

Electronic Delivery Systems: An Adolescent Educational Initiative

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Abstract

Adolescent consumption of Electronic Delivery Systems (EDS) is considered an epidemic by the Surgeon General for being the most commonly used method of consuming nicotine, chemically enhanced flavorings, THC, or other additives. The increase in prevalence can be correlated to delayed regulations and sanctions, increased advertisements, and disinformation throughout various platforms in the US. The current adolescent perception is that these devices are less harmful than conventional cigarettes, even though harmful carcinogenic agents and irritants are present. As a result, the current perception has increased the number of hospitalizations from pathophysiological disturbances in the brain and lungs, e-cigarette or vaping associated lung injury (EVALI), and addiction rates. Furthermore, to date, analysis of EDS in the local community of Seminole County, Florida, has been minimally addressed, although local school officials have declared concern. Due to the lack of data from the most rapidly growing EDS consumers, this project aimed to address knowledge, susceptibility, perceived risks, and intent for these devices' future consumption. An EDS assessment of adolescent quantitative knowledge from Forest Lake Academy (FLA) students in Orlando, Florida, was performed. Unfortunately, the scholarly project yielded a poor response rate (n=0) of the possible 428 students. Since no statistical analysis was performed, a literature review on incentives and the most appropriate methods to attract adolescents into participating into the scholarly project was evaluated.

Keywords: Electronic smoking, marijuana, THC, adolescents, perceived effects, adverse effects, prevalence, incidence, education, knowledge deficit.

Electronic Delivery Systems in Adolescents

Use of Electronic Delivery Systems (EDS) in the adolescent population has increased in prevalence, resulting in addiction, physiological damage, and hospitalization. As a result, many government and medical organizations have shown concern (CDC, 2019, OSG 2016, & NIH, 2018, SAMHSA, 2020). The problems associated with vaping identified at the national level are also present in Orlando, Florida, as well as in the local secondary schools. Possible solutions identified included addressing any knowledge or educational gaps that were present regarding adolescent misconceptions of the risks associated with using EDS.

Significance & Background of Identified Problem

Since the emergence of EDS, adolescent consumption increased 900% specifically from 2011 to 2015 (CDC, 2016; Truth Initiative, 2020). In 2012 -2016 the CDC estimated that as many as one-in-four high school students had consumed an EDS within 30-days. The National Institute of Health (NIH) has indicated that this consumption in growth resulted from experimentation (60.9%), flavor/taste (41.7%), social reasons (37.9%), relaxation/stress relief techniques (37.4), hallucinogenic effects (29%), boredom (28.7%), addiction to EDS (8.1%), and the implementation of misguided attempts to assist adolescents in quitting conventional cigarettes (6.1%) (CDC, 2019, OSG 2016, & NIH, 2018). The slow implementation of regulatory policies, also contributed to exponential growth, leading to the current national epidemic. Furthermore, with the lack of EDS regulation, misconceptions about these devices, and a knowledge gap regarding safety and health effects developed (Glasser et al., 2017, Morean, Kong, Camenga, Cavallo, & Krishnan-Sarin, 2015, Simmons et al., 2016).

In an attempt to combat the growth of EDS use, the US Food and Drug Administration (FDA) enforced the 2009 Tobacco Control Act as a way to begin regulation (SAMHSA, 2020).

As a result, EDS manufacturers were finally required to disclose both harmful, and carcinogenic agents (i.e., nickel, lead, chromium, and cadmium) (Drope et al., 2017, Hess et al., 2017, Pisinger & Dossing, SAMHSA, 2020, & Simmons et al., 2016). Additionally, the US Government established “The Real Cost” campaign, which was targeted to the adolescent population for the provision of societal and healthcare interventions. The implementation of The Real Cost campaign has seen some success, as every \$1 spent has saved \$128 in costs associated with smoking-related harms (CDC, 2019; SAMHSA, 2020; & OSG, 2016). These beginning attempts at regulation and prevention, however, have not curbed the accelerating growth in EDS use, as this growth directly results from adolescent perceptions of EDS as less harmful, toxic, and addictive in comparison to traditional cigarettes. Furthermore, adolescents have unfortunately developed inaccurate but positive views towards EDS, which include convenience, accessibility, social benefits, and novelty (CDC, 2019, Glasser et al., 2017, SAMHSA, 2020, & Simmons et al., 2016).

Paralleling the growth of EDS use nationally, electronic delivery systems employed for the delivery of nicotine or marijuana, have become second only to alcohol as the most frequently used illicit substance by Florida youths (DCF, 2019; SAMHSA, 2020). In Seminole County, where this scholarly project will be implemented, 23.3% of high school students have used an EDS device within the last 30 days (DCF, 2018). Given the current acceleration in consumption, at the national, state, and local level, cost-effective, evidence-based strategies are needed for the reduction and prevention of EDS use (Wang, et al., 2020 & OSG, 2016). To achieve this goal, the US Department of Health and Human Services has declared that it will be essential to employ a multifaceted approach that includes educating adolescents regarding the health-related risk of using these devices (2016).

