

SMOKING CESSATION STRATEGIES AND POLICY RECOMMENDATIONS:
HARM REDUCTION, ELECTRONIC CIGARETTES, AND ABSTINENCE GOAL SETTING

by

Benjamin Robert Brady

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Joe K. Gerald, MD, PhD Date: 7/2/2018




Cynthia A. Thomson, PhD, RDN Date: 7/2/2018



Nicole P. Yuan, PhD, MPH Date: 7/2/2018



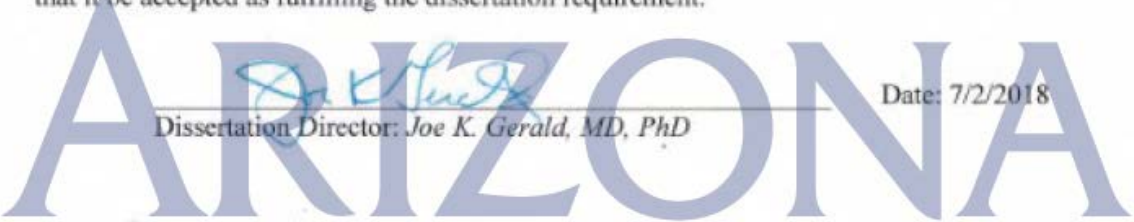
Uma S. Nair, PhD Date: 7/2/2018

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Dissertation Director: Joe K. Gerald, MD, PhD Date: 7/2/2018



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TABLE OF CONTENTS

LIST OF TABLES	7
LIST OF FIGURES	8
ABSTRACT.....	9
INTRODUCTION	10
Overview.....	10
No Safe Tobacco.....	11
Differentiated Risk.....	12
Differentiated Users.....	13
Tobacco Harm Reduction	14
SPECIFIC AIMS	18
Manuscript 1 – E-cigarette Policy Recommendations.....	18
Manuscript 2 - E-cigarette Use and Tobacco Cessation	19
Manuscript 3 – Quit Date Goal Setting	20
SUMMARY OF FINDINGS	22
Manuscript 1 – E-cigarette Policy Recommendations.....	22
Manuscript 2 - E-cigarette Use and Tobacco Cessation	24
Manuscript 3 – Quit Date Goal Setting	26
Key Conclusions.....	27
POLICY AND PRACTICE IMPLICATIONS	29
Nicotine Addiction is Influenced by Social-Ecological Factors.....	29
Acknowledging Product Heterogeneity Is Accurate and Ethical	30
Acknowledging User Heterogeneity Facilitates New Treatment Delivery Approaches	31
ROLE OF AUTHORS IN THE RESEARCH	33
Manuscript 1 – E-cigarette Policy Recommendations.....	33
Manuscript 2 - E-cigarette Use and Tobacco Cessation.....	34
Manuscript 3 – Quit Date Goal Setting	34
CONCLUSION.....	36
REFERENCES	38
APPENDIX A – MANUSCRIPT 1	47
APPENDIX B – MANUSCRIPT 2	84
APPENDIX C – MANUSCRIPT 3	110

LIST OF TABLES

Table 1. Evidence supporting abstinence-only and tobacco harm reduction strategies	17
Table 2. Electronic cigarette (e-cig) recommendation categories	22
Table 3. Adjusted odds ratios (AOR) of 30-day point prevalence tobacco abstinence (n=2,204) for e-cigarette use.....	25
Table 4. Adjusted odds ratios (AOR) of in-program quit attempts (n=90)	26

LIST OF FIGURES

Figure 1. Electronic cigarette (e-cig) policy recommendations and their underlying tobacco control objectives and use implications	23
Figure 2. Caller distribution across e-cigarette use categories	24

ABSTRACT

For this dissertation, I completed three manuscripts. In them, I explored tobacco cessation strategies and policy recommendations around electronic cigarette use and abstinence goal setting. In the first, I conducted a thematic analysis of e-cigarette position statements published by tobacco control, public health, and medical organizations. This study was designed to map the range of organizations' e-cigarette policy positions by identifying and categorizing the types of recommendations they proposed. The second was an empirical analysis of electronic cigarette (e-cigarette) use among callers at the Arizona Smokers' Helpline (ASHLine). In it, I examined if individuals who use e-cigarettes were more likely to have quit smoking at 7-month follow-up compared to those who never used e-cigarettes. In the third, I examined the quality of quit date goal setting among ASHLine callers using a tested rating scale. Compared to low quality quit date coaching, I assessed whether high-quality coaching was associated with increased in-program quit attempts or number of days to callers' first quit attempt. The goal of these projects was to explore the merits of integrating abstinence and harm reduction approaches within tobacco control. I argue that current approaches have assisted many, but not all smokers in making healthy behavior changes. Future tobacco control policies and cessation programs should consider offering more inclusive and flexible services that appeal to a wider range of smokers. Abstinence and harm reduction need not be positioned as mutually exclusive approaches to smoking prevention.

INTRODUCTION

Overview

Preventing tobacco use is an important US public health priority. Since the 1960s, tobacco control efforts have steadily lowered the national smoking rate.¹⁻³ However, reductions in tobacco use have not been consistent across all social groups. Individuals who have less education or a mental health condition, for example, smoke at twice the US average.^{4,5} In the past 15 years, as year-to-year reductions in the national smoking rate began to plateau,^{1,6,7} it became apparent that tobacco control policies were not equally benefiting all social groups;^{8,9} new ideas and tailored strategies would be needed to meet tobacco users' diverse needs.¹⁰ During this period, new forms of consumer nicotine products also emerged, including electronic cigarettes (e-cigarettes). As a result, conversations around diverse tobacco users became intertwined with discussions about new nicotine products, including their tobacco cessation effect and potential health risks.

In this dissertation, I present three independent research manuscripts. The projects address e-cigarettes and abstinence goal setting. In the first, I explored tobacco control and public health organizations' e-cigarette policy recommendations (Appendix A). In the second, I used quitline caller data to examine the relationship between e-cigarette use and tobacco cessation (Appendix B). In the third, I explored if coaching to set a quit date was associated with an increase in quitline callers' quit attempts (Appendix C). These manuscripts identify ways that tobacco users with different cessation goals may benefit from products like e-cigarettes or services that support explicit behavior change goals. Tobacco harm reduction and patient-centered approaches like shared decision-making may provide additional opportunities to improve tobacco cessation treatment services.

No Safe Tobacco

For over half a century, health professionals have targeted tobacco control as a primary prevention strategy to reduce death and disease in the United States.⁶ Within tobacco control, key agenda issues have included preventing initiation, reducing non-smoker exposure, and assisting current users to quit.¹¹ To accomplish these goals, policy interventions have focused on establishing a minimum smoking age, increasing cigarette sales tax, adopting smoke-free laws, restricting product advertising, and adding consumer warnings to packaging. To assist tobacco users, state-based quitlines and preventive research programs have also been implemented.¹¹ These efforts have been credited with reducing the prevalence of smoking in the US.¹²

In the early 1960s, when US tobacco control efforts began, over 42% of adults smoked.¹³ At that time, smoking was seen as a habit more than an addiction.¹⁴ Because the problem of smoking was not initially tied to the behavior but to its consequences, efforts were made to develop a “safer cigarette,” to reduce the harm of smoking for those who did not want to quit.¹⁵ However, by the late 1970s, these efforts were deemed a failure. Because the new cigarettes had comparably safer chemical compositions,^{16,17} manufactures capitalized on the claim that filtered and light cigarettes were a safer option and marketed the message that consumers need only to switch, not quit.^{15,18} Unfortunately, the marginal health gains achieved through low tar cigarettes were offset by lower rates of quitting¹⁹ and new health risks from compensatory smoking habits like inhaling more deeply.²⁰ In response, tobacco control distanced itself from tobacco manufactures and adopted the position that “there is no safe level of tobacco use.”^{21,22} In the US, abstinence from nicotine and tobacco, in all their commercial forms, became the exclusive focus of tobacco control.

The narrative that all non-medical forms of nicotine and tobacco are dangerous is straightforward. Its simplicity has facilitated health professionals' ability to develop and advance easy to understand health messages.²³ Possibly because of its simplicity, the idea that there is “no safe level of tobacco use” also became interpreted to mean that all tobacco is equally harmful and should be equally avoided.²⁴ As a result, differences between tobacco products were regularly downplayed or dismissed, particularly by US federal agencies.²⁵ It is uncommon for tobacco control stakeholders to articulate meaningful distinctions between types of tobacco products, their risks, how and when they are used, or why.²⁶ Efforts to make these distinctions have been seen as a threat that undermines the field's mission to de-normalize all forms of tobacco use.²⁷

Differentiated Risk

Despite its prominence, the view of equivalent product harm has been challenged. For example, critics argue that low-toxicant forms of moist snuff (snus) are substantially safer than combustible tobacco. Owing to a social experiment in the 1970s in which Sweden, unlike its neighbors, taxed snus at a lower rate than cigarettes, a significant portion of smokers switched from smoking to exclusive snus use.²⁸ This resulted in several decades of epidemiological data that has allowed researchers to conclude that snus is comparatively much safer than smoking²⁹ and results in lower incidence of tobacco related disease.³⁰ Smokeless products like snus are estimated to represent around 1-2% the overall health risk of long-term smoking.^{24,31,32}

More recently, the advent of e-cigarettes offers additional evidence of a “continuum of risk”³³ among nicotine products. Compared to snus' more limited appeal, e-cigarettes and vaping products have proliferated globally and have become part of a more public conversation about

differential product risk. Although nascent, the scientific literature on e-cigarettes suggests that they likely present a similar risk profile as snus and smokeless tobacco.³⁴ In one of the most comprehensive looks at the health risks from using e-cigarettes, the National Academies of Science reported that, “there is substantial evidence that except for nicotine, under typical conditions of use, exposure to potentially toxic substances from e-cigarettes is significantly lower compared with combustible tobacco cigarettes” and that “there is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users’ exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.”³⁵

Differentiated Users

Within tobacco control, some contend that the goal of de-normalizing all forms of tobacco is not likely to succeed.³⁶ They point out that de-normalization requires favoring abstinence-only policies which affect tobacco users differently. They believe that this disproportionately burdens disadvantaged groups who smoke at higher rates,^{37,38} and may deter those who are unwilling or unable to quit traditional cigarettes from switching to safer nicotine products.³⁹

Overtime, the prevalence of tobacco use has not uniformly declined among all tobacco users.⁷ This has resulted in important demographic differences among current smokers. Around 10% of college graduates smoke compared to 30% of individuals who did not complete high school.⁵ Over 36% of individuals with a mental health condition currently use tobacco compared to 25% of those without.⁴ Multiracial,^{40,41} American Indian and Alaska Natives,⁴² and gender and sexual minority groups⁴³ also use tobacco at rates above the national average. The majority of drug-involved smokers expect smoking cessation to make sobriety more difficult and report

lower desires to quit smoking.⁴⁴ Altogether, as many as 20% of tobacco users do not quit in their lifetime.⁴⁵ Tobacco users have not evenly benefited from abstinence-only policies.

Tobacco Harm Reduction

Critics of the abstinence-only agenda seek to articulate a coherent alternative, formulated on the principles of tobacco harm reduction (THR). In THR, abstinence is neither the default nor the only behavior-change option. It is a philosophical position that shifts the objective from preventing drug use to preventing disease from drug use.⁴⁶

Advocates argue that promoting THR does not require rejecting the merits of abstinence. Instead, THR represents additional options. They accept the original foundation of tobacco control—to prevent tobacco-related death and disease—and seek to add to it a missing degree of pragmatism.⁴⁷ When eliminating a harmful exposure is not possible, substituting a less harmful alternative like snuff⁴⁸ or an e-cigarette³² would still represent a positive change.

However, THR is controversial within tobacco control. It is rejected by many who perceive that it violates their professional standards or does not yet meet scientific benchmarks to be regarded as an evidence-based practice. For example, clinically trained health professionals may reject harm reduction because they believe it contradicts their oath to ‘do no harm;’⁴⁹ proscribing a therapy that has known or expected health risks would violate their ethical standards. For others, the evidence-base for THR is not yet sufficient to warrant policy consideration. Beyond acknowledging differences in harm among tobacco products, additional research is needed to establish appropriate regulations and practice guidelines.⁵⁰ These are important values that influence stakeholders’ perspectives.

Regarding e-cigarettes specifically, THR opponents fear that if regulations are too lax, the e-cigarette industry will use media to target youth⁵¹ and mislead the public through false safety claims.^{52,53} They point out that e-cigarettes contain harmful chemicals,⁵⁴ lack safety oversight,⁵⁵ may renormalize smoking behaviors,⁵⁶ and if unchecked, could provide a gateway to tobacco.⁵⁷ From this perspective, e-cigarettes may compromise existing tobacco control efforts and have a negative overall public health impact, despite lower individual harm.⁵⁸

Beyond professional norms and standards of evidence, disagreements around THR may also relate to differences in policy objectives. Some tobacco control organizations focus primarily on preventing nicotine addiction. For them, any exposure to tobacco would be a threat. Conversely, stakeholders that emphasize the goal of reducing disease or premature death from tobacco use may view continued exposure to a low harm tobacco product an acceptable trade-off if the alternative is continued smoking.

Thus, as I illustrate in Table 1, there is evidence to support abstinence-only and THR approaches. It is clear that smokers should quit, as soon as possible, and aids like nicotine replacement therapy (NRT) and behavior change coaching increase individuals' odds of remaining quit. However, evidence around THR also exists. E-cigarettes appear to work at least as well as NRT when used as a cessation aid and are less harmful to individuals who switch from smoking traditional cigarettes.³⁴ In contrast with NRT, using an e-cigarette to quit smoking may appeal to certain tobacco users because they were not designed for temporary use. Thus the policy question: if reduced-risk nicotine products are a viable alternative to smoking, are we comfortable endorsing long-term use of these products as an acceptable tobacco control objective?

How tobacco control stakeholders' answer this question will depend on these and other deeply held core values. For some, professional ethos like 'do no harm' influences their decision to reject e-cigarettes. Others support e-cigarette use based on their preference to value patient autonomy. These deontological differences highlight that evidence alone will neither fully substantiate nor undermine the merits of e-cigarettes within tobacco control. Instead, evidence needs to be discussed within the larger context of which values and prevention objectives should be prioritized. There will always be tradeoffs. In this dissertation, I emphasize that one of the merits for considering THR is that it may appeal to a subset of tobacco users who are ambivalent about quitting.

Table 1. Evidence supporting abstinence-only and tobacco harm reduction strategies

General Facts	
<ul style="list-style-type: none"> • Cigarette smoke contains over 7,000 chemicals, 70 of which cause cancer.⁵⁹ • The majority of smokers tried their first cigarette (81%) or were daily smokers (65%) before age 18.⁶⁰ • Smoking reduces life expectancy by an average of 10 years.⁶¹ • Smokers experience ambivalence around quitting.^{62,63} Millions are unable or unwilling to quit.⁶⁴ • In a given year, 69% of smokers report wanting to quit, 52% attempt it, and 6% succeed.⁶⁵ • Between 60% and 90% of smokers who make a quit attempt relapse within one year. Another 15% relapse in year two.⁶⁶ • It is estimated that the average smoker makes 30 quit attempts before achieving abstinence.⁶⁷ • Health is the most commonly reported reason for wanting to quit smoking.⁶⁸ • North American quitlines reach and serve 1-2% of smokers each year.⁶⁹ • Most smokers eventually quit, but only after years of harmful exposure.⁶¹ • Over 90% of smokers who quit do so without assistance.⁷⁰ • An estimate 20% of smokers never quit in their lifetime.⁴⁵ 	
Cessation Evidence - Abstinence	Cessation Evidence - THR
<ul style="list-style-type: none"> • NRT is deemed safe for dual and long-term use.^{71,72} • Using over-the-counter NRT, 7% of participants remain quit for six months or longer.⁷³ • Combining NRT with counseling, cessation rates increase to 29%.⁷⁴ 	<ul style="list-style-type: none"> • E-cig cessation RCTs show similar outcomes as NRT trials.⁷⁵ • Observational studies with robust e-cig use measures report positive correlations between e-cigs and tobacco cessation.³⁴ • In a non-representative survey of 19,000 e-cig users, 81% claimed that e-cigs helped them quit smoking.⁷⁶ • As of 2012, snus use in Sweden contributed to an adult smoking prevalence of 13% compared to EU's average of 28%.⁷⁷
Abstinence Health Benefit Evidence	THR Health Benefit Evidence
<ul style="list-style-type: none"> • Nicotine is as addictive as heroin, cocaine, and alcohol.⁵⁹ • Nicotine withdrawal includes feeling irritable, anxious, and having difficulty focusing.¹² • After 1 year of smoking abstinence, excess risk of heart disease is cut in half.⁷⁸ • After 5 years of smoking abstinence, stroke risk equals that of a non-smoker, risks of several cancers are cut in half.⁷⁸ • After 10 years of smoking abstinence, risk of dying from lung cancer is cut in half.⁷⁸ 	<ul style="list-style-type: none"> • Smokeless tobacco is not associated with tobacco-related morbidities, including cancer.⁷⁹ • Second-hand aerosols from ENDS are below thresholds for risky exposure. There is no bystander safety concern.⁸⁰ • Smokeless tobacco poses 1-2% the health risk of combustible tobacco.³¹ E-cigs are believed to present a similarly low risk profile.³² • In Sweden, for every 100,000 men over the age of 35, forty-seven die of lung cancer. The rate for Europe is 108.⁸¹ • Smoking for a >3 months likely poses more harm than a lifetime of exposure to reduced risk nicotine product.⁸²

Abbreviations: THR, tobacco harm reduction; e-cig, electronic cigarette; NRT, Nicotine replacement therapy; RCT, randomized controlled trial

SPECIFIC AIMS

I completed my aims for this dissertation in three independent manuscripts. The first is a literature scoping review examining e-cigarette use policy recommendations. The second and third are empirical analyses using data from callers who enrolled in services at the Arizona Smokers' Helpline (ASHLine). The second study assesses the relationship between e-cigarette use and tobacco cessation outcomes at 7-month follow up. The third examines the association between high quality coaching to assist callers to set a quit date and make an in-program quit attempt. The ASHLine studies are both observational, retrospective cohort designs that use logistical regression analysis to test the hypotheses outlined below.

Manuscript 1 – E-cigarette Policy Recommendations

Impetus. There is a lack of consensus on whether e-cigarettes facilitate or threaten existing tobacco prevention strategies. Some health organizations wish to reject e-cigarettes in favor of longstanding abstinence-focused policies. Others believe they present a viable harm reduction opportunity and should be embraced within tobacco control. The extent to which these divided views have influenced health and tobacco control organizations' e-cigarette use recommendations has not been well documented. Our purpose was to systematically describe the range of recommendations they present and the qualitative differences between them.

