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Electronic Cigarette Refill Liquids: Child-Resistant Packaging, Nicotine Content, and Sales to Minors[1,2]

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Purpose: To determine the accuracy of the labeled quantity of the nicotine content of the e-liquids sold in unlicensed vape stores, whether the packaging of e-liquids sold within the vape stores was child-resistant, whether minors were present within vape stores, and whether sales to minors occurred. This study was conducted across North Dakota prior to implementation of a new e-cigarette state law and provided a baseline assessment before enactment of the new legal requirements.
Design and Methods: We tested samples of e-liquids and performed observations in 16 stores that were selling e-cigarettes but were not legally required to be licensed for tobacco retail. The e-liquids were analyzed for nicotine content using a validated high-performance liquid chromatography method for nicotine analysis.
Results: Of the 70 collected e-liquid samples that claimed to contain nicotine, 17% contained more than the labeled quantity and 34% contained less than the labeled quantity by 10% or more, with one sample containing 172% more than the labeled quantity. Of the 94 e-liquid containers sampled, only 35% were determined to be child-resistant. Minors were present in stores, although no sales to minors occurred.
Conclusions: Mislabeling of nicotine in e-liquids is common and exposes the user to the harmful effects of nicotine. The lack of child-resistant packaging for this potentially toxic substance is a serious public health problem. E-cigarettes should be included in the legal definition of tobacco products, child-resistant packaging and nicotine labeling laws should be enacted and strictly enforced, and vape stores should be licensed by states.

Electronic cigarettes (e-cigarettes) are one type of electronic nicotine delivery system that is experiencing rapid growth in the United States, with sales more than doubling from 2012 to 2013 (Giovenco, Hammond, Corey, Ambrose, & Delnevo, 2015). E-cigarette makers increased yearly advertising spending from $6.4 million in 2011 to $18.3 million in 2012, including marketing on television, where regular cigarette advertising is banned (King, Patel,

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Nguyen, & Dube, 2015). From 2013 to 2014, e-cigarette use by U.S. teenagers tripled, with e-cigarettes now used more than any other tobacco product, including conventional cigarettes (Arrazola et al., 2015; Centers for Disease Control and Prevention [CDC], 2015a). Use among high school students increased from 660,000 students (4.5%) in 2013 to 2 million students (13.4%) in 2014 (CDC, 2015a). E-cigarette use more than tripled among middle school students, from 120,000 students (1.1%) in 2013 to 450,000 students (3.9%) in 2014 (CDC, 2015a). From 2010 to 2013, adults who have used an e-cigarette increased from 3.3% to 8.5%; current and former cigarette smokers who have ever used an e-cigarette increased from 9.8% to 36.5% and from 2.5% to 9.6%, respectively (King et al., 2015).

E-cigarettes include disposable and reusable products. At its most basic, e-cigarettes include a container of liquid that is often, but not always, a nicotine solution; a battery or other power source; an aerosol generator that heats the nicotine and other chemicals; and a flow sensor (Brown & Cheng, 2014). The aerosol generator turns the liquid into an aerosol that is inhaled by the user. Of interest to this study was the e-cigarette liquid refill solution (e-liquid; Pepper & Eisenberg, 2014). E-liquids can be purchased separately from the e-cigarette and typically contain nicotine, flavors, and solvent chemicals, including polyethylene glycol and vegetable glycerin, but may also contain contaminants, such as diethylene glycol, heavy metals, and potential carcinogens, such as nitrosamines (Cheng, 2014; Orellana-Barrios, Payne, Mulkey, & Nugent, 2015). This study did not assess substances, legal or illegal, added by consumers after purchase.