In Seminole County, specifically, FLA administrators and leaders have acknowledged a deficiency of an EDS curriculum for its students, addressing gaps in knowledge, risk beliefs, and relationships between EDS and students. Therefore, the purpose of this scholarly project will be to evaluate adolescent pre- and posttest knowledge, susceptibility, perceived risks, and intent of future consumption of EDS, as well as to determine if a formal educational module on EDS, results in a significant change.

PICOT Evidence Review Questions

Regarding adolescent knowledge of EDS and perceived health effects, two questions, posed in PICO format have assisted in the literature review. The first question is directed towards the clinical area of concern: Among high school adolescents (P), is there a knowledge deficit in perceived health effects of using electronic delivery systems (I), and does the comprehension of delivery systems change the intent to use or not to use them (O)?

The second question addresses innovations for the clinical problem: In adolescents attending FLA in the spring of the 2020-2021 academic cycle (P), does a 30-minute online educational module based on the health hazards and risks associated with the use of EDS (I) lead to a difference in adolescent pre and posttest knowledge, susceptibility, perceived risks, and intent to consume EDS (O)?

Search Strategies

The search strategy included databases (Google Scholar, Ovid and PubMed), government websites (The Centers for Disease Control and Prevention (CDC), The Office of the Surgeon General (OSG), U.S. Department of Health and Human Services (HHS), Substance Abuse and Mental Health Services Administration (SAMHSA), professional organizations (Florida Department of Children & Families (DCF), American Association of Nurse Anesthetists

(AANA)), nonprofit public health organizations such as The Truth Initiative, and article reference lists. Key Search Terms included: *electronic nicotine delivery systems AND systematic review OR Adolescent AND adolescent behavior/psychology AND marijuana smoking/epidemiology AND marijuana smoking/psychology*. MESH terms included: *adverse effects, aerosols/chemistry, environmental pollutants/analysis, nicotine/analysis, tobacco/chemistry, vaping, health risks, vulnerability, smoking/epidemiology, human, adolescent, young adult education*. The search limits were human subjects, years 2014 to 2020 and the English language. A total of 107 articles were initially retrieved. Articles were excluded after reviewing titles, abstracts, and purpose statements, to determine relevance. Inclusion criteria consisted of topics related to EDS's manufacturing, distribution, marketing, health risks, knowledge and perception, and prevention programs for adolescents. Thirty-one studies were ultimately retained.

GRADE Criteria

Literature was reviewed using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) tool. The initial rating was high + 4, as the majority of research consisted of systematic reviews. However, case reports, single site research, qualitative and cohort studies were also included. In addition, issues with study quality such as methodological flaws, small sample sizes, lack of control groups and self-reported assessments, paired with concerns regarding the possibility of publication bias resulted in a grading down by - 2. The overall rating was then increased by +1 as educational initiatives concerning adolescent smoking have resulted in a large magnitude of effect bringing the overall GRADE score to a 3 or Moderate quality. While the overall GRADE of the literature was moderate, the low risk of educational interventions coupled with education's possibly beneficial impact on adolescent

susceptibility, perceived risks, and intent of future consumption of EDS a strong practice recommendation can be made.

Terms and Definitions

Prior to the discussion of the literature definitions and terms must be clearly outlined.

- EDS: Also known as electronic delivery systems, will include electronic cigarettes (e-cigarettes), electronic nicotine delivery system, electronic pipes, vape pens, Juuls®, and vaping. EDS is defined as a handheld battery-operated device or “cigarette” that delivers aerosol vapor instead of a smoke, and typically contain nicotine, additives and other potentially harmful substances (i.e., Tetrahydrocannabinol) that are inhaled by the user.
 - THC: Also known as tetrahydrocannabinol, will include cannabis, cannabinoid, marijuana, hash oil, and is a compound defined as the main psychoactive ingredient in cannabis (Curran et al., 2016; Morean, Kong, Camenga, Cavallo, & Krishnan-Sarin, 2015).
 - Two separate labels are used to describe EDS consumers: “Ever-use” and “30-day use”.
 - Ever-use describes individuals who at any point in their life have used an EDS.
 - Thirty-day use refers to individuals who have used an EDS specifically, within the last thirty-days (Glasser et al., 2017, Kann et al., 2018, Morean, Kong, Camenga, Cavallo, & Krishnan-Sarin, 2015, Palamar, Ompad, & Petkova, 2014, Selph et al., 2020, Simmons et al., 2016, Sze et al., 2018).
1. Establish baseline knowledge of students attending FLA from the 2020-2024 cohorts regarding the use of electronic delivery systems and their risks by September 2021.
 2. Compare pre- and post-risk beliefs of students attending FLA from the 2020-2024 cohorts regarding the use of electronic delivery systems by September 2021.