Aim 1. Comprehensively review and identify the range of e-cigarette use policy recommendations presented in tobacco control and health organizations' e-cigarette position statements. This is achieved by:

- Using an inductive coding process to identify and classify e-cigarette recommendations.
- Identifying the frequency of each theme and provide examples of recommendations to illustrate each type.

Aim 2. Explore patterns between recommendation types and organizational attributes, including: (i) organizations' geographic location (country), (ii) organizations' type (governmental, professional, non-profit, commercial), and (iii) the year organizations published their statements.

Manuscript 2 - E-cigarette Use and Tobacco Cessation

Impetus. Most e-cigarette users are current smokers attempting to quit. However, evidence is mixed on whether e-cigarettes are an effective cessation aid. Early quitline studies suggest that e-cigarette users have lower rates of abstinence compared to non-e-cigarette users. They also highlight that smokers who use e-cigarettes face greater barriers to quitting and are more likely to have mental health conditions. Controlling for these differences, we examined if e-cigarette use was associated with smoking abstinence at 7-month follow-up among ASHLine callers.

Aim 1. Identify the adjusted odds of 30-day point prevalence tobacco abstinence for any e-cigarette use among ASHLine callers.

- Hypothesis: Controlling for differences between e-cigarette users and non-users, any e-cigarette use is positively associated with 30-day point prevalence tobacco abstinence.

Aim 2. Identify the adjusted odds of 30-day point prevalence tobacco abstinence for e-cigarette use, categorized by pattern of use among ASHLine callers. Patterns include: (i) sustained use (use at enrollment and follow up), (ii) adopted use (use at follow up but not enrollment), (iii) discontinued use (use at enrollment but not follow up), and (iv) never use (no use at enrollment or follow up).

- Hypothesis: Controlling for differences between e-cigarette users and non-users, compared to never use, sustained use and adopted use are positively associated with 30-day point prevalence tobacco abstinence.

Manuscript 3 – Quit Date Goal Setting

Impetus. At quitlines, it is recommended that callers be encouraged to set a quit date during their first coaching session. The limited research on this subject suggests that quit date goal setting does not routinely happen. However, high quality quit date coaching may improve callers' odds of making a quit attempt. Using a tested quit date coaching rating scale, we examined this hypothesis while controlling for factors known to influence smoking abstinence.

Aim 1. Identify the adjusted odds of making an in-program quit attempt among ASHLine callers receiving high quality quit date coaching. High quality coaching is assessed using a 10-point scale and in-program quits are self-reported periods of ≥ 24 -hour abstinence before a caller is exited from ASHLine's program.

- Hypothesis: Compared to low quality quit date coaching, high quality coaching is associated with higher odds of making an in-program quit attempt.

Aim 2. Identify the odds of making an in-program quit attempt within 14 days of an ASHLine caller's first coaching session for high quality quit date coaching.

- Hypothesis: Compared to low quality quit date coaching, high quality coaching is associated with higher odds of making an in-program quit attempt within 14-days.

Aim 3. Identify the odds of being abstinent at 7-month follow-up for high quality quit date coaching.

- Hypothesis: Compared to low quality quit date coaching, high quality coaching is associated with higher odds of being abstinent at 7-month follow-up.

SUMMARY OF FINDINGS

Manuscript 1 – E-cigarette Policy Recommendations

In the e-cigarette policy recommendation scoping review, we located and analyzed 81 tobacco control and health organizations' e-cigarette position statements published between 2011 and 2017. In them, we identified a range of five use recommendation categories—two that permitted use among current tobacco users and three that recommend against use by any individual (Table 2).

Table 2. Electronic cigarette (e-cig) recommendation categories

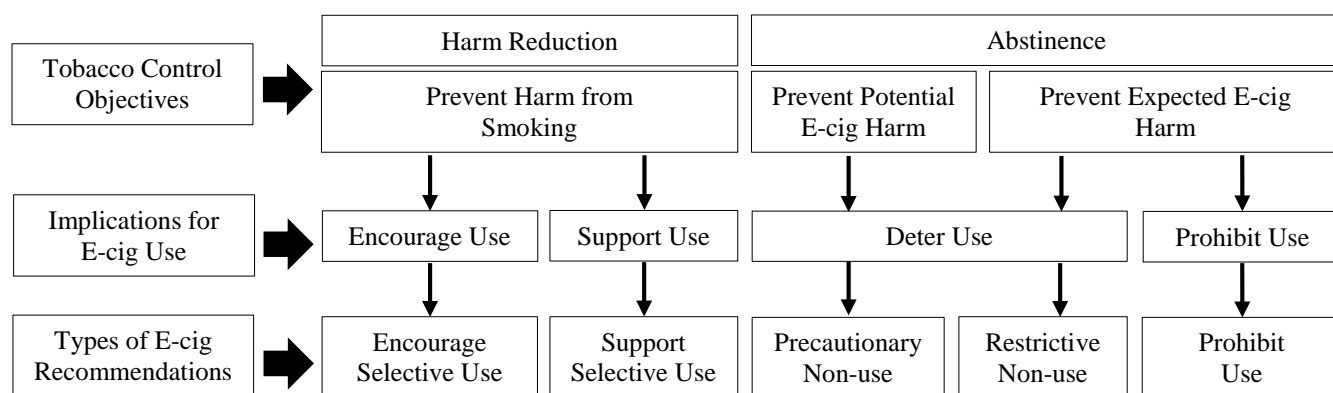
Frequency	Recommendation Categories
5	<u>Encourage Selective Use:</u> Encourage smokers to use e-cigs as a cessation aid or to switch to exclusive e-cig use. Regulation should prioritize innovation, user appeal, lower taxes, and health messages that characterize their lower harm.
20	<u>Support Selective Use:</u> Allow smokers to use e-cigs as a cessation aid. Users should also be advised about nicotine medications and counseling services. E-cigs should not disrupt existing tobacco policies like smoke-free laws.
19	<u>Precautionary Non-Use:</u> Though e-cigs are likely to be less harmful than cigarettes, it remains unknown whether they expose users to long-term risks or function as effective cessation aids. To be cautious, use is not recommended until additional information is available.
30	<u>Restrictive Non-Use:</u> Based on available evidence, e-cigs are counterproductive to tobacco control and should be opposed. Use is not recommended and regulations should focus on restricting commercial activities and product availability. E-cigs should be regulated like tobacco.
7	<u>Prohibit Use:</u> To prevent health risks, e-cig products should not be legally available.

Almost 70% of organizations did not recommend e-cigarette use, though their recommendations differed by tobacco control objective, geographic location, and organizational type. In categorizing recommendation types, we found that organizations diverged in how they

prioritized harm reduction and abstinence objectives. Figure 1 details how these objectives underlie different implications and recommendations for e-cigarette use.

Eighty-five percent of UK-based organizations favored e-cigarette use compared to 11% of US organizations. No organization in Canada or Australia recommended any form of e-cigarette use. Governmental organizations were more favorable than non-governmental or professional organizations and we found preliminary evidence that, compared to older position statements, more recent statements may be trending towards liberal-use positions.

Figure 1. Electronic cigarette (e-cig) policy recommendations and their underlying tobacco control objectives and use implications



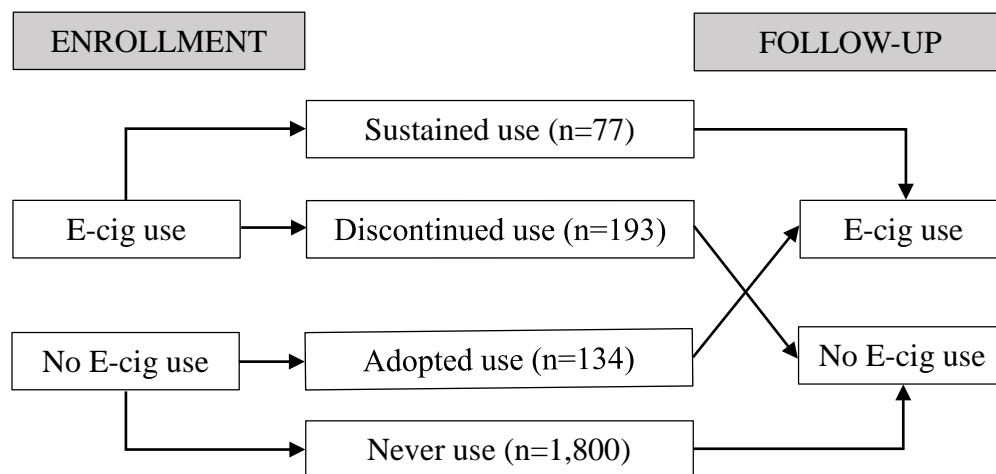
Limitations. A scoping review is useful for documenting and describing available policy positions. In attempting to locate and include position statements, we restricted our sample to English language texts that were searchable on the web. Because of this, we excluded three non-English statements and may have missed others. In addition, when multiple statements were found from the same organization, we only included the most recent. This may have biased the sample to be more favorable to e-cigarettes—early statements appear to have been more

restrictive towards e-cigarettes than recently published statements. Likewise, when multiple positions were located during coding, we opted to emphasize the position most favorable to e-cigarettes. This allowed us to highlight any positive framing around e-cigarettes as it was the minority position. The purpose of the paper was not to critically assess the virtue of an organization’s position, only to describe what positions exist.

Manuscript 2 - E-cigarette Use and Tobacco Cessation

Among 2,404 ASHLine callers (2014-2016), we found that 18% reported using e-cigarettes at the time of service enrollment, 7-month follow-up, or both. However, e-cigarette use at any of these time points (any e-cigarette use) was not associated with 7-month quit rates, in either a controlled or an uncontrolled regression analysis. When we classified e-cigarette use by categorical patterns—at the time of enrollment, follow-up, both, or neither (Figure 2)—we again found no statistically significant association.

Figure 2. Caller distribution across e-cigarette use categories



Callers who used e-cigarettes were statistically more likely than non-users to be younger, non-Hispanic, not intending to quit in the next 30-days, and reported having a mental health condition. However, controlling for these conditions did not change the observed association. The adjusted odds ratios from both analyses are presented in Table 3.

Table 3. Adjusted odds ratios (AOR) of 30-day point prevalence tobacco abstinence (n=2,204) for e-cigarette use.

	Multivariable model 30-day Quit AOR (95% CI)	p-value
Any e-cigarette use		
Never use	ref	-
Any use	1.02 (0.79-1.32)	0.86
Categorized e-cigarette use		
Never use	ref	-
Discontinued use	1.07 (0.75-1.53)	0.70
Adopted use	1.05 (0.69-1.59)	0.81
Sustained use	0.87 (0.50-1.50)	0.61

Limitations. This study was a retrospective cohort study of quitline callers. The data are observational and limited to the unique characteristics of tobacco users who utilize treatment services. They may not generalize to the general population of tobacco users and only allow for associative, not causal inferences. Due to caller attrition and exclusion due to missing data, callers included in this study also may not represent all quitline callers. The variables e-cigarette use and tobacco cessation status were also based on caller self-report and were not independently verified. Finally, the study was limited by the e-cigarette use measure. Future research should capture individuals' frequency of use, purpose for using, type of product, and amount of nicotine content, as each have been shown to affect tobacco cessation outcomes.

Manuscript 3 – Quit Date Goal Setting

In an analysis of 90 ASHLine callers' first coaching session, we found that those who received high quality quit date coaching had significantly higher odds of making an in-program quit attempt compared to those who received low quality quit date coaching. Forty-three of the 90 callers received high quality and 47 received low quality quit date coaching. The mean quality score was 3.1 in a possible range of -3 to 7. While in-program, 69 callers (77%) set a quit date goal and 39 (43%) made a quit attempt. We did not find that callers' mental health condition status affected the association between quality quit date coaching and in-program quitting. However, in an exploratory analysis we did find that high quality quit date coaching was statistically associated with higher odds of making a quit attempt within two-weeks of callers' first coaching session. The adjusted odds ratios for making a quit attempt and for making a quit attempt within two weeks are shown in Table 4.

Table 4. Adjusted odds ratios (AOR) of in-program quit attempts (n=90)

	Any in-program quit AOR (95% CI)	p-value
Quality of quit date coaching		
Low	ref	-
High	3.98 (1.55-10.20)	0.004
	In-program quit within two weeks AOR (95% CI)	p-value
Quality of quit date coaching		
Low	ref	-
High	7.92 (1.80-34.74)	0.006

Limitations. The same as with Manuscript 2, this study is limited by the observational nature of the data and the findings may not generalize to non-quitline cessation service settings. The findings were also based on a small cohort of callers who self-reported their tobacco use and

cessation outcomes related to in-program activities. Additional follow-up research is needed to confirm if high quality quit date coaching also translates to callers remaining quit long-term.

Key Conclusions

My co-authors and I identified that e-cigarette policy recommendations were not evenly distributed across geographic region or organizational type. When we explored the statistical association between e-cigarette use and cessation at 7-months among ASHLine callers, we did not find a relationship between e-cigarette use and tobacco cessation. Callers' quit outcomes were unaffected by their decision to use or not to use e-cigarettes. However, when we examined the relationship between quit date goal setting and making an in-program quit attempt, we found that high quality quit date coaching was significantly associated with higher odds of making a quit attempt and making a quit attempt within 14 days of callers' first coaching session.

These results highlight a few overarching conclusions. First, within tobacco control and public health, disagreement exists over e-cigarettes and whether they should be used by current smokers. We found that this disagreement relates to differences in how organizations prioritize harm reduction or abstinence-only objectives for quitting tobacco. As illustrated in Figure 1, organizations varied in whether they focused on preventing the harm from smoking or the harm from e-cigarettes. Second, when ASHLine callers self-selected e-cigarette use, it did not reduce their likelihood of quitting tobacco at 7-month follow-up compared to non-e-cigarette users. Third, goal setting is important. When coaches expressed clear parameters around setting a quit date goal for becoming tobacco abstinent, ASHLine callers were more likely to make a quit attempt while in-program and within two weeks of their first coaching session. High quality goal

setting depends upon explicit behavior change expectations and ensuring that assistance is accessible, whether in the form of NRT, coaching, or both.

Together, these findings indicate that in a client-centered, cessation service setting, it would be warranted to support callers who elect to use an e-cigarette. This position has been adopted by an ASHLine taskforce that reviewed a collective body of evidence, including preliminary findings from this research. I share this view. It reflects my perspective that tobacco control policies would benefit from becoming more inclusive of additional and alternative prevention objectives. However, I recognize that others may interpret these null findings differently. Although e-cigarette use did not reduce callers' odds of tobacco abstinence, it did not positively affect cessation rates either. Therefore, these data do not provide robust evidence that e-cigarettes should be promoted as a cessation aid. My view aligns with the "support selective use" position presented in the e-cigarette scoping review; I recommend waiting for additional and more compelling evidence before adopting a "promote selective use" position.

Finally, the findings of the quit date goal setting project may also suggest that to support e-cigarette use, it would be beneficial to pilot and evaluate whether focused goal setting and tailored coaching around callers' e-cigarette use would make it more purposeful and conducive towards quitting smoking. These findings may suggest that high-quality goal setting coaching may improve treatment outcomes even when the specified goal involves harm reduction behavior changes. In the policy implications that follow, I discuss this idea further, including reasons why it is reasonable to hypothesize that goal setting around a harm reduction objective may improve quitline callers' tobacco use and health outcomes.

POLICY AND PRACTICE IMPLICATIONS

On May 15, 2017, Scott Gottlieb, the commissioner of the US Food and Drug Administration, stated:

“...there’s probably no single intervention, or product we’re likely to create in the near future that can have as profound an impact on reducing illness and death from disease as our ability to increase the rate of decline in smoking ... We need to redouble efforts to help more smokers become tobacco-free. And, we need to have the science base to explore the potential to move current smokers – unable or unwilling to quit – to less harmful products, if they can’t quit altogether.”⁸³

Dr. Gottlieb’s statement makes at least two important points, though neither is controversial. The first is the most recognized—smoking is harmful to a person’s health and should be stopped. The second receives less attention—those who smoke vary in their interest or ability to quit. My dissertation focused on this second point.

Smokers constitute a diverse group of individuals who smoke for different reasons and hold different views regarding if, when, or how they desire to quit. However, within the tobacco control community, this point has not held equal weight in influencing policy decisions. Most tobacco cessation programs prioritize complete abstinence, regardless of smokers’ preference or ability.⁸⁴ Acknowledging heterogeneity among smokers opens the door to harm reduction policies and programs. This more nuanced view of smokers’ intentions presents at least three important implications for future policies and service delivery protocols.

Nicotine Addiction is Influenced by Social-Ecological Factors

The narrative that frames all tobacco use to be equally harmful or that all users will become addicted in the same way oversimplifies a more complex reality. The literature is more nuanced. Only 30% of individuals who ever smoke become dependent.⁸⁵ For those who become

dependent, biopsychosocial differences underlie meaningful variations in the ease or difficulty they face when attempting to quit.^{86,87} The way smokers understand addiction and ascribe meaning to their personal use differ substantially across cultural groups,⁸⁸ and vary over individuals' smoking career. Tobacco presents a different profile of harm depending on the form in which it is delivered, the user's biological, psychological predispositions, and the social-environmental context in which it is used.⁸⁹ The true risk profile lies at the intersection of these factors—between the drug, the user, and the setting.^{90,91}

Acknowledging Product Heterogeneity Is Accurate and Ethical

It is not true that all tobacco products are equally harmful.²⁶ When public health and tobacco control agencies use this message to deter tobacco use, they rely on misinformation and hyperbole. Health officials have a duty to provide the public with accurate information and recommendations for healthy living.⁹² Accurate, comparative risk assessments are necessary for smokers to make informed choices. Misleading claims and exaggerated messages only lead to confusion and loss of public trust.⁹³ They may also deter smokers who could benefit from switching to lower risk products like e-cigarettes.⁹⁴ Depending on an agency or organizations' tobacco control orientation and prevention objectives, there may be good reason to object to or promote e-cigarette use, but it is important to be clear about why. This was one of the implications discussed in Manuscript 1. With proper context, differing e-cigarette health messages and policy recommendations are possible without the need to misinform or exaggerate.

