An Original Survey Assessing E-Cigarette Regulation and Perceptions in all North Carolina Hospitals: A Research Design Proposal

By

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Abstract

Introduction: E-cigarettes are devices that heat a liquid solution, typically containing nicotine, to generate a vapor and simulate the act of smoking. Since first marketed in 2004 as a potential smoking cessation tool, use has become increasingly controversial, as data on safety and efficacy are limited. A movement toward establishing tobacco-free campuses has emerged among U.S. hospitals, but the extent to which e-cigarettes have been included in such policies has not been systematically researched. This master's paper offers a research design proposal for an online survey containing questions on tobacco and e-cigarette policy and perceptions which would be distributed to administrators in all North Carolina Hospitals.

Background: The literature on e-cigarettes is quickly expanding, but is still markedly limited. In lieu of federal regulatory policy, many states, such as North Carolina, have adopted their own policies, most commonly to prohibit the sale of e-cigarettes to minors. In April, 2014, the FDA declared its intent to make e-cigarettes subject to a series of stronger regulations; however, the proposed regulatory activity may not take effect for several years, if at all. On local levels, some hospitals, workplaces, and schools are beginning to include electronic cigarettes in tobacco-free campus policies, but the pervasiveness of this trend has not been systematically researched.

Purpose: This survey will examine what percentage of hospitals in N.C. have created policy regulating the use of electronic cigarettes on campus, where e-cigarette use is prohibited for those hospitals with existing policy (e.g. indoors only, indoors and on grounds), and which factors are motivators for and barriers to the creation of policy regulating use of e-cigarettes.

Methods: A 30-item online questionnaire that will be distributed via e-mail to administrators in all N.C. hospitals by the North Carolina Hospital Association in July-August, 2014. The survey contains questions on hospital tobacco policies and e-cigarette policies, motivators for and barriers to e-cigarette policy development, perceptions of e-cigarette safety, and how policies are communicated by hospital administration to hospital staff, patients, and visitors.

Anticipated Findings: We hypothesize that despite the tobacco-free campuses established by all N.C. hospitals, a majority of hospitals have not yet included any regulations prohibiting the use of electronic cigarettes on campus. A secondary hypothesis is that hospitals with stronger tobacco use treatment programs will have advanced regulations on the use of e-cigarettes more than those without strong treatment programs.

Discussion and Conclusions: Literature on e-cigarettes as a smoking cessation tool is limited, and federal regulation has been in a state of flux for several years. The FDA has recently called for a much stricter set of regulations for e-cigarettes, but NC hospitals would presumably not be affected for several years. Our results offer the opportunity for NC hospitals to work toward establishing uniform guidelines for e-cigarette regulation by learning for the experiences of peers, and may also be of value to public health stakeholders at multiple levels.

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An Original Survey Assessing E-Cigarette Regulation and Perceptions in all North Carolina Hospitals: A Research Design Proposal

Introduction

Electronic cigarettes (also called e-cigarettes, e-cigs, or electronic nicotine delivery systems) are battery-powered devices that heat a liquid solution, typically containing nicotine, to generate a vapor and simulate the act of smoking. E-cigarettes were first marketed in China in 2004 as a potential new tool for smoking cessation, and less than a decade later their use is exploding worldwide, with sales expected to approach $2 billion in 2013. E-cigarette use is controversial, though, as information on safety and efficacy is limited, and regulation of E-cigarettes is in a state of flux (Pepper & Brewer, 2013). There is also concern among public health officials that e-cigarettes may serve as a 'gateway' product to future smoking, particularly among adolescents who have never tried traditional cigarettes (Pepper, McRee, & Gilkey, 2013). Some also contend that electronic cigarettes may actually prevent smokers from quitting by continuing to perpetuate nicotine addiction, or deterring users from using tools already proven to be effective for cessation (Grana, 2013).

Over the last decade, a movement toward establishing tobacco-free campuses has emerged among U.S. Hospitals (Goldstein, 2009). The Joint Commission reported in 2009 that 45% of hospitals had adopted "smoke-free campus" policies by February 2008, with another 15% reporting that they would soon implement similar policies (Williams, Hafner, Morton et al., 2009). The American Nonsmokers' Rights Foundation reported in January 2014 that at least 3,810 local and/or state/territory/commonwealth hospitals, health care systems, and clinics had adopted 100% smoke-free campus grounds policies, "including but not limited to facility buildings, outdoor areas, and parking lots" (Accessed online, no page number available). However, research examining how many facilities have created regulations for the use of

electronic cigarettes, or added e-cigarettes to existing tobacco-free campus policies, is lacking. Additionally, it is unclear what factors motivate the development of such policy or serve as barriers to development, how policies may have been communicated to staff, patients and visitors, and what level of success hospitals have had in implementing regulations on e-cigarette use.

This master's paper offers a research design proposal for an online survey containing questions on tobacco and e-cigarette policy and perceptions that would be distributed to hospital administrators in all North Carolina Hospitals.

Background

The "smokeless non-tobacco cigarette" was invented by Herbert A. Gilbert in 1963, and the device heated a nicotine solution to produce steam ("Smokeless non-tobacco Cigarette", 2014). Despite receiving a patent in 1967, the device was never commercially manufactured, and a Chinese pharmacist named Hon Lik is actually credited with inventing the modern electronic cigarette in 2003 (Demick, 2009). A graphic representation of an electronic cigarette is provided below in *Figure 1*, outlining the main components and functionality. There is dramatic variation in the way E-cigarettes have been regulated worldwide, ranging from no restrictions on producers or consumers to wholesale bans of use and distribution (Bullen et al., 2013). Here, I will review the most pertinent existing literature on e-cigarettes, as well as how they have been regulated in the United States.

A Brief Overview of Existing Literature on E-Cigarettes

The existing literature on e-cigarettes is quickly expanding, but is still markedly limited. A small number of studies have been conducted to examine acute health effects of e-cigarettes such as cardiovascular risk, short term pulmonary effects, changes in complete blood count

(CBC), effects of secondary exposure to "vapor," and others. Researchers have also attempted to analyze the contents of various e-cigarettes, or whether indoor air quality is affected by their vapor. One large randomized control trial concluded that "E-cigarettes…were modestly effective at helping smokers to quit, with similar achievement of abstinence as with nicotine patches, and few adverse events," but ultimately stated that more research was needed for evidence-based guidelines to be developed (Bullen, Howe, McRobbie et al., 2013, p 269).

Overwhelmingly, the largest amount of existing literature on e-cigarettes pertains to users' preferences, beliefs on safety and efficacy, experience, and awareness, and a systematic review of this literature was published in November 2013 (Pepper and Brewer, 2013). Forty-nine studies published between 2006 and July 1, 2013 were ultimately included by the authors Exclusion criteria included articles not published in English, articles unrelated to electronic nicotine delivery systems (ENDS), dissertation abstracts and articles without original data on prespecified outcomes. Based on the data synthesis from three large national surveys, awareness of e-cigarettes in the United States more than tripled from 2009 to 2011, increasing from 16% to 58%, and use of E-cigarettes increased from 1% to 6%. Current smokers, men, those of younger age, and whites were more likely to have heard of e-cigarettes. The International Tobacco Control (ITC) Four-Country Survey (from 2010-2011) of current and former smokers reported that awareness was higher in the USA (73%) and UK (54%) than in Canada (40%) or Australia (20%), likely because e-cigarettes can be legally marketed and purchased in the USA and UK (Adkison, O'Connor, Bansal-Travers et al., 2013). A Polish survey suggested that e-cigarettes serving as a "gateway" to cigarettes may be a real concern. In a survey of 179 Polish users of E-cigarettes in 2009, 25 were reportedly non-smokers prior to trying an E-cigarette, and 5 of these (20%) were regularly smoking cigarettes by 2013 (Goniewicz, Lingas, Hajek, 2013). Data on the perceived cost of e-cigarettes among users are limited and often conflicting, though most dedicated users seem to believe they are cheaper than conventional cigarettes. In numerous studies, a large percentage of users reported

positive changes in their health after beginning use of an e-cigarette. Many reported improved breathing, reduced coughing, fewer sore throats, and improved overall health and fitness (presumably vs. conventional cigarette smoking). Some negative side effects have also been reported. As of early 2012, 47 case reports of adverse events have been received by the FDA, with 8 classified as serious adverse events (e.g. pneumonia, chest pain.) (Chen, 2013). In an online e-cigarettes forum, 326 of the 405 total health effects reported were ultimately negative, and the most frequently reported problems involved the mouth, throat, respiratory system, and neurological system (Hua, Alfi, and Talbot, 2013). In pooled data, the majority of reported side effects were minor, and included cough, mouth or throat irritation/dryness, vertigo, headaches, and nausea. Many of the side effects reported at baseline (often at the initiation of e-cigarette use) had resolved completely by the end of the respective study periods. The majority of people using e-cigarettes with a goal of smoking cessation reported that e-cigarettes either helped them quit or “reduce” use of traditional tobacco products, though Pepper and Brewer feel that a reduction may not actually be a positive public health outcome, as this could represent dual use of e-cigarettes and traditional cigarettes. While it is unclear whether a large number of people use e-cigarettes to circumnavigate smoking restrictions, 36% of users in one survey said they frequently use e-cigarettes in areas where smoking is banned (Dawkins, Turner, Roberts et al., 2013). In a survey at a convention of e-cigarette enthusiasts (n = 104), 90% said they were able to use e-cigarettes where smoking was banned (Foulds, Beldheer, and Berg, 2011). In a survey in e-cigarette users from a number of countries, a large number of people reported using e-cigarettes at work (71%), or in cafes, restaurants, or bars (43%), though Pepper and Brewer find these results difficult to interpret given varying smoking restrictions in each country (Etter and Bullen, 2013). Though in some surveys few report avoiding smoking restrictions as a motivating factor, pooled data from 3 surveys suggests that up to 40% use e-cigarettes for this reason. In general, reported satisfaction with e-cigarettes was very high, especially among committed users. Those who used e-cigarettes in prospective trials had more mixed reactions.

