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Exploratory Assessment of Manufactured E-Liquids and Do It Yourself (DIY) E-Liquids

By

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Bachelor of Science, The University of Georgia

A Thesis submitted to the Graduate Faculty
of Georgia State University in Partial Fulfillment

of the

Requirements for the Degree

MASTER OF PUBLIC HEALTH

ATLANTA, GEORGIA

30303

THESIS TITLE:

Exploratory Assessment of Manufactured E-Liquids and Do It Yourself (DIY) E-Liquids

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ABSTRACT

Introduction: Electronic Nicotine Delivery Systems (ENDS) debuted in 2006 within the U.S market as novel tobacco products and have been gaining popularity since. Without enforced regulations, prevalence of awareness and use has significantly increased. The purpose of this study is to explore the evolving landscape of ENDS using the Host, Agent, Vector, Environment (HAVE) model with a focus on manufactured e-liquids and do it yourself (DIY) e-liquids as the Agent.

Methods: Content analysis of e-cigarette web forums was conducted to identify popular brick and mortar point of sales (POS) for the purchase of ENDS products. POS were mapped out within a 1-, 2-, and 3- mile radius from three college campuses using Google Maps. An environmental scan was then conducted on randomly selected POS sites (N=17) where observations on e-liquid flavors and characteristics were identified. In addition, a content analysis of web forums was used to qualitatively characterize DIY e-liquids in depth.

Results: A total of 602 flavors were profiled in the POS environmental scans and five main flavor categories of e-liquids were identified: 1) Tobacco and Menthol (16.6%); 2) Desserts and Candies (16.6%); 3) Fruits (20.6%); 4) Drinks (10.1%); 5) Other (36.0%). Most flavored e-liquids were sold in stand-alone vials (91.0%). When sold with manufactured products, flavored e-liquids were sold in E-Hookahs (10.6%) compared to E-Cigarettes (4.7%). Most (96.8%) flavored e-liquids were available with and without nicotine. Based on content analysis of e-cigarette web forums, the words with the highest frequency in the DIY transcripts were: “flavor”, “mixing”, “liquid”, “calculators”, and “nicotine”.

Conclusions: Our findings indicate that for both manufactured and DIY e-liquids, flavors are a distinguishing and primary characteristic. Given these findings, increased surveillance efforts to monitor ENDS and e-liquids are necessary to inform regulatory science.

Key Words: ENDS, E-Cigarettes, E-Liquids, Do It Yourself, DIY

APPROVAL PAGE

Exploratory Assessment of Manufactured E-Liquids and Do It Yourself (DIY) E-Liquids

By
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Approved:

Dr. Shanta R. Dube, PhD - Committee Chair

Dr. Natalie D. Crawford, PhD - Committee Member

Date

AUTHOR'S STATEMENT

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CHAPTER I INTRODUCTION

1.1 Background

In 2003, Electronic Nicotine Delivery Systems (ENDS) were first manufactured in China. These products were later debuted in the U.S. market in 2006 as novel tobacco products and have been gaining popularity since^{1,2,3}. ENDS, such as e-cigarettes, are battery powered devices that heat a solution, typically containing nicotine, in order to create a vapor without the combustion of tobacco. This liquid is inhaled into the lungs and then exhaled similar to the use of traditional tobacco cigarettes. The solution, also known as e-liquid, can contain various levels of nicotine (including no nicotine) and is available in various flavors^{2,3,4}. While the average concentration of nicotine resulting from smoking traditional cigarettes was found to be 10 times greater than that of ENDS, the perceived risks and health benefits of these products as being safe alternatives or cessation devices is controversial⁵.

1.2 Purpose of Study

Studies have found that since 2006, the awareness and prevalence of use of ENDS has increased significantly among both youth and adults. The increase in use, especially among youth, has brought a large amount of attention to these products^{2,3,4}. A serious public health concern is that the use of ENDS may increase the risk of non-smokers developing nicotine dependence and ex-smokers or current smokers maintaining nicotine dependence⁶.

With the steady growth in popularity, the landscape of ENDS products is also constantly changing. The products are evolving daily and consumers have gotten more creative in their methods of use. Devices are now disposable, refillable, and customizable¹. E-liquid components, such as pure nicotine, are also sold separately for consumers to make their own liquids⁷, also

known as Do It Yourself (DIY) e-liquids. Therefore, there are thousands of different types of devices, different models, parts sold separately for devices, and flavor profiles to choose from, raising serious safety concerns especially since none of these products are currently regulated by the Food and Drug Administration (FDA).

ENDS are claimed to be designed to deliver nicotine without the toxic constituents of tobacco or tobacco combustion and carcinogens⁵. However, there is an extreme lack of literature regarding ENDS and e-liquids, and to our knowledge there is no literature about DIY e-liquids. The purpose of this study is to explore uncharted territory and solely focus on the evolving landscape of manufactured e-liquids and DIY e-liquids. Collecting reliable and valid data on ENDS, manufactured e-liquids, and DIY e-liquids is a priority for the FDA Center for Tobacco Products in order to inform their regulatory actions. The expected outcome of this research is two-fold: 1) inform FDA on regulating e-cigarettes as a tobacco product, including the e-liquids; and 2) provide valuable information needed to develop a testable survey instrument for population based surveys that can effectively measure risk and harm perceptions, as well as measure population level use of the products.

Research Questions

Question #1: What are the characteristics of manufactured e-liquids?

Question #2: What are the views and topics of importance on DIY e-liquids for ENDS users?

Because this study was exploratory, there are no hypotheses that are being tested.