Acknowledging User Heterogeneity Facilitates New Treatment Delivery Approaches

A more nuanced view of smoker heterogeneity should allow for personalized and tailored support for individuals attempting to make positive tobacco behavior changes. In this view, tobacco control may benefit from adopting patient-centered practices like shared decision-making (SDM) to promote more effective goal setting. Patient centered care involves “care that is respectful of and responsive to individual patient preferences, needs, and values.”⁹⁵ Within this tradition, SDM focuses on the role care providers play in interacting with patients to promote treatment decisions that reflect patients’ preferences. SDM is an ethical proposition to respect patient values and a clinical approach to improve treatment outcomes⁹⁶ and productivity.⁹⁷ In contrast to the unilateral extremes of paternalistic care (only providers make care decisions) and informed decision-making (only patients decide), SDM is seen as a middle ground in which both parties contribute.^{96,98}

A proposed model for practicing SDM emphasizes three key steps: (1) ensure that patients know options exist, (2) provide details about each option, and (3) consider patients’ preferences and decide together which option is best for them.⁹⁹ In a tobacco cessation service like a quitline, SDM could compliment current services by providing an alternative to abstinence-only goal setting. Given quitlines limited reach among tobacco users—only 1-2% utilize a quitline in a given year—and high attrition rates among those who enroll, offering alternative services may increase their appeal and increase opportunities for positive behavior changes. Drug users generally do not contact agencies or enter treatment programs seeking harm reduction services. When the option is presented, however, as many as 40% may be partially or exclusively interested in harm reduction options.¹⁰⁰

ASHLine's service model is designed to increase caller self-efficacy using cognitive behavior therapy and motivational interviewing techniques. Adding a SDM element to ASHLine services would not replace, but support these practices. SDM should be seen as a framework for initially engaging callers after which cognitive, behavioral, and motivational techniques can be used to assist callers in working towards the behavior change goal they set. When SDM is practiced, studies show that patients increase in knowledge, confidence in their decisions, and become more actively involved in their care.⁹⁹

In the third manuscript, we explored abstinence goal setting among ASHLine callers and found that the majority opted to set a quit date goal. When coaches established clear expectations around quitting and helped callers set specific goals, their odds of making a quit attempt improved. These are positive findings. Yet, if smokers are not a one-size-fit all group, a one-size-fit all approach will not appeal to all smokers. Treatment services can expand to incorporate SDM goal setting practices and adopt additional service options that reflect tobacco users' range of behavior change interests. The goal for all tobacco users should be clear: smokers should quit as soon as possible. If complete abstinence is not possible, coaching callers to switch to safer forms of tobacco or nicotine would still be a significant and laudable goal.

ROLE OF AUTHORS IN THE RESEARCH

I conceptualized and completed the attached manuscripts (Appendices A – C) with support from my committee and contributing co-authors. Committee members contributed to the completion of each project by providing feedback on the study designs, analyses, discussion points, and presentation in manuscript form. Additional co-authors also provided subject matter and methodological expertise specific to each project.

All three projects originated from my work as a member of ASHLine’s research and evaluation team. The two studies involving ASHLine caller data were conducted with funding from Arizona Department of Health Services Grants and the National Cancer Institute of the National Institutes of Health. The principle investigator, Dr. Cynthia Thomson, provided oversight and guidance in the human subject review process and data management.

Manuscript 1 – E-cigarette Policy Recommendations

The idea for Manuscript 1 followed from an effort to draft e-cigarette policy guidelines for ASHLine. I became involved in this effort by reviewing tobacco control and health organizations’ e-cigarette policy statements to identify their policy recommendations. After recognizing that similar organizations presented dissimilar and incongruent positions, ASHLine’s assistant director and evaluation manager, Dr. Uma Nair, supported my interest in further investigating these differences. Dr. Jennifer De La Rosa, a former ASHLine evaluation staff member, expressed interest in the project and became a valued supporter. I organized the literature selection process, developed criteria for coding the statements, and worked with Dr. De La Rosa who was a second reviewer in selecting and coding the literature. We invited Dr. Scott

Leischow, a senior tobacco policy researcher at Arizona State University, to provide guidance in framing the study and its implications. I wrote the initial draft of the manuscript and all members of the committee, along with Dr. De La Rosa and Dr. Leischow, provided feedback and editing.

Manuscript 2 - E-cigarette Use and Tobacco Cessation

Manuscript 2 began as a collaboration with members of ASHLine's research committee, including Dr. Tracy Crane, Dr. Nair, and Dr. Nicole Yuan. The work followed from Dr. Crane's initial analysis that matched 250 e-cigarette users and non-users. Dr. Crane was ASHLine's former clinical manager. Working with her, I proposed a non-matched logistic regression that included a second year of caller data and additional covariates. I selected variables to include in the analysis and was assisted by Patrick O'Connor, a member of ASHLine's evaluation team with expertise in biostatistics. He cleaned the dataset, recommending appropriate statistical tests, and ran analyses using SAS. I wrote the initial draft of the manuscript and all members of the committee and two additional co-authors, Dr. Crane and Mr. O'Connor, provided feedback in modifying the analysis design and editing the manuscript.

Manuscript 3 – Quit Date Goal Setting

The idea for manuscript 3 was developed during the dissertation proposal process. After reviewing a draft proposal, I was encouraged by committee members to use ASHLine caller data to explore my interest in tobacco cessation goal setting. After I located an instrument for assessing the quality of quit date coaching, committee members provided guidance in developing research questions and structuring a primary and secondary analysis. As before, I developed

scoring criteria and directed the coding process. Taylor Grogg, a member of ASHLine's evaluation team, assisted in locating coaching session recordings and was a second reviewer in the data audit, co-coding 17% of the calls. Dr. Laurie Krupski, ASHLine's current clinical manager, was invited to participate as a co-author. She designed the protocol used during the coaching sessions reviewed in this study. I organized and cleaned the dataset and conducted all statistical tests using Stata. I wrote the initial draft of the manuscript and all members of the committee along with Dr. Krupski provided feedback and manuscript editing.

CONCLUSION

Over time, tobacco control adopted the view that all smoking, nicotine, and tobacco use is equally problematic. This has resulted in an almost exclusive focus on abstinence-only programs and policies. To become more inclusive and to serve the diverse needs of a heterogeneous population of tobacco users, tobacco control should recommit to its original goal of preventing the consequences of tobacco use instead of use itself. Abstinence and THR can be regarded as complimentary propositions that, when combined, would provide a more inclusive pathway for tobacco control to reach and assist more tobacco users.

In the attached manuscripts, my co-authors and I explored findings from a scoping review and outcomes from quitline callers who used e-cigarettes to quit smoking and were coached to set quit dates. Whether callers used or did not use e-cigarettes, we found no difference in quit outcomes at 7-month follow-up. However, we did find that high quality quit date coaching was associated with increased odds of callers making a quit attempt. In both studies, callers seemed to benefit from having options (e-cigarettes) and participating in setting clearly defined goals (high-quality coaching).

In discussing the scoping review and ASHLine studies, I have focused on the opportunities and limitations in embracing alternative nicotine products and allowing harm reduction-oriented goal setting. As discussed in the e-cigarette recommendation scoping review, it is difficult to weigh these tradeoffs without also clarifying the assumptions and prioritized objectives that distinguish abstinence from harm reduction.

It is my view that a more comprehensive approach to tobacco control is possible. However, it would require broadening its mission and refocusing its priorities from eliminating tobacco to eliminating the harms from tobacco use. If it is not feasible to eliminate all tobacco

consumption, it would still be an important public health priority to provide safer forms of nicotine. It is possible to reduce tobacco harm through abstinence and harm reduction policies. The appeal of each will vary among tobacco users who face different barriers and hold different interests in quitting. By supporting more behavior change options, cessation services may be in a better position to engage and serve more tobacco users to stop smoking, even if they are not yet ready or able to become completely abstinent.

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APPENDIX A – MANUSCRIPT 1**Electronic Cigarette Policy Recommendations: A Scoping Review**

Benjamin R. Brady, MS, MPH

Jennifer S. De La Rosa, PhD

Uma S. Nair, PhD

Scott J. Leischow, PhD

Benjamin R. Brady, Research Specialist, Mel and Enid Zuckerman College of Public Health, University of Arizona, Tucson, AZ. Jennifer S. De La Rosa, Evaluation Associate, College of Medicine, University of Arizona, Tucson, AZ. Uma S. Nair, Assistant Professor, Mel and Enid Zuckerman College of Public Health, University of Arizona, Tucson, AZ. Scott J. Leischow, College of Health Solutions, Arizona State University, Phoenix, AZ.

Correspondence Mr. Brady; brb99@email.arizona.edu

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ABSTRACT

Objective: There is a lack of consensus on whether e-cigarettes or electronic nicotine delivery systems (ENDS) facilitate or threaten existing tobacco prevention strategies. This uncertainty is reflected in health organizations' conflicting ENDS position statements. We conducted a scoping review of position statements in published and gray literature to map the range and frequency of ENDS use recommendations. **Methods:** We collected 81 statements from international health organizations. Two coders independently performed qualitative content analysis to categorize ENDS use recommendations. We explored differences based on organization type, geography and the year recommendations were published. **Results:** We identified five recommendation types: encourage smokers to use ENDS as a cessation aid or as an alternative source of nicotine (n=5), support individuals who use ENDS to quit smoking (n=20), avoid using ENDS until more research is available (n=19), restrict ENDS access based on available evidence (n=30), and prohibit ENDS marketing and sale (n=7). **Conclusions:** Organizations presented diverse ENDS recommendations. The variation related to organizations' differing tobacco prevention priorities and their level of confidence in current ENDS research. These differences may create confusion. Additional research can examine whether this variability influences stakeholders' attitudes or behavior.

INTRODUCTION

Since their emergence in Europe in 2006 and the US in 2007,¹ electronic cigarette or electronic nicotine delivery systems (ENDS) use has steadily increased. In 2014, 13% of US adults had used ENDS at least once and 4% were current users.² In the same year, 38% of high school students had used ENDS and 16% were current users.³ Current use among high school students rose from 2% in 2011 to 16% in 2015.⁴ The rising popularity of ENDS, particularly in youth, coupled with unanswered safety questions raises important prevention questions.³

In the US and abroad, there is no consensus for regulating ENDS. At the October 2014 World Health Organization Framework Convention on Tobacco Control, differences in opinion were so great, “agreeing to disagree” was adopted as the consensus position.⁵ Some believe that ENDS provide an opportunity to reduce harm while others firmly believe they threaten the field’s longstanding, abstinence-centered approach to nicotine and tobacco.⁶

Experts who favor abstinence contend that if ENDS regulations are too lax, the e-cigarette industry will repeat tobacco manufacturer offences including using media to target youth⁷ and misleading the public through false safety claims.^{8,9} They point out that ENDS contain harmful chemicals,¹⁰ lack safety oversight,¹¹ may renormalize smoking behaviors,¹² and if unchecked, could provide a gateway to tobacco.¹³ From this perspective, ENDS may compromise existing tobacco control efforts and have a negative public health impact.¹⁴

Conversely, from a harm reduction perspective, advocates argue that ENDS provide a safer alternative to smoking, especially for smokers who do not desire to quit or find it difficult to do so.¹⁵⁻¹⁷ They are concerned that over-regulation will extinguish the ENDS market and eliminate the potential for a public health benefit.¹⁸ A growing body of evidence suggests that ENDS may function as cessation aids^{19,20} and that use is correlated with population-level

declines in smoking.^{21,22} Relative to smoking, ENDS products have been shown to be less toxic.^{23–25} Though long-term effects are unknown, the risk of premature mortality is expected to be comparable to smokeless tobacco,¹⁶ which is substantially less than that of smoking.²⁶ Using substitution models, researchers estimate that ENDS use will result in between two and seven million fewer premature deaths among those 15 years or older after 2016.²⁷

Amid these divided views, the US Surgeon General commented that health officials are in “desperate need of clarity.”²⁸ While scientific reviews provide important summaries of evidence,^{29,30} lawmakers, health care providers, and smoking cessation services still look for guidance to interpret and translate evidence into policies and treatment. Historically, public health, tobacco control, and medical organizations have provided this direction. They leverage their members’ expertise and act as authoritative voices to explain complex issues and recommend specific action.³¹

To date, dozens of organizations have published ENDS position statements. In a study that reviewed eight statements, the most common recommendations were: regulating ENDS manufacturing, marketing, and sales, applying cigarette laws to ENDS, banning sale to minors, and limiting the potential for ENDS to undercut tobacco control laws.³² In a subsequent study, authors found that organizations differed in their reliance on the precautionary principle and harm reductionism and in their perception of ENDS advantages and disadvantages.³³ This highlights an important philosophical distinction. Where harm reductionism entails a commitment to reduce harms from drug use without first requiring drug abstinence,³⁴ the precautionary principle justifies “risk-management” when the consequences of action are uncertain.³⁵ Harm reduction interventions focus on specific, known risks while the precautionary principle is usually cited in support of non-action, to prevent potential exposures to harm.

The purpose of this scoping review is to categorize and describe ENDS use recommendations presented by health and tobacco control organizations. To our knowledge, this has not yet been done. Identifying available options is an important first step to formulate policy guidance.³⁶ To do this, we conducted a comprehensive search of the published and gray literature and compiled a census of ENDS position statements. Using these statements, we inductively categorized organizations' positions to describe the types and prevalence of ENDS recommendations. We then examined whether the recommendations differed by organizational type, geographic region, or if certain recommendations became more frequent over time.

METHODS

Search Parameters

A scoping review is a literature review and knowledge synthesis technique.³⁷ Through a comprehensive evidence survey, scoping reviews describe and summarize the range and nature of research findings in a given area. They can be used to rapidly review and map fields of study, ascertain the feasibility of systematic reviews, and detail findings in areas of study to summarize and disseminate them to policy makers and practitioners.^{37,38} For issues like electronic cigarette use that are new, complex, or have not yet been comprehensively reviewed, scoping reviews are useful for defining the boundaries of available evidence.³⁹ Different from systematic reviews, scoping studies are designed to cover a broad set of literature and provide a big picture view of what is known. Instead of critiquing the individual quality of the reviewed sources, emphasis is placed on comprehensively classifying and describing actions that have been taken relative to a given topic.³⁸

In conducting our scoping review, we followed the six steps outlined by Arksey and O'Malley³⁸ and later enhanced by Levac et al.⁴⁰ and Daudt et al.⁴¹ After articulating our research question, two members of the study collaborated to identify relevant data sources. They provided a multidisciplinary perspective with strengths in content (tobacco control) and methodology (content analysis). We used a four-step search process to locate statements from US and international medical, public health, and tobacco control organizations. We first conducted a Google web search using two key word combinations:

- “electronic cigarettes policy position statement”
- (“electronic cigarette” OR “ENDS” OR “e-cigarette”) AND (“policy statement” OR “policy position”)

We reviewed the first 100 hits from each search. Second, from the web search, we located and reviewed lists of ENDS position statements that three organizations had previously compiled: Wikipedia, Cancer Council Victoria, and The Union for International Cancer Control. Third, we searched three scholarly journal databases, PubMed, Web of Science, and EMBASE using the keyword combinations mentioned above as well as the term “vape.” Finally, through snowball sampling, we included statements identified by searching references of references⁴² or that were inadvertently discovered during web searches to locate other organizations’ statements.

We completed these searches in November 2017. In total, 412 source records were reviewed and 81 statements were identified for inclusion (see Figure 1). We developed inclusion and exclusion criteria through a multi-session, iterative review. Two researchers reviewed each record—the first completed the selection process and the second audited and confirmed the results.⁴³ After removing 122 duplicate records, we used a two-step process to review the remaining 290. We first examined titles, abstracts, and introductory statements and excluded 75

records that were not related to ENDS. Second, we excluded records that did not contain policy recommendations. To be included, statements had to:

- represent the views of an organization and not an individual
- include explicit policy recommendations
- be written in English

Statements could have been published in scholarly journals, as organizational statements or reports, in text embedded on an organization's website, or as sections in larger reports. When multiple statements were found from the same organization, we included the most recent. We excluded primers, fact sheets, research articles, patient education materials, and advocacy toolkits.

- insert Figure 1 about here -

Data Analysis

We used inductive, qualitative content analysis to develop categories that describe organizations' positions towards regulating ENDS use.⁴⁴ Through open coding, we created five thematic categories and used them to classify the full sample.

1. Encourage selective use
2. Support selective use
3. Precautionary non-use
4. Restrictive non-use
5. Prohibit use

Initially, two reviewers coded 14 statements and discussed threshold criteria. Reviewers continued to meet while independently coding the full sample, further clarifying and refining the categories and criteria. The insights gained from discussing disagreement and alternative interpretations facilitated more trustworthy findings.⁴⁵ When multiple positions were identified in a single statement, we coded based on the most liberal (i.e., the most favorable towards

ENDS). This allowed us to reduce subjectivity in coding and increase replicability. For example, in the event of interrater disagreement, it was only necessary to point to the most liberal claim in the document rather than engage in a subjective criticism of the entire piece. Recognizing that most organizations recommended not using ENDS, we selected this coding scheme to highlight minority positions—any positive framing around ENDS.

In addition to ENDS recommendation categories, we collected information about organizational attributes including type and geographic area; we also recorded the year the statement was published. Organizations were grouped into four types:

1. governmental
2. non-governmental
3. professional
4. commercial

Government organizations are publically funded, guided by legislative action, and associated with a local, state, or national government. Non-governmental organizations are voluntary or quasi-governmental organizations that act partially or completely independent from government mandate. They provide not-for-profit services that benefit the public and are funded through grant or public contribution. Professional organizations are not-for-profit entities that service specific membership groups united by shared professional interests. Commercial organizations are for-profit firms that serve owner- or shareholder-defined interests. The - publication date was not listed in eight statements. We reached out to the author-organizations and identified dates for six; however, two remained undated.

To describe the recommendations, we present numerical and descriptive summaries, including definitions and illustrative language from the statements. We use visual charts to highlight patterns⁴⁶ between organization type, statement publication date, and ENDS use recommendations. Different from quantitative analyses used to establish the strength of an

association, categorical information in qualitative studies may be quantified and displayed in multi-variable matrices to visually represent their thematic overlap, provide context, and improve interpretation.^{47,48} This allows us to examine whether specific ENDS recommendations vary by organizational attribute.

RESULTS

We reviewed 81 statements publicized between 2011 and 2017 from organizations in 10 geographic areas:

1. Argentina (1)
2. Australia (10)
3. Canada (10)
4. Germany (1)
5. New Zealand (2)
6. Philippines (1)
7. Spain (1)
8. UK (20)
9. USA (28)
10. Multi-national organizations (7)

Types of organizations included health professional (n=43); non-governmental (n=20); governmental (n=17); and one commercial, UpToDate, Inc.—a medical information company owned by Wolters Kluwer Health.