Concerns were sometimes reported about the quality of e-cigarettes, including broken/malfunctioning components and leaky cartridges. The vast majority of users reported that they enjoyed the taste of e-cigarettes. Many also reportedly commented that they enjoyed the similarity of use of e-cigarettes to regular cigarettes, and that they used them much in the same way (e.g. after a meal). Overall, about two-thirds found e-cigarettes equally or more satisfying than traditional cigarettes. Most current and former smokers reported that e-cigarettes helped reduce their urge to smoke as well as some withdrawal symptoms. The majority of users believe that e-cigarettes are healthier for both themselves and others than regular cigarettes, and use them at least in part for this reason. Only a vast minority of users appear to be concerned about potential negative health effects or toxicity of e-cigarettes. The majority of users also believe that e-cigarettes can help people to quit or reduce smoking, and this is another major factor in motivation for use. Most using e-cigarettes for smoking cessation/reduction reported that they would recommend them to friends or family for the same purpose. Most users believe that e-cigarettes are less addictive than smoking. A majority of current smokers who have never tried e-cigarettes believe that e-cigarettes could satisfy their desire to smoke. Pepper and Brewer report three important additional themes observed regarding beliefs of users. First, many users are concerned about personal appearance (e.g. yellow teeth, odors/not smelling like smoke). Next, e-cigarette users actually feel a sense of camaraderie with each other – online forums are exploding, and many reportedly attend conventions. Last, some users express concern that e-cigarettes will be banned (though Pepper and Brewer state that they found no arguments by users that e-cigarettes should be exempt from smoke-free indoor air laws). Ultimately, the authors conclude that with e-cigarette use exploding despite potential concerns, more research is needed on perceived risk, effective public health messages, validity of self-reported cessation, and on different types of e-cigarettes (Pepper and Brewer, 2013).

Providers' beliefs and perceptions of e-cigarettes have been less studied. One study conducted a state-wide survey in Minnesota of 567 primary care physicians and nurse practitioners providing care for adolescents aged 11-17 years (Pepper, McRee, & Gilkey, 2013). 3923 providers were invited to participate in April 2013, and a total of 615 completed the online, cross-sectional survey (adjusted response rate of 28%). Questions were developed based on researchers previous work with adolescents, and piloted with 5 physicians prior to the study. Questions were aimed at assessing physicians' awareness of e-cigarettes, comfort level in discussing them with adolescent patients, risk beliefs, communication, and desire to receive further education on e-cigarettes. The participants also provided demographic and practice characteristics, provider type, year of training completion, and number of adolescent patients. Ultimately, 561 survey responses were included in the analysis – 46% were family medicine physicians, 20% pediatricians, and 34% nurse practitioners. Almost all providers were aware of e-cigarettes (92%), and 11% had previously treated an adolescent who admitted having used e-cigarettes. Most providers obtained their knowledge on e-cigarettes from places other than professional sources, such as news stories, patients, and advertisements. Family medicine physicians knew relatively more about e-cigarettes than pediatricians and nurse practitioners, and also described being more comfortable discussing them with patients (both $p < 0.05$). Almost universally, providers reported an interest in learning more about e-cigarettes (92%). A similar study was conducted by researchers from the University of North Carolina's Tobacco Prevention and Evaluation Program (TPEP). This study collected data on the attitudes of North Carolina physicians toward e-cigarettes via an online survey (Ranney, Kandra, Lee, and Goldstein, 2014). The survey was distributed via e-mail to a random sample of 787 physicians (156 family physicians, 161 internal medicine physicians, 159 obstetricians/gynecologists, 160 psychiatrists, and 151 surgeons) in July 2013. 128 responses were collected, for a response rate of 31%. Among responding physicians, 67% believe e-cigarettes are helpful for smoking cessation, 65% believe e-cigarettes lower risk of cancer (vs. cigarettes), 35% currently

recommend e-cigarettes to patients, 13% believe e-cigarettes are FDA-approved for smoking cessation, and only 12% “frequently” ask patients about e-cigarettes (“sometimes “ = 36%, “rarely” = 31%, “never” = 20%).

Regulation of E-Cigarettes

In the United States, the FDA initially classified e-cigarettes as drug delivery devices, which would make them subject to regulation under the Food, Drug, and Cosmetic Act (FDCA) prior to importation and sale in the U.S., but this was ultimately overruled by a Federal District Court Judge in January 2010, who stated, “the devices should be regulated as tobacco products rather than drug or medical products” (Duff, 2010). The FDA appealed, citing the right to regulation of e-cigarettes based on their previous ability to regulate nicotine replacement therapies such as nicotine gum or patches, but the appeals court ruled against the FDA in a 3-0 unanimous decision (Duff, 2010). The FDA has therefore only been able to regulate e-cigarettes as tobacco products, and has no power to block their import (Duff, 2010).

In the absence of federal regulation, many states have adopted their own policies, most commonly to prohibit the sale of e-cigarettes to minors. New Jersey took a strong stance early on against E-cigarettes, deciding to include them in their Smoke-Free Air Act in 2009 (Livio, 2010). The legislation was sponsored by Assemblywoman Connie Wagnor, who claimed, "… young people who use these things will get hooked on the nicotine and eventually move onto the real thing” (Livio, 2010). In 2013, Mayor Bloomberg signed similar practice into law for New York City, mandating that electronic cigarettes be regulated in the same way as traditional cigarettes (Winsor, 2013). On local levels, some hospitals, workplaces, and schools are beginning to include electronic cigarettes in previously-established “smoke-free campus” policies, though the pervasiveness of this trend has not been well-researched.

In April 2014, the FDA issued a new set of recommendations that once again call for tighter regulation of e-cigarettes (Young, 2014). The new recommendations reportedly include

a minimum age of 18 years to purchase e-cigarettes, a requirement for health warnings on all e-cigarette packaging, and a banning of the sale of e-cigarettes in vending machines (Young, 2013). The recommendations also include mandates on manufacturers requiring all products and ingredients be registered with the FDA, an FDA review process prior to any marketing being permitted, and the provision of scientific evidence prior to any claims of risk reduction (Young, 2014). Implementation of this (or similar) legislation is unlikely to occur immediately following the 75-day public comment period, and most agree that a move in this direction is likely several years away from being put into practice (Young, 2013).

Some challenge the immediate need for tighter regulation, citing mounting evidence for therapeutic benefits and potential harms to public health if e-cigarettes are 'over-regulated,' and calling for officials to use caution in determining the appropriate balance (Saitta, Ferro, Pelosa, 2014). FDA commissioner Margaret Hamburg contends, "It's really the wild, wild West out there…they're coming in different sizes, shapes and flavors…and there's very worrisome data that show that young people in particular are starting to take up e-cigarettes…and that might be a gateway to other harmful tobacco products…but until we can really regulate them, we can't have all the information we need and we can't take all the actions that we might want to, to be able to best address the public health issues associated with them" (Young, 2013 – accessed online, no page number available).

Hypothesis and Specific Aims of this Research Proposal

A number of states, including North Carolina, have 100% smoke-free hospital campuses. Others, like New York and South Carolina, have committed to making all hospital campuses 100% smoke free. We hypothesize, however, that despite this commitment, a majority of hospitals have not yet included any of their own regulatory policy prohibiting the use of electronic cigarettes on campus, including in or outside of the hospital. A secondary

hypothesis is that hospitals with stronger tobacco use treatment programs will have more advanced regulatory policy governing the use of e-cigarettes on their campuses than will those without strong treatment programs.

The survey has the following aims:

1. To determine what percentage of hospitals in North Carolina have created policy explicitly regulating the use of e-cigarettes on campus.
2. To examine where e-cigarette use is prohibited for those hospitals with existing policy (e.g. indoors only, indoors and on grounds)
3. To examine which factors are motivators for and barriers to the creation of policy regulating use of e-cigarettes.

The proposed questionnaire will aid us as we seek to understand: Perceptions of hospital administrators on the safety of e-cigarettes; whether hospitals with an existing policy for e-cigarettes created an entirely new policy, or added e-cigarettes to an existing policy regulating the use of tobacco products; the policy development process; and how policy regulating the use of e-cigarettes has been communicated to employees, patients, and visitors. For hospitals which have not created a policy regulating e-cigarettes, the survey will gauge the future interest in creating such a policy. Finally, the survey will examine hospital policies regulating tobacco product use, and the existence of other tobacco use programs (e.g. for employee smoking cessation, inpatient/outpatient consult programs for patients) to attempt to draw correlations with the likelihood of having a policy regulating the use of e-cigarettes. These data will allow us to examine whether certain hospitals (e.g. those more advanced in their tobacco control policies) are more likely to have created policy explicitly regulating e-cigarette use.

Methods

Rationale

Many people misunderstand survey research, assuming that it is "easy" or "simplistic," when it is neither. A rigorous web-based survey of hospital administrators offers a number of advantages. Surveys can yield a large amount of empirical data in a short time, and at a very low cost (Kelly, Clark, Brown, and Sitzia, 2003, p. 262). Standardized measurement is consistent across respondents – that is, all participants are asked the same questions in exactly the same phrasing and format – making surveys are a reliable method of inquiry when constructed appropriately (Blackstone, 2012, accessed online – no page number provided). Surveys are also versatile, and can meet analytical needs by enabling data collection on all desired variables (Fowler, 2002, p. 3).

