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Impact of E-cigarettes on Physician Recommendations of Tobacco Use Cessation Pharmacotherapy

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Impact of E-cigarettes on Physician Recommendations of Tobacco Use Cessation
Pharmacotherapy

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of
Philosophy at Virginia Commonwealth University.

by

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August 2015

Acknowledgement

This dissertation would not have been possible without the support of several people. First, I would like to thank Jennifer Elston Lafata, PhD, my advisor and dissertation committee chair, for her valuable insight and guidance. Her constructive feedback and reassuring presence motivated me and helped me overcome the difficulties I faced during the dissertation process. I hope to one day follow in her footsteps as an outstanding scholar and a dedicated mentor.

I also wish to thank my other committee members, Richard Brown, PhD, Levent Dumenci, PhD, Andrew Barnes, PhD, Randy Koch, PhD, and Robert Balster, PhD, for their assistance and direction throughout the dissertation process. Without their guidance, it would not have been possible to pursue this work.

I am ever grateful to my family and friends for their unrelenting support and encouragement during this entire process, which kept me going throughout all the struggles.

Finally and most importantly, I want to thank my girlfriend, Ana Christina Minerly, PhD, for always believing in my ability to follow my dreams and achieve my goals, and for reassuring and encouraging me in times of stress and uncertainty. Most of all I am thankful for giving me the greatest friendship I have ever known.

I dedicate this dissertation to my parents, Hayam El Shall and Yehia El Shahawy. They are an ongoing inspiration to me and the basis for many accomplishments throughout my career and in my personal life. Their unparalleled love and support are my greatest sources of strength.

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Abstract

IMPACT OF E-CIGARETTES ON PHYSICIAN RECOMMENDATIONS OF TOBACCO USE CESSATION PHARMACOTHERAPY

By Omar El Shahawy, MBBCh, MPH

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University

Virginia Commonwealth University, 2015.

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Introduction: E-cigarettes have been marketed as smoking cessation aids and harm reduction strategies. Prior regional surveys found that physicians are recommending them to patients despite the lack of evidence supporting these industry claims. Yet, little is known about physicians' beliefs regarding e-cigarettes and whether these beliefs are associated with them recommending e-cigarette use in clinical practice. **Methods:** This three-manuscript dissertation used a mixed-methods approach including both qualitative and quantitative research methods. The aims were to: (1) Uncover the factors associated with primary care physicians' (PCPs) decisions to recommend e-cigarettes to their patients for tobacco use cessation; (2) Estimate the prevalence of PCPs who recommend e-cigarettes to their patients as a tobacco use cessation aid; (3) Estimate the influence of factors identified in Aim 1 on PCPs' decisions to recommend e-cigarettes to their patients for tobacco use cessation; (4) Evaluate the conceptual model which demonstrates the factors contributing to PCPs' decisions to recommend e-cigarettes to their patients for tobacco use cessation. **Results:** Study 1 found that PCPs expressed a lack of information about e-cigarette safety and efficacy along with skepticism about the role of e-cigarettes in tobacco control in general and in smoking cessation in particular. However, once a

patient initiates a discussion with them, PCPs seem to be endorsing patients' interests in using e-cigarettes, as well as recommending e-cigarettes to particular types of patients who smoke for both smoking cessation and as a harm reduction strategy. Study 2 found that over three-quarters (82.7%, n=220) of PCPs reported previously discussing e-cigarettes with their patients. Overall, 57.8% (n=155) reported previously recommending e-cigarettes to an adult patient who smoked. Among those recommending e-cigarettes, the majority reported recommending them for smoking cessation and harm reduction (71.6%, n=111), 18.8% for smoking cessation only, and 9.6% for harm reduction only. The likelihood of recommending e-cigarettes to patients was associated with considering their patients' interest in using e-cigarettes, PCP's belief that e-cigarettes can help in quitting smoking, and PCP's belief that e-cigarettes limit secondhand smoke exposure for others. Study 3 found that PCPs intend to recommend e-cigarettes for smokers with prior unsuccessful quit attempts (mean=3.63, ±2.1), followed by heavy smokers wanting to quit (3.57, ±2.2), and heavy smokers refusing to quit (mean=3.50, ±2.2). The mean for PCPs' recommendation intentions was 3.04 (±2.0) for light smokers wanting to quit, and 3.01 (±1.9) for light smokers refusing to quit. Nevertheless, these recommendation intentions were driven by PCPs' beliefs and perceptions of e-cigarette benefit and harm; however, these intentions varied by patients' tobacco use profile. **Discussion:** Findings across the three studies highlight the significance of PCPs' beliefs in driving their recommendations of e-cigarettes versus evidence based knowledge, as well as, the importance of patients' factors and interest in using e-cigarettes for PCPs' recommendations for e-cigarette use.

Chapter 1: Introduction

Tremendous strides have been made in the United States (US) to control tobacco-related morbidity and mortality.[1] Nonetheless, a wide range of new and emerging tobacco products (See Table 1), are thriving that may threaten these achievements .[2] These products are being mostly marketed as "alternative" products to conventional cigarettes that are well known by the US public to be very harmful.[2-4] Some of these products burn or heat tobacco (i.e. combustible) and others are non-combustible products; both promise to reduce or eliminate the associated risk of conventional cigarettes and can subsequently mislead US consumers to believe that safe tobacco or nicotine use is currently possible.[5]

Table 1: Descriptions of Different Classes of New and Emerging Tobacco Products

o **Chewing tobacco** - Any leaf tobacco that is not intended to be smoked.
o **Cigars** - Any roll of tobacco wrapped in tobacco leaves or in any substance containing tobacco (other than any roll of tobacco which is a cigarette).
o **Dissolvable Tobacco (**known as "hard snuff"**)** – A tobacco product made from tobacco that dissolves away in your mouth and provides the same tobacco satisfaction as cigarettes or smokeless tobacco.
o **Electronic Nicotine Delivery Device (** known as "Electronic Cigarette"**)**– A unit comprised of a battery, an atomizer, and a cartridge that contains a liquid to be vaporized which is inhaled and exhaled, mimicking the action of smoking. The liquid often contains nicotine.
o **Hookah/Waterpipe** – Although known by many different names (e.g., hookah, narghile, shisha), the term waterpipe has been used for the last two decades in the English language scientific literature to refer to any of a variety of instruments that involve passing tobacco smoke through water before inhalation.
o **Snuff** - Any finely cut, ground, or powdered tobacco that is not intended to be smoked.
o **Snus** - A moist powder tobacco product originated from a variant of dry snuff, in the early 19th century in Sweden, consumed by placing it under the lip for extended periods of time. Snus is a form of snuff that is used in a manner similar to American dipping tobacco, but typically does not result in the need for spitting. Snus is also unique in that it is steam-cured rather than fire-cured, is not fermented and contains no added sugar.

Adapted: Barry et al, 2010

The current study focuses on the most recently introduced product in 2007,[6] which is rather a class of products called electronic nicotine delivery devices or e-cigarettes, which share

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some common features.[7, 8] These features include being battery-powered, converting nicotine-containing liquid into a vapor that can be inhaled, and producing white vapor upon exhalation (called vaping). Some e-cigarettes further mimic the conventional cigarette by having an LED that illuminates during use.[7, 9] Due to a lack of marketing restrictions and the availability of e-cigarette producers, including major tobacco companies, e-cigarettes have evolved rapidly to become one of the fastest growing classes of nicotine containing products in the US. [10] In fact, the sales of e-cigarettes are projected to surpass that of conventional cigarettes by the year 2021.[11] Further, the first generation e-cigarettes were not efficient in delivering nicotine.[12] Since the nicotine yield of e-cigarettes varies by design, e-cigarette nicotine concentration and other technical features, e-cigarettes have currently progressed to their third generation (called e-mods) undergoing a series of changes in all the aforementioned technical features. As such, they have become much more efficient in delivering nicotine than conventional cigarettes.[8, 12-14]

As evidenced by a number of research studies, e-cigarette experimentation, use, and promotion have been growing exponentially over the past few years.[6, 15-17] E-cigarette advertisements often target tobacco users with the claim that e-cigarettes can facilitate tobacco use cessation or provide a way to smoke without restrictions, and they often offer a "free trial" to make them more appealing.[3] In other words, manufacturers are relentless in their promotion of e-cigarettes as safe alternative to conventional cigarettes or as a smoking cessation aid.[14,15] Moreover, the e-cigarettes industry has been spending a substantial amount of money on advertising [18] that often targets youth and young adults.[19] Thus, on the US national level, younger individuals generally seem to be more susceptible to e-cigarette use than older individuals, irrespective of their smoking status.[20-22] In fact, teen use of e-cigarettes surpassed that of any other tobacco product in the US in 2014, raising concerns that e-cigarette use could

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become the new gateway to conventional cigarettes and other tobacco product initiation as well as further drug addiction.[23] Recent cross-sectional studies have found that former smokers are more prone to using e-cigarettes than never-smokers, and current smokers are much more prone to using e-cigarettes than both never and former smokers.[20-22] A recent US national trend assessment showed that e-cigarette use has been exponentially increasing among smokers and non-smokers alike over the past few years, with the use of e-cigarettes estimated to have reached more than 30% among daily and non-daily smokers in 2013 reflecting an evolving dual use of cigarettes and e-cigarettes. [24] Thus, e-cigarette dual use and gateway to other forms of tobacco use are two major concerns that have been long discussed among tobacco control researchers and have resulted in a concern that e-cigarettes could help renormalize tobacco use.[25]

E-cigarettes and Tobacco Control: The Debate over Harm Reduction and Smoking Cessation

E-cigarettes are believed to be safer than conventional cigarettes. This belief is held by many[26-30] including physicians.[31-33] However, e-cigarette vapors are not pure nicotine; they contain a complex mixture of potentially lethal chemicals.[34, 35] Thus, assessments of the abuse potential and long-term adverse events are still needed,[9] and the health implications are yet to be understood.[36] Whether e-cigarettes could be a safe substitute for regular cigarettes is not known,[37, 38] and pending any regulation by the US Food and Drug Administration (FDA), the safety issues associated with the use of currently marketed e-cigarette products in the US is not expected to be resolved anytime soon.[29] E-cigarettes contain nicotine in varying levels.[39] At times there is no nicotine,[29] and fewer carcinogens than are found in conventional cigarettes.[40, 41] On the other hand, other harmful ingredients have been found in e-cigarettes such as diethylene glycol which is a toxicant found in antifreeze.[42, 43] Moreover, the main constituent of the e-liquid

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(propylene glycol) has been rendered safe to use in some FDA-approved injectable drugs but has never been tested for inhalation in human lungs. The long- and short-term effects of inhaling such products remain unknown.[44] Thus, the potential of e-cigarettes to be a viable harm reduction strategy by minimizing tobacco use-related morbidity and mortality among those who use them is not known and is difficult to project given the unresolved safety concerns.[45] Nevertheless, there are researchers who support the use of e-cigarette for harm reduction,[14, 45] and others who do not support e-cigarette use as a harm reduction strategy as this approach is believed to be currently non-evidence based.[46]

E-cigarettes, since their emergence in the US market, have been heavily marketed as smoking cessation aids.[29] An abundance of websites contain testimonials from current and former tobacco users as well as endorsements by physicians who, based on experiences with a few patients, promote e-cigarettes as effective and safe cessation agents.[2, 4, 47] Although e-cigarettes are not currently regulated by the FDA, some cities in the US have banned use of e-cigarettes in public places.[48] Also, other countries have taken action to control the fast growing market of e-cigarettes. The European parliament issued a ban on e-cigarette advertising that is scheduled to go into effect in the 28 European union countries in 2016.[49] Further, the United Kingdom has banned nicotine liquid concentrations higher then 20mg/ml in an attempt to control the nicotine yield.[50]

Recently, there have been a number of studies aiming at exploring their effectiveness as a smoking cessation tool.[37, 51-53] However, most of these studies lack a rigorous research design or biochemical validation for nicotine abstinence, or they rely on self-reported data from online surveys[51] which could potentially include favorable biased responses from e-cigarettes enthusiasts.[54] For example, Polosa et al. (2011) followed 40 smokers who were unwilling to quit

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but attempting to experiment with e-cigarettes as a method of tobacco reduction and possibly cessation. They reported significant decreases in the amount of cigarettes smoked by study participants. Bullen et al. (2010) conducted a randomized cross-over trial in New-Zealand among 40 adult dependent smokers. The e-cigarettes that were used in this study were found to alleviate nicotine craving upon overnight abstinence.[38] Until 2013, use of e-cigarettes did not correlate with successful quit attempts.[55] However, there is evidence that smokers try it in an attempt to quit,[52] and the first clinical trial published in September of 2014 suggested that e-cigarettes could be as effective as nicotine patches in helping cigarette smokers quit.[56] Finally, a more recent cross-sectional study from England, without biochemical validation, surveyed smokers trying to quit with e-cigarettes, approved cessation medications, or with no assistance. This study found that there was a small, but statistically significant, continued abstinence among e-cigarette users.[57]

Each of the aforementioned studies concluded that e-cigarettes might have a future in the arena of smoking cessation, but acknowledged the need for more rigorously designed research. Furthermore, most of these existing studies either did not report financial disclosure or reported support by the manufacturers of these products.[37, 38, 51, 52] A recent meta-analysis of these existing studies supported e-cigarettes as a potentially effective smoking cessation aid.[58] Nevertheless, the available data regarding e-cigarettes efficacy in smoking cessation is not conclusive and thus, e-cigarettes have not been endorsed by any professional health organization as an effective tool for smoking cessation, including the American Heart Association,[59] the American Association for Cancer Research, the American Society of Clinical Oncology,[60] or the United States Department of Health and Human Services.[61] Additionally, the current tobacco use cessation guidelines state that the use of any tobacco product should be discontinued; quitting all forms of

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tobacco use is the only known method for decreased morbidity from tobacco.[62] There is valid concern that smokers would use other forms of tobacco in conjunction with e-cigarettes, creating dual users or continue using e-cigarettes exclusively.[4, 53] Thus, the prospects of e-cigarette use in smoking cessation are still unresolved.

Physician Tobacco Use Counseling: A Current Perspective

Many tobacco users are now identified and offered cessation assistance during physician office visits.[63, 64] Tobacco use cessation discussions with physicians are considered an evidence-based brief intervention to help tobacco users quit.[65, 66] In 1996, the US Public Health Service first published evidence-based clinical practice guidelines for treating tobacco use and dependence.[62, 67] Since that time, recommendations for physicians have remained unchanged.[62, 68] Physicians should ask patients about their tobacco use on every possible occasion as well as counsel current tobacco users using a 5 As approach *(ask about tobacco use, advise to quit, assess willingness to make a quit attempt, assist in quit attempt, and arrange follow-up).*[62, 69, 70] If the patient is not ready to quit, recommendations are for the clinician to divert from the 5 A's approach after the "Assess" step, and instead use brief motivational counseling based on a 5 R's approach (i.e., *relevance, risks, rewards, roadblocks, repetition*).[69] Primary care is an ideal venue for the delivery of such interventions,[62] as periodic health exams are regarded as a time for preventive health-related counseling by physicians on tobacco use among other issues.[71] A physician's visit serves as a trigger for tobacco use quit attempts.[72] Further, tobacco users perceive a physician's advice to quit as a strong motivator for a cessation attempt.[73-75] A Cochrane review concluded that brief advice by physicians versus no advice significantly increases quit rates,[76] and this brief advice is deemed as the standard of care for tobacco use cessation counselling.[62]

The emergence of e-cigarettes is believed to be interacting with physician cessation counseling behavior.[77] There is no identified published literature detailing physicians' counseling practices regarding e-cigarettes either inside or outside the US; however, there is anecdotal evidence that US physicians recommend e-cigarettes for tobacco use cessation based on their personal experiences and information obtained from their colleagues.[78] Such anecdotal information is beginning to be confirmed via large scale research efforts. For example, a recent survey of practicing physicians in North Carolina found that discussing e-cigarettes with patients was not an uncommon practice albeit being patient initiated.[32] Another online survey yielded similar conclusions using a quota sample of physicians practicing in different specialties.[33] Discussing smoking cessation recommendations with the advent of e-cigarettes, in light of inconclusive evidence regarding their safety and efficacy in cessation,[59-61] is likely to cause additional complexities for clinicians,[77] particularly among primary care physicians (PCPs) who currently deliver the vast majority of office-based physician tobacco cessation counseling[63, 64, 79] and are at the forefront of the US health care system. Despite guideline recommendations to do so,[62] even before the emergence of e-cigarettes, clinicians counseling current tobacco users have not always recommended FDA-approved cessation pharmacotherapy.[80] Some physicians have negative attitudes toward providing pharmacotherapy for cessation,[81] and these perceptions greatly moderate prescribing behavior.[82] A study by Bhatia et al (2006) found that there are four main drivers of physician pharmacotherapy choice: product characteristics; promotional activities; patient treatment history and co-morbidity; and price-related issues.[83] E-cigarettes are rapidly evolving with regard to the product characteristics with varying price categories and there is limited knowledge about their safety and efficacy for smoking cessation,[29] but PCPs are likely lacking information about these aforementioned topics.[31, 32] Additionally, promotional

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activities (a third driver) are abundant and currently unregulated, centering on the message that e-cigarettes are a safe alternative and can help in quitting.[3, 47] Such activities could be affecting PCPs beliefs and knowledge regarding e-cigarettes as some of them reported that they gather their information from their patients, the lay-press, and e-cigarette advertisements.[31] In summary, e-cigarettes represent a new product that could be challenging the use of FDA-approved pharmacotherapy cessation aids or more broadly altering the dynamics of smoking cessation counselling. E-cigarettes are likely a "hot topic" for discussion during physician office visits and their emergence could be forcing physicians to give an opinion on them once a tobacco use cessation discussion takes place, despite the lack of empirical evidence regarding the benefit of these products in smoking cessation.