CHAPTER II

REVIEW OF THE LITERATURE

2.1 Overview of Products

ENDS, of which e-cigarettes are the most commonly used products, deliver a vapor by heating a solution without the combustion of particles that users inhale^{2,3,4,8}. Typically, ENDS are composed of several components: a 1) mouthpiece, 2) battery, 3) microchip, 4) LED tip that glows when the device is in use, 5) cartridge that can hold liquid, and 6) a vaporization chamber which produces a vapor that is exhaled similar to that of a traditional cigarette (Figure 1)^{1,2,3}. ENDS are also available in various shapes and sizes. Some products are shaped to look like traditional cigarettes, hookah pens, cigars, cigarillos, and larger cylindrical or rectangular devices, while others resemble everyday items such as pens and USB memory sticks⁸. These devices are either disposable or rechargeable and have two plastic or metal interlocking tubes, one that contains the battery, and one that contains the atomizer used for heating and holding the e-liquid⁹. When a user inhales via the mouthpiece, a sensor in the device detects airflow and activates a heating element, usually a coil, which is in contact with the cartridge containing the e-liquid. As the airflow and temperature increase, the e-liquid is vaporized and an aerosol is formed and inhaled by the user¹⁰.

Cartridges, also called “cartomizers” or “atomized cartridges”, have built-in heating elements and can be refilled by the user with ready-to-use refill solutions, also referred to as “liquids”, “e-liquids”, or “juices”. These cartridges and ready-to-use refill e-liquids are available in various flavors such as tobacco, menthol, strawberry, apple, chocolate, vanilla, and several more¹⁰. Nicotine content is typically labeled either in numerical measurements such as 0 mg/mL-28 mg/mL or descriptive captions such as “extra strong/very high”, “strong/high”,

“regular/medium”, “light/low”, “ultra-light/very low”, or “zero/no nicotine”¹⁰. E-liquids are comprised of propylene glycol (PG) or glycerol/glycerin (or a mixture of the two), flavor constituents, water, dissolved nicotine, and in some cases added medications⁷. PG is a di-alcohol that could potentially induce a state of intoxication. When introduced into the body, PG is absorbed into the small intestine and is then transformed into energetic compounds. Whatever parts of PG that are not metabolized, are excreted through urine¹. Large bottles of e-liquids are available for purchase online with up to 720 mg of nicotine without stringent age verification methods. This is extremely dangerous considering this amount of nicotine is several times greater than the fatal dose of nicotine for a human⁷. Current users have also been found to buy these individual components, including pure nicotine, and make their own e-liquids (DIY) to refill devices typically without prior knowledge or education on handling toxic chemicals properly.

2.2. Marketing

Over recent years, consumer awareness and use of these products has increased. However, information on the availability and marketing of e-cigarettes in U.S. retail stores is limited¹¹. Product adoption patterns are driven and reinforced by tobacco and ENDS industry marketing, therefore it is important to understand advertising and marketing trends that consumers encounter¹². Because the FDA does not currently regulate ENDS, there are no laws against advertising and marketing. Marketed as an alternative to nicotine delivery and advertised as a smoking cessation tool, products such as e-cigarettes, e-hookahs, e-cigars, various flavored e-liquids, and other ENDS components are readily available and sold. The World Health Organization (WHO) estimates that \$3 billion US dollars was spent on ENDS globally, and it is estimated that 466 brands exist to date in 2014⁸.

A 2010 survey of ENDS users found that 96% of e-cigarettes were purchased from online sources¹¹. Therefore, the internet represents a main channel for marketing and selling ENDS products. However, a major concern exists due to the fact that only a small percentage of websites have age restrictions and age verification methods. This allows for easy youth access and marketing exposure¹². E-cigarette websites also frequently contain a wide variety of unfounded health claims, smoking cessation claims, and marketing claims. These claims could undermine smoking cessation and smoke-free policies¹². Marketing tactics also include images or features that appeal to youth and may encourage e-cigarette or tobacco initiation¹².

ENDS are widely available in retail outlets such as kiosks in shopping malls, online stores, gas stations, and several other locations¹⁰. In 2012, a study found that ENDS are available at approximately one-third of U.S. tobacco retailers such as tobacco stores, warehouse/supercenters, and convenience/gas stations. While pharmacy/drug stores sell nicotine replacement products, these point of sales (POS) derive less than 2% of sales from tobacco products. It was also found that areas with weaker tobacco control policies in both tax and smoke-free air are associated with greater availability of ENDS¹¹. Retail outlets are of interest because the products can be easily purchased and ready for use.

2.3 Safety and Harm Perceptions

Because ENDS are currently un-regulated and there is a lack of literature supporting any healthful benefits, there are several safety issues with the products. First and foremost, nicotine is an addictive substance and is highly toxic; it was formerly regulated as a pesticide^{1,4}. Absorption of nicotine into the circulatory systems is a concern because of the adverse side effects that have been documented¹. For those who actively use ENDS, studies have found that effects such as cough, sore throat, eye irritation, and an increase in airway resistance and heart rate are found

after smoking a single e-cigarette¹. In an animal study, chronic inhalation from an e-cigarette was found to augment inflammatory changes in the airway of a mouse, and short term usage was found to adversely affect lung function⁶. Similar case study reports have also documented that healthy people developed lipid pneumonitis and eosinophilic pneumonitis after using e-cigarettes⁶.

In an analytical study of two different brands of e-cigarette cartridges, the FDA found a number of impurities including polycyclic aromatic hydrocarbons and carcinogenic tobacco-specific nitrosamines. Also, while found at lower levels than traditional cigarette smoke, another study evaluated the vapor released from 12 different brands of e-cigarettes and found potentially toxic and carcinogenic substances⁹. Other studies have shown that while ENDS are effective in delivering nicotine to the body, there is also some evidence that the vapor may contain toxic compounds such as carbonyls, traces of nitrosamines, or even particles of heavy metal⁵.

The flavors in the e-liquids can also be dangerous. Depending on the flavor, the stability of the products can be affected. When found in flavors such as mint, vanilla, and fruit flavors, nicotine is often easily oxidized and may have a negative effect on the body⁷. Typically, the amount of nicotine degradation products and impurities are estimated to represent up to 4.4% of the overall nicotine content in e-liquids⁷. A study conducted by Etter et al., found that for a majority of the e-liquids, the levels were at 1%-2%. The study authors state that high amounts of nicotine-related impurities suggest that oxidative degradation of nicotine occurred during the manufacturing of the nicotine, during the manufacturing of the final liquid, or the e-liquid has an overall unstable formulation⁷.