3. Compare the prevalence of e-cigarette product use in students attending FLA in the 2020-2024 cohorts to the 2019 prevalence of e-cigarette product use in the state of Florida by September 2021.
4. Assess the tobacco product susceptibility of students attending FLA from the 2020-2024 cohorts regarding the use of electronic delivery systems and their risks by September 2021.
5. Determine if a relationship exists between specific risk beliefs and e-cigarette use in students attending FLA in the 2020-2024 cohorts by September 2021.
6. Determine if there is a relationship between pre and posttest knowledge scores and specific risk beliefs regarding electronic delivery systems within the FLA 2020-2024 cohorts after completing a 30-minute module by September 2021.
7. Determine if there is a difference between pre and posttest e-cigarette intentions within the FLA 2020-2024 cohorts after completing a 30-minute module by September 2021.
8. Determine if there is a difference between pre and posttest e-cigarette willingness responses within the FLA 2020-2024 cohorts after completing a 30-minute module by September 2021.
9. Relate the potential implications for scholarly project findings to FLA key players and make evidence-based recommendations to guide e-cigarette prevention efforts for students attending FLA by April 2022.

Methods

Design

The intent for this scholarly project was to employ a quantitative pretest-posttest, quasi experimental design. The pretest-posttest design is a well-accepted approach for the evaluation of interventional programs (Alessandri, Zuffiano, & Perinelli, 2017). In this scholarly project a baseline assessment of the prevalence of tobacco product use, student knowledge, risk beliefs, perceived risks, product susceptibility, e-cigarette intentions, and willingness to consume was intended to provide essential baseline data. The posttest would have facilitated a better understanding of the effects of the developed educational intervention in the FLA student population and has been employed for future tailoring of program content.

Setting

A suburban, private Seventh-day Adventist Christian high school for grade 9-12 students in Apopka, Florida.

Sample

The targeted population for this scholarly project included all adolescents attending FLA in the Fall of the 2021-2022 academic cycle. This scholarly project has employed convenience sampling and included all FLA students that met inclusion criteria. Given the importance of addressing the stated knowledge gaps, the best outcome was to enroll the entire targeted population of 428 students. This scholarly project included all students who attended FLA unless parents of those students who are under 18 years of age opt their child out. However, since participation was voluntary, it was understood that 100% participation was unlikely. Ultimately, the participation rate for this scholarly project was zero.

Ethical Considerations and Protection of Human Subjects

FLA students and parents of students that were younger than 18 years old were notified about the scholarly project via email. Both students and parents were also notified of the anonymous nature of the pretest-posttest and the parents were given access to review the Canvas course and pretest-posttest two weeks prior to its opening in compliance with the Protection of Pupils Rights Act (PPRA). To make pairing pretest and posttest data possible, the first pretest question asked the students to create their own identification number using a combination of their first and last initials, their mother's birth date and the number of children in their household. No personal identifiers or demographics were collected from participants.

Recruitment Methods and Implementation Procedures

Two separate emails, utilizing FLA's Microsoft Outlook account, were sent by the FLA registrar's office on August 11, 2021. One was sent to the parents or guardians, of students under the age of 18, the other to all FLA students, introducing the scholarly project, describing its voluntary nature, and providing information in general terms (See Attachment #1: Parent Email and Attachment #2: Student Email). Parents of students younger than 18-years-old were given an opportunity to review the pretest and posttest (sent to them as an email attachment) and the EDS course content (a Canvas course invitation, was generated for them by the FLA Information Technology Department (IT) before the project began. If they wished, parents were able to opt their child out of the Canvas course by emailing the registrar. A list of those students 18 years of age or older, as well as students whose parents had not opted them out, were compiled by the registrar and submitted to IT for enrollment in the EDS course: *The Truth Behind The Smoke*. Two weeks after the recruitment email, IT then generated an invitation for all students listed. Students 18 years and older not wishing to participate, had the choice not to click on the Canvas

link and enroll. Once enrolled, all students were able to click out of the Canvas course at any time if they decided they no longer wished to participate. This course was available for students and remained open for a full academic quarter. Once the Canvas course closed, pretest and posttest data from Microsoft Forms, contained in a Microsoft Excel spreadsheet, was downloaded to Microsoft Teams for analysis.

Data Collection

Canvas provided a secure environment to deliver course content with the ability to hide participant names and control users' access to specific features in a lock step manner. The initial plan was for students to be guided to Module 1, which was designed to welcome and familiarize them with course navigation. Module 2 contained an introduction and explanation of the anonymous nature of the pretest-posttest and included the actual pretest which was an anonymous survey created in Microsoft Forms. Microsoft Forms' data is fully encrypted both in transit and at rest, thus making survey responses anonymous, despite investigators, FLA personnel and parents having access to the Canvas course. The core content of the course was contained in Module 3 and was created for asynchronous delivery in one 30-minute module titled, "The Truth Behind the Smoke". The content was delivered via a Vimeo video presentation. Module 4, contained the 28-question posttest, again administered via an anonymous survey created in Microsoft Forms. Module 4 concluded with an exit page thanking students for their participation and provided further resource links on the subject of EDS.