Current Knowledge about Physicians' E-cigarettes Recommendations

Despite the ever growing access among the US public to medical information, the preference of the majority (70%) continues to be obtaining health information from their physicians. [84] Moreover, physicians remain the most trusted source of health information.[84, 85] In the absence of a clear set of recommendations from clinical practice organizations or regulatory actions from the FDA,[86] PCPs likely face a challenge when addressing patient inquiries regarding e-cigarettes. Understanding the burden on PCPs in providing tobacco counselling-related information is of critical importance as there are an abundance of opposing views and conflicting evidence regarding e-cigarette safety and benefits with no conclusive guidance in clinical practice.[37, 38] For example, the American Heart Association issued its first set of policy recommendations regarding e-cigarettes including counselling recommendations to physicians using the existing body of literature at the time.[59] They recommended that physicians screen for e-cigarette use. However, they acknowledged that there was no evidence to support e-cigarette

use or recommendation for cessation. On the other hand, there was also no evidence to support deterring patients who had previously tried other cessation aids unsuccessfully and were interested in using e-cigarettes.[59]

Existing surveys of physician attitudes and perceptions in the US confirm that e-cigarettes are being discussed, and that physician opinions are being solicited by patients, especially among primary care specialties.[31, 32] Four out of five physicians reported being asked about e-cigarettes by their patients who used tobacco in one study and nearly half of physicians who believed that e-cigarettes may assist in cessation already had recommended them to their patients.[32] Physicians who were younger, believed that e-cigarettes lowered the risk of cancer, had been asked more often about e-cigarettes by their patients and had a process in place to document tobacco treatment counseling were more likely to report making such a recommendation. These results were consistent with another survey that found that many physicians are being asked about e-cigarettes and are recommending e-cigarette use to their patients.[33] However, the full range of factors which contribute to physicians attitudes, perceptions and decisions to recommend e-cigarettes remains largely unknown.[31, 32] Without knowledge of the factors that are likely to impact e-cigarette recommendations in clinical practice, up-to-date program planning for addressing the current challenges in tobacco use counselling in physicians' offices remains at a standstill.

The Aims of My Research

The overarching objective of my dissertation research was to understand the patient, physician and other influences pertaining to the adoption of e-cigarettes into a primary care physician's tobacco cessation counseling. Since approximately half of the physician office visits in the US are with PCPs,[79] and tobacco use is screened in approximately 75% of the visits in

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primary care,[64] I targeted PCPs to evaluate physicians' behavior. My primary research question

was centered on understanding how e-cigarettes are being incorporated into primary care tobacco

use cessation counseling. I also identified the underlying salient factors that contributed to PCP

endorsement of e-cigarettes when engaging in tobacco use cessation counseling. My exploration

of how physicians and patients discuss e-cigarettes in clinical practice, and how these discussions

affect physicians' recommendations of their use, requires an in-depth understanding of

physicians' perceptions of e-cigarettes. My research was guided by the Theory of Reasoned

Action (TRA).[87, 88] Because the environment surrounding cessation discussions is also important,

I augmented the TRA with the concept of patient interest for a specific treatment option that is

highlighted by the Model of Clinical Decision Making (MCDM). TRA suggests that attitudes

and subjective norms contribute to physicians' intentions and subsequent decisions to

recommend e-cigarettes to their patients once the tobacco use cessation discussion takes place.[87, 89, 90] MCDM suggests the patient's interest in receiving a specific treatment becomes more

important for physicians if they are addressing a chronic problem that is not immediately life

threatening to the patient.[91] All these domains interrelate which prompted me to combine them in

a TRA-informed conceptual model. This resulting combined conceptual model guided my

research as depicted in Figure 1.
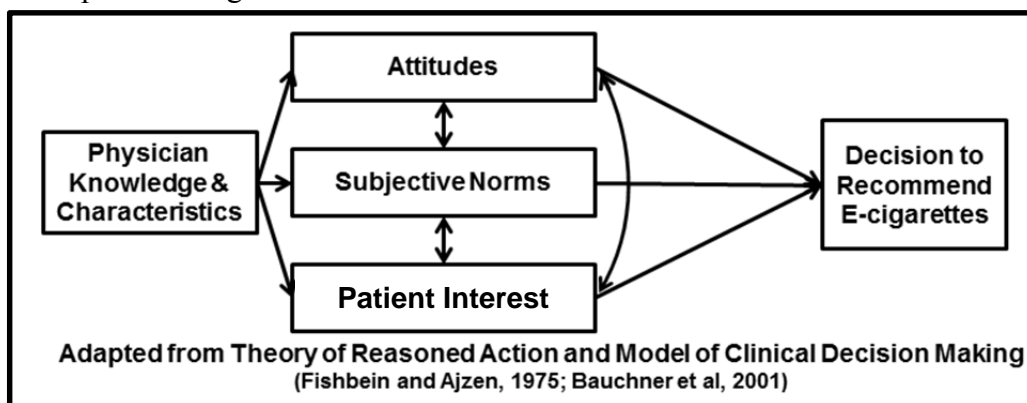
Figure 1: Model of the Factors Influencing Physicians' Decision to Endorse E-cigarettes

My research study was carried out in two phases. **Phase-1** used qualitative methods to discover the factors associated with PCP recommendation of e-cigarettes for tobacco use cessation. This formative research included an elicitation procedure to identify relevant behavioral outcomes and referents. To do so, I used semi-structured interviews in which PCPs were asked to provide three types of information: 1) Positive or negative feelings about recommending e-cigarettes as a tobacco use cessation aid (experiential attitude or affect), 2) Positive or negative attributes or outcomes of recommending e-cigarettes as a tobacco use cessation aid (behavioral beliefs), and 3) Individuals or groups to whom they might listen who are in favor of or opposed to the recommendation of e-cigarettes as a tobacco use cessation aid (normative referents). **Phase-2** used quantitative methods to estimate, among others variables, the prevalence of e-cigarette recommendation for tobacco use cessation and its related factors. In so doing, my research was designed to address the following aims:

Aim 1: Uncover the factors associated with PCPs' decisions to recommend e-cigarettes to their patients;

Aim 2: Estimate the prevalence of PCPs who recommend e-cigarettes to their patients;

Aim 3: Estimate the influence of factors identified in Aim 1 on PCPs' decisions to recommend e-cigarettes to their patients;

Aim 4: Evaluate the conceptual model which demonstrates the factors contributing to PCPs' decisions to recommend e-cigarettes to their patients.

Chapter 2: Primary Care Physicians' Beliefs and Practices Regarding E-cigarette Use by Patients Who Smoke: A Qualitative Assessment

ABSTRACT

Background: There is growing evidence that e-cigarettes are being discussed and recommended during physician office visits. Factors underlying these conversations and physician recommendations regarding e-cigarette use remain unknown. **Objective:** To explore primary care physicians' (PCPs') beliefs and practices about e-cigarettes. **Design:** Cross-sectional, semi-structured interviews with PCPs in 2014 were conducted and audio-recorded. **Study Population:** Participants were 15 general internal medicine and family practice physicians practicing in two settings in Virginia, USA. **Coding and Analysis**: Interview recordings were transcribed, and the content analyzed using the constant comparative method to identify key themes regarding PCPs' reported current practices and beliefs. **Results:** Five themes were identified: PCPs report 1) noncombustible tobacco products (such as e-cigarettes) receive little proactive screening attention within existing clinic processes, 2) patients commonly initiate e-cigarette discussions, and seek physician guidance regarding e-cigarette use, 3) a lack of knowledge regarding the potential harms and benefits of e-cigarettes, 4) believing e-cigarettes are a safer alternative to smoking combustible tobacco products, and 5) abandoning concerns regarding the potential harms of e-cigarettes in the context of highly addicted patients and those with extensive comorbidities. **Limitations:** Physician practices and beliefs are reported from two primary care practices and ability to generalize study findings may be limited. **Conclusions:** Despite acknowledging limited knowledge regarding e-cigarettes, findings suggest that some primary care physicians are currently recommending e-cigarettes to their patients for smoking cessation and relative harm reduction, often personalizing recommendation based on the patient's perceived level of addiction and current health status. Physicians need to be informed about the

evolving evidence regarding the risks and benefits of e-cigarettes to be able to competently steer e-cigarettes-related discussions with their patients.

Abbreviations

US	United States
PCP	Primary Care Physician
FDA	Food and Drug Administration
ACORN	Ambulatory Care Outcomes Research Network

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INTRODUCTION

A wide range of new and emerging tobacco products are thriving in the United States (US) despite limited knowledge of their health implications.[2, 29] One such product, the e-cigarette, is marketed as a cessation aid, harm reduction strategy or both.[2, 4] As evidenced by a number of recent studies, experimentation, use, and promotion of e-cigarettes have been growing exponentially over the past few years.[6, 24, 29, 92] Despite this growth, how e-cigarettes are perceived by physicians is not fully understood.[31, 32]

National clinical organizations such as the American Heart Association,[59] American Association for Cancer Research and the American Society of Clinical Oncology[60] have recently issued policy statements regarding e-cigarettes, advocating that physicians screen for the use of e-cigarettes, but continue to recommend only Food and Drug Administration (FDA)-approved pharmacotherapies for cessation. Most recently, the US Preventive Services Task Force continued to support the use of only FDA-approved pharmacotherapies for cessation, and not e-cigarettes, citing a lack of sufficient evidence surrounding e-cigarette potential to aid with smoking cessation.[61]

With the absence of either a comprehensive set of recommendations from professional organizations or regulatory actions from the FDA,[86] physicians are likely to rely on their own perceptions when discussing e-cigarette use with their patients who smoke. Current evidence suggests that e-cigarettes are being discussed in physicians' offices in multiple settings.[31-33, 77] Yet, to our knowledge, there are only two examples of published reports that include US-based primary care physicians (PCPs).[32, 33] Both reports rely solely on data from physician surveys, and found that patients actively solicit their PCP's opinions regarding e-cigarettes. Despite these studies, how PCPs approach e-cigarette discussions, and the full range of factors that contribute

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to their beliefs, perceptions and decisions to recommend e-cigarettes remain largely unknown.[31, 32]

The purpose of this study is to describe PCPs' current tobacco use screening behavior as it pertains to e-cigarettes, identify PCPs' current approaches to tobacco use cessation counseling as well as to explore their beliefs and practices about e-cigarettes, and to understand the context in which they might recommend e-cigarette use to their patients who smoke.

METHODS

Study Participants

Participants were family and general internal medicine physicians employed by a large university health system in Richmond, Virginia, supplemented by an additional sample of family medicine physicians practicing in the Virginia Ambulatory Care Outcomes Research Network (ACORN) located in northern Virginia. ACORN is a network of family medicine, internal medicine, paediatrics, nursing or other specialties with a mission to improve health and transform care delivery through primary care research and implementation.[93] We purposefully sampled from different practice settings to ensure that sampled physicians treated heterogeneous patient populations across a diversity of settings and geographic areas in Virginia. In April of 2014, we contacted all family and general internal medicine physicians working at the university health system (N=46) via e-mail to invite them to participate in the study. In July 2014, we invited another (n=40) family medicine physicians practicing in two ACORN clinics. To be eligible for participation, physicians had to report providing outpatient primary care to adult patients and discussing tobacco use with at least one of their patients within the past 30 days.

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Participants did not receive any compensation for participation. All aspects of the study were approved by the Institutional Review Board of the Virginia Commonwealth University.

Data collection

After providing written informed consent (Appendix 1), demographic and practice information (i.e. age, gender, race/ethnicity, primary speciality, weekly patient volume and year of training completion) was collected from each participant. Each PCP then participated in an in-depth, semi-structured interview. The interview guide was designed to elicit a) current tobacco use screening and counselling practices, b) perceptions of and beliefs regarding e-cigarettes and c) their screening and counselling practices surrounding e-cigarettes. For the current analyses we focused on responses to nine questions (See Figure 2: Text Box). All interviews were conducted in person by the study PI (O.S.) between April and August, 2014 at the PCPs' offices. Interviews were audio-recorded, and ranged between 23 and 55 minutes. Prior to analysis all interviews were transcribed verbatim.

Coding and Analytic Methods

Prior to coding, names and other identifying information were removed from transcripts. Transcripts of audio-recorded interviews were analyzed using the constant comparative method proposed by Glaser.[94] The research team (O.S., R.B., J.E.L) conducted bi-weekly meetings during which themes were identified and discussed. A consensus process was used to achieve agreement on the inclusion of themes. Initially, as the methodology requires, a first set of transcripts (n=5) was analyzed. Once an exhaustive analysis of this original data set was complete, further sub-samples of transcripts were analyzed at a time until no additional themes

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were identified. The themes which emerged from these data were compared with those from the original data set and if necessary, new thematic categories were defined. This process continued until no new themes emerged. No further interviews were needed to be conducted after the 15th interview. The emerging themes were intended to be descriptive of PCPs' behaviors during tobacco use cessation counseling with their patients who smoke and their beliefs regarding e-cigarettes. This iterative process resulted in further refinement of the themes: reported themes were agreed upon by the three authors.

> 1. How do you typically ask your patients to find about their tobacco use status?
> 2. How do you go about counselling patients who are current tobacco users?
> 3. Have you ever asked any of your patients about their e-cigarette use?
>   If yes, "How did you go about doing that?"
> 4. Have any of your patients ever asked you about e-cigarettes?
>   If yes, "Can you estimate how often over the past year?" AND
>   "Can you tell me a typical question patients asked?"
> 5. Do you know if any of your patients use e-cigarettes?
>   If yes, " What are your thoughts about that?
> 6. Did you recommend e-cigarettes to any of your patients?
>   If yes→ continue probing Was there something specific about the patient that led you to recommend/NOT recommend it? What was it about the patient? Something they said?
> 7. What are your thoughts regarding e-cigarettes and other modes of tobacco use? > How do you think e-cigarettes compare to other tobacco use available?
> 8. What are your thoughts regarding e-cigarettes and smoking cessation? > How do you think e-cigarettes compare to other cessation aids available?
> **9.** Are there specific patients that you might be more or less likely to recommend e-cigarettes to? >Give me an example of patient you are more likely/least likely to recommend e-cigarettes for.

Figure 2: (Text Box) Semi-structured Interview Questions with Main Probes Used

RESULTS

Study Population

Fifteen PCPs, seven from the university health system and eight from ACORN consented to participate in the study. Eleven participants were family medicine physicians and four were general internal medicine physicians. The mean age of participants was 43.1 years (SD=±10.3) and on average they had been practicing for 15.4 years (SD=±10.6). PCPs were evenly distributed by gender (i.e., 53% male and 47% female), and were predominantly white (60%) or Asian (20%). The average patient volume was 63.2 patients per week (SD=±31.9).

Themes

Thirteen PCPs reported discussing e-cigarettes with their patients; of those, six reported having previously recommended e-cigarette use to at least one of their patients. Five overarching themes emerged from the qualitative analysis: 1) PCPs acknowledge that noncombustible tobacco products (such as e-cigarettes) receive little proactive screening attention within existing clinic processes, 2) PCPs report that patients commonly initiate e-cigarette discussions, and seek physician guidance regarding e-cigarette use, 3) PCPs express a lack of knowledge regarding the potential harms and benefits of e-cigarettes, 4) PCPs believe that e-cigarettes are a safer alternative to smoking combustible tobacco products, and 5) PCPs' concerns regarding the potential harms of e-cigarettes are abandoned in highly addicted patients and those with extensive comorbidities. Each theme is described below with illustrative interpolations from transcript data.

Theme 1: PCPs acknowledge that noncombustible tobacco products (such as e-cigarettes) receive little proactive screening attention within existing clinic processes.

While participating PCPs reported established processes to screen for combustible tobacco products, none reported a similar process for new and emerging tobacco products, including e-cigarettes. There were multiple office-based processes reported to screen for patient smoking status. Generally, these processes started with nursing staff screening for use and documenting results in the electronic health record for later PCP follow up during office discussions. Most PCPs indicated that they ask about their patients' smoking status as part of their routine screening process, but do so without probing into smokeless tobacco products –

> *"Typically we'll ask as part of the routine screening, but I will admit that for most routine visits, I generally don't probe into smokeless tobacco products."* [PCP A]

PCPs also reported particularly not screening for e-cigarette use –

> *"I don't ask specifically about smokeless tobacco, chewable tobacco, e-cigarettes. It's generally just 'Do you smoke?' or 'Were you a smoker in the past?' and then 'How much, over what period of time?"* [PCP B]

Some of the PCPs expressed having less concern about noncombustible tobacco products –

> *"Usually lesser for some reason that I am worried about chewing tobacco or snuff. I don't ever specifically ask about e-cigarettes. So, 90% of patients I ask the question "do you smoke?" and leave it at that."* [PCP C]

However, a few PCPs reported probing for different tobacco products–

> *"I ask them if they're smoking, but then generally I'll also get down to then 'Are you chewing? Are you using the dip?"* [PCP D],

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and with exception of one physician, none of those PCPs reported ever probing for e-cigarette use.

Theme 2: PCPs report that patients commonly initiate e-cigarette discussions, and seek physician guidance regarding e-cigarette use.

PCPs consistently expressed that it is patients who usually initiate e-cigarette discussions–

> *"E-cigarettes have definitely been coming up in the last six months. I would say maybe the last year, but in the last six months more and more patients are mentioning it as an alternative or something they are looking to instead of traditional smoking."* [PCP E]

Furthermore, patients' expression of interest was expressed to be a primary reason for a PCP to recommend them for smoking cessation–

> "I *believe in patient-centered care, and I think that changing your health behaviors is really hard. So whatever my patient thinks is going to help them with quitting smoking, I would support, and that would include e-cigarettes, if they wanted to do that."* [PCP F]

The salience of patients' interest in trying e-cigarettes was common across all PCPs, both those who recommended e-cigarettes to their patients–

> *"If they bring it up and they have a motivation I'm usually very encouraging."* [PCP A],

and those who had not previously recommend e-cigarette use to their patients prior to the study–

> *"Somebody who comes to me and specifically says, I am thinking of switching then the patient preference would be a factor in this case."* [PCP G]

For some PCPs, discussion of e-cigarettes was reported as relatively frequently

> *"E-cigarettes come up all the time now, sometimes*
> *our patients have started doing them on their own,*
> *or they have friends who are doing them and they*
> *ask about them, so they come up pretty routinely*
> *now."* [PCP D]

Theme 3: PCPs express a lack of knowledge regarding the potential harms and benefits of

e-cigarettes.