Due to the lack of regulation and research done on these products, other quality control issues lie with the device itself. Battery voltage and unit circuitry characteristics vary between

brands and sometimes even similar products. These differences can cause the products' ability to heat the e-liquid to an aerosol to vary. This may, in turn, affect the delivery of the nicotine and other constituents while also contributing to the formation of toxicants in the emissions that are released⁸. Product characteristics, user puffing behavior, and nicotine solution concentrations are also thought to affect the efficiency of nicotine delivery and the possibility of creating by-products⁸.

The main health risk from nicotine exposure while using ENDS seems to be inhalation, however, nicotine overdose by ingestion or through dermal contact is also extremely dangerous^{4,8}. WHO states that most countries do not monitor these incidents, therefore data on the prevalence of occurrence is limited. However, one report from U.S. data indicated that the number of nicotine poisoning incidents has increased greatly as the use of ENDS have increased^{4,8}. WHO hypothesizes that the actual number of cases is probably much higher than those reported^{4,8}. In 2014, the CDC conducted a study tracking telephone calls to poison centers for exposures to ENDS. From 2010 to 2014, poison centers reported 2,405 e-cigarette exposure calls from across the U.S. and U.S. territories. The most common adverse health effects in these calls were vomiting, nausea, and eye irritation. One case reported was a suicide death from intravenous injection of nicotine liquid. Further, exposure was most common among persons aged 0-5 years and persons 20 years or older⁴.

2.4 Surveillance of ENDS

The prevalence of use and awareness of ENDS has dramatically increased since it was introduced into the U.S. market^{4,8}. Prior studies have found that e-cigarette availability increased from 3% in 2010, to 7% in 2011, to 31% in 2012¹¹. If these rates continue, sales are forecasted to increase by a factor of 17 by 2030⁸. While there is no data available on ENDS use at the global

level for many countries, data from North America show that ENDS use has approximately doubled between 2008 and 2012 in both adults and adolescents⁸. The most recent statistics for the United States show that in 2013, 47% of smokers and ex-smokers tried e-cigarettes, but the prevalence of consistent use was only 4% in this group. However, with the ever increasing rates of use and product availability, this number has probably increased greatly in under a year⁸.

Studies have found that susceptibility of traditional cigarette smoking among middle and high school students has not changed since 2000. Preventing cigarette smoking in these early stages is crucial to controlling the smoking epidemic¹³. The 2014 Surgeon General's report found that nicotine use can have adverse effects on adolescent brain development¹⁴. Therefore, preventing the exposure and use of ENDS products in adolescents is critical. Due to the lack of enforced regulations, many states have no restrictions on sales of ENDS products to minors⁴. Between 2011 and 2012, e-cigarette use doubled among middle and high school students¹⁴. Among high school students, ever e-cigarette use increased from 4.7% to 10.0%, and current e-cigarette use almost doubled from 1.5% to 2.8%¹⁴. CDC has found that high school students who use e-cigarettes are two times more likely to have intentions to use conventional cigarettes. This is reflected by the fact that in this survey, among high school students, 80.5% of current e-cigarette users reported current conventional cigarette smoking¹⁴. For 2014, current use of e-cigarettes by themselves was only 0.6% among high school students and 0.4% among middle school students¹⁵.

Continued monitoring and surveillance of ENDS awareness and use is needed because of the recent increases in e-cigarette use among youth and adults. Most national tobacco surveys, such as The National Youth Tobacco Survey, include only a single question asking about e-cigarette use¹⁵. With the constant changes in ENDS product development, marketing, and sales,

an important endeavor is to accurately ascertain type of ENDS that consumers are using. Accurate measurement is critical to determine risks, possible health benefits, and perceptions around use. This information can then be used to better understand ENDS and e-liquid evolution to support the development of regulations to protect users and those that are exposed to these products.

2.5 Theoretical Basis of the Study

For the purpose of this study, a new application of an existing epidemiological model for tobacco control will be used. The host, agent, vector, environment (HAVE) model has traditionally been used to study the interplay of various influences on tobacco use in populations¹⁶. The host is defined as the consumer or potential consumer of the product. In tobacco control, individuals that use traditional cigarettes and ENDS are the hosts. The agent is the factor that is required for a disease to occur similar to how tobacco products and tobacco smoke cause addiction and disease. Tobacco products and ENDS that are marketed, sold, and used are agents. The vector is the organism or object that distributes the agent. Tobacco and ENDS companies and other users can act as vectors by distributing tobacco and ENDS products. The environment is composed of the external influences that the host, agent, and vector operate by. Familial, social, cultural, historical, economic, political, legal and media-related factors affect awareness and use of tobacco and ENDS products¹⁶. As Figure 2 depicts, this study will use the HAVE model with a particular focus on e-liquids as the agent.

Using the HAVE model, the agent of e-liquids will be assessed with a focus on characterizing aspects about manufactured e-liquids and DIY e-liquids. Manufactured e-liquids are available in various nicotine concentrations and flavors. Therefore, it is important to assess characteristics of these liquids to inform future research to ensure product quality and that

marked amounts are being sold. Constituents of DIY e-liquids are also readily available to make homemade e-liquids. Understanding DIY e-liquids will allow the ability to assess the characteristics of liquid nicotine distributors are as well as how and where ENDS users are accessing and purchasing components to e-liquids.

Understanding how these products are marketed and sold is important from the perspective of characterizing consumer and harm perceptions. Characterizing the agent of e-liquids in terms of content and product constituents, will inform future research to address the host, vector, and environment elements of the HAVE model for ENDS. In addition, collecting reliable and valid information on manufactured e-liquids and DIY e-liquids is crucial and may be used to further inform FDA regulatory actions.

