYANT



Hollings Cancer Center

yourtango

An NCI-Designated Cancer Center

X