Regardless of whether a PCP had recommended e-cigarettes, all expressed a lack of

knowledge about e-cigarette safety and their efficacy as a smoking cessation aid. One PCP who

had not recommended e-cigarette use said–

> *"The safety is not listed there and you don't know*
> *what they're actually putting into it. They may not*
> *be labeling it correctly and that you may be putting*
> *other carcinogens in yourself and maybe you're not*
> *getting as much smoke, but there are other things*
> *that you're getting."* [PCP H]

On the other hand, a PCP who had previously recommended e-cigarettes said–

> *"I wouldn't say it's safe, because nicotine can make*
> *your heart rate go up, and vaso-constrict, if*
> *somebody takes the e-cig and takes 30 or 40 puffs in*
> *a row, that's probably not good for their coronary*
> *vasculature. So I guess in certain ways you could*
> *have more harm to the heart than a regular*
> *cigarette, perhaps, in certain situations."* [PCP I]

With regards to the efficacy of e-cigarettes for smoking cessation, one PCP commented on the

need for scientific evidence and commented that such evidence regarding e-cigarettes is lagging

behind that for other established FDA-approved pharmacotherapies by saying–

> *"I want to see a research study that shows that*
> *that's helped. There are great research studies with*
> *Chantix, with Wellbutrin, with patches and with*

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> *doctors' counseling. So we know that patients on average, 7% of patients quit smoking just on their own volition. If you start adding things like Chantix and Wellbutrin, you can get it up to 15 to 23%. I want to see a study like that, that randomizes people to e-cigarettes versus Chantix, versus patches, versus doctors just telling people to quit smoking, and when I see that, then I'll say it's an effective means of helping people quit, but there's no data on that. It has to be studied."* [PCP F]

Moreover, PCPs expressed not only that they have a lack of knowledge but that there is not yet enough information regarding e-cigarettes and that it is not easy to find such information by saying–

> *"I tell them is that we don't have a lot of data on the e-cigarettes because they're not FDA-regulated yet and so individual safety data is complicated. The only stuff I've been able to find is from the manufacturers and some Australian stuff, and of course that's all done by the people that sell the cigarettes. So, I just give them all the information that we have, which is not much, and if they want to try it, I say I don't really have a strong objection to you doing that."* [PCP D]

Theme 4: PCPs believe that e-cigarette use is a safer alternative to other tobacco products.

All PCPs expressed concerns about the potential harms of e-cigarette use. However, most PCPs expressed that e-cigarette use is likely safer than the use of traditional tobacco products –

> *"I think, in general taken as a whole, they're safer than smoking, chewing tobacco, pipes, cigars probably."* [PCP I]

Most of the PCPs used cigarette smoking as the benchmark for establishing a comparison for e-cigarettes' safety as a nicotine delivery product, one PCP elaborated on this by saying–

> *"What I want to know is that they are safer than cigarettes, because it's that risk-benefit thing. So if someone's already smoking cigarettes, if I can't get*

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> *to perfect, which is nothing, and there are some risks associated with the inhaled nicotine, but it's less than the inhaled cigarettes, I'll take the e-cigarettes. I can't imagine it's not safer than the actual cigarettes, because cigarettes are just known to be bad for you in so many ways."* [PCP D]

In addition to that, PCPs acknowledged that their perception of e-cigarettes being safer than other combustible tobacco products, is a factor in their recommendation when coupled with the interest of their patient to try e-cigarettes, one PCP explicitly explained that by saying–

> *"There is a perception- kind of automatic response- that it must be safer. Because it is not smoking, so it's got to be better than smoking. And what I have tried to tell patients is that we don't actually know that to be the case. We don't know anything about e-cigarettes in terms of safety, we don't know if they are harmful, we don't know if they are not harmful, we do know smoking is harmful, so I often times let patients come to a decision that they are more comfortable with"* [PCP E]

However, the same PCP further shared more skepticism about the absolute safety with e-cigarettes, while still acknowledging the likely relatively safety benefit of e-cigarettes compared to traditional cigarettes by saying–

> *"I am very, very skeptical about a lot of it, I think it's being advertised as a safer, healthier alternative, I don't think it is true and if it is, it won't be safe, it will be safer and it still won't be something that is very good for people. The vapor from the e-cigarettes has some of the chemicals that you find in tobacco smoke, and the liquid itself of e-cigarettes is incredibly dangerous"* [PCP E]

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Theme 5: PCPs' concerns regarding the potential harms of e-cigarettes are abandoned in highly addicted patients and those with extensive comorbidities.

PCPs reported recommending e-cigarettes to heavy smokers or to patients with existing co-morbidities–

> *" The people who are smoking like a pack a day and really chimneys, I'm like you want anything that you can do that's an action that gets in the right direction. So I usually am pretty encouraging of it in that setting."* [PCP K]

In other instances, PCPs were more inclined to recommend e-cigarettes for heavy long-term smokers who have previously tried quitting and failed with conventional cessation medications and who may be addicted to the social habit of smoking. For example one PCP said–

> *"If somebody said to me, 'Doc, I've already tried the gum. I've tried the patches. It didn't work for me, and I'm not really interested in taking these antidepressant medicines that you've talked about with the craving. I think I'm just so hooked on the physical act of smoking that I think the e-cigarettes are going to be a better way for me to bridge to using,' so I would probably recommend e-cigarettes."* [PCP J]

Similarly, a PCP acknowledged that recommending e-cigarettes for cessation could be a good option for a cessation attempt with patients with smoking related co-morbidities–

> *"When I think of any therapy that I might recommend to someone without really feeling like it's super well-established or that I really understand all the risks and benefits, it's like people who stand the most to gain by using it, so people who are like long-term smokers or who I know will do really poorly with some of the medications or other options that are out there, people who I just think behaviorally would be more amenable to something like that, I guess those would be the people that I would think more of using it"* [PCP K].

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DISCUSSION

Five themes emerged in our current study and the information within these themes suggests that despite routine screening for conventional tobacco use, screening for e-cigarette use seems not to be yet established in primary care. However, smokers and their physicians frequently discuss e-cigarettes during primary care office visits. Although PCPs report not typically initiating these e-cigarette discussions, citing a general lack of knowledge regarding the potential benefits and harms of e-cigarettes, they nonetheless perceive e-cigarettes to be a safer alternative to other tobacco products, particularly combustible cigarettes. Furthermore, some PCPs acknowledge recommending e-cigarettes to at least some of their patients who smoke. They tend to be more likely to recommend e-cigarettes for harm reduction and smoking cessation to certain patient profiles including those thought to be highly addicted to smoking, whose current health status is perceived as warranting immediate action, and who have had a prior failed quit attempt using FDA-approved pharmacotherapies. Moreover, patients' interest in trying e-cigarettes appeared to be a particularly salient facilitator in PCPs' decisions to recommend e-cigarette use.

Faced with little empirical evidence,[2, 60] difficulty finding relevant risk/benefit information, and a void in professional guidelines,[62] PCPs seem to be developing their own approaches to incorporating e-cigarette use into their reportedly increasing patient inquires about e-cigarette use ,[31-33] and tobacco use related counseling. Prior research[31-33] has shown that PCPs in general believe that e-cigarettes are safer than traditional cigarettes. While PCPs in our study share that belief, they were less consistent in acknowledging the efficacy of e-cigarettes as a smoking cessation aid. Nonetheless, most PCPs in our sample reported being more willing to recommend the use of e-cigarettes to patients they perceived as highly addicted or those with

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extensive smoking-related comorbidities than to other smokers. Because such recommendations are being made despite PCPs' overall skepticism regarding the efficacy of e-cigarettes as a smoking cessation aid, this suggests that PCPs' willingness to recommend e-cigarettes may be driven by their belief in e-cigarettes' capacity for relative harm reduction.

Our results indicate that, in spite of PCPs uncertainty about e-cigarettes, they are recommending them to patients and these recommendations are supported by patient interest in trying e-cigarettes. Thus PCPs in our study seemed to adopt a patient centered approach when communicating with their patients about e-cigarettes.[95] When patients raised the topic of e-cigarettes, PCPs reported explaining the limited information they know about e-cigs, and actively supporting a patient's decision to try them. In fact, it is plausible to suggest that patients are a likely source of information for PCPs about e-cigarettes and may be indirectly driving PCPs' e-cigarette beliefs and practices. Yet, it is also likely that patient and physician e-cigarette knowledge is directly influenced by industry marketing and advertising as well as lay press publications regarding the evolving market of e-cigarettes.[31, 96] This coupling of indirect and direct influence on PCPs is reminiscent of the influence of historical conventional tobacco advertising, but is differentiated by the aid of the global spread afforded by social media.[97, 98]

Despite recommendations to screen and counsel patients for e-cigarette use,[59, 60] expecting most PCPs to proactively do this is likely unrealistic given the void in relevant evidence to help PCPs steer a conversation once patients' use of, or interest in using, e-cigarettes is established. Instead, it appears that increasingly frequent office-based interactions regarding e-cigarettes are causing PCPs to develop non-evidence based opinions and then use those opinions in their routine tobacco use cessation counseling to address their patients' inquiries about e-cigarettes. Despite the FDA and many researchers racing to fill these evidence voids, the reality

is that it will take many years before we understand the full range of public health benefits and risks associated with e-cigarettes,[29, 61] and thus the health and other implications of current PCP beliefs and practices regarding e-cigarettes.

Limitations

The results of our study should be interpreted in the context of several limitations. First, study data were collected between May and August of 2014, and given the rapidly evolving e-cigarette market the applicability of findings to today's practices should be interpreted with caution. Second, PCPs interviewed were limited to those practicing within two Virginia settings and included only a small number of the potentially eligible physician subjects within these settings. As such, care should be taken when generalizing findings to other settings and providers. Nevertheless, to our knowledge this is the first study to use qualitative research methods to assess comprehensively PCPs' beliefs and practices regarding e-cigarettes and articulates underlying reasons behind PCPs' recommendations of e-cigarettes.

CONCLUSION

In conclusion, PCPs expressed a lack of information about e-cigarette safety and efficacy along with skepticism about the role of e-cigarettes in tobacco control in general and in smoking cessation in particular. However, once a patient initiates a discussion with them, PCPs seem to be endorsing patients' interest in using e-cigarettes, as well as recommending e-cigarettes to particular types of patients who smoke for both smoking cessation and as a harm reduction strategy. Such findings serve to illustrate the importance of generating and rapidly disseminating evidence regarding e-cigarette safety and efficacy for smoking cessation to US physicians.

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Without such effort, PCPs will continue to devise their own beliefs and practices regarding e-cigarettes that are likely to be difficult to change once established.[99]

Chapter 3: Physicians' Knowledge, Beliefs and Practices Regarding E-cigarettes: Results from a national survey of US primary care physicians

ABSTRACT

Background: E-cigarette use is exponentially increasing in the United States despite limited knowledge about their potential harms or benefits. **Objective:** To understand the extent to which PCPs report e-cigarette discussions and recommendations as well as their knowledge and beliefs regarding e-cigarettes and how these influence their propensity to recommend e-cigarettes to their adult patients who smoke. **Methods:** We used a modified Dillman approach to administer a mailed survey to a national random sample (N=1430) of office-based primary care physicians (PCPs) between February and May, 2015. Survey content was informed by existing literature and qualitative research. Chi-square tests and t-tests were used for bivariate analysis, as appropriate to compare PCPs who recommend and do not recommend e-cigarettes. M-Plus with full information likelihood estimation was used to identify factors associate with PCPs who reported previously recommending e-cigarettes. **Results:** 328 PCPs returned the survey for a 24% response rate. 82.7% of eligible PCPs (n=220) reported previously discussing e-cigarettes with their patients and 57.8% (n=155) reported previously recommending e-cigarettes to their patients who smoke. The majority reported recommending them for smoking cessation and harm reduction (71.6%, n=111), 19.2% for smoking cessation only, and 9.6% for harm reduction only. PCPs' knowledge regarding e-cigarettes, particularly potential harms, was low, but beliefs regarding e-cigarettes ability to help in quitting smoking and to help limit secondhand smoker exposure to others, decreasing cancer risk and the perception that e-cigarettes offer a relative harm reduction tool compared to other tobacco products was high. Patients' interest in using e-cigarettes (odds ratio=1.31, 1.09-1.58) and the PCP having favorable beliefs regarding e-cigarettes ability to help in quitting smoking (odds ratio=1.80, 1.45-2.24), to limit secondhand smoke exposure for others (odds ratio=1.45, 1.15-1.83), to reduce harm compared to other

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tobacco (odds ratio=1.11, 1.05-1.16), and deter patients from using conventional cessation medications (odds ratio=0.78, 0.64-0.95) were associated with PCPs' reports of previously recommending e-cigs to their patients who smoke **Limitations:** Having a low response rate and potential for response bias limit ability to generalize beyond sample. **Conclusion:** Results illustrate an opportunity to improve PCPs' e-cigarette-related knowledge while their practice is still developing. The impact of improving PCPs' knowledge on their recommendations is unknown. However, once their practice is established it is difficult to change.

Abbreviations

US	United States
PCP	Primary Care Physician
AMA	American Medical Association
GIM	General Internal Medicine
FP	Family Practice
GP	General Practice
FDA	United States Food and Drug Administration

INTRODUCTION

E-cigarette use has been increasing exponentially in the United States (U.S.) among smokers and non-smokers alike.[20, 22, 24, 29, 92, 98] Although, e-cigarettes have been marketed as both a harm reduction strategy and as a smoking cessation aid,[22, 29, 92, 98] evidence regarding e-cigarette safety and their efficacy as a smoking cessation aid is still emerging.[22, 32, 61] E-cigarette use has been linked to a steep increase in calls to poison centers, mostly among children (ages 0-5), in the US between 2012 to 2014 to report side effects due to inhalation or skin contact like nausea or vomiting.[100] As of yet, e-cigarettes has not been linked directly to any serious adverse events;[101] however, the liquid nicotine used in e-cigarettes can contain some of the toxicants and carcinogens found in traditional cigarettes,[40, 41, 102-104] and studies suggest that e-cigarette use can cause acute adverse pulmonary effects.[105, 106] Moreover, the amount of nicotine delivered by e-cigarettes varies greatly from no nicotine to levels higher than that found in conventional cigarettes.[12, 13, 35] Furthermore, while some early studies point to the potential for e-cigarettes to serve as an effective smoking cessation aid,[37, 38, 51, 52, 107] many such studies have been industry sponsored and/or criticized for their methodological limitations.[37, 38, 52]

E-cigarette production and marketing are not currently regulated by the U.S. Food and Drug Administration (FDA),[36, 108] and the US Preventive Health Services Task Force recently concluded that there was insufficient evidence to recommend their use as a smoking cessation aid.[61] National clinical organizations such as the American Heart Association,[59] the American Association for Cancer Research, and the American Society of Clinical Oncology[60] have issued position statements regarding e-cigarettes. These organizations generally have advocated that clinicians screen for the use of e-cigarettes, but offer little guidance once e-cigarette use is identified,[59-61] advising only that physicians share the limited evidence base regarding their

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safety and efficacy while continuing to recommend FDA-approved pharmacotherapies for smoking cessation.[59-61]

Given the limited guidance from national clinical organizations and the general lack of conclusive evidence regarding either the full health implications of e-cigarettes or their efficacy in smoking cessation,[2, 29, 31] physicians may be relying on their patients, the e-cigarette industry and information in the lay press as sources of e-cigarette-related information.[31] Recent finding suggest that patients are seeking advice from their physicians regarding e-cigarette use and that some physicians are recommending e-cigarettes to their patients who smoke.[8, 30, 31] Physicians and patients alike, seem to believe that e-cigarettes can help with quitting,[2, 8, 30-32] and are less harmful in comparison to conventional cigarettes.[17, 31-33, 92] Our own qualitative study found that despite acknowledging limited evidence regarding the benefits and risks associated with e-cigarettes, some primary care physicians (PCPs) recommend e-cigarettes to their patients who smoke for both smoking cessation and harm reduction purposes.[109] Furthermore, we found that a PCP's propensity to recommend e-cigarettes to a given patient seemed to be influenced by that patient's interest in trying e-cigarettes.

Despite insights from such studies, it remains uncertain how PCPs, who currently deliver the vast majority of office-based physician tobacco use cessation counseling,[63, 64, 79] are incorporating e-cigarettes into their counseling practices and what factors might be influencing this incorporation. To address this knowledge gap, we surveyed PCPs nationwide to understand the extent to which they report e-cigarette discussions and recommendations as well as their knowledge and beliefs regarding e-cigarettes and how these influence their propensity to recommend e-cigarettes to their adult patients who smoke.

METHODS

Sample Selection

Using the American Medical Association's (AMA's) Masterfile, we identified a sample of General Internal Medicine (GIM), Family Practice (FP) or General Practice (GP) physicians aged 75 years or younger actively delivering office-based care. We contacted a random sample of N=1,430 PCPs supplied by an authorized vendor of the AMA's 2015 Masterfile (Medical Marketing Service, Schaumburg, IL; 2015).

Survey Development and Administration

The survey included items adapted from validated instruments of clinicians' tobacco use cessation counseling beliefs and practices,[80, 110] and those specific to e-cigarette beliefs and practices developed from results of our qualitative research.[109] It also included e-cigarette-related knowledge items developed in consultation with a leading expert in e-cigarette toxicity and regulatory policy. Once developed, the survey was refined in response to comments from five experts in psychometrics and patient-provider communication. The instrument also was pretested for clarity and ease of understanding via semi-structured cognitive interviews with a convenience sample of 10 PCPs practicing in an academic medical center; those PCPs provided an informed consent for participation and received no compensation (Appendix 2). The final 32-item questionnaire took approximately 15-20 minutes to complete, and was administered via the US postal service using a Dillman process[111] between February and May 2015 (Appendix 3). All correspondence, except for the postcard, was signed by the study PI (O.S.). As a token of appreciation, physicians who retuned the survey received a $10 gift card to a retailer of their

choice. All aspects of the study were approved by the Institutional Review Board at the Virginia Commonwealth University.