In constructing the ENDS use categories, we sought to capture similarities and differences in organizations' emphasis on preventing harm from smoking or from using ENDS. No organization recommended that ENDS be promoted to non-smokers. For most, preventing youth use and exposure to marketing messages was a concern and there was general agreement that increased oversight would improve ENDS product safety, content quality, and that

additional research would be beneficial. Organizations disagreed, however, in how they prioritized different tobacco control objectives.

Organizations did not neatly fit into a simple dichotomy of supporting or opposing ENDS. They varied in the degree and reason for which they supported or opposed use. The categories demonstrate how two organizations may share the same tobacco control rationale while disagreeing on its implications for use. Conversely, others may endorse the same implications for use based on different tobacco prevention objectives. We identified three: prevent smoking harm, prevent potential ENDS harm, and prevent expected ENDS harm. Linking these objectives with recommendations for ENDS use allowed us to position organizations along a spectrum of use restriction. Moving from restrictive to liberal, each position is incrementally more liberal in regards to ENDS market presence and organizations' priorities in preventing nicotine consumption (see Figure 2).

- Insert Figure 2 about here -

We labeled two of the five categories as “selective use” to reflect organizations recommending use only by select populations—individuals with a history of smoking. Organizations that recommended against using ENDS for precautionary reasons cited a lack of evidence. They warned about the potential for ENDS harm. Those that recommended restricting individual's ability to use based their position on the strength of available evidence. They warned about expected ENDS harm. A complete list of organizations and their categorized recommendations is presented in Table 1.

insert Table 1 here (the AMA numerical citations in the table are formatted for this location)

ENDS use categories

Encourage selective use. Individuals with a history of smoking should be encouraged to consider ENDS as a cessation aid. If they are not ready or able to quit, it is also appropriate to promote switching to exclusive ENDS use. For ENDS to provide an alternative to smoking, regulations should prioritize product innovation, user appeal, lower taxes, and health messages that characterize their lower harm.

“Consideration should be given to a proactive strategy to encourage disadvantaged smokers to quit smoking as quickly as possible including the use of [ENDS], where appropriate, to help reduce the health inequalities caused by smoking.” (Public Health England, 2015)⁵²

“There are likely to be substantial benefits to individual and population-level public health by successfully encouraging more smokers to switch to using e-cigarettes.” (UK New Nicotine Alliance, 2017)⁵¹

“Combine existing best practice with the most popular quitting method (e-cigarettes)” ... “Regulate to promote product development” (The British Psychological Society, 2017)⁴⁹

Support selective use. Individuals with a history of smoking may be supported to use ENDS as a cessation aid. The focus is on assisting individuals who self-select ENDS use. Clinicians have discretion to fully or reluctantly support ENDS use, on a case-by-case basis. Individuals should be advised about the effectiveness of licensed / approved medications and cessation services and some organizations believe these should be tried before supporting ENDS use. Regulating ENDS as medicinal products would improve product safety and allow marketing restrictions. As such, the controlled availability of ENDS must not interrupt existing tobacco control policies, like smoke-free laws.

“Once [cessation] service-users have considered all the options, and if they want to quit using e-cigarettes, they should be supported to do so.” (NHS Health Scotland, 2015)⁶¹

“It is up to the clinician’s judgement whether to support the use of e-cigarettes. We do not discourage the use of e-cigarettes so long as smokers are aware of the uncertainty about their safety and efficacy as therapeutic devices.” (UpToDate, 2017)⁷²

“We would like to see the medicinal regulation of all e-cigarettes to ensure the safety, quality and efficacy of these products and to ensure they are regulated according to how they are increasingly being used – as cessation aids.” (British Heart Foundation, 2014)⁵⁵

Precautionary non-use. Though ENDS are likely to be less harmful than cigarettes, it remains unknown whether they expose users to long-term health risks or function as effective cessation aids. It is also possible that ENDS may undermine tobacco control efforts. Given the lack of information, use is not recommended. To be cautious, individuals who smoke should be encouraged to quit using already approved cessation medications. These recommendations are provisional and should not change until additional safety measures are in place and/or additional evidence is available. Continued research is recommended.

“At this point in time, there is a lack of sufficient evidence around the benefit, efficacy and safety of these products; therefore, e-cigarettes should not be considered safe or effective in helping individuals quit and should not be recommended for use as a cessation aid.” (Middlesex-London Health Unit, 2013)⁸⁰

“The USPSTF concludes that the current evidence on the use of ENDS for conventional smoking cessation is insufficient. Evidence is lacking and conflicting, and the balance of benefits and harms cannot be determined. Given the established safety and effectiveness of behavioral and pharmacotherapy interventions, the USPSTF recommends that primary care providers direct patients who smoke to these other interventions.” (US Preventive Services Task Force, 2015)⁸⁹

“The [World Federation of Public Health Associations] endorses WHO’s call for caution and seeks the application of the precautionary principle by governments.” (Public Health Association Australia, 2015)⁸⁵

Restrictive non-use. ENDS are counterproductive to tobacco control and should be opposed. Based on available evidence or until new research suggests otherwise, use is not

recommended and regulations should focus on restricting commercial activities and product availability. To prevent ENDS from undermining existing tobacco control policies, they should be regulated like tobacco.

“Many questions remain about e-cigarettes and their long-term impact ... But we know enough about these health risks to take action now to protect the health of our nation’s young people. We cannot wait.” (US Dept. Health Human Services, Office of the Surgeon General, 2016)³

“Based on the current scientific evidence ... the Canadian Lung Association has determined electronic cigarettes are potentially harmful to lung health and are NOT an approved smoking cessation aid. There are many Health Canada approved therapies to help someone quit smoking; the e-cigarette is NOT one of them” (original emphasis). (Canadian Lung Association, 2016)¹⁰⁶

“As outlined in this document, there is a case for tighter controls on electronic cigarette use to help ensure young people are protected from the erosion of Australia’s world-leading efforts in tobacco control.” (Cancer Council Australia & Heart Foundation Australia, 2014)¹⁰⁸

Prohibit use. To prevent health risks, ENDS products should not be legally available. If this is not politically feasible, the most restrictive regulations possible are recommended. This position is not contingent on organizations’ confidence in available evidence.

“The PMA together with various medical associations called for a total ban on the manufacture and sale of electronic cigarettes or e-cigarettes, which allegedly deliver unwanted chemicals into the body and could cause cancer and other deadly disease.” (The Philippine Medical Association, 2013)¹²⁶

“We are very clear. We strongly call for: a ban on the sale of electronic cigarettes ... a ban on the use of electronic cigarettes in smoke-free areas ... a ban on the advertising and promotion of electronic cigarettes.” (Heart Foundation, Australian Medical Association South Australia & Asthma Foundation SA, 2015)¹²⁵

“The Canadian Medical Association believes that, in the absence of solid evidence of harms or benefits, electronic cigarettes containing nicotine should not be authorized for sale in Canada.” (Canadian Medical Association, 2014)¹²²

Twenty-five organizations recommended ENDS use—five encouraged and 20 supported. Fifty-six organizations recommended not using ENDS (see Figure 3). Among them, 19 recommended not using until more information is available and 30 recommended restricting access based on available evidence. Seven organizations recommended prohibiting ENDS regardless of their confidence in the available evidence. The five statements encouraging selective ENDS use were publicized more recently (2015 – 2017) compared to the seven recommending ENDS prohibition (2013 – 2015). The other positions were fairly evenly distributed between 2014 and 2016 (see Figure 4).

- *insert Figure 3 about here* -

- *insert Figure 4 about here* -

In the UK, 17 of 20 organizations encouraged or supported selective use. Conversely, only three of 28 US organizations found selective use acceptable. No US organization proposed prohibiting ENDS use and 18 recommended restrictive regulations. Among the 10 Canadian and 10 Australian organizations, none condoned selective ENDS use and most favored restricting or prohibiting use. Two organizations in Spain and Germany were similar to their European counterparts in the UK; both recommended to support selective use. Among the 17 governmental organizations, more favored recommending selective ENDS use than discouraging it. An even number of non-governmental organizations recommended selective ENDS use, precautionary regulations, and restrictive regulations. Nine professional organizations recommended use while eight recommended precautionary, 20 restrictive, and six prohibitive regulations. The commercial organization, UpToDate, Inc. recommended supporting selective use.

DISCUSSION

We identified five types of ENDS use recommendations—two favored ENDS use and three opposed. These demonstrate how organizations do not neatly fit into simplistic camps that either support or oppose ENDS. Seventy percent of organizations recommended deterring ENDS use, with restrictive non-use being the predominate position. Organizations in the UK disproportionately favored liberal use recommendations compared to those in Australia, Canada, and the US, which favored more restrictive recommendations. Over half of governmental organizations favored ENDS use compared to only 20% of professional organizations.

In the ENDS categories, we identified three prevention objectives for regulating ENDS: prevent smoking harm, prevent potential ENDS harm, and prevent expected ENDS harm. These reflected diverse prevention priorities that balance ethical principles like autonomy, justice, beneficence, and nonmaleficence.¹²⁸ For example, although the World Health Organization (WHO) and Truth Initiative agree that ENDS are safer than traditional cigarettes, they presented different use recommendations. The WHO recommends not using for precautionary reasons. This is based on the objective articulated in its position statement to “minimize as far as possible potential health risks to [ENDS] users and protect non-users from exposure to their emissions.”⁹¹ Conversely, Truth Initiative supports selective use. This follows from its stated mission to make tobacco a “thing of the past.” For those who already use it, however, “and are unable or unwilling to stop, we support movement to the exclusive use of less harmful alternatives with the goal of eventually stopping all tobacco and nicotine use.”⁷⁰ The WHO prioritizes preventing all harmful emissions whereas the Truth Initiative emphasizes a continuum of harm and preventing the worst of them. These differences reflect trade-offs in balancing outcome desirability with perceived feasibility.

In addition to prioritizing different prevention objectives, organizations also varied in their degree of confidence in available literature and scientific evidence. Some organizations cited the precautionary principle and recommended not supporting ENDS use until more information is available. Even more suggested that there is sufficient evidence to recommend regulations that restrict access to ENDS. It is worth noting that evidence alone does not dictate a policy recommendation, it informs already valued prevention objectives. In our sample, organizations claimed that there is sufficient evidence to support both restricting and encouraging ENDS use. Those that prioritized protecting individuals from the harm of smoking cited evidence that ENDS are a safer alternative. Likewise, those concerned about harms from ENDS concluded that ENDS are not entirely risk-free, to users or anti-smoking norms. Research supports both of these positions.³⁰

Recommendation patterns

About three-quarters of the statements were written between 2014 and 2016. In recent statements, there appears to be a trend towards more liberal ENDS use recommendations. In 2017, 70% of the publicized statements recommended supporting or encouraging use. This may be the result of organizations publishing their first statements or updating their prior recommendations based on newly available data. For example, in 2015 the American Cancer Society (ACS) stated that it could not recommend ENDS use “because it isn’t known yet if they are safe and effective.” This was the position included in our sample. After our sample was collected, the ACS updated their position to support selective use, “the exclusive use of e-cigarettes is preferable to continuing to smoke combustible products.”¹²⁹ Future research should

explore whether such updates constitute a general trend and explore reasons and factors that contribute to organizations changing their position.

Geographically, UK and US organizations presented starkly different positions. This has been characterized as a difference in focus between abstinence in the US and harm reduction in the UK.¹³⁰ Though it has already been noted that a consensus has developed among UK stakeholders in favor of ENDS,¹³¹ our review is the first to contrast it with other regions, including the US, Canada, and Australia. We also identified patterns across organizational types. Over half of governmental organizations condoned ENDS use. By contrast, only 19% of professional organizations recommended use. These differences may reflect the organizations' relationships to downstream constituents. For example, professional health organizations represent the interests of a clinically-trained membership. Congruent with their practice, they are more likely to evaluate ENDS as a cessation therapy and are reluctant to recommend ENDS until they are established as "evidence-based," following standards set for clinical practice.¹³² The fact that ENDS are more commonly supported or promoted by governmental organizations may reflect their focus on population health. Consistent with other substances of abuse, a public health view of ENDS would be more open to harm reduction as it takes a more expansive view of health and social benefit.^{133,134}

Implications for future research

That recommendations were more similar within countries than across them suggests that tobacco control priorities are responsive to national context. In the US, organizations decidedly favor restricting use. In 2017, however, the US Food and Drug Administration (FDA) pivoted towards harm reduction.¹³⁵ Acknowledging a "continuum of risk," the FDA suggested that

ENDS could be a promising component of a balanced tobacco policy. In the US, it will be interesting to see how this shift may affect other organization's positions towards ENDS. Additional research could explore how organizations' recommendations are influenced, including whether some organizations hold greater inter-organizational network influence. It will also be important to monitor if other organizations also adopt more liberal use recommendations and if their recommendations are associated with an increase in ENDS use.

Implications for developing future position statements

Policy statements from respected health organizations represent an authoritative voice that can clarify complex questions and promote a collective response. When they present contradictory recommendations, they may confuse and limit the public and professionals' ability to unify behind their recommendations. Unfortunately, uncertainty¹³⁶ and misperceptions¹³⁷ involving ENDS are common. To address this, we suggest that organizations present their recommendations in context of explicitly stated, underlying tobacco control objectives. As the public, service providers, policymakers, and other stakeholders look to these organizations to guide their decision-making, they would benefit from this context. Dissimilar recommendations would not be seen as contradictory, but relevant or irrelevant depending on how their underlying objective aligns with stakeholders' goal for tobacco and nicotine use. ENDS can be "good" or "bad," for multiple reasons, depending on how they are used and what they are used for. Given this complexity, The WHO and Truth initiative were unique in providing this context—most statements did not.

Limitations

There are a few limitations to this work. First, a scoping review is useful for comprehensively describing available policy positions. Our methodology used multiple approaches to identify and include all available reports, demonstrated by our 81-statement sample. It is possible we missed statements that were not publically available on the web. We were also limited by only including English language texts—we located and excluded 3 non-English statements. To present the most current recommendations, we included all reports through November 2017. However, we did not include earlier statements from the same organizations. ENDS research is rapidly expanding and as such will continue to influence organizational opinion. Our analysis does not account for the number of organizations that revised their statements, how their revisions affected their recommendations, or differences in how they supported their positions with scientific evidence. Finally, our focus on ENDS use recommendations did not address the use of specific ENDS products. We treated e-cigarettes, vaping devices, and other electronic nicotine devices as a single, general category and did not consider other tobacco/nicotine products or use behaviors like poly-use. In this way, our results may not be comprehensive for specific groups that may preferentially select unique products or methods of consuming tobacco and nicotine.

Conclusion

In this review, we explored 81 ENDS position statements and identified a diverse range of ENDS use recommendations. Almost 70% of organizations recommended that ENDS not be used, though for different reasons and with different degrees of restriction. Organizations' recommendations differed in terms of their tobacco control objectives, geographic location, and

organizational type. UK-based organizations are more favorable towards ENDS use compared to the US, Canada, and Australia, and governmental organizations are more favorable than non-governmental or professional organizations. It may be that organizations are trending towards more liberal recommendations, but future research is required.

CONFLICT OF INTEREST STATEMENT

All authors of this review report no conflicts of interest.

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Figure 1. Sample selection and inclusion process for selecting electronic nicotine delivery systems (ENDS) policy statements

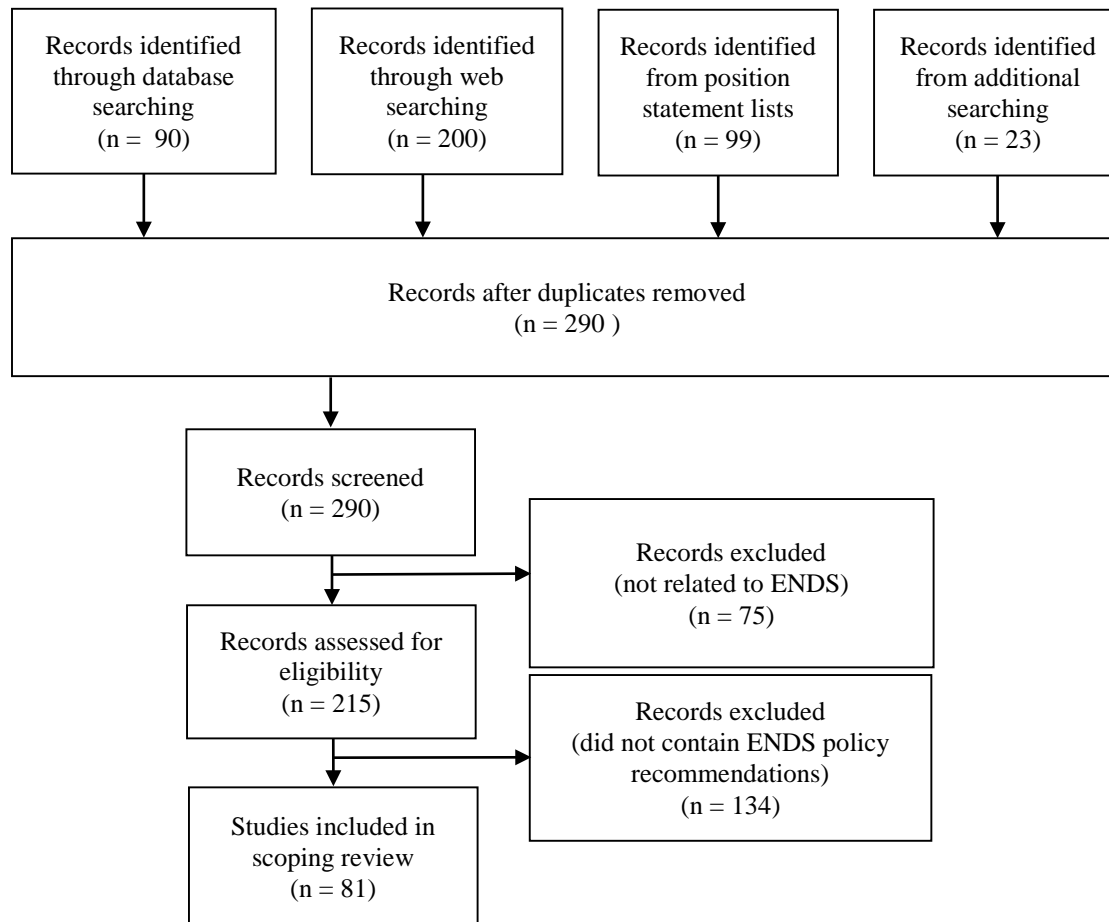


Figure 2. Electronic nicotine delivery systems (ENDS) policy recommendations and their underlying tobacco control objectives and use implications