FIGURES AND TABLES

Figure 1. Components of a Typical E-Cigarette¹⁷

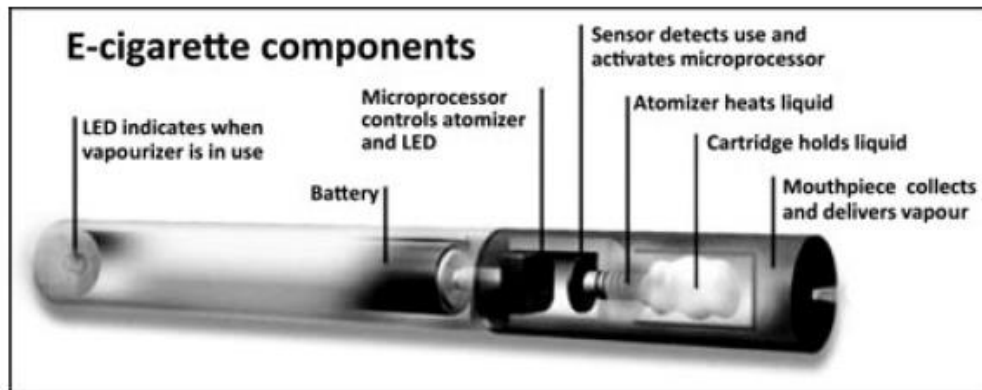
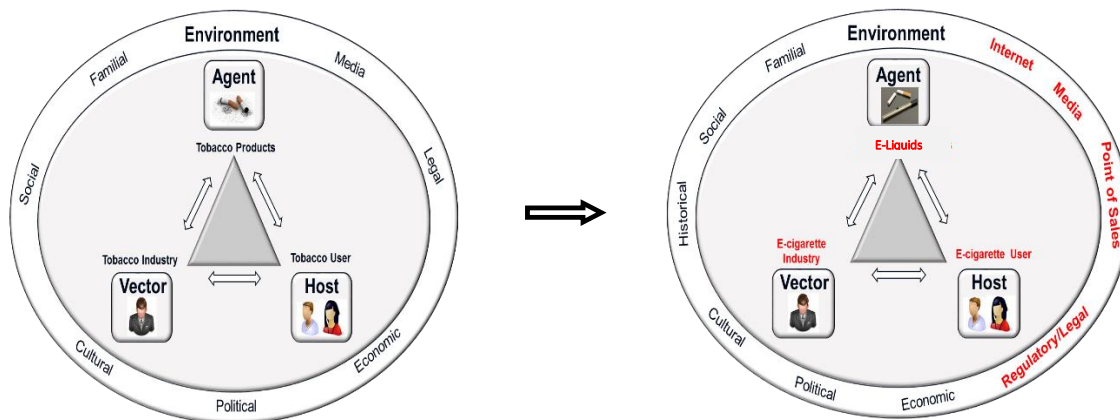


Figure 2. The Host, Agent, Vector, Environment (HAVE) Epidemiologic Model for Tobacco Control Adapted for Understanding Novel Tobacco Products¹⁶.



REFERENCES

1. Bertholon JF, Becquemin MH, Annesi-Maesano I, Dautzenberg B. Electronic Cigarettes: A Short Review. *Respiration*. 2013. doi:10.1159/000353253.
2. Regan AK, Promoff G, Dube SR, Arrazola R. Electronic nicotine delivery systems: adult use and awareness of the “e-cigarette” in the USA. *Tobacco Control* 2013;22(1):19-23. doi:10.1136/tobaccocontrol-2011-050044.
3. King BA, Patel R, Nguyen KH, Dube SR. Trends in Awareness and Use of Electronic Cigarettes Among U.S. Adults, 2010-2013. *Nicotine & Tobacco Research* 2014. doi:10.1093/ntr/ntu191.
4. Centers for Disease Control and Prevention. Calls to Poison Centers for Exposures to Electronic Cigarettes, United States, September 2010 - February 2014. *Morbidity and Mortality Weekly Report*. April 4, 2014; 63(13):292-293. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm>.
5. Czogala J, Goniewicz ML, Fidelus B, Zielinska-Danch W, Travers MJ, Sobczak A. Secondhand Exposure to Vapors From Electronic Cigarettes. *Nicotine & Tobacco Research*. 2014;16(6):655-662. doi:10.1093/ntr/ntt203.
6. Lam DCL, Nana A, Eastwood PR, Asian-Pacific Society of Respiriology (APSR). Electronic cigarettes: “Vaping” has unproven benefits and potential harm. *Respirology*. 2014;19(7):945-947. doi:10.1111/resp.12374.
7. Etter J-F, Zäther E, Svensson S. Analysis of refill liquids for electronic cigarettes. *Addiction*. 2013;108(9):1671-1679. doi:10.1111/add.12235.
8. Electronic nicotine delivery systems Report by WHO. *Conference of the Parties to the WHO Framework Convention on Tobacco Control*. 2014;FCTC/COP/6/10. http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf?ua=1.
9. Electronic cigarettes. *JAMA*. 2014;311(2):195-195. doi:10.1001/jama.2013.283624.
10. Goniewicz ML, Kuma T, Gawron M, Knysak J, Kosmider L. Nicotine Levels in Electronic Cigarettes. *Nicotine & Tobacco Research* 2012;nts103. doi:10.1093/ntr/nts103.
11. Rose SW, Barker DC, D’Angelo H, et al. The availability of electronic cigarettes in US retail outlets, 2012: results of two national studies. *Tobacco Control* 2014;23(Suppl 3):iii10-iii16. doi:10.1136/tobaccocontrol-2013-051461.
12. Grana RA, Ling PM. “Smoking Revolution.” *American Journal of Preventive Medicine*. 2014;46(4):395-403. doi:10.1016/j.amepre.2013.12.010.
13. Dube SR, Arrazola RA, Lee J, Engstrom M, Malarcher A. Pro-Tobacco Influences and Susceptibility to Smoking Cigarettes Among Middle and High School Students—United States, 2011. *Journal of Adolescent Health*. 2013;52(5):S45-S51. doi:10.1016/j.jadohealth.2012.07.007.