Measures and Variables

E-cigarette recommendations

Our main outcome variable was whether or not the PCP reported previously recommending e-cigarettes for smoking cessation, harm reduction or both to his/her adult patients who smoke. We categorized PCPs as "never" versus "ever" recommending e-cigarettes, regardless of reason for recommendation. We also ascertained PCP-reported e-cigarette discussion frequency and initiation. For the latter, response categories were: *I usually raise the topic, my patients usually raise the topic,* and *it is equally as likely that I or my patients raise the topic*. An additional item was used to assess the extent to which PCPs considered patients' interest in trying e-cigarettes when recommending e-cigarettes by asking whether patient's *interest is/would be a primary reason for recommending e-cigarettes* (*Strongly Disagree* to *Strongly Agree*) and was scored from one to seven.

Knowledge about e-cigarettes

Five items assessed PCPs' knowledge regarding e-cigarettes. One item assessed whether *e-cigarettes are currently regulated by the FDA*. Two were risk-related: *the nicotine liquid used in e-cigarettes can contain carcinogens* and *e-cigarettes can adversely affect lung function*. Two items were product feature-related: *some e-cigarettes can deliver more nicotine than traditional cigarettes* and *some e-cigarette brands do not deliver nicotine*. Responses were *true, false* or *I*

don't' know. For analyses these variables were coded as a three-level categorical variables or as a binary variable (correct versus otherwise).

Beliefs about e-cigarette

PCPs' e-cigarette beliefs were assessed using five 7-point Likert scale items (*Very Unlikely* to *Very Likely*). For example, we assessed whether PCPs believed e-cigarettes can *help patients quit smoking*. An additional belief item assessed whether the PCP believed *e-cigarettes can create dual tobacco users* (*Strongly Disagree* to *Strongly Agree*).

We also asked PCPs to rate how harmful e-cigarettes and five other tobacco products are to the health of their patients using a 7-point Likert scale (*Not at All Harmful* to *Extremely Harmful*). The products were traditional cigarettes; tobacco pipes; waterpipes [hookah or narghile]; cigars, cigarillos and little cigars; and smokeless tobacco. We constructed 5 items to assess PCPs' perceived reduced harm of e-cigarettes relative to these other products by subtracting their e-cigarette score from each of the other scores. For each constructed item, a positive score indicated relatively less harm, zero indicated equal harm, and a negative score indicated relatively more harm. A total relative harm reduction score was produced by summing the resulting scores across the five items (Cronbach α=0.93).

Counseling self-confidence

PCPs were asked to indicate their confidence in two items: their *ability to counsel patients about tobacco use in general* and their *ability to counsel patients about e-cigarettes use* by indicating their level of agreement using a 7-point Likert scale (*Strongly Disagree to Strongly Agree*).

Other physician characteristics

The survey included questions regarding PCPs' practice setting (i.e. practice size, average number of patients seen per week, and percent of professional time spent providing care to adult patients). It also included prior training in smoking cessation counseling, whether or not PCPs had a medical school affiliation, and demographic characteristics (gender, age and year of residency completion). Information on clinical training (Medical doctor vs Doctor of Osteopathy), specialty (GIM, FM, and FP), board certification, medical school training (US versus foreign) and geographic practice region-were ascertained from the AMA Masterfile.

Statistical Analysis

Descriptive statistics were used to characterize the sample. Prior to conducting analyses, we assessed item non-response, finding it not to exceed 3.3%. Nonetheless, M-Plus with full information likelihood estimation was used for inferential analyses. Differences in physicians who reported recommending e-cigarettes compared to those who reported not recommending e-cigarettes were tested using Chi-square tests and t-tests, as appropriate. For categorical variables (i.e. knowledge items), when an overall Chi-square test established statistical significance, the Wald test of parameter constraints was used to test for pairwise differences. For the multiple logistic regression model testing, we included PCPs' e-cigarette beliefs, knowledge, and their consideration of patient interest in trying e-cigarettes, controlling for PCPs' gender, age, years of practice, specialty, board-certification, medical school training, geographic location, number of patients per week, percentage of time providing care to adult patients, practice size, having an academic affiliation, having had a prior training in smoking cessation counseling, their

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confidence in their ability for tobacco use counselling in general and for e-cigarettes in particular. Variables were considered statistically significant at p<0.05.

Prior to initiating analyses, the representativeness of PCP respondents in terms of age, gender, clinical training, specialty and practice region was assessed using z tests of differences in proportions. No significant differences were found between survey respondents and PCPs in the AMA Masterfile except for PCPs' specialty. Survey respondents disproportionately were FP physicians (57.9% vs. 49.1%) and not GIM physicians (39.2% vs. 48.0%). We therefore used a post stratification weight (GIM=1.2, FP=0.84, and GP=1) to match the proportions in the AMA Masterfile.

RESULTS

Sample Characteristics

A total of 328 surveys were returned. Among those, 50 were ineligible (37 not in direct patient care, seven not in primary care, and six retired). The survey response rate, adjusted for ineligible cases, was 24%.[112] The final weighted sample size was 274 PCPs (Table 2). Most survey respondents were males (62.9%). Mean years of practice was 19.9 ($\pm$11.1). The majority spent at least half of their time providing care to adult patients (84.5%). Most were board certified in either GIM or FM (83.2%), and 79% attended medical school in the US. Approximately a third reported prior training in smoking cessation counseling (33.8%) or had an affiliation with a medical school (36%). Sample PCPs reported having higher self confidence in counseling patients on conventional tobacco use (M=6.3) relative to e-cigarettes-related counseling (M=4.3).

Table 2: Physician Characteristics: Overall and by E-cigarette Recommendation Status

Physician Characteristic	All (N=274)†	Recommenders (n=155)	Non-Recommenders (n=114)
DEMOGRAPHICS AND CLINCAL TRAINING			
Gender (%)*			
Male	62.9	68.4	55.8
Female	37.1	31.6	44.2
Years of Practice (mean, SD)	19.9 ($\pm$11.1)	20.2 ($\pm$10.9)	19.8 ($\pm$11.4)
Age (mean, SD)	52.2 ($\pm$10.7)	52.1 ($\pm$10.6)	52.4 ($\pm$10.7)
Board-certification (%)			
Yes	83.2	84.6	16.8
No	16.8	15.4	18.6
Specialty (%)			
Family or General Practice	52.3	50.6	54.4
General Internal Medicine	47.7	49.4	45.6
Medical school training (%)			
United States	79.0	76.9	82.5
Foreign Medical School	21.0	23.1	17.5
CLINICAL PRACTICE INFORMATION			
Geographic region (%)			
North-East	17.6	18.1	17.5
South	34.4	38.7	29.8
Midwest	24.9	22.6	27.2
West	23.1	20.6	25.4
Practice Size (%)			
1-2	33.8	37.3	28.6
3-10	33.7	33.3	35.7
11 or more	32.5	29.4	35.7
Mean number of patients/week (mean, SD)**	81.3 ($\pm$35.5)	87.5 ($\pm$32.7)	74.5 ($\pm$37.4)
Time providing care to adult patients (%)			
Less than 49%	15.5	12.9	18.6
50-75%	19.5	20.1	18.6
More than 75%	65.0	66.9	62.8
Academic Affiliation (%)			
Yes	36.0	33.1	42.0
No	64.0	66.9	58.0
TOBACCO USE COUNSELING CHARACTERISTICS			
Trained in smoking cessation counseling (%)			
Yes	33.8	30.1	39.5
No	66.2	69.9	60.5
Confidence in ability for tobacco use counseling in general (mean, SD)	6.3($\pm$1.1)	6.3($\pm$1.1)	6.3($\pm$1.0)
Confidence in ability for e-cigarette use counseling (mean, SD) ***	4.3($\pm$1.9)	4.6($\pm$1.7)	3.8($\pm$2.2)

† There were 5 missing entries from the recommendation status variable

* Significant difference by gender (χ^2=4.48, p=0.034)

** Significant difference by mean number of patients/week ($t_{(263)}$=-3.03, p=0.003)

*** Significant difference by confidence in e-cigarette counseling ($t_{(263)}$=-0.78, p=0.001)

E-Cigarettes Recommendations

Over three-quarters (82.7%, n=220) of PCPs reported previously discussing e-cigarettes with their patients. Among those, 24.7% (n=51) reported discussing e-cigarettes *rarely* with their patients, 53.2% (n=109) reported discussing e-cigarettes *sometimes* and 22.1% (n=45) reported discussing them *often* or *almost always*. Furthermore, while half of the PCPs reported that patients usually initiated these discussions (51.2%), 16.2% reported initiating discussions themselves, with the remainder reporting that discussions were initiated equally as likely by them or their patients (32.6%).

Overall, 57.8% (n=155) reported previously recommending e-cigarettes to an adult patient who smoked. Among those recommending e-cigarettes, the majority reported recommending them for smoking cessation and harm reduction (71.6%, n=111), 18.8% for smoking cessation only, and 9.6% for harm reduction only. PCPs who reported initiating e-cigarette discussions more than or equally as likely as their patients were significantly more likely to recommend e-cigarettes (84.0%) compared to those who reported that their patients usually initiated e-cigarette discussions (55.7%) [$\chi^2(1)=19.47$, p<.001]. On average PCPs indicated a moderate level of agreement that their patients' interest in using e-cigarettes influenced or would influence their decision to recommend e-cigarettes (mean=4.09, ±1.8), with those PCPs who recommend e-cigarettes having a significantly higher level of agreement (mean=4.62, ±1.6) compared to PCPs who do not recommend e-cigarettes [mean=3.33, ±1.9; t $_{(208.3)}$ =1.29, p<.001].

As illustrated in Table 2, there were few significant differences between physicians who recommended and did not recommend e-cigarettes. Recommenders were more likely to be male

(68.4% vs. 55.8%) and reporting seeing significantly more patients per week (M=87.5 vs. 74.5) than non-recommenders.

Knowledge about E-cigarettes

Few PCPs (7.6%) answered all 5 knowledge questions correctly. Two-thirds (66.4% and 65.0%, respectively) of PCPs correctly knew that e-cigarettes are not currently regulated by FDA and that some e-cigarette brands can deliver more nicotine than traditional cigarettes (Table 3), with the remainder mostly choosing *I don't know* (27.2% and 27.8%, respectively). Almost half of the PCPs answered *I don't not know* for the three other knowledge questions: whether the liquid in e-cigarettes can contain carcinogens, e-cigarettes could adversely affect lung function, and some e-cigarette brands do not deliver nicotine (44.9%, 54.0% and 47.2%, respectively), with only one third answering these questions correctly (36.9%, 32.8% and 36.2%, respectively). Those recommending e-cigarettes were more likely to answer the two risk-related items (i.e., e-cigarettes can contain carcinogens and can negatively affect lung function) incorrectly compared to non-recommenders, but other differences in knowledge were not detected by the PCP's e-cigarette recommendation status.

On the other hand, PCPs were more likely to answer knowledge items correctly versus otherwise if they had previously discussed e-cigarettes with their patients: 69.5% vs. 41.3% correct regarding FDA regulation (p<.001), 70.0% vs. 39.1% regarding delivering more nicotine (p<.001), 40.5% vs. 13.0% regarding e-liquid content (p<.001), 40.9% vs. 15.2% regarding delivering no nicotine (p=0.001). The one exception was for the lung function question where there was no statistically significant difference in correct knowledge by the PCPs' reported discussion status (33% vs. 26%, p=0.35).

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Table 3: Physician E-cigarette Knowledge Assessment: Overall and by E-cigarette Recommendation

E-cigarette Knowledge Items[¥]	Response Assessment (%)	ALL N=270[†]	Recommenders n=152	Non-recommenders n=113	χ^2 p-value
E-cigarettes are not currently regulated by the FDA	Correct	66.4	68.4	63.7	0.440
	Incorrect	6.4	7.2	5.3	
	Don't Know	27.2	24.3	31.0	
Some e-cigarettes can deliver more nicotine than traditional cigarettes	Correct	65.0	71.2	56.5	0.014*
	Incorrect	7.1	7.8	6.2	
	Don't Know	27.8	20.9	37.2[††]	
The nicotine liquid used in e-cigarettes can contain carcinogens	Correct	36.9	38.4	34.8	0.006*
	Incorrect	18.3	23.8[††]	10.7	
	Don't Know	44.9	37.7	54.5	
E-cigarettes can adversely affect lung function	Correct	32.8	34.2	37.1	0.002*
	Incorrect	13.2	19.1[††]	5.3	
	Don't Know	54.0	46.7	63.7	
Some e-cigarette brands do not deliver nicotine	Correct	36.2	44.7	24.8	0.004*
	Incorrect	16.6	13.8	20.4[††]	
	Don't Know	47.2	41.4	54.9	

¥ All items are stated as factually correct
† There were 5 missing entries from the recommendation status variable
*Statistically significant via χ^2 test (3x2)
†† Proportion remained significant via Wald test of parameter constraints at p<0.05 (correct responses was the reference group).

Beliefs about E-cigarettes

Overall, PCPs tended to agree with three negative beliefs regarding e-cigarettes (Table 4): Mean agreement ratings on a 7-point scale were 5.0 (±1.6) for sustaining nicotine addiction, 4.8 (±1.4) for creating dual tobacco users, and 4.8 (±1.5) for discouraging patients' use of conventional cessation medications. Mean agreement ratings were 5.4 (±1.6) for limiting secondhand smoke exposure, 4.2 (±1.6) for decreasing patients' cancer risk and 4.0 (±1.6) for helping smokers quit. In all cases, recommenders held significantly stronger positive beliefs and weaker negative beliefs compared to non-recommenders. In general, PCPs' beliefs did not differ by their having correct knowledge regarding e-cigarette. The exceptions were that PCPs with

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correct knowledge regarding the impact of e-cigarettes on lung function and that e-liquids could

contain carcinogens held significantly weaker belief regarding e-cigarettes potential to reduce

cancer risk (data not shown).

Table 4: Mean Beliefs Ratings Regarding E-cigarette Use Outcomes: Overall and by E-cigarette Recommendation Status

E-cigarettes Use Outcomes	All N=273[†] Mean (SD)	Recommenders n=155 Mean (SD)	Non-recommenders n=113 Mean (SD)	Degrees of Freedom	t-test p-value
Limit secondhand smoke exposure to patients' families and friends	5.4 (±1.6)	5.9 (±1.3)	4.7 (±1.7)	201.8[a]	<.001
Sustain patients' nicotine dependence	5.0 (±1.6)	4.8 (±1.4)	5.2 (±1.7)	213.3[a]	0.036
Create dual tobacco users	4.8 (±1.4)	4.6 (±1.4)	5.1 (±1.4)	266[b]	0.005
Patients are less likely to use conventional cessation medications	4.8 (±1.5)	4.6 (±1.4)	5.1 (±1.7)	265[b]	0.011
Decrease patients' cancer risk	4.2 (±1.6)	4.7 (±1.5)	3.6 (±1.6)	265[b]	<.001
Help patients quit smoking	3.9 (±1.6)	4.6 (±1.3)	3.0 (±1.6)	207.0[a]	<.001

[†] There were 5 missing entries from the recommendation status variable
[a] equal variances not assumed
[b] equal variances assumed
SD, Standard Deviation

The mean score for the overall relative e-cigarette harm reduction measure was 8.6

(SD=±6.6, range -5 to 30), indicating an overall perception of relative harm reduction.

Physicians who recommended e-cigarettes on average indicated relatively more harm reduction

from e-cigarettes (M= 10.7, SD=±6.1) compared to those who did not recommend e-cigarettes to

their patients (M= 5.8, SD= ±6.1), (t $_{(262)}$ = -4.9, p <.001).

Logistic Regression Results: Factors Associated with Recommending E-cigarettes

Controlling for other factors, the more a PCP reported considering their patients' interest

in using e-cigarettes, the more likely they were to have recommended e-cigarettes (Table 5): for

every point increase in agreement with the statement that they consider their patients' interest,

the likelihood that they recommended e-cigarettes increased by 31%. Similarly, for every point

increase in a PCP's belief that e-cigarettes can help in quitting smoking, there was 80% increase

in the likelihood of the physician recommending e-cigarettes and for every point increase in a

PCP's belief that e-cigarettes limit secondhand smoke exposure for others, there was 45%

increase in the likelihood of the physician recommending e-cigarettes. Likewise, for every point

increase in a PCP's perception of e-cigarettes' relative harm reduction compared to other tobacco

products, there was an increased likelihood of the PCP recommending e-cigarette use by 11%.

On the other hand, for every point increase in the PCP's belief that e-cigarettes would deter

patients from using conventional cessation medication, there was a 22% reduction in the

likelihood they recommend e-cigarettes. No other factors were found to be associated with PCPs'

likelihood of recommending e-cigarettes.