Public health officials are concerned that e-cigarette use among youth will become a gateway to regular cigarettes and other tobacco products. E-cigarettes often have attractive packaging and flavored liquids that appeal to youth. Nicotine negatively affects fetal lung development and fetal and adolescent brain development (England, Bunnell, Pechacek, Tong, & McAfee, 2015). The aerosol released from e-cigarettes contains particulate matter and is not considered as safe as clean air (California Department of Public Health & California Tobacco Control Program, 2015; CDC, 2015b). Additionally, federal regulation and oversight of e-cigarettes and e-liquids are lacking (Orellana-Barrios et al., 2015). A systematic literature search showed several studies in which the labeling of the nicotine content on e-liquid containers varied significantly from the measured actual content; of the six studies that analyzed "refillable solutions," one reported a range of ±100% deviation from the label (Cheng, 2014). Davis, Dang, Kim, and Talbot (2015) reported that 35 of 54 nicotine fluids varied by more than ±10% from the labeled amount. Hutzler et al. (2014) reported that seven of 10 liquids with claims that they were nicotine free contained 0.1 to 15 mg/mL of nicotine.

A study by the Salt Lake County Health Department (2014) in Utah showed that the advertised nicotine content of e-liquids was not consistent with the actual nicotine content; 61% of the e-liquids that did not list a nicotine amount of zero differed by at least 10% of the labeled nicotine content. The difference ranged from 88% less to 840% more than advertised. Additionally, 28% of the samples that had listed amounts of nicotine did not have child-resistant caps. E-liquids are not federally required to have child-resistant packaging (Orellana-Barrios et al., 2015).

In North Dakota (ND), legislation enacted August 1, 2015 (NDCC § 12.1-31-03.2.1), prohibits the sale of e-cigarettes to minors and requires child-resistant packaging for liquid nicotine containers per federal standards (North Dakota Legislative Council, 2015; Sixty-Fourth Legislative Assembly of North Dakota, 2015). The number of calls to U.S. poison centers related to human exposure to e-cigarettes (exposure calls) has dramatically increased, from one in September 2010 to 215 in February 2014, representing a 47% proportionate increase in e-cigarette exposure calls within the total e-cigarette and conventional cigarette exposure calls (Chatham-Stephens et al., 2014). From September 2010 to February 2014, 2405 e-cigarette exposure calls occurred. Slightly more than half involved children younger than 5 years of age. E-cigarette-related poisoning can occur through ingestion, inhalation, or absorption through the skin or eyes, commonly resulting in nausea, vomiting, and eye irritation. The American Association of Poison Control Centers (2014) supports federal legislation to require child-proof packaging for liquid nicotine because of the death of a 1-year-old, possibly due to ingestion of liquid nicotine (Hugher, 2014).

The purposes of this study were to determine the accuracy of the labeled quantity of the nicotine content of the e-liquid containers sold in unlicensed vape stores; to determine whether the packaging of e-liquids sold in vape stores was child-resistant; and to assess for the presence of minors within vape stores. We also assessed for any sales to minors of e-cigarettes, e-liquid, or other tobacco products within the vape store.

Methods

The settings for this cross-sectional study were 16 unlicensed vape stores across ND prior to implementation of the state's e-cigarette law. Data collection occurred from June 9, 2015, to June 16, 2015, between 10:00 am and 2:30 pm. The data collection form was based on questionnaires used by the Salt Lake County Health Department and the North Dakota Center for Tobacco Prevention and Control Policy questionnaires, which were modified with permission. The study was determined to be exempt by the appropriate institutional review board.

We included stores that sold e-cigarettes but did not have a license to sell tobacco products. When the study was conducted, a state license was not required for stores that sold e-cigarettes because they were not considered a tobacco product (ND State Attorney General's Office, personal communication, May 2015). We evaluated these stores because they were comparatively new and were considered unlikely to be compliant with the prohibition against the sale

of e-cigarettes to minors. In addition, public officials were concerned that the requirement for child-resistant packaging on e-liquids would not be met by vape stores. The study served as a baseline evaluation of vape stores prior to enactment of the state law.