14. Centers for Disease Control and Prevention. Notes from the Field: Electronic Cigarette Use Among Middle and High School Students — United States, 2011–2012. 62(35);729-730. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm>. Accessed October 4, 2014.
15. Centers for Disease Control and Prevention. Notes from the Field: Tobacco Use Among Middle and High School Students — United States, 2013. 2014.63(45);1021-1026. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6345a2.htm?s_cid=mm6345a2_e.
16. Giovino GA. Epidemiology of tobacco use in the United States. *Oncogene*. October 21, 2002; 21(48). doi:10.1038/sj.onc.1205808.
17. Foulds J, Veldheer S, Berg A. Electronic cigarettes (e-cigs): views of aficionados and clinical/public health perspectives. *International Journal of Clinical Practice*. 2011;65(10):1037-1042. doi:10.1111/j.1742-1241.2011.02751.x.

CHAPTER III**MANUSCRIPT**

Chapter 3 is the full manuscript that will be submitted for publication.

Intended Journal of Publication: Nicotine & Tobacco Research

Exploratory Assessment of Manufactured E-Liquids and Do It Yourself (DIY) E-Liquids

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ABSTRACT

Introduction: Electronic Nicotine Delivery Systems (ENDS) have gained popularity as novel tobacco products since their debut in the U.S market in 2006. Without enforced regulations, prevalence of awareness and use has significantly increased. The purpose of this study is to explore the evolving landscape of ENDS using the Host, Agent, Vector, Environment (HAVE) model with a focus on e-liquids as the Agent.

Methods: Content analysis of e-cigarette web forums was conducted to identify popular brick and mortar point of sales (POS) for the purchase of ENDS. POS were mapped within a one-, two-, and three- mile radius from three college campuses. An environmental scan was conducted on randomly selected POS sites (n=17) where observations on e-liquid flavors and characteristics were identified. A content analysis of web forums was also used to qualitatively characterize do it yourself (DIY) e-liquids in depth.

Results: A total of 602 flavors were profiled in the POS environmental scans and five main flavor categories of e-liquids were identified: 1) Tobacco and Menthol (16.6%); 2) Desserts and Candies (16.6%); 3) Fruits (20.6%); 4) Drinks (10.1%); 5) Other (36.0%). Most (91.0%) flavored e-liquids were sold in stand-alone vials. Significantly more flavored e-liquids were sold in E-Hookahs (10.6%) compared to E-Cigarettes (4.7%). E-liquids were available with and without nicotine. Content analysis of DIY transcripts found the most commonly used words to describe e-liquids was: “flavor”, “mixing”, “liquid”, “calculators”, and “nicotine”.

Conclusions: We identified various types of e-liquids and common descriptors used to label these products. Increased surveillance efforts to monitor ENDS and e-liquids are necessary to inform regulatory science.

Key Words: ENDS, E-Cigarettes, E-Liquids, Do It Yourself, DIY

INTRODUCTION

Electronic Nicotine Delivery Systems (ENDS), first manufactured in China in 2003 and later debuted in the U.S. market in 2006 as novel tobacco products, and have been steadily gaining popularity^{1,2,3}. ENDS, such as e-cigarettes, are battery powered or disposable devices that heat a solution, typically containing nicotine, in order to create a vapor without the combustion of tobacco. They are often marketed as an alternative to nicotine delivery and advertised as a smoking cessation tool widely available at retail outlets such as kiosks in shopping malls, online stores and gas stations⁴.

Studies have found that since 2006, the awareness and prevalence of ENDS use has increased significantly among both youth and adults^{2,3,6}. A serious public health concern is that the use of ENDS may increase the risk of non-smokers developing nicotine dependence and ex-smokers or current smokers maintaining their dependence on the drug⁸. The increase in use among youth has also brought attention to these products because of the vulnerability of this population to initiate and become nicotine dependent^{2,3,6}. Between 2011 and 2012, e-cigarette use doubled among middle and high school students⁹. Among high school students, ever e-cigarette use increased from 4.7% to 10.0%, and current e-cigarette use increased from 1.5% to 2.8%⁹. CDC also found that high school students who use e-cigarettes are two times more likely to have intentions to use conventional cigarettes. This is reflected by the fact that in this survey, among high school students, 80.5% of current e-cigarette users reported current conventional cigarette smoking⁹. For 2014, current use of only e-cigarettes was 0.6% among high school students and 0.4% among middle school students¹⁰.

Typically, ENDS are composed of several components: a 1) mouthpiece, 2) battery, 3) microchip, 4) LED tip that glows when the device is in use, 5) cartridge that can hold liquid, and

6) a vaporization chamber which produces a vapor that is exhaled similar to that of a traditional cigarette^{1,2,3}. ENDS are also available in various shapes and sizes. Some products are shaped to look like traditional cigarettes, hookah pens, cigars, cigarillos, and larger cylindrical or rectangular devices, while others resemble everyday items such as pens and USB memory sticks⁵. The solution used with ENDS, also known as e-liquid, e-juice or juice, can contain various levels of nicotine (including no nicotine) and is available in various flavors^{2,3,5,6}. Nicotine content is labeled either in numerical measurements or descriptive captions such as “extra strong/very high”, “strong/high”, “regular/medium”, “light/low”, “ultra-light/very low”, or “zero/no nicotine”⁴. E-liquids are comprised of propylene glycol (PG) or glycerol/glycerin (or a mixture of the two), flavor constituents, water, dissolved nicotine, and in some cases other medications. Large bottles of e-liquids are available for purchase online with up to 720 mg of nicotine⁷ which is extremely dangerous considering this amount of nicotine is several times greater than the fatal dose of nicotine for a human⁷. Consumers use e-liquids, including pure nicotine, to make their own liquids⁷, also known as Do It Yourself (DIY) e-liquids which raises additional safety concerns given that the Food and Drug Administration (FDA) do not regulate these products.