Specific to this project, there are a number of reasons why an online questionnaire made sense. Within the framework of a 1-year master's program, a central concern has obviously been the time required to complete a proposed master's project. The first author, a medical student, had no resources for a larger project. After developing an interest in e-cigarettes, and specifically with how they are being regulated in North Carolina's hospitals, I strongly considered two approaches for data collection: In-depth interviewing, or the creation of a web-based survey. In-depth interviewing has the potential advantage of introducing a strong qualitative element to the study, but there are several potential barriers to this approach.

The first is the sample size – there are over 120 hospitals in North Carolina, and conducting interviews with an official in each hospital in timely fashion was not feasible within the project timeline. If interviews were to be conducted in person, not only would time be a limiting factor, but also the cost of transportation, lodging, etc. (Kelly, Clark, Brown, and Sitzia, 2003, p. 262). Additionally, without precise, consistent delivery of the interview questions, the reliability and validity of my results would suffer (Blackstone, 2012 – accessed online, no page

number available). To meet the goal of generating a large amount of data in a short time at low to zero cost, and providing a clear picture of how e-cigarettes are being treated by NC hospitals at present, a web-based survey was the most appropriate research design.

Developing the Web-Based Questionnaire

Using the University of North Carolina's survey development software, Qualtrics, I created a 30-item online questionnaire with the help of my faculty advisor, Dr. Sue-Tolleson Rinehart of the Department of Pediatrics, School of Medicine, and the Gillings School of Global Public Health. Dr. Adam Goldstein of the UNC Department of Family Medicine, Director of UNC Tobacco Programs, is sponsoring my research, and has also assisted with creation of the survey. We created the survey to address the specific aim of determining whether hospitals have, or are creating, policies to regulate e-cigarette use. The survey contains questions on hospital tobacco policies and e-cigarette policies, motivators for and barriers to e-cigarette policy development, perceptions of e-cigarette safety, and how policies are communicated by hospital administration to hospital staff, patients, and visitors. A version of the online survey exported to Microsoft Word has been included in *Appendix B*.

Distribution, Completion, and Data Collection

The sample will include hospital administrators in North Carolina with knowledge of current tobacco use policies. One administrator per hospital will receive an e-mail message requesting participation in the survey. The North Carolina Hospital Association (NCHA) is supporting the project, and has agreed to distribute the survey to all hospitals because it, too, is interested in the results. The NCHA will distribute the invitation to participate in the survey in 3 rounds of e-mails. Each e-mail from the NCHA will include a custom introductory letter containing a link to the anonymous survey which we have provided to the NCHA, and a longer,

more detailed explanation of the project will also be included with each message as an attachment. Each of these documents can be viewed in *Appendix B*.

The survey respondents will complete the survey anonymously, and no respondent will be identified by name or by hospital. The initial invitation will be sent to hospital administrators in July, 2014. The second and third invitations will be sent at 7 and 14 days following the initial invitation, respectively. Data collection will end one month after the initial invitation to participate. After opening the survey, the user will be provided additional introductory information, and will be given the opportunity to opt in or opt out of completing the questionnaire, as can be seen in the first screen of the web survey. Because the primary investigator is a medical student, and the survey is going to senior hospital administrators, we will not offer incentives or rewards of any kind for survey completion. We will offer any participating hospital a copy of our results, which they may request by e-mail as desired.

I will perform the primary data analysis, including frequency distributions and chi-square analysis for categorical variables, with Stata, under the guidance of my Faculty Advisor, Dr. Tolleson-Rinehart, as well as Dr. Goldstein in the UNC Department of Family Medicine. Data analysis will conclude in August. We intend to submit a version of this master's paper, updated to include results after data analysis, for publication.

Limitations

According to Kelly, Clark, Brown, and Sitzia, an appropriately executed questionnaire requires significant prior effort to plan the content of the research tool, questionnaire layout, question formatting and wording, piloting, and the covering letter (2003, p. 263). In planning the content of this questionnaire, Dr. Goldstein's expertise has been instrumental. His previous tobacco-related research, and focus on North Carolina Hospitals as they universally implemented tobacco-free campus policies, have provided an important perspective, guiding the content of the questionnaire. Dr. Sue Tolleson-Rinehart has over 30 years of experience in

survey research. Her methodological expertise has been a tremendous resource in refining the layout of the questionnaire, and ensuring that questions are appropriately worded and ordered. We also meticulously drafted a series of accompanying letters to be e-mailed along with the survey, including 3 introductory letters specific to each of the three respective rounds of dissemination, and a longer, more detailed explanation of the project and its goals. Experts suggest that piloting be performed on a small sample of the target population, to help identify whether all questions are easily understood, whether sufficient response categories are included, and whether any questions are systematically missed by respondents (Kelly, Clark, Brown, and Sitzia, 2003, p. 263). In our case, time constraints and the need to preserve the entire respondent population for the survey itself rather than reducing it by drawing a pilot sample, have prevented extensive piloting. Ultimately, piloting was limited to 5 classmates from my cohort in the School of Public Health, who took the survey and provided feedback. Insufficient piloting could threaten the validity of our results, though the survey has content validity and my advisors have extensive experience in methods and content specific to this survey.

For all the advantages a web-based questionnaire presented for this project, there are a number disadvantages and limitations inherent to survey research. Despite the versatility of surveys in that many types of questions on many topics can be asked, they are rather inflexible in the sense that the research relies on a single survey instrument – the questionnaire (Blackstone, 2012 – accessed online, no page number available). For instance, if it becomes clear as responses come in that a particular question is a problem for respondents, no additional information can be provided, as might be possible during a face-to-face interview. Securing a high response rate is always a challenge in survey research, but is crucial to the validity of the results (Kelly, Clark, Brown, and Sitzia, 2003, p. 264). Non-response bias occurs in those surveys with a high non-response rate, where the results may be misleading and only representative of those who replied, rather than the sample population as a whole (Kelly, Clark,

Brown, and Sitzia, 2003, p. 264). The involvement of the North Carolina Hospital Association (NCHA) in the distribution of the survey is expected to enhance participation, but if we are unable to meet participation goals (ideally >80%, but >60% at minimum to achieve acceptable internal validity), a significant potential for biases may result.

Additionally, some degree of response bias seems inevitable in this study. Even without any apparent bias in the survey itself, with a perfectly constructed questionnaire, the respondents – hospital administrators – are still facing a larger climate, where many of their biggest stakeholders are demanding action on e-cigarettes. Because e-cigarettes are currently such a public health focal point, despite whatever efforts have been made to maintain the best survey practices in this project, we will still likely 'have our thumb on the scale' to some degree because of this external pressure respondents may already be facing. The presumption, when answering this survey, is almost certainly against e-cigarettes, and survey respondents may therefore not feel entirely free in presenting their views.

Anticipated Findings

As a primary goal in our analysis, we seek to better understand what percentage of hospitals have created policy regulating e-cigarette use, the details of existing policies, and what factors may serve as barriers or motivators to the development of these policies. Additionally, we will look for associations between the existence of policy for e-cigarettes and hospital-specific characteristics – for instance, are those hospitals more advanced in their tobacco regulation policies more likely to have policy specific to e-cigarettes? Accordingly, frequency distributions and measures of association, including Pearson's chi-square test, will be central to data analysis.

Frequency Distributions

A frequency distribution is used to provide a summarized grouping of data divided into individual classes and the number of occurrences in each class. Our proposed questionnaire, which is available for reference in *Appendix B*, requires the respondent to choose an answer(s) from a limited set of possible answers. Hence, pooled responses will be operationalized as categorical variables during data analysis. Categorical variables, however, are actually a qualitative method of scoring data, and we will use of coding systems to allow the desired quantitative data analysis. For example, Question 5 from the survey asks respondents, "Does your hospital currently have a program to help employees quit smoking?" There are 2 possible responses, "Yes" and "No." In our analysis, a response of "No" would be coded as 0, and "Yes" as 1. Analysis could include a simple univariate frequency table on the responses to this question, as depicted in *Table 1*. Depending on the number of response categories and the type of question being asked, it may be intuitive to present data in histograms, line charts, bar charts, or pie charts, as frequency distributions are commonly presented in all of these ways. As an example, Question 8 asks respondents, "Which of the following best describes your current policy regulating the use of e-cigarettes?", and requires the choice of 1 of 4 potential categorical responses. Here, response data might be intuitively visualized with a pie chart, as depicted in *Figure 2*. Were individual frequency tables and or graphic representations provided for every response, the result would be a bulky, unintuitive presentation of our response data. Instead, a series of larger tables pooling frequency distributions of groups of questions (one table for each of the 5 sections in the survey, in this case) will be included in the findings, with frequency distributions for individual questions discussed sequentially within the text, and graphs and or charts for results of interest will also be included as desired. See *Table 2* for the proposed table pooling frequency distributions for responses in Section 1 of the survey, which contains questions on regulations for the use of tobacco products in hospitals.

Measures of Association

In addition to examining the frequency distributions, our analysis will also search for associations, or non-independence, among categorical variables using Pearson's Chi-square test. Pearson's Chi-square tests examine whether a difference between "observed" and "expected" frequencies due to chance, or whether such differences represent actual non-independence between variables. To perform a Chi-square test, a dependent variable (the outcome of interest, Y) and an independent variable (which might influence outcomes, X) are designated.