To identify vape stores, we obtained a list of stores selling e-cigarettes from the ND agency that provides funding to local public health agencies that report openings of vape stores. Because American Indian reservations do not have to comply with ND's tobacco laws, stores situated on reservations were excluded. Reports were obtained from all counties. We compared the most recent list of stores licensed to sell tobacco issued by the state Attorney General's office with our list of unlicensed vape stores to ensure that none of the vape stores in our study were licensed. A data collector located one additional store while driving past it, which was included in the study after determining that it was not licensed. Twenty-six vape stores were initially identified. Of these, two stores were no longer in business, one store owner denied selling e-liquids at the time, one store owner denied ever selling e-liquids, and six stores had state tobacco licenses, resulting in a total of 16 vape stores included in the study.

This study included four variables: (1) nicotine levels in the e-liquids for e-cigarettes, (2) child-resistant packaging of e-liquids, (3) presence of minors in the stores, and (4) observed sales of e-liquid or other tobacco products to minors appearing to be younger than the age of 18 years.

There are six more common e-liquid strengths available for purchase from stores or on the Internet, containing 0, 6, 12, 18, 24, and 36 mg/mL of nicotine. Data collectors were instructed to purchase all of the six more common strengths of e-liquids that were available. When possible, they purchased e-liquid containers that appeared to be made by the local stores rather than those readily identifiable as commercialized containers sold by tobacco companies. During data collection, it was reported that other concentrations were sometimes available; therefore, we included some of these less common strength concentrations in the analysis. Additionally, stores were asked by the data collector whether they could add extra nicotine to the e-liquids. Each variable was tallied for descriptive summary statistics. Nicotine content for the common strength concentrations was reported as mean actual concentration and standard deviation for each labeled concentration. For the less common strength concentrations, the mean and range were reported.

Nicotine Levels

Nicotine levels were assessed in the e-liquids sold in nicotine liquid containers for e-cigarettes using the validated high-performance liquid chromatography method for nicotine analysis adapted from Trehy et al. (2011), and the method compatibility and linearity were evaluated. A Shimadzu LC-2010A-HT (Columbia, Maryland) equipped with a UV-detector was used to perform the analysis of the samples. The detection and quantification of nicotine were performed at 260 nm. The sample matrix commonly consisted of any one of the following or a mixture of two or more of the ingredients, such as vegetable glycerin, propylene glycol, ethylene glycol, flavor-inducing chemicals, and water. To assay the nicotine present in the liquid cartridges, a cleanup step for the sample was included in the preparation, using a solid-phase extraction method.

The U.S. Food and Drug Administration (FDA) Center for Tobacco Products has not published any criteria for nicotine in currently regulated tobacco products (i.e., cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco; Center for Tobacco Products, personal communication, June 2015). However, the American E-Liquid Manufacturing Standards Association (2015) voluntary guidelines recommend that the nicotine content be within a 10% variation from the label. Therefore, we reported the actual variation of nicotine content found within the e-liquid containers compared with that labeled on the container.

Child-Resistant Packaging

In 2014, ND passed NDCC § 12.1-31-03.2.1 (North Dakota Legislative Council, 2015; Sixty-Fourth Legislative Assembly of North Dakota, 2015). Under this law, any nicotine liquid container sold in ND must satisfy the child-resistant effectiveness standards set forth in Title 16 CFR 1700 § 15(b)(1) when tested in accordance with the method described in title 16, CFR, part 1700, § 20. This standard is the U.S. Consumer Product Safety Commission's Poison Prevention Packaging Act of 1970, 1700.15 Poison Prevention Packaging Standards, b (1) (Consumer Product Safety Commission; U.S. Government Publishing Office, 2012).

On receiving each e-liquid container, packaging details were noted, including how the package was closed (i.e., a child safety cap) and whether it had a seal on the lid to prevent tampering. Part 1700 § 20, "Testing Procedure for Special Packaging" (U.S. Government Publishing Office, 2012), requires a minimum of 50 children to conduct the child test. The U.S. Consumer Product Safety Commission (2005) stated that pharmacists are responsible for ensuring that the packages they dispense, including dropper bottles, meet special packaging guidelines. Due to the time and financial constraints of this study, in lieu of assessing child-resistant effectiveness with groups of children, a panel of three expert practicing pharmacists assessed child-resistant effectiveness of the liquid nicotine containers and reached agreement on whether the packages were child-resistant.