The main health risk from nicotine exposure while using ENDS seems to be inhalation, however, nicotine overdose by ingestion or through dermal contact is extremely dangerous⁵. A CDC study found poison centers reported 2,405 e-cigarette exposure calls from across the U.S. and U.S. territories from 2010-2014. The most common adverse health effects in these calls were vomiting, nausea, and eye irritation. One case reported was a suicide death from intravenous injection of nicotine liquid. In addition, exposure was most common among persons aged 0-5 years and persons 20 years or older⁶.

ENDS are claimed to be designed to deliver nicotine without the toxic constituents of tobacco or tobacco combustion and carcinogens¹¹. However, there is an extreme lack of research regarding ENDS and manufactured e-liquids, and absolutely no literature about DIY e-liquids. On a current U.S. national tobacco survey, The National Youth Tobacco Survey, there is only a single question asked about ENDS use¹⁰. There are very few other statistics available to determine the increasing rates of use, therefore, there is also a severe gap in surveillance.

The present study focuses on assessing manufactured e-liquids and DIY e-liquids and is part of a larger three-phase pilot study, where the overarching objective was to characterize ENDS at point of sales. As shown in Figure 1, the host, agent, vector, environment (HAVE) model informs this research and has been used to study the interplay of various influences on tobacco use in populations¹². Using the HAVE model, the agent will be assessed with a focus on characterizing aspects about manufactured e-liquids and DIY e-liquids. Collecting reliable and valid data on manufactured e-liquids and DIY e-liquids is crucial in order to inform regulatory actions. This study will provide preliminary data on what is currently marketed and sold as manufactured e-liquids, as well as, provide an overview of DIY e-liquids to inform FDA regulatory action, as well as help in measurement development for use in population based surveys to monitor attitudes, perceptions and use of these products.

METHODS

Data

Data used for this study was collected through a pilot study entitled, “Understanding the E-Cigarette Landscape: An Environmental Scan of Point of Sales and Website Forums” funded by Georgia State University’s (GSU), School of Public Health, Tobacco Center of Regulatory Science (TCORS) in 2014. The three specific aims of the pilot study were to: 1) assess where

ENDS users purchase their products through a content analysis of web forum blogs; 2) conduct environmental scans at brick and mortar (BM) point of sales (POS) identified in phase 1 to begin to characterize ENDS product configurations; and 3) to use data from phases 1 and 2 to inform the development of novel survey measures about ENDS. The institutional review board at GSU deemed this study to be exempt for these phases of the pilot study given that no human subjects were involved. For the purpose of this analysis, only data collected about e-liquids were used.

Existing data from two separate e-cigarette and vapor web-based forums, <http://www.vaportalk.com> and <http://www.e-cigarette-forum.com>, were analyzed to identify brick and mortar POS for the environmental scan. These web-based forums are blogs where ENDS users discuss and share the latest about e-cigarettes. Two graduate students used key words and strings including “buy”, “bought”, “purchase”, “juice”, “e-liquid”, “e-cigarette”, “e-hookah”, “mall kiosks”, “gas stations”, “convenience stores”, “pharmacy/drug stores”, “tobacco/smoke shop” to find blog postings discussing the various ENDS and e-liquids that are available and the POS from which individuals typically purchase products from. While exploring the online blogs, DIY e-liquids emerged as a common trend among ENDS users. In order to delve further into this culture, key words and strings including “DIY”, “Do It Yourself”, “e-liquid”, “make”, and “recipe” were used to find blog postings focused on DIY e-liquids. The relevant blog postings were collected, compiled, and de-identified transcripts were created for each online forum. DIY transcripts were compiled separately from the POS transcripts in order to highlight the particular culture of individuals combining e-liquid components to make their own “juice”.

A content analysis was conducted on the POS transcripts in order to identify and rank most commonly stated BM locations in the blog postings based on frequency and conduct

observations of the various products that are available. Based on the content analysis, the most commonly cited BM POS were: 1) Specialty Stores – vape, tobacco, smoke shops; 2) Walmart; 3) Gas Stations/Convenience Stores; 4) Walgreens; 5) Shopping Mall; 6) Grocery Store; 7) Rite Aid. These BM POS were used as inclusion criteria and POS were mapped out within a one-, two-, and three- mile radius from two urban college campuses, Georgia State University and Georgia Institute of Technology, and one rural college campus, The University of Georgia using Google Maps. Once all locations were mapped using Google Maps, four POS within a one-mile radius, and two POS within each two- and three- mile were randomly selected at each campus. More POS were selected within the one-mile radius in order to thoroughly explore the availability of ENDS found in close proximity to the colleges.

For the purpose of this manuscript, only POS with manufactured products and e-liquids were included. The environmental scans were specifically conducted during peak daylight hours and only those POS that were deemed as safe by the researchers were entered. As a result, 7 POS were excluded from this study: 6 did not have ENDS of any kind and 1 appeared unsafe to enter. Therefore, the final dataset included data from 17 POS (70.8%), which included: 3 gas stations, 2 drug stores, 2 grocery stores, 8 specialty stores, 1 mall store, and 2 other stores (e.g. Walmart). The two researchers went to each of these POS together and catalogued findings via pictures taken on mobile phones. These pictures were later organized into a database defining product characteristics such as types of devices, configurations of products, and e-liquid data including nicotine concentration and liquid flavors.

Because DIY e-liquids are a new area in the realm of ENDS, key words and strings were used to also qualitatively conduct a content analysis of DIY transcripts.

For the purpose of this study, the primary sampling unit is e-liquid flavor. The flavors were characterized in terms of the following:

Manufactured E-Liquid:

Manufactured e-liquids are defined as e-liquids that are pre-made and can be readily bought either with or without ENDS products.

Manufactured With ENDS E-Liquid:

Manufactured with ENDS e-liquids are manufactured e-liquids that are only sold in or with ENDS products such as e-cigarettes and e-hookahs.