**Table 5: Multiple Logistic Regression Results: Factors Associated with Physicians'
Likelihood of Recommending E-cigarettes (N=274)**

Predictor Variables	Standardized Estimate	OR (95% CI)	P-value
Physician Consideration of Patients' Interest in Using E-cigarettes	0.173	1. 31 (1.09,1.58)	**0.01***
Physicians' E-cigarette Belief			
Limit secondhand smoke exposure to patients' families and friends	0.209	1.45 (1.15, 1.83)	**0.006***
Sustain patients' nicotine dependence	0.021	1.04 (0.85, 1.27)	0.757
Create dual tobacco users	0.053	1.11 (0.86, 1.45)	0.492
Patients become less likely to use conventional cessation medications	-0.131	0.78 (0.64, 0.95)	**0.031***
Decrease patients' cancer risk	-0.099	0.84 (0.66, 1.06)	0.213
Help patients quit smoking	0.336	1.80 (1.45, 2.24)	**<.001***
Perceived relative harm reduction score	0.230	1.11 (1.05, 1.16)	**0.001***
Physicians' E-cigarette Knowledge			
E-cigarettes are not currently regulated by the FDA			
Correct[a]	1		
Incorrect	0.019	1.26 (0.31, 5.05)	0.78
Don't Know	0.029	1.21 (0.56, 2.56)	0.68
Some e-cigarettes can deliver more nicotine than traditional cigarettes			
Correct[a]	1		
Incorrect	-0.016	0.83 (0.09, 6.94)	0.88
Don't Know	-0.207	0.26 (0.12, 0.54)	**0.002***
Some e-cigarette brands do not deliver nicotine			
Correct[a]	1		
Incorrect	-0.071	0.47 (0.21, 1.51)	0.34
Don't Know	-0.093	0.58 (0.30, 1.13)	0.18

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Table 5: Continued

Predictor Variables	Standardized Estimate	OR (95% CI)	P-value
Physicians' E-cigarette Knowledge (Continued)			
The nicotine liquid used in e-cigarettes can contain carcinogens			
Correct[a]	1		
Incorrect	0.073	1.72 (0.68, 4.38)	0.33
Don't Know	-0.052	0.74 (0.35, 1.55)	0.51
E-cigarettes can adversely affect lung function			
Correct[a]	1		
Incorrect	0.077	1.92 (0.61, 5.99)	0.34
Don't Know	-0.021	0.88 (0.41, 1.89)	0.79
Physicians' Demographics and Clinical Training			
Gender (Female)	-0.017	0.90 (0.48, 1.68)	0.88
Age in years	-0.097	0.97 (0.91, 1.04)	0.53
Years of practice	0.075	1.02 (0.95, 1.09)	0.24
Specialty (General Internal Medicine)	0.009	1.06 (0.55, 2.02)	0.78
Board-certification (Yes)	0.04	1.36 (0.59, 3.14)	0.51
Medical school training (United States)	-0.098	0.49 (0.18, 1.31)	0.62
Clinical practice information			
Geographic region			
Midwest[a]	1		
North-East	0.009	1.07 (0.47, 2.43)	0.88
South	0.112	1.98 (0.95, 4.13)	0.12
West	0.11	2.13 (0.89, 5.06)	0.14
Number of patients/week	0.066	1.00 (0.99, 1.01)	0.38
Time providing care to adult patients[b]	-0.003	0.99 (0.72, 1.35)	0.96
Practice Size[b]	-0.034	0.88 (0.57, 1.35)	0.64
Academic Affiliation (Yes)	-0.103	0.53 (0.27, 1.03)	0.11
Tobacco use counseling characteristics			
Trained in smoking cessation counseling (Yes)	0.021	1.14 (0.63, 2.05)	0.71
Confidence in ability for tobacco use counseling in general	-0.043	0.89 (0.70, 1.13)	0.43
Confidence in ability for e-cigarette use counseling	0.079	1.12 (0.94, 1.34)	0.25

*Significant p-value (all bolded)

[a] Reference Group

[b] Ordinal variables

OR, Odds Ratio; CI, Confidence Interval; FDA, United Stated Food and Drug Administration

DISCUSSION

Patient-physician discussions about e-cigarettes are becoming common place in primary care. Consistent with that reported by others,[31-33] PCPs in our sample reported being asked by their patients about e-cigarettes; however, they were also initiating e-cigarette-related discussions with their patients. Such discussions are occurring despite many PCPs expressing uncertainty or incorrect knowledge regarding e-cigarettes. Those recommending e-cigarettes report doing so

both to help their patients stop smoking and as a harm reduction strategy. While socio-demographic, training and practice setting characteristics did not seem to be associated with a PCP's likelihood of recommending e-cigarettes, their consideration of patients' interest in trying e-cigarettes and beliefs about the benefits and harms associated with e-cigarette use as well as beliefs regarding the relative harm of e-cigarettes in comparison to other tobacco/nicotine products were associated with physician reports of recommending e-cigarettes to their patients who smoke.

Patient–physician discussions around e-cigarettes assessed in prior studies[31-33] accounted only for the possibility of patients inquiring about e-cigarettes, not that physicians may be initiating such discussions. A substantial number of PCPs reported initiating e-cigarette discussions with their patients, and those PCPs who did report initiating such discussions were also more likely to recommend e-cigarette use to their patients. Because prior studies have not measured physician initiation of discussions, it is not known if this is a continuation of an existing practice, or whether PCPs might be becoming more proactive regarding e-cigarette-related discussions. What is known is that the majority of PCPs report both discussing and recommending e-cigarettes with their patients—likely at a rate higher than previously has been reported. [8, 30, 31]

The overall knowledge base regarding e-cigarettes that is informing PCP-patient e-cigarette discussions and recommendations is highly variable. Although, the FDA regulatory status has been long communicated via their website,[36, 108] scientific journals,[59, 60] the lay press [113], and on some e-cigarette industry websites, [114, 115] one third of PCPs nationwide were still not aware that the FDA does not currently regulate e-cigarettes. Also, PCPs were unaware that e-cigarettes can contain carcinogens or could adversely affect lung function. Such findings imply

that facts contained in recent position statements published by US medical organizations may not be reaching PCPs.[59, 60] Furthermore, the clear void in knowledge regarding the potential harms associated with e-cigarettes may be indicative of the influence that industry marketing may be having, as such marketing tends to focus solely on the potential benefits of e-cigarettes and is void of any risk communication or transparent product labeling.[40, 41, 98, 102-104] Such an influence could also explain PCPs' generally correct knowledge that some e-cigarettes can deliver more nicotine than that found in traditional cigarettes, as this information is also consistent with current industry marketing messages.[19, 96, 116, 117] Since those PCPs who reported prior e-cigarette-related discussions with their patients were more likely to have had correct e-cigarette-related information, patients could also potentially be a source of PCPs' information[31] or that those discussions might serve as a trigger for PCPs to look for e-cigarettes-related information. Thus, not only could industry marketing be reaching end users of e-cigarettes, but it could be also directly and indirectly informing PCPs knowledge.[31] This is potentially important as PCPs' knowledge of the potential harms associated with e-cigarettes was associated with weaker beliefs regarding the potential of e-cigarettes to reduce the risk of cancer. This suggests that informing PCPs about the potential risk of e-cigarettes could result in less recommendation of e-cigarette via altering their beliefs. Regardless, it seems that PCPs' current knowledge base is both inadequate and not a driving factor behind PCPs' decisions to recommend e-cigarettes to their patients who smoke, perhaps due to the limited evidence-based sources of information available.[27, 28, 31]

Like prior studies,[28, 31-33, 92] we found PCPs generally to have favorable beliefs regarding the ability of e-cigarettes to assist with both smoking cessation and harm reduction. In fact, beyond patients' interest in trying e-cigarettes, only these favorable beliefs towards e-cigarettes

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distinguished recommenders from non-recommenders. Our results clearly illustrate that PCPs are recommending e-cigarettes to their patients who smoke for both harm reduction and smoking cessation. Since these beliefs are likely informed by industry marketing[109] and not evidence-based information, it seems highly plausible that physician recommendations to use e-cigarettes will continue to grow in absence of empirical evidence, and their belief that little evidence exists,[109] may even hinder their active looking for e-cigarette-related information.[118, 119]

Our prior qualitative assessment[109] suggested that patients' interest in using e-cigarettes was a key factor associated with PCPs' recommendation of e-cigarette use. Results here further support this finding. PCPs appear to be adopting a patient-centered approach when recommending e-cigarettes in that they take the patient's interest in trying e-cigarettes into account. As a patient's involvement in a recommendation generally translates to a higher likelihood of adherence, [120] it is likely that many such recommendations are translating into e-cigarette use. Future studies are needed to assess the impact of PCPs' recommendations on e-cigarette use initiation and smoking cessation/continued nicotine dependence.

Limitations

The response rate, while low, was comparable to other physicians' surveys,[121] including those recently published on e-cigarettes[31-33] and reflective of well-documented declining PCP responses to mailed surveys.[121] Nevertheless, there is a potential for response bias that limits the generalizability beyond the study sample. Respondents and non-respondents could have differed in un-measured ways such as their interest in the topic[122] or exposure to e-cigarettes discussions with patients. After weighting, our sample respondents, however, mirrored those in the AMA Masterfile. Nevertheless, caution should be taken when generalizing results to the national

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population of PCPs since the AMA sample is updated on voluntary basis and PCPs' related information might not be up-to-date.

Furthermore, e-cigarette products are diverse and our study did not include examination of PCPs' beliefs regarding different e-cigarette types, if any. Likewise, although our survey content, and thus findings, were informed via in-depth interviews with practicing PCPs,[109] there may be other important unmeasured factors associated with PCPs' e-cigarette recommendations.

CONCLUSION

Discussions regarding and physician recommendations for e-cigarette use are now commonplace among primary care office visits. This new norm has occurred despite limited evidence regarding the potential harms and benefits of e-cigarettes, and despite PCPs acknowledging their knowledge limitations. Our results illustrate both the importance of rapidly fostering the development of this knowledge base as well as an opportunity to disseminate what is currently known to PCPs. Whether altering this knowledge will impact PCPs' recommendations for e-cigarettes is not known. What is well known, however, is that once physicians' practice is established it is difficult to change,[99, 123] and currently PCPs in the US—the frontline for preventive care and tobacco use counseling—are establishing their e-cigarette practices mostly in absence of knowledge of either the potential harms or benefits of e-cigarette.

Chapter 4: Factors Associated with Primary Care Physicians' Intention to Recommend E-cigarette Use to their Adult Patients Who Smoke

ABSTRACT

Background: E-cigarette use has been increasing in the United States over the past few years. Physicians are currently recommending the use of e-cigarettes to their patients for smoking cessation and harm reduction. **Objective**: Assess and compare the factors influencing PCPs' intent to recommend e-cigarette use for patients with different tobacco use profiles. **Methods:** Using a modified Dillman approach, we administered a mailed survey to a national random sample (N=1430) of office-based primary care physicians (PCPs) between February and May, 2015. Survey content and our conceptual model were informed by existing literature and qualitative research. Paired t-tests were used to compare PCPs' recommendation intention for different patient types. M-Plus with full information likelihood estimation was used to test our conceptual model, and to identify the factors associated with PCPs' intentions of recommending e-cigarette use to patients with different tobacco use profiles. **Results:** We had a 24% response rate. The overall mean physician recommendation intention was 16.7 (± 9.5, range= 5 to 35). Intentions were highest for smokers with prior unsuccessful quit attempts (mean=3.63, ±2.1), followed by heavy smokers wanting to quit (3.57, ±2.2), and heavy smokers refusing to quit (mean=3.50, ±2.2). The mean for PCPs' recommendation intentions was 3.04 (±2.0) for light smokers wanting to quit, and 3.01 (±1.9) for light smokers refusing to quit. The main predictor variables in our conceptual model were all significantly associated with PCPs' intentions in addition to PCPs' knowledge (R^2=0.54, p<.001). PCPs intentions were varied by patient type. **Limitations:** There is a potential for response bias which limits the ability to generalize beyond the sample. **Conclusion:** PCPs' intent to recommend e-cigarettes to their adult patients who smoke is strongly influenced by PCPs' beliefs as well as PCPs' consideration of patients' interest in using e-cigarettes and their tobacco use profile. This recommendations' personalization is

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consistent with patient centered care. The impact of PCPs' practice is not ascertained; however, it could potentially have negative consequences on the health of their patients unless e-cigarettes turn out to be an effective cessation aid and/or harm reduction strategy. Future research should examine e-cigarettes harms and benefits regarding different tobacco use profiles to accommodate PCPs' perceptions and practice setting challenges.

Abbreviations

US	United States
PCP	Primary Care Physician
TRA	Theory of Reasoned Action
AMA	American Medical Association

INTRODUCTION

E-cigarette use has been increasing steadily in the United States (US) over the past few years.[24] Evidence regarding the potential of e-cigarettes for smoking cessation is inconclusive and their role as a harm reduction strategy is still unknown.[29, 45, 46, 54, 59, 60] Nevertheless, a recent national survey of primary care physicians (PCPs) in the US revealed that more than half of PCPs are recommending e-cigarettes to their adult patients who smoke.[124] The same study found that PCPs generally believe e-cigarettes could help with smoking cessation and perceive e-cigarettes as less harmful than other tobacco products.[124]

Early studies found that physicians' beliefs regarding the ability of e-cigarettes to decrease cancer risk for patients, being younger,[32] or being a male physician[33] were all factors associated with physicians' recommendations for e-cigarette use.[31-33] We recently reported similar findings among a national sample of PCPs.[124] That study also found that PCPs report considering their patients' expressed interest in trying e-cigarettes and the perceived relative harm reduction potential of e-cigarettes when recommending their use to patients who smoke.[124] Likewise, findings from our own qualitative study suggested that physicians may be considering their patients' tobacco use profile when deciding whether to recommend e-cigarette use.[109] Despite this prior research, our understanding of the factors influencing PCPs' e-cigarette use recommendations remains in its infancy, and to date has not been grounded within an established theoretical framework. Identifying theory-based and modifiable factors associated with PCPs' recommendations for e-cigarettes could provide a critical knowledge base to our understanding of how e-cigarettes are being integrated within clinical practice, and thus enable tobacco control efforts to be well-poised to impact e-cigarette recommendation behaviors regardless of the direction in which they may need to be modified pending emerging evidence.[125]

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Although previous studies have established that the Theory of Reasoned Action (TRA) provides a useful framework for explaining variability in physician intentions to recommend treatments to patients, [89, 126-128] to our knowledge no prior study has identified the factors influencing PCPs' intent to recommend e-cigarette use to their patients who smoke, or how such factors may vary across patients with different tobacco use profiles. We address these knowledge voids by testing the appropriateness of a TRA-informed conceptual model for understanding PCPs' intentions to recommend e-cigarette use to their patients who smoke.[109, 124] Additionally, we compare and contrast the factors influencing PCPs' intent to recommend e-cigarette use for patients with different tobacco use profiles (i.e. different patient types).

Theory of Reasoned Action Informed Conceptual Model

The TRA[129] suggests that attitudes and subjective norms contribute to PCPs' intentions to recommend e-cigarettes to their patients who smoke. PCPs' intentions subsequently shape their decision as to whether or not to recommend e-cigarettes.[87, 130] For TRA testing, attitudes and subjective norms items are developed via semi-structured interviews. Overall attitudes and subjective norms measures are created via utilizing the item total scores to account for the strength of the attitudes and subjective norms held by the person, and the individual items help understand the different factors driving attitudes and subjective norms to be able to plan effective TRA-based behavioral interventions.[87, 89, 90]

The Model of Clinical Decision Making proposes that patient interest in using a specific treatment have a greater impact on physicians' decision making when treating a chronic condition that is not immediately life threatening.[91] Given the push to deliver patient-centered care and the expectation that patient interests play a role in clinician recommendations,[91, 131] we

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adapted the TRA to explicitly account for PCPs' consideration of patients' interest in trying e-cigarettes. Finally, results from our prior research suggested that a PCP's overall relative harm reduction perception of e-cigarettes compared to other tobacco products is likely a salient factor in their decision to recommend e-cigarette use.[124]

The overall purpose of this study is to test the theoretical tenets of the resulting conceptual model (Figure 3). To accomplish that, we address two specific research objectives. First, we test the utility of the TRA in predicting PCPs' overall intentions to recommend e-cigarettes in the expanded TRA-informed conceptual model (adding patient interest and relative harm reduction to the model) using the total TRA item scores (Objective 1). Upon verifying the expanded conceptual model, we test the association of all independent variables from our conceptual model, including the individual items forming the PCPs' attitudes and subjective norms, with PCPs' intentions to recommend e-cigarettes for each patient type and compare differences in the associations identified (Objective 2).
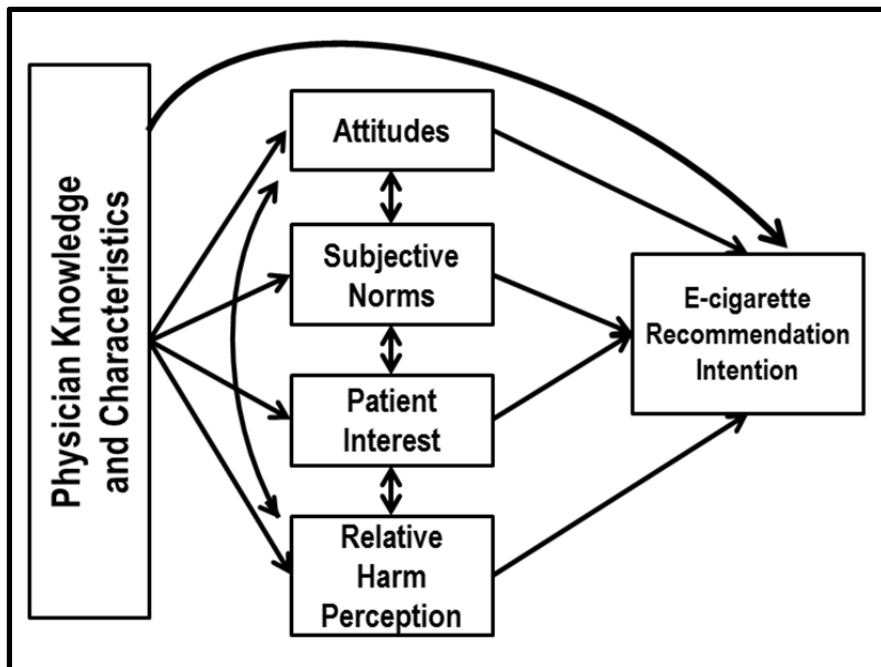
Figure 3: Model of Physician Intention of E-cigarette use Recommendation

METHODS

Participants and Data Collection

Using the American Medical Association (AMA) Masterfile, we invited a nationally representative random sample of N=1,430 general internal medicine, family medicine and general practice physicians to complete a mailed survey. We used a modified Dillman approach to administer the survey.[111] Physicians received up to two reminders to participate in the study and received a $10 gift card to a retailer of their choice as a token of appreciation upon returning the survey. There was no difference between responders and the national AMA pool of physicians except for the distribution of family medicine and general internal medicine specialties. Additional information regarding the sample, and survey administration process are reported elsewhere.[124] All aspects of the study were approved by the Institutional Review Board of the Virginia Commonwealth University.