Presence of Minors and Sales to Minors

The presence of minors and sales of e-cigarettes, e-liquids, or other tobacco products to minors were assessed. Minors were defined as youth appearing to be younger than 18 years of age. The age of youth was assessed by observation using the data collector's best judgment without further substantiation of age (Yes/No). To determine sales, data collectors noted the presence of youth, and one of the study's researchers followed up with the data collectors to

ascertain whether any sales of products described previously were made to the minor(s). Inter-rater reliability was not assessed during data collector training, although data collectors were all experienced in discrete data collection.

Results

All stores meeting the study's definition were assessed ($N = 16$). All concentrations of e-liquid in each store were requested for purchase; requests for additional alternate concentrations were included, where possible. No 36-mg/mL e-liquids were available for purchase. The number of e-liquid samples analyzed for child-resistant packaging was 94. Because one of the 94 samples was not labeled for nicotine content, 93 samples were analyzed for nicotine content, with 70 claiming to contain nicotine and 23 labeled as containing no nicotine. Sales clerks in four stores stated that they could add more nicotine to the e-liquid containers. One store provided all of its eight solutions by mixing the concentrations from stock bottles.

Nicotine Content

Labeled nicotine concentrations among the 70 samples that claimed to contain nicotine ranged from 3 mg/mL to 24 mg/mL. Allowing for a 10% tolerance in concentration, 36 (51%) were outside the labeled concentration, with 24 (34%) containing less nicotine than labeled and 12 (17%) containing more than labeled. Actual variation ranged from 66% (2.0/6.0 mg/mL) below the labeled amount to 172% more than (13.6/5.0 mg/mL) the labeled concentration.

Of the 23 samples with a label claim of 0 mg/mL, 10 (43%) contained nicotine. The average amount of nicotine in these samples was 0.19 mg/mL, with the highest level at 0.48 mg/mL. Among the 51 more common concentrations, 22 (43%) varied by more than 10%, and among the 19 less common concentrations, 14 (74%) varied by more than 10% (Table 1). The less common concentrations (3 mg/mL, $n = 7$; 5 mg/mL, $n = 2$; 10 mg/mL, $n = 3$; 15 mg/mL, $n = 2$; 16 mg/mL, $n = 3$; and 20 mg/mL, $n = 2$) were significantly more likely to be outside the acceptable range ($\chi^2 = 5.17$, $p = .02$; Table 2). Appendices A and B (online supplement) provide the results for each sample labeled as 0 mg/mL and greater than 0 mg/mL, respectively.

Labels on several samples claimed a specific nicotine content amount in large print; however, a statement indicating that a higher level of nicotine might be present appeared on the container in smaller print. Figure 1 shows a container that claims a nicotine level of 6 mg/mL in large print, whereas the small print states, "May contain up to 35 mg of nicotine per mL." Also, some e-liquid labels included claims of containing vitamin B12 and vitamin C.

Table 2 Nicotine content of less common concentrations of e-liquid ($n = 19$).

Mean (label), mg/mL	7.17
Mean (actual), mg/mL	9.29
Range (label), mg/mL	3.00–20.00
Range (actual), mg/mL	2.22–25.91
>10% below label, *n* (%)	9.00 (47)
>10% above label, *n* (%)	5.00 (26)

Packaging

Packaging was variable. One package looked like a cigarette lighter, with no child-resistant features. The rest were glass or plastic vials of various sizes and colors that had a screw cap closure of some kind ($n = 93/94$, 99%). Bottles generally contained 15 mL or 30 mL of liquid. Often, different size containers were provided for different strengths at the same store. Most had labels provided by the manufacturer, which contained a variety of information and warnings about the product, but information varied from manufacturer to manufacturer. Also, some containers had no label and were written on with a magic marker.