Data Storage

This project was implemented within an academic setting thus, prior to implementation, all services and software were confirmed to be FERPA compliant. (Canvas 2015; Instructure, 2020; Microsoft, 2019).

Instruments

This scholarly project employed selected portions of the Adolescent E-Cigarette Pilot Study survey which was initially developed and piloted in electronic form (Rohde et.al., 2018). The survey had consistent results across three studies with the original subsection of risk beliefs as well as the adapted dangers, harmful effects and willingness to use e-cigarettes sections achieving an alpha of > 0.08 for both pretest and posttests (Rhode et.al., 2018; Noar et.al., 2019 & Reznicek, 2019). These results confirmed the reliability and validity of the selected tool.

Data Analysis

Despite the scholarly project 44-day availability and project investigators face-to-face recruitment, neither survey was completed by any FLA students. Therefore, an analysis of data could not be performed.

Planning

Stakeholder buy-in was key for implementation. FLA key stakeholders were onboarded early in the summer of 2020 and include Dr. Glen Baker, Principal of FLA, Susan Becker, Vice-Principal of FLA, Jaymie Pottinger Vice-Principal of FLA, the FLA Board of Directors, and Information Technologists. Buy-in was easily obtained as Dr. Baker was already aware of increasing EDS use but a clear delineation of FLA student knowledge gaps, and the prevalence of EDS use within FLA had yet to be quantified. An additional need for baseline data to better describe the problem at FLA was also expressed. During interviews conducted as part of DNAP 791 course requirements, the stakeholders were questioned regarding the resources that would be required for the successful implementation of this scholarly project. Interviewees identified time as the most needed resource, both on the part of the sub-investigators and FLA staff. Specifically, time commitments on the part of the registrar and the IT department. Stakeholders

made clear that these time commitments would be significant and should not be underestimated, thus necessitating early onboarding of key stakeholders.

Implementation

The implementation of this scholarly project began with the IRB determination of not research. Once this decision was obtained, the course content was submitted to the Florida Conference of Seventh-day Adventist for review and approval. Once conference approval was obtained, the sub-investigators provided the registrar with the approved emails, a written protocol and education on the rollout process. An appointment was also made with IT to transfer the Canvas course shell from AHU to FLA and orient the IT department on timing requirements and proper course rollout. The Canvas course was opened from August 25, 2021, to October 8, 2021. Video conferencing or phone calls were employed for any ongoing issues or difficulties encountered during implementation.

Barriers and Facilitators

The barriers for this project were expected to be the selection of a protected population as participants and the additional requirement of the Florida Conference approval. Both anticipated barriers were not problematic as this project was designed as a quality improvement initiative and incorporated curriculum, instruction, and assessment best practices. The actual barrier was identified in a pre-implementation interview with the FLA principal. At the time, Dr. Baker cited a lack of incentivization would likely result in minimal participation, as students expect reasonable compensation for both their time and effort.

Facilitators were the support of key stakeholders and the use of Canvas LMS by both AHU and FLA. The value of engaged stakeholders and compatible software between institutions resulted in a smooth, efficient implementation and cannot be overstated.

Limitations

While a poor pretest-posttest response rate resulting in a small sample size was an anticipated limitation, a rollout with no student response was not expected. No other limitations were identified.

Timeline

In the fall of 2020, the scholarly project application was submitted to SRC/IRB. Once IRB determined this scholarly project as not research, the project was submitted for review and approved by the Florida Conference of Seventh-day Adventists in spring of 2021. Pre project key player education occurred while approval from the Florida Conference was pending. Once the Florida Conference approval was obtained, project implementation then began in the fall of 2021. Additional local dissemination occurred at AHU via poster and PowerPoint presentations in spring of 2022.

Dissemination and Recommendations

Given the lack of data, dissemination of actual project results as intended, was not possible. Thus, based upon feedback and concerns expressed by key players from FLA in a post implementation interview, a literature review regarding best practices and ethical options for project incentivization was conducted and the results shared with AHU key players, with the intent of improving future project outcomes as part of dissemination (Appendix A).