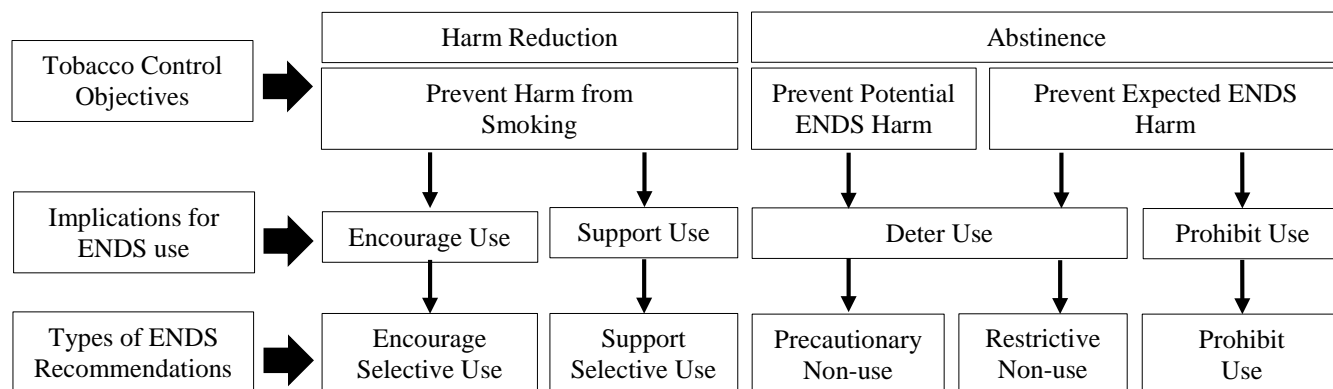


Table 1. Organizations' electronic nicotine delivery systems (ENDS) recommendation positions

ENDS Recommendation Categories	Promoting Organizations
ENCOURAGE SELECTIVE USE: Encourage individuals with a history of smoking to use ENDS as a cessation aid or to switch to exclusive ENDS use. ENDS regulation should prioritize product innovation, user appeal, lower taxes, and health messages that characterize their lower harm.	British Psychological Society, ⁴⁹ Hertfordshire County Council, ⁵⁰ New Nicotine Alliance UK, ⁵¹ Public Health England, ⁵² Royal College of Physicians ⁵³
SUPPORT SELECTIVE USE: Support individuals with a history of smoking to use ENDS as a cessation aid. Users should be advised about other licensed medications and counseling services. Regulating ENDS as medicinal products would improve product safety and allow marketing restrictions. ENDS availability and use must not interrupt existing tobacco control policies like smoke-free laws	American Academy of Pediatric Dentistry, ⁵⁴ British Heart Foundation, ⁵⁵ British Medical Association, ⁵⁶ Camden and Islington Stop Smoking Service, ⁵⁷ Cancer Research UK, ⁵⁸ Faculty of Public Health UK, ⁵⁹ International Union Against Tuberculosis and Lung Disease, ³² Ministry of Health - New Zealand, ⁶⁰ NHS Health Scotland, ⁶¹ NHS Public Health Wales, ⁶² Primary Care Respiratory Society UK, ⁶³ Public Health Nottinghamshire County, ⁶⁴ Royal College of General Practitioners, ⁶⁵ Scottish Directors of Public Health and Scottish Health Promotion Managers, ⁶⁶ Society of Behavioral Medicine, ⁶⁷ The German Cancer Research Center, ⁶⁸ The Spanish Society of Pneumology and Thoracic Surgery, ⁶⁹ Truth Initiative, ⁷⁰ UK National Centre for Smoking Cessation and Training, ⁷¹ UpToDate ⁷²
PRECAUTIONARY NON-USE: Though ENDS are likely to be less harmful than cigarettes, it remains unknown whether they expose users to long-term risks or function as effective cessation aids. Use is not recommended until additional information is available. To be cautious, individuals who smoke should be encouraged to quit using already approved cessation medications. These recommendations should not change until additional safety measures are in place and/or additional evidence is available. Continued research is recommended.	Amer. Assoc. Cancer Research & Amer. Society Clin. Oncol., ⁷³ American Cancer Society, ⁷⁴ Australia National Health and Medical Research Council, ⁷⁵ British Dental Association, ⁷⁶ Cancer Society of New Zealand, ⁷⁷ Lung Foundation Australia, ⁷⁸ Mayo Clinic, ⁷⁹ Middlesex-London Health Unit, ⁸⁰ National Institute for Occupational Safety and Health, ⁸¹ Non-Smokers' Rights Assoc. / Smoking and Health Action Foundation, ⁸² Oncology Nursing Society, ⁸³ Ontario Campaign for Action on Tobacco, ⁸⁴ Public Health Association Australia, ⁸⁵ Royal Pharmaceutical Society, ⁸⁶ Stroke Foundation Australia, ⁸⁷ Tobacco Control Network, ⁸⁸ US Preventive Services Task Force, ⁸⁹ World Federation of Public Health Associations, ⁹⁰ World Health Organization ⁹¹
RESTRICTIVE NON-USE: ENDS are counterproductive to tobacco control and should be opposed. Based on available evidence, use is not recommended and regulations should focus on restricting commercial activities and product availability. ENDS should be regulated like tobacco.	American Academy of Pediatrics, ⁹² American Association for Respiratory Care, ⁹³ American College of Occupational and Environmental Medicine, ⁹⁴ American College of Physicians, ⁹⁵ American Diabetes Association, ⁹⁶ American Heart Association, ⁹⁷ American Lung Association, ⁹⁸ American Medical Association, ⁹⁹ American Nurses Association, ¹⁰⁰ American Public Health Association, ¹⁰¹ Argentinean Association of Respiratory Medicine, ¹⁰² Australian Medical Association, ¹⁰³ BC Alliance for Healthy Living, ¹⁰⁴ Canadian Cancer Society, ¹⁰⁵ Canadian Lung Association, ¹⁰⁶ Canadian Paediatric Society, ¹⁰⁷ Cancer Council Australia & Heart Foundation Australia, ¹⁰⁸ Cancer Council NSW, ¹⁰⁹ European Network for Smoking and Tobacco Prevention, ¹¹⁰ Heart and Stroke Foundation, ¹¹¹ National Association of County and City Health Officials, ¹¹² National Association of Local Boards of Health, ¹¹³ National PTA, ¹¹⁴ Nevada Tobacco Prevention Coalition, ¹¹⁵ Society for Public Health Education, ¹¹⁶ Tobacco Free Amarillo, ¹¹⁷ Toronto Public Health, ¹¹⁸ US Surgeon General, ³ Washoe County – Nevada, ¹¹⁹ World Medical Association ¹²⁰
PROHIBIT USE: To prevent health risks, ENDS products should not be legally available.	Canadian Dental Hygienists Association, ¹²¹ Canadian Medical Association, ¹²² Cancer Council Western Australia, ¹²³ Forum of

	Intern Respir Society, ¹²⁴ Heart Foundation & Australia Medical Association SA & Asthma Foundation SA, ¹²⁵ Philippine Medical Association, ¹²⁶ SmokeFree Tasmania, ¹²⁷
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Figure 3. Electronic nicotine delivery systems policy recommendation frequencies

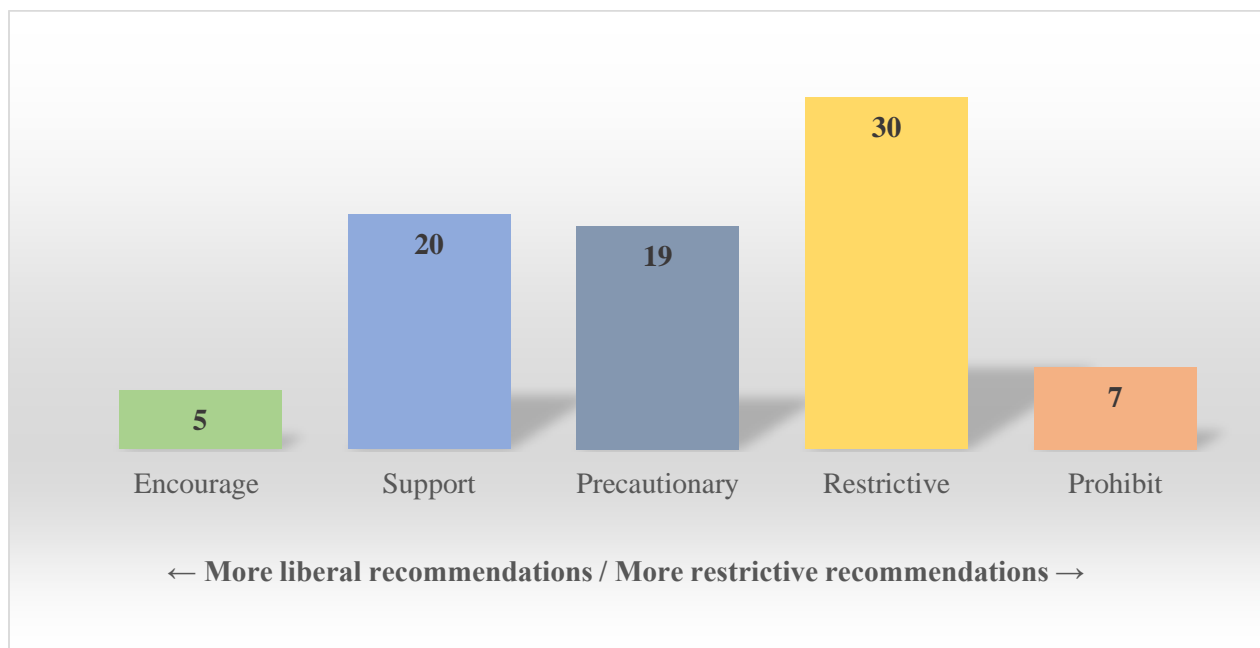
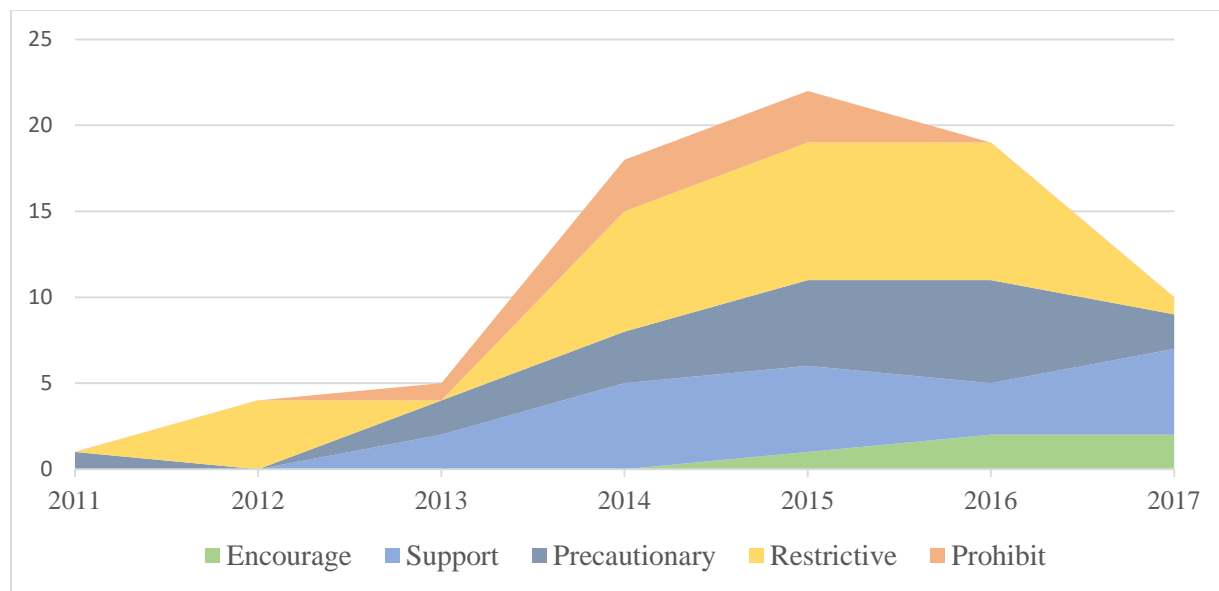


Figure 4. Distribution of electronic nicotine delivery system policy recommendations by year (2011-2017)



APPENDIX B – MANUSCRIPT 2**No Association between Electronic Cigarette Use and Smoking Cessation: Findings from a State-Based Quitline**

Benjamin R. Brady MS, MPH,¹

Tracy E. Crane PhD, RDN,^{2,3}

Patrick A. O'Connor MS,¹

Uma S. Nair PhD,¹

Nicole P. Yuan PhD¹

¹Mel and Enid Zuckerman College of Public Health, University of Arizona

²College of Nursing, University of Arizona

³University of Arizona Cancer Center

Correspondence to: Benjamin Brady

3950 South Country Club Road, STE 300, Tucson, AZ 85714

Email: brb99@email.arizona.edu

Phone: 520-621-2553

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ABSTRACT

Introduction. Most e-cigarette users are current smokers attempting to quit smoking. Evidence is mixed on e-cigarette's effectiveness as a cessation aid. Research suggests that smokers who use e-cigarettes face greater barriers to quitting and are more likely to have mental health conditions.

Aims: To examine the association between e-cigarette use and smoking cessation outcomes among quitline callers.

Methods. We examined 2,404 callers who enrolled for services and completed enrollment and 7-month follow-up surveys between 4/2014 and 6/2016. In a primary analysis, we examined the association between any e-cigarette use and 30-day point prevalence tobacco cessation. In an exploratory analysis, we evaluated these relationships by patterns of e-cigarette use: adopted, discontinued, sustained, and non-use. We used multivariable logistic regression to control for callers' characteristics, tobacco history and program utilization.

Results. Eighteen percent of callers reported e-cigarette use. Compared to non-users, callers using e-cigarettes were more likely to be younger, non-Hispanic, and report a mental health condition. There was no difference in nicotine replacement medication use, number of coaching sessions, or program completion. Compared to non-users, the adjusted odds of smoking cessation were not statistically different for callers who used e-cigarettes (OR=1.02, 95% CI 0.79-1.32). Results were similar when examining cessation by patterns of e-cigarette use.

Conclusions. E-cigarette users reported similar tobacco cessation outcomes as non-users. This suggests that e-cigarette use neither facilitates nor deters smoking cessation attempts among quitline callers. E-cigarettes should be considered a reasonable cessation strategy for callers who self-select use as part of their quit attempt.

INTRODUCTION

Electronic cigarette (e-cigarette) use is increasing in the US.^{1,2} In 2014, 12% of adults used e-cigarettes and almost 4% used them daily.³ Among those who have ever used an e-cigarette, 70% currently smoke traditional cigarettes and 20% are former smokers.⁴ Between 70% and 80% of e-cigarette users report use as a smoking cessation aid.^{5,6} Among US smokers, twice as many report using an e-cigarette as part of their quit attempt as compared to a nicotine patch or gum.⁷

Recent reviews suggest that e-cigarette use may help smokers quit⁸⁻¹² with predictors of success being frequent use,¹³⁻¹⁵ use of advanced e-cigarette products,¹⁶ and use with the specific purpose of quitting.¹⁷ However, e-cigarette users appear to be a unique subgroup of smokers who tend to experience greater difficulty in quitting. Compared to non-users, they are more likely to be heavy smokers,¹⁴ have a mental health condition,¹⁸ and have made more prior quit attempts.¹⁹ Given that more quit attempts is related to higher nicotine dependence, this may inhibit successful quitting.^{20,21}

E-cigarette use is common among smokers who utilize US quitline services. In 2012, 31% of quitline callers reported having ever using an e-cigarette.²² Between 2013 and 2015, 10% of quitline participants were using e-cigarettes at the time of enrollment.²³ These estimates are consistent with rates in the general population of smokers, 38% ever use and 11% current use, respectively.²⁴ In a small sample of quitline callers, most e-cigarette users stated that doing so helped them cut down or quit smoking, though they differed in whether they preferred e-cigarettes to other nicotine replacement therapies or medications approved by the US Food and Drug Administration (FDA).²⁵ In a separate quitline study, those who used e-cigarettes for a

purpose other than quitting tobacco were less likely to be abstinent at follow-up compared to those using e-cigarettes as a cessation aid.¹⁷

To assess the association between e-cigarette use and smoking cessation, patterns of e-cigarette use and user characteristics must be taken into account. Prior studies of e-cigarette use in quitline settings did not control for these factors²² or restricted their analysis to a distinctive population of tobacco users.¹⁷ The purpose of this study was to examine the association between e-cigarette use and smoking cessation within a general population of smokers participating in a quitline program. Using caller data from the Arizona Smokers' Helpline (ASHLine), we first assessed this association among participants who reported using an e-cigarette at any time during their quit attempt. We then investigated patterns of e-cigarette use in an exploratory analysis to examine if smoking cessation outcomes varied for e-cigarette users who adopted, discontinued, or sustained use between enrollment and follow-up. Adjusting for mental health status, cessation medication use, and program utilization, we hypothesized that in the primary analysis, callers ever using e-cigarettes would not experience different odds of quitting compared to those who did not use. In the exploratory analysis, we hypothesized that adopting or sustained e-cigarette users would have greater odds of quitting tobacco.

METHODS

Study Sample and Setting

In this retrospective cohort study, we examined data from ASHLine callers who received smoking cessation assistance between April 2014 and June 2016. Program callers were eligible for analysis if they completed enrollment and 7-month follow-up surveys and responded to the e-cigarette use and covariate questions at both time points (Figure 1). We used de-identified data

and followed STROBE checklist guidelines.²⁶ The University of Arizona’s Institutional Review Board reviewed our study protocol and deemed it to be exempt.

ASHLine is a state-based quitline that provides telephone-based behavioral coaching and up to four weeks of nicotine replacement therapy (NRT)—patches, gum, and lozenges—to support cessation for tobacco users living in Arizona. Participants are assigned a coach trained in motivational interviewing and cognitive behavioral strategies for quitting tobacco. Coaches proactively call program participants and assist them to identify triggers, set quit dates, develop strategies to manage their urges to smoke, set cessation goals and provide positive reinforcement. To promote relapse prevention, callers are encouraged to continue participating in weekly or biweekly coaching sessions until they become 90-days abstinent. After 90-days, callers receive a certificate of achievement and are graduated from the program.