For example, suppose we are interested in examining whether an association exists between a hospital's use (or lack of use) of the Voluntary Joint Commission Tobacco Set (VJCTS) and the manner in which e-cigarette use is currently being regulated in the hospital. These data will stem from questions 4 and 8 in the proposed survey. Here, we designate the type of e-cigarette regulation policy as the dependent variable (Y), and the choice of whether or not to use the VJCTS as the independent variable (X). *Table 3* shows representative table for this potential Chi-square analysis, including null and alternative hypothesis. Here, the null hypothesis (H0) is that e-cigarette regulation policy type is not related to whether or not a hospital is using the Voluntary JC Tobacco Set, and the alternative hypothesis is that e-cigarette regulation policy type is related to whether or not a hospital is using the VJCTS. The p value for this Chi-square analysis will simply tell us whether or not there is an overall association between use of the VJCTS and type of e-cigarette regulation.

We can test for specific associations, however, by doing a Chi-square analysis for individual pairs. For instance, suppose we would like to know whether those hospitals who responded "Yes" to using the VJCTS are more likely to have some policy regulation the use of e-cigarettes in their hospital, and that "E-Cig Policy Types" 1-3 involve some level of e-cigarette regulation, but that "E-Cig Policy Type 4" signifies no regulation of e-cigarettes in the hospital.

Here, we can create a new variable in the Stata data analysis software which lumps responses from each of policy types 1-3 into a single response, to be compared with policy type 4 in a Chi-square analysis. In this case, we've essentially reduced the Chi-square analysis to a 2x2 table looking for associations between a Yes/No response to using the VJCTS to a Yes/No response to having a policy which regulates e-cigarette use. *Table 4* shows a representative table for this second Chi-square analysis. Here, the null hypothesis (H0) is that hospitals using the VJCTS are not more likely to have a policy regulating the use of e-cigarettes, and the alternative hypothesis (H1) that hospitals using the VJCTS are more likely to have a policy regulating the use of e-cigarettes.

After performing Chi-square testing to examine all potential associations of interest, results could potentially be presented in summary tables. An example of this might be to create a table entitled "Factors Associated with an Increased Likelihood of having an Existing Policy Regulating the Use of E-Cigarettes," which sequentially lists the variables with significant associations and their associated p values. After doing frequency distributions to provide a snapshot of how NC hospitals are currently regulating e-cigarettes, measures of association such as Chi-square analysis will allow us to begin to examine why e-cigarettes are regulated as they are.

Discussion and Conclusions

The results of the proposed study could provide timely and valuable information to NC hospitals and policy-makers, but a number of challenges exist. As with all survey research, achieving sufficient participation will be crucial to the validity of our results. Another central charge has been determining the appropriate individual(s) within hospitals to participate in the survey, as those with knowledge of such policy may carry a different title or reside within a different department in one hospital vs. another. Our hope is that through collaboration with the

North Carolina Hospital Association, which has agreed to distribute the survey, will help address both these issues. However, our collaborative efforts have presented a number of hurdles in addition to the potential advantages. While seemingly obvious, allowing much more time than expected is a valuable lesson for those new to collaborative research. Collaborative efforts can be difficult to execute when time constraints exist, and collaborators and the primary researchers may or may not be operating on a similar timeline. Returning to the issue of participation, if we are unable to meet response rate goals (ideally >80%, but >60% at minimum to achieve acceptable internal validity), a significant potential for biases may result. Additionally, even with a perfectly-constructed questionnaire and a very high level of participation, there is still a great potential for response bias in this project.

Respondents in many NC hospitals are likely under external pressure from a number of stakeholders to address e-cigarettes in their smoke-free campus policies, and therefore may not feel completely free in their answers as they complete the questionnaire. Prevention Partners, which has worked closely with North Carolina hospitals in establishing tobacco-free campus policies, is supporting this project, and has been advocating for tighter inclusion of e-cigarettes in these policies for some time. Dr. Melva Fager Okun, DrPH and Senior Program Manager at Prevention Partners, has even provided feedback on the online questionnaire. Regarding Prevention Partners' e-cigarette policy efforts, Dr. Fager Okun has explained, "Over the last five years, I have encouraged all hospitals to specify that the 'tobacco-free campus policy' includes the prohibition of e-cigarettes. I know several (hospitals) have done such, and it's still an issue…at one academic hospital in NC, legal staff held it up for 6 months, saying (e-cigarettes) couldn't be included because they are a legal product...I also think there is great confusion among hospital staff – whether these products are allowed, and if not, what to do. I encourage the enforcement for them should be the same as for cigarettes and other tobacco products."

North Carolina's 14 State Operated Healthcare Facilities for mental health and substance abuse have already committed to including e-cigarettes in their tobacco-free campus

policies. Jim D. Martin, Director of Policy and Programs for the Tobacco Prevention and Control Branch of the NC Department of Health and Human Services, explains the 14-point rationale for this decision. He says that e-cigarettes have the potential to interfere with support of recovery concepts and allowing individuals to achieve a healthier lifestyle, an effect of coercion and conflict, disruption of efforts to focus on diagnostic or therapeutic activities, interference with medication effects and other treatment, nicotine interference with medication levels, cycling of withdrawal, a conflict with the mission to support individuals in all addictions, health risks for staff and patients in breathing "vapor" from e-cigarettes, inconclusive literature on user safety, a lack of evidence for e-cigarettes as an effective smoking cessation tool, and that other NRT and medications for smoking cessation are available which do not propose the above concerns.

Returning to the concern about response bias in this survey, it is important to acknowledge that our survey respondents are likely feeling pressure from a number of channels, such as Prevention Partners and the NC Department of Health and Human Services, to establish regulations for e-cigarette use on hospital campuses. This is the air our respondents are breathing, regardless of whether we have been able to minimize biases intrinsic to the questionnaire itself, and so our use of best practices cannot obviate possible challenges to validity and reliability.

Nonetheless, if the NCHA is able to identify the appropriate respondents and secure a high participation rate, the results of this proposed study may be of real value. The literature on e-cigarettes is quickly expanding, but is still markedly limited. E-cigarettes are being prescribed and utilized as a viable smoking cessation tool across the United States in the absence of substantial evidence for this indication. Many physicians report limited knowledge of e-cigarettes, to the extent that patients are the primary source of information on e-cigarettes in at least one study (Pepper, McRee, and Gilkey, 2013). There is evidence for concern, also, that e-cigarettes may serve as a gateway to nicotine addiction for those who may not smoke traditional cigarettes, particularly adolescents. Many are also concerned that the use of e-cigarettes may

“re-normalize” the act of smoking, or that regular smokers have begun dual use with e-cigarettes to allow them to circumnavigate restrictions on smoking in certain public places. Additionally, information on safety and efficacy is limited, regulation of E-cigarettes is in a state of flux, and public interest continues to increase.

In the absence of federal regulation, many states have adopted their own policies for regulating e-cigarettes, though in most states e-cigarettes are not subject to nearly the regulation of traditional tobacco products. Despite the mission of state mental health and substance abuse facilities, it is unclear how North Carolina hospitals are approaching e-cigarettes. The FDA has recently issued a new proposed set of recommendations that again call for tighter regulation of E-cigarettes, but it may be years before any such regulations are put into practice, leaving states to arrive at their own conclusions in the meantime.

This research proposal is therefore significant in its potential to provide a snapshot of current e-cigarette regulation by North Carolina hospitals, and to begin to probe for explanations for hospital perceptions and actions regarding e-cigarette use. On the road to establishing uniform guidelines for e-cigarette regulation, much as state-wide directives were established for tobacco-free campus policies several years ago, this research proposal offers our state hospitals the opportunity to learn from the approaches and experiences of their peers. Our hope is that the results of this research will also be of interest to anti-tobacco advocacy groups beyond Prevention Partners, and public health stakeholders on local, state, and federal levels.

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Tables and Figures

(By Order of Appearance in Text)