Questionnaire Development

As previously reported,[109] and recommended for constructing TRA-based questionnaire items,[89, 129, 132, 133] we used qualitative semi-structured interviews to elicit salient PCP beliefs regarding the outcomes associated with, facilitators of, and barriers to recommending e-cigarettes to patients who smoke. We also used semi-structured cognitive interviews with 10 PCPs practicing in an academic medical center to pre-test the final survey instrument for clarity and ease of understanding. Regardless of the wording of the TRA measures' items, all were scored in such a way that higher scores represented positive responses toward the intended behavior (i.e. intent to recommend e-cigarettes to patients who smoke). [87]

For the study's intention measure, we assessed PCPs' behavioral self-prediction of recommending e-cigarettes to different patient types. When measuring clinical practice recommendation intentions, measuring a physician's likelihood (i.e. behavioral self-prediction) of performing the simulated behaviors is known to be a better proxy measure of the behavioral performance than measuring a physician's desire towards the overall behavior (i.e. recommending e-cigarettes in general).[90, 134, 135] Measuring intention in such way mimics a "real-life" behavioral situation that more closely approximates complex clinical decisions.[90, 134, 135] For the attitudes and subjective norms, based on cognitive testing of the final survey instrument, their items were only represented by their belief components and not the evaluative components to minimize survey burden. Adding the evaluative component for an item when the corresponding belief component has obviously a positive or negative outcome could be a source of annoyance,[136] which was confirmed via our cognitive interviews. Additionally, prior studies have found that using the evaluative components added little variance to TRA measures.[137, 138]

Measures

E-cigarette use recommendation intention

The PCPs' likelihood of recommending e-cigarettes over the next three months was ascertained using 7-point Likert scales (*Not at All Likely* to *Very Likely*). Based on results from semi-structured interviews,[109] we assessed likelihood for five different patient types: heavy smokers refusing to quit, heavy smokers wanting to quit, light smokers refusing to quit, light smokers wanting to quit, and smokers with prior unsuccessful quit attempts. A total intention score was computed by summing responses across each of the five patient types (Cronbach **α**

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=0.94). The overall summed score was used for Objective 1. The intention score for each patient type was used for Objective 2.

Attitudes

We measured attitudes using four items with a 7-point Likert bipolar response scale. PCPs were invited to indicate the likelihood (*Very Unlikely* to *Very Likely*) of their patients' use of e-cigarettes resulting in the following: 'help patients quit smoking,' 'decrease their cancer risk,' and 'limit secondhand smoke exposure to patients' families and friends' as well as their agreement (*Strongly Agree* to *Strongly Disagree*) with 'e-cigarette use can create dual tobacco users.' A total overall attitude score was computed (Cronbach **α**=0.84) and used for Objective 1. The four individual items were used for Objective 2.

Subjective norms

We measured subjective norms using four items with a 7-point Likert bipolar response scale. We asked PCPs to indicate whether the following groups would *disapprove* or *approve* of their e-cigarette recommendation: 'specialty physicians to whom I refer my patients,' 'the professional societies to which I belong,' 'my primary care physician colleagues,' and 'my patients who smoke.' A total subjective norm score was computed (Cronbach **α** =0.71) and used for Objective 1. The four individual items were used for Objective 2.

Patients' interest in trying e-cigarettes

We assessed PCPs' consideration of their patients' interest in trying e-cigarettes by asking whether *patient's interest is/would be a primary reason for recommending e-cigarettes.*

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Responses were presented on a 7-point Likert scale (*Strongly Disagree* to *Strongly Agree*) and used in all analyses.

Relative harm reduction

To compute an e-cigarette relative harm reduction perception measure we asked physicians to rate how harmful e-cigarettes and five other tobacco products are to the health of their patients using a 7-point Likert scale (*Not at All Harmful* to *Extremely Harmful*). Tobacco products considered were traditional cigarettes; tobacco pipes; waterpipes [hookah or narghile]; cigars, cigarillos and little cigars; and smokeless tobacco. We constructed five relative harm reduction items by subtracting the e-cigarette score from each of the other tobacco product scores. A total relative harm reduction score was produced by summing the five constructed items (Cronbach α =0.93). The resulting overall harm reduction score was used in all analyses with positive scores indicating relatively less harm from e-cigarettes.

Knowledge and other control variables

When testing associations, we controlled for a number of other PCP characteristics, including e-cigarette knowledge. A knowledge score (range 0-5) was constructed by summing the number of correct responses the PCP gave to five true/false knowledge questions. These questions were based on the current literature and expert opinion, [124] and included items such as '*the nicotine liquid used in e-cigarettes can contain carcinogens*' and '*some e-cigarettes can deliver more nicotine than traditional cigarette.*' We also collected information on year of birth (for age computation), gender, years of clinical experience post training completion, and average number of patients seen per week.

Statistical Analysis

Descriptive statistics were used to characterize the sample and intentions of PCPs to recommend e-cigarettes. We used paired sample t-tests to compare mean PCP recommendation intention scores by patient types. Although item non-response did not exceed 3.3%, we nevertheless used M-Plus with full information likelihood estimation for model testing in support of both objectives. To address Objective 1, we tested a path model reflecting the full conceptual model (i.e., inclusive of patient interest and relative harm reduction). To address Objective 2, we used a multivariate, multivariable regression model to simultaneously compare and contrast the model components associated with physician intention to recommend e-cigarette use to different patient types. For all analyses, we used post-stratification weights to account for the disproportionate survey response rate between family physicians and general internal medicine physicians.[124] In all models, we report the standardized estimates of the beta coefficients, and their p-values as well as the adjusted R^2. Variables were considered statistically significant at p<0.05.

RESULTS

Sample Characteristics

Data from a total of 274 participants were used in the analysis. The survey response rate adjusted for ineligible cases was 24%.[112] The majority of respondents were males (63%). Mean years of practice was 19.6 ($\pm$11.2), mean age was 52.2 ($\pm$10.7) years, mean number of patients seen per week was 81.3 ($\pm$35.5), and the mean knowledge score was 2.3 ($\pm$1.5) of a possible 5 points. The mean overall total score for the relative e-cigarette harm reduction perception was 8.6 ($\pm$9.0, range= -5 to 30) reflecting a perception that e-cigarettes were relatively less harmful

than other tobacco products. PCPs generally agreed that patient interest in trying e-cigarette would influence their recommendation decisions (mean=4.1, ±1.8, range 1 to 7). The mean attitude and subjective norms scores are presented in Table 6.

Table 6: Mean Attitude and Subjective Norm Scores: Individual Items and Overall (N=274)

Measures	Mean (SD)	Cronbach's alpha
Individual attitude items (range: -3 to +3)		
Help quit smoking	-0.04 (±1.6)	
Limit second-hand smoke exposure	1.39 (±1.6)	
Decrease cancer risk	0.24 (±1.6)	
Create dual tobacco users (reverse scored)	-0.82(±1.4)	
Total Attitudes (range -12 to 12)	0.77(±4.6)	0.84
Individual subjective norm items (range: -3 to +3)		
Specialty physicians	-0.33 (±1.2)	
Professional societies	-0.50 (±1.2)	
Primary care physician colleagues	-0.33 (±1.3)	
Patients who smoke	0.51 (±1.2)	
Total subjective norm (range -12 to 12)	-0.63(±4.1)	0.71

E-cigarette Recommendation Intentions

The overall mean physician recommendation intention was 16.7 (± 9.5, range= 5 to 35). Intentions were highest for smokers with prior unsuccessful quit attempts (mean=3.63, ±2.1), followed by heavy smokers wanting to quit (3.57, ±2.2), and heavy smokers refusing to quit (mean=3.50, ±2.2). The mean for PCPs' recommendation intentions was 3.04 (±2.0) for light smokers wanting to quit, and 3.01 (±1.9) for light smokers refusing to quit. As shown in Table 7, mean intentions to recommend e-cigarette use for smokers with unsuccessful quit attempts was not significantly different than that for heavy smokers, but was significantly higher than that for light smokers, irrespective of the willingness to quit. Similarly, recommendation intention for heavy smokers was significantly higher than that for light smokers irrespective of the willingness

to quit. Physicians' recommendation intentions were not differentiated by the patient's

willingness to quit, regardless of whether the patient was a heavy or light smoker.

Table 7: Comparison of Physicians' E-cigarette Recommendation Intentions for Different Patient Types (N=274)

Patient Type Comparisons	Mean (SD)	T- Statistic	P-value
Smokers with prior unsuccessful quit attempts	3.63 (±2.1)	0.93	0.351
vs. Heavy smokers wanting to quit	3.57 (±2.2)		
vs. Heavy smokers refusing to quit	3.48 (±2.2)	1.87	0.062
vs. Light smokers wanting to quit	3.03 (±2.0)	6.76	<.001
vs. Light smokers refusing to quit	2.99 (±1.9)	7.78	<.001
Heavy smokers wanting to quit	3.58 (±2.2)	0.95	0.345
vs. Heavy smokers refusing to quit	3.50 (±2.2)		
vs. Light smokers wanting to quit	3.04 (±2.0)	5.98	<.001
vs. Light smokers refusing to quit	3.58 (±2.2) 3.01 (±1.9)	6.17	<.001
Heavy smokers refusing to quit	3.50 (±2.2)	3.92	<.001
vs. Light smokers wanting to quit	3.05 (±2.0)		
vs. Light smokers refusing to quit	3.01 (±1.9)	5.47	<.001
Light smokers wanting to quit	3.04 (±2.0)	0.41	0.683
vs. Light smokers refusing to quit	3.01 (±1.9)		

E-Cigarette Use Recommendation Intentions and the Expanded Theory of Reasoned Action

Results from the path model are shown in Figure 4. The overall PCPs' intentions to recommend e-cigarette use was significantly associated with the PCPs' total attitudes and subjective norms, consideration of patients' interest, e-cigarette relative harm perception and e-cigarette knowledge (R^2=0.54, p<.001). PCPs who had a more favorable attitude towards e-cigarettes, believed more strongly in the relative harm reduction ability of e-cigarettes compared to other tobacco products, perceived that recommending e-cigarettes would be generally approved of by their salient referents, and had better e-cigarette-related knowledge were more likely to intend to recommend e-cigarettes to their patients who smoke. Similarly, PCPs who perceived their patients to be interested in trying e-cigarettes were also significantly more likely to intend to recommend them to their patients. Upon testing the path model indirect effects, we found that attitudes mediated the effect of knowledge (β=-0.049, p=0.023) and gender (β=-0.065, p=0.008) on intentions, relative harm reduction perception mediated the effect of knowledge (β=-0.052, p=0.007) and gender (β=-0.037, p=0.030) on intentions, and subjective norms mediated the effect of age (β=-0.082, p=0.016) and years of practice (β=0.073, p=0.025) on intentions.
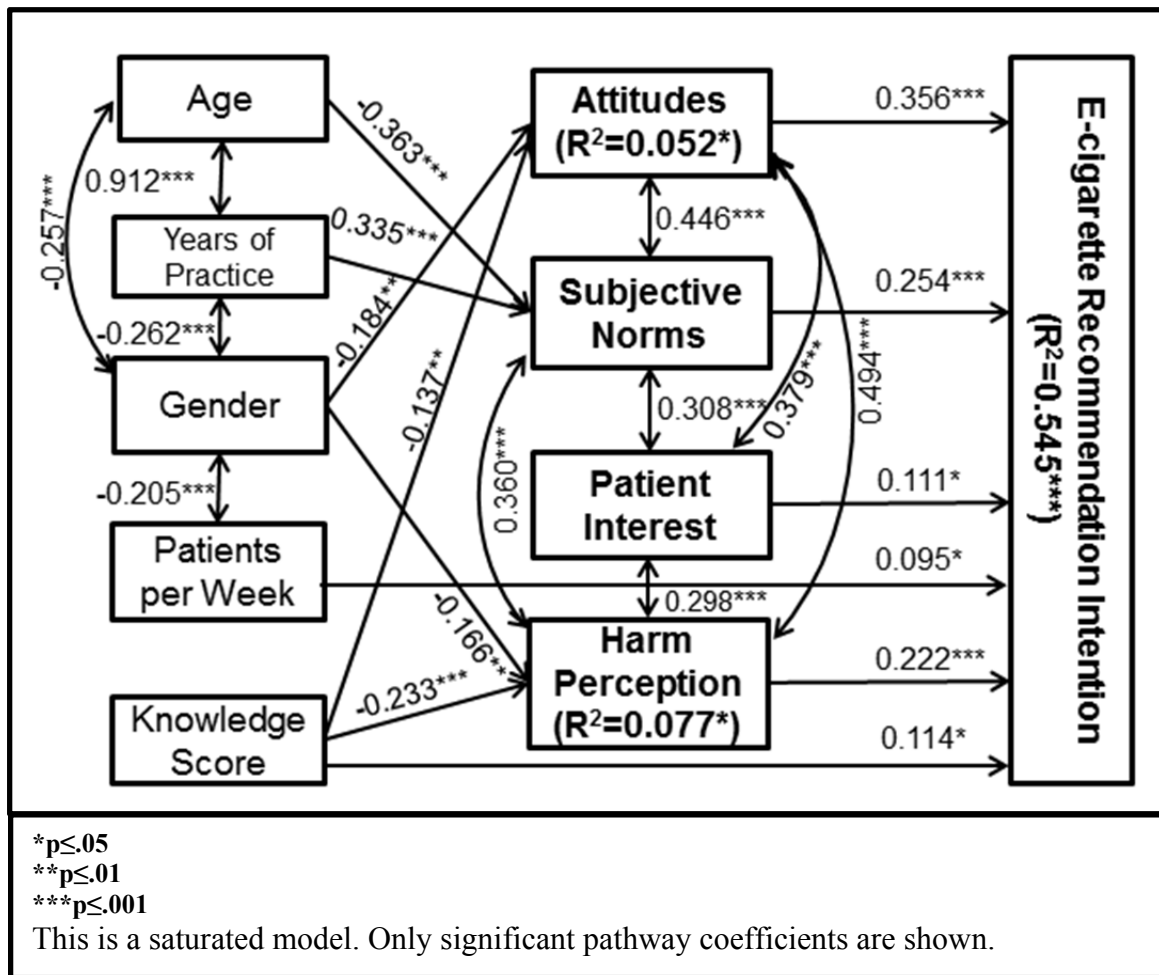
Figure 4: Conceptual Model Fit Utilizing Observed TRA Measures

Factors associated with E-Cigarette Recommendation Intentions by Patient Types

Results from the multivariate multivariable regression model showed that increased PCPs' perception of approval by their PCP colleagues and patients who smoke (two of the social norm measures) were associated with their intentions to recommend e-cigarette use regardless of patient type. Increased belief that e-cigarettes could help patients quit smoking (an attitude measure) was also associated with PCPs' intentions for all patient types. Furthermore, increased belief that e-cigarettes decrease cancer risk for smokers and the relative harm reduction potential of e-cigarettes were associated with increased intentions to recommend e-cigarettes to all patient types, except for light smokers wanting to quit. Consideration of the patient's interest in using e-cigarettes was significantly associated with physician's intentions to recommend e-cigarettes for

smokers with unsuccessful quit attempts, and for light smokers. The PCPs' e-cigarette

knowledge was generally not significantly associated with their recommendation intention; the

exception was among smokers with prior unsuccessful quit attempts where knowledge was

positively associated with recommendation intent.

Table 8: Multivariate, Multivariable Model Results: Factors Associated with Physicians' Intent to Recommend E-Cigarettes by Patient Types (N=274)

Patient Type	Explanatory Variables (A=Attitude), (SN=Subjective Norm)	Standardized β coefficient	*P* for β	Model's *R* squared
Heavy Smoker Refusing to Quit	Help Quitting (A)	0.267	<.001	0.487*
	Decrease Cancer Risk (A)	0.163	0.011	
	Primary Care Physician Colleagues (SN)	0.228	0.014	
	Patients Who Smoke (SN)	0.147	0.002	
	Relative Harm Reduction of E-cigarettes	0.162	0.006	
	Number of Patients Seen per Week	0.131	0.003	
Heavy Smoker Wanting to Quit	Help Quitting (A)	0.214	<.001	0.562*
	Decrease Cancer Risk (A)	0.169	0.005	
	Specialty Physicians (SN)	-0.154	0.018	
	Primary Care Physician Colleagues (SN)	0.383	<.001	
	Patients Who Smoke (SN)	0.094	0.042	
	Relative Harm Reduction of E-cigarettes	0.209	<.001	
	Number of Patients Seen per Week	0.134	0.003	
	E-cigarette Knowledge	0.142	0.001	
Light Smoker Wanting to Quit	Help Quitting (A)	0.259	<.001	0.443*
	Primary Care Physician Colleagues (SN)	0.272	0.004	
	Patients Who Smoke (SN)	0.124	0.016	
	Patient Interest in Using E-cigarettes	0.189	<.001	
Light Smoker Refusing to Quit	Help Quitting (A)	0.205	<.001	0.417*
	Decrease Cancer Risk (A)	0.139	0.049	
	Primary Care Physician Colleagues (SN)	0.316	0.001	
	Patients Who Smoke (SN)	0.148	0.006	
	Patient Interest in Using E-cigarettes	0.125	0.019	
	Relative Harm Reduction of E-cigarettes	0.156	0.017	
Smokers with Prior Unsuccessful Quit Attempts	Help Quitting (A)	0.270	<.001	0.566*
	Decrease Cancer Risk (A)	0.154	0.012	
	Primary Care Physician Colleagues (SN)	0.316	0.001	
	Patients Who Smoke (SN)	0.145	0.002	
	Patient Interest in Using E-cigarettes	0.106	0.032	
	Relative Harm Reduction of E-cigarettes	0.209	<.001	
	Number of Patients Seen per Week	0.100	0.020	
	E-cigarette Knowledge	0.090	0.038	

*p-value <.001
Only Significant predictors are presented in the table.