Measures

We assessed e-cigarette use by asking, “are you using e-cigarettes?” at enrollment and 7-month follow up. In the primary analysis, e-cigarette use reported at the time of enrollment, follow-up, or both were classified as any use. To account for differences in e-cigarette use, in the exploratory analysis we created four user categories: (1) sustained user—use at enrollment and follow up, (2) discontinued user—use at enrollment but not at follow up, (3) adopted user—use at follow up but not enrollment, and (4) non-user—no use at enrollment or follow up (Figure 2). The primary outcome was smoking cessation 7-months after enrollment, measured as self-reported, 30-day point prevalence abstinence.

We selected additional covariates based on a review of the literature. Low income, racial minority, and chronically ill individuals are known to smoke at disproportionately high rates.^{27,28}

Smoking history, dependence, and perceived ability to quit are also known to affect odds of cessation.²⁹ To account for these factors, we included demographic and tobacco history variables. At enrollment, callers self-reported their gender (male, female), age (18-24, 25-44, 45-64, 65+), race (white, non-white), ethnicity (Hispanic, non-Hispanic), and education (HS or less, some college or more). We measured chronic health status (yes, no) as having been diagnosed with at least one of the following conditions: asthma, hypertension, cancer, COPD, diabetes, or heart disease. We assessed mental health status (yes, no) as having been diagnosed with at least one of the following: anxiety disorder, depression, bipolar disorder, schizophrenia, or alcohol or drug abuse disorder.

At the time of enrollment, we used the Fagerstrom test to assess nicotine dependence (low 0-2, moderate 3-5, heavy 6-10).³⁰ Home smoking bans were assessed and individuals were assigned to one of three categories: smoking not allowed anywhere in the home (full ban), smoking allowed in some places (partial ban), and smoking allowed anywhere (no ban). We dichotomized callers' confidence in quitting as not confident (not or somewhat confident) and confident (confident, very confident, or extremely confident). Callers' intention to quit smoking in the next 30-days was assessed using a single-item measure (yes, no). We also included program engagement variables to control for variance in treatment engagement or intensity: self-reported use of cessation medication during the quit attempt (yes, no), number of coaching sessions (0-3, 4-7, 8+) and program completion status (completed, did not complete). We created coaching session categories based on prior literature that showed limited effect from few sessions^{31,32} and declining effect after 90 or more total minutes of counseling, or about 8 sessions.³² To complete the program, callers participated in coaching sessions for at least 90 days after becoming tobacco abstinent.

Primary Analysis

We used chi-squared and t-tests to examine demographic, smoking history, and program differences between callers who used and did not use e-cigarettes. We fit logistic regression models to examine unadjusted and adjusted odds ratios (OR) and 95% confidence intervals (CI) of 30-day point prevalence abstinence for e-cigarette use at enrollment or 7-month follow-up. Prior to analyses, we used literature to guide the variable selection process. Covariates that were originally continuous (age, Fagerstrom score, and number of coaching sessions) were tested in the logistic unit using restricted cubic splines and did not meet linearity.³³ They were categorized to meet the assumptions for logistic regression. Wald Tests were used to assess interactions between e-cigarette use and mental health, gender, age, and Fagerstrom score.

Initially, we included all the variables presented in Table 1 in a full model, except ethnicity. It was not included due to a high degree of missingness (33%). This represents our full model. To avoid model over fit, we used backwards selection to identify and remove variables that were not significantly associated with 30-day abstinence at 7-month follow up. We excluded covariates with a p-value >0.2. Gender, age, mental health, nicotine dependence, home smoking ban, intention to quit, and program completion remained. This represents our reduced model. We used a likelihood ratio test to assess differences between the full and reduced models.

Exploratory Analysis

To examine our exploratory hypothesis, we changed the primary independent variable by categorizing e-cigarette use to reflect four patterns of use—did not use e-cigarettes, adopted use, discontinued use, and sustained use. We used ANOVA and chi-squared tests to examine group differences by caller characteristics and program utilization. We used logistic regression models

to assess unadjusted and adjusted odds of 30-day abstinence for the different e-cigarette use patterns. Backwards variable selection was again used to remove covariates that overfit the full model. The reduced model in the exploratory analysis included the same covariates as in the primary analysis, with the exception that race was retained and age was removed. As before, a likelihood ratio test was used to compare the exploratory full and reduced models. All statistical tests were based on a significance level of 0.05 and were performed in SAS 9.4 (SAS Institute, Cary, NC).

RESULTS

Primary Analysis

Between April 2014 and June 2016, 2,404 ASHLine callers provided complete information in enrollment and 7-month follow-up surveys. Just over 12% of callers reported using e-cigarettes at the time of enrollment and 18% at enrollment or follow-up. Compared to non-users, callers who used e-cigarettes at any time during their quit were more likely to be younger, non-Hispanic, not intending to quit tobacco in the next 30-days, and reported having a mental health condition. Callers' gender, race, education, other chronic health conditions, nicotine dependence, home smoking bans, and confidence to quit were not statistically different between callers who used e-cigarettes at any point during their quit attempt and those who did not. E-cigarette use was not associated with callers' utilization of program services—about 70% of all callers used NRT and received around 5.5 coaching sessions. About 27% of non-users and 23% of e-cigarette users remained in the program until completion (Table 1).

In a crude model, e-cigarette use was not associated with quitting. Compared to non-users, the unadjusted odds of quitting were not statistically significant for callers who used e-

cigarettes (OR=0.90, 95% CI 0.72-1.12). Results from the multivariable logistic regression model are provided in Table 2. No interaction terms were included because they were all found not to be significant in the model. The likelihood ratio test showed there was not a significant difference in fit between the full and reduced models, so we used the reduced model ($p < 0.77$). In the reduced model, the adjusted odds of any e-cigarette use was also non-significant (OR=1.02, 95% CI 0.79-1.32). However, callers who completed ASHLine's program and received coaching for 90-days while abstinent were over three times more likely to be quit at follow-up compared to those who exited early (OR=12.33, 95% CI 9.70-15.67) regardless of e-cigarette use. Compared to no or low dependence, high nicotine dependence (OR=0.68, 95% CI 0.51-0.91) was negatively associated with being quit at follow-up. Likewise, the absence of indoor smoking bans was associated with lower odds of being quit (OR=0.70, 95% CI 0.54-0.90). Having a mental health condition neared statistical significance (OR=0.82, 95% CI 0.67-1.00).

Exploratory Analysis

In the exploratory analysis, descriptive findings of the patterns of e-cigarette use were similar to the primary analysis, with a few important differences. All three e-cigarette user groups were younger and less likely to be Hispanic than non-users. However, the sustained user group differed from the other e-cigarette groups. Nearly 60% of sustained users reported having a mental health condition compared to 44% of non-users. At enrollment, a higher proportion of sustained users also reported intending to quit smoking in the next 30-days compared to never, adopted, or discontinued users, though sustained users received fewer coaching sessions and were less likely to complete the program than the other groups of e-cigarette users (Table 3).

We reassessed the same interaction terms and again found them to be non-significant. Similar to the primary analysis, we did not identify an association between e-cigarette use and smoking cessation. Compared to non-users, the unadjusted odds of quitting were not significant for discontinued users (OR=0.91, 95% CI 0.73-1.13), adopted users (OR=0.84, 95% CI 0.64-1.10), or sustained e-cigarette users (OR=0.78, 95% CI 0.54-1.12). The exploratory multivariable logistic regression model results are provided in Table 4. The likelihood ratio test did not show a significant difference in fit between the full and reduced models ($p < 0.62$). As before, we presented findings from the reduced model. In the adjusted, reduced model, the odds of quitting remained unchanged. Callers who discontinued (OR=1.07, 95% CI 0.75-1.53), adopted (OR=1.05, 95% CI 0.69-1.59), or sustained e-cigarette use (OR=0.87, 95% CI 0.50-1.50) were no more likely to be quit at 7-month follow-up compared to callers who never used e-cigarettes.

DISCUSSION

E-cigarette use is common among smokers who utilize quitline services. We found that 12% of ASHLine callers used e-cigarettes at enrollment, similar to the 10% average among 25 US state-based quitlines.²³ However, we found that e-cigarette use was not associated with 7-month quit rates. These results remained when we looked at e-cigarette use in a crude or a controlled analysis as well as when we classified e-cigarette use as any / no use or by categorical patterns of use—at the time of enrollment, follow-up, both, or neither. Our results are congruent with previous observational studies that have found no association between e-cigarette use and tobacco cessation,³⁴ including a study of callers to an employer and health-plan sponsored quitline.¹⁷

A strength of this study is that it controlled for co-morbid mental health conditions among smokers in a quitline setting. Prior research has shown that quitline callers may have twice the prevalence of mental health conditions than the national average of tobacco users³⁵ and those with mental health conditions experience greater difficulty in quitting.^{36,37} In this study, the prevalence of having a mental health condition was even greater among individuals who used e-cigarettes, particularly among sustained users. This may indicate that in a quitline setting, e-cigarette users are a unique group of tobacco users who experience additional barriers in quitting.

As of 2015, no US quitline service provider had implemented a specialized e-cigarette protocol.³⁸ In a survey of quitline staff in the US and Canada, it was found that the majority of counselors perceive e-cigarettes to be ineffective, addictive, and more similar to cigarettes than NRT.³⁹ Most counselors recommended that callers only consider using approved NRT and cessation medications. The authors concluded that counselors' negative attitudes may shape how callers view e-cigarettes. Although e-cigarettes have not been found to increase quitting among quitline callers, they do not appear to deter it either. It is appropriate for cessation counselors to emphasize that FDA-approved cessation medications are recommended as evidence-based therapies. However, e-cigarettes need not be positioned in a zero-sum relationship with other cessation medications. Quitline callers who prefer to use an e-cigarette may be better served by developing more inclusive and flexible protocols that appeal to a wider range of smokers. Doing so would sustain a client-centered approach to service delivery, a strategy shown to foster a productive client-provider relationship, especially when treatment depends on caller preferences and values.⁴⁰

As a result of this study, the Arizona Smokers' Helpline created an e-cigarette coaching protocol that emphasizes the following caller assistance guidelines: (1) neither encourage nor

discourse e-cigarette use, (2) recommend that callers consider FDA-approved nicotine medication as a first-line therapy, (3) allow callers to self-select whether e-cigarette use is right for them, and (4) provide accurate information that e-cigarettes are less harmful than smoking, but not risk-free. These guidelines place our e-cigarette protocol in alignment with ASHLine's larger objective to encourage and allow callers to collaborate in the therapeutic process.⁴¹ With greater buy-in, callers may be more likely to complete cessation programs and counselors better positioned to promote other positive lifestyle changes like instituting home smoking bans,⁴² two factors that were shown in this study to be more strongly associated with quitting than e-cigarette use. As quitlines develop counseling protocols around e-cigarette use, it will be important to consider that e-cigarettes appear to present a different proposition to different tobacco users.⁴³

Future Research

It is important to continue exploring how e-cigarette use may impact quitting. This information can inform how quitlines and other cessation services counsel callers who use e-cigarettes. Future research should explore the effectiveness of e-cigarette protocols like ASHLine's. For example, in our exploratory analysis, we found that sustained e-cigarette users received fewer coaching calls and had the lowest program completion rates. Despite this, sustained users were the most likely group to report an intention to quit in the next 30-days when they enrolled. It may be that these individuals self-select e-cigarettes because of lower appeal or benefit from traditional NRT and abstinence-focused services. In line with the Food and Drug Administration's new "nicotine-focused framework,"⁴⁴ future research should examine the feasibility of a quitline supporting switching to lower harm nicotine products, such as e-cigarettes, alongside standard nicotine abstinence counseling. To our knowledge, this has not

been piloted in a quitline setting. Harm reduction protocols may benefit individuals who experience greater barriers to quitting, such as having a mental illness.⁴⁵ Future research should also explore how offering free NRT through quitline services affects callers' decision to use e-cigarettes, including the nicotine content within the vaping device. In a systematic review, it was found that observational studies with more precise and detailed measures of e-cigarette use, including duration of use, device type, and purpose, demonstrate positive impacts from e-cigarette use on cessation among regular and intentional users.³⁴ It will be important for future research to include these measures; they likely designate meaningful distinctions among e-cigarette users that go beyond the four patterns of use described in this study.

Limitations

There are several limitations to this study. In addition to measuring any e-cigarette use, more robust measures of e-cigarette use are needed. The null findings in the present analysis may be due to our study's small sample as well as to the limited measure of e-cigarette use. As a cohort of quitline callers, these results may not generalize to all tobacco users. The sample may also be biased from excluding callers lost at follow-up or missing values for key variables. Finally, these data are based on caller self-report, including callers' e-cigarette and smoking status. Self-reported outcomes, especially when they are socially expected, are known to be inflated. In quitline settings, however, the degree of inflation has been shown to be minor.⁴⁶ Finally, because the results are observational in nature, they should not be used to infer causality.

Conclusion

E-cigarette users appear to be a distinct group of smokers that may self-select and possibly benefit from combined cessation approaches and services. Instead of promoting a mutually exclusive dichotomy between e-cigarettes and FDA-approved nicotine replacement therapies, quitlines may consider creating protocols aimed at informing and supporting callers who are interested in either quit strategy or a combination thereof.²⁵ Given the variety of e-cigarette product types and modes of using, it will be important for quitlines to determine how best to tailor counseling protocols to assist e-cigarette users who are heterogeneous in how they vape⁴⁷ and why.⁴³

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Figure 1. Sample selection diagram

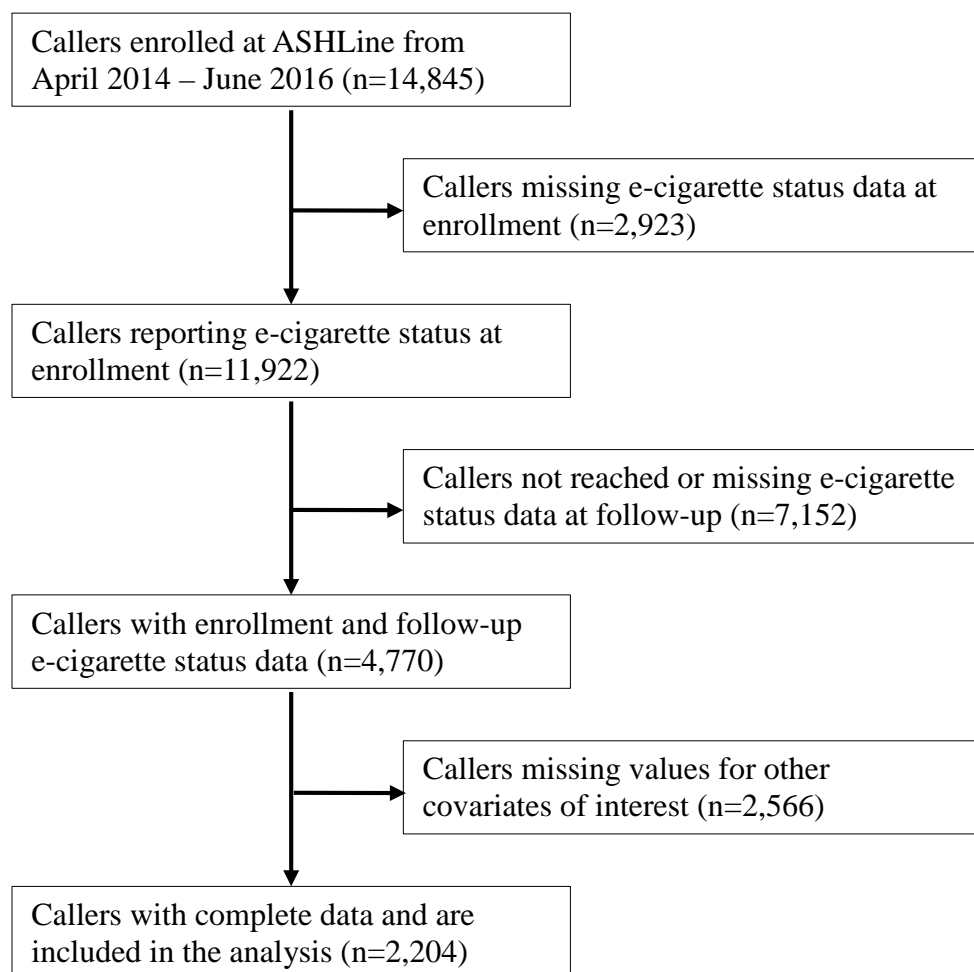


Figure 2. Caller distribution across e-cigarette use categories

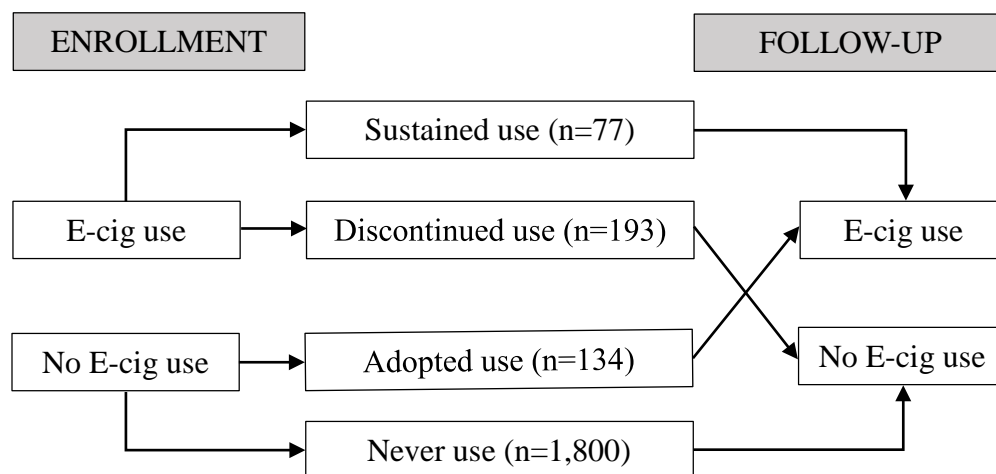


Table 1. ASHLine caller demographics, smoking history, program engagement, and follow-up responses by dichotomous e-cigarette use status (April 2014 – June 2016). Categorical variables display n (%) and continuous variables display mean (SD).