Most caps were judged to be similar to child-resistant prescription closures, which require downward force at the same time as they are unscrewed for opening ($n = 71/94$, 76%). Some of the tops could be opened easily with minimal downward pressure on the first attempt ($n = 14/94$, 15%), and 9 (10%) needed no downward pressure at all; therefore, these were classified as nonresistant. The closures that opened with minimal downward force often worked correctly if tightened completely when put back on. In addition, many of the closures, despite otherwise being child-resistant screw tops, were eyedroppers with rubber bulbs ($n = 51/94$, 54%). The pharmacists noted that these bulbs could easily be chewed on by a child to obtain access to the liquid in the container; the bulbs might also become detached from the dropper and become a choking hazard. Thus, such tops were scored as not child-resistant. In sum, of the 94 e-liquids sampled, 33 (35%) were determined to be

Table 1 Nicotine content of the common concentrations of e-liquid.

Nicotine content	6 mg/mL $n = 15$	12 mg/mL $n = 14$	18 mg/mL $n = 14$	24 mg/mL $n = 8$
Mean	5.49	11.02	17.30	24.21
SD	1.22	2.84	3.23	1.82
Range	2.02–7.64	4.22–13.73	11.38–24.76	22.39–26.81
>10% below label, *n* (%)	7 (46.67)	4 (28.57)	4 (28.57)	0 (0.00)
>10% above label, *n* (%)	1 (6.67)	2 (14.28)	2 (14.28)	2 (25.00)

Figure 1 E-liquid refill container labeled as 6 mg nicotine (top), with warning, "May contain up to 35 mg of nicotine per mL" (bottom).

fully child-resistant. Excluding those labeled as containing no nicotine, 25/72 (35%) were determined to be fully child-resistant.

Most of the packages stated that the product was not meant to be used by minors and had warnings about the poisonous nature of the product, but the warnings were not consistent. Many labels mentioned that the product was not FDA approved. One label stated that the product was "FDA registered." Although the FDA registers manufacturing establishments, it does not register products; thus, this statement may be misleading to consumers (FDA).

Presence of Minors and Sales to Minors

Minors, youth who appeared to be younger than age 18, were present in two stores. In no cases were any sales to minors observed.

Discussion

Key Results

This study included 16 vape stores; 94 e-liquid containers were assessed for child-resistant packaging, and 93 were analyzed for nicotine content. Similar to Hutzler et al. (2014), we found nicotine present in the products claiming to be nicotine-free. Similar to other studies, mislabeling occurred (Cheng, 2014; Davis et al., 2015; Hutzler et al., 2014; Salt Lake County Health Department, 2014); most commonly, there was less than the amount on the label. Taking into account the 10% tolerance for variation, 51% of the e-liquid samples had amounts that were above or below the amount shown on the label. Actual variation ranged from 66% below the labeled amount to 172% more than the labeled amount. Less common concentrations were significantly more likely to be outside the acceptable range than were the more common concentrations.

The lack of child-resistant packaging is gravely concerning. Excluding e-liquids labeled as not containing nicotine, 65% were determined not to be fully child-resistant. Warning labels were not consistent.

Limitations

This study had some limitations. Only unlicensed vape stores ($N = 16$) were included in the study, and licensed tobacco retail stores ($N = 1482$) were excluded because tobacco retail stores were not required to identify the types of tobacco or nicotine products sold, which may limit generalizability only to unlicensed vape stores. Studies in the future should be expanded to include all vendors who sell e-cigarettes. In addition, the sample size was small, which may further limit generalizability. There may have been more vape stores in existence than were located by our identification method because of the fast-growing number of stores and the absence of licensing regulations for selling e-cigarettes, which would have permitted identifying all vape stores. We also estimated the number of flavors that were available in each vape store.

Because our assessment of sales to minors was based on observation only, results may have been different had a minor actually attempted to purchase e-cigarettes. The time of day in which the data were collected may have been a factor in the number of minors who were present in the vape stores. Because there are no federal or state criteria regarding child-resistant packaging for e-liquid containers, we based our assessment of child-resistant containers on comparable packaging for prescription drugs. Data collection was performed discreetly to avoid behavior change among shoppers and store owners (Bohac et al., 2010) and to prevent store owners from discussing the study with one another.