Figure 1: A Graphic Representation of E-Cigarette Functionality

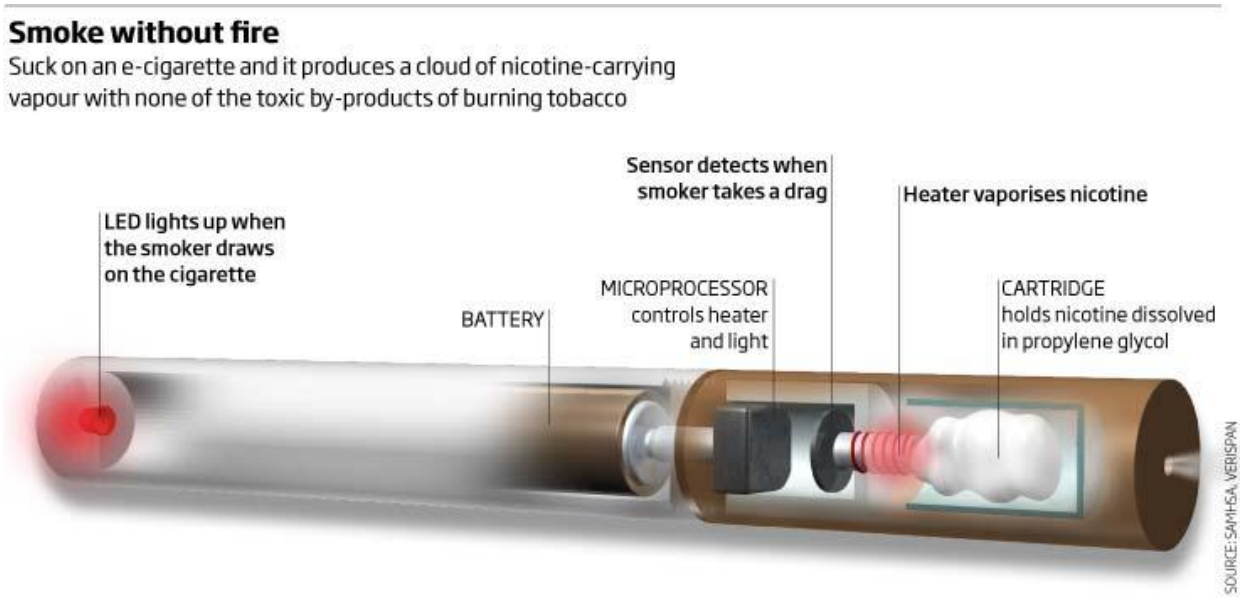


Image provided by E-cigarettereviews.com

Table 1: A Potential Univariate Frequency Distribution for Q5

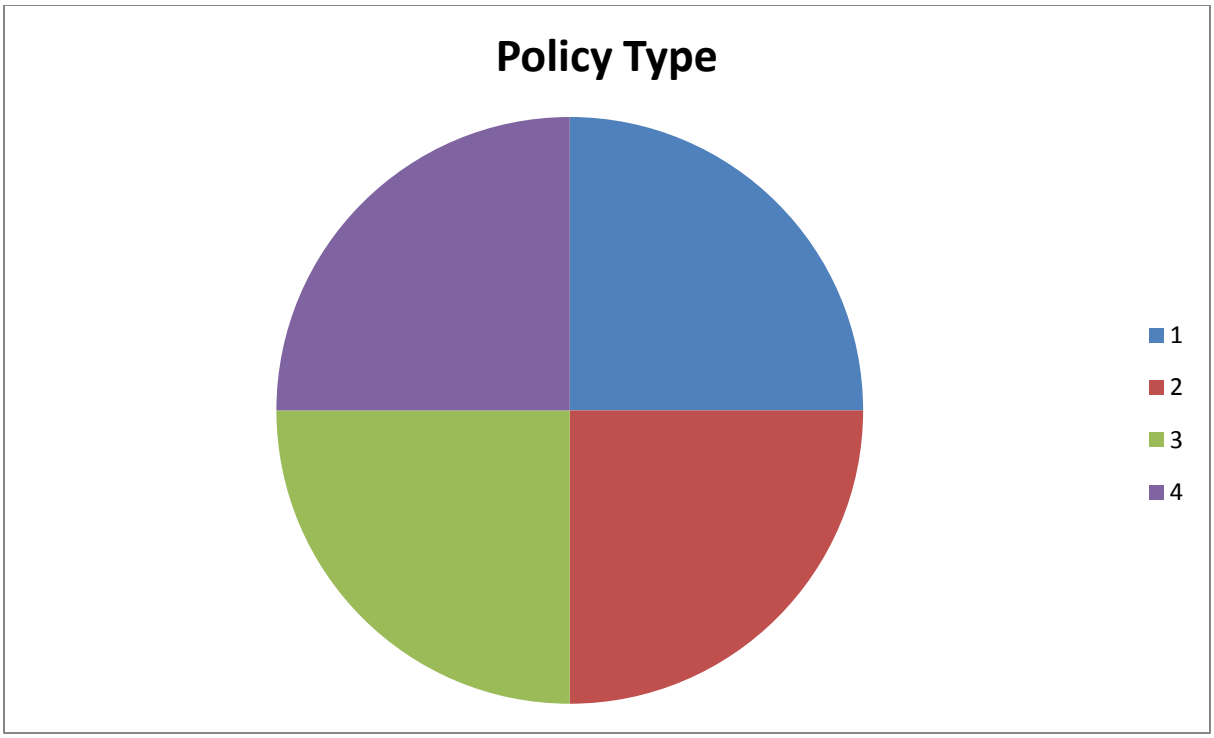
Response	Frequency	Percent	Cumulative
0: No	?	?	?
1: Yes	?	?	100
Total	**50**	**1.00**	

* *Q5 Does your hospital currently have a program to help employees quit smoking?*

- ❍ *Yes*
- ❍ *No*

*** Here, we assume 50 responses to Q5, with an unknown percentage of respondents answering "Yes" or "No," respectively.*

Figure 2: A Potential Pie Chart for Q8 Response Data



** Q8 Which of the following best describes your current policy regulating the use of e-cigarettes?*

- *Use is not allowed indoors or on the grounds (1)*
- *Use is not allowed indoors, and use outdoors is limited to certain areas (2)*
- *Use is not allowed indoors, but there are not any restrictions on outdoor use (3)*
- *There are currently no restrictions on E-CIGARETTES indoors or outdoors at our hospital(s) (4)*

Table 2: Frequency Distribution Data for Section 1 – Hospital Tobacco Policies

Question	Responses (n)	Percentage (%)	Mean (S.D.)
(1) Current policy regulating the use of tobacco products *No use allowed indoors or on grounds* *No use indoors, outdoors limited to certain areas* *No use indoors, but no restrictions on outdoor use*			
(2) Extent use of cigarettes and other tobacco products on campus by the groups below currently a problem (0 = not a problem, 10 = major problem) *Hospital Staff* *0-2* *3-5* *6-8* *9-10* *Patients* *0-2* *3-5* *6-8* *9-10* *Visitors* *0-2* *3-5* *6-8* *9-10*			**X (S.D.)** **X (S.D.)** **X (S.D.)**
(3) Extent to which litter from cigarettes and tobacco products is currently a problem (0 = not a problem, 10 = major problem) *0-2* *3-5* *6-8* *9-10*			**X (S.D.)**
(4) Hospital currently using the voluntary Joint Commission Core Measure Tobacco Treatment Set *Yes* *No*			
(5) Hospital currently has a program to help employees quit smoking *Yes* *No*			
(6) Hospital currently has a program to help inpatients quit smoking *Yes* *No*			
(7) Hospital currently has a program to help outpatients quit smoking *Yes* *No*			

Table 3: Is Hospital Use of the Joint Commission Tobacco Set Associated with the Type of E-Cigarette Regulation Policy in the Hospital?

E-Cig Regulation Policy Type	Using JC Tobacco Set		Total
	0: No	1: Yes	
0: E-Cig Policy Type 1			
1: E-Cig Policy Type 2			
2: E-Cig Policy Type 3			
3: E-Cig Policy Type 4			
Total			

Pearson's X_2 = _____ p (X_2 ≠ ____) = _____

Null Hypothesis (H_0): E-cigarette regulation policy type is not related to whether or not a hospital is using the Voluntary JC Tobacco Set.

Alternative Hypothesis (H_1): E-cigarette regulation policy type is related to whether or not a hospital is using the Voluntary JC Tobacco Set.

Table 4: Are Hospitals Using the Joint Commission Tobacco Set more likely to have a Policy Regulating the Use of E-Cigarettes?

E-Cig Regulation Policy Type	Using JC Tobacco Set		Total
	0: No	1: Yes	
0: E-Cig Policy Type 1, 2, or 3			
1: E-Cig Policy Type 4			
Total			

Pearson's X_2 = _____ p ($X_2 \neq$ ____) = _____

Null Hypothesis (H_0): Hospitals using the Voluntary JC Tobacco Set are not more likely to have a policy regulating the use of e-cigarettes.

Alternative Hypothesis (H_1): Hospitals using the Voluntary JC Tobacco Set are more likely to have a policy regulating the use of e-cigarettes.

Appendix A: A Limited Systematic Review of Provider Awareness and Perceptions of E-Cigarettes

Introduction

Electronic cigarettes (also called E-cigarettes, E-cigs, or electronic nicotine delivery systems) are battery-powered devices which heat a liquid solution, typically containing nicotine, to generate a vapor and simulate the act of smoking. E-cigarettes were first marketed in China in 2004 as a potential new tool for smoking cessation, and less than a decade later their use is exploding worldwide. In the United States, E-cigarette use is highly controversial. Information on safety and efficacy is limited, regulation of E-cigarettes is in a state of flux, and public interest continues to increase (Pepper & Brewer, 2013). There is also tremendous concern among public health officials that E-cigarettes may serve as a 'gateway' product to future smoking, particularly among adolescents who have never tried traditional cigarettes (Pepper, McRee, & Gilkey, 2013). Some also contend that electronic cigarettes may actually prevent smokers from quitting by continuing to perpetuate nicotine addiction, or deterring users from using tools already proven to be effective for cessation (Grana, 2013). Several national organizations, including the U.S. Preventive Services Task Force and the American Academy of Pediatrics have emphasized the important role of healthcare providers in prevention of risky behaviors, such as tobacco use, by providing counseling to patients and/or family members (Pepper et al., 2013). Current guidelines from various entities include tobacco use screening as a part of routine care, educating about the health risks of tobacco use, asking the family and friends of patients about tobacco use, and providing cessation counseling when necessary (Pepper et al., 2013). Thousands of physicians in the United States are reportedly recommending electronic cigarettes to patients who wish to quit smoking, with no existing evidence-based reason for doing so, under the assumption that these devices are safe and could potentially be helpful.

Despite the overall relatively small number of existing studies on E-cigarettes, the literature on electronic cigarettes is rapidly expanding, and a recent systematic review was conducted to analyze user awareness, use, reactions, and beliefs. However, no similar systematic review has been conducted on literature pertaining to health care providers. This review seeks to increase the understanding of provider awareness and beliefs regarding electronic cigarettes, to identify any relevant gaps in existing research, and to provide directions for future research.

Background

The "smokeless non-tobacco cigarette" was invented by Herbert A. Gilbert in 1963, and the device heated a nicotine solution to produce steam ("Smokeless non-tobacco Cigarette", 2014). Despite receiving a patent in 1967, the device was never commercially manufactured, and a Chinese pharmacist named Hon Lik is actually credited with inventing the modern electronic cigarette in 2003 (Demick, 2009). There is dramatic variation in the way E-cigarettes have been regulated worldwide, ranging from no restrictions on producers or consumers to whole sale bans of use and distribution (Bullen et al., 2013).