	Non-Users n=1,800 (81.7%)	E-cig Users n=404 (18.3%)	p-value
<i>Baseline demographic and tobacco use behaviors</i>			
Gender			0.46
Female	1,042 (57.9)	242 (59.9)	
Male	758 (42.1)	162 (40.1)	
Age			0.17
18-24	41 (2.3)	15 (3.7)	
25-44	361 (20.1)	92 (22.8)	
45-64	974 (54.1)	213 (52.7)	
65+	424 (23.6)	84 (20.8)	
Mean (SD)	54.5 (13.5)	52.1 (14.0)	0.002
Race			0.23
White	1,512 (84.0)	349 (86.4)	
Non-White	288 (16.0)	55 (13.6)	
Ethnicity ^a			0.001
Hispanic	100 (8.9)	9 (3.1)	
Non-Hispanic	1,020 (91.1)	280 (96.9)	
Education			0.08
High School / GED or less	748 (41.6)	149 (36.9)	
Some college or more	1,052 (58.4)	255 (63.1)	
Any mental health condition ^b			0.01
Yes	800 (44.4)	207 (51.2)	
No	1,000 (55.6)	197 (48.8)	
Any chronic health condition ^c			0.37
Yes	1,205 (66.9)	261 (64.6)	
No	595 (33.6)	143 (35.4)	
Nicotine dependence (Fagerstrom 0-10 scale)			0.09
No / very low	352 (19.6)	61 (15.1)	
Moderate	771 (42.8)	190 (47.0)	
High	677 (37.6)	153 (37.9)	
Mean (SD)	4.7 (2.3)	4.8 (2.3)	0.26
Home smoking bans			0.09
Smoking not allowed (full ban)	842 (46.8)	176 (43.6)	
Smoking allowed in some places (partial ban)	510 (28.3)	106 (26.2)	
Smoking allowed anywhere (no ban)	448 (24.9)	122 (30.2)	
Confidence to quit			0.37
Not or somewhat confident	339 (18.8)	84 (20.8)	
Confident, very confident, or extremely confident	1,461 (81.2)	320 (79.2)	
Intention to quit in next 30 days			0.02
Yes / already quit	1,681 (93.4)	364 (90.1)	

No / don't know	119 (6.6)	40 (9.9)	
<i>Program utilization</i>			
Used quit medication during quit attempt			0.35
Yes	1,307 (72.6)	284 (70.3)	
No	493 (27.4)	120 (29.7)	
Number of coaching sessions			0.60
0-3 sessions	648 (36.0)	149 (36.9)	
4-7 sessions	644 (35.8)	151 (37.4)	
8+ sessions	508 (28.2)	104 (25.7)	
Mean (SD)	5.7 (3.9)	5.5 (3.7)	0.30
Program completion status			0.09
Exited before completion	1,316 (73.1)	312 (77.2)	
Completed program	484 (26.9)	92 (22.8)	
<i>7-month Follow-up</i>			
30-day point prevalence quit rate			0.34
Quit	728 (40.4)	153 (37.9)	
Not quit	1,072 (59.6)	251 (62.1)	

^aEthnicity is missing for 795 callers

^bMental health conditions: anxiety, depression, bipolar disorder, alcohol/drug abuse, or schizophrenia

^cChronic health conditions include: asthma, cancer, COPD, diabetes, heart disease, or hypertension

Abbreviations: SD, standard deviation

Table 2. Adjusted odds ratios (AOR) of 30-day point prevalence tobacco abstinence (n=2,204) for dichotomous e-cigarette use.

	Multivariable model 30-day Quit AOR (95% CI)	p-value
E-cigarette use		
Never use	ref	-
Any use	1.02 (0.79-1.32)	0.86
Gender		
Female	ref	-
Male	1.14 (0.93-1.40)	0.19
Race		
White	ref	-
Non-white	0.83 (0.63-1.10)	0.19
Mental health condition		
No	ref	-
Yes	0.82 (0.67-1.00)	0.06
Nicotine Dependence (Fagerstrom)		
No / very low	ref	-
Moderate	1.01 (0.77-1.33)	0.94
High	0.68 (0.51-0.91)	0.008
Home smoking bans		
Smoking not allowed	ref	-
Smoking allowed in some places	0.88 (0.69-1.11)	0.27
Smoking allowed anywhere	0.70 (0.54-0.90)	0.006
Intention to quit in next 30 days		
No / don't know	ref	-
Yes / already quit	1.40 (0.93-2.11)	0.11
Program completion status		
Exited before completion	ref	-
Completed program	12.33 (9.70-15.67)	<.0001

Table 3. ASHLine caller demographics, smoking history, program engagement, and follow-up responses by categorized e-cigarette use (April 2014 – June 2016). Categorical variables display n (%) and continuous variables display mean (SD).

	Non-Users n=1,800 (81.7%)	Discontinued Users n=193 (8.8%)	Adopted Users n=134 (6.1%)	Sustained Users n=77 (3.5%)	p- value
<i>Demographic and tobacco use behaviors</i>					
Gender					0.71
Female	1,042 (57.9)	119 (61.7)	76 (56.7)	47 (61.0)	
Male	758 (42.1)	74 (38.3)	58 (43.3)	30 (39.0)	
Age					<.0001
18-24	41 (2.3)	4 (2.1)	3 (2.2)	8 (10.4)	
25-44	361 (20.1)	37 (19.2)	37 (27.6)	18 (23.4)	
45-64	974 (54.1)	114 (59.1)	57 (42.5)	42 (54.5)	
65+	424 (23.6)	38 (19.7)	37 (27.6)	9 (11.7)	
Mean (SD)	54.5 (13.5)	52.1 (14.0)	53.1 (15.2)	48.2 (14.5)	0.0001
Race					0.31
White	1,512 (84.0)	172 (89.1)	112 (83.6)	65 (84.4)	
Non-White	288 (16.0)	55 (13.6)	22 (16.4)	12 (15.6)	
Ethnicity ^a					0.006
Hispanic	100 (8.9)	7 (5.1)	1 (1.0)	1 (2.0)	
Non-Hispanic	1,020 (91.1)	130 (94.9)	100 (99.0)	50 (98.0)	
Education					0.19
High School / GED or less	748 (41.6)	65 (33.7)	55 (41.0)	29 (37.7)	
Some college or more	1,052 (58.4)	128 (66.3)	79 (59.0)	48 (62.3)	
Any mental health condition ^b					0.04
Yes	800 (44.4)	97 (50.3)	65 (48.5)	45 (58.4)	
No	1,000 (55.6)	96 (49.7)	69 (51.5)	32 (41.6)	
Any chronic health condition ^c					0.06
Yes	1,205 (66.9)	137 (71.0)	79 (59.0)	45 (58.4)	
No	595 (33.6)	56 (29.0)	55 (41.0)	32 (41.6)	
Nicotine dependence (Fagerstrom 0-10 scale)					0.33
No / very low	352 (19.6)	28 (14.5)	21 (15.7)	12 (15.6)	
Moderate	771 (42.8)	97 (50.3)	57 (42.5)	36 (46.8)	
High	677 (37.6)	68 (35.2)	56 (41.8)	29 (37.7)	
Mean (SD)	4.7 (2.3)	4.8 (2.3)	4.8 (2.3)	4.9 (2.2)	0.68
Home smoking bans					0.36
Smoking not allowed (full ban)	842 (46.8)	81 (42.0)	61 (45.5)	34 (44.2)	

Smoking allowed in some places (partial ban)	510 (28.3)	56 (29.0)	30 (22.4)	20 (26.0)	
Smoking allowed anywhere (no ban)	448 (24.9)	56 (29.0)	43 (32.1)	23 (29.9)	
Confidence to quit					0.17
Not or somewhat confident	339 (18.8)	32 (16.6)	33 (24.6)	19 (24.7)	
Confident, very confident, or extremely confident	1,461 (81.2)	161 (83.4)	101 (75.4)	58 (75.3)	
Intention to quit in next 30 days					0.004
Yes / already quit	1,681 (93.4)	172 (89.1)	117 (87.3)	75 (97.4)	
No / don't know	119 (6.6)	21 (10.9)	17 (12.7)	2 (2.6)	
Program utilization					
Used quit medication during quit attempt					0.74
Yes	1,307 (72.6)	137 (71.0)	95 (70.9)	52 (67.5)	
No	493 (27.4)	56 (29.0)	39 (29.1)	25 (32.5)	
Number of coaching sessions					0.13
0-3 sessions	648 (36.0)	59 (30.6)	56 (41.8)	34 (44.2)	
4-7 sessions	644 (35.8)	74 (38.3)	47 (35.1)	30 (39.0)	
8+ sessions	508 (28.2)	60 (31.1)	31 (23.1)	13 (16.9)	
Mean (SD)	5.7 (3.9)	6.1 (3.8)	5.2 (3.7)	4.6 (3.4)	0.03
Program completion status					0.04
Exited before completion	1,316 (73.1)	139 (72.0)	108 (80.6)	65 (84.4)	
Completed program	484 (26.9)	54 (28.0)	26 (19.4)	12 (15.6)	
7-month Follow-up					
30-day point prevalence quit rate					0.32
Quit	728 (40.4)	80 (41.5)	49 (36.6)	24 (31.2)	
Not quit	1,072 (59.6)	251 (62.1)	85 (63.4)	53 (68.8)	

^aEthnicity is missing for 795 callers

^bMental health conditions: anxiety, depression, bipolar disorder, alcohol/drug abuse, or schizophrenia

^cChronic health conditions include: asthma, cancer, COPD, diabetes, heart disease, or hypertension

Abbreviations: SD, standard deviation

Table 4. Adjusted odds ratios (AOR) of 30-day point prevalence tobacco abstinence (n=2,204) for categorized e-cigarette use.

	Multivariable model 30-day Quit AOR (95% CI)	p-value
E-cigarette use		
Never use	ref	-
Discontinued use	1.07 (0.75-1.53)	0.70
Adopted use	1.05 (0.69-1.59)	0.81
Sustained use	0.87 (0.50-1.50)	0.61
Gender		
Female	ref	-
Male	1.14 (0.93-1.40)	0.22
Age		
18-24	1.06 (0.57-1.98)	0.85
25-44	1.19 (0.92-1.54)	0.18
45-65	ref	-
65+	1.11 (.86-1.43)	0.42
Mental health condition		
No	ref	-
Yes	0.83 (0.67-1.02)	0.08
Nicotine Dependence (Fagerstrom)		
No / very low	ref	-
Moderate	1.02 (0.76-1.34)	0.90
High	0.70 (0.52-0.93)	0.01
Home smoking bans		
Smoking not allowed	ref	-
Smoking allowed in some places	0.88 (0.69-1.11)	0.27
Smoking allowed anywhere	0.70 (0.54-0.90)	0.01
Intention to quit in next 30 days		
No / don't know	ref	-
Yes / already quit	1.41 (0.94-2.12)	0.10
Program completion status		
Exited before completion	ref	-
Completed program	12.40 (9.74-15.79)	<.0001

APPENDIX C – MANUSCRIPT 3**Higher Quality Quit Date Coaching Enhances Quit Attempts among Quitline Callers**

Benjamin R. Brady MS,¹ MPH, Uma S. Nair PhD,¹ Joe K. Gerald, MD, PhD,¹ Nicole P. Yuan PhD,¹ Laurie A. Krupski PhD,¹ Cynthia A. Thomson PhD, RDN^{1,2}

¹Mel and Enid Zuckerman College of Public Health, University of Arizona

²University of Arizona Cancer Center

Correspondence to: Benjamin Brady

3950 South Country Club Road, STE 300, Tucson, AZ 85714

Email: brb99@email.arizona.edu

Phone: 520-621-2553

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ABSTRACT

Introduction. At tobacco quitlines, coaching and cessation medications are commonly structured around setting a quit date for making a quit attempt. However, limited literature evaluating this practice suggests that quitline callers do not routinely set quit dates. High quality quit date coaching may increase the frequency of caller quit attempts. In this study, we examine the quality of quit date coaching and its association with in-program quit attempts and the timing of callers' first quit attempt.

Methods. Using call recordings, we scored the quality of quit date coaching among 90 callers enrolled at Arizona Smokers' Helpline between 8/2017 and 12/2017. The primary exposure was quality of quit date coaching assessed using Lorencatto et al.'s rating scale. Inter- and intra-rater reliability of coding was assessed (Cohen's kappa). Multivariable logistic regression was used to examine the association between quality of coaching and in-program quit attempts (>24 hrs. tobacco free).

Results. The mean quality coaching score was 3.1 (range: -3 to 7). Sixty-nine callers (77%) set a quit date and 39 (43%) made a quit attempt. Compared to callers who received low quality coaching, the adjusted odds of in-program quitting for high quality coaching was OR 3.98, 95% CI 1.55-10.20 and for making a quit attempt within two weeks OR 7.92, 95% CI 1.80-34.74.

Conclusions. Quit date goal setting is an important element of quitline services and callers benefit from high quality quit date coaching. Quitlines should establish rigorous training and quality improvement measures to assure that high quality quit date coaching is provided to all callers.

INTRODUCTION

Tobacco use remains the leading preventable cause of death and disease in the US and globally.¹ Quitting is difficult, and most tobacco users make multiple attempts before they successfully become abstinent.² Clinical practice guidelines recommend that cessation services like those offered by quitlines provide nicotine replacement medication and coaching to educate and support tobacco users to develop coping skills and make positive behavior changes.³ Quitlines improve individuals' odds of quitting and have become the standard of care for tobacco cessation.⁴

At quitlines, it is recommended that services are structured around setting a quit date as a goal for callers to become tobacco abstinent.^{5,6} Quit dates provide a point of focus for providing behavior change coaching and establishing a schedule to begin using cessation medication. In their first session, coaches should encourage callers to select a day, usually within two weeks, after which they will no longer smoke or use tobacco.^{7,8}

Despite quitlines' emphasis on setting quit dates, many callers do not. In a research trial, only 32% of quitline participants who indicated an intention to quit in the next 30 days set a quit date goal.⁹ Several factors may influence the decision to set a quit date. However, without quality coaching to support quit date goal setting, callers are not likely to do so. To examine the quality of goal setting coaching, Lorencatto and a group of UK researchers developed a rating scale and scored quitline counselors on how well they assisted callers in setting quit date goals. The researchers found, on average, that counselors' effort were "low quality," resulting in only 21% of callers making an in-program quit attempt.⁶ However, compared to low quality coaching, callers who received high quality coaching were more likely to make an in-program quit attempt (OR 2.60, 95% CI 1.54 – 4.40). Addressing the quality of goal setting is an important step to

improve coaches' ability to work with callers and clarify potential discrepancies between their desired behavior change and current behavior.

In this study, we explored the quality of quit date coaching, quit date goal setting, and quitline callers' frequency of making a quit attempt. To advance Lorencatto et al.'s work,⁶ we examined whether the quality of quit date coaching was associated with setting a quit date and making an in-program quit attempt among callers to the Arizona Smokers' Helpline (ASHLine). We hypothesized high quality coaching would increase the odds of making a quit attempt. Recognizing that smokers with mental health conditions (MHC) have historically smoked at higher rates and experienced greater difficulty in quitting,¹⁰⁻¹² we also examined whether having a MHC modifies the effect of receiving high quality coaching. In exploratory analyses, we assessed the association between quality of quit date coaching and the timing of callers' first quit attempt. Given that Lorencatto's quality rating scale prioritizes setting quit dates within two weeks of the first coaching session, we hypothesized that callers who receive high quality coaching will make a quit attempt sooner than those who receive low quality coaching. Finally, we examined callers' odds of being quit at 7-month follow-up.

METHODS

Study setting

ASHLine provides behavioral coaching and four weeks of nicotine replacement therapy (NRT) in the form of patches, gum, and lozenges. Callers are assigned a dedicated coach and receive motivational interviewing and elements of cognitive behavioral therapy delivered over seven sessions. Coaches contact enrolled callers weekly to help them identify triggers, set quit

dates, develop strategies to manage their urges to smoke, and provide support. Once quit, check-in calls are made less frequently. Callers are encouraged to remain in the program for 90-days or until they have received all seven coaching sessions.

Study sample

We selected callers who enrolled at ASHLine between August and December 2017. During this period, ASHLine utilized a coaching protocol that included guidelines for delivering quit date coaching congruent with Lorencatto et al.'s quality goal setting scale.⁶ We included unique callers who consecutively exited ASHLine's coaching services. Of the 175 callers who exited between January 1 and January 9, 2018, 90 met the study's inclusion criteria. Reasons for exclusion are provided in Figure 1.

We conducted a power analysis and identified that we needed a sample of at least 88 callers. This estimate assumed one tail directionality, alpha error probability of 0.05, beta error probability of 0.20, and an expected odds ratio (OR) of 2.0. The OR estimate was based on results from Lorencatto et al.'s study.⁶

Data collected in the enrollment survey and during counseling sessions were de-identified for analysis. We followed STROBE checklist guidelines¹³ and the study was reviewed and approved by the university's Institutional Review Board.

Measures

Primary independent variable. Quality of quit date coaching is the primary independent variable. We analyzed audio recordings of callers' first coaching session and measured quit date coaching quality using Lorencatto et al.'s rating scale.⁶ The scale is comprised of 10 components that reflect positive or negative elements of quit date coaching (Table 1). One point was awarded or subtracted based on the presence of each element and were aggregated into a total score for each caller with a potential range of -3 to 7. To accommodate ASHLine's process for providing NRT to callers, criterion for setting a specific quit date was defined as either selecting a date (i.e., mm/dd/yy) or an event (i.e., arrival of NRT). Because NRT sent from ASHLine can take between five and ten days to arrive at callers' place of residence, this coding assured that in the analysis callers were positively awarded for setting a specific timeline for initiating their quit attempt. Upon conclusion of scoring, we found that callers' quality goal setting was bimodally distributed with a median quality score of 3.0. For analysis, we dichotomized scores and organized callers into low (-3 to 3) and high-quality groups (4 to 7).

In scoring quality coaching, one reviewer coded all 90 sessions and a second scored a subset of 15 sessions. This process allowed us to audit the data and assess criteria clarity. External audits are useful for confirming agreement and verifying data trustworthiness.^{14,15} Dual coding only select portions of the data also reduces the cost and effort of multiple coding entire datasets.¹⁶ To complete the audit, the first five sessions were co-coded and compared using Cohen's kappa statistic.¹⁷ Based on observed discordance, criteria were adjusted and the next five sessions were again co-coded and compared. Once the criteria were deemed satisfactory, the primary reviewer scored all remaining sessions. Five additional sessions were randomly selected and co-coded to assess agreement within the full sample. A total of 15 sessions were included in

the inter-rater data audit comprising 180 data points (12 codes for each caller's session). To examine intra-rater reliability, 10 sessions (120 data points) were also repeat-coded by the primary reviewer at different time points and compared using Cohen's kappa.