Discussion

Consistent with the assumptions laid in our Theory of Reasoned Action informed conceptual model, PCPs' intentions to recommend the use of e-cigarettes to their patients who smoke were largely driven by their attitudes and subjective norms.[124] Additionally, PCPs' consideration of patient interest in using e-cigarettes and their relative harm perceptions of e-cigarettes were significant drivers as well. However, neither PCPs' intentions, nor the drivers of those intentions were uniform across all patient types. Physicians' intentions to recommend e-cigarettes were particularly high among heavy smokers and those with unsuccessful quit attempts relative to light smokers. Similarly, physicians' beliefs that e-cigarettes can decrease cancer risk for patients was significantly associated with their intentions to recommend e-cigarettes for all patient types except for light smokers wanting to quit. Conversely, consideration of patients' interest in using e-cigarettes was associated with PCPs' intentions to recommend e-cigarettes for light but not for heavy smokers. Such findings are consistent with the finding that e-cigarettes are being recommended by PCPs for harm reduction[33, 124] as well as for smoking cessation, [32, 124] but also illustrate how PCPs' intent to recommend e-cigarettes may be highly personalized to specific patient contexts and situations.

Variation in PCPs' tobacco use counseling recommendations are well established,[76, 139-141] with PCPs being known to deliver counseling more frequently to heavy smokers.[139] PCPs also tend to recommend higher doses of cessation pharmacotherapies or more intensive behavioral interventions to help heavy smokers quit.[76, 140, 141] The increased intention to recommend e-cigarettes for patients perceived to be heavy smokers or those patients who have tried to quit multiple times, could indicate that e-cigarette recommendations are not yet a standard approach to tobacco use counseling in primary care but instead one that is being used selectively. Despite

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that fact that the morbidity linked to smoking is comparable regardless of the amount a patient smokes[142] and that that all forms of tobacco use should be avoided completely,[62] prior studies have continually shown PCPs behave differently when targeting "heavy" versus "light" smokers.[76, 140, 141] Our results are no different: PCPs' intention to recommend e-cigarettes caries by patient tobacco use. This could mean that e-cigarettes are being incorporated into physician cessation counseling in the same manner that other cessation aids are used. PCPs' advice of different tobacco use counseling treatments has not always been tied to patients' willingness to quit,[143] which was also observed in PCPs' recommendation intentions for e-cigarette use. It is possible that PCPs are incorporating e-cigarettes into their counseling in a way that is similar to other cessation medications, or that e-cigarettes could be regarded by PCPs as a part of an intensive counseling approach aiming at improving the likelihood of future cessation attempts among those unmotivated to quit.[140] Whether e-cigarette recommendations are made after offering recommended evidence-based cessation therapies cannot be known without future studies.

PCPs appear to be taking a patient-centered approach to e-cigarette recommendations. We found PCPs' intent to recommend e-cigarettes—regardless of patient type—to be associated with their patients' perceived approval. However, when it comes to PCPs' consideration of patient interest in trying e-cigarettes, it was not consistently associated with their recommendation intention for all patient types. This association was significant for light smokers and those with unsuccessful quit attempts, but not for heavy smokers. This suggests that, despite patients being a salient referent for PCPs when making their treatment decisions, once PCPs perceive smokers to be of higher risk their consideration of patient interest contributes less to their recommendation decision as they perceive their patient status to warrant immediate

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attention regardless of the patient's interest.[91] This in itself suggests that PCPs' relatively high recommendation intention for heavy smokers, not being driven by their patients' interest, could be an implicit endorsement for e-cigarettes' harm reduction potential for heavy smokers. On the other hand, patients' interest was a driver for PCPs' intention to recommend e-cigarette use to light smokers. Given that patient interest is likely growing because of industry marketing,[24, 27, 96] in addition to a growing proportion of light smokers in general,[144] it is very likely that PCPs' intention to recommend e-cigarettes to light smokers, and hence their future recommendations,[145] could grow. The likely impact of this personalized approach by PCPs according to patient types could be assessed in future studies. Specifically, whether such an approach by PCPs might have its intended results, such as helping patients quit smoking, or possibly unintended results, such as creating dual tobacco users, needs to be ascertained.

Having accurate e-cigarette knowledge was directly associated with physicians' intentions to recommend e-cigarettes and was mediated by PCPs' attitudes and relative harm reduction perception. This suggests that PCPs who take the time to gather information about e-cigarettes could be developing favorable beliefs regarding e-cigarettes. Since evidence-based information sources continue to be limited for e-cigarettes, it is likely that physicians who seek information on e-cigarettes are finding industry-sponsored material.[31, 124] Such material is currently unregulated and known to minimize what is known regarding the potential risks associated with e-cigarette use.[30, 146] Consistent with this, our prior research has found PCPs to be more knowledgeable of the potential benefits of e-cigarettes relative to their potential harms.[124] Thus, not only is research needed to assess the health and other benefits and risks associated with e-cigarette use, but efforts are needed to help synthesize and disseminate what little is known about the impact of e-cigarettes, particularly known risks.

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Limitations

We studied PCPs intentions to recommend e-cigarettes, which although likely associated with, may not translate to their e-cigarette-related recommendations. Future longitudinal studies are needed to test how PCPs' intentions would affect their actual recommendation behavior. Care also should be taken when generalizing findings to other populations of PCPs. As is increasingly the case with physician surveys,[121] we had a relatively low response rate, and respondents and non-respondents could have differed in un-measured ways such as their interest in the topic[122] or exposure to e-cigarettes discussions with patients. Furthermore, although the sample was drawn from the AMA Masterfile it may not be representative of the population of PCPs practicing in the US. However, the response rate was comparable to other physician surveys,[121] including those recently published on e-cigarettes[31-33] and we used post-stratification weights to correct for the known response bias by PCP reported primary specialty.

Furthermore, the available sample size precluded testing individual attitude and subjective norms items in the path model. Thus, our ability to understand the influence of specific beliefs and subjective norms is limited. However, the overall measures used had good internal consistency. Additionally, the patient types used were chosen to mimic clinical practice situations that PCPs commonly face. They did not, however, fully account for the complex situations that PCPs could encounter during e-cigarettes related discussions, and thus may have missed important clinical considerations. Likewise, e-cigarette products are diverse and our study did not include examination of PCPs' beliefs regarding different e-cigarette types, if any. Furthermore, although our survey content, and thus findings, were informed via in-depth interviews with practicing PCPs,[109] there may be other important unmeasured factors associated with PCPs' e-cigarette recommendations.

CONCLUSION

PCPs' intent to recommend e-cigarettes to their adult patients who smoke is strongly influenced by their beliefs regarding e-cigarettes, particularly the potential for harm reduction relative to other tobacco products, and by the social norms influenced by their primary care colleagues and patients. Consistent with such influential factors, PCPs' intent to recommend e-cigarettes is not uniform across patient types. Instead, PCPs' are considering specific patient scenarios characterized by both the amount a patient smokes and their prior failed quit attempts. While such personalization is consistent with patient centered care, and because PCPs' intentions are likely to translate to future recommendations,[145, 147] this may help sustain nicotine dependence or create dual use, among primary care patients that could have otherwise quit completely using pharmacotherapies that are approved by the US Food and Drug Administration. This may also cause unknown harms to patients, many of which are potentially heavy smokers already heavily exposed to known smoking harms, unless e-cigarettes are ultimately identified as an effective harm reduction strategy. Finally, the e-cigarette related research agenda should examine e-cigarettes harms and benefits regarding different patient types to account for PCPs perceptions and real practice setting challenges.

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Chapter 5: Conclusions

The three studies presented in this dissertation build upon each other. My qualitative assessment of Primary Care Physicians (PCPs) beliefs and practices regarding the use of e-cigarettes by patients who smoke provided the first in-depth study of PCPs' beliefs and recommendations pertaining to e-cigarettes. Until now, published literature assessing PCPs' practices regarding e-cigarettes[31-33] has not been informed by a formative step. By stepping back and conducting this formative research, I was able to gain valuable insights into the dynamics that occur between PCPs and patients in clinical practice. My formative research yielded several important results that in turn guided the instrument development, conceptual model, and methods used in my quantitative research. First, the results provided a provisional understanding of the attention that PCPs give to e-cigarettes in their routine tobacco use counseling and how the communication regarding these products tends to occur. They also highlighted the fact that e-cigarettes are recommended for both smoking cessation and harm reduction that some PCPs are proactively raising the topic of e-cigarettes with their patients who smoke, and the general lack of a knowledge base about e-cigarettes held by most PCPs. There were two important points that were clear from the interviews: PCPs believe that e-cigarettes are a safer alternative to smoking combustible tobacco products, and although they did not typically seem to be recommending e-cigarette use to their patients, their concerns regarding the potential harms of e-cigarettes are abandoned in highly addicted patients and those with extensive comorbidities. In other words, PCPs' decision to recommend e-cigarettes seemed to be influenced by their patients' tobacco use profile and PCPs' perceived level of addiction of those patients.

Another important finding was that at least some PCPs seemed to consider their patients' interest in trying e-cigarettes, suggesting that PCPs adopting a patient centered approach could be incorporating e-cigarettes into their clinical practice. Nevertheless, these findings were drawn from a small sample of PCPs practicing in two settings in Virginia. Thus, there was a need to test the different assumptions and findings in a larger and more diverse sample of PCPs.

Building on these findings, the aims of my second study were to estimate the prevalence of PCPs who recommend e-cigarettes to their patients as a smoking cessation aid or as a harm reduction strategy and to identify PCPs' beliefs, e-cigarette-related knowledge, and other factors associated with their recommending e-cigarettes to their adult patients who smoke. Through mailed surveys to a national sample of office-based PCPs, these aims were addressed. Findings from this study indicated that PCPs' recommendations of e-cigarettes have become commonplace in primary care practice settings for smoking cessation as well as for harm reduction. Furthermore, results from my survey confirmed that PCPs are not only being asked by their patients about e-cigarettes, as previous studies have indicated, [31-33] but also that PCPs themselves are initiating such discussions and those who reported initiating discussions were more likely to recommend e-cigarettes which reflects that there could be some PCPs who actively advocate for e-cigarette use. PCPs' recommendations of e-cigarettes to their adult patients who smoke were mainly associated with having favorable beliefs towards e-cigarettes' ability to help patients quit smoking, be exposed to less harm than as from other tobacco products, and reduce second hand smoke exposure to other people. Those PCPs seemed to decide intuitively rather than factually, given their lack of correct information, which is a common decision-making process in cases of uncertainty.[148] PCPs who reported recommending e-cigarettes were also more likely to take patients' interest in using e-cigarettes in consideration.

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However, PCPs -regardless of whether or not they recommended e-cigarettes to their patients who smoke- had limited knowledge about the features and potential harms of e-cigarettes, and often did not know that e-cigarettes are not regulated by the United States Food and Drug Administration. Collectively, this could mean that PCPs are being influenced by industry marketing rather than relying on the limited evidence-based sources available regarding e-cigarettes. Results from this study, therefore, highlighted the need to disseminate the existing knowledge regarding the potential harms and benefits of e-cigarettes to PCPs so that they can accurately discuss e-cigarettes with their patients. Without such knowledge, neither physicians nor patients can make informed decisions regarding e-cigarette use.

In my last study, I used a conceptual model that was informed by the Theory of Reasoned Action (TRA); which proposes that physicians' behavioral intent, in this case the intention to recommend e-cigarettes to their patients who smoke, is determined by both attitudes and subjective norms. I supplemented these TRA domains with the domain of patient interest from the Model of Medical Decision Making and findings from my formative research to predict PCPs' intentions to recommend e-cigarettes. This was done using the same physician sample and cross-sectional survey employed in my second paper. It is important to note that patient interest in treatment was significant in all of the analysis I performed throughout the dissertation. This finding illustrates the likely influence of patient preferences in the context e-cigarettes,[148] and the need to better understand how patient beliefs and preferences regarding e-cigarettes are being formed.

Of interest here were not only the factors that drive physicians overall intent to recommend e-cigarettes, but whether the intent and the factors behind that intent may vary across different types of patients. The types of patients considered were classified based on nicotine

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dependence levels (heavy versus light smokers), willingness to quit, and prior quit attempts. Each of these was identified as a potentially important tobacco use attribute in my formative research.

The overall PCPs' intentions to recommend e-cigarette use was significantly associated with the PCPs' total attitudes and subjective norms, consideration of patients' interest, e-cigarette relative harm perception and e-cigarette knowledge. However, PCPs' propensity to intend to recommend e-cigarettes to their patients varied by patient type, as well as the factors fuelling those intentions. PCPs' perception of e-cigarettes potential to decrease patients' cancer risk, as well as consideration of patients' interest in trying e-cigarettes differentiated the five patient types I included in the study. On the other hand, PCPs' belief that e-cigarettes can help patients quit smoking was associated with all patient types. While such personalization is consistent with patient centered care, there could also be unintended consequences like potentially initiating dual use or sustaining nicotine addiction in patients who are already heavily dependent on nicotine. Moreover, this variability in recommendation intention by patient type mimics PCPs' practice with conventional smoking cessation aids. Despite the fact that being a light smoker does not carry substantially less risk compared to being a heavy smoker,[62] PCPs seem to perceive the risk to be different, and act accordingly. For example, in my qualitative interviews in phase one, a PCP mentioned that " *The people who are smoking like a pack a day and really chimneys, I'm like you want anything that you can do that's an action that gets in the right direction. So I usually am pretty encouraging of it in that setting*"[109]. This highlights the perception that smoking more cigarettes is more harmful than smoking fewer cigarettes per day and therefore warrants a need to recommend anything including e-cigarettes for this particular population.

Taken together, findings from these three studies have important implications for both research and practice. Of particular note is the general lack of what limited factual information there is regarding e-cigarettes among PCPs. There is a need for comprehensive mapping of PCPs' sources of information, as well as their preferred channels of communication, in order to know how to effectively disseminate e-cigarette information to PCPs. Differences in nicotine delivery and other features of e-cigarettes might pose complexity for physicians' information gathering, and eventually their decision making. As was noted in the second study, the assessment of the actual impact of a PCP's recommendation to a patient to use e-cigarettes has yet to be explored. This seems important as it has been suggested that physician-patient communication regarding e-cigarettes might be shaping patients' perception and their decision to use e-cigarettes.[33]

My findings also indicated a need for more in-depth research regarding how PCPs are incorporating e-cigarette recommendations in clinical practice. While results from my dissertation research indicated clearly that physicians are advocating for the use of e-cigarettes for some patients, my research was unable to determine whether such recommendations are being made as first line therapies for particular types of patients or only after other evidence-based therapies have been exhausted. Additionally, I was unable to ascertain whether there are specific subgroups of patients with whom PCPs are more likely to introduce the idea of trying e-cigarettes. Likewise, we have a limited understanding of the dynamics and conversational context of patient-physician e-cigarette discussions and how those may impact physician recommendations or patient adherence to those recommendations. PCPs appear to be applying their usual counseling techniques regarding e-cigarettes, which are routine and familiar. This approach could misguide patients' use of such products or render current tobacco use counseling

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ineffective. Finally, there is a need for further studies to better understand the risk and benefit profile of e-cigarettes in order to inform PCPs and patients alike.

Despite the efforts of some US cities to regulate e-cigarettes use and marketing, there are no approved or pending regulatory actions as of yet on a country level in the US. Other countries have taken drastic measures to limit e-cigarette advertising and vaping in public. For example, the European parliament issued a ban on e-cigarette advertising that is scheduled to go into effect in the 28 European union countries in 2016.[49] PCPs in the US are well positioned to serve as strong advocates and partners with public health organizations like the American Lung Association to lobby for quick and strict measures that could eventually limit the exponential spread of e-cigarette use among smokers and non-smokers. Taking such early stance is important given that active, or passive, approval of e-cigarettes by PCPs could help spread e-cigarette use as was the case with conventional cigarettes in the forties and fifties. [149] The current silence from the regulatory US-authorities, approval of and recommendation by some physicians and the widespread advertising and marketing of e-cigarettes could be misperceived by the public as a proof of e-cigarette safety. In fact e-cigarette diffusion mimics that of dietary supplements where despite the lack of rigorous empirical evidence or FDA regulation[150] products are heavily marketed,[151] and PCPs recommend them to their patients.[152] The result has been continued use of these products among US consumers. [151]

My results also have immediate practice implications which could be addressed while the evidence base surrounding the impact of e-cigarettes on patient health and other outcomes continues to evolve. Collectively, my results pointed to a clear lack of knowledge regarding e-cigarettes among PCPs. In particular, there appears to be a void in knowledge regarding known potential risks and harms associated with e-cigarette use. Existing position statements of clinical

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care organizations in the United States, while silent on many factors pertaining to e-cigarettes, all advocate for clinicians to discuss available albeit limited evidence with their patients. If clinicians are not informed of what is currently known regarding both the potential benefits and harms associated with e-cigarettes, they cannot be in a position to have such conversations and thus to support their own and their patients' informed decision making. Such information needs to be communicated efficiently on a continual basis given the rapidly evolving evidence base. Additional efforts are needed to correctly inform the public about e-cigarettes to help them make an informed decision about its use and because it seemed that their perceptions are also shaping PCPs' perceptions and decisions.

Appendix 1: Semi-structured Interviews Consent Form

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Impact of E-cigarettes on Physician Recommendations of Tobacco Use Cessation Pharmacotherapy in Primary Care

VCU IRB NO.: HM20000547

If any information contained in this consent form is not clear, please ask the study staff to explain any information that you do not fully understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE OF THE STUDY

The purpose of this research study is to find out about physicians attitudes and practice pertaining to tobacco use cessation counseling in primary care practice. You are being asked to participate in this study because you are a primary care physician.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to you.

In this study you will be asked to complete one in-person interview. The interview will last about 45 minutes to 1 hour. In the interview you will be asked about your practice regarding tobacco use cessation counseling recommendations and your perspective about cessation aids.