Interpretation

There appears to be considerable variability in selling practices for e-liquid products in ND, likely due to poor manufacturing processes and the lack of regulation. Mislabeling of nicotine content occurred 51% of the time, especially in the less common concentrations. Inaccurate labeling can be hazardous because individuals are not expecting to be exposed to higher levels of nicotine than

the label indicates. The presence of nicotine in e-liquids labeled nicotine-free exposes the user to the harmful effects of the nicotine.

The overwhelming lack of child-resistant packaging for this potentially toxic substance is of grave concern. In addition to the potential for children to access the e-liquids that contain nicotine, adults also may not be as careful with storage of "nicotine-free" e-liquids near children. Because nicotine affects fetal lung development and fetal and adolescent brain development (England et al., 2015) and with the dramatic increase of poison center calls, particularly concerning children younger than 5 years of age who have had exposures to e-cigarettes, it is imperative that federal regulations be enacted and enforced to stop the preventable poisonings and deaths of children related to e-cigarettes and e-liquids.

E-cigarettes and e-liquids should be included in the legal definition of tobacco products; federal child-resistant packaging laws and strict control on nicotine labeling should be enacted and enforced; and vape stores should be licensed by states, as are other tobacco retailers. New legislation in ND requires child-resistant packaging, and we recommend strict enforcement and follow-up of this requirement.

This study was conducted in one state and our results likely are typical for other states. Even so, we encourage replication of our study in other states.

Clinical Implications for Nursing

It is important for nurses to be aware of the major health risks to children and adolescents posed by e-cigarettes and e-liquids, as outlined in Table 3. Nurses could educate children, youth, parents, and policy makers on these risks and be prepared to answer questions related to e-cigarettes and e-liquids. Specifically for young children, parents should be educated to place e-cigarettes and e-liquids out of reach to prevent accidental poisoning and death (American Association of Poison Control Centers, 2014; Chatham-Stephens et al., 2014) and to call their poison hotline if nicotine is ingested by young children. All parents and adolescents could be taught that exposure to nicotine can affect fetal lung development and fetal and adolescent brain development (England et al., 2015), that secondhand exposure to vapor from e-cigarettes may contain carcinogens (Goniewicz et al., 2014), and that e-cigarette vapor is not as safe as clean air (Marynak et al., 2014). Parents and adolescents could also receive education that although fires and explosions related to e-cigarettes are considered rare and cannot be fully prevented by the user, using the appropriate charging supply has been recommended by the U.S. Federal Emergency Management Agency (2014). Finally, in line with Provisions 8 and 9 of the Code of Ethics for Nurses with Interpretive Statements (American Nurses Association, 2015), nurses could engage in the development of and advocacy for legislation and policies to promote health; thus nurses could advocate for legal public health protections, including local, state, and federal regulations (Sattler & Davis, 2008), from the dangers of e-cigarettes and e-liquids by communicating with local, state, and federal authorities.

Table 3 Potential risks of e-cigarettes and e-liquids to children and adolescents.

Poisoning and death from nicotine ingestion, inhalation, or absorption through skin or eyes [a,b]
Decreased fetal lung development due to nicotine exposure [c]
Decreased fetal brain development due to nicotine exposure [c]
Altered adolescent brain development due to nicotine exposure [c]
Exposure to toxic aerosolized constituents, including nicotine particulate matter, and to carcinogens [d]
Use of flavored products, advertising that attracts youth attention, and other techniques previously used by tobacco companies to increase cigarette use by youth may increase e-cigarette use by youth [e,f,g]
E-cigarette use may be a potential gateway to other tobacco use [h]
Lack of laws in many states that prohibit purchase by minors [h]

[a] American Association of Poison Control Centers, (2014).
[b] Chatham-Stephens et al. (2014).
[c] England et al. (2015).
[d] Goniewicz et al. (2014).
[e] Legacy (2014).
[f] U.S. Department of Health and Human Services (2012).
[g] Centers for Disease Control and Prevention (2016).
[h] Marynak et al. (2014).

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