Dependent variables. The primary dependent variable was making an in-program quit attempt. This was defined *a priori* as abstinent from tobacco for at least 24 hours, consistent with recommended guidelines.¹⁸ These data were based on caller self-report and were collected by coaches who assessed callers' tobacco use status in each phone session and recorded the date of their in-program quit attempts. In the primary analysis, quit attempts were classified as a dichotomous outcome (yes, no). In the exploratory analyses, we assessed whether quality of quit date coaching was associated with time (in days) until making the first quit attempt. We dichotomized days until quit (1-14, 15+) to reflect the two-week, optimal time frame as defined in Lorencatto et al.'s quality of goal setting rating scale.⁶ We also assessed smoking abstinence at 7-month follow-up. This was measured as self-reported, 30-day point prevalence abstinence.

Covariates. To account for potential differences in callers' motivation and ability to quit, we selected control variables prior to analysis, based on literature review. In quitline settings, researchers have found that household smoking bans,¹⁹ not having a mental or chronic health condition,^{10,12,20} and higher confidence to quit²¹ are positively associated with quitting. In other settings, living with other smokers²² and having higher nicotine dependence²³ and lower levels of education²⁴ have been found to be negatively associated with cessation outcomes. We also included self-reported age, race, gender and ethnicity which are known psychosocial determinants of smoking.²⁵

We measured comorbidities by callers' self-report of ever having been diagnosed by a healthcare professional with: asthma, cancer, COPD, diabetes, heart disease, or hypertension

(yes, no). Mental health status was similarly assessed as having ever been diagnosed with: anxiety disorder, depression, bipolar disorder, schizophrenia, or alcohol / drug abuse disorder (yes, no). The Fagerstrom test was used to measure nicotine dependence (low 0-2, moderate 3-5, heavy 6-10)²⁶ and home smoking bans were categorized as smoking not allowed anywhere in the home (full ban), smoking allowed in some places (partial ban), and smoking allowed anywhere (no ban). We dichotomized other smokers in the home (yes, no) and callers' confidence in being able to remain quit for a 24-hour period. Caller confidence was defined as not confident (not or somewhat confident) and confident (confident, very confident, or extremely confident). Finally, we included a categorized count of callers' previous ASHLine enrollments (0, 1+).

Primary Analysis

This study was a retrospective cohort study. We described characteristics for callers who received high and low quality quit date coaching (Table 2). We used chi-square, Fisher exact, and unpaired two-sample *t*-tests to examine differences between them. We used multivariable logistic regression models to examine the adjusted and unadjusted odds and 95% confidence intervals (95% CI) for making an in-program quit attempt by quality of quit date coaching. Our *a priori* hypothesis was that, compared to low quality coaching, high quality goal setting would be associated with higher odds of making a quit attempt. To examine potential moderation from having a mental health condition, we used a likelihood ratio test to assess its interaction with quality of quit date coaching.

In a multivariable logistic regression model, we included the client demographic, tobacco history, and program utilization variables listed in Table 2. This represented our full model. To

avoid over fitting the model, we used backwards selection to remove variables not significantly associated with making an in-program quit attempt. Covariates were excluded with a p-value >0.05 . Quality of quit date coaching and age remained in the model. This represented our reduced model. We used a gamma test to examine the pairwise association among the independent variables.²⁷ We used a likelihood ratio test to examine differences between the full and reduced models.

Exploratory Analyses

In the exploratory analyses, we assessed the relationship between quality of quit date coaching and making a quit attempt within two weeks of initiating coaching services. For this, we fit a second logistic regression using a subset of callers from the original sample who made an in-program quit attempt ($n=39$). Beginning with the same set of covariates used in the primary analysis, we again used backwards selection to fit a reduced model. We forced quality of quit date coaching into the model and set a stopping rule to drop all other variables with a p-value >0.05 . Only quality of quit date coaching remained. We repeated these steps to also examine the odds of smoking abstinence among callers reached at 7-month follow-up ($n=33$) by quality of quit date coaching. As before, only quality of coaching remained in the reduced model. The full and reduced models for both of the exploratory analyses were compared using a likelihood ratio test. Statistical tests were performed using Stata 15.1 (StataCorp LLC, 2017 College Station, TX).

RESULTS

We review 90 ASHLine callers' first coaching session delivered by 15 coaches. The inter-rater Cohen's kappa was 0.79 and the intra-rater Cohen's kappa was 0.92, representing "moderate" and "almost perfect" levels of agreement.¹⁷ Forty-three callers received high quality quit date coaching and 47 received low quality coaching with a mean quality score was 3.1. While in-program, 69 callers (77%) set a quit date goal and 39 (43%) made a quit attempt. Among callers who made a quit attempt, 33 (85%) had recorded a quit date goal and 25 (64%) received high quality coaching. Compared to those who received low quality quit date coaching, callers who received high quality coaching were more likely to have set a quit date in their first coaching session ($p < 0.001$) and to have made an in-program quit attempt ($p = 0.007$). No other demographic, tobacco use history, or program engagement characteristic were statistically different between the high- and low-quality group (Table 2).

In the adjusted model, callers who received high quality coaching were more likely (OR 3.98, 95% CI 1.55-10.20) to make an in-program quit attempt than those who received low quality coaching (Table 3). Compared to callers 45-64 years old, those over 65 were also more likely to make a quit attempt (OR 3.83, 95% CI 1.15-12.68). Pairwise association tests showed no association between covariates in the reduced model. We found that MHC did not moderate the association between quality quit date coaching and in-program quitting; the likelihood ratio test showed that the interaction term was not significant in the model ($p = 0.27$).

In two exploratory analyses, we first found that among callers who made an in-program quit attempt, the odds of making a quit attempt within two weeks of the first coaching session

was greater (OR 7.92, 95% CI 1.80-34.74) for those who received high quality quit date coaching compared to low quality coaching. In the second, we explored long-term quit outcomes among 33 callers reached at follow-up (37% response rate). Of those, 14 indicated that they had not smoked in the past 30-days for an overall quit rate of 42%. The quit rate was 50% for callers who received high quality quit date coaching and 33% for those who received low quality coaching. However, the odds of being quit were not significant (OR=2.00, 95% CI 0.49-8.24) for callers who received high quality quit date coaching compared to low quality coaching. As with the primary analysis, we used the reduced model in both exploratory analyses; the likelihood ratio tested showed no difference between full and reduced models for each.

DISCUSSION

Consistent with Lorencatto et al.'s study, we found that delivery of high quality quit date coaching was positively associated with callers making an in-program quit attempt.⁶ Higher quality goal setting was also associated with increased odds of callers reporting a quit attempt within two weeks of their first coaching session. Callers' long-term odds of being quit was not significantly different for those who received high quality vs. low quality quit date coaching. This is likely due to the small sample.

In Lorencatto et al.'s pilot study, using the quality of goal setting rating scale, an average quit date quality coaching score of 1.6 was described with 21% of the sample initiating a quit attempt.⁶ In our sample, both quit date coaching quality and prevalence of quit attempts were higher with an average quit date quality coaching score of 3.1 and 43% of sampled callers reporting an in-program quit attempt. This difference may reflect ASHLine coaching protocols

and routine training that include components from the quality of goal setting rating scale; prior coach training was not described in the Lorencatto study.

These findings highlight the importance of high quality coaching in regards to quit date goal setting. Further, they suggest that when quality quit date coaching is consistently delivered, a higher portion of callers will initiate a quit attempt. The quality of goal setting rating scale stresses the importance of setting a proximal quit date and combining it with NRT or other cessation medications. These stood out as important elements of quit date coaching. Setting a proximal quit date orients callers' use of cessation medication and provides a point of focus around which to plan subsequent counseling sessions.^{28,29} Because most quitlines limit callers' number of counseling sessions, timely initiation of this process is important. Early and open discussions around setting quit date goals may clarify program objectives, normalize callers' expectations, and facilitate coach and callers' ability to articulate potential ambivalence around quitting tobacco.

Strengths of our study include a statistically powered sample size, review of recorded coaching calls in a sample of coaches trained in quit date quality coaching, and use of a validated instrument for assessing coaching quit date quality. While using the quality of goal setting rating scale may introduce bias in scoring, our data suggest this was well-controlled in our sample with high inter- and intra-coder reliability kappa scores. Limitations include the self-reported nature of our primary outcomes including quit attempt and timing of quit attempts. This is an observational study based on a small cohort of callers enrolled in a single quitline. Therefore, the results may not translate to other tobacco cessation services or to the general population of tobacco users. The sample may also be biased as 5% of potential participants were excluded due to missing data, although a comparison of demographic and clinical characteristics did not

suggest any significant differences. We did not assess NRT use and unmeasured differences among coaches which may also have influenced the findings. Finally, the study was designed to assess the primary research question. The exploratory analyses may have been underpowered due to small samples.

Future Research

We found evidence that high quality quit date coaching improves callers' likelihood of making a quit attempt. We suggest four areas where future research may examine this relationship further. First, future work should determine if standardized training emphasizing high quality quit date coaching practices would further improve quit date coaching and enhance the frequency of caller quit attempts. It has been shown that instruments like structured checklists improve protocol compliance and outcomes in care delivery settings.³⁰ It will be important to develop similar instruments and a fidelity monitoring process to ensure routine delivery of high quality quit date coaching.

Second, to facilitate standardized quit date coaching, it may be beneficial to explore ways to improve the quality of goal setting rating scale. Measurement instruments vary in how they aggregate score components.³¹ Some dichotomize quality by measuring indicators using an "all or nothing" logic. Others equally weight scale elements and create a composite score by summing present elements.³² Lorencatto et al.'s scale uses the latter method.⁶ An additional approach is to weight elements that are regarded as more important than others.³³ We suspect this third option may be better suited for measuring the quality of quit date goal setting. In our study, we identified a bimodal distribution in the quality of quit date coaching scores. This suggests that

some elements may ‘stick together.’ If there are core elements like setting proximal quit dates, future research could assess whether less important elements are dependent upon them. Given the large callers who desire to begin reducing their smoking prior to a quit date. To examine this further within smoking cessation services, future studies should measure callers’ intention and progress in reducing, at enrollment and as a behavior change strategy in their coach-facilitated quit plan.

Finally, future studies should further explore the association between quality of quit date goal setting and long-term quitting and relapse. For example, a larger follow-up sample would allow a more detailed view of the relationship between MHC and quit date coaching. Despite evidence that having a MHC decreases quitline callers’ likelihood of quitting tobacco,^{10,11,20} we did not find that MHC modified the effect between quality of quit date coaching and in-program quitting. Using long-term follow-up data, it would be possible to explore if individuals with a MHC, controlling for quality of goal setting, experience greater difficulty in remaining quit.

Conclusion

Quit date goal setting is an important element of tobacco cessation counseling, though it has not yet been robustly evaluated in the literature. We found that when callers received high quality quit date coaching, their odds of making an in-program quit attempt was four times greater than when quit date coaching was lower quality. This approach also translated to making a quit attempt within two weeks of the initial coaching call. Future research should explore interventions to promote high quality quit date coaching including routine monitoring of quit date coaching and callers’ goal setting practices.

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CONFLICTS OF INTERESTS

The authors declare no conflict of interest.

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Figure 1. Sample selection and exclusion criteria diagram

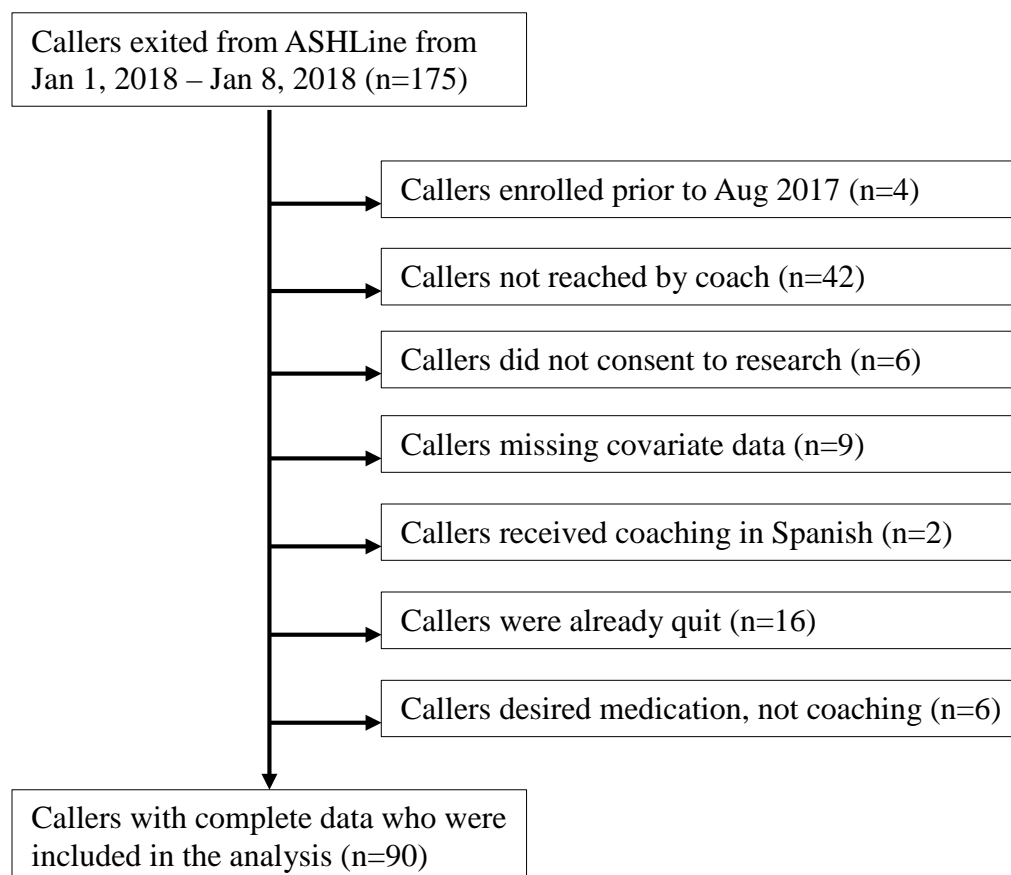


Table 1. Lorencatto et al.'s Quality of Goal Setting Rating Scale

Score	Quit Date Goal Setting Components
-1	Coach encourages clients to reduce or cut down smoking before a scheduled quit date
-1	Set a “flexible” quit date or a goal that is not clearly defined as a specific day / date
-1	The quit date is not scheduled within 14 days following the first coaching session and/or does not allow client time to obtain NRT or cessation medication
1	The coach encourages clients to set a quit date goal
1	Agreed quit date is a specific date (dd/mm/yy) or event (e.g., arrival of NRT)
1	Quit date is scheduled within 14 days following the first coaching session
1	The quit date is scheduled to allow time to first obtain NRT or cessation medication
1	Coach discourages clients from beginning to reduce or cut down smoking / provides advice that reducing is less effective than abruptly quitting on a planned date
1	Coach explains that a quit date entails becoming completely abstinent (e.g., NRT replaces cigarettes, no smoking, not even a puff, after the quit date)
1	Coach provides information and examples about effective behavior changes or NRT / cessation medication use strategies to support quitting and remaining quit

Abbreviations: NRT, nicotine replacement therapy

Table 2. ASHLine client characteristics by quality of quit date coaching (August 2017 – December 2017). Categorical variables display n (%) and continuous variables display mean (SD)

	All clients n=90	High quality coaching n=43 (48%)	Low quality coaching n=47 (52%)	p-value ^a
<i>Client demographic, tobacco use history, and program engagement characteristics</i>				
Gender				0.76
Female	55 (61)	27 (63)	28 (60)	
Male	35 (39)	16 (37)	19 (40)	
Age				0.46
18-24	4 (4)	3 (7)	1 (2)	
25-44	24 (27)	9 (21)	15 (32)	
45-64	42 (47)	22 (51)	20 (43)	
65+	20 (22)	9 (21)	11 (23)	
Mean (SD)	51.4 (14.8)	52.0 (15.5)	50.8 (14.3)	0.69
Race				0.46
White	68 (76)	34 (79)	34 (72)	
Non-White	22 (24)	9 (21)	13 (28)	
Ethnicity				0.51
Hispanic	10 (11)	6 (14)	4 (9)	
Non-Hispanic	80 (89)	37 (86)	43 (91)	
Education				0.41
High School / GED or less	42 (47)	22 (51)	20 (43)	
Some college or more	48 (53)	21 (49)	27 (57)	
Any mental health condition ^b				0.22
Yes	50 (56)	21 (49)	29 (62)	
No	40 (44)	22 (51)	18 (38)	
Any chronic health condition ^c				0.23
Yes	56 (62)	24 (56)	32 (68)	
No	34 (38)	19 (44)	15 (32)	
Nicotine dependence (Fagerstrom)				0.19
No / very low (0-2)	16 (74)	9 (21)	7 (15)	
Moderate (3-5)	36 (40)	13 (30)	23 (49)	
High (6-10)	38 (42)	21 (49)	17 (36)	
Other smoker(s) in the home				0.23
Yes	34 (38)	19 (44)	15 (32)	
No	56 (62)	24 (56)	32 (68)	
Home smoking rules				0.88
Smoking allowed anywhere (no ban)	14(16)	7 (16)	7 (15)	
Smoking allowed in some places (partial ban)	9 (10)	5 (12)	4 (9)	
Smoking not allowed (full ban)	67 (74)	31 (72)	36 (77)	
Confidence to stay quit for 24 hours				0.12
Not or somewhat confident	50 (56)	21 (49)	29 (62)	

Confident, very confident, or extremely confident	40 (44)	22 (51)	18 (38)	
Number of ASHLine enrollments				0.51
0	75 (83)	37 (86)	38 (81)	
1 or more	15 (17)	6 (14)	9 (19)	
<i>Quit date goal setting and quality coaching</i>				
Set a quit date goal in first session				<0.001
Yes	56 (62)	43 (100)	13 (28)	
No	34 (38)	0 (0)	34 (72)	
Made an in-program quit attempt				0.007
Yes	39 (43)	14 (30)	25 (58)	
No	51 (57)	33 (70)	18 (42)	

^aTwo group t-tests were used to assess continuous variables. Due to low expected values (<5), Fischer exact tests were used to evaluate age, ethnicity, and home smoking rules. Remaining categorical variables were tested using chi-square.

^bMental health conditions: anxiety, depression, bipolar disorder, alcohol/drug abuse, or schizophrenia

^cChronic health conditions: asthma, cancer, COPD, diabetes, heart disease, or hypertension

Abbreviations: SD, standard deviation

Table 3. Adjusted odds ratios (OR) of in-program quit attempts (n=90)

	Multivariable model In-program quit OR (95% CI)	p-value
Quality of quit date coaching		
Low	ref	-
High	3.98 (1.55-10.20)	0.004
Age		
18-24	0.38 (0.03-4.30)	0.44
25-44	1.21 (0.40-3.66)	0.73
45-64	ref	-
65+	3.83 (1.16-12.68)	0.03