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Appendix A

Incentives in research are essential to robust participation, however, federal guidelines require researchers to address ethical concerns. There is a disagreement in the literature, however, regarding incentives and how to best address ethical issues such as coercion, manipulation, and vulnerable populations so that when implemented, research is ethically upright, and benefits both the institution and society (Afkinich et al., 2020; Flodgren et al., 2011). Thus, each institution's IRB has differing sets of rules and regulations on incentives (Afkinich et al., 2020; Halpern et al., 2021; Knox & Burkhart 2007). Variability in IRB policies, however, result in difficulties designing research that meets all ethical requirements but still result in meaningful participation rates. Thus, a balance must be achieved in which research is performed ethically but still fulfills its purpose.

There are many options employed by researchers for incentivizing. One of the most effective yet controversial, is monetary compensation (Afkinich et al., 2020; Flodgren et al., 2011). While remuneration may be offered it should not result in coercion or manipulation of subjects (Parkinson et al., 2019; Halpern et al., 2021). Therefore, compensation must be distributed equitably, at a wage appropriate level, and discussed during the informed consent and assent process to meet legal and ethical requirements (Florida Health, 2021; Hayden, 2020; Hopkins Medicine, 2020; Schoeppe et al., 2014). An additional concern, however, is the possibility that monetary compensation may inadvertently take advantage of vulnerable populations. One of which are children and adolescents. When focusing on minors, in particular adolescents, remuneration offered should be compensatory for time spent (Parkinson et al., 2019; Halpern et al., 2021). Of concern, is that adolescents may use compensation to partake in risk-taking behavior, possibly contributing to behavioral problems (i.e., teenagers using EDS, may

choose to purchase more of it), violating local, state, and national IRB standards (Gordon, 2020; Pratt et al., 2017; Schoeppe et al., 2014). It is therefore recommended that if monetary compensation is utilized, the best practice would be to reimburse the parents of the participants. There are, however, additional options that may limit risk taking behaviors. These options employ extrinsic motivators such as gift cards/vouchers, tickets, certificates, non-financial donations and other non-monetary incentives such as social rewards (i.e., praise and recognition) (Hokke et al., 2018; Knox & Burkhart 2007; Parkinson et al., 2019; Schoeppe et al., 2014). The use of social rewards may be adequately effective as they are known to encourage participation and would still abide by ethical standards and legal requirements (Kray et al., 2018).

While prevention of coercion and participant manipulation is of primary importance, appropriate compensation of participants must also be addressed. Many institutional IRBs recognize that there are costs involved with participation in research, and participants should not be disadvantaged by their participation, and therefore appropriate compensation for time/expenses should be considered and appropriately compensated for. Research driven Universities such as University of California, Berkley and Duke University go so far as to state that payment to research participants should not be viewed as a benefit; rather, it should be considered compensation for the time and inconvenience associated with participation in research activities (Duke, 2021; Berkeley, 2017).

In addition to ethical concerns, however, researchers must comply with federal guidelines specific to incentives that meet criteria for taxable income. The reporting of taxable income, however, requires the collection and retention of personal data from participants to include names, addresses and social security numbers. If researchers intend to collect data anonymously, this creates significant difficulties with research ethics and safe data storage requirements. Thus,

many IRBs have seen an increase in the engagement of outside grant-making agencies as an attempt by researchers to be in compliance with IRB requirements, while still preserving participant's anonymity (NIH, 2017). This practice, however, may not be necessary if incentives are offered below certain limits. The Department of Treasury Internal Revenue Service form 1099-MISC and 1099-NEC states that only income of 600 dollars or more annually must be reported (IRS, 2020). Which leaves researchers and institutions with the reasonable practice of employing micro-compensations such as 10-30 dollars to be utilized for recruitment and participation. As it is highly unlikely that participants will reach the 600 dollar annual reporting requirement many institutions do not require the collection of personal data when micro compensations are employed (Duke, 2021; Berkeley, 2017). This approach bypasses the need for any federal reporting and monitoring by both the researchers and participants

Researchers who cannot afford micro compensation often consider the use of random awards as an incentive. However, the use of random awards meets criteria for a lottery as defined by the state of Florida. Unfortunately, in order for lotteries to be held legally, "substantial considerations" cannot be a condition for entry (Florida Statute 849.09). As enrollment in research has been determined to be a substantial consideration by the Office of General Counsel, Florida law prohibits this practice (CFR, 2021; HHS, 2021). Thus, in the case of non-funded research, the use of social rewards may be the only viable option.

Given the above findings, prevention of ethical misconduct must remain of primary importance. It is equally clear, however, that researchers can and in certain circumstances should compensate participants for their time. This could be achieved via the provision of micro-incentives or social rewards without the risk of ethical misconduct, the need for collection of participant personal data, and still meet federal tax requirements.