A Brief Overview of Existing Literature

A small number of studies have been conducted to examine acute health effects of E-cigarettes such as cardiovascular risk, short term pulmonary effects, changes in complete blood count (CBC), effects of secondary exposure to "vapor," and others. Researchers have also attempted to analyze the contents of various E-cigarettes, or whether indoor air quality is affected by their vapor. One large randomized control trial concluded that, "E-cigarettes…were modestly effective at helping smokers to quit, with similar achievement of abstinence as with

nicotine patches, and few adverse events," but ultimately stated that more research was needed for evidence-based guidelines to be developed (Bullen, Howe, McRobbie et al., 2013).

Overwhelmingly, the largest amount of existing literature on E-cigarettes pertains to users' preferences, beliefs on safety and efficacy, experience, and awareness, and a systematic review of this literature was published in November 2013 (Pepper and Brewer, 2013). 49 studies published between 2006 and July 1, 2013 were ultimately included. Exclusion criteria included articles not published in English, articles unrelated to electronic nicotine delivery systems (ENDS), dissertation abstracts and articles without original data on prespecified outcomes. Based on the data synthesis from three large national surveys, awareness of E-cigarettes in the United States more than tripled from 2009 to 2011, increasing from 16% to 58%, and use of E-cigarettes increased from 1% to 6%. Current smokers, men, those of younger age, and whites were more likely to have heard of E-cigarettes. The International Tobacco Control (ITC) Four-Country Survey (from 2010-2011)of current and former smokers reported that awareness was higher in the USA (73%) and UK (54%) than in Canada (40%) or Australia (20%), likely because e-cigarettes can be legally marketed and purchased in the USA and UK (Adkison, O'Connor, Bansal-Travers et al., 2013). A Polish survey suggested that E-cigarettes serving as a "gateway" to cigarettes may be a real concern. In a survey of 179 Polish users of E-cigarettes in 2009, 25 were reportedly non-smokers prior to trying an E-cigarette, and 5 of these (20%) were regularly smoking cigarettes by 2013 (Goniewicz, Lingas, Hajek, 2013). Data on the perceived cost of E-cigarettes among users are limited and often conflicting, though most dedicated users seem to believe they are cheaper than conventional cigarettes. In numerous studies, a large percentage of users reported positive changes in their health after beginning use of an E-cigarette. Many reported improved breathing, reduced coughing, fewer sore throats, and improved overall health and fitness (presumably vs. conventional cigarette smoking). Some negative side effects have also been reported. As of early 2012, 47 case

reports of adverse events have been received by the FDA, with 8 classified as serious adverse events (e.g. pneumonia, chest pain.) (Chen, 2013). In an online e-cigarettes forum, 326 of the 405 total health effects reported were ultimately negative, and the most frequently reported problems with in the mouth, throat, respiratory system, and neurological system (Hua, Alfi, and Talbot, 2013). In pooled data, the majority of reported side effects were minor, and included cough, mouth or throat irritation/dryness, vertigo, headaches, and nausea. Many of the side effects reported at baseline (often at the initiation of e-cigarette use) had resolved completely by the end of the respective study periods. The majority of people using e-cigarettes with a goal of smoking cessation reported that e-cigarettes either helped them quit or "reduce" use of traditional tobacco products, though Pepper and Brewer feel that a reduction may not actually be a positive public health outcome, as this could represent dual use of E-cigarettes and traditional cigarettes. While it is unclear whether a large number of people use E-cigarettes to circumnavigate smoking restrictions, 36% of users in one survey said they frequently use e-cigarettes in areas where smoking is banned (Dawkins, Turner, Roberts et al., 2013). In a survey at a convention of E-cigarette enthusiasts (n = 104), 90% said they were able to use e-cigarettes where smoking was banned (Foulds, Beldheer, and Berg, 2011). In a survey in e-cigarette users from a number of countries, a large number of people reported using e-cigarettes at work (71%), or in cafes, restaurants, or bars (43%), though Pepper and Brewer find these results difficult to interpret given varying smoking restrictions in each country (Etter and Bullen, 2013). Though in some surveys few report avoiding smoking restrictions as a motivating factor, pooled data from 3 surveys suggests that up to 40% use e-cigarettes for this reason. In general, reported satisfaction with e-cigarettes was very high, especially among committed users. Those who used e-cigarettes in prospective trials had more mixed reactions. Concerns were sometimes reported about the quality of e-cigarettes, including broken/malfunctioning components and leaky cartridges. The vast majority of users reported that they enjoyed the taste of e-cigarettes. Many also reportedly commented that they enjoyed the similarity of use of

e-cigarettes to regular cigarettes, and that they used them much in the same way (e.g. after a meal). Overall, about two-thirds found e-cigarettes equally or more satisfying than traditional cigarettes. Most current and former smokers reported that e-cigarettes helped reduce their urge to smoke as well as some withdrawal symptoms. The majority of users believe that e-cigarettes are healthier for both themselves and others than regular cigarettes, and use them at least in part for this reason. Only a vast minority of users appear to be concerned about potential negative health effects or toxicity of E-cigarettes. The majority of users also believe that e-cigarettes can help people to quit or reduce smoking, and this is another major factor in motivation for use. Most using E-cigarettes for smoking cessation/reduction reported that they would recommend them to friends or family for the same purpose. Most users believe that E-cigarettes are less addictive than smoking. A majority of current smokers who have never tried E-cigarettes believe that e-cigarettes could satisfy their desire to smoke. Pepper and Brewer report three important additional themes observed regarding beliefs of users. First, many users are concerned about personal appearance (e.g. yellow teeth, odors/not smelling like smoke). Next, E-cigarette users actually feel a sense of camaraderie with each other – online forums are exploding, and many reportedly attend conventions. Last, some users express concern that E-cigarettes will be banned (though Pepper and Brewer state that they found no arguments by users that E-cigarettes should be exempt from smoke-free indoor air laws). Ultimately, the authors conclude that with E-cigarette use exploding despite potential concerns, more research is needed on perceived risk, effective public health messages, validity of self-reported cessation, and on different types of E-cigarettes (Pepper and Brewer, 2013).

Regulation of Electronic Cigarettes

In the United States, the FDA initially classified E-cigarettes as drug delivery devices, which would make them subject to regulation under the Food, Drug, and Cosmetic Act (FDCA) prior to importation and sale in the U.S., but this was ultimately overruled by a Federal District Court Judge in January 2010, who stated, “the devices should be regulated as tobacco products rather than drug or medical products” (Duff, 2010). The FDA appealed, citing the right to regulation of E-cigarettes based on their previous ability to regulate nicotine replacement therapies such as nicotine gum or patches, but the appeals court ruled against the FDA in a 3-0 unanimous decision (Duff, 2010). Hence, the FDA has therefore only been able to regulate E-cigarettes as tobacco products, and has no power to block their import (Duff, 2010).

In lieu of federal regulation, many states have adopted their own policies, most commonly to prohibit the sale of E-cigarettes to minors. New Jersey took a strong stance early on against E-cigarettes, deciding to include them in their Smoke-Free Air Act in 2009 (Livio, 2010). The legislation was sponsored by assemblywoman Connie Wagnor, who claimed, "… young people who use these things will get hooked on the nicotine and eventually move onto the real thing". In 2013, Mayor Bloomberg signed similar practice into law for New York City, mandating the electronic cigarettes be regulated in the same way as traditional cigarettes (Winsor, 2013). On local levels, some hospitals, workplaces, and schools are beginning to include electronic cigarettes in previously-established “smoke-free campus” policies, though the pervasiveness of this trend has not been well-researched.

In April 2014, the FDA stormed back into the spotlight, issuing a new set of recommendations which again call for tighter regulation of E-cigarettes (Young, 2014). The new recommendations reportedly include a minimum age of 18 years to purchase E-cigarettes, a requirement for health warnings on all E-cigarette packaging, and a banning of the sale of E-cigarettes in vending machines (Young, 2013). The recommendations also include mandates on manufacturers requiring all products and ingredients be registered with the FDA, an FDA review process prior to any marketing being permitted, and the provision of scientific evidence

prior to any claims of risk reduction (Young, 2014). Implementation of this (or similar) legislation is unlikely to occur immediately following the 75-day public comment period, and most agree that a move in this direction is likely several years away from being put into practice (Young, 2013). Some challenge the immediate need for tighter regulation, citing mounting evidence for therapeutic benefits and potential harms to public health if E-cigarettes are 'over-regulated,' and calling for officials to use caution in determining the appropriate balance (Saitta, Ferro, Pelosa, 2014). FDA commissioner Margaret Hamburg contends, "It's really the wild, wild West out there…they're coming in different sizes, shapes and flavors…and there's very worrisome data that show that young people in particular are starting to take up E-cigarettes…and that might be a gateway to other harmful tobacco products…but until we can really regulate them, we can't have all the information we need and we can't take all the actions that we might want to, to be able to best address the public health issues associated with them" (Young, 2013 – accessed online, no page number available).

The Role of Health Care Providers

Under existing regulations – or the lack thereof – physicians play not only an important role in counseling those patients interested in smoking cessation, but an active role in preventive efforts through tobacco use screening and education on the harms of tobacco use. It is unclear whether a national minimum age requirement of 18 years would have a dramatic effect on minors' ability to acquire E-cigarettes, though this is unlikely to completely solve the problem based on smoking trends in this age demographic. If the FDA were to adopt a more radical policy regulating E-cigarettes as medical devices, and requiring a prescription to obtain them, perhaps there would actually be a large-scale shift in the current role for providers.