Stand-Alone E-Liquid Vials:

Stand-alone e-liquid vials are manufactured e-liquids that are available in individual dropper-type bottles and are sold independently of ENDS products. These e-liquids are typically used as refill solutions in reusable devices.

Zero Nicotine Available:

E-liquids are typically sold with various nicotine concentrations, including zero nicotine. For the purpose of this study, zero nicotine available refers to e-liquids that are available containing nicotine, but are also available without any nicotine.

DIY E-Liquid:

DIY e-liquids are defined as e-liquids that are made by consumers that purchase individual components such as propylene glycol (PG), vegetable glycol/glycerin (VG), various nicotine concentrations (including pure nicotine), and flavorings. Blog transcripts captured the different components, recipes, and overall culture surrounding the DIY e-liquids.

Analysis

The Statistical Package for the Social Sciences (SPSS) v21 was used to isolate and analyze manufactured e-liquid data. Frequency tables were produced to complete a descriptive analysis of the e-liquid products that were available based on characteristics such as flavor category, e-liquids sold with manufactured products, product type, stand-alone e-liquid vials, and whether the e-liquid was available in zero nicotine.

DIY e-liquids were assessed through a thorough content analysis of blog transcripts in NVIVO 10 in which the frequency of most commonly used terms was discovered. The language used for DIY e-liquid culture was also qualitatively observed through the content analysis.

RESULTS

Through the POS environmental scans, 602 total flavors were profiled. Further analysis of the data indicated there are five main flavor categories of e-liquids: 1) Tobacco and Menthol (16.6%); 2) Desserts and Candies (16.6%); 3) Fruits (20.6%); 4) Drinks (10.1%); 5) Other (36.0%). Tobacco and Menthol flavors essentially mimic the flavors of traditional tobacco products. “Cotton candy”, “fruity pebbles”, “gummi bear”, and “key lime pie” are some examples of Desserts and Candies flavors. Fruit flavors included a wide range of different types of fruits such as “georgia peach”, “green apple”, and “melon mania”. Drink flavors utilized typical drink names that are already in the market as beverages such as “pina colada”, “earl grey tea”, and “red bull”. The Other category of flavors are all miscellaneous flavors that could not be easily categorized otherwise. Some examples of Other flavors include “red pirate”, “midnight express”, and “dragons breath”.

Most flavored e-liquids were sold in stand-alone vials (91.0%). When sold with manufactured products, flavored e-liquids were most commonly sold in e-hookahs (10.6%).

Table 1 further depicts the frequency of e-liquid characteristics within these flavor categories. Of the 602 flavored e-liquids that were profiled, nicotine concentrations, particularly zero nicotine, were only observed for 583. All 583 (96.8%) of these flavored e-liquids were available containing nicotine and also zero nicotine. When nicotine concentration was observed, flavored e-liquids were most commonly sold in stand-alone vials (94.0%) and in e-hookahs (11.0%) when found sold with a manufactured ENDS product.

Figure 2 depicts the top 50 most commonly used words that were found within the transcripts. The content analysis of DIY web forums revealed the most frequently used words: “flavor”, “mixing”, “liquid”, “calculators”, and “nicotine”. Through the content analysis, several themes of DIY e-liquids emerged. Individuals on the web forums discussed the specifics of how to DIY e-liquids in terms of what perceived safety measures should be taken, what supplies were needed, explicit directions as to what to mix and for how long the e-liquid should steep, and finally e-liquid measurements and conversions were discussed. Some bloggers shared explicit directions as to what the perceived safe retail strengths of nicotine are, how to purchase bulk e-liquid base ingredients including propylene glycol (PG) and vegetable glycerin (VG), how to store e-liquids that are made, and the availability of 99% pure nicotine. Further, e-juice calculators are readily found online, used and, discussed on the blogs. DIY e-liquid users also shared recipes for particular e-liquid flavors such as “apple pie”, for example. Qualitatively, it was found that the web forums are a place for DIY-users to ask for tips and questions, share recipes and other information, including the positive benefits of making e-liquids at home.

DISCUSSION

Our study found that e-liquids and e-liquid constituents are readily used and available in today’s market in a variety of stores. Manufactured e-liquids are found in a various assortment of

flavors of which our study identified over 600 unique flavors across 3 different college campuses equally. All flavored e-liquids that are available with different nicotine levels were also found sold with zero nicotine. DIY e-liquids were also discovered to be a common practice among ENDS users in which PG, VG, flavorings, and ranging concentrations of nicotine (12mg to 99% pure) are bought and mixed at home, typically without prior knowledge or education on handling toxic chemicals properly.

Policy Implications

Past studies have found that flavored e-liquids increase the use of ENDS, particularly in youth. Our findings confirmed the availability of e-liquids available in a multitude of flavors. The accessibility of flavored e-liquids, particularly those that fall under the Desserts and Candies category, and the presence of zero nicotine in these flavors can spark interest and lure more youth to initiate the use of ENDS products. Enforced regulations are needed to control the flavors that are manufactured and to prohibit the sale of ENDS products to minors. In addition, strict regulations should be placed on the purchase of e-liquid constituents, such as nicotine, for DIY e-liquids to prevent access to toxic substances, particularly to avoid exposure for children and adolescents.

Manufactured e-liquids are available in various nicotine concentrations and flavors. Therefore, it is important to assess characteristics of these liquids to inform regulatory science to ensure product quality and that marked amounts are being sold. Constituents of DIY e-liquids are also readily available to make homemade e-liquids. Understanding DIY e-liquids will allow the ability to assess the characteristics of liquid nicotine distributors are as well as how and where ENDS users are accessing and purchasing components to e-liquids.

Limitations

A limitation of this study is that it was based solely on observed qualitative data. A supplementary quantitative study to empirically examine the availability of ENDS across a variety of retail stores and the categories of availability of various e-liquid products would strengthen the findings of this study. Further, because this small pilot study focused on select POS around three college campuses, the findings may not be generalizable to all e-liquids and ENDS users in the U.S. Nonetheless, the finding that there are approximately 600 distinct type of flavors warrants attention, and further post market surveillance.