Appendix B

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Purpose	Variables	Setting/Subjects	Measurement and Instruments	Results	Evidence Quality
<p>Study One To summarize and review numerous studies that have examined potential adverse effects of passive exposure from inhaling (EC).</p> <p>Study Two To provide a systematic review of the health consequences of Electronic Cigarettes (EC).</p>	<p>Study One Independent Variable: Measuring the impact of passive smoke exposure from EC Dependent Variable: Impact of EC versus conventional cigarette smoke (CC).</p> <p>Study Two Independent Variable: Obtaining significant data without bias. Author states 26 studies (34%), had conflict of interest. Dependent Variable: Efficacy of research data in the limited number of articles published for this review (n=76).</p>	<p>Study One Setting: Research from 1996 to 9/10/2015 based out of US, UK, and Australia, Subjects: Direct passive exposure studies with human volunteers (n = 4). Direct passive exposure studies in animal models (n = 1). Indirect exposure studies with human volunteers (± smoking machine) using ECs (n = 7). Indirect exposure studies with no human volunteers (n = 4).</p> <p>Study Two Setting: Research published prior to August 2014. Subjects: Humans, and animal studies (mice</p>	<p>Study One Direct passive exposure with human volunteers and animal models. Indirect exposure studies with human volunteers and no human volunteers.</p> <p>Study Two 76 studies were reviewed for the investigation of health effects due to ECs. In this systematic review there were many limitations such as: conflict of interests, small studies, lack of long term, and methodological concerns.</p>	<p>Study One Direct passive (DP) impaired lung growth. Indirect human: carcinogen levels increased. Study Two Unconfirmed possibility of cytotoxicity .Fine number of carcinogenic compounds found in various ECs.</p>	<p>Methodological flaws Study One: Indication of research states conflict of interests by EC manufacturer and Tobacco Companies. Study Two: Indication of research states conflict of interests by EC manufacturer and Tobacco Companies. Inconsistency: none Indirectness: none Imprecision none Publication bias Study Two: Statement made against bias or financial influence. Financial support: Yes.</p>
<p style="text-align: center;">Design</p> <p>Study One Systematic review using PRISMA guideline.</p> <p>Study Two Systematic review using PRISMA recommendations.</p>				<p style="text-align: center;">Implications</p> <p>Study One EC vapors indicate risk concerns, but less risk than CC. Study Two Pulmonary obstruction w/in 10 mins for healthy and pulmonary diseased volunteers. Vaping increased HR,</p>	

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Purpose	Variables	Setting/Subjects	Measurement and Instruments	Results	Evidence Quality
<p>Study One: To provide an estimate of electronic nicotine delivery system (ENDS) current and increasing use among youth globally.</p> <p>Study Two: To provide the perceived health effects of electronic cigarettes among adults.</p>	<p>Study One: Independent Variable: Changes in ENDS use in youth ≤ 20 years old by country over time. Dependent Variable: Prevalence of ENDS use in youth ≤ 20 years old by country.</p> <p>Study Two: Independent Variable: How these perceptions motivate the use of electronics cigarettes. Dependent Variable: Perceived effects on health.</p>	<p>Study One: Subjects: 36 surveys, 99-75,643 Individuals ≤ 20 years old, use of ENDS in 13 countries between 2008-2015. Setting: Individual surveys in US, Korea, New Zealand, UK, Poland, Canada, Hungary, China, France, Ireland, Italy, Iceland and Greece. Study Two: Subjects: 11- 19,414 Adults ≥ 18 years old. Mean of 4,677 individuals per study.</p> <p>Setting: College campus, online e-cigarette forums</p>	<p>Study One: Individual surveys, self-reported. Study two: Telephone and online/Internet surveys focus groups.</p>	<p>Study One: Current use of ENDS among youth were highest in Poland 62.1% and lowest in Italy 5.9%. Increase use of ENDS among youth. Poland 20.9% in 2010 to 62.1% in 2013. US 2.7% in 2011 to 47.3% in 2013. Study Two: The perceived health effects of e-cigarettes are, contain less toxins and are less toxic to both user and nonuser, than traditional cigarettes.</p>	<p>Study One: Methodological flaws: Study didn't survey never-smokers. Inconsistency: Could only obtain changes in ENDS use in 7 counties instead of original 13. Indirectness: None Imprecision None Publication bias None Study Two: Methodological flaws: Low quality evidence Inconsistency: None Indirectness: None Imprecision: Sample was either too small or too large. Publication bias: None bias</p>
Design				Implications	
<p>Study One: Systematic review and meta-analysis.</p> <p>Study Two: Systematic review</p>				<p>Study One: Use of ENDS seems to be increasing in youth ≤ 20 years by country. Study Two: Health perception may be influencing continued use.</p>	