As the use of E-cigarettes balloons in the United States, an arms race between manufacturers and health policy officials is quietly unfolding. There is reasonable data on the subjective experience of E-cigarette users, but no systematic approach has been taken to better understand the experience of health care providers. As the landscape continues to shift, it is important to examine health care providers' level of awareness of electronic cigarettes, their perceptions of the safety and efficacy of these products, and whether and how they approach discussing e-cigarettes with patients across a variety of health care settings. Such an analysis is important in establishing how different types of providers are treating E-cigarettes with patient groups across a variety of clinical settings, particularly because the scarcity of data from well-conducted randomized control trials on E-cigarettes as smoking cessation devices makes establishing evidence-based guidelines for practice essentially impossible at this stage.

In spite of all the unknowns, though, several factors seem relatively certain. First, there has been a significant increase in public interest in E-cigarettes in recent years, and use has increased in a number of groups, including many not using them as smoking cessation aids. Second, that whether or not they are currently allowed to be marketed as such in the United States, E-cigarettes are still being utilized by many as smoking cessation devices. Third, that for as long as E-cigarettes are used for smoking cessation, health care providers can be reasonably expected to play some role in their utilization. In addition to these conditions, there is evidence to suggest that brief, preventive counseling sessions with a primary care provider can decrease risky behaviors in adolescents, including smoking (Ozer, Adams, & Orrell-Valente, 2011). Though E-cigarettes are not explicitly mentioned in any current guidelines, knowledge about all nicotine-containing devices is important for practitioners seeking to deliver comprehensive tobacco-related counseling to their patients (Pepper et al., 2013) Thus, a systematic review is necessary for examining health care providers' awareness, attitudes, and perceptions regarding electronic cigarettes.

Methods

This review aims to increase understanding on health care providers' awareness of electronic cigarettes, attitudes toward them, and perceptions of their safety and efficacy as tobacco cessation devices. The focus is the subjective experience of providers, as this has important implications for clinical practice. Accordingly, articles that will not be reviewed include those focused on the experience of E-cigarette users, and all other intervention trials, studies, and reports on E-cigarettes which do not include components related to physician experience.

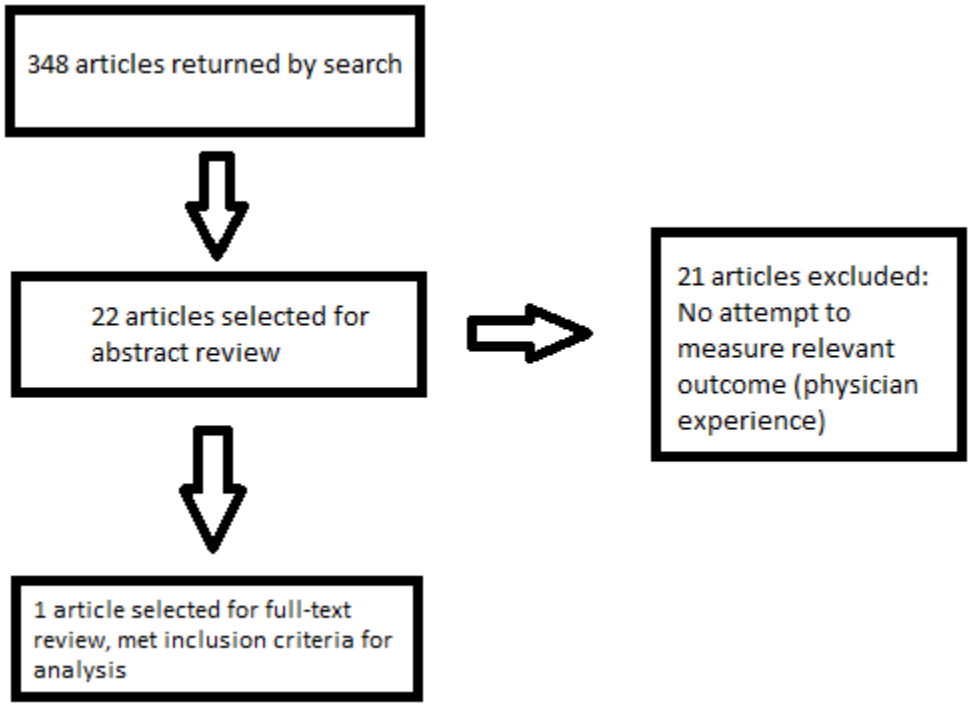
Article Search

A single investigator searched Pubmed for articles published between January 1, 2004 – April 22, 2014 using the search terms "electronic cigarette" OR "electronic cigarettes" OR "e-cigarette" OR "e-cigarettes" OR "e-cig" OR "e-cigs" OR "electronic nicotine delivery device." This search returned a total of 348 articles. The start date for article inclusion was chosen with respect to the invention of the E-cigarette in China in late 2003, and should include all relevant literature from the United States, as E-cigarettes did not begin to be imported and used until several years later. Articles excluded were those not published within the specified time frame, and those not published in English. Prior to the article search, discussions with experts on E-cigarette policy indicated that literature on the subject of this review would be very limited. This, in addition to the relative dearth of all literature pertaining to E-cigarettes, influenced the decision to avoid establishing more stringent exclusion criteria (for study type or quality, etc.) prior to conducting a literature search. Of the 348 articles returned in the original search, 22 were selected for abstract review based on any apparent potential to contain measures of the physician experience with E-cigarettes. Abstract review produced only one potentially relevant article, which was confirmed by full-text review to be highly relevant to the aim of the review.

Multiple policy experts confirmed that this study was the only published study to their knowledge attempting to examine the physician experience with E-cigarettes, and the literature search was subsequently not expanded to databases other than Pubmed. One expert was part of a research group which recently conducted a similar study now being reviewed for publication, but only the single published article will be included for analysis in this review.

Results

Figure 1: Inclusion and Exclusion Process for Articles



Of the 348 articles returned by the search strategy, only one article ultimately met inclusion criteria for analysis (see Figure 1). This study was conducted as a state-wide survey of 567 primary care physicians and nurse practitioners providing care for adolescents aged 11-

17 years (Pepper et al., 2013). A total of 3923 providers were invited to participate in April 2013, and a total of 615 completed the online, cross-sectional survey (adjusted response rate of 28%). Questions were developed based on researchers previous work with adolescents, and piloted with 5 physicians prior to the study. Questions were aimed at assessing physicians' awareness of E-cigarettes, comfort level in discussing them with adolescent patients, risk beliefs, communication, and desire to receive further education on E-cigarettes. The participants also provided demographic and practice characteristics, provider type, year of training completion, and number of adolescent patients. Ultimately, 561 survey responses were included in the analysis – 46% were family medicine physicians, 20% pediatricians, and 34% nurse practitioners. Almost all providers were aware of E-cigarettes (92%), and 11% had previously treated an adolescent who admitted having used E-cigarettes. Most providers obtained their knowledge on E-cigarettes from places other than professional sources, such as news stories, patients, and advertisements. Family medicine physicians knew relatively more about E-cigarettes than pediatricians and nurse practitioners, and also described being more comfortable discussing them with patients (both $p < 0.05$). Almost universally, providers reported an interest in learning more about E-cigarettes (92%).

Discussion and Directions for Future Research

While the study performed by Pepper et al. is a good start to building an evidence base on physician awareness and beliefs regarding E-cigarettes, there are a number of limitations to their findings. On a positive note, the survey participants include family medicine physicians, pediatricians, and nurse practitioners. Unfortunately, the data is collected from only one state, and only from a relatively small number of providers serving adolescent patients between the ages of 11-17 years. External validity is in some ways a concern, therefore, because the beliefs

and experiences of physicians treating an adolescent population may not be generalizable to all primary care physicians in the United States, for instance. Of additional concern is the low response rate to the survey – about 28% after being adjusted based on the American Association for Public Opinion Research formula. A low response rate can increase the odds of a number of threats to internal validity, and namely for selection bias, as those responding may be more informed on E-cigarettes, or more passionate about the policy implications surrounding them, for example. The authors contend that the respondents did not differ from non-respondents based on demographic or practice characteristics, but these factors are not sufficient to rule out selection bias. Building off the approach taken by Pepper et al, though, there are some logical next steps for future research efforts.

A cross-sectional, web-based survey is an appropriate study design, but the population of health care providers (N) must be scaled up to increase the statistical power of results. The population should also be broadened to include (at very least) a representative sample of all primary health care providers – including family practice physicians, internal medicine physicians, pediatricians, physicians assistants, and nurse practitioners – as primary health providers are the principal source of tobacco cessation counseling, preventive care, and education for most patients. This population should be drawn from a national sample to improve the external validity of results. Next, steps must be taken to increase response rate in order to avoid introducing selection bias and other potential confounders. Ideally, a response rate of 80% or greater would be achieved, with 60% as the minimum rate acceptable. These rates are based on previous discussions with experts on survey methodology from the UNC Department of Family Medicine's Tobacco Prevention and Evaluation Program (TPEP), and from the UNC School of Public Health. As with the Pepper et al. study, care should be taken to collect demographic information and detailed information about practices and providers. Practice location (rural vs. urban, etc.), patient population characteristics (age, sex, income,

smoking prevalence), and provider type and date of completion of training should all be recorded.

The survey should aimed at eliciting information on providers' previous awareness of and experience with E-cigarettes, the sources from which providers have obtained information on E-cigarettes, provider attitudes toward the safety and efficacy of E-cigarettes, comfort level for discussing E-cigarettes with patients, how often E-cigarettes are discussed with and recommended for patients interested in smoking cessation, how populations are screened for use of tobacco products and E-cigarette use, how counseling is provided to those using E-cigarettes for smoking cessation, and how counseling is provided to those who have used or may use E-cigarettes for purposes other than smoking cessation. The survey should be of reasonable length (i.e. to permit completion in less than 10-15 minutes), and constructed in a logical flow with questions formatted in accordance with established principles of survey methodology.