Future Research

Future research must be conducted to determine the health effects of flavored e-liquids and ENDS on users. While some knowledge regarding DIY e-liquids was discovered, further studies need to be done to fully understand the culture and possible implications of individuals making their own e-liquids. Understanding how these products are marketed and sold is important from the perspective of characterizing consumer and harm perceptions. Characterizing the agent of e-liquids in terms of content and product constituents, will inform future research to address the host, vector, and environment elements of the HAVE model for ENDS. In addition, collecting reliable and valid information on manufactured e-liquids and DIY e-liquids is crucial and may be used to further inform FDA regulatory actions.

The findings of this study can be used to enhance future surveillance and research through the use of reliable survey measures with more detailed information on e-liquids and ENDS. With the dramatic increase in rates of awareness and use, and the constantly changing landscape of ENDS, accurate survey measures are critical in order to determine risks, possible health effects, and perceptions around use. This information can then be used to better

understand e-liquids and ENDS evolution while developing regulations to protect users and those that are exposed to these products.

ACKNOWLEDGEMENTS

The authors of this paper would like to thank Jennifer Koncul for her help in data collection and documentation. The pilot data used for this was from the pilot study “A Pilot Study to Understand the Evolution of Electronic Cigarettes (E-Cigarettes): An Environmental Scan at Point of Sales in Southeast United States” funded under GSU’s RO1 research project “Conducting Consumer Behavior, Risk Perception and Media Research on Novel Tobacco Products” and was supported by Grant Number: 1P50DA036128-01.

REFERENCES

1. Bertholon JF, Becquemin MH, Annesi-Maesano I, Dautzenberg B. Electronic Cigarettes: A Short Review. *Respiration* 2013. doi:10.1159/000353253.
2. Regan AK, Promoff G, Dube SR, Arrazola R. Electronic nicotine delivery systems: adult use and awareness of the “e-cigarette” in the USA. *Tobacco Control* 2011; 22(1);19-23. doi:10.1136/tobaccocontrol-2011-050044.
3. King BA, Patel R, Nguyen KH, Dube SR. Trends in Awareness and Use of Electronic Cigarettes Among U.S. Adults, 2010-2013. *Nicotine & Tobacco Research* 2014. doi:10.1093/ntr/ntu191.
4. Goniewicz ML, Kuma T, Gawron M, Knysak J, Kosmider L. Nicotine Levels in Electronic Cigarettes. *Nicotine & Tobacco Research* 2012;nts103. doi:10.1093/ntr/nts103.
5. Electronic Nicotine Delivery Systems Report by WHO. Conference of the Parties to the WHO Framework Convention on Tobacco Control: FCTC/COP/6/10. Available at: http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf?ua=1
6. Centers for Disease Control and Prevention. Notes From The Field: Calls to Poison Centers for Exposures to Electronic Cigarettes, United States, September 2010 - February 2014. *Morbidity and Mortality Weekly Report*. April 4, 2014; 63(13); 292-293.
7. Etter J-F, Zäther E, Svensson S. Analysis of refill liquids for electronic cigarettes. *Addiction* 2013;108(9):1671-1679. doi:10.1111/add.12235.
8. Lam DCL, Nana A, Eastwood PR, Asian-Pacific Society of Respiriology (APSR). Electronic cigarettes: “Vaping” has unproven benefits and potential harm. *Respirology* 2014; 19(7);945-947. doi:10.1111/resp.12374.
9. Centers for Disease Control and Prevention. Notes From The Field: Electronic Cigarette Use Among Middle and High School Students — United States, 2011–2012; 62(35);729-730. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm>. Accessed October 4, 2014.
10. Centers for Disease Control and Prevention. Notes From The Field: Tobacco Use Among Middle and High School Students — Unites States, 2013. 2013; 63(45);1021-1026. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6345a2.htm?s_cid=mm6345a2_e.
11. Czogala J, Goniewicz ML, Fidelus B, Zielinska-Danch W, Travers MJ, Sobczak A. Secondhand Exposure to Vapors From Electronic Cigarettes. *Nicotine & Tobacco Research* 2014;16(6):655-662. doi:10.1093/ntr/ntt203.
12. Giovino GA. Epidemiology of tobacco use in the United States. *Oncogene*. October 21, 2002; 21(48). doi:10.1038/sj.onc.1205808.

FIGURES AND TABLES

Table 1. Frequency and Percent of E-Liquid Characteristics by Flavor Categories (N=602)

Variable	Classification	E-Liquid Flavor Category					Total
		Tobacco and Menthol	Desserts and Candies	Fruits	Drinks	Other	
		n (%)					
Manufactured ENDS	Yes	27 (28.1)	5 (5.2)	38 (39.6)	12 (12.5)	14 (14.6)	96 (15.9)
	E-Cigarette	15 (53.6)	2 (7.1)	6 (21.4)	3 (10.7)	2 (7.1)	28 (4.7)
	E-Hookah	10 (15.6)	3 (4.7)	30 (46.9)	9 (14.1)	12 (18.8)	64 (10.6)
	Both	2 (50.0)	0 (0.0)	2 (50.0)	0 (0.0)	0 (0.0)	4 (0.7)
	No	73 (14.4)	95 (18.8)	86 (17.0)	49 (9.7)	203 (40.1)	506 (84.1)
Stand-Alone Vials	Yes	82 (15.0)	98 (17.9)	105 (19.2)	53 (9.7)	210 (38.3)	548 (91.0)
	No	18 (33.3)	2 (3.7)	19 (35.2)	8 (14.8)	7 (13.0)	54 (9.0)
Zero Nicotine Available	Yes	87 (14.9)	99 (17.0)	123 (21.1)	59 (10.1)	215 (36.9)	583 (96.8)**

** Zero Nicotine Available had 19 (3.2%) missing values that could not be observed during the POS environmental scans