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Purpose	Variables	Setting/Subjects	Measurement and Instruments	Results	Evidence Quality
<p>Study One: To provide a quantifiable concentration of toxic metals in popular brands of e-cig.</p> <p>Study Two: To provide an assessment on the safety and efficacy of electronic cigarettes.</p>	<p>Study One: Independent Variable: Concentrations found in liquids and its toxicity for users.</p> <p>Dependent Variable: Testing 10 liquid refills from the 5 brands via mass spectrometry for metal concentrations.</p> <p>Study Two: Independent Variable: Adverse events after e-cigarettes use.</p> <p>Dependent Variable: Use of e-cigarettes for smoking reduction</p>	<p>Study One: Subjects: 10 cartridges from 5 brands of e-cigs with largest market share.</p> <p>Setting: United States.</p> <p>Study Two: Subjects: 11 studies involving 16,406 participants.</p> <p>Setting: Systemic review covered the literature published from January 2003 to July 2017.</p>	<p>Study One: 50, 250µL samples were collected and mixed with Fisher Optima Trace Element Grade. Final volume of 5ml per sample to examine trace metals of nickel, chromium, manganese, cadmium and lead were vortexed then analyzed via plasma mass spectrometry.</p> <p>Study two: RCT used a CONSORT 2010 statement, non-RCT used Newcastle–Ottawa Scale for quality assessing, observational studies and online surveys.</p>	<p>Study One: Metal content varied among manufactures. Marked concentrations of Ni, Cr and Mn in the samples. When inhaled these metals have serious health implications.</p> <p>Study Two: 49.1-51.6% of individuals experienced cough, oral irritation, depression, nausea and insomnia.</p> <p style="text-align: center;">Implications</p> <p>Study One: Health concerns have been noted. Nickle being a Group 1 carcinogen associated with bronchitis and lung cancer.</p> <p>Study Two: Long term exposure to e-cigarettes shows reduced safety and efficacy.</p>	<p>Study One: Methodological flaws: Did not measure the effect of heating element. Inconsistency: None Indirectness: None Imprecision Exclusion of two samples due to sample volume. Publication bias None</p> <p>Study Two: Methodological flaws: Control group is generally missing in both observational studies. Inconsistency: None Indirectness: None Imprecision: None Publication bias: None</p>
Design				Implications	
<p>Study One: Single Study</p> <p>Study Two: Systematic review and meta-analysis.</p>					

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Purpose	Variables	Setting/Subjects	Measurement and Instruments	Results	Evidence Quality
<p>Study One: To evaluate the quality of research on the chemistry of Electronic Nicotine Delivery Systems (ENDS) and evaluate aerosol exposures.</p> <p>Study Two: To provide a user's current perception and use of future use of E-cigarettes</p>	<p>Study One: Independent Variable: Patterns of "typical" ENDS use associated with aerosol distribution.</p> <p>Dependent Variable: Concentrations of acrolein and formaldehyde in the aerosol.</p> <p>Study Two: Independent Variable: Participants reasons for use and appeal of e-cigarettes.</p>	<p>Study One: Subjects: ENDS devices and chemical compounds found within device derived from smoking machines and volunteer vapers.</p> <p>Setting: Peer reviewed journal available to July 2013.</p> <p>Study Two: Subjects 108 current e-cigarettes users</p> <p>Setting: Focus groups held in Tampa bay Florida</p>	<p>Study One: Calculations were made based on the worst-case personal exposure of a vaper; [mg/m³]=mg/(mL liquid) x (mL liquid)/puff x puffs (8 hr. day) x 1/(m³ air inhaled in 8 hr.).</p> <p>Study Two: Online survey conducted. Research contacted participates and asked if wanted to attend focus group. Criteria as followed (1) ≥18 years old; (2) had smoked cigarettes daily for at least one year; and (3) had used e-cigarettes in the past 30 days. Interview guide was used during focus groups to maintain cohesiveness.</p>	<p>Study One: Majority of predicted exposures are <<1% of Threshold Limited Values; predicted exposures to acrolein and formaldehyde are typically <5% TLV.</p> <p>Study Two: Out of 108 survived only 31 individuals met criteria and were willing to participate. Majority thought e-cigarettes were a better than alternatives and was more socially acceptable.</p>	<p>Study One: Methodological flaws: Test methods consisted of 5 vapers in 60m³ over 5 hrs.</p> <p>Inconsistency: Concentrations were expressed stringent</p> <p>Indirectness: None</p> <p>Imprecision: None</p> <p>Publication bias CASAA Research Fund.</p> <p>Study Two: Methodological flaws: Didn't not survey never smoker or users <18 years old.</p> <p>Inconsistency: None</p> <p>Indirectness: None</p> <p>Imprecision: None</p> <p>Publication bias: None</p>
Design					
<p>Study One Systematic review adhering to PRISMA guidelines.</p> <p>Study Two: Primary Qualitative study</p>	<p>Dependent Variable: Patterns of user consumption of e-cigarettes compared to other tobacco cessation products.</p>				<p>Implications</p> <p>Study One: Divert attention to propylene glycol & glycerin</p> <p>Study Two: Users perceptions of e-cigarettes could impact public health.</p>