With use of electronic cigarettes continuing to gain momentum, and numerous physicians encouraging them as a viable smoking cessation tool, research in a number of areas is paramount. Clinical data from well-constructed randomized control trials on E-cigarette safety and efficacy is almost completely lacking, particularly with regard to long-term health outcomes. With benefits and harms largely unknown, and unlikely to be available in the near future, data from other types of studies can play an important role. A cross-sectional, online survey administered to a representative national sample of at least 5000 primary care providers of all types could be of great value, particularly in the near-term. Such a study is relatively inexpensive and can be conducted quickly, and should provide important data if adequate survey construction, administration, and participation is achieved. Without available data for use in the formulation of evidence-based recommendations, studies focusing on how physicians currently perceive and treat E-cigarettes can provide timely, valuable information for both health care providers and policy makers.

Appendix B: Methods

Methods

The choice to conduct a web-based survey is discussed at length in the body of this paper.

Here I present the final web-based questionnaire.

Proposed Hospital E-Cigarette Policy Questionnaire
(imported from Qualtrics web format into Microsoft Word)

Thank you for your willingness to tell us about e-cigarette use at your hospital. I am a medical student in the Health Care and Prevention joint MD-MPH degree program at the University of North Carolina. My faculty advisor in the MD-MPH program is Dr. Sue Tolleson-Rinehart in the Department of Pediatrics, who is Associate Director of the MD-MPH program. Dr. Adam Goldstein, Professor of Family Medicine and the Director of UNC's Tobacco Prevention and Evaluation Program, is sponsoring my research. Drs. Tolleson-Rinehart and Goldstein have supervised this survey, and we have received support from the North Carolina Hospital Association (NCHA).

Our goal is to better understand how hospitals have or have not regulated the use of e-cigarettes on campus. ***This survey should take less than 15 minutes to complete***.

This survey has been approved by the UNC IRB (study number 14-1084). If you have any questions, you may contact the IRB at 919-966-3113 or irb_questions@unc.edu. Please don't hesitate to contact me, or my faculty mentors, Drs. Goldstein and Tolleson-Rinehart, with any question.

Below, please choose to continue or opt out of the survey. Thank you very much for your time and thoughts.

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- ❍ I am willing to complete the survey.
- ❍ I am not willing to take the survey at this time.

Section 1: These questions are about TOBACCO USE AND POLICY at your hospital.

Q1 Which of the following best describes your current policy regulating the use of tobacco products (other than e-cigarettes)?

❍ Use is not allowed indoors or on the grounds.
❍ Use is not allowed indoors, and use outdoors is limited to certain areas
❍ Use is not allowed indoors, but there are not any restrictions on outdoor use

Q2 To what extent is use of cigarettes and other tobacco products (not including e-cigarettes) on campus by the groups below currently a problem? Please move the slider bars below to a number that is closest to your own view of the problem on your campus. 0 = Not a Problem at all 10 = Major Problem

_____ Hospital Staff
_____ Patients
_____ Visitors

Q3 To what extent is litter from cigarettes and other tobacco products (such as cigarette butts, chewing tobacco waste, or packaging) a problem at your hospital? 0 = Not a problem 10 = Major Problem

_____ Slide bar to answer

Q4 Is your hospital currently using the voluntary Joint Commission Core Measure Tobacco Treatment Set? You can find them at: http://www.jointcommission.org/core_measure_sets.aspx

❍ Yes
❍ No

Q5 Does your hospital currently have a program to help employees quit smoking?

❍ Yes
❍ No

Q6 Does your hospital currently have a program to help inpatients quit smoking?

❍ Yes
❍ No

Q7 Does your hospital currently have a program to help outpatients quit smoking?

❍ Yes
❍ No

Section 2: These questions are about your hospital's policy for use of ELECTRONIC CIGARETTES (E-CIGARETTES) on campus.

Q8 Which of the following best describes your current policy regulating the use of e-cigarettes?

- ❍ Use is not allowed indoors or on the grounds.
- ❍ Use is not allowed indoors, and use outdoors is limited to certain areas
- ❍ Use is not allowed indoors, but there are not any restrictions on outdoor use
- ❍ There are currently no restrictions on E-CIGARETTES indoors or outdoors at our hospital(s)

Q9 Which of the following best describes the implementation of your policy regulating the use of e-cigarettes?

- ❍ E-cigarettes were added into existing policy regulating use of tobacco products
- ❍ A new policy specific to e-cigarettes was developed
- ❍ We do not have an e-cigarette policy

Q10 How effective or ineffective has your policy regulating the use of e-cigarettes been thus far? Please use the slider bar below. 0 = Very Ineffective 10 = Very Effective

_____ Slide bar to answer

Q11 How has your policy regulating the use of e-cigarettes been communicated to hospital staff? (Mark all that apply)

- ❑ Verbal communication
- ❑ Written communication (for example, with a memo)
- ❑ Notice from CEO
- ❑ E-mail
- ❑ Changing tobacco policy signs around the hospital
- ❑ Not explicitly communicated to staff
- ❑ Other _____

Q12 How has your policy regulating the use of e-cigarettes been communicated to patients and visitors? Mark all that apply.

- ❑ Verbal communication
- ❑ Written communication (for example, with a memo, or note in hospital rooms)
- ❑ E-mail
- ❑ Changing tobacco policy signs around the hospital
- ❑ Not explicitly communicated to patients and visitors
- ❑ Other _____

Q13 How has your policy regulating the use of e-cigarettes been enforced? Mark all that apply.

- ❑ By security
- ❑ By higher management
- ❑ Encouraging staff to take an active role in policy enforcement

- ❑ Encouraging patients and visitors to take an active role in policy enforcement
- ❑ Creation of a specific group or task force to oversee enforcement (please describe members of this group below) _____
- ❑ Other: _____

Q14 Which of the following are barri-ers to the development of a policy regulating use of e-cigarettes? Mark all that apply.

- ❑ The policy was not included in existing tobacco policy
- ❑ E-cigarettes are not considered a “tobacco product”
- ❑ Cost of implementation (e.g. to create new signs advertising policy)
- ❑ Difficulty of enforcing policy
- ❑ Resistance from staff
- ❑ Resistance from patients and visitors
- ❑ Belief that e-cigarettes are safe
- ❑ Limited understanding of e-cigarette safety based on current data
- ❑ Legal concerns
- ❑ Other _____
- ❑ None of these is a barrier

Q15 Which of the following are motivators for the development of a policy regulating use of e-cigarettes? Mark all that apply.

- ❑ Concern that e-cigarettes may be harmful to users
- ❑ Concern that e-cigarettes may be harmful through second-hand exposure / harm indoor air quality
- ❑ Concern that use of e-cigarettes might “re-normalize” smoking on campus, or lead to increased smoking of traditional cigarettes
- ❑ Concern that e-cigarettes are being marketed to or used by youth.
- ❑ Funding to subsidize costs of implementation
- ❑ Legislation prohibiting e-cigarette use in other public places (e.g. restaurants, workplaces, movie theaters) but NOT hospitals.
- ❑ Legislation regulating e-cigarette use specifically in hospitals
- ❑ Other _____
- ❑ None of these is a motivator

Q16 How would you describe your hospital’s current level of motivation to develop a policy regulating the use of e-cigarettes?

	Very Low	Low	Uncertain of Motivation	High	Very High

Q17 How soon is your institution likely to develop a policy regulating the use of e-cigarettes?

- ❍ 6 to 12 months
- ❍ >12 months
- ❍ Don't know

Section 3: These questions are about the safety of e-cigarettes.

Q18 In your opinion, how safe or unsafe are e-cigarettes for users?

	Very Unsafe	Unsafe	Uncertain whether Safe or Unsafe	Safe	Very Safe

Q19 In your opinion, how safe or unsafe are e-cigarettes for those exposed to second-hand "vapor"?

	Very Unsafe	Unsafe	Uncertain whether Safe or Unsafe	Safe	Very Safe

Q20 Have any of the following occurred in your hospital(s) as a result of e-cigarette use? Mark all that apply.

- ❑ Fires/burns
- ❑ Complaints filed regarding use of e-cigarettes
- ❑ Arguments/confrontations over e-cigarette use have been witnessed
- ❑ Other adverse event (please describe below): _____

Section 4: These questions are about attitudes and perceptions regarding the use of e-cigarettes at the hospital.

Q21 To what extent are the following groups using e-cigarettes on campus currently a problem? 0 = Not a problem 10 = Major Problem

_____ Hospital Staff
_____ Patients
_____ Visitors

Q22 To what extent is litter from e-cigarette components/accessories a problem at your hospital? 0 = Not a problem 10 = Major Problem

_____ Slide bar to answer

Q23 To what extent do you agree or disagree with the following statement: "Having an existing policy regulating the use of tobacco products on campus makes it significantly easier to implement policy regulating the use of e-cigarettes."

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree

Q24 Overall, how important or unimportant is it for hospitals to adopt policies regulating the use of e-cigarettes on campus?

	Very Unimportant	Somewhat Unimportant	Uncertain of Importance	Somewhat Important	Very Important

Section 5: DEMOGRAPHICS

Q25 Is your hospital public or private?

- ❍ Public
- ❍ Private

Q26 How many beds does your hospital have?

Q27 How many hospitals are owned / operated by your hospital system?

	1	2	3	4	5	6	7	8	9	10	>10

Q28 Does your hospital have an ACGME residency office?

- ❍ Yes
- ❍ No

Q29 Does your hospital gift shop sell any of the following items? Mark all that apply.

- ❑ Nictotine Gum
- ❑ Nicotine Lozenges
- ❑ Nicotine patches
- ❑ E-cigarettes

Q30 Thank you for taking the survey! Please use the space below to tell us anything else about e-cigarette use at your hospital.