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The interview will be audio recorded so we are sure to get all the information. The audio recording will not be shared with others and no names will be recorded on the tape.

Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

RISKS AND DISCOMFORTS

We do not expect that you will experience any risks or discomforts by participating. If there are any questions that make you uncomfortable or that you do not want to talk about, you do not have to answer. You may decide to discontinue the interviews at any time. If you become upset, the study staff will give you names of counselors to contact so you can get help in dealing with these issues.

BENEFITS TO YOU AND OTHERS

You may not get any direct benefit from this study, but, the information we learn from participants in this study may help to improve tobacco use cessation counseling for patients and physicians in the future.

COSTS

There are no costs for participating in this study other than the time you will spend being interviewed.

PAYMENT FOR PARTICIPATION

You will receive a $35 gift card as a thank you for your participation in the interview.

ALTERNATIVES

Taking part in this research study is voluntary. Instead of being in this research study, you have the following option:

- Decide not to participate in this research study

CONFIDENTIALITY

Your confidentiality is very important to us. Potentially identifiable information about you will consist of audio recordings and transcriptions of interviews. Data is being collected for research purposes only. Your data will be identified by ID numbers, not names, and stored separately from medical records in a locked research area. All study related documents and audio tapes will be stored in a secure location until the study has ended and all data analyses is complete. At that time, all study material will be placed in a secured long term storage facility until it is deemed appropriate to destroy the study material.

The results of this research study may be presented at meetings or published, but your name will not ever be used in these presentations or papers.

We will not tell anyone the answers you give us; however, the consent form signed by you may be looked at or copied for research or legal purposes by Virginia Commonwealth University.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

You do not have to participate in this study. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study.

Your participation in this study may be stopped at any time by the study staff without your consent. The reasons might include:

- the study staff thinks it necessary for your health or safety;

- you have not followed study instructions; or

- administrative reasons require your withdrawal.

If you are removed from the research study, the research Investigator will explain to you why you were removed

QUESTIONS

If you have any questions, complaints, or concerns about your participation in this research, contact:

Omar El Shahawy, MBBCh, MPH (804) 628-2997 or

Jennifer Elston Lafata, PhD (804) 628-3293

The researcher and study staff named above are the best persons to call for questions about your participation in this study.

If you have any general questions about your rights as a participant in this or any other research, you may contact:

Office of Research

Virginia Commonwealth University

800 East Leigh Street, Suite 3000

P.O. Box 980568

Richmond, VA 23298

Telephone: (804) 827-2157

Contact this number for general questions, concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk with someone else.

General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.

CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

 Participant name printed   Participant signature   Date

_____

Name of Person Conducting Informed Consent

Discussion / Witness

(Printed)

_____ _____

Signature of Person Conducting Informed Consent   Date

Discussion / Witness

_____ _____

Principal Investigator Signature (if different from above)   Date

Appendix 2: Cognitive Interviews Consent Form

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Impact of E-cigarettes on Physician Recommendations of Tobacco Use Cessation Pharmacotherapy in Primary Care

VCU IRB NO.: HM20000547

SPONSOR: American Lung Association

If any information contained in this consent form is not clear, please ask the study staff to explain any information that you do not fully understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE OF THE STUDY

The purpose of this research study is to find out about physicians attitudes and practice pertaining to tobacco use cessation counseling in primary care practice. You are being asked to participate in this study because you are a primary care physician.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to you.

In this study you will be asked to complete one in-person interview. The interview will last about 45 minutes to 1 hour. In the interview you will be asked about your understanding of a series of questions and their relevance regarding tobacco use cessation counseling

recommendations and how these questions capture your prespective pertaining to cessation aids. The interview will be audio recorded so we are sure to get all the information. The audio recording will not be shared with others and no names will be recorded on the tape.

Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

RISKS AND DISCOMFORTS

We do not expect that you will experience any risks or discomforts by participating. If there are any questions that make you uncomfortable or that you do not want to talk about, you do not have to answer. You may decide to discontinue the interviews at any time. If you become upset, the study staff will give you names of counselors to contact so you can get help in dealing with these issues.

BENEFITS TO YOU AND OTHERS

You may not get any direct benefit from this study, but, the information we learn from participants in this study may help to improve tobacco use cessation counseling for patients and physicians in the future.

COSTS

There are no costs for participating in this study other than the time you will spend being interviewed.

PAYMENT FOR PARTICIPATION

You will receive a $35 gift card as a thank you for your participation in the interview.

ALTERNATIVES

Taking part in this research study is voluntary. Instead of being in this research study, you have the following option:

- Decide not to participate in this research study

CONFIDENTIALITY

Your confidentiality is very important to us. Potentially identifiable information about you will consist of audio recordings and transcriptions of interviews. Data is being collected for research purposes only. Your data will be identified by ID numbers, not names, and stored separately from medical records in a locked research area. All study related documents and audio tapes will be stored in a secure location until the study has ended and all data analyses is complete. At that time, all study material will be placed in a secured long term storage facility until it is deemed appropriate to destroy the study material.

The results of this research study may be presented at meetings or published, but your name will not ever be used in these presentations or papers.

We will not tell anyone the answers you give us; however, the consent form signed by you may be looked at or copied for research or legal purposes by the sponsor of the research, or by Virginia Commonwealth University.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

You do not have to participate in this study. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study.

Your participation in this study may be stopped at any time by the study staff without your consent. The reasons might include:

- the study staff thinks it necessary for your health or safety;

- you have not followed study instructions;

- the sponsor has stopped the study; or

- administrative reasons require your withdrawal.

If you are removed from the research study, the research Investigator will explain to you why you were removed

QUESTIONS

If you have any questions, complaints, or concerns about your participation in this research, contact:

Omar El Shahawy, MBBCh, MPH (804) 628-2997 or

Jennifer Elston Lafata, PhD (804) 628-3293

The researcher and study staff named above are the best persons to call for questions about your participation in this study.

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CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

 Participant name printed   Participant signature   Date

_____

Name of Person Conducting Informed Consent

Discussion / Witness

(Printed)

_____ _____

Signature of Person Conducting Informed Consent   Date

Discussion / Witness

_____ _____

Principal Investigator Signature (if different from above)   Date

A National Survey of Primary Care Physicians in the United States About E-cigarettes

Instructions

- We would like to know your opinions and ideas about e-cigarettes. Please answer each of the following questions **whether or not** you have previously discussed or recommended e-cigarettes to your adult patients.

- There **are no right or wrong answers**, we want to know your personal opinion as a practicing physician.

- Questions in this survey pertain to **your adult patients who smoke any type of tobacco.** The survey takes approximately 15-20 minutes to complete. Upon return of your completed survey, you will receive a $10 gift card of your choice as a small "thank you" for your help with the study.

- You may use a **pen or pencil** to complete this survey.

- Please mark your answers as follows:

  Correct marking= ●   Incorrect marking = ⊠ ⊘ ⊖

- Unless instructed otherwise, **mark only one answer** per item.

- Some questions may seem similar, but please answer each question.

- Your answers are strictly **confidential**; please **do not** put your name on the survey.

Thank you very much for taking the time to complete this survey!

Please return the completed survey in the enclosed stamped envelope.

Section One: E-cigarette Discussions and Experiences

1. Have you <u>ever discussed</u> *e-cigarettes* with your adult patients who smoke?

   ○ **No** → Go to question #**2**

   ○ **Yes** → *How often have you discussed e-cigarettes with your patients?*   → <u>When you discuss e-cigarettes with your patients, who usually raises the topic?</u>

○ **Rarely**	○ **I usually raise the topic**
○ **Sometimes**	○ **My patients usually raise the topic**
○ **Often**	○ **It is equally as likely that I or my patients raise the topic**
○ **Almost always**	

2. <u>Over the *PAST* three months,</u> how often have you **recommended** e-cigarettes to any of your adult patients who smoke?

	Never	Rarely	Sometimes	Often	Almost Always
For smoking cessation	0	1	2	3	4
For harm reduction	0	1	2	3	4

3. We are interested in knowing your thoughts about the impact of recommending e-cigarettes to adult patients who smoke. **In general**, do you think your recommending e-cigarettes to patients is …..

Harmful			Neither			Beneficial
1	2	3	4	5	6	7

Valuable			Neither			Worthless
1	2	3	4	5	6	7

Bad Practice			Neither			Good practice
1	2	3	4	5	6	7

Pleasant			Neither			Unpleasant
1	2	3	4	5	6	7

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4. How likely is it that your patients' use of e-cigarettes would result in each of the following?

	Very Unlikely			Neither Likely Nor Unlikely			Very Likely
Sustain their nicotine dependence	①	②	③	④	⑤	⑥	⑦
Help them to quit smoking	①	②	③	④	⑤	⑥	⑦
Limit secondhand smoke exposure to their families and friends	①	②	③	④	⑤	⑥	⑦
Decrease their cancer risk	①	②	③	④	⑤	⑥	⑦
Make patients less likely to use conventional cessation medications	①	②	③	④	⑤	⑥	⑦

5. Please indicate your level of agreement with each of the following statements.

	Strongly Disagree			Neither Disagree Nor Agree			Strongly Agree
I feel under pressure to recommend e-cigarettes to my patients	①	②	③	④	⑤	⑥	⑦
Screening for e-cigarette use is as important as screening for traditional cigarette use	①	②	③	④	⑤	⑥	⑦
E-cigarette use can create dual tobacco users	①	②	③	④	⑤	⑥	⑦
I am concerned about future litigation if/when I recommend e-cigarettes	①	②	③	④	⑤	⑥	⑦
Most people who are professionally important to me recommend e-cigarettes	①	②	③	④	⑤	⑥	⑦

6. Over the _NEXT_ three months, how likely are you to recommend e-cigarettes to each of the following types of patients?

	Not at All Likely			Neither			Very Likely
Heavy smokers refusing to quit	①	②	③	④	⑤	⑥	⑦
Light smokers wanting to quit	①	②	③	④	⑤	⑥	⑦
Former smokers with a recent relapse	①	②	③	④	⑤	⑥	⑦
Smokers with prior unsuccessful quit attempts	①	②	③	④	⑤	⑥	⑦
Smokers with COPD	①	②	③	④	⑤	⑥	⑦
Heavy smokers wanting to quit	①	②	③	④	⑤	⑥	⑦
Light smokers refusing to quit	①	②	③	④	⑤	⑥	⑦
Smokers with a previously diagnosed mental illness	①	②	③	④	⑤	⑥	⑦

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7. Please indicate the extent to which each of the following groups disapprove or approve of your recommending
e-cigarettes to your patients who smoke.

	Disapprove			Neither			Approve
Specialty physicians to whom I refer my patients	①	②	③	④	⑤	⑥	⑦
The professional societies to which I belong	①	②	③	④	⑤	⑥	⑦
My primary care physician colleagues	①	②	③	④	⑤	⑥	⑦
My patients who smoke	①	②	③	④	⑤	⑥	⑦
Most people whose opinion I value in my profession	①	②	③	④	⑤	⑥	⑦

8. Please indicate the extent to which you agree or disagree with each to the following statements.

	Strongly Disagree			Neither Agree Nor Disagree			Strongly Agree
Whether I recommend e-cigarettes to my patients, is entirely up to me	①	②	③	④	⑤	⑥	⑦
I am confident I could recommend e-cigarettes if I wanted to	①	②	③	④	⑤	⑥	⑦
Recommending e-cigarettes to my patients is easy to do	①	②	③	④	⑤	⑥	⑦
I am confident in my ability to counsel patients about **e-cigarettes use**	①	②	③	④	⑤	⑥	⑦
I am confident in my ability to counsel patients about **tobacco use in general**	①	②	③	④	⑤	⑥	⑦

9. How much does each of the following factors affect the difficulty/ease of you recommending e-cigarettes to your patients who smoke?

	Makes it Very Difficult			Neutral			Makes it Very Easy
The current safety standards for e-cigarettes	①	②	③	④	⑤	⑥	⑦
Patients' interest in trying e-cigarettes	①	②	③	④	⑤	⑥	⑦
Currently available information on e-cigarettes	①	②	③	④	⑤	⑥	⑦
Time available for tobacco use counseling during office visits	①	②	③	④	⑤	⑥	⑦
My current knowledge of e-cigarettes	①	②	③	④	⑤	⑥	⑦

You are now done with two sections! Please keep going.

Section Three: E-cigarettes in relation to tobacco products and tobacco dependence treatment

10. How harmful are the following tobacco products to the health of your patients?

	Not at All Harmful			Moderately Harmful			Extremely Harmful
Traditional cigarettes	①	②	③	④	⑤	⑥	⑦
Tobacco Pipes	①	②	③	④	⑤	⑥	⑦
Waterpipes (Hookah or Narghile)	①	②	③	④	⑤	⑥	⑦
E-cigarettes	①	②	③	④	⑤	⑥	⑦
Cigars, Cigarillos and Little cigars	①	②	③	④	⑤	⑥	⑦
Smokeless tobacco	①	②	③	④	⑤	⑥	⑦

11. We are interested in your knowledge of e-cigarettes. **Please indicate whether each of the following statements are true or false**	True	False	I Don't Know
E-cigarettes are currently regulated by the FDA	⊙	⊙	⊙
Some e-cigarettes can deliver more nicotine than traditional cigarettes	⊙	⊙	⊙
The nicotine liquid used in e-cigarettes contains carcinogens	⊙	⊙	⊙
E-cigarettes do not diminish lung function	⊙	⊙	⊙
Some e-cigarette brands do not deliver nicotine	⊙	⊙	⊙

Thanks, you are almost done with section three!

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12. What is your level of agreement with each of the following statements?

	Strongly Disagree		Neither Agree or Disagree			Strongly Agree	
E-cigarettes are a gateway to smoking among non-smokers	①	②	③	④	⑤	⑥	⑦
My patients' interest in e-cigarettes is/would be the primary reason for my recommending them	①	②	③	④	⑤	⑥	⑦
More FDA regulations for e-cigarettes would encourage me to recommend them	①	②	③	④	⑤	⑥	⑦

13. *The following questions are about you*.	**Yes**	**No**
Have you ever tried **traditional cigarettes?**	◌	◌
Have you ever tried **e-cigarettes?**	◌	◌

16. Have you used any tobacco product within the **last 30 days**? (check all that apply)

- ◌ **Yes, traditional cigarettes**
- ◌ **Yes, e-cigarettes**
- ◌ **Yes, other tobacco products**
- ◌ **No, but I used to smoke in the past**
- ◌ **No, and I have never smoked on a regular basis**

17. In general, how much would you trust information about medical topics from each of the following sources?

	Not at All	A Little	Some	A Lot
Peer-reviewed research studies	⓪	①	②	③
FDA publications/recommendations	⓪	①	②	③
Professional conferences/scientific meetings	⓪	①	②	③
Patients' experiences	⓪	①	②	③
The lay press	⓪	①	②	③
CDC publications/recommendations	⓪	①	②	③
US Preventive Services Task Force publications/recommendations	⓪	①	②	③
Your physician colleagues	⓪	①	②	③
Newsletters or other information sent to you from medical societies to which you belong	⓪	①	②	③

Thanks, you are almost done, only two pages left!

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The Next questions are about the patients you deliver care to and how you spend your time <u>in a typical week.</u>

Write a number in this box

18. <u>During a typical **week**</u>, approximately how many **adult patients** do you see? _____

19. What is the size of your practice?

Solo practice	○	Partner practice	○	3 - 5	○	6 - 10	○	11 or more	○

20. Which answer represents the most approximate percentage for each of the following?

	None	Less than 25%	25-49%	50-75%	More than 75%
How many of the patients you see in a typical week do you consider to be your regular patients?	○	○	○	○	○
During a typical week, approximately how much of your professional time do you spend providing primary care to adult patients?	○	○	○	○	○

More about You

21. Have you ever **received formal training in smoking cessation counseling**?
    - ○ Yes
    - ○ No

22. Do you have an **affiliation with a medical school, such as an adjunct, clinical, or other faculty appointment**?
    - ○ Yes
    - ○ No

23. What is your **gender**?
    - ○ Male
    - ○ Female

Write in this box

24. What is the **year of your birth**? **19** _____

25. What is your **ethnicity**?
    - ○ Hispanic or Latino
    - ○ Not Hispanic or Latino

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26. What is your **race**? (Check all that apply)

- ☉ White
- ☉ Black/African American
- ☉ Asian
- ☉ Native Hawaiian/other Pacific Islander
- ☉ American Indian/Alaska native

27. In what year did you start practicing medicine, after completing residency or fellowship?

Write in this box

> _____

Your Gift Card Selection

28. What kind of gift card would you like?

- ☉ Amazon
- ☉ Target

Thank you very much for completing the survey.

Please return the completed survey in the enclosed stamped envelope.

<u>or mail it to:</u>

Omar El-Shahawy
830 East Main street (9th floor)
Social and Behavioral Health Department
School of Medicine
Virginia Commonwealth University
PO Box 980149
Richmond, VA, 23298

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Vita

Omar El Shahawy was born on November 5th, 1977 in Cairo, Egypt and is an Egyptian citizen. He obtained his medical degree at the University of Ain Shams in Cairo, Egypt, in 2002 and his Master of Public Health (with Merit) in international health development from the Royal Tropical Institute and the Vrjie University in Amsterdam, The Netherlands, in 2007. He first came to VCU as a Hubert Humphrey Fellow in 2010, a training fellowship supported by the U.S. Department of State and the National Institute on Drug Abuse. During his Fellowship, he enhanced his experience in drug abuse policy and prevention, with a particular focus on gender issues in adolescent and marginalized groups. He also collaborated on a number of research projects with different universities across the United States. Later on, he joined the doctoral program at the Department of Social and Behavioral Health at VCU. While at the Program, he published seven manuscripts and presented his research in a number of conferences in the United States and abroad. Omar also received a number of travel awards in addition to the Massey Cancer Center and the Department of Health Behavior and Policy Dissertation awards. His current research interests include novel tobacco products, water-pipe tobacco, smoking cessation, and patient–physician decision-making.

<u>**Publications**</u> (* indicates primary data)

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