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Purpose	Variables	Setting/Subjects	Measurement and Instruments	Results	Evidence Quality
<p>Study One: Provide important evidence that HS students are using e-cigarettes to vaporize cannabis.</p> <p>Study Two: Review relevant primary care interventions for tobacco use prevention and cessation in children and adolescents</p>	<p>Study One: <u>Independent Variable:</u> Self reporting anonymous survey <u>Dependent Variable:</u> High school student use of cigarettes, e-cigarettes, and Cannabis</p> <p>Study Two: <u>Primary outcome:</u> How the use primary care interventions effect tobacco initiation.</p> <p><u>Secondary outcome:</u> How the use primary care interventions effect health and harm outcomes.</p>	<p>Study One: <u>Subjects:</u> High school students (N = 3847) <u>Setting:</u> 5 High schools in southeastern Connecticut</p> <p>Study Two: <u>Subjects:</u> Twenty-four RCTs (N = 44 521) met inclusion criteria. Children & adolescents up to 18 yrs. for cessation and age 25 yrs. for prevention. <u>Setting:</u> Primary care settings in US and Western Europe</p>	<p>Study One: Participants' responses were summed and transformed into a 3-point ordinal scale, whereby scores 0 to 4 were classified as low SES (22.0%), 5 to 6 as moderate SES (46.8%), and 7 to 9 as high SES (31.2%)</p> <p>Study Two: Tobacco use initiation, tobacco use cessation, health outcomes, and harm.</p>	<p>Study One: HS adolescents were 27 times as likely to use e-cigarettes to vaporize cannabis. Study Two: Decreased likelihood of cigarette smoking initiation compared with control at 7 to 36 months' follow-up (13 trials, n = 21 700; 7.4% vs 9.2%; relative risk [RR], 0.82 [95% CI, 0.73-0.92]).</p>	<p><u>Methodological flaws:</u> Study 1: Study May not be sufficient in all US due to studying being done in state where cannabis and e-cigarettes are illegal Study 2: No individual study was done on solely on E-cigarettes prevention or cessation. <u>Inconsistency:</u> Study 1: Self-reporting Survey Study 2: None <u>Indirectness:</u> Study 1: None Study 2: Non <u>Imprecision</u> Study 1: None Study 2: None <u>Publication bias:</u> Study 1: None Study 2: None</p>
Design					
<p>Study One: Statistical analyses Cross sectional Binary logistic regression</p> <p>Study Two: Systematic review</p>					
				Implications	
				<p>Study One: Research is needed to determine if e-cigarette serve as a gateway</p> <p>Study Two: Research is needed to identify effective behavioral interventions for adolescents who smoke cigarettes.</p>	

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Purpose	Variables	Setting/Subjects	Measurement and Instruments	Results	Evidence Quality
<p>Study One To assess multiple Electronic Nicotine Delivery Systems (ENDS), level of harm, and relationship to smoking cessation, poly-use, or gateway effect.</p> <p>Study Two To provide an updated report on Electronic Nicotine Delivery Systems in which, includes nine major topics of discussion.</p>	<p>Independent Variable: Limited number of products available for research.</p> <p>Dependent Variable: Health effects of ENDS.</p> <p>Study Two Independent Variable: Gaps in longitudinal data. Dependent Variable: Comprehension of ENDS</p>	<p>Study One Setting: 2017 review of data/information. Subjects: General population that consumes any of the following nicotine substances: tobacco, nicotine replacement therapy (NRT), snus, and ENDS.</p> <p>Study Two: Setting: 687 published empirical research literature. Subjects: Middle school students, High school students, Young adults (18-24 years old), and adults (greater than or equal 18 years old).</p>	<p>Study One National Youth Tobacco Survey, National Health Interview Survey, National Survey on Drug Use and Health and Centers for Disease Control and Prevention.</p> <p>Study Two: Middle and High School student's data was obtained through the National Youth Tobacco Survey and Monitoring Future Survey. Whereas 18-24 age group were surveyed by the National Health Interview Survey.</p>	<p>Study One ENDS is "likely" to be less harmful than conventional cigarettes. Passive ends elevate nicotine levels in bystanders. Unknown definitive CV effects.</p> <p>Study Two <18 years ever use 2011=3.3%, 2014 =19.8%. 18-24 years ever use 2011=6.9%, 2014 =21.6%. >18use 2011= 6.2%, 2014 =12.614.1%.</p>	<p>Study One Methodological flaws: Heterogeneity of sample Inconsistency: None Indirectness: None Imprecision: None Publication bias: Authors made no disclosures Financial support None statements made. Methodological flaws: None Inconsistency: None Indirectness: None Imprecision: None Publication bias: None Financial support: Yes.</p>
Design					
<p>Study One Research review.</p> <p>Study Two Systematic review of published empirical research literature.</p>					
				Implications	
				<p>Study One 18-24 & >18 use of ENDS increases Study Two Unknown long-term health issues, trending.</p>	